

Pertussis immunisation for pregnant women

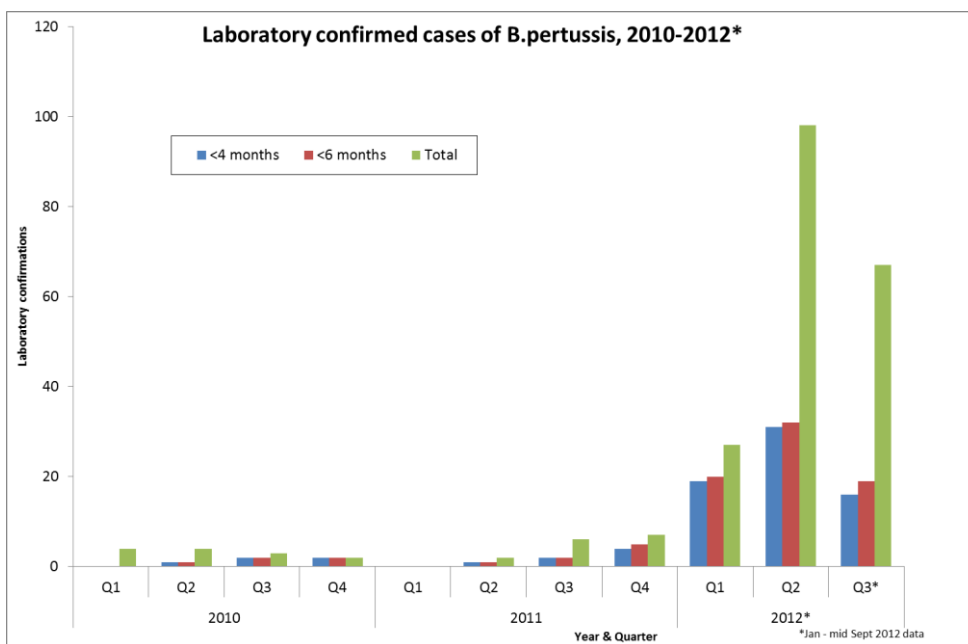
Introduction

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 has been a considerable increase in pertussis activity across the UK starting in mid-2011. The current outbreak is the largest seen in the UK for over a decade. Almost 5000 cases of pertussis have been confirmed so far this year in England and Wales. Although most cases are in adolescents and young adults, the highest rates are in infants less than three months of age, who are at highest risk complications and deaths. There have been nine deaths so far this year – all in infants below the age of routine immunisation. Most cases in infants are in those too young to be protected through routine immunisation.

A similar picture has been seen in Northern Ireland with 192 cases of pertussis confirmed here to mid-September in 2012, compared to 15 cases in 2011. There has also been a large increase in babies under 4 months and 6 months who are too young to be completely vaccinated against pertussis (see graph below).

Figure 1: Confirmed cases of pertussis in Northern Ireland, 2010-2012*, totals, infants under 4 months, infants under 6 months of age and all age groups.



Recent increases in pertussis have been reported from a number of other countries, including the United States of America (USA).

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 pertussis until they can receive their routine immunisations from two months of age. Therefore, a temporary immunisation programme has been introduced to offer pregnant women immunisation against pertussis in response to the current outbreak.

This factsheet provides information on the disease, the vaccine and the temporary 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.

