Public Health England

Protecting and improving the nation's health

The rotavirus vaccination programme

Information for healthcare practitioners

Contents

Change history

Version number	Change details	Date
01.00	• new information document	2018
02.00	• reformatted to current template • added hyperlinks • updated epidemiological information in background section	19 March 2021
03.00	• section on Severe Combined Immune Deficiency (SCID) added • updated content on use of reflux medication and rotavirus vaccine formulated for the UK market • minor rewording, layout and formatting changes	16 September 2021

Background

In 2009, the Joint Committee on Vaccination and Immunisation (JCVI) considered the evidence on the burden of rotavirus infection and the cost effectiveness of immunisation to protect against rotavirus. This advice was reiterated in 2011 following consideration of a further cost effectiveness study and in November 2012, a vaccine was procured at a cost effective price.

On 1 July 2013, Rotarix vaccine was introduced into the childhood immunisation schedule to protect infants against the most common strains of rotavirus and rapidly achieved a very high vaccine uptake of 93% for the 2 dose schedule by 25 weeks of age.

Rotavirus is a common cause of gastroenteritis among children under 5 years of age and, before the introduction of the immunisation programme, around 12,700 children were admitted to hospital and an estimated 130,000 children visited their GP with rotavirus gastroenteritis each year in England and Wales.

Each season, since the introduction of the vaccination programme, the total number of laboratory-confirmed cases of rotavirus has remained low. In April 2020, Public Health England (PHE) reported 953 laboratory-confirmed cases of rotavirus in England and Wales during weeks 27, 2019 to week 13, 2020. This is 49% lower than the 5-season average (post-vaccine) for the same period in the seasons 2014 to 2015 to 2018 to 2019 (1,872).

Rotavirus

The rotavirus chapter of the green book includes detailed information on rotavirus disease, the history and epidemiology of the disease and the vaccination programme.

Rotavirus is highly infectious and causes gastroenteritis, it is the most common cause of gastroenteritis among young children and infections are often recurrent. Most children will experience 1 or more rotavirus infections by 5 years of age.

Rotavirus infection spreads mainly via the faecal-oral route and causes gastroenteritis which usually lasts from 3 to 8 days and can cause dehydration. This can be very serious, especially in young infants, who may require hospitalisation for intravenous rehydration.

Incidence of rotavirus by age

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 5 years of age.

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

The rotavirus vaccination programme

The rotavirus vaccination programme has been 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 the US. In the US, a review of the first 3 years of post licensure data has shown that rotavirus related hospital admissions for young children have been cut by more than two-thirds since rotavirus vaccination was introduced.

In England and Wales, it is estimated that 10,884 laboratory-confirmed infections and 50,427 all-cause acute gastroenteritis (AGE) associated hospital admissions were averted in 2013 to 2014 following the introduction of the infant immunisation programme. Atchison and others described a 77% decline in laboratory-confirmed rotavirus infections and a 26% decline in all-cause AGE-associated hospitalizations in infants in 2013 to 2014, compared with the prevaccination era, with large reductions also being observed in older children, adults, and older adults. A graph showing the impact of rotavirus vaccination since its introduction is available as part of the weekly laboratory report for rotavirus in England and Wales on the PHE norovirus and rotavirus surveillance webpage.

Rotavirus vaccine protects against the most common strains of rotavirus. It doesn't protect against other causes of gastroenteritis such as norovirus or bacteria such as salmonella. However, as rotavirus is the most common cause of gastroenteritis in young infants, it has a significant impact on the total number of young children who become ill with gastroenteritis and the number of infants with severe disease. Although some vaccinated infants may still get rotavirus infection, the disease is usually milder.

Rotavirus vaccination schedule

All children should be offered vaccine to protect against rotavirus with their primary vaccines scheduled at 8 weeks and 12 weeks of age. Children should receive 2 doses of

Rotarix vaccine, which is the vaccine offered as part of the UK national childhood vaccination programme, with an interval of at least 4 weeks between doses.
Infants who have received their first dose of vaccine before 15 weeks of age (14 weeks and 6 days) can receive their second dose of Rotarix vaccine as long as it is given before 24 weeks of age (23 weeks and 6 days).

