



Public Health  
England

Protecting and improving the nation's health

# **Vaccination against pertussis (Whooping cough) for pregnant women- 2016**

## **Information for healthcare professionals**

## About Public Health England

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Updated June 2016  
PHE publications gateway number: 2016111  
Document Version No. v.4

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## Background

The recommendation for the timing of administration of the prenatal pertussis containing vaccine to pregnant women has been reviewed by the Joint Committee on Vaccination and Immunisation (JCVI).

From 1<sup>st</sup> April 2016, pertussis containing vaccine should be offered to pregnant women from 16 weeks gestation, ideally after their foetal anomaly scan (usually at around 20 weeks). This will provide greater opportunity for pregnant women to access the vaccine, will provide additional benefit to the neonate where delivery is premature and will potentially improve neonatal antibody levels.<sup>1</sup>

The pertussis in pregnancy programme was introduced in 2012 as the UK reported the largest increase in pertussis activity in over two 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 too young to be protected through routine vaccination. In England and Wales, a total of 14 infant deaths were reported in 2012.

In 2014, the Joint Committee on Vaccination and Immunisation recommended that the temporary pertussis vaccination programme for pregnant women be continued for at least a further 5 years. This decision was made in light of the success of the vaccination programme in saving infant lives and against the continued increase in pertussis incidence. Babies born to vaccinated mothers are 90% less likely to get disease than babies whose mothers were unvaccinated.

Two different studies led by Public Health England demonstrated high vaccine effectiveness<sup>2,3</sup> and the greatest proportionate fall in confirmed cases and hospital admissions were observed in those under three months of age.

Although the numbers of deaths in babies born in the three and a half years since the maternal vaccination programme was introduced has fallen, in England, there have been a further 16 deaths in babies aged ten weeks or younger with confirmed pertussis during this time. Only two of these babies had mothers who were vaccinated during pregnancy and in both cases, vaccination was too close to delivery to confer optimal passive protection to the infant.

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<sup>1</sup> JCVI Minutes of the meeting on 3 February 2016. Available at: <https://app.box.com/s/iddfb4ppwkmjtjusir2tc>

<sup>2</sup> Amirthalingam G et al, effectiveness of maternal pertussis vaccination in England: an observational study, *The Lancet*, Volume 384, No.9953, p1521-1528, 25 October 2014

<sup>3</sup> Dabrera G et al. A case-control study to estimate the effectiveness of maternal pertussis vaccination in protecting newborn infants in England and Wales, 2012-2013. *Clin Infect Dis*. 60(3):333-7, 1 Feb 2015

## What is 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 one to two weeks into coughing fits which can be severe. The cough can often last for two to three months and because of this, pertussis is known as the '100 day cough' in some countries.

## Who does it affect?

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

# Vaccination against pertussis for pregnant women

## What is the purpose of the programme?

The purpose of this 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 two months of age.

## Why has the recommendation for the timing for when the vaccine should be offered been changed?

- During 2012, it was recommended that pregnant women should be vaccinated from weeks 28 to 38 of their pregnancy, with the optimum time for transfer of maternal antibodies being between weeks 28 and 32

- A recent study<sup>4</sup> however, showed that reasonable levels of pertussis antibodies were demonstrated in neonates through transplacental transfer from mothers vaccinated earlier in pregnancy
- As a result of this study, JCVI has recommended that women should be offered pertussis-containing vaccine between gestational weeks 16 and 32 to maximise the likelihood that the baby will be protected from birth
- Offering the vaccine from week 16 of pregnancy gives pregnant women greater opportunity to take up the offer of vaccination and will offer some protection to infants born prematurely who may be particularly vulnerable to complications from pertussis
- For operational reasons, vaccination is probably best offered on or after the foetal anomaly scan at around 18- 20 weeks. Offering at this time will also avoid any associations with unrelated adverse events identified up to or at the routine anomaly antenatal scan being made.
- Women may still be immunised after week 32 of pregnancy until delivery but this may not offer as high a level of passive protection to the baby.