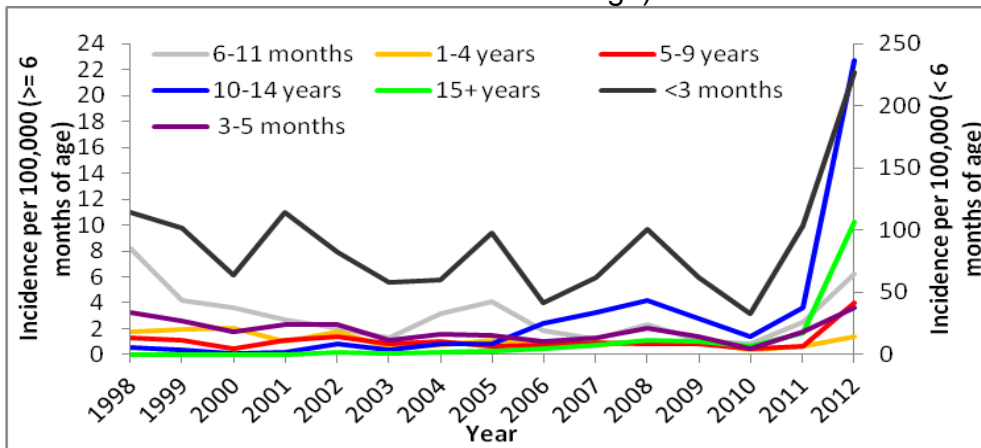
Immunisation provides protection against pertussis. However, neither immunisation nor natural infection provides life-long protection against pertussis. Pertussis infection can occur in adolescents and adults who received all their routine immunisations against pertussis in childhood but the infection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

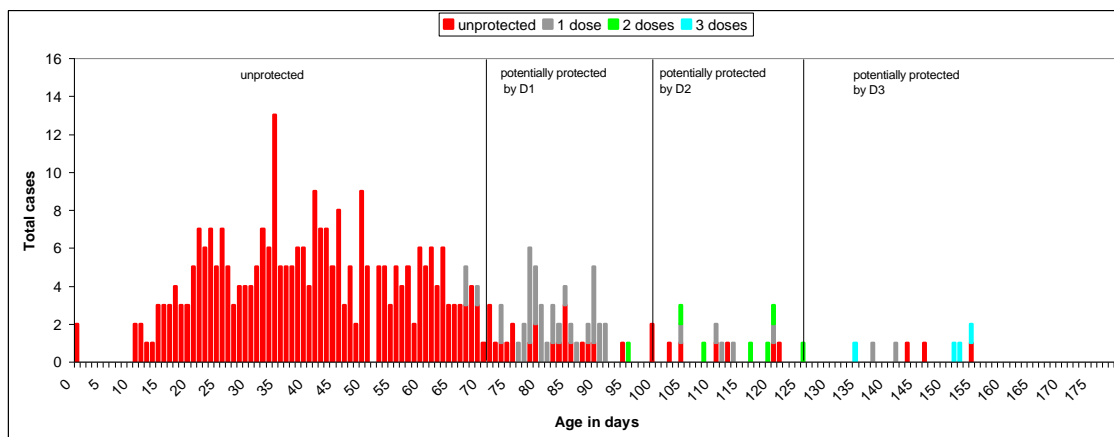
In recent history, outbreaks of pertussis have tended to occur every three to four years. However, there has been a considerable increase in pertussis activity across the UK starting in mid-2011. The current outbreak is the largest seen in the UK for over a decade. The reasons for this are not fully understood. Almost 5000 cases of pertussis have been confirmed so far this year in England and Wales. Although most cases are in adolescents and young adults, the highest rates are in infants less than three months of age, who are at highest risk complications and deaths. There have been nine deaths so far this year – all in infants below the age of routine immunisation. Most cases in infants are in those too young to be protected through routine immunisation.

Figure 2: Incidence of pertussis by age In England and Wales 1998 to 2012 (axis on right hand side for infants under six months of age)



Excludes 12 cases with age not known (8 in 2002, 2 in 2003 and 2 in 2004)

Figure 3: Age in days of confirmed cases of pertussis in infants (cases from 1 January 2011 to 10 June 2012) in England and Wales. Protection based on assumption that antibody response occurs 10 days after first vaccine dose and seven days after second dose.



Source of both figures - Health Protection Agency

More information on the progress of the outbreak in England and Wales is available at the Health Protection Agency website: <http://www.hpa.org.uk/Topics/InfectiousDiseases/InfectionsAZ/WhoopingCough/>

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 (with the Pediacel® vaccine), and given a booster at three years and four months of age (with either the Repevax® or Infanrix-IPV® vaccines). 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 – a temporary programme

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.

