



Public Health
England



NHS public health functions agreement 2019-20

Service specification No.4

Immunisation against diphtheria, tetanus, poliomyelitis, pertussis, Hib and HepB programme

NHS England and NHS Improvement



NHS public health functions agreement 2019-20

Service specification No.1A Pertussis pregnant women immunisation programme

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Promoting equality and addressing health inequalities are at the heart of NHS England and NHS Improvement 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 and those who do not share it (as required under the Equality Act 2010); and
- Given due 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 (in accordance with the duties under sections 13G and 13N of the NHS Act 2006, as amended).

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Service specification No.4

This is a service specification to accompany the 'NHS public health functions agreement 2019-20 (the '2019-20 agreement').

This service specification is to be applied by NHS England and NHS Improvement in accordance with the 2019-20 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 2019-20 agreement was made between the Secretary of State and NHS England and NHS Improvement Board, unless otherwise specified. Any changes in other published documents or standards may have effect for the purposes of the 2019-20 agreement in accordance with the procedures described in Chapter 3 of the 2019-20 agreement

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

The 2019-20 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 the immunisation programme

- 1.1 This document relates to the DTaP/IPV/Hib/Hep vaccine which is given to children to help protect them from developing the following preventable childhood diseases; diphtheria, tetanus, poliomyelitis, pertussis (whooping cough), Haemophilus influenzae type B (Hib) and hepatitis B. This vaccine forms part of the national childhood immunisation programme, which aims to prevent children from catching vaccine preventable childhood diseases that are associated with significant mortality and morbidity. The purpose of the service specification is to enable NHS England and NHS Improvement to commission DTaP/IPV/Hib/HepB immunisation services to a standard that will continue to minimise the number of infections and outbreaks caused by these organisms. This means high levels of 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.
- 1.2 This specification provides a brief overview of the vaccines including the diseases they protect against, the context, evidence base, and wider health outcomes, and should be read alongside the core service specification which underpins national and local commissioning practices and service delivery.
- 1.3 The existing programme provides a firm platform on which local services meet the needs of their local population and work towards improving health outcomes. This specification is intended to inform a consistent and equitable approach to the provision of the commissioning and delivery of the DTaP/IPV/Hib/HepB vaccines across England. It is important to note that this programme can change in the light of emerging best practice and scientific evidence. NHS England and NHS Improvement and providers will be required to reflect these changes accordingly in a timely way as directed by the national schedule.
- 1.4 [*Immunisation against infectious disease*](#) (known as 'The Green Book'), issued by Public Health England, provides guidance and the main evidence base 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 official public health letters and with additional evidence, advice and recommendations issued by the [Joint Committee on Vaccination and Immunisation \(JCVI\)](#). Whilst DTaP/IPV/Hib/HepB vaccine forms part of the routine childhood immunisation programme, it also forms part of the targeted neonatal Hepatitis B immunisation programme for babies born to Hepatitis B infected mothers. This specification should be read in conjunction with service specification number one for neonatal Hepatitis B immunisation.
- 1.5 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 wider reviews of the Section 7A agreement.

2 Population needs

Background

- 2.1 The DTaP/IPV/Hib/HepB vaccine is routinely used to protect against diphtheria, tetanus, pertussis (whooping cough), polio, Hib and Hepatitis B related infections.
- 2.2 Diphtheria
- 2.3 Diphtheria is a serious disease that usually starts with infection of the upper respiratory tract or the skin. The organism releases diphtheria toxin which can quickly cause cardiac, respiratory and neurological complications. In severe cases, it can be fatal and the case-fatality ratio remains high despite modern treatments. Prior to the 1940s, diphtheria was a common disease in the UK with more than 61,000 cases notified in 1940. The introduction of immunisation in the 1940s resulted in a dramatic fall in incidence and less than thirty cases have been reported in the last ten years. Most recently, reported cases have been imported from the Indian subcontinent or Africa, where diphtheria remains endemic, emphasising the importance of the vaccination.

Tetanus

- 2.4 Tetanus is a painful disease that causes muscle spasm and respiratory paralysis. It is caused when tetanus spores that are found in soil and manure get into the body through open cuts or burns. Tetanus affects the nervous system and can be fatal. The vaccine was nationally introduced in 1961 and the disease had almost disappeared in children under the age of 15 by the 1970s. Between 1984 and 2004, there were around 200 reported cases of tetanus, largely in the over-45 year old population, with the highest incidence in adults aged over 65 years. There have also been reported cases of tetanus in injecting drug users. Tetanus can never be eradicated because the spores are commonly present in the environment, including soil. Tetanus is not spread from person to person.

Poliomyelitis (polio)

- 2.5 Polio is a virus that attacks the nervous system and can lead to permanent paralysis, usually of the lower limbs. If the respiratory muscles are affected then it can be fatal. Before the polio vaccine was introduced, as many as 8,000 cases of polio occurred in the UK in epidemic years (the early 1950s). The last case of natural polio acquired in the UK was in 1984. By 2014, polio remained endemic in only a small number of countries. Although the risk of importation to the UK is low, vaccination continues to be important.

Pertussis (whooping cough)

- 2.6 Whooping cough is a respiratory disease that causes paroxysms of coughing which may be followed by the characteristic whoop. It is not usually serious in older children, but leads to a prolonged and irritating cough. In babies under one year old the infection can be very serious and sometimes fatal. Before the introduction of immunisation in the 1950s, the average annual number of notifications exceeded 120,000 in the UK. Since the mid-1990s, vaccine coverage has been consistently over 90% by the second birthday, with fewer than 6,000 notifications per year. Since

the final quarter of 2011, a major increase in cases has been observed, resulting in an increase in deaths and hospitalisations in infants too young to be vaccinated. In response to this outbreak a programme to protect infants, by vaccinating women in pregnancy was launched in October 2012. This has resulted in a fall in cases and deaths in infancy but the numbers of cases in older children and young adults remains high, confirming the continuing need to maintain coverage of infant vaccination.

