Immunisation against meningococcal B disease for infants aged from two months

Practice Nurse Training Information
July /August 2015
South West Screening & Immunisation Team
Meningococcal B programme

Routine cohort:

• Starting on the 1 September 2015 all infants born on or after the 1 July 2015 will be eligible for the meningococcal B vaccine at 2, 4 and 12 months

Catch-up cohort:

• A catch-up programme will also commence on the 1 September 2015 for infants born from 1 May to 30 June 2015

The JCVI agreed that these infants would be offered the meningococcal B vaccine when they attend for their remaining primary immunisation appointments from 1 September 2015
## Schedule breakdown – Routine & Catch-up

<table>
<thead>
<tr>
<th>Cohort</th>
<th>Dates of birth</th>
<th>Recommended immunisation schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Routine</strong></td>
<td>Those born on or after 1 July 2015</td>
<td>2, 4 and 12 months (2+1)</td>
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<tr>
<td><strong>Catch-up</strong></td>
<td>Those born on or after 1 May to the 30th June 2015</td>
<td>If second routine primary immunisation appointment due on or after 1st September then follow this schedule: 3, 4 and 12 months (2+1)</td>
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<tr>
<td></td>
<td><strong>Those born before 1 May 2015 are NOT eligible to receive the vaccine</strong></td>
<td>If third routine primary immunisation appointment due on or after 1st September then follow this schedule: 4 and 12 months (1+1)</td>
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</tbody>
</table>
Why routinely immunise infants at 2 months of age
Why immunise infants from 2 months?

• Meningococcal disease can affect all age groups but the highest rates of disease are seen in the first year of life

• Cases of invasive meningococcal disease increase from birth and peak at around 5 months of age before declining gradually over subsequent months

• In considering all the evidence as well as the vaccine safety and efficacy, the JCVI decided to prioritise young infants from 2 months of age with the aim of providing optimal protection as early as possible and before the peak increase in disease
Immunisation against meningococcal B disease

- The use of Bexsero® vaccine
The recommended vaccine

**Brand name:** Bexsero®

Multi-component *inactivated vaccine* marketed by GlaxoSmithKline

- **Licensed** for use from 2 months of age
- Available through General Practitioner (GP) services from 1 September 2015
- Routinely **recommended** for infants at 2 months of age as part of the primary immunisation schedule at 2, 4 and 12 months
- “Catch-Up” for infants at 3 and 4 months of age as part of the primary immunisation schedule
- Schedule and interval dependant on child’s age on 1 September 2015
The recommended vaccine: Bexsero®

- Bexsero® is the recommended vaccine for the routine infant immunisation programme and is the only market authorised meningococcal B vaccine in the UK.
- Bexsero® will be centrally supplied through ImmForm in packs of 10.
- It is important immunisers familiarise themselves with the vaccine and its product information to avoid administration errors.

Image courtesy of GlaxoSmithKline (GSK)
Please note: Bexsero® is now owned and supplied by GSK. Initial stocks of Bexsero® will be supplied in Novartis packaging until 2016.
How is Bexsero® administered?

- Bexsero® is subject to additional monitoring under the black triangle labelling scheme (MHRA)

- **Recommended** that Bexsero® be administered via intramuscular injection (IM) ideally on its own in the infants' left thigh (antereolataral aspect) so that any local reactions can be accurately monitored.

- For older infants aged 12 months, Bexsero® should be administered via IM injection (IM) ideally on its own in the child's left thigh.

- The site at which each vaccine is given should be noted in the infants' health records.

- Where it is not practically possible to administer the vaccine on its own i.e. at 12 months, other vaccines can be administered in the left thigh at the same time rather than delay immunisation.
Administration and Supply

• The vaccines are supplied in packs containing 10 pre-filled syringes each with a volume of 0.5mls of suspension per syringe

• During storage, the contents of the syringe may settle with off-white deposits being noticeable

• Before use, the pre-filled syringe must be shaken well forming an homogenous suspension that should be administered immediately

• The vaccine should not be administered where there are variations in physical appearance (i.e. not an homogenous suspension) or signs of foreign particulate are observed after shaking

• Bexsero® has a shelf life of two years when stored in its original packaging in a refrigerator at the recommended temperatures of +2°C and +8°C
Initial Supply and Ordering

- **Initial vaccine supplies will have a short-shelf life** (April 2016).
- It is important **not** to over-order vaccines and only order what is needed for the 2-4 week period.
- Healthcare professionals are encouraged to familiarise themselves with Public Health England’s **protocol for ordering, storing and handling of vaccines** to ensure vaccines are stored and monitored as per national recommendations.
Administration of Bexsero®

Bexsero® should only be administered:

• Against a prescription written manually or electronically by a registered medical practitioner or other authorised prescriber
• Against a Patient Specific Direction
• Against a Patient Group Direction
Contraindications

Bexsero® should not be administered to those who have had:

1. A confirmed anaphylaxis to a previous dose of the vaccine OR

2. A confirmed anaphylaxis to any constituent or excipient of the vaccine

• There are very few infants who cannot receive meningococcal vaccines

• Where there is doubt, appropriate advice should be sought rather than withholding immunisation
Precautions

