



22 June 2015

NHS England Gateway Number: 03517  
PHE Gateway Number: 2015116

**NHS England Regional Directors and Directors of  
Commissioning Operations  
NHS England/ Public Health England Screening and  
Immunisation Leads  
Clinical Commissioning Groups Clinical Leaders and  
Accountable Officers  
General Practitioners  
Local Medical Committees  
Local Authority Chief Executives and Directors of  
Public Health**

**For information:**

**Chief Pharmacists of NHS Trusts  
NHS Foundation Trusts  
NHS Trusts**

Dear Colleague,

**Introduction of MenB immunisation for infants**

We are writing to advise you that immunisation against meningococcal B disease (MenB) will be added to the childhood immunisation programme as part of the routine schedule in England from 1 September 2015.

This letter provides the information you need to introduce the new MenB vaccine, Bexsero®. It includes guidance on those infants eligible for vaccination; clinical advice on use of Bexsero®; details of how to order the vaccine; new data collection arrangements to measure vaccine uptake; and funding arrangements.

Bexsero® should be offered routinely to all babies born on or after 1 July 2015, when they attend for their first and third routine childhood immunisations, at the age of two months and again at four months. A booster should also be offered at 12-13 months of age together with current routine immunisations.

A limited one-off catch-up programme for infants born between 1 May 2015 and 30 June 2015 will also be offered. So any children born on or after 1 May 2015 should be vaccinated as below:

- those who have not already received any routine vaccinations, should have MenB at the same time as their first and third routine infant vaccinations
- those who have already received their first dose of routine vaccinations should have MenB at the same time as their second and third routine infant vaccinations
- those who have already received their first and second dose of routine vaccinations should have MenB at the same time as their third routine infant vaccinations
- a booster of MenB should also be offered at 12-13 months

Further detailed clinical guidance for healthcare professionals is set out in **Annex A**. This notes the importance of clear advice to healthcare professionals and parents or guardians about the increased risk of fever from the vaccine and the prophylactic use of paracetamol following vaccination. Information and resources will be made available to support these communications locally, before the start of the new programme.

An enhanced service will be offered to general practice to deliver meningococcal B vaccinations in 2015/16 in England:

[GP Contract documentation 2015/16](#)

The meningococcal chapter of the Green Book (*Immunisation against infectious disease*) has been updated and will be available here:

[Meningococcal chapter of the Green Book](#)

The Joint Committee on Vaccination and Immunisation's (JCVI) statement about meningococcal B disease and the use of MenB vaccine is available at:

[JCVI meningococcal B statement](#)

The introduction of MenB immunisation will have an important role in reducing cases of meningitis and septicaemia and their complications in infants, and provide reassurance to parents who are concerned about the devastating consequences of this disease. We do not underestimate the additional work the introduction of this routine immunisation will bring, and we would like to take this opportunity to thank all involved in delivering the childhood immunisation programme for their continuing hard work.

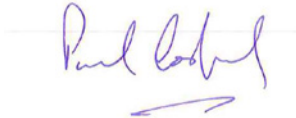
*From NHS England and Public Health England*

If you have any queries about the content of this letter please contact [immunisation@phe.gov.uk](mailto:immunisation@phe.gov.uk)

Yours faithfully,

A handwritten signature in black ink, appearing to read 'Barbara Hakin', enclosed in a thin black rectangular border.

**Dame Barbara Hakin**  
**National Director: Commissioning Operations, NHS England**

A handwritten signature in purple ink, appearing to read 'Paul Cosford', with a horizontal line underneath.

**Professor Paul Cosford**  
**Director for Health Protection and Medical Director, Public Health England**

## CLINICAL GUIDANCE ON IMMUNISATION OF INFANTS AGAINST MENINGOCOCCAL B DISEASE

1. This guidance is based on advice from the Joint Committee on Vaccination and Immunisation (JCVI)<sup>1</sup>, the UK's independent advisory committee of immunisation experts. Full guidance can be found in the updated chapter on meningococcal disease included in *Immunisation against infectious disease* ('the Green Book')<sup>2</sup> at the following link.

