



the safest way to protect your baby

This factsheet describes the rotavirus infection and the vaccine that protects against it. It also provides the background to the development and introduction of the vaccination programme.



The disease

What is rotavirus?

Rotavirus infection is the most common cause of gastroenteritis (inflammation of the intestines) in children under five years of age worldwide.

How common is rotavirus infection in children?

Rotavirus is a highly infectious virus. In England and Wales it causes around 130,000 diarrhoea cases resulting in a GP visit a year in under fives and leads to hospital stays for around 13,000 children.

What are the symptoms of rotavirus?

Rotavirus can cause severe diarrhoea, stomach cramps, vomiting, dehydration and mild fever. These symptoms usually last from three to eight days.

How is rotavirus spread?

Rotavirus is highly contagious and is mainly transmitted by the faecal oral route, although respiratory transmission may also occur.

What is the most effective way of preventing rotaveus?

Apart from w. cination, good hygiene is the most is portant way of preventing the spread of rota virus.

How is rotavirus treated?

There is no specific treatment for rotavirus if the child is not dehydrated and has no increased risk of dehydration. Those at risk of dehydration are advised to take an oral rehydration solution.

When should a child with rotavirus be taken to hospital?

Admission to hospital is usually recommended if a child has signs and symptoms of severe dehydration such a

- a decreased level of conscious ess such as appearing drowsy or uniwar of their surroundings
- pale or blotchy skip
- cold hands and feet
- rapid heartbeat (tachycard a)
- rapid breathing (tachyprioea)
- a weak pulse.

What hap ens in hospital?

Thatme that hospital usually involves replacing lost fluids and other nutrients directly into a vein (intravenous fluid therapy). Most children respond well to treatment and are able to leave hospital after a few days.

Antibiotics are not used to treat rotavirus, as antibiotics are not effective against viruses.

Are there any areas of the country that are particular hotspots for rotavirus infection?

No; cases occur across the country.

Is immunity to rotavirus life-long?

Once someone has had a rotavirus infection they usually develop immunity, although it may be short lived and infections with illness can occur.

The vaccine will protect those under one year of age who are most susceptible to serious consequences from infection. The length of immunity to vaccine or infection is not completely known, however, clinical trials have shown two doses of the vaccine to be protective for several years.

The immunisation programme

How can infants be protected against rotavirus?

Vaccination will help provide protection.

Why introduce a vaccination programme?

The Joint Committee on Vaccination and Immunisation (JCVI) – the independent experts that advise the Government on immunisation – advised that vaccinating infants against rotavirus would have a significant impact on reducing gastroenteritis, and that a vaccination programme for infants should be introduced if vaccine can be procured at a cost effective price. The Government has established that the vaccine can be procured at a cost effective price.

What will the impact of the programme be?

We expect to see the number of waiting and diarrhoea cases caused a could see cut by about a half and was could see 70% fewer hospital stars for rotavirus infection in infarts as a result of this vaccination protramme.

When will the programme starks

The programme will start in July 2013.

When should children receive the vaccine?

The two dose course of re avirus vaccine will be offered to it fant alongside other routine immunisations vine they are two and three months of age. Children over 15 wieks of age at the start of the programme will be too old to receive the vaccin.

How will ne vaccine be administered?

The vaccine will be administered orally liquid.

How many children will be eligible for vaccination in a year?

Around 700,000 infants a year in England will be offered the vaccine once it is introduced into the routine childhood immunisation programme.

What is the experience in other countries? Do other countries vaccinate children against rotavirus?

Yes. Many countries around the world use rotavirus vaccine as part of routine immunisation programmes. These countries have seen a reduction in severe hospitalisations as a result of rotavirus infections.

