Meningococcal B immunisation programme

Factsheet for healthcare professionals

Background

In March 2014, the Joint Committee on Vaccination and Immunisation (JCVI) recommended the introduction of a routine infant meningococcal B immunisation programme. The immunisation programme consists of a 2+1 schedule at two, four and twelve months of age and started on 1 September 2015. The purpose of the immunisation programme is to reduce the burden and severity of invasive meningococcal disease caused by *Neisseria meningitidis* capsular B in the UK by protecting those who are at increased risk of disease.

What is meningococcal disease?

Meningococcal disease is caused by invasive infection with the bacterium *Neisseria meningitidis*, also known as meningococcus. The bacteria commonly colonises the nasopharynx of humans without causing invasive disease and 5-11% adults and up to 25% of adolescents are asymptomatic carriers of the bacteria. Meningococci can be transmitted by respiratory aerosols, droplets or by direct contact with the respiratory secretions of someone carrying the bacteria. Twelve different capsular types of the bacteria have been identified and Group B has been responsible for the majority of laboratory confirmed cases in the United Kingdom.
In Northern Ireland, 33 cases of invasive meningococcal disease were notified in 2015, 28 of which were laboratory confirmed and 20 were confirmed as capsular Group B. Invasive meningococcal disease most commonly causes either meningitis, septicaemia or a combination of both. The incubation period is two to seven days and clinical presentation ranges from severe acute and overwhelming features to mild prodromal symptoms.

Who is affected by meningococcal disease?

Meningococcal disease can affect all age groups but rates of disease are highest in children under two years of age. The number of cases increases from birth and peaks at five months before declining gradually until 24 months. Cases of meningococcal disease remain low until 12 years of age and then gradually increase to a smaller peak at 18 years before declining again.

Individuals with asplenia, splenic dysfunction or complement disorders are also at increased risk of invasive meningococcal disease and should be immunised in accordance with the schedule for immunisation of individuals with underlying medical conditions: green book chapter 7.

Who is the vaccine recommended for?

The meningococcal B vaccine is recommended to be given at 2, 4, and 12 months as part of a child's routine immunisation schedule.

Routine cohort

All infants born on or after 1 July 2015 are eligible for the meningococcal B vaccine if they start the schedule before their second birthday. Children in Northern Ireland who have uncertain / incomplete vaccination histories remain eligible for the vaccine up until they are two years and six months if they start the vaccine schedule before their second birthday.

If a child in the **routine cohort** (born on/after 1July 2015) presents for their first Men B vaccine between their first and second birthday they only require a schedule of two vaccines (leaving two months between each vaccine). If a child presents late for their first vaccine **before their first birthday** they should still receive three vaccines with two months between each vaccine. The third dose should be given after the child's first birthday.

Catch-up cohort

When the programme was introduced in September 2015 it was agreed that a small **catch-up cohort** (children born from 1 May 2015-30 June 2015) would also be eligible for meningococcal B vaccine. These children were offered meningococcal B vaccine at their routine vaccine appointments and if they were attending for their second routine appointment they received a 3, 4 and 12 month (2+1) schedule. If they were attending for their third appointment they followed a 4 and 12 month (1+1) schedule.

Children in this catch-up cohort only remain eligible for the vaccine up until they are 2 years old. This means that from the 30 June 2017 no child will be eligible for the Men B vaccine unless they were born after the 1 July 2015 / are in one of the at-risk categories outlined in for immunisation of individuals with underlying medical conditions: green book chapter 7.

If a child in the **catch-up cohort** (children born from 1May 2015-30 June 2015) presents for their first Men B vaccine between their first and second birthday they only require a schedule of two vaccines (leaving two months between each vaccine).

What is the recommended vaccine for the programme?

Bexsero® is the recommended vaccine for the routine infant immunisation programme and is the **only** market authorised meningococcal B vaccine in the UK. This vaccine is a multi-component inactivated vaccine made from three *Neisseria meningitidis* proteins produced by recombinant DNA technology (*Neisseria meningitidis* group B NHBA fusion protein, *Neisseria meningitides* group B NadA protein, *Neisseria meningitidis* group B fHbp fusion protein) and a preparation of *Neisseria meningitidis* capsular group B outer membrane vesicle (OMV) *Neisseria meningitidis* group B strain NZ98/254).

