

Pertussis immunisation for pregnant women

Introduction

The routine childhood immunisation programme has been very effective in reducing the overall numbers of cases of pertussis. Before the introduction of routine immunisation against pertussis in the 1950s, large epidemics occurred every three to five years affecting up to 150,000 people and contributed to about 300 deaths each year in the UK. In comparison, over the last ten years (2002 to 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 and Wales.

However, there was a considerable increase in pertussis activity across the UK starting in mid-2011. The outbreak was the largest seen in the UK for over a decade. In Northern Ireland 314 cases of confirmed pertussis were notified to PHA in 2012 compared to 15 the year before, and 70 of these were in babies aged under 3 months old. A programme was therefore introduced to protect vulnerable babies from pertussis by offering vaccine to their mothers during pregnancy. In 2012, fourteen infant deaths were reported in England and Wales from pertussis and all deaths occurred in infants who were born before the introduction of the pertussis vaccine programme for pregnant women. Up to 31 October 2014, 10 deaths were reported in infants with confirmed whooping cough who were born after the introduction of the maternal programme. Nine of these 10 infants were born to unvaccinated mothers and all 10 infants were too young to have received their first dose of pertussis-containing vaccine and be fully protected

by vaccination themselves. The vaccination programme has been successful in reducing the number of babies infected with pertussis before they are old enough to be vaccinated, with less than 10 cases per year in Northern Ireland in babies under three months old in 2013 and 2014, however this did rise to 20 cases in 2015 and so vaccination should still be offered to all pregnant women for each pregnancy.

Young infants are particularly vulnerable to complications, hospitalisation and death from pertussis. Vaccinating pregnant women against pertussis should help provide their newborn infants with protection against serious complications from pertussis until they can receive their routine immunisations from two months of age. This factsheet provides information on the disease, the vaccine and immunisation programme and a section on frequently asked questions.

The disease

What is pertussis?

Pertussis (commonly known as whooping cough) is an infection caused by the bacterium *Bordetella pertussis*.

What are the symptoms of pertussis

Pertussis causes an irritating cough that often develops into prolonged bouts of coughing. In children, the bouts of coughing are commonly followed by a characteristic 'whoop' sound (except in infants) and may be accompanied by vomiting. In adolescents and adults, the symptoms may only be a prolonged cough.

How is pertussis spread?

Pertussis bacteria are spread from person to person mainly by respiratory droplets in the air expelled during coughing or sneezing. The bacteria can also be spread indirectly, through contact with respiratory droplets on another person or object and then transfer to the mouth or nose.

How serious is pertussis?

In infants, pertussis can be very serious and infants under six months of age are at most risk of severe complications. Infection can lead to pneumonia, weight loss (due to repeated vomiting), hypoxia (inadequate oxygen supply) which can result in brain damage, and death. Less serious complications include bloodshot eyes, nosebleeds, facial swelling, mouth ulcers and ear infections.

Who can catch pertussis?

Anyone at any age can get pertussis.

Immunisation provides protection against pertussis. However, neither immunisation nor natural infection provides life-long protection against pertussis. Pertussis infection can occur in adolescents and adults who received all their routine immunisations against pertussis in childhood but the infection tends to be milder.

The UK childhood immunisation programme offers three doses of pertussis containing vaccine: one dose at two, three and four months of age. Some protection is provided by the first dose but completion of the three dose course is important and is highly effective in protecting infants from serious disease. A booster immunisation is given pre-school, after the infant course has been completed, to provide longer-term protection.

How severe is the current pertussis outbreak?

In recent history, outbreaks of pertussis have tended to occur every three to four years. However, there has been a considerable increase in pertussis activity across the UK starting in mid-2011. The recent outbreak is the largest seen in the UK for over a decade. The reasons for this are not fully understood. More information on the progress of the outbreak in England is available at the Public Health England website: www.gov.uk/government/collections/pertussis-guidance-data-and-analysis

Prevention of pertussis infection

How can people be protected against pertussis infection?

Immunisation is highly effective in protecting against pertussis infection. Children are vaccinated at two, three and four months of age and given a booster at three years and four months of age. These combination vaccines all contain acellular pertussis antigens but also provide protection against other diseases. However, neither immunisation nor natural infection provides life-long protection against pertussis. Pertussis infection can occur in adolescents and adults who received all their routine immunisations against pertussis in childhood but these infections tend to be milder.

Before they receive their routine immunisations, infants may have little or no immunity to pertussis. The immunity their mothers gained from immunisation or a natural infection is likely to have diminished such that there may be little or no immunity for pregnant women to pass on to their babies when in the womb.

Immunising pregnant women

Why offer pregnant women immunisation against pertussis?

In response to the current outbreak, independent experts on immunisation – the Joint Committee on Vaccination and Immunisation (JCVI) – have advised that pregnant women should be offered immunisation against pertussis to help protect their newborn infants before they can receive their routine immunisations.

How does immunising pregnant women protect babies?

