Public Health England

Protecting and improving the nation's health

Pertussis (whooping cough) vaccination programme for pregnant women

Information for healthcare practitioners

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Public Health England exists to protect and improve the nation's health and wellbeing, and reduce health inequalities. We do this through world-leading science, research, knowledge and intelligence, advocacy, partnerships and the delivery of specialist public health services. We are an executive agency of the Department of Health and Social Care, and a distinct delivery organisation with operational autonomy. We provide government, local government, the NHS, Parliament, industry and the public with evidence-based professional, scientific and delivery expertise and support.

Public Health England
Wellington House
133-155 Waterloo Road
London SE1 8UG
Tel: 020 7654 8000
www.gov.uk/phe
Twitter: @PHE_uk
Facebook: www.facebook.com/PublicHealthEngland

For queries relating to this document, please contact: Immunisation.lead@phe.gov.uk

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Background

In 2012, the UK reported the largest increase in pertussis activity in over 2 decades. At that time, the greatest numbers of cases were in adolescents and young adults but the highest rates of morbidity and mortality occurred in infants less than 3 months old. Infants in this age group are most at risk of serious disease and are too young to be protected through routine vaccination.

The Annual report of laboratory confirmed cases of pertussis in England (2018) reported that in those infants less than 3 months old, the incidence of laboratory confirmed cases of pertussis was 240 per 100,000 in 2012 with a total of 14 infant deaths reported in England and Wales.

In reponse to the national outbreak, described as the largest seen in the UK for over a decade, the Department of Health (DH) issued a letter from the Chief Medical Officer (CMO) which announced the introduction of a temporary immunisation programme for pregnant women.

The aim of the programme was to boost pertussis antibodies in the vaccinated woman in late pregnancy, so that pertussis specific antibodies would be passed from the mother to her baby to provide the infant with protection until they attended for their own routine vaccines at 8 weeks old.

The programme commenced on 1st October 2012 with the recommendation that pregnant women were to be vaccinated ideally between weeks 28 to 38 of their pregnancy, with the optimal time for vaccination being between weeks 28 and 32 of pregnancy.

In June 2014, the Joint Committee on Vaccination and Immunisation (JCVI) reviewed the maternal pertussis vaccination programme and agreed that ‘acceptance of the programme amongst pregnant women was good and that relatively high coverage, coupled with high effectiveness of the vaccine had resulted in a reduction in disease and mortality in young infants’.

Two different studies led by Public Health England (PHE) (An observational study on the effectiveness of maternal pertussis vaccination in England and a Case-Control Study to Estimate the Effectiveness of Maternal Pertussis Vaccination in Protecting Newborn Infants in England and Wales, 2012–2013), demonstrated high vaccine effectiveness of 91% for infants aged <3 months based on 82 infants; that the greatest proportionate fall in confirmed cases and hospital admissions were observed in those under 3 months of age; and that maternal vaccination is effective in preventing pertussis infection in infants less than 8 weeks old.

In light of the success of the vaccination programme in saving infant lives and against the continued increase in pertussis incidence, JCVI recommended in the minutes of a meeting held on 4th June 2014, that the programme continue for at least a further 5 years.

A study published in January 2016 showed that reasonable levels of pertussis antibodies were demonstrated in neonates through transplacental transfer from mothers vaccinated earlier in pregnancy.

The authors recommended extending the window of maternal immunisation to include the second trimester of gestation as this could help to reduce the possibility for missed immunisation, minimise the number of women vaccinated close to their delivery date and could potentially allow pre-term infants to benefit from the programme.

The minutes from a meeting held in February 2016 noted that JCVI reviewed pertussis epidemiology, the impact of maternal vaccination on infant antibody response and evidence on optimal timing of maternal vaccination.

Following the review, they advised that from 1st April 2016, vaccination should be recommended from the 16th week of pregnancy as this would give pregnant women greater opportunity to take up the offer of vaccination and would offer some protection to infants born prematurely who may be particularly vulnerable to complications from pertussis and would potentially improve neonatal antibody levels.