What are the contraindications for receiving Bexsero®?

There are very few infants who cannot receive meningococcal vaccines. Where there is doubt, instead of withholding immunisation, appropriate advice should be sought from a consultant paediatrician with immunisation expertise, a member of the local immunisation team or from PHA Health Protection Duty-room (Tel: 03005550119)

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

For the composition and full list of excipients of the vaccine, please refer to the manufacturer's Summary of Product Characteristics (SPCm).

What adverse reactions are commonly associated with the administration of Bexsero®?

In clinical vaccine trials, the **most common adverse reaction** observed in infants and children under two years of age was a high rate of fever (>38°C) when Bexsero® was administered with the other routine childhood vaccines (see below).

Other **very common** (occur in more than 1 in 10 children) adverse reactions observed in infants and children (up to the age of 10 years) are tenderness at the injection site (including severe tenderness defined as crying when moving injected limb), rash, swelling or induration at the injection site, irritability, change in feeding/eating, sleepiness and unusual crying.

Bexsero® is a newly licensed vaccine and is subject to additional monitoring under the **black triangle** (▼) labelling scheme by the Medicines and Healthcare Regulatory Agency (MHRA). All suspected adverse reactions should be reported to the MHRA using the Yellow Card scheme.

The manufacturers Summary of Products Characteristics (SPCm) states that infants were at an increased risk of fever when Bexsero® was administered at the same time as other routine childhood vaccines.

How common is fever after vaccination with Men B and can it be prevented?

In one clinical trial, fever (>38°C) was reported in 51-62% of infants receiving Bexsero® and routine vaccines administered together, although high fever (>39°C) was less common (6-12%). Overall, fever (>38°C) after any vaccination was reported in 76% of infants receiving Bexsero® and routine vaccines together, compared to 51% in infants receiving the routine vaccinations alone. In that study, however, only six of the 1,885 recruited infants attended the hospital because of fever within two days after vaccination with Bexsero®.

In a subsequent study, 70% of infants receiving Bexsero® had fever >38.5°C at least once in the first three days after any primary dose. However, fever was less common (39%) in infants receiving prophylactic paracetamol just before or at the time of vaccination followed by two further administrations at four to six hour intervals after vaccination by parents/guardians. Of note, only ~5% of infants receiving paracetamol had fever >39°C and the frequency of medically-attended fever within three days of vaccination was <2% for any vaccination visit, irrespective of whether the Bexsero® was administered alone or together with the routine vaccinations.

The latter study was also important because it showed that responses to Bexsero® and the routine vaccinations were not affected by administering prophylactic paracetamol at the time of vaccination.

In another vaccine study that did not include Bexsero®, infants receiving three doses of paracetamol (at vaccination and at 6-8 hour intervals) were half as likely to develop any post-vaccination fever, and also half as likely to develop high fever (>39°C), compared with infants receiving two doses of paracetamol (first dose at 6-8 hours after vaccination and another 6-8 hours later). Thus, the greatest benefit in reducing post-vaccination fever appears to come from the paracetamol dose given around the time of vaccination.

For the Bexsero® programme, the JCVI has recommended three doses of paracetamol to be given to infants receiving Bexsero® with their routine primary immunisations at two and four months or for a child < 1 year receiving their vaccines later than the routine scheduled appointments.

Guidance on the use of prophylactic infant paracetamol suspension with Bexsero® vaccine

Given that fever has been a very common adverse reaction in trials, and in light of concerns raised that an increase in fever may have a detrimental impact on the uptake of future immunisations, the JCVI recommended the use of prophylactic paracetamol at the time of immunisation with Bexsero®.
The JCVI agreed that parents and healthcare professionals needed to be informed and educated about the change in advice regarding the use of prophylactic paracetamol and the reactogenicity of Bexsero® when administered concomitantly with other routine childhood immunisations to reduce anxiety and concerns.

This is a change to previous advice whereby the prophylactic use of antipyretics was not routinely recommended as there was some evidence that antipyretics lowered the immune response to some of the routine infant vaccinations. Additionally, it was also felt that a low grade fever was to be expected following immunisation and such a response was an indication that the vaccine was triggering the appropriate immunological response. The latter remains true. However, the incidence of fever greater than 38°C when Bexsero® is administered at the same time as other childhood vaccines is greatly increased.