It is preferable that the full course of 2 doses of Rotarix be completed before 16 weeks of age, but it must be completed by 24 weeks of age.

Infants who have not received their first dose before 15 weeks of age (14 weeks and 6 days) should not be offered Rotarix vaccine but should still receive their other routine primary immunisations.

Infants may receive their first dose of primary immunisations from 6 weeks of age in exceptional circumstances (such as pre-travel) but it is not routinely recommended before 8 weeks of age. Rotarix vaccine is licensed from 6 weeks of age.

Administration of the first dose to infants less than 8 weeks of age

If the first dose is administered when the infant is aged between 6 and 8 weeks of age as a planned dose (for example if the family plans to travel before the infant is 8 weeks old), then this dose does not need to be repeated. The infant can have the second dose at the recommended age of 12 weeks.

If the first dose is given before 6 weeks of age, this dose should be discounted. The infant should continue to receive the recommended 2 dose schedule at 8 and 12 weeks in accordance with the routine rotavirus immunisation schedule and irrespective of the interval between the dose administered early and the first routine dose.

Administering the first dose to infants older than 8 weeks of age

If the infant presents before they are 15 weeks of age (up to 14 weeks and 6 days) then they should be offered their first dose. The second dose should be given at least 4 weeks later and must be given before the infant reaches 24 weeks of age.

Vaccination is initiated before 15 weeks of age when background intussusception rates are reportedly low to prevent vaccine association with natural incidence of intussusception.

Inadvertent administration of the first dose of Rotarix vaccine to a child aged 15 weeks or older

Children who inadvertently receive the first dose of Rotarix vaccine at age 15 weeks or older should still receive their second dose 4 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, a known adverse event associated with this vaccine.

No specific clinical action needs to be taken if the first dose of vaccine is inadvertently given after 15 weeks of age but, as with all parents of infants receiving rotavirus vaccination, the parents should be made aware of the symptoms of intussusception and advised to seek medical advice if concerned. 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 Rotarix vaccine over 24 weeks of age, no specific clinical action needs to be taken but immunisers should be reminded that Rotarix vaccine should not be given to infants older than 24 weeks, even if they haven’t completed the 2 dose schedule.

Interval between doses

It is recommended that the 2 doses of Rotarix vaccine are given with a minimum interval of 4 weeks between them. If the immunisation schedule is interrupted (for example, if there is an interval between doses that is longer than the recommended 4 weeks), then the second dose can be given at any time as long as the infant is still less than 24 weeks of age (23 weeks and 6 days) at the time of second vaccination. If the infant is aged 24 weeks or older, the second dose should not be given.

Less than 4 week interval between doses

Rotavirus vaccine is different to other infant vaccines in that it is a live oral vaccine and the second dose is given to provide the infant with a second opportunity to develop an immune response rather than as a booster. An optimal interval of 4 weeks is recommended to allow the infant to respond to the first dose of vaccine before receiving the second dose. However, if a dose is inadvertently given from 3 f weeks after the first, no further doses are required as viral replication is likely to have occurred within this time period.

If the interval between the 2 doses is less than 3 weeks, the infant should receive an additional dose of the rotavirus vaccine. This additional dose should be at least 4 weeks after the first dose of rotavirus vaccine so long as this first dose was administered after 6 weeks of age and as long as the infant is still under 24 weeks of age at the time of the additional dose. The interval between the additional dose and the prematurely administered dose of rotavirus vaccine is not relevant.

Rotavirus vaccine

The European Medicines Agency (EMA) have authorised 2 rotavirus vaccine for use. Rotarix and RotaTeq. The vaccine being used in the UK is called Rotarix. It is a live attenuated vaccine which contains a weakened form of the virus in order to protect against gastroenteritis caused by rotavirus. This is an oral vaccine and must not be injected.