Haemophilus influenzae type b (Hib)

2.7 Hib is an infection that can cause invasive infections such as septicaemia, septic arthritis, pneumonia and meningitis. All of these illnesses can be fatal. Individuals can carry Hib bacteria in their nose and throat without showing signs of the disease. Hib is spread through coughing, sneezing or close contact with a carrier. Since the introduction of the Hib immunisation in the UK, disease incidence has fallen. In 2010, there were only 30 reported cases of confirmed invasive Hib infection in England and Wales.

Hepatitis B (HBV)

2.8 Hepatitis B is a viral infection that attacks the liver and can cause both acute and chronic disease. It is a major global health problem, and the most serious type of viral Hepatitis. It is estimated that about 180,000 people in the UK are living with the chronic consequences of Hepatitis B, such as liver cirrhosis and liver cancer. Most of the UK chronic burden of disease is in people who have acquired Hepatitis B overseas in endemic countries during childhood before arrival in the UK. The virus is highly contagious and is transmitted through contact with blood or other body fluids of an infected person. In the UK babies born to Hepatitis B infected mothers are at greatest risk of infection for which there is a universal antenatal screening programme and selective neonatal Hepatitis B immunisation programme (see service specification No.1). Since 1992, the World Health Organisation has recommended that all countries introduce Hepatitis B immunisation as part of the routine infant programme to protect against future exposure risks.

DTaP/IPV/Hib/HepB vaccine – key details

2.9 The key details are that:

- DTaP/IPV/Hib/HepB has a strong evidence base, an excellent safety profile and is highly effective.
- DTaP/IPV/Hib/HepB vaccine replaced DTaP/IPV/Hib for which coverage in England at 12 months of age stood at 93.0% (regional variation 88.4% - 95.7% (Cover data Q4 2015/6)). Data on coverage for the DTaP/IPV/Hib/HepB are not yet available.
- Three doses of the DTaP/IPV/Hib/HepB vaccine as part of the routine infant immunisation schedule are needed to provide maximum protection for infants against these diseases.

- Continued high vaccine coverage is required in order to provide both individual and herd immunity.

2.10 DTaP/IPV/Hib/HepB immunisation forms part of the childhood immunisation programme – a key part of the Healthy Child Programme (HCP) as described in the core service specification.

3 Scope

Aims

- 3.1 The aim of the DTaP/IPV/Hib/HepB vaccine is to protect all children from six preventable childhood infections that are associated with significant mortality and morbidity.

Objectives

- 3.2 The aim will be achieved by delivering a population-wide, evidence-based, immunisation programme that:
- identifies the eligible population and ensures effective timely delivery with optimal coverage based on the target population set out in paragraph 4.2;
 - 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; and
 - is supported by regular and accurate data collection using the appropriate returns.

Direct health outcomes

- 3.3 In the context of health outcomes, the DTaP/IPV/Hib/HepB vaccine 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; and
 - minimise adverse physical/psychological/clinical aspects of immunisation (e.g. anxiety, adverse reactions).

Baseline vaccine coverage

- 3.4 Local services must ensure that they maintain and improve current immunisation coverage (with reference to vaccine coverage public health outcomes framework indicators) with the aim of 100% of relevant individuals being offered immunisation in accordance with the Green Book and other official DH/PHE guidance. This is in addition to performance indicators and key deliverables that are set out in annex B of the NHS Public Health Functions Agreement (Section 7A) for 2019-20.

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 DTaP/IPV/Hib/HepB vaccine programme, based on that best practice that NHS England and NHS Improvement must use to inform local commissioning, contracts and service delivery. There is also scope to enable NHS England and NHS Improvement and providers to enhance and build on specifications to incorporate national or local service aspirations that may include increasing local innovation in service delivery. It is essential, in order to promote a nationally aligned, high-quality programme focusing on improved outcomes, increasing coverage and local take-up that all the following core elements are included in contracts and specifications.

Target population

4.2 Providers will be required to make the DTaP/IPV/Hib/HepB vaccine available to:

- all children as part of the childhood immunisation programme's primary immunisation course. Further guidance can be obtained from the Green Book regarding recommendations for use of the vaccine and specific circumstances.

Vaccine schedule

Hexavalent vaccine (DTaP/IPV/Hib/HepB) Dose 1	8 weeks
Hexavalent vaccine (DTaP/IPV/Hib/HepB) Dose 2	12 weeks old
Hexavalent vaccine (DTaP/IPV/Hib/HepB) Dose 3	16 weeks old

4.3 The vaccination status of every child or young person must be checked and missing doses offered as appropriate to ensure that everyone has completed an age-appropriate course. Further information on scheduling is available in the relevant chapters of the Green Book <https://www.gov.uk/government/organisations/public-health-england/series/immunisation-against-infectious-disease-the-green-book>.

4.4 In order to provide early protection, providers should aim to complete the schedule as near as possible to the recommended ages. Sufficient immunisation appointments must be available so that individuals can receive vaccinations on time – waiting lists are not acceptable.

Vaccine ordering

4.5 All centrally procured vaccines must be ordered via the ImmForm online ordering system details of which are given in the core immunisation specification.