The minutes from a meeting held in June 2016 advised that the emergency maternal programme should continue as a routine programme.

For operational reasons, it was advised that vaccination be offered on or after the foetal anomaly scan at around 18 - 20 weeks of pregnancy. Offering scans at this time will avoid any associations with unrelated adverse events occurred or at the routine anomaly antenatal scan being made.

PHE have reported that vaccine coverage has been around 70% since 2016 and that coverage between October and December 2019 remained above 70%, increasing from 70.6% in October to 73.5% in December 2019.

Although the number of deaths decreased in babies born since introducing the vaccination programme 7 years ago in England, still, twenty babies passed away with confirmed pertussis during this time.

The Annual report for 2019 of laboratory confirmed cases of pertussis in England reports that ‘all of the deaths in 2012 and those that have occurred following the introduction of the maternal programme were in infants too young to be fully protected by infant vaccination.

Only two of the infants born after the introduction of the maternal programme had a mother who had been vaccinated during pregnancy. In both cases the vaccination was too close to delivery to confer optimal passive protection in the infant.’

Evaluation of the safety of pertussis vaccination in pregnant women in England has demonstrated no safety concerns.

Pertussis (Whooping cough)

Pertussis, also known as whooping cough, is a respiratory infection caused by Bordetella pertussis bacteria. Pertussis usually begins with mild, cold-like symptoms which develop over 1 to 2 weeks into coughing fits which can be severe. The cough often can last for 2 to 3 months and because of this, in some countries, pertussis is known as the “100-day cough”.

Pertussis most commonly affects infants and very young infants are at highest risk of serious complications, of needing admission to hospital or of dying. However, pertussis does occur in older children, adolescents and adults. In all age groups, apart from children who have recently been vaccinated (those aged from 4 months to around 9 years), the number of cases of pertussis in the UK has been high in recent years.

Pregnant women diagnosed with confirmed or suspected pertussis

Although it might be expected that a woman diagnosed with whooping cough during pregnancy would transfer antibodies to her unborn baby, not all women make sufficiently high levels of antibodies following natural infection to ensure high levels can be passed across the placenta to the infant. As high levels of antibodies are made following vaccination, offering vaccine from 16 weeks of pregnancy should ensure that optimal antibody levels can be passed to the baby.

Pertussis vaccination programme for pregnant women

Aim of the programme

The aim of the programme is to protect infants by boosting pertussis immunity in pregnant women.

Although most women will have been vaccinated or exposed to natural whooping cough in childhood, if they are given pertussis containing vaccine from week 16 of pregnancy, the vaccine will temporarily boost their antibody levels.

This enables the mother to transfer a high level of pertussis antibodies across the placenta to her unborn child which should passively protect her infant against pertussis until he/she is due the first dose of primary immunisations at 8 weeks of age.

Although it is recommended that women are offered the vaccine between weeks 16-32 of pregnancy, women may still be immunised after week 32 of pregnancy until delivery. However, this may not offer as high a level of passive protection to the baby, particularly if they are born pre-term.

Safety of vaccine administration during pregnancy

There are no concerns about the safety of pertussis-containing inactivated vaccine at any stage in pregnancy. Inactivated vaccines are routinely used in other countries and in the last few years, pertussis-containing vaccines have been given in pertussis vaccine in pregnancy programmes in countries such as USA, New Zealand and Australia.

Inactivated vaccines contain no live organisms, cannot replicate and therefore cannot cause infection in either the mother or the foetus.

Since the introduction of the pertussis vaccine in pregnancy programme in October 2012, the Medicines and Healthcare products Regulatory Agency (MHRA) has continually monitored the frequency and type of adverse events using the Yellow Card Scheme and the Clinical Practice Research Datalink to follow pregnancy outcomes following vaccination.

The MHRA has found no safety concerns relating to pertussis vaccination in pregnancy based on a large observational cohort study of 18,000 vaccinated women with similar rates of normal, healthy births in vaccinated and in unvaccinated women.