Rotarix vaccine constituents

Rotarix vaccine does not contain thiomersal, any adjuvant or any other preservatives and it does not contain latex. A full list of vaccine excipients can be found in the marketing authorisation holder's Summary of Product Characteristics (SPC). The vaccine contains a small amount of sugar (sucrose) to improve the taste.

Interchangeability of other rotavirus vaccines with Rotarix

Some countries use an alternative vaccine called RotaTeq to protect infants against rotavirus. Rotarix is a 2 dose course whilst RotaTeq is a 3 dose course. Where possible, it is recommended that infants should complete their course with the vaccine that they started with.

A formal evaluation of the interchangeability of the 2 vaccines found that 'mixed schedules are safe and induce comparable immune responses when compared with vaccination with only 1 of the licenced rotavirus vaccines given in the full series.'

However, every effort should be made to enable the infant to complete the course with the vaccine that they started with. If this is not possible and the child is:

- aged under 15 weeks (up to age 14 weeks and 6 days) previous doses of RotaTeq should be discounted and a 2 dose course of Rotarix started
- aged over 15 weeks (beyond 14 weeks and 6 days) and has already received at least 1 dose of RotaTeq, procure further dose(s) of RotaTeq from the vaccine manufacturer as there are no central supplies of this vaccine. If RotaTeq cannot be procured, 2 doses of Rotarix vaccine should be offered with a 4 week interval between doses providing the infant is younger than 24 weeks of age at vaccination for both doses

In the event that the recommended schedule cannot be completed, reassurance should be provided that a partial course of vaccination will provide the infant with some immunity against gastroenteritis and the current high vaccine coverage in the UK should also provide some indirect (herd) protection.

Vaccine storage

In accordance with the manufacturer's instructions for storage, Rotarix vaccine must be stored in the original packaging in a refrigerator between +2ºC and +8ºC and used immediately after opening. It should not be used after the expiry date shown on the box.

Inadvertent storage outside the recommended temperature range

Administering vaccine that has been stored outside of the manufacturer's instructions may require a prescription or Patient Specific Direction (PSD). If Rotarix vaccine has been stored outside the manufacturers recommended temperature range, advice should be taken from the manufacturer and vaccine stock should be assessed for evidence of damage, including potential for reduced potency.

Vaccine presentation

Rotavirus vaccines are for oral administration and must not be injected.

The presentation of Rotarix vaccine changed during 2017 from a pre-filled oral applicator to a single dose in a squeezable prefilled tube with a cap (Figures 1A and 1B).

The tube contains 1.5ml of a clear, colourless liquid for oral administration, it is ready to use and no reconstitution or dilution is required.

Before use, the vaccine should be visually inspected for any foreign particulate matter and/or abnormal physical appearance. If either are observed, the vaccine should be discarded.

Figure 1A: Change to Rotarix vaccine presentation – new presentation

Figure 1B: Change to Rotarix vaccine presentation – old presentation

Vaccine administration

The name and batch number of the vaccine should be clearly recorded in the infant's records.

It is recommended that Rotarix vaccine be given at the beginning of the vaccination visit, before the administration of any intramuscular vaccines which may unsettle the infant and increase the likelihood of vomiting.

The infant should be held in a seated position so that they are leaning slightly backwards and the manufacturer's instructions should be followed (Figure 2).