Additionally, a recent study showed that giving a dose of paracetamol around the time of vaccination followed by a further two doses at 6-8 hourly intervals, significantly reduced the rates of fever associated with vaccination without affecting the immunogenicity of Bexsero® or other routine infant vaccines. Therefore, parents should be advised to give 2.5ml (120mg/5ml) of paracetamol suspension to their babies at the time of immunisation or as soon as possible after the vaccines are administered. Parents will also be advised to give two further doses at four to six hourly intervals. (See Table)

Table: Dosage and timing of infant paracetamol suspension (120mg/5ml) for the **routine immunisation programme in infants < 1 year.**

Age of baby	Dose 1	Dose 2	Dose 3
2 months-<1 year	One 2.5ml as soon as possible after vaccination	One 2.5ml 4-6 hours after 1st dose	One 2.5ml 4-6 hours after 2nd dose

Note: Parents should also be advised not to give paracetamol to their child before vaccination in case it masks an illness that would mean the child's vaccinations should be delayed.

Healthcare professionals should provide parents with the Immunisation for babies up to one year old vaccine leaflet before their two month primary vaccination appointment, for example when the parents register their baby at the practice or when they attend the 6-8 week check. This will alert parents to the need to buy liquid paracetamol in preparation for the two month immunisation appointment (page 15-18). Most local pharmacies, supermarkets and many local stores stock liquid paracetamol suspension.

What should health professionals advise parents regarding the discrepancy between the paracetamol packaging and patient information leaflet (PIL) advising a maximum of two doses of paracetamol post immunisations for infants aged two months? (Note: older packaging may still contain this advice)

The Commission on Human Medicines (CHM) has been consulted regarding the licencing restriction on Pharmacy (P) and General Sales List (GSL) paracetamol products which advise consulting a GP or pharmacist if more than two doses are required for a two month old infant post-immunisation. The reason for this licensing is to ensure early diagnosis of systemic bacterial infection. The CHM supported the PHE recommendations for three doses of paracetamol post-immunisation with Men B and supported use of paracetamol for up to 48 hours post immunisations if required to manage post-immunisation fever in two month olds. This recommendation is based on the likelihood that fever is due to immunisation, this recommendation does not extend to fever at any other time and if the infant is otherwise unwell parents should trust their instincts and not delay seeking medical attention for the infant. Most infant paracetamol suspension manufacturers have updated their PILs since this consultation.

Parents can therefore be reassured that it is appropriate to follow PHA post-immunisation paracetamol dosing recommendations.

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) for a particular vaccine. When this occurs, the recommendations in the Green Book are based on current expert advice received from the JCVI and should be followed.

Does liquid paracetamol need to be administered when children receive their 12 months booster dose of Bexsero®?

In clinical vaccine trials, the most common adverse reaction observed in infants and children under two years of age was a high rate of fever (>38°C) when Bexsero® was administered at the same time as other routine childhood vaccines. As a result, the JCVI recommended the use of prophylactic liquid paracetamol when infants receive Bexsero® at the same time as other routine childhood vaccines such as DTaP/IPV/Hib at two, three and four months of age. As these vaccines are not administered as part of the12 month booster vaccines, there is no additional requirement to offer liquid paracetamol at that time.

Can ibuprofen be offered as an alternative to paracetamol to reduce post-vaccination fever after Bexsero® is administered with other routine vaccines?

In a head-to-head clinical trial of paracetamol versus ibuprofen to reduce post-vaccination fever, ibuprofen (two or three doses) did not reduce the rate or intensity of post-vaccination fever compared to the control arm where infants did not receive any anti-pyretic. This finding needs to be validated in further studies but this does suggest that paracetamol should be the only recommended anti-pyretic to reduce post-vaccination fever in infants. Ibuprofen should, therefore, not be recommended as an alternative to paracetamol in this instance.

Should parents be worried about fever after vaccination?

Fever after vaccination with or without Bexsero® is common and nearly always under 39°C.