[Meningococcal chapter of the Green Book](#)

### Background to the introduction of MenB vaccine

2. The incidence of invasive meningococcal disease (IMD) in England has decreased by more than half since the early 2000s. In 2014, there were 628 confirmed cases and 32 deaths from meningococcal disease in England, including 400 cases and 15 deaths attributed to MenB. MenB cases were diagnosed in infants from birth, peaking at 5 months of age before declining slowly. Half of all MenB cases occurred in children under 5 years of age. The epidemiology of IMD is similar in Wales, Scotland and Northern Ireland. A UK study suggests that around a tenth of survivors of MenB disease have major physical and/or neurological disabilities, including amputation, deafness, epilepsy and/or learning difficulties; around one third of cases result in less severe physical and/or neurological disabilities.

3. The declining incidence of IMD in the UK has been attributed to natural secular trends, as often observed with many infectious diseases. Historically, the UK has witnessed many prolonged outbreaks of IMD, attributed to the introduction of a new virulent meningococcal strain into the population. For example, an increase in meningococcal group C (MenC) disease occurred in the mid-1990s, and ultimately resulted in the introduction of MenC vaccination in 1999. Therefore, while IMD incidence is currently low, rapid increases are expected and could occur with any serogroup; an increase in MenW disease, for example, has been observed since 2009.

4. Bexsero® is a novel multi-component, protein-based meningococcal vaccine that took almost 20 years to develop and license. Data from clinical trials show Bexsero® to be immunogenic in infants, children, adolescents and adults, resulting in high concentrations of bactericidal antibodies that can kill most MenB strains in laboratory tests. The evidence for clinical effectiveness (ie preventing invasive meningococcal disease in humans) is limited because it would require very large trials over a long period; serological evidence has correlated well with protection for

---

<sup>1</sup> JCVI statement: <https://www.gov.uk/government/publications/meningococcal-b-vaccine-jcvi-position-statement>

<sup>2</sup> The Green Book meningococcal chapter: <https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book>

other meningococcal vaccines. Bexsero® has not been routinely implemented in any country worldwide, but preliminary results from a recent MenB outbreak in Princeton University where more than 17,000 adolescents received Bexsero®, and from Québec's Saguenay-Lac-Saint-Jean region where more than 45,000 infants, young children and adolescents were vaccinated with Bexsero®; are encouraging. One of the components of the vaccine – the outer membrane vesicle (OMV) – has also been successfully used to control outbreaks of specific MenB strains in the past. For example, the effectiveness of such a vaccine was estimated to be 73% in New Zealand.

5. Bexsero® contains OMV as one of its components along with three other highly-conserved meningococcal surface proteins identified through reverse vaccinology. Given the available data, Bexsero® is expected to have high short-term vaccine effectiveness against most (88%) MenB strains causing invasive disease in England.

6. Safety data from clinical trials totalling over 6,000 participants were reviewed by the European Medicines Agency (EMA). These data indicated that infants given Bexsero® along with their routine immunisation had higher rates of low grade fever (50-80%) compared to rates of around 50% in infants who were given their routine immunisations without Bexsero®. However, concomitant administration of prophylactic paracetamol reduced fever rates without affecting immunogenicity of Bexsero® or the routine infant immunisations given concomitantly. This is in contrast to a previous study, without Bexsero®, showing that paracetamol lowered the immunogenicity of some of the infant vaccines.

7. JCVI noted the increased risk of fever when Bexsero® was administered with other childhood immunisations and agreed that there would be a need to educate parents and healthcare professionals on the potential reactogenicity of administering Bexsero® in the infant schedule. Good communication will help to reduce parental anxiety by ensuring that parents or guardians have the necessary information they need on the increased risk of fever and the prophylactic use of paracetamol following the infant doses of vaccine. Effective communication on this subject will also reduce the impact of fever on the health service.

8. Providers should take opportunities to direct parents to information on MenB vaccination and on the use of paracetamol following vaccination ahead of the two month appointment. Written information on the use of paracetamol following MenB vaccination should ideally be provided to parents before their two month vaccination appointment so that they are aware of the need to purchase an infant liquid paracetamol preparation. This should be reinforced by health professionals during the infant's routine immunisation appointment, and further written information supplied at that time.

