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NHS public health functions agreement 2017-18

Service specification No. 31 Meningococcal group B (MenB) programme

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Promoting equality and addressing health inequalities are at the heart of NHS England's values. Throughout the development of the policies and processes cited in this document, we have:

- Given due regard to the need to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic (as cited under the Equality Act 2010) and those who do not share it; and
- Given regard to the need to reduce inequalities between patients in access to, and outcomes from healthcare services and to ensure services are provided in an integrated way where this might reduce health inequalities

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Service specification No. 31

This is a service specification to accompany the 'NHS public health functions agreement 2017-18 (the '2017-18 agreement').

This service specification is to be applied by NHS England in accordance with the 2017-18 agreement. Where a specification refers to any other published document or standard, it refers to the document or standard as it existed at the date when the 2017-18 agreement was made between the Secretary of State and NHS England Board, unless otherwise specified. Any changes in other published documents or standards may have effect for the purposes of the 2017-18 agreement in accordance with the procedures described in Chapter 3 of the 2017-18 agreement

Service specifications should be downloaded in order to ensure that commissioners and providers refer to the latest document that is in effect.

The 2017-18 agreement is available at www.gov.uk (search for 'commissioning public health').

All current service specifications are available at www.england.nhs.uk (search for 'commissioning public health').

This service specification is not intended to replicate, duplicate or supersede any other legislative provisions that may apply. It must always be read in conjunction with the core service specification and the online version of the [Green Book](#).

1. Purpose of MenB immunisation programme

- 1.1. This document relates to immunisation to protect against invasive disease caused by capsular group B meningococcal (MenB) bacteria. For the purposes of brevity, this immunisation is henceforth referred to as “MenB immunisation”.
- 1.2. The purpose of this service specification is to enable NHS England to commission immunisation services to a standard that will minimise infections, outbreaks and associated morbidity and mortality due to MenB bacteria. This means achieving high levels of immunisation coverage across England as well as within upper tier local government areas and within the context of populations with protected characteristics as defined by the Equality Act 2010.
- 1.3. This specification provides a brief overview of the vaccine including the disease it protects against, the context, evidence base, and wider health outcomes. It should be read alongside the core service specification which underpins national and local commissioning practices and service delivery.
- 1.4. These arrangements underpin national and local commissioning practices and service delivery. This specification will also promote a consistent and equitable approach to the provision of the commissioning and delivery of the MenB immunisation programme across England. It is important to note that this programme can change and evolve in the light of emerging best practice and scientific evidence. NHS England and providers will be required to reflect these changes accordingly in a timely way as directed by the national schedule.
- 1.5. [Immunisation against infectious disease](#) (known as ‘the Green Book’), issued by Public Health England (PHE) is the main source of guidance for all immunisation programmes. This service specification must be read in conjunction with the core service specification, the online version of the Green Book, all current relevant official public health letters, and with additional evidence, advice and recommendations issued by the [Joint Committee on Vaccination and Immunisation](#) (JCVI).
- 1.6. This service specification is not designed to replicate, duplicate or supersede any relevant legislative provisions that may apply, e.g. the Health and Social Care Act 2012. The specification will be reviewed annually and amended in line with any new recommendations or guidance, and in line with reviews of the Section 7A agreement.

2. Population needs

Background

- 2.1. 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 10% of survivors of MenB disease have major physical and/or neurological disabilities, including amputation, deafness, epilepsy and/or learning difficulties, and around 30% have less severe physical and/or neurological disabilities.
- 2.2. The number of cases of meningitis and septicaemia caused by meningococcal group B (MenB) infection in eligible infants has nearly halved since routine MenB vaccination of infants was introduced in September 2015. Protection against any MenB infection was shown to be very high, with disease rates in vaccinated children less than one fifth of the rate in unvaccinated infants. The number of MenB cases in infants aged less than one, the age group most likely to be affected by MenB, dropped by around half. Only 37 cases have been recorded in the eligible age group since the programme began; this compares to an average of 74 cases in the same period from the previous 4 years.
- 2.3. The vaccine in use, 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 (i.e. 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 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. In New Zealand, for example, the effectiveness of such an OMV vaccine was estimated to be 73%.
- 2.4. 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.

- 2.5. 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.