Fever is a normal and expected response of the immune system against the vaccine antigens and generally not harmful, but parents are often concerned about the risk of febrile convulsions or “fever fits”. Typically, febrile convulsions occur from six months to five years of age and are very uncommon in younger age groups. In clinical trials involving several thousand infants receiving their routine vaccinations (including Bexsero®), febrile convulsions are very rarely reported. In one of the largest Bexsero® trials, where 1885 infants were recruited and vaccinated at four different visits without paracetamol prophylaxis, only one infant developed a febrile convulsion two days after receiving Bexsero®. In the subsequent study of 364 infants receiving Bexsero® with or without paracetamol , there wasn’t a single case of febrile convulsion after any of the four vaccination visits.

What if a baby still has a fever after having had the three doses of paracetamol?

Some babies may still develop fever after vaccination, even after taking paracetamol. If a baby still has a fever after the first three doses of paracetamol but is otherwise well you can continue giving the baby paracetamol. At least four hours should be left between doses and no more than four doses a day should ever be given in a 24 hour period. The child should be kept cool by making sure that they don’t have too many layers of clothes or blankets on, and by giving them plenty of fluids. If parents/carers are concerned about their baby at any time then they should trust their instincts and speak to their GP or call out-of-hours. Paracetamol is recommended for the prevention and treatment of fever after immunisation as there is evidence that it is safe and effective. If 48 hours after vaccination your baby still has a fever you should speak to your GP or out-of-hours for advice.

What happens if the infant spits out the paracetamol suspension?

If the infant spits out or regurgitates at least half of the paracetamol suspension, then an additional dose (one dose of 2.5ml spoonful) of liquid paracetamol should be administered.

Does liquid paracetamol affect the immune response to the oral rotavirus vaccine?

Ideally the rotavirus and paracetamol should be given at separate times, but the live vaccine virus should not be affected by close sequential administration of paracetamol syrup. A small volume of paracetamol is unlikely to add significantly to the volume or nature of the fluid present in the gut and therefore should not prevent the vaccine virus replicating to levels that provide a stimulus to the immune system.

Vaccine eligibility for the routine meningococcal B immunisation programme

Why is the national programme being routinely offered to infants aged two months?

Meningococcal disease can affect all age groups, but the rates of disease are highest in the first two years of life. Cases increase from birth and peak around five months before declining. In considering the epidemiological and economic evidence as well as vaccine safety and efficacy, the JCVI decided to prioritise young infants with the aim of providing optimal protection as early as possible.

How will the programme be delivered?

Bexsero® will be available through General Practice (GP) services from the 1 September 2015. Parents attending their GP practice for their child's routine primary immunisations at two and four months of age will be offered meningococcal B vaccine.

How effective is the vaccine?

Bexsero® has been shown to be immunogenic in infants and toddlers. Vaccine-induced antibodies have been shown to be bactericidal (ie they kill the bacteria) against most meningococcal strains causing invasive disease in the UK. The effectiveness of Men B vaccine was assessed in a national observational cohort study completed by Public Health England following the introduction of Men B vaccine to the routine schedule in September 2015. The two-dose priming schedule was highly effective in preventing Men B disease in infants and the cases of Men B in vaccine eligible infants in England halved in the first 10 months of the programme. The vaccine was shown to be 82.9% effective in preventing Men B disease in infants.[iii] We have seen a similar reduction in cases of Men B in vaccine eligible infants in Northern Ireland.

How many doses are required to ensure protection?

Clinical trials for Bexsero® in infants initially included three doses followed by a booster in the second year of life. Recent studies, however, indicate that two Bexsero® doses given two months apart at two and four months will induce bactericidal antibodies against meningococcus group B in nearly all infants. Vaccine responses will also be boosted after the 12-13 month dose.

How long does protection last for?

The duration of protection following the recommended routine Bexsero® schedule has not been established, although in reviewing all of the available evidence, the JCVI agreed the most plausible duration of protection is 18 months following a two dose primary course and 36 months following the additional booster dose administered at 12 months. Bexsero® should, therefore, protect infants and toddlers during their period of highest risk of meningococcal B infection.

Should eligible infants born on or after 1 May 2015 who have already completed their primary immunisations be recalled to the practice to receive Bexsero®?

Infants that are born in the catch-up cohort, ie born between 1 May 2015 and 30 June 2015 are eligible to receive Bexsero® until they reach two years of age.

