Vaccination against Rotavirus using Rotarix® vaccine

Questions and Answers

**Background**

From 1 July 2013 a new vaccine will be introduced into the childhood immunisation schedule to protect infants against the most common strains of rotavirus.¹ Rotavirus is the commonest cause of gastroenteritis in young children and results in a significant number 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 evidence on the burden of rotavirus infection and the cost effectiveness of rotavirus immunisation. 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 vaccine into the routine childhood immunisation schedule if it could be procured at a cost effective price.² This advice was reiterated in 2011 following consideration of a further cost effectiveness study.

**What is rotavirus?**

Rotavirus is a highly infectious virus which causes gastroenteritis, resulting in diarrhoea, vomiting and abdominal pain, usually lasting three to eight days. It is the commonest cause of gastroenteritis among young children. Nearly all children will experience at least one rotavirus infection by five years of age, many on more than one occasion.

Gastroenteritis can cause dehydration which can be very serious, especially in young infants who may require hospitalisation for intravenous rehydration. It is estimated that about 1 in 5 children in Wales need medical attention before their fifth birthday because of rotavirus infection, and 1 in 10 of those are admitted to hospital. In England and Wales every year an estimated 130,000 children will visit their GP and approximately 12,700 children with rotavirus gastroenteritis will be hospitalised.

Rotavirus is highly infectious, and spread is mainly via the faecal-oral route. Although good hygiene measures can help prevent spread, the robustness of rotavirus and the low infectious dose (10–
100 virus particles), makes these measures relatively ineffective in preventing spread.

**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 under five years of age.

Young infants are also more likely to suffer from dehydration if they become infected with rotavirus than older children or adults.

**Is Wales the only country introducing the rotavirus vaccine?**

The rotavirus vaccination programme is being 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.³

**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 (e.g. norovirus) or bacteria (e.g. 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 by 23 weeks and 6 days of age.⁴ Infants will be offered two doses with an interval of 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 a child is 16 weeks, but must be completed by 23 weeks and 6 days of age.

**When will infants receive the vaccine?**

- Children born on or after 6th May 2013 should be offered Rotarix® vaccine at same time as their primary
immunisations at 2 months of age (8 weeks) from July 1st 2013.

- Two doses of the rotavirus vaccine, should be given, one at the 2 month appointment (8 weeks) and one at the 3 month appointment (12 weeks). Both doses should be given by 23 weeks and 6 days.

- The minimum age for vaccination with Rotarix® is 6 weeks and 0 days.

- The first dose of Rotarix® must be given by 14 weeks and 6 days.

- The minimum interval between the first and second doses of Rotarix® is 4 weeks.

- The second dose of Rotarix® must be given by 23 weeks and 6 days.

- Infants who present for their first vaccination at 15 weeks and 0 days of age or later 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 vaccines before 8 weeks of age. Rotarix® is licensed from 6 weeks of age.

**What if the infant does not receive the first dose at the scheduled visit aged 8 weeks?**

If the infant presents under 15 weeks of age (i.e. by 14 weeks and 6 days) then they should be offered their first dose.

Infants who present for their first dose at 15 weeks 0 days of age or later **should not** be offered Rotarix®.

For practical purposes, Rotarix® can be given with other routine vaccines at the scheduled visits at 2 and 3 months (8 and 12 weeks), or at 2 and 4 months (8 and 16 weeks), or at 3 and 4 months (12 and 16 weeks). However a child presenting at the 4 month (16 weeks) visit for a first dose should not be started on 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 up to 23 weeks and 6 days of age the second dose should be given. If the infant is aged 24 weeks 0 days or older the second dose must not be given.

Why can’t the first dose of vaccine be given to children over 14 weeks and 6 days or the second dose over 23 weeks and 6 days of age?

This is in line with recommendations from the World Health Organisation (WHO) because of insufficient data on safety of a first dose of rotavirus vaccine in older infants.

As they get older, some infants (about 120 per 100,000 aged under one year) develop a bowel condition called intussusception where the part of the intestine prolapses, or telescopes, into another part causing an obstruction. The background risk of intussusception increases to peak at around 5 months of age. Research from some countries suggests that Rotarix® 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. The benefits of vaccination in preventing the consequences of rotavirus infection outweigh this small potential risk in young children. Because of this potential risk, and to reduce the likelihood of a temporal association with rotavirus vaccine, the first dose of vaccine should not be given after 14 weeks 6 days of age.

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.

It is an oral vaccine which must not be injected.