## Timing

9. The vaccine will be included in the childhood immunisation programme from 1 September 2015. The vaccine will be available to order through the [ImmForm website](#)<sup>3</sup> from the beginning of August. All infants scheduled to receive their primary

<sup>3</sup> ImmForm website: [www.immform.dh.gov.uk](http://www.immform.dh.gov.uk)

vaccines from this date should be offered the vaccine and booster as below. The routine cohort (those born on or after 01/07/2015) should receive two doses in infancy, with their first and third routine vaccinations, followed by a booster after the age of 12 months. The catch up cohort (those born between 01/05/2015 to 30/6/2015) should receive one or two doses, with their routine infant vaccinations, followed by the booster dose.

**Recommended schedule for those born on or after 01/05/2015 (routine and catch-up cohorts)**

| Attending for the first time on or after 1 <sup>st</sup> September for       | Recommended immunisation schedule   |
|--|---|
| First dose of DTaP-IPV-Hib, first dose PCV13 and first dose of Rotavirus     | Give MenB at same visit, a further dose in two months and a booster at age 12-13 months (2+1) |
| Second dose of DTaP-IPV-Hib and first dose MenC and second dose of Rotavirus | Give MenB at same visit, a further dose in one month and a booster at age 12-13 months (2+1)  |
| Third dose of DTaP-IPV-Hib and second dose of PCV13                          | Give MenB at same visit and a booster at 12-13 months (1+1)                                   |

N.B. Children are no longer eligible for Bexsero® after their second birthday.

**Recommendations for use of the meningococcal group B vaccine (Bexsero®)**

*Administration*

10. Bexsero® vaccine is given intramuscularly into the upper arm or anterolateral thigh. It is recommend that all doses of Bexsero® be given in the **left thigh**, ideally on their own, so that any local reactions can be monitored more accurately. If another vaccine needs to be administered in the same limb, then it must be given at least 2.5cm apart.

11. If the infant has a bleeding disorder, the vaccine should be given by deep subcutaneous injection to reduce the risk of bleeding.

12. Please note the information on fever and the administration of liquid paracetamol.

13. Full guidance on the administration technique is included in the relevant chapter of the Green Book.

*Dosage*

14. **Routine Immunisation Schedule:** infants should receive 0.5mL Bexsero® ▼ with their routine vaccinations as outlined above.

15. For vaccination of eligible children (born on or after 01/07/2015) with uncertain or incomplete immunisation status please refer to the [Meningococcal chapter of the Green Book](#) and the **Vaccination of individuals with uncertain or incomplete immunisation status** algorithm:

<https://www.gov.uk/government/publications/vaccination-of-individuals-with-uncertain-or-incomplete-immunisation-status>

#### *Paracetamol*

16. Administration of a 2.5ml dose of paracetamol oral suspension (120mg/5ml) by the parent or guardian at the time of or shortly after the first two MenB vaccinations (with a further two doses four to six hours later) should reduce the likelihood or intensity of fever without diminishing the immune response.

#### *Contraindications*

17. There are very few individuals who cannot receive meningococcal vaccines. When in doubt, appropriate advice should be sought from a consultant paediatrician, consultant in communicable disease control, or screening and immunisation team staff, rather than withholding immunisation.

18. Bexsero® should not be given to:

- infants with a confirmed anaphylactic reaction to a previous dose of Bexsero®
- infants with a confirmed anaphylactic reaction to any component of the vaccine

19. Administration of Bexsero® should be postponed in infants suffering from acute severe febrile illness.

20. Other minor illnesses without fever or systemic upset are not valid reasons to postpone immunisation.

#### *Immunosuppression and HIV infection*

21. Bexsero® can be given to infants with HIV infection (regardless of CD4 count) or immunosuppressed in accordance with the routine schedule.

#### *Concomitant administration with other vaccines*

22. 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. As mentioned above, it is recommended that Bexsero® be given in the left thigh, ideally on its own, so that any local reactions can be monitored more accurately. If another vaccine needs to be administered in the same limb, then it must be given at least 2.5cm apart.

#### *Consent*

23. See Chapter Two of *Immunisation against infectious disease* ('the Green Book'):

[The Green Book - Chapter Two](#)

## Pharmacy issues

### *Vaccine brand name and supplier*

24. Bexsero® – supplied by GlaxoSmithKline (NB. Initially packaging will say 'Novartis' (name of original manufacturer) but this is likely to change in 2016).

### *Presentation*

25. Bexsero® is supplied as a prefilled syringe in a **pack of 10**, without needles and with one patient information leaflet (PIL). Additional PILs will be supplied with each pack of 10 Bexsero® ordered.