Infants that are included in the routine cohort, ie born after 1 July 2015 are eligible to start Bexsero® vaccination schedule until they are two years of age. Infants who start the Men B schedule just before their second birthday are able to receive the second dose 8 weeks after the first dose even if this is after their second birthday. These infants are no longer eligible to receive this second dose after the age of two years and six months.

Any child in the "catch-up" cohort who received at least one vaccine before the age of one year, but missed the dose after their first birthday, can receive this dose up to the age of two years. Any child in the catch-up cohort who has received no men B vaccines can receive two doses at least two months apart.

The JCVI recommendation is that all infants in the eligible cohorts should receive the vaccine as part of their routine primary immunisation appointments. Subsequently, an active call/recall system has not been recommended or agreed with General Practitioners, for those who may have already completed their primary immunisations before the start of the programme.

Can the vaccine be offered to infants outside of the national programme?

GPs can, based on their clinical judgement, write a HS21 prescription for the men B vaccine for those who are not eligible under the childhood vaccination programme. Clinical judgement should take into account the recommendations of JCVI as published in the Green Book. Information about patients who should be offered men B and who are not part of catch-up/routine cohort are provided in chapter 7 of the Green Book and include patients with asplenia, splenic dysfunction and complement disorders.

JCVI have advised that it is not cost-effective for NHS to offer vaccination to older children who are not in the catch-up / routine cohort (born before 1 May 2015). If a parent requests Men B vaccine for their child and the GP does not feel that it is appropriate, the vaccine can only be given under a private arrangement. Under contract regulations GPs cannot write private prescriptions for their own patients. [v]

Vaccine administration

How is Bexsero® administered and where is it administered?

The Bexsero® vaccine comes in a box that contains a prefilled syringe with a volume of 0.5mls. 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 so that any observable deposits are thoroughly mixed into the liquid forming a homogenous suspension that should be administered immediately. The vaccine should not be administered where there are variations in physical appearance (ie not a homogenous suspension) or signs of foreign particulate are observed after shaking.

It is recommended that Bexsero® be administered via intramuscular injection into the infant's **left thigh** (anterolateral aspect), ideally on its own, so that any local reactions can be monitored more accurately. Bexsero® is a newly licensed vaccine that is subject to additional monitoring under the black triangle labelling scheme and any local reactions should be reported to the MHRA using the Yellow Card Scheme.

If for any reason it is necessary to administer another vaccine in the same limb, then a space of

2.5cms should be left between vaccine sites. The sites of administration of each vaccine should be noted in the individual's health records. Children with a bleeding disorder can have the vaccine administered by sub-cutaneous injection and the regional PGD can be used for this purpose (see chapter 4 the Green Book).

Healthcare professionals are reminded that some infants may receive additional vaccines as part of a selective immunisation programme around 12 months of age, such as Hepatitis B and BCG. Healthcare professionals are reminded that vaccines should not be administered into the same limb as the BCG vaccine for a period of three months from administration. Healthcare professionals are encouraged to discuss any recent immunisations at the 12 month booster appointment with parents.

Does Bexsero® contain latex?

The tip cap of the syringe may contain natural rubber latex. Although the risk for developing allergic reactions is very small, healthcare professionals should consider the benefit-risk prior to administering this vaccine to subjects with known history of hypersensitivity to latex. Further advice about administering vaccines to patients with a latex allergy can be found in chapter 6 of the Green Book. For a full list of excipients, healthcare professionals should read the manufacturer's Summary of Products Characteristics (SPCm).

Does Bexsero® contain any preservatives such as thiomersal?

No, Bexsero® does not contain thiomersal. For a full list of excipients, healthcare professionals should read the manufacturer's Summary of Products Characteristics (SPCm).

Does Bexsero® contain any porcine gelatin?

No, Bexsero® does not contain porcine gelatin. For a full list of excipients, healthcare professionals should read the manufacturer's Summary of Products Characteristics (SPCm).

Should Bexsero® be administered separately to other vaccines?

Bexsero® can be given at the same time as the other vaccines administered as part of the routine childhood immunisation programme, including pneumococcal, measles, mumps and rubella (MMR), diphtheria, tetanus, pertussis, polio and Hib.

What should I do if a parent is concerned about the number of vaccines being administered to their child in one session?

