The infant rotavirus vaccination programme –
Q&As for healthcare practitioners

**Background**

In July 2013 a new vaccine will be introduced into the childhood immunisation schedule\(^1\). This will protect infants against the most common strains of rotavirus. Rotavirus is the commonest cause of gastroenteritis among children and results in a significant number of young children being admitted to hospital each year. The vaccine which will be used for this programme is called Rotarix®.

In 2009, the JCVI (Joint Committee on Vaccination and Immunisation) considered the evidence on a) the burden of rotavirus infection and b) the cost effectiveness of rotavirus immunisation. Based on the available evidence, JCVI advised that the licensed rotavirus vaccines would have a significant impact on reducing gastroenteritis in young children and that the UK health departments should introduce the vaccines if they could be procured at a cost effective price\(^2\). This advice was reiterated in 2011 following consideration of a further cost effectiveness study.

In November 2012, the vaccine was procured at a price which meant the programme would be cost effective. It has now been confirmed that the programme will start on 1\(^{st}\) July 2013\(^1\).

**Rotavirus**

**What is rotavirus?**

Rotavirus is a highly infectious virus which causes gastroenteritis and is the commonest cause of gastroenteritis among young children. Infections are often recurrent. Most children will experience at least one or more rotavirus infection by five years of age.

Rotavirus infection causes gastroenteritis that usually lasts from three to eight days.

Gastroenteritis can cause dehydration, which can be very serious especially in young infants requiring hospitalisation for intravenous rehydration.

Rotavirus is highly infectious and spreads mainly via the faecal-oral route.

**Who is affected by rotavirus?**

Rotavirus can affect people of all ages but the highest incidence is in young children. It is estimated that rotavirus infections cause around half of all gastroenteritis in children less than five years of age.
As mentioned previously, young infants are also more likely to suffer from dehydration if they become infected with rotavirus than older children or adults.

**The rotavirus vaccination programme**

The rotavirus vaccination programme will be introduced in all parts of the UK. Rotavirus vaccination is also part of the routine infant immunisation programme in a number of other countries including Australia, Canada and USA. In the USA, studies have shown that rotavirus related hospital admissions for young children have been cut by more than two thirds since rotavirus vaccination was introduced.

**Does the vaccine protect against all causes of gastroenteritis in young children?**

The Rotarix® vaccine protects against the most common strains of rotavirus. It doesn’t protect against other types of virus (i.e. norovirus) or bacteria (i.e. Salmonella) that can cause gastroenteritis. However, as rotavirus is the most common cause of gastroenteritis in young infants, it will have a significant impact on the total number of young children who become ill with gastroenteritis and the number with severe disease.

**How many doses will infants receive?**

The objective of the programme is to provide two doses of Rotarix® to infants before 24 weeks of age (i.e. 23 weeks and 6 days). Infants will be offered two doses with an interval of at least four weeks between doses: at 8 weeks (2 months) and again at 12 weeks (3 months). It is preferable that the full course of two doses of Rotarix be completed before 15 weeks (i.e. 14 weeks and 6 days of age), but it must be completed by 24 weeks (i.e. 23 weeks and 6 days).

**When will infants receive the vaccine?**

- All children scheduled to receive their primary vaccines at age 8 weeks and 12 weeks should be offered the rotavirus vaccine, that is, two doses, four weeks apart. Both doses should be given by 24 weeks of age (i.e. 23 weeks and 6 days).

- Infants who have received their first dose of vaccine by week 15 (i.e. 14 weeks and 6 days) can receive their second dose of Rotarix® as long as it is given by week 24 (i.e. 23 weeks and 6 days).

- Infants who have not received their first dose by week 15 of age (i.e. 14 weeks and 6 days) should not be offered Rotarix®.

- Infants may receive their first dose of primary immunisations from 6 weeks of age in exceptional circumstances e.g. pre-travel but it is not routinely
recommended to offer infants vaccine before 2 months of age. Rotarix® is licensed from 6 weeks of age.

What if the infant does not receive the first dose at age 2 months?

If the infant presents before they are 15 weeks of age (i.e. 14 weeks and 6 days) then they should be offered their first dose. The second dose should be given at least four weeks later and must be given before 24 weeks of age (i.e. 23 weeks and 6 days).

Infants who present for their first dose after 15 weeks of age (i.e. 14 weeks and 6 days) should not be offered Rotarix®.

What if it is more than four weeks since the first dose?

If the course is interrupted, it should be resumed but not repeated. If the infant is still less than 24 weeks of age (i.e. 23 weeks and 6 days) the second dose should be given. If they are aged 24 weeks or older the second dose must not be given.

Why can’t the first dose of vaccine be given to children over 15 weeks?