26. The vaccine is presented as a clear, colourless liquid, free of visible particles, for **intramuscular** administration.

27. The vaccine is ready to use (no reconstitution or dilution is required).

28. The vaccine is to be administered **intramuscularly** without mixing with any other vaccines or solutions.

29. Upon storage a fine off-white deposit may be observed in the pre-filled syringe containing the suspension. Before use, the pre-filled syringe should be well shaken in order to form a homogeneous suspension. The vaccine should be visually inspected for particulate matter and discoloration prior to administration. In the event of any foreign particulate matter and/or variation of physical aspect being observed, do not administer the vaccine.

30. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

### *Vaccine supply (including ImmForm registration)*

31. Bexsero® should be ordered online via the [ImmForm website](#) and is distributed by Movianto UK (Tel: 01234 248631) as part of the national childhood immunisation programme. The vaccine is expected to be available to order from the beginning of August 2015. Further details will be published as an ImmForm news item and through [Vaccine Update](#)<sup>4</sup> in due course.

32. Centrally purchased vaccines for the national immunisation programme for the NHS can only be ordered via ImmForm and are provided free of charge to NHS organisations. Vaccines for private prescriptions, occupational health use or travel are NOT provided free of charge and should be ordered from the manufacturer. For outbreaks and contacts, vaccine should be procured locally directly from the manufacturer. Further information about ImmForm is available at [ImmForm Helpsheet](#) or from the ImmForm helpdesk at [helpdesk@immform.org.uk](mailto:helpdesk@immform.org.uk) or Tel: 0844 376 0040.

### *Liquid paracetamol supply*

33. Sachets of paracetamol oral suspension (120mg/5ml) with measuring devices will also be available to order through the ImmForm website<sup>3</sup> for an initial period from

---

<sup>4</sup> Vaccine Update: <https://www.gov.uk/government/collections/vaccine-update>



the start of the programme, until communications advising parents on the need to have paracetamol in advance of the vaccination appointment are well established. Further details on ordering of paracetamol and measuring devices will be published as an ImmForm news item and through Vaccine Update<sup>4</sup> in due course.

### *Storage*

34. Vaccines should be stored in the original packaging between +2°C to +8°C and protected from light. All vaccines may be sensitive to some extent to heat and cold. Do not freeze. Freezing may cause increased reactogenicity and loss of potency for some vaccines. It can also cause hairline cracks in the container, leading to contamination of the contents.

35. The vaccine should be used immediately after opening.

### *Vaccine stock management*

36. Please ensure sufficient fridge space is available for the new vaccine. Each site holding vaccine is asked to review current stocks of all vaccines. Two to four weeks of stock is recommended, and higher stock levels should be reduced to this level. Please remember that the vaccine will be supplied in packs of 10. A review of available fridge space will be necessary to ensure adequate storage capacity at the start of the programme.

37. Effective management of vaccines throughout the supply chain is essential to reduce vaccine wastage. Local protocols should be in place to reduce vaccine wastage to a minimum. Even small percentage reductions in vaccine wastage will have a major impact on the financing of vaccine supplies.

38. Any cold chain failures must be documented and reported to the local immunisation co-ordinator and reported through the ImmForm website on the stock incident page.

### **Reporting of adverse reactions**

39. Suspected adverse reactions (ADR) to vaccines should be reported via the Yellow Card Scheme (<https://yellowcard.mhra.gov.uk/the-yellow-card-scheme/>). Chapter Nine<sup>5</sup> of the Green Book gives detailed guidance which ADRs to report and how to do so. Additionally, Chapter Eight<sup>6</sup> of the Green Book provides detailed advice on managing ADRs following immunisation.

40. It is recommended that all doses of Bexsero® be given in the **left thigh**, ideally on their own, so that any local reactions can be monitored more accurately.

41. Any reported adverse incidents, errors or events during or post vaccination must follow determined procedures. In addition teams must keep a local log of reports and discuss such events with the local immunisation co-ordinator.

---

<sup>5</sup> The Green Book, chapter nine - surveillance and monitoring for vaccine safety: <https://www.gov.uk/government/publications/surveillance-and-monitoring-for-vaccine-safety-the-green-book-chapter-9>

<sup>6</sup> The Green Book, chapter eight - vaccine safety and adverse events following immunisation: <https://www.gov.uk/government/publications/vaccine-safety-and-adverse-events-following-immunisation-the-green-book-chapter-8>

### *Surveillance*

42. The programme will be carefully monitored by Public Health England (PHE) and the Medicines and Healthcare products Regulatory Agency (MHRA).

