NHS public health functions agreement 2018-19
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’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 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.1A

This is a service specification to accompany the ‘NHS public health functions agreement 2018-19 (the ‘2018-19 agreement’).

This service specification is to be applied by NHS England in accordance with the 2018-19 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 2018-19 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 2018-19 agreement in accordance with the procedures described in Chapter 3 of the 2018-19 agreement.

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

The 2018-19 agreement is available at www.gov.uk (search for ‘commissioning public health’).

All current service specifications are available at http://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 pertussis pregnant women immunisation programme

1.1 This document relates to the pertussis (whooping cough) vaccine for pregnant women, given to help protect their newborn infants against serious complications from the infection until they receive their routine immunisations from two months of age.

1.2 The purpose of the service specification is to enable NHS England to commission pertussis for pregnant women immunisation services to a standard that will minimise infections and outbreaks caused by this organism. This means achieving high levels of coverage across England as well as within upper tier local government areas and within the context of populations with characteristics as defined by the Equality and Diversity Act.

1.3 This specification provides a brief overview of the vaccines including the disease they protect against, the context, evidence base, and wider health outcomes, and should be read alongside the core immunisation service specification which underpins national and local commissioning practices and service delivery.

1.4 In 2014 the Joint Committee on Vaccination and Immunisation (JCVI), independent experts on immunisation, recommended that the temporary pertussis vaccination in pregnancy programme should continue for at least a further five years. JCVI’s advice can be found by accessing the following link: https://www.gov.uk/government/groups/joint-committee-on-vaccination-and-immunisation#minutes (see Minute 2016 02, paragraphs 35 - 39).

1.5 Approximately 650,000 women a year are eligible to receive the pertussis vaccination in this programme. This specification is intended to inform a consistent and equitable approach to the commissioning and delivery of the programme across England.

1.6 *Immunisation against infectious disease* (known as the Green Book), issued by Public Health England (PHE) provides guidance and has the latest information on vaccines and vaccination procedures for all the vaccine preventable infectious diseases that may occur in the UK. The chapter relating to the maternal pertussis programme can be found here: https://www.gov.uk/government/publications/pertussis-the-green-book-chapter-24.

1.7 This service specification must be read in conjunction with the core immunisation service specification, the online version of the Green Book and all relevant official public health letters, and additional evidence, advice and recommendations issued by the JCVI.

1.8 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 Before the introduction of routine immunisation against pertussis in the 1950s large epidemics occurred every three to five years that affected up to 150,000 people and contributed to about 300 deaths a year. In comparison, between 2002 and 2011 there were on average 800 cases of pertussis with over 300 babies needing admission to hospital and four babies dying each year in England.

2.2 There has been a considerable increase in pertussis activity across England and Wales since mid-2011. In 2011, the UK saw the largest outbreak for over a decade. In 2012, the number of laboratory confirmed cases continued to increase peaking in October (1,628) with the total for 2012 reaching 9,711, almost 9-fold higher than 2011: http://webarchive.nationalarchives.gov.uk/20140714084352/http://www.hpa.org.uk/hpr/archives/2013/news0513.htm.

2.3 During 2012, 14 infant deaths were reported; the highest number of infant deaths in more than 15 years. In response to the heightened pertussis activity and increase in infant deaths, a vaccination programme for pregnant women was introduced in October 2012 to protect infants from birth. Since the introduction of the programme on 1 October 2012 there have been 18 deaths in infants following confirmed pertussis. Of these 16 were born to mothers who had not been immunised against pertussis during pregnancy: https://www.gov.uk/government/publications/pertussis-laboratory-confirmed-cases-reported-in-england-2017.

2.4 Young infants are particularly vulnerable to complications, hospitalisation and death from pertussis. Immunising pregnant women against pertussis helps provide their newborn infants with protection against serious complications from the infection until they receive their first routine immunisation at two months of age. While providing vital protection for infants, this programme will not have any effects on the transmission of pertussis across the population.

2.5 PHE will continue to monitor the levels of pertussis and JCVI will continue to review the programme.

2.6 Key details

- In February 2016 JCVI advised that pregnant women should be offered a single 0.5 ml dose of dTaP/IPV vaccine between gestational weeks 16 and 32 to maximise the likelihood that the baby will be protected from birth. For operational reasons, vaccination is best offered on or after the foetal anomaly scan at around 20 weeks. Women may still be immunised after week 32 of pregnancy but this may not offer as high a level of passive protection to the baby. Vaccination late in pregnancy may, however, directly protect the mother against disease and thereby reduce the risk of exposure to her infant. This single dose should be...
given irrespective of the number of foetuses in the pregnancy. The vaccine recommended for this purpose as set out in the Green Book also provides protection against tetanus, diphtheria and polio.

- JCVI stated there were no safety issues with earlier pertussis vaccination in pregnancy.
- Midwives and GPs should make pregnant women aware of the pertussis in pregnancy immunisation programme and the offer of vaccination, ideally at routine antenatal visits.
- Vaccine uptake is monitored with a monthly data collection through ImmForm.
3. **Scope**

**Aims**

3.1 The aim of the vaccination programme for pregnant women is to provide passive protection against pertussis to infants by offering immunisation to their pregnant mothers to boost antibody levels such that they pass pertussis-specific antibodies through their placenta.

**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;
- 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;
- 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 pertussis vaccine programme aims to:

- provide passive protection against pertussis to infants;
- achieve high coverage among 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 they maintain and improve current immunisation coverage (with reference to relevant vaccine coverage public health outcomes framework indicators, PHOF) with the aim of 100% of identified cohort being offered immunisation in accordance with the Green Book and other official DH/PHE guidance. This includes performance indicators and key deliverables that are set out in Annex B of the NHS Public Health Functions Agreement (Section 7A) for 2018-19.
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 temporary pertussis vaccine programme, based on the 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, 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 The dTaP/IPV vaccine should be offered to:

- all pregnant women, in each pregnancy; and
- new mothers (up to two months after the birth of the baby) who missed the opportunity to be vaccinated during pregnancy to reduce the risk of the mother contracting pertussis in the post-partum period and therefore prevent her from infecting her infant.

Vaccine schedule

4.3 A single 0.5ml dose of dTaP/IPV should be administered:

- Ideally between 16 and 32 weeks gestation, to maximise the likelihood that the baby will be protected from birth. For operational reasons, vaccination is best offered on or after the foetal anomaly scan at around 20 weeks.
- After 32 weeks gestation pregnant women may still be immunised but this may not offer as high a level of passive protection to the baby.
- From 38 weeks of pregnancy until the time of delivery vaccine must still be offered to women who have not been vaccinated to directly protect the mother against disease and thereby reduce the risk of exposure to her infant thereby providing indirect protection.
- to new mothers (up to two months after the birth of the baby) who missed the opportunity to be vaccinated during pregnancy, to reduce the risk of the mother contracting pertussis in the post-partum period and infecting her infant.

4.4 In order to provide protection, providers must aim to administer the vaccine as near as possible to the recommended times. Sufficient immunisation appointments must be
available so that individuals can receive vaccinations on time. Waiting lists are not acceptable.

4.5 Detailed recommendations on the administration of the vaccine are set out in chapter 24 of the Green Book. This guidance must be followed at all times.

Vaccine ordering

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

4.7 Vaccines can be ordered by:

- GP practices/hospital pharmacies for delivery to their location; and
- appropriate providers (with a wholesale dealer's licence) for delivery to their location.