It is understandable that some parents may become concerned about the number of vaccines being administered in one session, particularly at 2 and 12 months of age when four vaccines are scheduled to be administered. While these concerns are understandable, parents should be reassured by confident and knowledgeable healthcare professionals that the aim of immunisation is to provide protection against harmful diseases at the very earliest opportunity. Studies have demonstrated that there are no harmful effects from administering multiple vaccines in one session and there is no evidence to support arguments of "overloading" the immune system". From the moment a child is born, they are continually being exposed to a huge number of bacteria and viruses on a daily basis that the immune system is able to cope with and as a result becomes stronger (CDC). Additionally, administering multiple vaccines in one session is a routine occurrence in most countries around the world with no evidence of harmful effects.

What should I do if a parent requests Men B vaccine to be administered separately to the other routine primary immunisations?

Parents should be discouraged from delaying immunisation as this inevitably delays protection. The immunisation schedule has been designed to ensure optimal protection against diseases that are most common in the very young such as whooping cough, pneumococcal, Hib and meningococcal disease. These diseases can be life-threatening and it is important for children to receive protection at the earliest possible opportunity.

What should I do if Bexsero® was not administered at the appropriate age in a child who is eligible for the vaccine eg a child who has recently moved to Northern Ireland from another country?

When the administration of Bexsero® has been delayed in eligible cohorts they should be recalled as soon as possible and advice re additional immunisation appointments should be offered to ensure the infants are immunised according to their eligibility. Bexsero® can be administered at any time before or after other routine primary immunisations.

Children < 1 year should be given three vaccines with a minimum space of two months between each vaccine and the third vaccine being given after their first birthday. If a child in the routine cohort is age 1-2 years they should be given two vaccines with a minimum of two months between each vaccine. If they receive their first men B vaccine within 2 months of their second birthday, they are able to complete the course by receiving a second dose 8 weeks after their first dose even if this falls after their second birthday. They are not eligible to receive this second dose after the age of two years and six months.

Note: If Bexsero® is administered separately to other routine primary immunisations, the use of liquid paracetamol does not need to be advised as the risk of fever is reduced.

Can Bexsero® be administered at the same time as Men ACWY vaccines?

Two studies assessing protein-based meningococcal B vaccines given with the Men ACWY vaccines reported similar vaccine responses with no significant adverse events. Therefore, currently available evidence indicates that Bexsero® can be safely co-administered with Men ACWY conjugate vaccines and other conjugate vaccines (pneumococcal, Hib/MenC) without affecting the immune response to either vaccines.

Does Bexsero® provide cross protection against other meningococcal capsular groups, such as Men A, C, W and Y?

Whilst Bexsero® has broad coverage against most Men B strains causing invasive meningococcal disease (IMD) in England; it does not offer complete protection. Similarly studies to demonstrate protection against other capsular strains remain ongoing. Thus individuals requiring protection against ACWY should receive the ACWY vaccine and should not assume to be protected against these capsular groups even if they have received a complete course of Bexsero®.

The manufacturer's Summary of Product Characteristics (SPCm) states that infants under six months of age should receive three doses of Bexsero® with a minimum of one month interval in addition to the booster dose at 12 months of age. Why is Bexsero® only being recommended as a two dose schedule in infants aged under 6 months?

As yet unpublished findings of a clinical trial have shown that nearly all infants develop bactericidal antibodies against Men B following two doses of Bexsero® given two months apart and this finding formed the basis of the JCVI recommendation for a 2+1 schedule.

Healthcare professionals are reminded that in some circumstances the recommendations regarding vaccines given in the Green Book may differ from those in the Summary of Product Characteristics for a particular vaccine. When this occurs, the recommendations in the Green Book are based on current expert advice received from the JCVI and this advice should be followed.

Why are infants in the 'catch-up' cohort being offered a different schedule (3, 4 and 12 month or 4 and 12 month) to that recommended for the routine cohort (2, 4 and 12 month)?

From the 1 September 2015, children born on or after 1 May 2015 were to be offered at least one dose of Bexsero® as part of their routine immunisations at three and four months of age. These children should have received a booster dose of Bexsero® as part of the 12 months booster immunisations.

