Vaccination against pertussis (whooping cough) - the replacement of Repevax® with Boostrix®-IPV - an update for midwives

August 2014
Key Message

There is a lot of pertussis around at the moment and babies who are too young to start their vaccinations are at greatest risk

- The incidence of pertussis increased dramatically as part of a national outbreak in 2012 and 2013 and still remains well above pre outbreak levels. During the first 12 weeks of 2014 there were 98 laboratory confirmed cases, in the whole of 2011 and 2010 there had been 119 and 82 confirmed cases respectively.
Aims of resource

• To support staff involved in discussing vaccination against pertussis with pregnant women by providing evidence based information

• To raise awareness of current pertussis epidemiology and the impact of pertussis on young infants

• To promote uptake of vaccination against pertussis through increasing awareness amongst midwives
Learning Outcomes

After completing this resource a midwives will be able to:

• Understand their role in raising the issue of vaccination against pertussis with all women in the antenatal period and providing women with evidence based information about this vaccination
• Describe the aetiology and epidemiology of pertussis
• Have an understanding of how pertussis is transmitted and the severity of it in young infants
• Discuss the important role of vaccination against pertussis during pregnancy for young infants
• Be aware of sources of additional information
Contents

1. What is pertussis?
2. Why vaccinate pregnant women against pertussis?
3. Vaccination against pertussis (whooping cough) the use of Boostrix®-IPV
4. The role of the midwives
5. Resources
What is pertussis?
What is pertussis?

• Pertussis is an acute bacterial infection caused by *Bordetella pertussis*
• It is highly contagious and can be passed from person to person through droplets from the nose and throat of infected individuals when coughing and sneezing
• Infants and young children are the most vulnerable group, with the highest rates of complications and mortality
What is pertussis? (cont.)

**Incubation period**
- The incubation period is on average 7-10 days (range 5-21 days)

**Infectious period**
- Patients with pertussis are most infectious in the initial catarrhal stage and during the first three weeks after the onset of cough
Clinical presentation of pertussis

- **Initial stage**
  - Early symptoms:
  - are similar to those of a cold
  - can last for one to two weeks, before becoming more severe.

- **Second or Paroxysmal Stage**
  - Characteristic symptoms:
  - Intense bouts of coughing sometimes referred to as ‘paroxysms’ of coughing
Clinical presentation of pertussis (cont.)

Convalescent stage

Symptoms:

- Slowly become less severe
- Generally last 2-6 weeks but can persist for months
Clinical presentation of pertussis in infants and young children

- Infants *may not* make the ‘whoop’ sound after coughing, but they may start gagging or gasping and may temporarily stop breathing
- Young children may also seem to choke or become cyanosed when they have a bout of coughing

Pertussis - Possible complications of in infants and young children

Infants and young children are usually most severely affected and more likely to develop severe complications such as:

- Pneumonia
- Temporary pauses in breathing as a result of severe difficulty with breathing
- Weight loss due to excessive vomiting
- Seizures or brain damage
- Encephalitis (an acute inflammation of the brain)
- Low blood pressure, requiring medication
- Kidney failure, requiring temporary dialysis
- In severe cases pertussis can be fatal in infants and young children
Possible complications of pertussis in older children and adults

Complications in older children and adults are usually much less serious than those in infants and young children. May include:

- nosebleeds and burst blood vessels in the whites of the eye from intense bouts of coughing
- bruised ribs as a result of intense coughing
- hernia due to intense coughing
- a swollen face
- ulcers on the tongue and mouth
- ear infections such as otitis media
Why vaccinate pregnant women against pertussis?
Why vaccinate pregnant women against pertussis?

Current epidemiology of pertussis in Scotland - what does it show us?

Laboratory reports of Bordetella pertussis reported to HPS 2000-2013
Before the vaccination programme the highest rates of pertussis were among young infants

Laboratory reports of Bordetella pertussis and rate per 100,000 by age band in 2012
How can we help prevent pertussis - childhood vaccination programme?