Vaccination should not be initiated for infants aged after 15 weeks of age (i.e. 14 weeks and 6 days) (this is in line with recommendations from WHO) because of insufficient data on safety of a first dose of rotavirus vaccine in older infants. Both doses should be given by 24 weeks of age (i.e. 23 weeks and 6 days)

The vaccine

What vaccine is being given?

The vaccine that will be used is Rotarix®. It is a live attenuated vaccine (a weakened form of virus which cannot cause disease in the infant but which protects against rotavirus).

This is an oral vaccine which must not be injected.

As described previously the Rotarix® vaccine is already in use in a number of other countries

How should the Rotarix® vaccine be stored?

Rotarix® must be stored in accordance with the manufacturer’s instructions. As with most vaccines Rotarix® should be stored in a refrigerator between +2°C and +8°C.

The vaccine should be stored in the original packaging. This makes it easy to identify in the vaccine refrigerator and will protect it from light.
How is the vaccine presented?

- The vaccine is presented as a prefilled oral applicator containing 1.5ml oral suspension.
- It is ready to use (no reconstitution or dilution is required).
- It is a clear, colourless liquid, free of visible particles.
- It should be visually inspected for any foreign particulate matter and/or physical appearance. In the event of either being observed, discard the vaccine.

How is the vaccine given?

- Give the oral Rotarix® vaccine at the beginning of the visit, before administration of any intramuscular vaccines.
- The infant should be seated in a reclining position.
- Remove the protective tip from the oral applicator.
- Administer orally (i.e. into the child’s mouth, towards the inner cheek) the entire content of the oral applicator.
- The vaccine must **not** be injected.

What happens if the baby spits the vaccine out?

If the infant spits out or regurgitates most of the vaccine, a single replacement dose may be given at the same visit.

Can the baby be fed before or after receiving the vaccine?

Yes, there are no restrictions on the infant’s feeding before or after immunisation.
Can Rotarix® be given at the same time as other vaccines?

Rotavirus vaccine can be given at the same time as the other vaccines administered as part of the routine childhood immunisation programme, including BCG, and so should ideally be given at the scheduled two month and three month vaccination visits. However, rotavirus vaccine can also be given at any time before or after the routine infant immunisations and at any time before or after BCG vaccine. The recommendation for administering live vaccines either at the same time or after an interval of four weeks only applies to injectable live viral vaccines and, therefore, not to BCG or to oral rotavirus vaccine.

As mentioned previously it is suggested that Rotarix® is given at the beginning of the visit before administration of intramuscular vaccines which may unsettle the infant.

As Rotarix® is a live vaccine, can it be passed onto others?

There is a potential for transmission of the live attenuated virus in Rotarix® from the infant to severely immunocompromised contacts through faecal material for at least 14 days5,7. However, vaccination of the infant will offer protection to household contacts from wild-type rotavirus disease and outweigh any risk from transmission of vaccine virus to any immunocompromised close contacts.

Those in close contact with recently immunised infants should as always observe good personal hygiene e.g. washing their hands after changing a child’s nappy.

Are there any infants who can’t have Rotarix®?

There are very few infants who cannot receive Rotarix®. Where there is any doubt, appropriate advice should be sought on the circumstance under which the vaccine could be given from appropriate registered healthcare practitioners e.g. child’s paediatrician, Immunisation Co-ordinator or Consultant in Public Health.

Rotarix® should not be given to:

- infants with a confirmed anaphylactic reaction to a previous dose of rotavirus vaccine
- infants with a confirmed anaphylactic reaction to any components of the vaccine
- infants with a previous history of intussusception
- infants aged 24 weeks of age or over (i.e. beyond 23 weeks and 6 days)
- infants presenting for the first dose of vaccine over 15 weeks of age
- infants with Severe Combined Immunodeficiency (SCID) disorder
- infants who have a malformation of the gastrointestinal tract that could predispose them to intussusception
- infants with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrose-isomaltase insufficiency
Administration of rotavirus vaccine should be postponed in infants:
  • suffering from acute severe febrile illness. This is to avoid confusing the
diagnosis of any acute illness by wrongly attributing any signs and symptoms
to adverse effects of the vaccine
  • suffering from acute diarrhoea or vomiting. This is to ensure that the vaccine
is not regurgitated or passed through the intestines too quickly, which could
reduce the effectiveness of the vaccine

Can the vaccine be given to children who are immunocompromised?

Rotavirus vaccine should not be administered to infants known to have severe
combined immunodeficiency disorder (SCID). Although the vaccine is a live
attenuated virus, with the exception of severe combined immune-deficiency (SCID),
the benefit from vaccination may exceed any risk in other forms of
immunosuppression. Therefore, there are very few infants who cannot receive
rotavirus vaccine. Given the high risk of exposure to natural rotavirus however, the
benefit of administration is likely to outweigh any theoretical risks and therefore
should be actively considered. Where there is doubt, appropriate advice should be
sought from the child’s paediatrician, an immunisation coordinator or Consultant in
Public Health rather than withholding vaccination.