### What is the recommended vaccine for the programme and why?

Since 1 July 2014, the recommended vaccine for the programme has been Boostrix-IPV® (which contains diphtheria, tetanus, acellular pertussis and inactivated polio antigens – dTaP/IPV). Boostrix-IPV® is licensed as a booster from four years of age and contains low dose diphtheria suitable for adults. Boostrix-IPV® is not licensed for use in children **under four years** of age and should **not** be used for the pre-school booster.

Boostrix-IPV® can be ordered via [Immform](#).

### Is the vaccine safe to administer in 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 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

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<sup>4</sup> Eberhardt C, Maternal Immunization earlier in pregnancy maximises antibody transfer and expected infant seropositivity against pertussis, Clinical Infectious Diseases, Volume 62, Issue 7, p829-836, 20 January 2016

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**<sup>5</sup> 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.

As a result of this study, and in light of the success of the temporary programme in saving infant lives, in 2014, the JCVI recommended the programme be extended for at least the next 5 years (until 2019), at which point it will be reviewed again.

### How often should pregnant women be offered the pertussis vaccine?

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 during **each and every** pregnancy whilst the programme is in place, ideally between weeks 16 and 32 of pregnancy.

### Can the vaccine be offered to women who are more than 32 weeks pregnant?

Yes, 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 two weeks after a pertussis booster. So 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.

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

If the woman reaches 38 weeks of pregnancy and has still 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

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<sup>5</sup> Donegan K, Safety of pertussis vaccination in pregnant women in UK: observational study, BMJ, 2014;349:g4219

pertussis infection and thereby reduce the risk of her becoming a source of infection to her infant.

**If a woman did not receive pertussis vaccine in pregnancy, can she still be offered pertussis vaccine after delivery?**

Yes. For women who did not receive their vaccine in pregnancy, pertussis-containing vaccine can be offered in the two months following birth ie 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.

**If a woman presents for pertussis vaccine during (or shortly after) pregnancy but has never received (or not completed) a primary schedule of vaccination against diphtheria, tetanus and polio, should she be given any further vaccinations?**

These women should be offered a single dose of dTaP/IPV (Boostrix-IPV® vaccine). They should then be offered Td/IPV (Revaxis®) at appropriate intervals if any subsequent doses of vaccine are needed to complete a three dose primary course. See [PHE Vaccination of individuals with uncertain or incomplete immunisation status](#)

The rationale for a single dose of pertussis containing vaccine is that it is likely that most pregnant women, whether or not they have been vaccinated, would have been naturally exposed to pertussis in early childhood so will not be immunologically naïve to pertussis. 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. Please note that MMR should be given after the baby is born, usually at the 6 – 8 week check, to women who have not completed a two dose course prior to their pregnancy.

**If a woman had confirmed or suspected whooping cough during pregnancy, should she still be offered pertussis vaccine?**

Yes, pertussis vaccine should still be offered.

Although it might be expected that a woman diagnosed with whooping cough during pregnancy would transfer antibodies to her unborn baby, not all women may make sufficiently high levels of antibodies following natural infection to ensure high levels can be passed across the placenta to the infant. As we know that 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 her baby.

## What should you do if a woman has recently received a pertussis containing vaccine and she is now pregnant?

The woman should be offered a dose of Boostrix-IPV® (dTaP/IPV) during her pregnancy from week 16 to maximise the antibodies she can transfer across the placenta to her unborn infant. If a pregnant woman has received a dose of pertussis containing vaccine after week 16 of pregnancy, then she would not need a second dose

If the pregnant woman received pertussis containing vaccine before week 16 of her pregnancy 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 rationale for repeating the dose is to ensure optimum levels of antibody pass to her unborn baby. If a repeat dose is given, there should be an interval of at least four weeks from the previous dose to minimise the risk of local reaction

## Vaccine administration

### How is the vaccine administered?

Boostrix-IPV® is administered by a single intramuscular injection into the upper arm (deltoid region). One dose has a volume of 0.5ml and comes as a pre-filled syringe.

Prior to use, the pre-filled syringe should be shaken well to obtain a turbid white suspension. Healthcare professionals are encouraged to read the Summary of Product Characteristics (SPC) to familiarise themselves with the product.