### **Personal Child Health Record (the "Red Book")**

43. Arrangements have been made for the Red Book record of childhood vaccinations to be amended to reflect the changes to the childhood schedule, including MenB vaccination. It is important that information about vaccinations given is recorded in the Red Book, when it is available. Further information on the details to be recorded is given in Chapter Four of the Green Book. It should be noted that the parents of the first eligible cohorts will have old versions of the Red Book that will not include information about MenB and the updated advice on the use of prophylactic paracetamol, and so it is very important that health professionals advise them of the changes.

### **Patient Group Directions**

44. The preferred method for the supply and administration of medicines is via Patient Specific Directions (PSD). A PSD may be provided by the GP or an independent nurse prescriber at the six to eight week check and recorded in the infant's medical records or Personal Child Health Record (PCHR or Red Book). See [MHRA FAQ](#) for the requirements for a PSD.

45. Organisations may choose to authorise a Patient Group Direction (PGD) to allow registered nurses, who are signed up to and authorised to use the PGD, to administer MenB vaccination under Patient Group Direction (PGD) when it is appropriate to do so and a PSD is not available.

46. A national clinically authorised PHE MenB PGD template will be available for NHS England Areas to adopt and authorise for their commissioned services if appropriate. National guidance for the supply and/or administration of paracetamol will be available.

### **Vaccine coverage data collection**

#### *ImmForm and COVER*

47. In order to facilitate timely monitoring of vaccine uptake once the programme is introduced, a temporary automated monthly data collection is being implemented via ImmForm. Monthly automated surveys will extract vaccine coverage data from GP systems for children who reach six months (26 weeks) in the evaluation month. The first cohort routinely offered the vaccine at two and four months of age will be aged six months in February 2016 and provisional vaccine coverage for each of the priming doses will be collected in early March 2016. This approach poses minimal or no burden to the NHS.

48. A scope for a temporary ImmForm coverage data collection is attached at **Annex B**.

49. This data collection will run in parallel with the routine quarterly and annual COVER data collections which will evaluate vaccine coverage for children at 12

months of age. The first quarterly evaluation will be published in December 2016, for children aged 12 months in the July to September 2016 quarter.

### **Child Health Information Systems**

50. The [COVER Information Standards Notice](#)<sup>7</sup> published in November 2014 stated that the MenB data collection would be activated if and when a national MenB programme was introduced. Child Health Information System (CHIS) IT suppliers have therefore already been instructed to add a new field to record a MenB vaccine and NHS England commissioners are required to check that this change has been implemented locally. Commissioners should also instruct CHIS IT suppliers and Child Health Record Departments that the MenB data flows for the quarterly and annual COVER collection should be activated from the 1 September 2015. For read codes see **Annex C**.

51. NHS England is responsible for the commissioning of CHIS and associated Child Health Records Department activities. Infants will be called for their immunisation against MenB at the same time as for their other immunisations offered at two and four months, via the local CHIS or their GP surgery (whichever is the usual method of call/ recall used in the area).

52. The provider must ensure that information on vaccines administered is documented in the general practice record.

53. The provider must ensure that information on vaccines administered is submitted in a timely manner directly to any relevant population immunisation register, in most areas the CHIS. Where possible this should aim to be within two working days.

54. Arrangements will also be required by the CHIS system to inform neighbouring areas when children resident in their area are immunised outside their local area.

### **MenB vaccine scheduling via CHIS and GP systems**

55. NHS England commissioners of the national immunisation programmes and the CHIS are instructed to directly contact local CHIS providers to ensure that they are ready and able to include the MenB vaccine on their schedules. If in your area scheduling is done by GP practices and not the CHIS then you will need to communicate with primary care colleagues to make sure they too are ready for this change. CHIS IT suppliers and CHIS managers should be instructed of the eligible cohorts and schedule recommended by the JCVI and the start date of the programme.