Antibodies produced in response to immunisation help the body to fight infections and reduce the severity of infections.

By immunising pregnant women against pertussis, the antibodies produced will cross the placenta to the foetus so that when the infant is born he/she already has antibodies against pertussis. This immunity is short-lived, diminishing over a few months. Therefore infants should still be vaccinated in accordance with the routine childhood immunisation schedule. While breastfeeding is important for infants' general health, it will not by itself prevent them becoming infected with pertussis.

JCVI considers this is the most effective approach to help protect newborn infants from infection or to reduce the severity of symptoms and the risk of serious complications.

Why not vaccinate infants at birth?

There are few studies about the immune responses of newborn infants to pertussis-containing vaccine and there is some evidence to suggest that this approach may result in poorer immune responses to subsequent routine doses of vaccine.

When should pregnant women receive the vaccine?

The Joint Committee on Vaccination and Immunisation (JCVI) have considered all the recent evidence on this and agree that the vaccination should now be offered from the 16th gestational week of pregnancy.

Pregnant women who do not get the vaccine earlier in pregnancy, may still be offered the vaccine up to the onset of labour to reduce the risk of the mother contracting pertussis in the post-partum period and therefore prevent her from infecting her infant.

When will the temporary programme stop?

This temporary immunisation programme was introduced in 2012 and was extended in 2014 for a further five years. The immunisation programme will be kept under review by JCVI.

Which vaccine should be used and how many doses should be given?

A single dose of Boostrix-IPV® vaccine will be offered to pregnant women from the 16th week of pregnancy. This is a combination vaccine that provides protection against diphtheria, tetanus, and polio in addition to pertussis. There are no single pertussis vaccines available. Boostrix-IPV® is the only vaccine against pertussis that is authorised for use in adults and currently available in the UK.

How safe is this vaccine for pregnant women?

Boostrix-IPV® is a combined inactivated viral, bacterial and toxoid vaccine. There is no evidence of risk to pregnancy or breast-feeding from inactivated viral or bacterial vaccines or toxoids.

There is no evidence to suggest that the use of Boostrix-IPV® during pregnancy is unsafe for either the mother or unborn baby.

Before being authorised, all vaccines are thoroughly tested to ensure that they are of high quality, and to assess their safety and ability to produce an immune response. Once authorised and in use, vaccines are carefully monitored, including any use in pregnancy.

The licence for Boostrix-IPV allows for its use in pregnancy when clearly needed, and when the possible benefits outweigh the possible risks.

It is standard practice with most medicines not to test them on pregnant women. This is why the manufacturer's information leaflet includes this statement, and not because of any specific safety concerns or evidence of harm in pregnancy.

Pertussis-containing vaccine has been used routinely in pregnant women in the UK since October 2012 and the Medicines and Healthcare Products Regulatory Agency (MHRA) is carefully monitoring its safety.

Boostrix (similar to Boostrix-IPV but without the polio component) is one of the vaccines routinely recommended in the US for immunisation of pregnant women. Experience in the US has identified no safety concerns with the use of the vaccine in pregnancy.

There is no evidence of risk to the pregnant woman or unborn child with inactivated vaccines like Boostrix-IPV. An inactivated vaccine is one that does not contain 'live' organisms.

What side effects may be seen from the vaccination?

There may be some mild side effects such as swelling, redness or tenderness where the

vaccine is injected in the upper arm just as with any vaccine. These only last a few days. Other side effects can include fever, irritation at the injection site, swelling of the vaccinated arm, loss of appetite, irritability and headache. Serious side effects are extremely rare.

As with all vaccines, there is a very rare possibility (approximately one in a million doses) of this vaccine causing a severe allergic reaction called anaphylaxis. All health professionals responsible for immunisation should be trained to recognise and treat anaphylaxis.

A full list of possible side effects is available in the Patient Information Leaflet (PIL) that is provided with the vaccine.

Adverse events should be reported using the Yellow Card system <http://yellowcard.mhra.gov.uk/>

Are there any reasons for the vaccine not to be given?

There are very few medical reasons why any vaccine should not be given. Boostrix-IPV® should not be given to those who have had:

- a confirmed anaphylactic reaction to a previous dose of pertussis, diphtheria, tetanus or polio vaccines;
- a confirmed anaphylactic reaction to any component of the vaccine or to any substances carried over from manufacture including; neomycin, polymyxin, aluminium hydroxide, aluminium phosphate please see complete list of components in Boostrix-IPV SPC;
- an encephalopathy (brain disorder) of unknown origin within seven days of previous immunisation with pertussis-containing vaccine.

If a patient is acutely unwell and has a fever, immunisation should be postponed until they have recovered. This is to avoid wrongly associating any cause of fever, or its progression, with the vaccine and to avoid increasing any pre-existing fever. Having a minor illness without a fever, eg a cold, is not a reason to delay immunisation.

Does the vaccine need to be given with every pregnancy? What about women who have been immunised relatively recently?