- The main measure for reducing the impact (morbidity and mortality) from pertussis is the current childhood vaccination programme
- What does this current vaccination programme look like?
  - Pertussis is part of the infant vaccination programme
  - 5-in-1 vaccine (DTaP/IPV/Hib) is offered to infants at two, three and four months of age.
  - This protects against pertussis, diphtheria, tetanus, polio and *Haemophilus influenzae* type b
  - A booster dose of pertussis containing vaccine is given when children are about three years and four months old
Immunity against pertussis

- Vaccination against pertussis does not give life-long immunity
- Individuals who have had pertussis can become reinfected and spread infection to others
- This spread of infection is important particularly in children too young to be vaccinated
How can we try to protect young children too young to be vaccinated against pertussis?

Due to the dramatic increase in cases of pertussis in the UK the Scottish Government and the Department of Health have recommended:

- That pregnant women receive a dose of pertussis containing vaccine from 28-38 weeks, with the ideal time being 28-32 weeks gestation
- That pregnant women receive one dose of Boostrix®-IPV
- That this is considered the best way to provide protection to infants in the first weeks of life
Why vaccinate pregnant women against pertussis?

• The immunity acquired by vaccination will be passed across the placenta by antibodies and should help protect the baby in the first few weeks of life when they are at risk of serious complications if they become infected with pertussis.
Why vaccinate pregnant women against pertussis? (cont.)

- **Helps protect the baby** – Babies born to mothers vaccinated at the recommended time during pregnancy should have higher levels of antibodies than those born to unvaccinated mothers, which should help protect the infant until they start receiving their own immunisations.

- **Helps protect the mother** – Reduces the risk of the mother catching pertussis and passing it on to the young infant.

- Programme to date has been shown to be very effective at reducing the number of cases in infants, although levels in older children and adults remain high.
Impact of the vaccination programme

Laboratory reports of Bordetella pertussis in infants under one year by year and four-week period, 2012 and 2013

Vaccination of pregnant women
Vaccination against pertussis (whooping cough)
The use of Boostrix®-IPV
Why has the vaccine used changed from Repevax® to Boostrix®-IPV

- The vaccine used for pregnant women is changing from Repevax® to Boostrix®-IPV
- This change is due to a change in national procurement to replace Repevax® with Boostrix®-IPV
Vaccination against pertussis (whooping cough) - the use of Boostrix®-IPV

**Brand name**
- Boostrix®-IPV

**Generic Name**
- Diphtheria, Tetanus, Pertussis (acellular component) and Poliomyelitis (inactivated) vaccine (dTaP/IPV)

- Marketed by GlaxoSmithKline
- Inactivated (i.e. the vaccine cannot cause pertussis)
- Licensed for use from age 4 years and above
- Presented as prefilled syringe
Vaccination against pertussis (whooping cough) - the use of Boostrix®-IPV

**Boostrix®-IPV composition - active ingredients**

- **Diphtheria Toxoid** not less than 2IU
- **Tetanus Toxoid** not less than 20IU

**Pertussis antigens**

- Pertussis Toxoid 8 micrograms
- Filamentous Haemagglutinin 8 micrograms
- Pertactin 2.5 micrograms

**Poliovirus (inactivated)**

- Type 1 40 D antigen units
- Type 2 8 D antigen units
- Type 3 32 D antigen units
Vaccination against pertussis (whooping cough) - the use of Boostrix®-IPV (cont.)

**Boostrix®-IPV composition**

**Adjuvant**
- Aluminium hydroxide, hydrated (0.3mg aluminium)
- Aluminium phosphate (0.2mg aluminium)

**Residual substances**
- Neomycin, polymyxin

**Excipients**
- Medium 199 (as stabilizer containing amino acids, mineral salts, vitamins and other substances)
- Sodium chloride
- Water for injection
Administration of Boostrix®-IPV

Licensing

• The Green Book states that
  “Pertussis-containing vaccines may be given to pregnant women when 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 (Plotkin & Orenstein 2004)”

• The vaccine marketing authorisation holder’s Summary of Product Characteristics states that it has not been tested on pregnant women

• The advice from JCVI differs from that in the SPC and Patient Information Leaflet for Boostrix®-IPV. 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
Administration of Boostrix®-IPV (cont.)