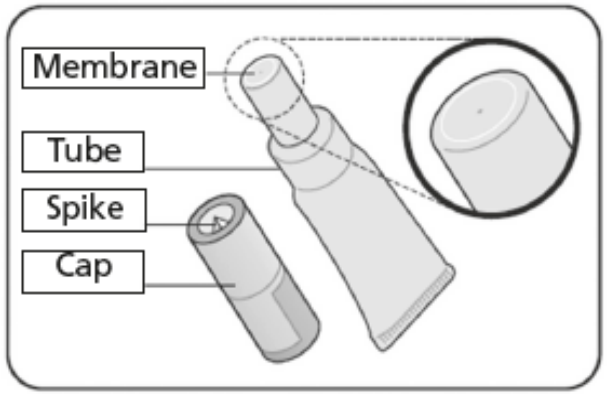
Figure 2: Manufacturer's instructions for the administration of Rotarix vaccine

A What you need to do before giving Rotarix

- Check the expiry date.
- Check the tube has not been damaged nor is already open.
- Check the liquid is clear and colourless, without any particles in it.

If you notice anything abnormal, do not use the vaccine.

- This vaccine is given orally - straight from the tube.
- It is ready to use - you do not need to mix it with anything.



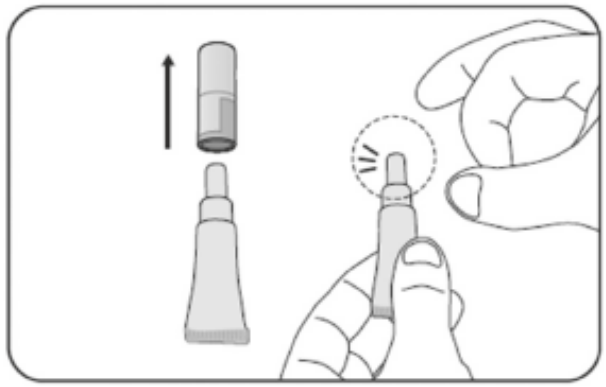
B Get the tube ready

1. Pull off the cap

- Keep the cap – you need this to pierce the membrane.
- Hold the tube upright.

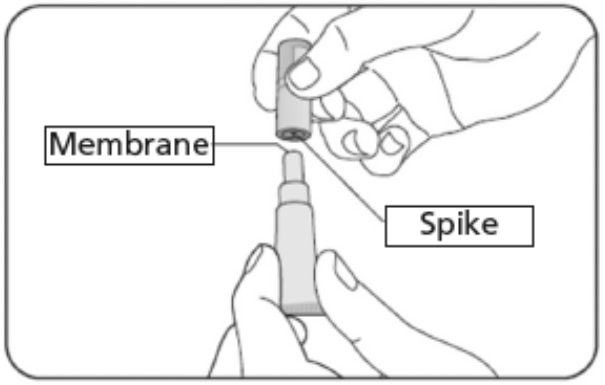
2. Repeatedly flick the top of the tube until it is clear of any liquid

- Clear any liquid from the thinnest section of the tube by flicking just below the membrane.



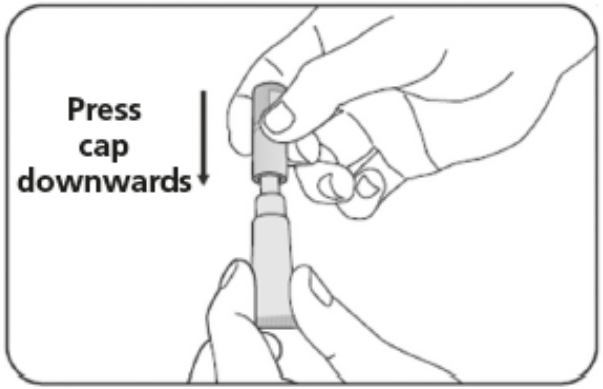
3. Position the cap to open the tube

- Keep the tube held upright.
- Hold the side of tube
- There is a small spike inside the top of the cap - in the centre.
- Turn the cap upside down (180°).



4. To open the tube

- You do not need to twist. Press the cap down to pierce the membrane.
- Then lift off the cap.