### What are the contraindications for receiving Boostrix-IPV®

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



### What is the minimum interval period that should be observed between administering seasonal influenza vaccine and pertussis (dTaP/IPV) vaccine to pregnant women?

The seasonal influenza vaccine should be offered to women at any stage of pregnancy during 'flu season', usually from September each year. Boostrix-IPV® (dTaP/IPV) should be offered to women from 16 weeks of pregnancy

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 in an attempt to reduce the number of appointments required.

### Can you give Repevax® (dTaP/IPV) vaccine if there is no Boostrix-IPV® (dTaP/IPV) available?

From 1 July 2014, Boostrix-IPV® replaced Repevax® (dTaP/IPV) as the recommended vaccine for this programme and this vaccine can be ordered via [Immform](#). Boostrix-IPV® (dTaP/IPV) should be reserved for pregnant women and Repevax® (dTaP/IPV) and Infanrix IPV® (DTaP/IPV) should be used for the pre-school booster vaccine.

However, in those exceptional circumstances where there is no Boostrix-IPV® (dTaP/IPV) vaccine when a woman attends for vaccination and it is very unlikely that she will present again, it would be preferable to give Repevax® (dTaP/IPV).

Boostrix-IPV® is not licensed for use in children **under four years** of age and should **not** be used for the pre-school booster.

### If a pregnant women has recently received a Td/IPV (Revaxis®) vaccine, when should Boostrix-IPV® be administered?

A four week minimum interval period is normally observed between a course of successive vaccines to ensure an adequate response. There is good evidence to suggest that dTaP/IPV may be administered to adults as soon as one month after Td/IPV (Revaxis®) without significantly increasing the frequency or severity of side effects.

### What should you do if Boostrix-IPV® (dTaP/IPV) is given to a pregnant woman before 16 weeks in error?

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.

### What should you do if you inadvertently administer Revaxis® (Td/IPV) vaccine to a pregnant woman when Boostrix-IPV® should have been given?

As Revaxis does not protect against pertussis, a dose of Boostrix-IPV® (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.

### What should you do if you inadvertently administer Menitorix® (Hib/MenC) vaccine to a pregnant woman when Boostrix-IPV® should have been given?

Due to the packaging similarities between Boostrix-IPV® and Menitorix®, healthcare professionals are encouraged to familiarise themselves with the two vaccines so that vaccine errors do not occur. Please see page 8 of [Vaccine Update April 2014](#)

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 Boostrix-IPV® 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.

### What should you do if you inadvertently administer Repevax® (dTaP/IPV) or Pediacel® (DTaP/IPV/Hib) vaccine to a pregnant woman when Boostrix-IPV® should have been given?

Until 1 July 2014, Repevax® (dTaP/IPV) was the recommended vaccine for the pertussis vaccination in pregnancy programme. Therefore, women who have inadvertently received Repevax® instead of the recommended Boostrix-IPV® should be reassured that no further action is required.

Women who have inadvertently received Pediacel® (DTaP/IPV/Hib) instead of the recommended Boostrix-IPV® should be reassured that Pediacel® does offer protection against pertussis and that no further action is required. Such women should also be advised that Pediacel® 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 Pediacel® 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.

### Can Boostrix-IPV® (dTaP/IPV) be administered at the same time as anti-D treatment?

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

### Can Boostrix-IPV® (dTaP/IPV) be given to breastfeeding mothers?

Yes, Boostrix-IPV® (dTaP/IPV) 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.

**A worried parent wants to know how to protect her baby who is too young for routine immunisations. Can the first dose of primary immunisation be offered before two months of age?**

Infants may receive their first dose of primary immunisations from 6 weeks of age in exceptional circumstances eg pre-travel but it is not routinely recommended to offer infants vaccine before two months of age. 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.

The best way to protect newborn babies from pertussis is to ensure 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.

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

**Where can I get further information?**

Public Health England (2016) Immunisation against infectious diseases: *Pertussis Chapter 24* [internet] accessed 13 June 2016  
<https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book>

NHS Choices (2016). Whooping cough in pregnancy programme [ internet] accessed 13 June 2016. <http://www.nhs.uk/conditions/pregnancy-and-baby/pages/whooping-cough-vaccination-pregnant.aspx>