### **Funding and service arrangements**

56. NHS England and the GPC have agreed to the introduction of an enhanced service to be offered to GP practice to deliver meningococcal B vaccinations alongside existing children's vaccination programmes in England. Further details of

---

<sup>7</sup> COVER information standards notice: <https://www.gov.uk/government/publications/cover-of-vaccination-evaluated-rapidly-cover-programme-information-standards>

funding and delivery requirements will be incorporated into the [enhanced service specification](#)<sup>8</sup>. The supporting implementation guidance can be found at this link: [www.nhsemployers.org/vandi](http://www.nhsemployers.org/vandi)

57. NHS England intends to support the calculation of payments for meningococcal B using the Calculating Quality Reporting Service (CQRS) to minimise the reporting requirements for GP practices. Details of the technical requirements for these programmes can be found on the [NHS Employers website](#)<sup>9</sup>.

### **Communications and information for parents and health professionals**

58. An Integrated Communications Strategy has been produced for the introduction of the MenB vaccine to the childhood immunisation programme. The strategy is led by PHE and provides communications colleagues in partner organisations with information and resources to assist with the delivery of the programme. Partners include DH, NHS England and national meningitis charities.

59. Patient information flyers, leaflets and posters are being produced for parents, to support the introduction of the vaccine, and will include specific resources providing advice on the use of paracetamol. They will be NHS branded and available from the DH/ PHE [Publications Orderline](#). Existing immunisation information booklets, such as the child's 'Red Book', will be amended to reflect the new schedule. In addition to the new Green Book chapter, there will be a Q&A factsheet for health professionals.

60. Materials for health care professionals will be made available here from July: [Professional MenB Information](#)

61. Materials for parents will be made available here from July: [www.nhs.uk](http://www.nhs.uk)

### **Training**

62. The national immunisation team has organised one national conference (16<sup>th</sup> June 2015) and four regional training events (23<sup>rd</sup>, 24<sup>th</sup>, 25<sup>th</sup> and 26<sup>th</sup> June 2015) aimed at 'training the trainers' such as Screening and Immunisation Team staff, Health Protection Team staff and immunisation training providers. Local NHS England and PHE colleagues are requested to help to cascade this training locally to frontline immunisers in preparation for the 1 September 2015 roll-out.

63. In addition, training resources in the form of a standard slide set, a recorded walk through of the slides and a mock video consultation including a discussion about the use of paracetamol will be made available on the PHE website.

---

<sup>8</sup> NHS England service specification. <http://www.england.nhs.uk/commissioning/gp-contract/>

<sup>9</sup> NHS Employers website: [www.nhsemployers.org/vandi](http://www.nhsemployers.org/vandi)

**Scope of Temporary sentinel MenB immunisation coverage survey**

This paper sets out the scope for the temporary sentinel data collection that will be undertaken to rapidly evaluate the MenB vaccination programme. The current planning assumption is for a 1<sup>st</sup> September 2015 start date. The current proposed schedule and eligible cohorts are as follows:

|                        | <b>Babies born on or after</b> | <b>Priming dose</b> | <b>Priming dose</b> | <b>Booster</b> |
|------------------------|--------------------------------|---------------------|---------------------|----------------|
| <b>Routine cohort</b>  | 01/07/2015                     | 2 months            | 4 months            | 12-13 months   |
| <b>Catch-up cohort</b> | 01/05/2015 to 30/06/2015       | 3 months            | 4 months            | 12-13 months   |
|                        |                                | n/a                 | 4 months            | 12-13 months   |

**Aim**

1. To automatically collect monthly coverage data from sentinel GP practices (ie GP practices that have automated data extraction facilities) to:
  - facilitate monitoring and evaluation of the implementation of the national routine MenB vaccination programme by Public Health England (PHE), NHS England and Department of Health (DH),
  - identify areas where coverage of 1<sup>st</sup> or 2<sup>nd</sup> dose is low,
  - provide epidemiological data to allow assessment of the impact of the programme,
  - provide data for vaccine safety assessment,
  - provide information to the public and ministers.