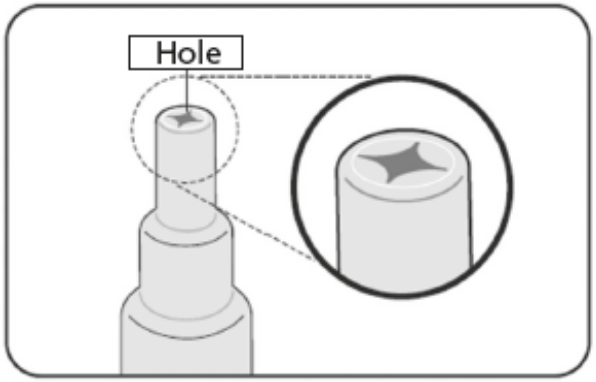
C Check the tube has opened correctly

1. Check the membrane has been pierced

- There should be a hole at the top of the tube.

2. What to do if the membrane has not been pierced

- If the membrane has not been pierced return to section B and repeat steps 2, 3 and 4.



D Give the vaccine

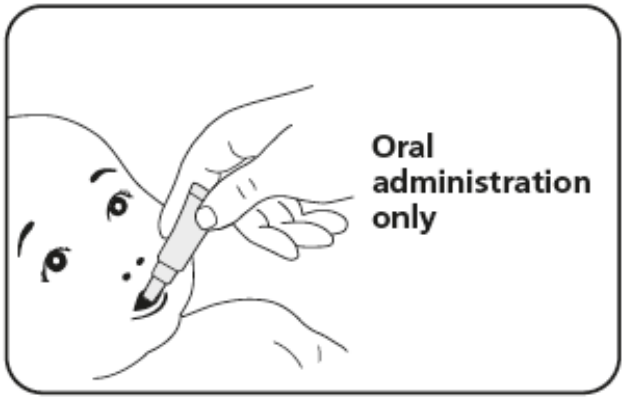
- Once the tube is open check the liquid is clear, without any particles in it.
  If you notice anything abnormal, do not use the vaccine.
- Give the vaccine straight away.

1. Position the child to give the vaccine

- Seat the child leaning slightly backwards.

2. Administer the vaccine

- Squeeze the liquid gently into the side of the child's mouth - towards the inside of their cheek.
- You may need to squeeze the tube a few times to get all of the vaccine out - it is okay if a drop remains in the tip of the tube.



Administering an incomplete dose of vaccine

If the infant spits out or regurgitates most of the vaccine, a single replacement dose may be given at the same visit. If the infant has already left the surgery when this occurs, there is no need for them to return to the surgery for a repeat dose.

Infant feeding pre and post administration of Rotarix vaccine

There are no restrictions on the infant's feeding, including breastfeeding, before or after immunisation.

Administering rotavirus vaccine via a feeding tube

Consideration should be given as to why the infant has a feeding tube. Rotarix is contraindicated if the infant has an uncorrected gastrointestinal malformation that predisposes to intussusception. However, as the vaccine contains a very small volume of fluid, infants with feeding tubes should preferably be given the vaccine orally unless there is a specific defined clinical contraindication, such as an absent gag reflex. In such cases, the vaccine may be administered via the feeding tube.

Administering Rotarix vaccine at the same time as other vaccines

Rotarix vaccine can be given at the same time as the other vaccines administered as part of the routine childhood immunisation programme but should ideally be given at the scheduled 8 week and 12 week vaccination visits. Chapter 11 of the green book includes recommendations for time intervals when giving more than 1 live vaccine.

Administering Rotarix vaccine at the same time as liquid paracetamol

If liquid paracetamol is required on the same day that Rotarix vaccine is due to be administered, for example if MenB vaccine is scheduled to be given at the same appointment, the vaccine and the liquid paracetamol should be administered with short interval between them. Further information on paracetamol use when administering MenB vaccine can be found in the PHE Paracetamol Protocol.

The live vaccine virus is unlikely to be affected by close sequential administration of a small volume of paracetamol syrup. However, leaving a short interval between the vaccine and the paracetamol syrup may reduce the chance of the rotavirus vaccine being vomited back up.

Transmission of vaccine virus

Anderson reported that there is a potential for transmission of the live attenuated virus in Rotarix vaccine from the infant to severely immunocompromised contacts through faecal material for at least 14 days. 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 which should include handwashing after changing the infant's nappy.