Meningococcal disease

- 2.6. *Neisseria meningitidis* is the bacterium responsible for meningococcal disease, a serious, life-threatening infection characterised by meningitis (infection and inflammation of the lining of the brain), septicaemia (blood poisoning) or both.
- 2.7. Meningococcal infection is spread by prolonged close contact. Around 5-10% of adults carry the bacteria harmlessly in their throats without any signs or symptoms of the disease. Carriage rates are very low in infants and young children but can be as high as 25% in teenagers. It is not fully understood why disease develops in some individuals but not in others.
- 2.8. Approximately one in ten people who develop meningococcal disease will die. With early diagnosis and treatment most people make a full recovery, but around a tenth of survivors of MenB disease may have major physical and/or neurological disabilities, including limb amputation, deafness, epilepsy and/or learning difficulties.

Men B immunisation – key details

- 2.9. The key details are that:
- MenB vaccine should be given to babies at two and four months of age, with a booster at 12 – 13 months.
 - Immunisation should take place as part of the national schedule, and should be given at the same visit as the other scheduled vaccines.
 - The parent / carer should be advised to purchase their own supply of liquid paracetamol and to administer a dose of 2.5ml liquid paracetamol (120 mg/5 ml) at the time of, or soon after, vaccination. Two further 2.5ml doses of liquid paracetamol (120 mg/5 ml) are recommended to be given 4 to 6 hours apart, after both primary doses of MenB vaccination, but not the booster. Further information on the administration of liquid paracetamol following MenB immunisation can be viewed at: <https://www.gov.uk/government/publications/menb-vaccine-and-paracetamol>

3. Scope

Aims

- 3.1. The aim of the MenB immunisation programme is to protect infants and young children against MenB disease which can cause meningitis and septicaemia.

Objectives

- 3.2. The aim will be achieved by delivering an evidence-based immunisation programme that:
- identifies the eligible population and ensures effective timely delivery with optimal coverage;
 - is safe, effective, of a high quality and is independently monitored;
 - is delivered and supported by suitably trained, competent healthcare professionals who participate in recognised ongoing training and development in line with national standards;
 - delivers, manages and stores vaccine in accordance with national guidance;
 - is supported by regular and accurate data collection using the appropriate returns.

Direct health outcomes

- 3.3. In the context of health outcomes, the MenB immunisation programme aims to:
- Protect the health of individuals and the wider population;
 - Reduce the number of preventable infections and their onward transmission;
 - Achieve high coverage in the target cohort;
 - Minimise adverse physical/psychological/clinical aspects of immunisation (e.g. anxiety, adverse reactions).

Baseline vaccine coverage

- 3.4. Local services must aim to offer MenB vaccination to 100% of eligible individuals in accordance with the Green Book and other official DH/PHE guidance including performance indicators and key deliverables that are set out in Annex B of the NHS Public Health Functions Agreement (Section 7A) for 2017-18.

4. Service description / care pathway

Local service delivery

- 4.1. The delivery of immunisation services at the local level is based on evolving best practice. This section of the document specifies the high-level operational elements of the national MenB immunisation programme, based on best practice that NHS England must use to inform local commissioning, contracts and service delivery. There is also scope to enable NHS England and providers to enhance and build on specifications to incorporate national or local service aspirations that may include increasing local innovation in service delivery. However, in order to promote a nationally aligned high-quality programme focusing on improved outcomes, increasing coverage and local take-up, it is essential that all the following elements are included in contracts and specifications.

Target population

- 4.2. Providers will be required to make the MenB vaccine available to:
- All eligible children both registered and unregistered with a GP, as part of the childhood immunisation programme's primary immunisation course. The first dose should be given to children at 2 months of age, the second dose at 4 months of age, and a third booster dose at 12 - 13 months.
 - Immunisation should take place as part of the national schedule, and should be given at the same visit as other scheduled vaccines.

Vaccine schedule

- Routine schedule for all infants:

Priming Dose	Priming Dose	Booster
2 months	4 months	12 - 13 months

- In order to provide early protection, providers should aim to complete the schedule as near as possible to the recommended ages
- Further information on scheduling is available in the relevant chapters of *Immunisation against infectious disease* (The Green Book)
<https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book>

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Vaccine ordering

- 4.3. All centrally procured vaccines must be ordered via the ImmForm online ordering system (<http://www.immform.dh.gov.uk>), details of which are given in the core specification.