Health Protection Scotland

NHS National Services Scotland

NHS Education for Scotland

Vaccination against pertussis (whooping cough) – an update for registered healthcare practitioners

Questions and Answers

April 2016

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April 2016 Update

Pertussis vaccination now recommended for pregnant women from 16 weeks gestation

In February 2016 JCVI advised that maternal pertussis immunisation can take place from week 16 of pregnancy (Eberhardt et al., 2016; JCVI February 2016 minute). This is because new evidence shows vaccination earlier in pregnancy would be likely to improve neonatal antibody levels and would increase opportunities during pregnancy for vaccination. The change in advice also provides additional benefit where delivery may be premature.

Vaccination should be offered from gestational week 16 to maximise the likelihood that the baby will be protected from birth. Women may still be immunised after week 32 of pregnancy but this may not offer as high a level of passive protection to the baby. Vaccination late in pregnancy may, however, directly protect the mother against disease and thereby just 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 i.e. up until their child receives their first dose of pertussis-containing vaccine.

References

Eberhardt C, Blanchard-Rohner G, Lemaitre B et al. (2016) Maternal Immunization earlier in pregnancy maximises maternal antibody transfer and expected infant seropositivity against pertussis. Clin Infect Dis 62(7): 829-836.

JCVI February 2016 minute - https://www.gov.uk/government/groups/joint-committee-on-vaccination-and-immunisation

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Background

There has been a dramatic increase in pertussis activity in the UK starting in mid 2011. In Scotland there were 1927 and 1188 laboratory confirmed cases of pertussis in 2012 and 2013 respectively and 504 in 2014, compared 119 and 82 confirmed cases in the whole of 2011 and 2010 respectively. The current national outbreak is the largest seen in the UK for over a decade. Whilst pertussis activity is now lower than during the peak of the outbreak it persists at raised levels compared to recent years. The highest incidence of pertussis has been in young infants; the same age group that is also most at risk of serious complications and even death from pertussis.

The Scottish Government has introduced a temporary programme to vaccinate pregnant women against pertussis to protect their infants, in the first few weeks of life before they are old enough to receive routine infant vaccinations. This decision was taken on the advice of the Joint Committee on Vaccination and Immunisation (JCVI).The JCVI reviewed the epidemiology of the disease and the safety and effectiveness of this approach. The committee is of the opinion that vaccinating pregnant women is likely to be the most effective strategy to provide protection to newborn infants and that there is no evidence of excess risk to the mother or her baby.

By immunising pregnant women against pertussis, the antibodies produced will cross the placenta to the fetus 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 the infant should still be immunised at 8 weeks of age according to the routine infant immunisation schedule.

This immunisation programme has been shown to be very effective at reducing pertussis in young infants at a time when levels in older children and adults remain high. As pertussis is still circulating at high levels in Scotland, it is important that pregnant women continue to be vaccinated to protect their young infants before they are old enough to start their course of immunisations at 8 weeks of age.

The vaccine used for this programme has changed from Repevax® to Boostrix®-IPV. This change is due to the national procurement of vaccines and a different supplier of the vaccine for this immunisation programme.

Vaccination against pertussis for pregnant women is considered the best way of providing protection to infants in the first weeks of life before they are old enough to start receiving their own primary immunisations.

Pertussis

What is pertussis?

Pertussis (commonly known as whooping cough) is an infection with the bacteria Bordetella pertussis.

Pertussis causes long bouts of coughing and choking, making it hard to breathe. The 'whoop' noise is caused by gasping for breath after each bout of coughing, although not all cases will make the whooping' sound which can make it difficult to recognise the disease.

Pertussis is a very infectious disease that is easily spread by coughing and sneezing.

Who is affected by pertussis?

Pertussis can affect people of all ages, but infection is usually most severe in young infants.

Young infants are most likely to develop severe potentially life threatening complications including pneumonia, seizures or brain damage, encephalitis (an acute inflammation of the brain) and even death.

The vaccine programme

Is Scotland the only country that is seeing an increase in cases of pertussis?