Further information on the shedding of viral antigen by rotavirus vaccinees can be found in chapter 6 of the green book.

Vaccine contraindications and precautions

Rotarix vaccine contraindications

There are very few infants who cannot receive Rotarix vaccine. Where there is any doubt, appropriate advice should be sought from appropriate registered healthcare practitioners such as the child's paediatrician, a local screening and immunisation team or a Consultant in Public Health.

Rotarix vaccine should not be given to:

- infants presenting for the first dose of vaccine at 15 weeks of age or older (beyond 14 weeks and 6 days)
- infants aged 24 weeks of age or over (beyond 23 weeks and 6 days)
- babies born to mothers that used medical biologicals during their pregnancy (see below)
- infants with Severe Combined Immunodeficiency (SCID) disorder
- infants with a confirmed anaphylactic reaction to a previous dose of the vaccine
- infants with a confirmed anaphylactic reaction to any components of the vaccine
- infants with a previous history of intussusception
- infants who have a malformation of the gastrointestinal tract that could predispose them to intussusception (there are extremely few conditions that might predispose to intussusception, please see page 22).
- infants with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrose-isomaltose insufficiency

Infants born to mothers that used medical biologicals during their pregnancy

Rotavirus vaccine should not be given to infants of mothers that used immunosuppressive biological therapy during their pregnancy because of the potential that these will have a postnatal influence on the infant's immune status.

It is recommended that immunisation with live vaccines should be delayed for 6 months in children born to mothers who were on immunosuppressive biological therapy (TNFα antagonists and other biological medicines such as Infliximab) during pregnancy. As Rotarix vaccine is contraindicated in infants presenting for the first dose after 15 weeks of age (beyond 14 weeks and 6 days), infants whose mothers received such treatment during pregnancy will not be eligible to receive Rotarix vaccine but they should benefit from herd (indirect) protection.

Infants born to mothers who received non biological immunosuppressive therapy such as steroids, cyclosporine, tacrolimus or azathioprine at any time during their pregnancy can safely have the rotavirus vaccine at the appropriate age.

The rotavirus chapter of the green book (27b) contains further information on the vaccination of infants born to mothers on biologicals during their pregnancy but if there is any doubt as to whether an infant due to receive rotavirus vaccine (or any other live attenuated vaccine) may be immunosuppressed due to the mother's therapy, including exposure through breast-feeding, specialist advice should be sought.

Administering rotavirus vaccine to breastfed infants whose mothers are receiving immunosuppressive therapy

A 2017 review of the literature concluded that it is safe for mothers to breastfeed while on immune suppression that includes steroids, cyclosporine, tacrolimus or azathioprine.

Breastfed infants of mothers taking immunosuppressive therapy can receive rotavirus vaccine at the appropriate age. Rotarix vaccine should not be administered to breastfeeding infants whose mothers are using biological medicines such as Infliximab. Further advice should be taken if there is any doubt as to whether it is safe for a breast fed infant who may be immunosuppressed due to the treatment their mother is taking, to receive a rotavirus vaccine.

Immunocompromised infants

Rotarix vaccine should not be administered to infants known to have severe combined immunodeficiency disorder (SCID) or to infants whose mothers have used biological medicines, such as Infliximab, during pregnancy and/or breastfeeding.

Even though the vaccine is a live attenuated virus, given the high risk of exposure to natural rotavirus and severe disease, the benefit of administration in those with other forms of immunosuppression is likely to outweigh any theoretical risks and therefore should be strongly considered, in collaboration with the clinician dealing with the child's underlying condition.

From clinical trials with HIV infected infants, the safety profile was similar between Rotarix vaccine 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 (HIV-exposed infants).

Severe Combined ImmunoDeficiency (SCID) and rotavirus vaccine

It is important that infants receive rotavirus vaccine in early life to protect against gastrointestinal illness. However, rotavirus vaccine is a live vaccine and SCID is the major contraindication to rotavirus vaccination.