From clinical trials with HIV infected infants, the safety profile was similar between
Rotarix® and placebo recipients. Therefore vaccination is advised in HIV infected
infants. Additionally infants with unknown HIV status but born to HIV positive
mothers should be offered vaccination.

Can premature infants receive the vaccine?

It is important that premature infants have their immunisations at the appropriate
chronological age, according to the schedule. As with other vaccinations, the
occurrence of apnoea following vaccination is especially increased in infants who
were born very pretermly.

Very premature infants (born ≤ 28 weeks of gestation) who are in hospital should
have respiratory monitoring for 48-72 hours when given their first immunisations,
particularly those with a previous history of respiratory immaturity. If the child has
apnoea, bradycardia or desaturations after the first routine immunisation, the second
immunisation should also be given in hospital, with respiratory monitoring for 48-72
hours.

As the benefit of vaccination is high in this group of infants, vaccination should not be
withheld or delayed.
Should rotavirus vaccine be offered to hospitalised infants?

Infants, including those that are born prematurely should be offered rotavirus vaccine at their chronological age, if the infant is clinically stable. Hospitalised pre-term infants are particularly vulnerable to rotavirus infection and its complications and should be vaccinated as per recommendations. Delaying vaccination until discharge from hospital places the infant at a risk of acquiring the infection or receiving the vaccination too late and at a time where the risk of intussusception is greatest.

Rotarix® is a highly attenuated vaccine virus with a very low risk of clinical disease even in vulnerable infants. Infants vaccinated whilst in hospital do not need to be isolated from other infants. Aprons and Gloves should be worn for nappy changes and standard infection control precautions followed at other times to reduce the risk of transmission of the vaccine virus until discharge.

JCVI considered that the benefits of vaccination for this at-risk population at the appropriate time on neonatal units far outweighed any potential risk of transmission of this highly attenuated vaccine virus.

If the child has already had rotavirus infection can they still receive the vaccine?

If a child has had confirmed or suspected natural rotavirus infection they should still receive the Rotarix® as scheduled to provide protection against future infection.

If the child is suffering from acute diarrhoea or vomiting the administration of the rotavirus vaccine should be postponed. This is to make sure that the vaccine is not regurgitated or passed through the intestines too quickly, which could reduce the effectiveness of the vaccine.

Does Rotarix® contain thiomersal?

No, there is no thiomersal or any other preservatives in Rotarix®

Does Rotarix® contain latex?

The plunger stopper and protective tip cap are both rubber butyl which should not affect latex sensitive individuals.

What are the potential side effects of this vaccine?

The most common adverse events observed following the administration of Rotarix® are:

- diarrhoea
- irritability

Other reactions commonly reported are
- vomiting
- abdominal pain
- flatulence
- skin inflammation
- regurgitation of food
- fever
- loss of appetite

The full list of adverse reactions associated with Rotarix® is available in the marketing authorisation holder’s Summary of Product Characteristics.

**Anaphylaxis**

As with all vaccines, there is a very rare possibility of this vaccine causing a severe allergic reaction called anaphylaxis. All registered healthcare practitioners responsible for immunisation should be trained to recognise and treat anaphylaxis.

Parents/guardians should be advised to seek medical advice if there is any severe adverse event including severe vomiting and diarrhoea with a fever.

**Is there a link between rotavirus vaccine and intussusception?**

Research from some countries suggests that Rotarix® may be associated with a very small increased risk of intussusception within seven days of vaccination, possibly 2 cases per 100,000 first doses given and the Rotarix® prescribing information includes this as a possible side effect. The benefits of vaccination in preventing the consequences of rotavirus infection outweigh the small potential risk in young infants.

Because of the potential risk, and to reduce the likelihood of a temporal association with rotavirus vaccine, the first dose of vaccine should not be given after 15 weeks of age.

Parents/guardians should be advised to contact their doctor immediately if their infant develops severe vomiting or abdominal pain and pass what looks like red current jelly in their stools.

**What is intussusception?**

Intussusception is a naturally-occurring condition of the intestines with a background annual incidence of around 120 cases per 100,000 children aged under one year.
Intussusception occurs when a section of the bowel folds in on itself like a telescope closing. When this occurs, it creates a blockage in the bowel.

The main symptom of intussusception is severe abdominal pain that comes and goes. Each episode tends to last 2-3 minutes and in between episodes the infant will look very pale, tired and floppy.