A similar increase in pertussis has also been seen in the rest of the UK, the United States and a number of other countries. The highest incidence of cases is in infants under one year of age, the group most at risk of complications from pertussis infection.

Why are there so many more cases of pertussis since 2012?

The reasons for this increase are currently been investigated. In the meantime the important thing is to ensure that young infants are protected.

Why is the focus on pregnant women?

By immunising pregnant women against pertussis, the antibodies produced will cross the placenta to the fetus so that when the infant is born he/she already has antibodies against pertussis, which should provide protection in the first weeks of life before the infant is able to start the routine infant immunisation schedule.

Does a woman who was vaccinated as a child or already had pertussis still need the vaccine?

Yes. The protection gained from both vaccination and natural infection is not life-long and wanes over time. Therefore there will not be sufficient protection from previous vaccination or natural infection to pass to the infant to protect them during the first weeks of life.

Does a woman who has recently been vaccinated still need to be vaccinated?

Yes, pregnant women who have received immunisation against pertussis, diphtheria, tetanus and/or polio relatively recently should be offered a dose of Boostrix®-IPV, but with a gap of at least one month between immunisations. Although cumulative doses may increase the likelihood of injection site reactions or fever, this is outweighed by the expected benefit to the infant.

What about women pregnant with twins or triplets?

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

What about women who are pregnant again while this pertussis vaccination programme is in place?

Women who become pregnant again while the programme is in place should be offered immunisation during each pregnancy to maximise transplacental transfer of antibody.

How long will the protection last in the infant?

The immunity provided from vaccination of the pregnant women will help protect the infants in the early weeks of life while they are too young to receive their own childhood immunisations. It is important that women are encouraged to ensure their infants start their childhood immunisations at 8 weeks of age in order to gain longer term protection.

Has the programme worked so far?

The programme has been very effective at reducing the incidence of pertussis in young infants at a time when levels have remained high in adults and older children. During 2012 there were 140 confirmed cases in infants under one year of age, this reduced to 19 in 2013 and 20 in 2014. This impact will only be maintained if vaccine uptake levels remain high.

Due to the success of the maternal vaccination programme in protecting infants and evidence of the safe use of acellular pertussis vaccine in the maternal programme (Donegan et al., 2014), in June 2014 the Joint Committee on Vaccination and Immunisation (JCVI)

advised that this temporary programme should continue for at least a further five years. https://www.gov.uk/government/publications/vaccine-update-issue-217-july-to-august-2014

The Vaccine

Which vaccine will be offered to pregnant women?

Pregnant women will be offered a single dose of Boostrix®-IPV .This vaccine protects against pertussis and also diphtheria, tetanus and polio.

Why did the vaccine for pregnant women change?

The vaccine used for this programme has changed from Repevax® to Boostrix®-IPV. This change is due to the national procurement of vaccines and a different supplier of the vaccine for this immunisation programme.

There have been no safety concerns about pertussis vaccination of pregnant women which, as with all vaccination programmes, is monitored by the MHRA.

Is there not a vaccine which only contains pertussis?

There is no vaccine which protects only against pertussis. All currently available licensed pertussis vaccines in the UK are part of combined vaccines.

The Summary of Product Characteristics (SPC) for Boostrix®-IPV says it hasn't been tested in pregnant women, so why are we recommending this vaccine?

This statement follows the routine exclusion of pregnant women from clinical trials, and not because of any specific safety concerns or evidence of harm in pregnancy. The advice from the JCVI and the recommendations in the CMO letter (http://www.sehd.scot.nhs.uk/cmo/CMO(2012)09.pdf) should be followed. There is no evidence of risk to pregnancy or the infant from inactivated vaccines such as Boostrix®-IPV . Use of Boostrix®-IPV is not contraindicated in pregnancy and does not affect breast-feeding.

Boostrix®-IPV has been used worldwide, and its safety has been well established.

What evidence is there for the safety of Boostrix®-IPV in pregnant women?

There is no evidence of risk to pregnancy or the infant from inactivated vaccines such as Boostrix®-IPV.