In the USA, Bakari and others reviewed reports made to the Vaccine Adverse Events Reporting System (VAERS) for all available reports of rotavirus vaccination and SCID and identified 9 reports of rotavirus associated with gastroenteritis in infants that were subsequently diagnosed with SCID. They went on to describe reports of severe gastroenteritis and prolonged viral shedding in immunocompromised infants involving the rotavirus vaccine strain even though the rotavirus vaccine strains are attenuated.

More recently, Ladhani and others conducted a prospective national surveillance study and also reported prolonged excretion of vaccine derived virus with detection of Rotarix vaccine derived G1P[8] strains in infants older than 5 months being associated with an underlying SCID diagnosis. They concluded that those infants with the vaccine derived G1P[8] rotavirus strain that were identified more than 7 weeks after being given rotavirus vaccine were often found to have underlying SCID.

Evaluation of the introduction of newborn screening for Severe Combined Immunodeficiency (SCID)

From 1 September 2021, SCID screening will form part of the routine newborn screening test at 5 days for infants born in areas participating in the SCID evaluation. All babies born from 1 September 2021 who attend for their routine 8 week immunisations from 27 October 2021, should have their records checked for their SCID screening results before rotavirus vaccine is administered. It is necessary to adopt this guidance nationally to ensure consistency and safety for all babies across the country.

SCID screening results will be available to GPs and parents for all babies should have a result available by 42 days of age, if not before. Babies in non-screening areas will be

assigned a ‘SCID screening not offered’ result. Parents and GP practices will receive a direct communication from the immunology team to alert them that a child has a suspected or confirmed SCID diagnosis and this will include information on which vaccines should not be given.

Immunisers should make reasonable efforts to ascertain the SCID screening outcome before administering rotavirus vaccine. This would involve checking for a record in the Red Book, the GP record, screening outcome information sent by CHIS, or with the parent or caregiver. In the absence of an abnormal SCID screening result, or if no result can be found, rotavirus vaccination can go ahead. PHE have developed an algorithm to assist immunisers with this check (see the PHE rotavirus collection). It is advised that practices include this algorithm in their local protocols.

In areas where SCID screening will not be offered routinely, immunisers need to be aware that there may be movers-in who have been tested and have a result available from another area it is important to use all opportunities to remind parents and caregivers to bring the Red Book and the letter with the outcome of newborn bloodspot screening when they are invited for their routine 8 week immunisation appointment. This could include an explicit mention in the invitation letter (CHIS or GP) and text message reminders.

- if the SCID screening result is reported as SCID not suspected, rotavirus vaccine can be administered
- if a SCID screening was not offered or a result is not available, rotavirus vaccine can be administered
- infants for whom SCID screening was declined can be vaccinated with rotavirus vaccine
- if the SCID screening result is reported as SCID suspected, the baby will be referred to an immunology team. Following further assessment parents and GP practices will receive a direct communication from the immunology team to inform them whether a child has been confirmed to have a significant immunological disorder and this will include information on which vaccines should not be given

As the first dose of rotavirus vaccine is contraindicated for infants aged 15 weeks and older, it should not be offered to any infant beyond this age. Other vaccines offered at the 8 week appointment should go ahead without delay.

As rotavirus vaccine is a live vaccine, it is important that SCID screening results are included in the infant record as soon as they become available. This will ensure that infants in whom rotavirus vaccine is contraindicated do not inadvertently receive it. It will also ensure that infants screened as SCID not suspected receive rotavirus vaccination as per the routine schedule.

SCID suspected infant inadvertently given rotavirus vaccine

All GP practices should update their immunisation protocols to ensure SCID screening results are available to immunisers before the routine 8 week appointment.