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 dedicated vaccine refrigerator between +2°C and +8°C.
The vaccine should be stored in the original packaging. This makes it easy to identify and will protect it from light.

**How is the vaccine presented?**

- The vaccine is presented as a prefilled oral applicator containing 1.5ml of a sucrose-based 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, the vaccine should be discarded.

**How is the vaccine given?**

- Oral Rotarix® vaccine should be given at the beginning of the visit, before administration of any intramuscular vaccines.
- The infant should be held in a reclining position, but not lying flat.
- The protective tip from the oral applicator should be removed.
- The entire content of the oral applicator should be administered into the child’s mouth, towards the inner cheek.
- The vaccine must **not** be injected.

Images courtesy of GSK⁵

**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?

Yes, Rotarix® can be given at the same time as the other vaccines administered as part of the routine childhood immunisation programme. It should ideally be given at the scheduled 2 month and 3 month immunisation visits⁴.

Rotarix® can also be given at the same time as BCG vaccine, and at any interval before or after.

As Rotarix® is a live vaccine, can the vaccine virus be passed on to others?

There is potential for transmission of the live attenuated virus in Rotarix® from the infant to close contacts through faecal material for at least 14 days.⁴,⁶ However, vaccination of the infant will offer protection to household contacts from wild-type rotavirus disease and outweigh any potential risk from transmission of vaccine-type virus to any immunocompromised close contacts. Those in close contact with recently vaccinated infants should observe good personal hygiene, including washing their hands after changing a child’s nappy.

Are there any infants who can’t be given Rotarix®?

There are very few infants who should not receive Rotarix®. Where there is any doubt, appropriate advice should be sought on the circumstance under which the vaccine could be given from appropriate healthcare practitioners e.g. Paediatrician, Immunisation Coordinator or Consultant in Health Protection.

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 older than 23 weeks and 6 days of age,
- infants presenting for the first dose of vaccine older than 14 weeks and 6 days 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-isomaltose 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 (SCID) disorder. There is a lack of safety and efficacy data on the administration of rotavirus vaccine to infants with other immunosuppressive disorders. However, given the high risk of exposure to wild-type rotavirus infection the benefits of administration is likely to outweigh any theoretical risks and therefore should be actively considered, if necessary in collaboration with the clinician dealing with child’s underlying condition. Where there is doubt, appropriate advice should be sought from the specialist providing care to the child rather than withholding the vaccine.

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?**

Yes. 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 prematurely.
Rotarix® may be given to babies born at 27 weeks of gestation or later according to the same vaccination schedule as babies born at full term.

Very premature infants (born at 28 weeks of gestation or earlier) 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 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.

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

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

Does Rotarix® contain thiomersal?

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

What are the potential side effects of the 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 Summary of Product Characteristics.\(^5\)

Parents or guardians are advised to seek medical advice if there is any severe adverse event.

**Anaphylaxis**

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

**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 and the NHS leaflet 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.\(^4\)

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 14 weeks and 6 days of age.

Parents/guardians are advised to contact the doctor immediately if the infant develops pain, vomiting and passes what looks like red currant jelly in their nappies.

**What is intussusception?**

Intussusception is a naturally-occurring condition, 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. In between episodes the infant will look very pale, tired and floppy. After around 12 hours the pain becomes more constant and the infant will usually not want to feed and may vomit. Due to vomiting
the infant may become dehydrated. The infant may pass what appears to be red currant jelly in the stool.

Intussusception can be life threatening and requires prompt medical treatment.

The NHS Wales leaflet states ‘In very rare cases (about two in every 100,000 babies vaccinated), the vaccine can affect the baby’s lower gut and they may develop pain, vomiting, and may pass what looks like red jelly in their nappies, usually within seven days of vaccination. If this happens, you should contact your doctor immediately.’

Where can I get more information?

The Chief Medical Officer Rotavirus letter

Immunisation against infectious disease, (The Green Book)

Marketing authorisation holder’s Summary of Product Characteristics
http://www.medicines.org.uk/emc/medicine/17840/SPC/Rotarix


More information on the clinical presentation of gastroenteritis in children is available from
http://www.nhsdirect.wales.nhs.uk/encyclopaedia/g/article/gastroenteritis/
References:


5 Rotarix SPC http://www.medicines.org.uk/emc/medicine/17840/SPC/Rotarix


This Q and A was first developed by NHS Education for Scotland and has been amended for use in Wales by the Vaccine Preventable Disease Programme, Public Health Wales.