Women who become pregnant again while the programme is in place should be offered immunisation during **each** pregnancy to maximise the level of antibodies that they pass on to their infants. Pregnant women who have received immunisation against pertussis, tetanus, diphtheria and/or polio relatively recently should be offered immunisation, although cumulative doses may increase the likelihood of injection site reactions or fever, this is far outweighed by the expected benefits.

Why has the recommendation changed to allow vaccination from the 16 weeks gestation rather than 28 weeks?

JCVI advice was updated to allow vaccination of pregnant women from 16 weeks gestation. A recent study (www.ncbi.nlm.nih.gov/pubmed/26797213) showed that maternal immunisation against pertussis in the second trimester significantly increased neonatal antibodies. Offering maternal immunisation earlier than the current 28 week recommendation should not only improve infant protection, it will also provide more opportunity for pregnant women to be offered the pertussis vaccine during pregnancy

Frequently asked questions

What pertussis vaccine should be given to pregnant women?

Pregnant women should only be offered a single dose of Boostrix-IPV® vaccine.

Where should the vaccine be given?

The vaccine should be given intramuscularly in the deltoid area of the pregnant woman's upper arm.

When should the vaccine be given?

The vaccine should be given ideally from the 16th gestational week of pregnancy to facilitate antibody transfer. If not given in the earlier stages of pregnancy, vaccination can be given up to delivery.

It should be noted that immunisation after week 38 is unlikely to provide passive protection to the infant but would potentially protect the mother from pertussis infection and thereby reduce the risk of exposure to her infant. For women who have not received the 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.

Is the vaccine safe?

Boostrix-IPV® is an inactivated viral, bacterial and toxoid vaccine. There is no evidence of risk to pregnancy with inactivated viral or bacterial vaccines or toxoids such as Boostrix-IPV®.

What if a women received Boostrix-IPV® during a previous pregnancy?

Pregnant women should be offered immunisation for each pregnancy while the programme is in place.

What about pregnant women carrying more than one child?

The same amount of antibodies should be passed on to each baby after immunisation. Only one dose of Boostrix-IPV® is needed for each pregnancy.

Can Boostrix-IPV® be given at the same time as influenza vaccine?

There are no reasons why Boostrix-IPV® cannot be administered at the same time as influenza vaccine. However, influenza immunisation should not be delayed in order to give Boostrix-IPV® at the same visit. This is because pregnant women are at risk of severe illness at any stage of pregnancy from influenza.

Can Boostrix-IPV® be given at the same time as anti-D treatment?

Boostrix-IPV® can be administered at the same time as anti-D treatment. Boostrix-IPV should not be delayed if an individual is receiving Anti-D treatment.

Is there an alternative way of protecting babies from pertussis?

Vaccinating pregnant women is likely to be the most effective approach to providing protection against pertussis to young infants until they receive their routine immunisations.

What if a baby or someone else in the family may have pertussis?

If pertussis is suspected in a baby or another family member health advice should be sought as early as possible from your GP

<http://www.publichealth.hscni.net/directorate-public-health/health-protection/immunisationvaccine-preventable-diseases>

Glossary of terms

Acellular vaccine

An acellular vaccine contains only parts of cells, which can produce immunity in the person receiving the vaccine.

Adverse reaction

A side effect of any medicine including vaccines.

Anaphylaxis

An immediate and severe allergic reaction.

Antibody/antibodies

Protein(s) produced by the body to neutralise or destroy toxins and disease-carrying organisms.

Anti-D treatment

Treatment to prevent Rhesus disease

Bacterium/bacteria

Single cell micro-organisms, some of which cause disease. Others are essential for our bodies to work properly.

Contraindication

A reason why a vaccine should not be given.

Boostrix-IPV®

Combined vaccine that protects against four different diseases – diphtheria, tetanus, pertussis (or whooping cough) and polio.

Diphtheria

Diphtheria is a disease that usually begins with a sore throat and can quickly cause problems with breathing. It can damage the heart and nervous system and, in severe cases, it can kill.

Immune response

The body's response to an immunisation or infection.

Immunisation

The priming of the body's immune system with a vaccine.

Pertussis (whooping cough)

Whooping cough is a disease that can cause long bouts of coughing and choking which can make it hard to breathe. It can last for up to ten weeks. It is not usually serious in older children, but it can be very serious in babies under one year old.

Pneumonia

Inflammation of the lung from a variety of causes, such as viruses and bacteria, particularly *Streptococcus pneumoniae*.

Poliomyelitis/polio

A disease caused by a virus that attacks the nervous system leading to paralysis of the muscles. If it affects the chest muscles it can kill.

Tetanus

Tetanus is a painful disease that affects the muscles and can cause breathing problems. It is caused by bacteria that are found in soil and manure and can get into the body through open cuts or burns. Tetanus affects the nervous system and, if it is not treated, it can kill.

Vaccines

Vaccines are manufactured in different ways using part of the germ or virus that causes the disease. Vaccines work by helping the body produce an immune response against the disease but do not cause the disease itself.



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