The study found no evidence of an increased risk of stillbirth in the 14 days immediately after vaccination or later in pregnancy and found no evidence of an increased risk of any of an extensive predefined list of adverse events related to pregnancy.

Protecting each pregnancy

The purpose of the pertussis vaccination programme is to boost immunity in women during pregnancy so that pertussis antibodies are passed from mother to baby to passively protect infants in the first months of life before they reach the age of routine infant vaccination.

This is achieved by vaccinating pregnant women from 16 weeks of pregnancy in order to maximise the transplacental transfer of pertussis antibodies. Therefore, it is important for all women to be offered the pertussis vaccine, ideally between weeks 16 and 32, of every pregnancy.

Women beyond 32 weeks of pregnancy

Administering the vaccine between weeks 16 and 32 of pregnancy is likely to ensure sufficient levels of pertussis antibodies are transferred across the placenta, providing passive immunity to the unborn child.

The vaccine can be offered to pregnant women up until they go into labour. However, this is not the optimal time for immunisation since antibody levels in adults peak about 2 weeks after a pertussis booster. A vaccine administered shortly before labour may mean that there is insufficient time for the mother to make a good response and have antibodies to pass across the placenta.

If the woman reaches 38 weeks of pregnancy and has not received the vaccine, it should still be offered. Although immunisation after week 38 of pregnancy may not provide passive protection to the infant, it would potentially protect the mother from pertussis infection and reduce the risk of her becoming a source of infection to her infant.

Post-natal vaccination

Women who did not receive pertussis containing vaccine during pregnancy can be offered it in the 2 months following birth (up until their child receives their first dose of pertussis containing vaccine). This will protect the woman and may prevent her from becoming a source of infection for the infant but will not provide direct protection for the infant.

Pregnant women and women presenting shortly after giving birth with an incomplete or unknown vaccination history (primary vaccination against diphtheria, tetanus and polio)

Women who have not completed a primary course of 3 doses of tetanus, diphtheria and polio containing vaccines may be offered these whilst they are pregnant.
The relevant chapters of the Green book (Immunisation against infectious disease) advise that tetanus, diphtheria and polio containing vaccines 'may be given to pregnant women when the need for protection is required without delay.

There is no evidence of risk from vaccinating pregnant women or those who are breast-feeding with inactivated viral or bacterial vaccines or toxoids (chapter 6:contraindications and special considerations).

If a course of tetanus, diphtheria and polio containing vaccination is commenced before week 16 of pregnancy, a four-week interval should be left between each dose.

Once the woman reaches 16 weeks of pregnancy or around the time of her fetal anomaly scan, she should be offered a dose of dTaP/IPV vaccine, preferably 4 weeks after any Td/IPV dose that has been given. The dose of dTaP/IPV offered should be counted as one of the 3 primary doses of tetanus, diphtheria and polio vaccines if this primary course has not been completed.

Women who have not completed their primary course of tetanus, diphtheria and polio (Td/IPV) containing vaccinations by the end of their pregnancy should be offered any outstanding doses.

The dTaP/IPV they received in pregnancy should be counted as one of their primary doses and any outstanding doses should be given as Td/IPV vaccine.
See PHE Vaccination of individuals with uncertain or incomplete immunisation status.

Most pregnant women will not be immunologically naïve to pertussis as they will have been primed during childhood, either through vaccination in infancy or through natural exposure during childhood.

They will therefore not require additional doses of pertussis containing vaccine unless they become pregnant again.

Any other outstanding vaccines should also be offered as appropriate. As MMR is a live vaccine, and live vaccines are contraindicated during pregnancy, any woman who has not completed a two-dose course prior to their pregnancy should receive it after the baby is born (which may be at the 6 – 8 week check if it has not been possible to offer it before this).