The advice of JCVI is available at: <http://transparency.dh.gov.uk/category/minutes-2/jcvi-minutes/>

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 immunised in accordance with the routine childhood immunisation schedule. Whilst breast-feeding is important for infants' general health, it will not by itself prevent them becoming infected with pertussis.

Whilst it is not known precisely how effective this approach will be, JCVI considers it is likely to be 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 immunise 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?

Immunisation should ordinarily be offered in the period weeks 28 to 38 of pregnancy (inclusive); the optimal time is in the period weeks 28 to 32 (inclusive). Immunisation should still be offered up to term (see below). Eligible women may need to be specially called, but if possible, vaccination can be given at a routine antenatal visit. Immunisation during weeks 28 to 38 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. Early immunisation in this period lowers the risk that preterm infants are born before the immunisation of their mother.

Pregnant women who are beyond week 38 of pregnancy should be offered immunisation up to the onset of labour so that some direct protection may still be provided to the infant. In addition, immunisation 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.

When will the temporary programme stop?

This temporary immunisation programme has been introduced in response to the current outbreak of pertussis and will continue for the time being. 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 Repevax® vaccine. This is a combination vaccine that provides protection against diphtheria, tetanus, and polio in addition to pertussis. There are no single pertussis vaccines available. Repevax® 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?

Repevax® 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 Repevax® 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. Repevax® has been used in the UK childhood immunisation programme from more than 10 years and is used in other countries and has an excellent safety record. However, as with other medicines, vaccines can have side effects. These are outlined in the next section.

Clinical trials do not typically involve pregnant women. However, vaccines are inadvertently given to women who do not know that they are pregnant. Based on limited use of Repevax in pregnant women, there is no evidence of any risks to pregnancy or the unborn child. An almost identical vaccine (without the polio component) is routinely recommended for use in pregnant women in the United States. There is no evidence of risk to pregnancy found from use of this vaccine. Furthermore, tetanus, diphtheria and polio vaccines have been given singly or in combination to pregnant women without evidence of harm to the pregnant women or her baby.

What side effects may be seen from the vaccination?

The most common side effects in adults include headache, nausea, vomiting, diarrhoea, joint and muscle pain, weakness, mild fever and injection site reactions (redness and inflammation).

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. Repevax® 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 (formaldehyde, glutaraldehyde, neomycin, streptomycin, polymyxin B or bovine serum albumin)
- 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, e.g. 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.

Experience from other countries

Similar increases in pertussis have occurred in other countries.

Routine immunisation of pregnant women against pertussis was introduced in the United States of America in June 2011 using a similar vaccine (without the polio component). It is too early to know what the impact of this programme has been there.

Frequently asked questions

What pertussis vaccine should be given to pregnant women?

Pregnant women should only be offered a single dose of Repevax® 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 in the period week 28 to 38 (inclusive) of pregnancy with the period week 28 to 32 being optimal. If not given in this period, vaccination can be given up to delivery.

Is the vaccine safe?

Repevax® 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 Repevax®. Use of Repevax® in pregnant women to date has not revealed any risk to pregnancy or the unborn child.

Why does the Patient Information Leaflet state that Repevax® should not be used in pregnancy?

This says that the vaccine is not recommended for use in pregnancy because of the routine exclusion of pregnant women from clinical trials, and not because of any specific safety concerns or evidence of harm in pregnancy. Use in pregnancy is not contraindicated.

What if a women received Repevax® 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 Repevax® is needed for each pregnancy.

Can Repevax® be given at the same time as influenza vaccine?

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

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

There are no reasons why Repevax® cannot be administered at the same time as anti-D treatment.

Is there an alternative way of protecting babies from pertussis?

Immunising 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. The Health Protection Agency has published guidelines on the management of cases of pertussis at:

<http://www.hpa.org.uk/Topics/InfectiousDiseases/InfectionsAZ/WhoopingCough/Guidelines/>

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.

dTaP/IPV (Repevax®)

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.