

NHS public health functions agreement 2016-17

Service specification No.1A

Pertussis pregnant women immunisation
programme

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Document Status

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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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Pertussis pregnant women immunisation programme

Prepared by Public Health England

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This is a service specification to accompany the 'NHS public health functions agreement 2016-17 (the '2016-17 agreement') published in December 2015.

This service specification is to be applied by NHS England in accordance with the 2016-17 agreement. This service specification is not intended to replicate, duplicate or supersede any other legislative provisions that may apply.

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 2016-17 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 2016-17 agreement in accordance with the procedures described in Chapter 3 of the 2016-17 agreement

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

The 2016-17 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:

<https://www.gov.uk/government/collections/immunisation-against-infectious-disease-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 that is 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. Independent experts on immunisation – the Joint Committee on Vaccination and Immunisation (JCVI) advises pertussis vaccination in pregnancy should continue for at least the next five years. As per JCVI advice pregnant women between 16 and 38 (inclusive) of pregnancy (the optimal time for immunisation is in weeks 16 to 32, inclusive) should be offered immunisation against pertussis to help protect their newborn infants before they can receive their routine immunisations. JCVI's advice can be found by accessing the following link: <https://www.gov.uk/government/publications/whooping-cough-vaccination-programme-for-pregnant-women-extension-to-2014>
- 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. It includes a chapter on the routine pertussis programme given to children as part of the childhood immunisation programme. 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](#).
- 1.7. 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, over the last ten years (2002 – 2011) there have been on average 800 cases of pertussis with over 300 babies needing admission to hospital and four babies dying each year in England.
- 2.2.
- 2.3. 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#prtsss>).
- 2.4. 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 temporary vaccination programme for pregnant women was introduced in October 2012 to protect infants from birth. After the introduction of the routine pertussis programme for pregnant women in October 2012, the overall laboratory confirmed pertussis cases in England fell each month from November 2012 to June 2013, then increased slightly in July and August 2013 before decreasing again in September 2013, in line with seasonal trends. High levels of pertussis in all age groups aged 1 year or older have, however, continued when compared to equivalent periods in the years prior to 2012. Provisional data show that in August and September, 393 and 383 cases respectively were newly confirmed, compared with 355 cases in July (<http://webarchive.nationalarchives.gov.uk/20140714084352/http://hpa.org.uk/hpr/archives/2013/hpr4713.pdf>). Although cases have continued to decline across all age groups, the number of confirmed cases in infants less than 3 months of age has shown a disproportionate decline compared with older age groups since the introduction of the temporary vaccination programme.
- 2.5. Young infants are particularly vulnerable to complications, hospitalisation and death from pertussis. Immunising pregnant women against pertussis may help 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.
- 2.6. PHE will continue to monitor the levels of pertussis and JCVI will review the programme in five years' time.

2.7. Key details

- JCVI has recommended a single dose of the dTaP/IPV vaccine to pregnant women in the period weeks 16 to 38 (inclusive) of pregnancy (the optimal time for immunisation is in weeks 16 to 32, inclusive). This dose should be given irrespective of the number of fetuses in pregnancy. The vaccine recommended for this purpose as set out in the Green Book also provides protection against tetanus, diphtheria and polio.
- The customary time to offer pertussis immunisation will be after the foetal anomaly scan, (also known as the 20-week scan) which usually takes place between 18 and 20 weeks gestation.
- GPs should offer the vaccine from 20 weeks gestation (by which time the foetal anomaly scan should have taken place) and before week 38 of pregnancy, with understanding that it can be offered up to the onset of labour.
- Maternity service providers offering pertussis immunisation as part of antenatal care are not obliged to restrict the offer to only after 20 weeks of gestation. The vaccine can be offered at any time from 16 weeks, ideally at the same visit as the foetal anomaly scan.
- JCVI has stated they have no concerns about the safety of use at any stage of 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 indirect 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 indirect protection against pertussis to infants
 - achieve high coverage among the target cohort
 - 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 2016-17.

4. Service description/care pathway

- 4.1. PHE undertakes the purchase, storage and distribution of vaccines at a national level. It together with the HSCIS holds surveillance and coverage data hold the coverage and surveillance data and have the public health expertise for analysing the coverage of, and other aspects of, immunisation services. It is also responsible for the implementation of the national immunisation schedule, clinical guidance via the Green Book, including the national communication strategy, setting standards and following recommendations as advised by JCVI and other relevant organisations.

Local service delivery

- 4.2. 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 that 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 core elements specification which is set out in the core service specification.

Target population

- 4.3. The dTaP/IPV vaccine should be offered to:
- pregnant women in the period weeks 20 to 38 (inclusive) of pregnancy: the optimal time for immunisation is in weeks 20 to 32 (inclusive).

Vaccine schedule

- 4.4. Immunisation during or after the 16th week of pregnancy is likely to maximise levels of anti-pertussis antibodies in the pregnant women in time for optimal transplacental transfer to the unborn child. The service should immunise the target population in the period weeks 20 to 38 of pregnancy (inclusive); the optimal time is in weeks 16 to 32 (inclusive) and in line with section 2.7 above.
- 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.
 - Pregnant women who miss vaccination and are beyond week 38 of pregnancy must be offered immunisation up to the onset of labour so that some direct protection may still be provided to the infant.

- 4.5. Vaccination of pregnant women, even after 38 weeks, will reduce the risk of the mother contracting pertussis in the post-partum period and therefore prevent her from infecting her infant. Detailed recommendations on the administration of the vaccine are set out in the [pertussis chapter](#) 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;
 - appropriate providers (with a wholesale dealer's licence) for delivery to their location.