The JCVI has no concerns about the safety of the use of this vaccine in pregnancy. In the United States there is similar recommendation for the vaccination of pregnant women against pertussis.

In USA the Advisory Committee on Immunisation Practices (ACIP) reviewed the available evidence and recommended a vaccination programme for pregnant women. The vaccine used in USA, Tdap, is similar to the one recommended for use in Scotland (but does not provide protection against polio).The ACIP reviewed published and unpublished data from Vaccine Adverse Event Reporting, pregnancy registries, and small studies. ACIP concluded that available data from these studies did not suggest any elevated frequency or unusual patterns of adverse events in pregnant women who received Tdap and that the few serious adverse events reported were unlikely to have been caused by the vaccine. Both tetanus and diphtheria (Td) and tetanus toxoid vaccines have been used extensively in pregnant women worldwide to prevent neonatal tetanus.

Since the introduction of the maternal pertussis programme in October 2012, the Medicines and Healthcare products Regulatory Agency (MHRA) has used the Yellow Card Scheme and the Clinical Practice Research Datalink to follow pregnancy outcomes following vaccination. The study based on a cohort of 18,000 vaccinated women showed that they had similar rates of normal, healthy births as unvaccinated women. The study also found no evidence of an increased risk of stillbirth and no evidence of an increased risk of any of an extensive list of adverse events related to pregnancy in vaccinated mothers (Donegan et al., 2014).

Can Boostrix®-IPV be given at the same time as other vaccines (including flu)?

Concomitant administration of Boostrix®-IPV and other vaccines or with immunoglobulins has not been studied. It is unlikely that co-administration will result in interference with the immune response. The vaccines should be given at a separate site, preferably in a different limb. If more than one vaccine is given in the same limb, they should be given at least 2.5cm apart. The sites at which each vaccine is given should be noted in the individual's records. However, influenza immunisation should not be delayed until week 16 or after pregnancy in order to give Boostrix®- IPV at the same visit. 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?

There is no reason why Boostrix®-IPV cannot be administered at the same time as anti-D treatment.

What are the potential side effects of this vaccine?

There may be pain, swelling or redness at the injection site. A small painless nodule may form at the injection site. There may be low grade fever, malaise, shivering, fatigue, headache, aching muscles and joint pain.

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. The possible known side effects are not expected to be any different in pregnant women compared with other adults, and the benefits outweigh these possible reactions.

Can I give Repevax® if I haven't got any Boostrix®-IPV?

Yes. "In those circumstances where there is no Boostrix®-IPV (dTaP/IPV) vaccine when a pregnant woman attends for vaccination, Repevax® (dTaP/IPV) may be given as a suitable alternative."
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/424448/Green_Book_Chapter_24_Pertussis_v2_0_April_2015.pdf

Are there any pregnant women who can't get the vaccine?

There are very few medical reasons why Boostrix®-IPV should not be given. Boostrix®-IPV should not be given to pregnant women 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 (neomycin, polymixin B);
- if the subject has experienced an encephalopathy of unknown aetiology, occurring within 7 days following previous vaccination with pertussis-containing vaccine;
- to subjects who have experienced transient thrombocytopenia or neurological complications following an earlier immunisation against diphtheria and/or tetanus.

Where can I get more information?

CMO Letter (2012): http://www.sehd.scot.nhs.uk/cmo/CMO(2012)09.pdf.

CMO Letter (2013): http://www.sehd.scot.nhs.uk/cmo/CMO(2013)03.pdf.

CMO Letter (2016) http://www.sehd.scot.nhs.uk/cmo/CMO(2016)08.pdf

Green Book: https://www.gov.uk/government/publications/pertussis-the-green-book-chapter-24

The NES training slides: http://www.nes.scot.nhs.uk/education-and-training/by-theme-initiative/public-health/health-protection/immunisation/pertussis-(whooping-cough).aspx.

Information for pregnant women is available at: http://www.immunisationscotland.org.uk/vaccines- and-diseases/whooping-cough.aspx.