After 12 hours or so the pain becomes more constant and the infant will usually go off food and may vomit. Due to vomiting the infant may become dehydrated.

Intussusception can be life threatening and requires prompt medical treatment.

**Is it alright for babies who have recently received rotavirus vaccine to be taken swimming?**

There is no reason for recently vaccinated babies not to be taken swimming since the vaccine virus is highly attenuated and it should also be killed by chlorine.

**Can rotavirus vaccine be given via a feeding tube if a baby has one in situ?**

Given the very small volume of fluid in a dose of rotavirus vaccine, children with feeding tubes should preferably be given the vaccine orally, unless absolutely necessary to give it via the tube.

**Can infants who have recently received an antibody-containing blood product (e.g. blood transfusion or HBIG) still receive live rotavirus vaccine?**

Rotavirus vaccine may be administered at any time before, at the same time as, or after administration of any blood product, including antibody-containing products, following the routinely recommended immunisation schedule for infants who are eligible for vaccination. There are no data currently available as to whether the immune response to rotavirus vaccine in infants is affected by blood products. However, as infants receive two doses of rotavirus vaccine, they have two opportunities to make a good antibody response to the vaccine.

**Can rotavirus vaccine be given to infants who are receiving anti-reflux medications including antacids?**

The rotavirus vaccine itself actually contains antacid (calcium carbonate) in the diluent to protect the virus during its passage through the stomach and prevent its inactivation due to the acidic environment. Reflux medicines should therefore not affect the immune response to the vaccine and infants taking these medications should receive the vaccine as scheduled.
If the first dose of rotavirus vaccine is inadvertently given to a child age 15 weeks 0 days or older, what advice should be given and should the child still receive a second dose four weeks later?

Children who inadvertently receive the first dose of rotavirus vaccine at age 15 weeks or older should still receive their second dose four weeks later (providing that they will still be under 24 weeks of age at this time). The reason for the 15 week age limit is not only to provide protection before the main burden of disease but also to avoid a temporal association with intussusception. Intussusception is a naturally-occurring condition where part of the intestine prolapses, or telescopes, into another part causing an obstruction. The background risk of intussusception in the UK increases rapidly after three months to peak at around five months of age. Research from some countries suggests that rotavirus vaccine may be associated with a very small increased risk of intussusception within seven days of vaccination (possibly two cases per 100,000 first doses given). Although there is no clear evidence that the risk of intussusception increases if the first dose of rotavirus vaccine is given later than 15 weeks, it will be more difficult to ascertain, if the child develops intussusception, whether this was due to the vaccine or was naturally occurring. No specific clinical action needs to be taken if the vaccine is inadvertently given after 15 weeks of age but, as with all parents of children receiving rotavirus vaccination, the parents should be aware of the symptoms of intussusception. A risk review should also be carried out to ascertain why the vaccine was given outside the national recommendations and steps taken to ensure it doesn't happen again.

Similarly, if a child inadvertently receives rotavirus vaccine over 24 weeks of age, no specific clinical action needs to be taken but immunisers should be reminded that rotavirus vaccine should not be given to infants older than 24 weeks, even if they haven’t completed the two dose schedule.

Where can I get more information?

Joint letter from DH, PHE and NHS England April 2013: “Important changes to the national immunisation programme in 2013/14: introduction of rotavirus vaccination for babies at 2 and 3 months”
www.gov.uk/government/organisations/public-health-england/series/immunisation

The Green Book Rotavirus chapter

Training slides www.gov.uk/government/organisations/public-health-england/series/immunisation

Marketing authorisation holder’s Summary of Product Characteristics
http://www.medicines.org.uk/emc/medicine/17840/SPC/Rotarix
Medicines and Healthcare products Regulatory Agency (MHRA) – for reporting adverse reactions.  
http://www.mhra.gov.uk

More information on the clinical presentation of rotavirus from NHS Choices  
http://www.nhs.uk/conditions/Rotavirus-gastroenteritis/Pages/Introduction.aspx

References:

1. Joint letter from DH, PHE and NHS England (30th April 2013): Important changes to the national immunisation programme in 2013/14: introduction of rotavirus vaccination for babies at 2 and 3 months”  
www.gov.uk/government/organisations/public-health-england/series/immunisation

2. JCVI statement on Rotavirus 2009  


4. Rotavirus Green Book Chapter  

5. Rotarix SPC, available on ema website  
http://www.medicines.org.uk/emc/medicine/17840/SPC/Rotarix


8. MMWR Prevention of Rotavirus Gastroenteritis AmongInfants and Children Recommendations of the Advisory Committee on Immunization Practices (ACIP) February 6, 2009 / 58(RR02);1-25 (available at http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5802a1.htm?s_cid=rr5802a1_e)

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