Breastfeeding mothers

dTaP/IPV vaccine can be given to women who plan to breast feed. There is evidence that pertussis antibodies in breast milk are increased after immunisation in pregnancy and breastfeeding may therefore help reduce the likelihood of a baby becoming ill with pertussis. However, whilst there may be some pertussis antibodies transferred to the infant in the breast milk of vaccinated women, this will not be enough to replace the need for the infant to complete the recommended primary immunisation schedule on time.

Recommended vaccine for the programme

Low dose diphtheria, tetanus, pertussis (acellular component) and poliomyelitis (inactivated) vaccine (dTaP/IPV) should be used for this programme.

dTaP/IPV vaccine is a prescription only medicine and immunisers should refer to the Pertussis vaccination in pregnancy, dTaP/IPV PGD for full information on the supply and administration of it.

Since 1 July 2014, the recommended vaccine for the programme has been Boostrix-IPV (dTaP/IPV) which is licensed as a booster from 4 years of age and contains low dose diphtheria suitable for adults. Repevax (dTaP/IPV) vaccine may be used as an alternative if Boostrix vaccine is not available.

Boostrix-IPV and Repevax can be ordered via Immform and are provided free of charge for this programme.

Repevax (dTaP/IPV) vaccine as an alternative to Boostrix-IPV (dTaP/IPV)

Although Boostrix-IPV replaced Repevax (dTaP/IPV) From 1 July 2014 as the recommended vaccine for this programme, either vaccine is suitable for the vaccination of pregnant women to protect their unborn babies from pertussis.

Single antigen pertussis vaccine

Monovalent pertussis vaccines are not available. Pregnant women requesting monovalent vaccine should be reassured of the safety and efficacy of dTaP/IPV vaccine during pregnancy.

Vaccine administration

dTaP/IPV is supplied as a 0.5ml dose in a pre-filled syringe and should be administered as a single intramusclar injection into deltoid region of the upper arm.

Healthcare professionals are encouraged to read the PGD and the Summary of Product Characteristics (SmPC) prior to administration to familiarise themselves with the product.

Vaccine contraindications

There are few individuals who cannot receive pertussis-containing vaccines. The vaccines should not be administered to those who have had:

- a confirmed anaphylactic reaction to a previous dose of pertussis-containing vaccine or
- a confirmed anaphylactic reaction to any component of the vaccine, including neomycin or polymyxin

Administering dTaP/IPV vaccine at the same time as anti-D treatment

dTaP/IPV is an inactivated vaccine which will not be affected by, nor interfere with, anti-D treatment. The administration of TdaP/IPV vaccine should not be delayed due to the individual receiving anti-D treatment.

Pregnant women previously vaccinated against pertussis

If a pregnant woman received pertussis containing vaccine before week 16 of her pregnancy, either in error or for occupational or contact reasons, then she should be offered a second dose when she reaches 16 weeks of pregnancy or around the time of her antenatal fetal anomaly scan.

The dose should be repeated to maximise the antibodies she can transfer across the placenta to her unborn baby. If a repeat dose is required, there should be an interval of at least 4 weeks from the previous dose to minimise the risk of local reaction.

If a pregnant woman has received a dose of pertussis containing vaccine after week 16 of pregnancy for occupational or contact reasons this should be counted as a valid dose and she would not need a repeat dose.

Influenza vaccine and dTaP/IPV vaccines

The seasonal influenza vaccine should be offered to women at any stage of pregnancy during ‘flu season’ which is usually from September each year. dTaP/IPV should be offered to women from 16 weeks of pregnancy regardless of the time of year.

Both vaccines are inactivated vaccines containing different antigens and therefore may be administered at the same time or at any interval from each other. No minimum interval needs to be observed between these vaccines.

Both vaccines should be given at the recommended time and vaccination should not be delayed to reduce the number of appointments required.

dTaP/IPV following administration of a Td/IPV (Revaxis) vaccine

Please also refer to page 10 (Pregnant women and women presenting shortly after giving birth with an incomplete or unknown vaccination history (primary vaccination against diphtheria, tetanus and polio).