**Data to be collected**

2. Data will be collected on the following:
  - i. The number of infants in a GP practice who, in the survey month, reach 26 weeks of age (**denominator 1**).
  - ii. The number of infants in denominator 1 who received (a) 1<sup>st</sup> dose and (b) 2<sup>nd</sup> dose of Bexsero® (MenB vaccine) from 8 weeks of age up to 26 weeks of age, including vaccinations given by other healthcare providers.
  - iii. The number of infants in a GP practice who, in the survey month, reach their first birthday (**denominator 2**).
  - iv. The number of infants in denominator 2 who received (c) 1<sup>st</sup> dose and (d) 2<sup>nd</sup> dose of Bexsero® (MenB vaccine) from 8 weeks of age up to their first birthday, including vaccinations given by other healthcare providers.
  - v. The number of infants in a GP practice who, in the survey month, reach 78 weeks of age (**denominator 3**).
  - vi. The number of infants in denominator 3 who received (d) a booster dose of Bexsero® after their first birthday up to 78 weeks of age, including vaccinations given by other healthcare providers.

3. Denominator and numerator data will allow vaccine coverage for each dose to be calculated. The count of doses given will help vaccine supply planning. The denominator and numerators (dose 1, dose 2 primary doses and booster dose), will be broken down by gender and ethnicity as for other recently introduced collections (rotavirus and shingles vaccines). As for all new collections these variables will be considered experimental and subject to validation and audit.
4. Monthly automated surveys will run from the proposed start of the programme (1<sup>st</sup> September 2015), so that September data (1/09/15 to 30/09/15 inclusive) will be collected in early October 2015. A review will be conducted in March 2017 on continuing the sentinel collection. The automated collection will allow PHE to collect monthly data with minimal or no burden to the NHS and provide quick and timely uptake figures. This data collection will run in parallel to a proposed COVER data collection, but will be able to provide early estimates of coverage at six months of age.
5. Data will be extracted automatically for each monthly survey as follows:

| Survey Month  | Data from Date (inclusive) | Data to Date (inclusive) |
|---------------|----------------------------|--------------------------|
| October 2015  | 01 September 2015          | 30 September 2015        |
| November 2015 | 01 December 2015           | 31 December 2015         |
| Etc           | etc                        | etc                      |

**NOTES**

1. All surveys are from the **start of the calendar month (inclusive)**
2. Each survey includes **data up until the survey month end (inclusive)**

6. The source of data will be automated collections from GP Practices to ImmForm and will be sentinel ie data will only be collected from practices with automated data extraction facilities (currently more than 95% of all English practices). Data from GP practices included within the sentinel scheme can be aggregated by NHS England organisations (Clinical Commissioning Groups (CCGs), former Area Teams (ATs) and NHS England local teams (LTs), and by Local Authorities (LAs) through the ImmForm website. This will enable stakeholders to do the following:
  - assess coverage rates at the local, regional and national levels
  - compare uptake with other anonymous CCGs, ATs, LTs, LAs
  - view data and export data into Excel, for further analysis (ie gender and ethnicity)

**End of the Survey**

7. The continuation of the sentinel collection will be reviewed in March 2017, by which time the COVER programme data should be available.

**Annex C**

The **read codes** for the MenB vaccine doses are as follows:

|  | Read V2 | CTV3  | SNOMED CT       |
|--|---------|-------|-----------------|
| Meningococcal B vaccine 1 <sup>st</sup> dose                       | 65710   | XacJs | 957771000000107 |
| Meningococcal B vaccine 2 <sup>nd</sup> dose                       | 65711   | XacJt | 957521000000103 |
| Meningococcal B vaccine 3 <sup>rd</sup> dose                       | 65712   | XacJu | 957541000000105 |
| Meningococcal B vaccine 4 <sup>th</sup> dose *                     | 65713   | XacJv | 957561000000106 |
| Meningococcal B vaccine contra-indicated                           | 8I23P   | XacJx | 957601000000106 |
| Meningococcal B vaccine declined                                   | 8IHC    | XacJy | 957621000000102 |
| Meningococcal B vaccine given by other healthcare provider         | 65714   | XacJw | 957581000000102 |
| First meningitis B vaccination given by other healthcare provider  | 65715   | XacKp | 958381000000107 |
| Second meningitis B vaccination given by other healthcare provider | 65716   | XacKq | 958401000000107 |
| Third meningitis B vaccination given by other healthcare provider  | 65717   | XacKr | 958421000000103 |
| Fourth meningitis B vaccination given by other healthcare provider | 65718   | XacKs | 958441000000105 |

\*As per [The Green Book meningococcal disease chapter 22](#) children and adults in a risk group require a 4<sup>th</sup> dose of meningococcal B vaccine.