- **Minor illnesses without fever or systemic** upset are not valid reasons to postpone immunisation

- **Pregnancy and breast-feeding**

  Meningococcal vaccines may be given to pregnant women when clinically indicated. There is no evidence of risk from vaccinating pregnant women or those who are breast-feeding with inactivated virus or bacterial vaccines or toxoids

- **Premature infants**

  It is important that premature infants have their immunisations at the appropriate chronological age, according to the schedule

- **Immunosuppression and HIV infection**

  Individuals with immunosuppression and human immunodeficiency virus (HIV) infection (regardless of CD4 count) should be given meningococcal vaccines in accordance with the routine schedule
Possible adverse reactions and fever prophylaxis

**Most commonly** reported

- Fever (>38°C), tenderness at the injection site (including severe tenderness), rash, swelling or induration at the injection site, irritability, change in feeding/eating, sleepiness and unusual crying

**Less commonly** reported

- Fever (>40°C), eczema, urticaria (hives; itching), Kawasaki syndrome, seizures and pallor

**Paracetamol Prophylaxis**

- Fever was less common (39%) in infants receiving prophylactic paracetamol just before or at the time of immunisation followed by 2 further administrations at 4-6 hourly intervals after immunisation

- **Prophylactic ibuprofen** is not recommended because it does not prevent post-immunisation fever
Dosage and timing of infant Paracetamol suspension (120mg/5ml) for the routine immunisation programme at 2 and 4 months

<table>
<thead>
<tr>
<th>Age of baby</th>
<th>Dose 1</th>
<th>Dose 2</th>
<th>Dose 3</th>
</tr>
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<tbody>
<tr>
<td>2 months/4 months</td>
<td>One 2.5ml as soon as possible after vaccination</td>
<td>One 2.5ml 4-6 hours after 1\textsuperscript{st} dose</td>
<td>One 2.5ml 4-6 hours after 2\textsuperscript{nd} dose</td>
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</table>

If baby still febrile after the first three doses of paracetamol but is otherwise well, parents can continue giving paracetamol at recommended intervals up to 48 hours post-vaccination. Do not exceed four doses in a day.

If any concern at all speak to GP or call NHS 111.
Ordering paracetamol and syringes

- Until the programme becomes established, GP practices will be able to order single 5 ml sachets of liquid paracetamol (120mg/5ml) and accompanying 2.5ml syringes via ImmForm

- Sachets of liquid paracetamol should only be offered to those attending for their first Men B vaccine and only to parents who do not have timely access to over-the-counter medicines

- Parents should be instructed to buy some infant strength liquid paracetamol to complete the two remaining recommended doses of paracetamol at home and in preparation for the child’s second primary Men B vaccine
Should parents be worried about fever after vaccination?

- Fever after vaccination with or without Bexsero® is common and nearly always <39°C
- Fever is a normal and expected response of the immune system against the vaccine antigens and not harmful
- Parents are often concerned about the risk of febrile seizures or “fever fits”
- Parents should be reassured that febrile seizures generally occur in infants from 6 months to 5 years of age and are very uncommon in younger age groups
- It is important that parents are reassured and are advised of the importance of administering prophylactic paracetamol to reduce the risk and intensity of post-immunisation fever

“Healthcare professionals are reminded that in some circumstances the recommendations regarding vaccines given in the Green Book chapters may differ from those in the Summary of Product Characteristics (SPC). When this occurs, the recommendations in the Green Book are based on current expert advice received from the JCVI and should be followed”
Paracetamol recommendation

- The Commission on Human Medicines (CHM) has been consulted regarding the licencing restriction on Pharmacy (P) and General Sales List (GSL) paracetamol products.
- The current licensure advises consulting a GP or pharmacist if more than 2 doses are required for a 2 month old infant post-immunisation to ensure early diagnosis of systemic bacterial infection.
- The CHM supported PHE’s recommendations for 3 doses of paracetamol post-immunisation with MenB.
- The CHM also supported use of paracetamol (every 4-6 hours) for up to 48 hours after immunisations if needed.
- This recommendation is based on the likelihood that fever is due to immunisation.
Do nurses need a PGD to supply or administer paracetamol

- A PGD is **not** a legal requirement for the supply or administration of over-the-counter medicines and is therefore not required by nurses.
- To enable nursing colleagues to practice in accordance with the NMC Standards for Medicines Management, PHE will make available a Homely Remedy Protocol.
- Homely Remedy Protocols are not prescriptions but protocols that enable the supply and administration of general sales list (GSL) and pharmacy only (P) listed medicines in community settings.
- The protocol includes a written instruction that has been developed and agreed upon in consultation with relevant qualified professionals (medical practitioner/pharmacist).

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Reporting suspected adverse reactions

Yellow card scheme

- Bexsero® is a newly licensed vaccine and is subject to additional monitoring under the black triangle labelling scheme
- All suspected adverse reactions should be reported to the MHRA using the yellow card scheme
- Success depends on early, complete and accurate reporting
- Report even if uncertain about whether vaccine caused condition
- [http://mhra.gov.uk/yellowcard](http://mhra.gov.uk/yellowcard)
- See chapter 8 of Green Book for details