If Td/IPV vaccine has been given as part of a primary course, a four-week minimum interval period is normally recommended to be observed before dTaP/IPV is given to ensure an adequate response. There is good evidence to suggest that dTaP/IPV may be administered to adults as soon as 1 month after Td/IPV (Revaxis) without significantly increasing the frequency or severity of side effects.

Inadvertent vaccine administration errors

dTaP/IPV administered before 16 weeks of pregnancy

If the dose was given before 16 weeks of pregnancy, it should be repeated once the woman reaches 16 weeks of pregnancy or around the time of her fetal anomaly scan. A minimum interval of four weeks between doses should be observed to reduce the risk of a local reaction. Repeating the dose will ensure that the unborn baby benefits from optimal transfer of maternal antibodies.

Infanrix hexa (DTaP/IPV/Hib Hep B) vaccine administered in error

Women who have inadvertently received Infanrix hexa (DTaP/IPV/Hib/HepB) instead of the recommended dTap/IPV vaccine should be reassured that Infanrix hexa does offer protection against pertussis and that no further action is required.

Such women should also be advised that Infanrix hexa contains a high dose of diphtheria that is not normally given to adults because it is more likely to cause a localised reaction. Women who have inadvertently received Infanrix hexa should be informed of the higher risk of localised reactions.

Healthcare professionals should report the administration error via their local governance system(s) so that the appropriate action can be taken, lessons can be learned and the risk of future errors minimised.

Td/IPV (Revaxis) vaccine administered in error

As Td/IPV vaccine (Revaxis) does not protect against pertussis, a dose of dTaP/IPV should be given as soon as possible after the error is realised.

Healthcare professionals should report the administration error via their local governance system(s) so that the appropriate action can be taken, lessons can be learned and the risk of future errors minimised.

Menitorix (Hib/MenC) vaccine administered in error

Due to the packaging similarities between one of the dTaP/IPV vaccines (Boostrix-IPV) and Menitorix, healthcare professionals are encouraged to familiarise themselves with the 2 vaccines so that vaccine errors do not occur. Please see page 8 of Vaccine Update April 2014 and the visual guide to vaccines poster.

Women who have inadvertently received Menitorix instead of the recommended Boostrix-IPV should be reassured that there is no known risk as this is an inactivated vaccine, which means that it doesn't contain any live organisms. Since inactivated vaccines cannot replicate, they cannot cause infection in either the mother or her baby.

There is no known risk associated with giving inactivated vaccines at any stage of pregnancy. As Menitorix (Hib/Men C) does not protect against pertussis, a dose of dTaP/IPV vaccine should be administered as soon as possible after the error is realised.

Healthcare professionals should report the administration error via their local governance system(s) so that the appropriate action can be taken, lessons can be learned and the risk of future errors minimised.

Primary vaccination of infants whose mother did not receive pertussis vaccine during pregnancy

The best way to protect newborn babies from pertussis is to make sure that the baby has benefited from the transfer of maternal antibodies before it was born.

When a pregnant woman has pertussis containing vaccine at the recommended time during her pregnancy, the unborn baby will receive some of those antibodies and will be protected during their first few weeks of life, until they are old enough to make a good response to their own vaccines.

The green book (chapter 11) advises that 'Immunisations should not be given before the scheduled age unless there is a clear clinical indication for this.
The first set of primary immunisations can be given from 6 weeks of age if required in certain circumstances such as travel to an endemic country.

Administering the first set of primary immunisations before 6 weeks of age is not recommended, as it may result in a sub-optimal response to the vaccine which could undermine good control.

The schedule has been designed to provide optimum protection for infants at the earliest opportunity. Administering vaccines early may have a negative impact on the immune response that the infant makes.

Once a baby starts their routine vaccination schedule, it is important that they have all their vaccines at the recommended time.

Further information

Public Health England Immunisation against infectious diseases: Pertussis Chapter 24
www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book

NHS.UK (2019). Whooping cough in pregnancy programme
www.nhs.uk/conditions/pregnancy-and-baby/whooping-cough-vaccination-pregnant/

Whooping cough: vaccination in pregnancy programme resources