The childhood immunisation programme as at May 2013

The current programme dates and vaccines are as follows:

2, 3 and 4 months

Infants are vaccinated against whooping cough (pertussis), diphtheria, polio, *Haemophilus influenzae* type b (Hib) and tetanus

2 and 4 months

Infants are vaccinated against pneumococcal disease

3 and 4 months

Infants as valctinated agains (mentagococcal grace) Colinease (Men C)

12-13 months

Infants are vaccinated against MMR and receive boosters for pneumococcal disease, men C and Hib

3 years and 4 months

Children receive a pre-school broater against who pping ough, diphtheria, polio an tetaras

3 years and 4 months

Children receive a second vaccination against MMR

12 to 13 years

Girls are vaccinated against cervical cancer

13 to 18 years

Children or young adults receive a further vaccination against diphtheria, tetanus and polio.

The vaccine

What vaccine will be used?

Rotarix®, manufactured by GlaxoSmithKline, will be the vaccine used in the routine childhood immunisation programme.

How will the vaccine be administered?

The vaccine is given orally. Two doses are given to infants at two and three months of age, and it can be given at the same time as other routine childhood vaccines.

How effective is the vaccine?

Rotarix® has been shown to protect against gastroenteritis due to around 90% of the rotavirus strains that are in circulation in the UK.

How long does the protection offered by the vaccine last?

The vaccine offers broad protection against rotavirus currently sixulating as well as emerging strates and sustained high levels of protection for several years.

Is a boos or required?

s this a live vaccine?

Yes it is a live vaccine, and contains live viruses that have been attenuated (weakened) to make them harmless to infants, but provide protection.

Is it safe?

Vaccine safety was thoroughly considered by JCVI before it make its recommendation to vaccinate infanciagainst rotavirus. Rotarix has been used extensively in other countries and has a good safety record

As they get older, some infa one in a thou sand eskage in their lower that cause ussusception). It is extremely the nonths of age and ccur between five months esearch from some and a uncries suggests that Rotarix® may be ass ciated with a very small increased of intussusception within seven days of vaccination, possibly two cases per 100,000 first doses given, and the Rotarix® prescribing information includes this as a possible side effect. To reduce the risk of this happening, the first dose of the vaccine will not be given to babies older than 15 weeks of age.

Wasn't the first rotavirus vaccine (RotaShield) removed from the market because of safety concerns?

The first generation vaccine that was introduced into the US had to be withdrawn because an association was seen between the vaccine and a small risk of developing intussusception. To date, there is no evidence suggesting a causal association between Rotarix® and the development of intussusception.

As a live virus, should close contacts take precautions?

Those in close contact with recently vaccinated infants should observe good personal hygiene.

There is a potential for transmission of live attenuated vaccine in Rotarix® from the infant to severely immunocompromised contacts through faecal material for at least 14 days (Anderson, 2008). 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.

What side effects may be seen from vaccination?

The most common side effects are diarrhoea and irritability. A full list of possible side effects is available in the Patient Information Leaflet (PIL) that provided with the vaccine.

As with all vaccines, there is a very care (approx one in a million) cossibility of this vaccine causing a severe all rgic reaction called anaphylaxis. (If health professionals responsible for immunisation should be trained to recognise and treat anaphylaxis.

Is the vaccine made in eggs? Does this a fect children with allergies?

This vaccine is not made in eggs and should not adversely affect children with allergies, although those with a history of allergy to the vaccine or constituents of the vaccine should not be vaccinated.

Are there any reasons for the vaccine not to be given?

Vaccination should not be given to infants with:

- hypersensitivity to the active sub tance or to any of the excipients
- hypersensitivity after previous administration of rotavirus vacco
- history of intussus tept on a form of bowel blockage)
- subjects with unconjected congenital malformation of the gastrointestinal tractal at would predispose for intuitive attion
- in severe combined impunodeficiency (SCID) disorder.

Administration of Rotarix® should be postponed in subjects suffering from cute severe febrile illness. The presence of a minor infection is not a contraindication for immunisation.

Administration of Rotarix® should be postponed in subjects suffering from diarrhoea or vomiting.

Does the vaccine contain thiomersal?

No.



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