- The advice from JCVI should be followed. There is no evidence of risk to pregnancy or the infant with inactivated vaccines such as Boostrix®-IPV.
- Use of Boostrix®-IPV is not contraindicated in pregnancy and does not affect breast-feeding.
Administration of Boostrix®-IPV

- Vaccine comes as a suspension – shake before use to obtain a homogeneous turbid white suspension
- Given by intramuscular injection into the deltoid
- 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
Vaccination against pertussis (whooping cough) - the use of Boostrix®-IPV

Contraindications

- A confirmed anaphylactic reaction to a previous dose of diphtheria, tetanus, pertussis or poliomyelitis containing vaccine
- A confirmed anaphylactic reaction to any component of the vaccine
- 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
Vaccination against pertussis (whooping cough) - the use of Boostrix®-IPV (cont.)

Precautions

• Acute illness
  - Defer immunisation until recovered
• Recent immunisation against pertussis, diphtheria, tetanus and/or polio
  - Ensure a gap of at least one month between immunisations
• Current neurological deterioration
  - Follow advice in Green Book
• If any of the following events are known to have occurred in temporal relation to receipt of pertussis containing vaccine, the decision to give doses of pertussis containing vaccine should be carefully considered:
  - Temperature of $\geq 40.0^\circ$C within 48 hrs of vaccination, not due to another identifiable cause
  - Collapse or shock-like state (hypotonic-hyporesponsiveness episode) within 48 hours of vaccination
  - Persistent, inconsolable crying lasting $\geq 3$ hours, occurring within 48 hours of vaccination
  - Convulsions with or without fever, occurring within 3 days of vaccination
Vaccination against pertussis (whooping cough) - the use of Boostrix®-IPV

Adverse reactions

- Pain, swelling or redness at injection site
- A small painless nodule may form at injection site
- Low grade fever, malaise, shivering, fatigue, headache, aching muscles and joint pain
Vaccination against pertussis (whooping cough) - the use of Boostrix®-IPV

Reporting suspected adverse reactions

• Yellow card scheme
  - Voluntary reporting system for suspected adverse reaction to medicines/vaccines
  - Success depends on early, complete and accurate reporting
  - Report even if uncertain about whether vaccine caused condition
  - [http://yellowcard.mhra.gov.uk/](http://yellowcard.mhra.gov.uk/)
  - See chapter 8 of Green Book for details
Vaccination against pertussis (whooping cough) - the use of Boostrix®-IPV

- Women who become pregnant again while the programme is in place should be offered immunisation during each pregnancy to maximise transplacental transfer of antibody
- One dose of Boostrix®-IPV is recommended for women expecting twins and higher multiple pregnancies
- Vaccination may be offered to new mothers who have never previously been vaccinated against pertussis, up to when their child receives their first vaccination. A single dose of Boostrix®-IPV is recommended in these circumstances and should be ideally be given as soon as possible following birth
Vaccination against pertussis (whooping cough) - the use of Boostrix®-IPV

Data management

• Vaccination against pertussis will be recorded in the women’s GP records and maternity records as per local arrangements
• Standard data set will be collected as per other vaccination programmes
Vaccination against pertussis (whooping cough) - the use of Boostrix®-IPV

Providing longer term protection against pertussis

- The protection the infant acquires from the mother by the transfer of antibodies across the placenta is only short term
- It is very important that parents ensure their infants start their immunisation schedule at 8 weeks to receive more long lasting protection
Key role of the midwife

- To provide clear and concise information to every pregnant woman regarding vaccination against pertussis
Resources

• Green book: http://www.dh.gov.uk/greenbook
• Patient group direction
  • http://www.immunisationscotland.org.uk
  • http://www.nhsinform.co.uk/health-library/articles/w/whooping-cough/introduction
• HPS FAQ on pertussis: http://www.documents.hps.scot.nhs.uk/immunisation/whooping-cough/whooping-cough-faqs.pdf
Key Message

There is a lot of pertussis around at the moment and babies who are too young to start their vaccinations are at greatest risk

- 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 their own primary immunisations