The aim of this JCVI recommendation is to extend protection to those infants who are most likely to benefit from the vaccine, before reaching an age when they are most at risk of meningococcal B disease, even if immunogenicity data for these modified schedules are limited. Additionally, children receiving a priming dose of Bexsero® in infancy should make a good response to the 12 months booster dose of Bexsero®. Children in the catch-up cohort will no longer be eligible to complete the Men B schedule after their second birthday.

Are infants born before the 1 May 2015 going to be offered Bexsero® as part of a catch up programme?

The JCVI did **not** recommend a catch up programme for infants born **before the 1 May 2015** after reviewing the cost-effectiveness model. Since the vaccine was only found to be cost-effective at a very low price, a sustainable approach had to be followed for implementation. As meningococcal disease peaks around 5 months of age before declining, the priority of the meningococcal B immunisation programme is to ensure that Bexsero® is offered routinely to infants who are due to receive their routine primary immunisations on or after the 1 September (those born on or after 1 July 2015) with a limited catch up for those infants born from 1 May 2015 to 30 June 2015) which will provide protection to this most vulnerable group prior to the peak in incidence of disease at 5 months of age.

What should I do if I have inadvertently administered the second dose of Bexsero® at 3 months of age to an infant following the routine schedule (2, 4 and 12 months)?

In the event that the second dose of Bexsero® is administered one month earlier than recommended, infants should be offered an additional dose of vaccine at four months to ensure protection against meningococcal B disease.

As Bexsero® has been associated with an increase in fever when administered concomitantly with other routine childhood vaccines, infants inadvertently given Bexsero® at three months should be given liquid paracetamol as recommended for the 2-month or 4-month Bexsero®.

What should I do if an infant who was born outside of the eligible cohorts inadvertently receives Bexsero®?

Infants born before 1 May 2015 are not recommended to receive Bexsero® and should not be offered additional meningococcal B vaccinations. Healthcare professionals should reassure parents that no further action is required and should report the administration error via their local governance system(s) so that appropriate action can be taken, lessons can be learnt and the risk of future errors minimised.

What should I do if the vaccine was administered at less than the recommended dose?

In the event that Bexsero® is administered at less than the recommended dose, vaccination will need to be repeated because the dose that the infant received may not be sufficient to evoke a full immune response. Where possible, the dose of Bexsero® should be repeated on the same day or as soon as possible after. In the event that the additional dose of Bexsero® cannot be administered at the same visit or day, arrangements should be made to administer the additional dose as soon as possible, thus not to delay future doses.

As Bexsero® has been associated with an increase in rates of fever when administered concomitantly with other childhood vaccines; prophylactic paracetamol should be offered with this Bexsero® dose.

Can Bexsero® be administered earlier than 8 weeks (2 months) to eligible infants travelling abroad?

The immunisation schedule has been designed to provide early protection against infections that are most dangerous for the very young. Recommendations for the age at which vaccines should be administered are informed by the age-specific risk for a disease, the risk of complications and the ability to respond to the vaccine. Therefore, vaccines should be administered as closely to the schedule as possible.

In certain circumstances, some vaccines may be administered slightly earlier, i.e. at 6 weeks for those infants that are due to travel to another country. This is only advisable where the benefit of immunisation outweighs the risk, ie in providing early protection against childhood diseases that are common in most other countries. This rationale does not apply to meningococcal B disease as the level of risk is higher in the UK than in other countries. Additionally Bexsero® is only licensed for use from the age of two months, thus those wishing to administer the vaccine earlier than recommended will be using an "off-label" licensed vaccine that will require a patient specific direction (PSD).

For these reasons, we are not recommending that Bexsero® is administered earlier than recommended for travel purposes. Infants should be offered other routine primary immunisations prior to travel and delay the administration of Bexsero® until the child arrives back in the UK.

Useful links

Meningococcal B Vaccination

- Bexsero® ▼ Summary of Product Characteristics, Novartis Vaccines. Updated 11 October 2016
- https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/554011/Green_Book_Chapter_22.pdf
- Meningococcal B (MenB) vaccination programme. Clarification re prescribing Men B vaccine. HSS(MD)9/2015 :Department of Health (NI) issued July 2016
- Vaccination of individuals with uncertain or incomplete immunisation status. Public Health England. Updated 20 June 2016.

General

- Joint Committee on Vaccination and Immunisation.

References

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03/17