If an infant with a SCID suspected result is inadvertently given rotavirus vaccine their management should be discussed with the local specialist immunology team to whom they are referrred. In addition, this event should be regarded and managed as a serious untoward incident (SUI) and action should be taken to ensure that all immunisers are aware of the SCID screening evaluation and the Rotarix vaccination recommendations and contraindications for infants screened as part of this evaluation.

Infants with prolonged GI symptoms after receiving rotavirus vaccine

Assessment of infants with prolonged GI symptoms after receiving Rotarix vaccine, particularly more than 7 weeks after vaccination and accompanied by failure to thrive, should include the possibility of an underlying immune deficiency including SCID.

Postponing administration of rotavirus vaccine

Immunisers are reminded that a first dose of rotavirus vaccine should not be administered once an infant reaches 15 weeks of age.

Every effort should be made to identify whether an infant has a SCID screening outcome result. This should include checking the red book, checking the GP records and confirming with the parents whether they have seen an immunologist and have an outcome letter. Where there is an absence of a SCID screening result rotavirus vaccine can be administered and does not need to be deferred.

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
- awaiting being seen by an immunologist and receiving advice about vaccination

There are very few infants who cannot receive rotavirus vaccine. Where there is doubt, appropriate advice should be sought from the child’s paediatrician, a screening and immunisation team or Consultant in Public Health rather than withholding vaccination.

Diarrhoea after Rotarix vaccination

Parents should be informed that diarrhoea can occur after vaccination with Rotarix vaccine

If an infant develops chronic or persistent diarrhoea and/or diarrhoea with blood and/or mucous after Rotarix vaccination, the infant should have a thorough clinical assessment including plotting of length, weight and dietary history. Very rarely, chronic, persistent and severe diarrhoea after Rotarix vaccine can be due to a severe underlying immune deficiency and should be considered in the assessment. Stool samples should be taken for microbiology and culture as well as testing for viruses. Although it cannot be assumed that the diarrhoea is related to the vaccine, if rotavirus is identified in the stool, the sample should be sent to the Virus Reference Department at PHE Colindale to determine whether or not it is a vaccine strain.

Vaccination of premature infants

It is important that premature infants have their immunisations at the appropriate chronological age if clinically stable. As the benefit of vaccination is high in this group of infants, rotavirus vaccination should not be withheld or delayed. Please see chapter 27b of the green book for further information on the vaccination of premature infants with other vaccines that may be administered at the same time as Rotarix vaccine.

Premature babies born in the evaluation areas are likely to be screened for SCID in the hospital setting. Premature babies with intermediate results (this result only applies to premature babies), that is, neither SCID suspected, nor SCID not suspected, will require a repeat sample at 37 weeks corrected gestation or discharge, whichever is earlier. Rotavirus vaccine should not be given until the result of the repeat test is available.

Vaccination of hospitalised infants

Hospitalised pre-term infants are particularly vulnerable to rotavirus infection and its complications and should be vaccinated as soon as they become eligible. Delaying vaccination until discharge from the neonatal unit may result in premature infants being too old to receive their first dose of vaccine which should be given before they reach 15 weeks of age (up to age 14 weeks and 6 days).

Rotarix vaccine contains a highly attenuated vaccine virus with a very low risk of clinical disease even in vulnerable infants such as those born prematurely. 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 to others.

JCVI considered that the benefits of vaccination for premature infants in neonatal units at their chronological age far outweighed any potential risk of transmission of this highly attenuated vaccine virus to other infants in the neonatal unit.

Vaccination of an infant that has previously had rotavirus infection

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

If the child is suffering from acute diarrhoea and/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

Potential side effects of Rotarix vaccine

The most common adverse events observed following the administration of Rotarix vaccine are diarrhoea and irritability.

Other reactions commonly reported include:

- abdominal pain
- flatulence
- skin inflammation
- regurgitation of food
- fever
- loss of appetite

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

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

Risk of 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.

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 3 months of age to peak at around 5 months of age. The background annual incidence is around 120 cases per 100,000 children aged under 1 year.

Research from some countries suggests that rotavirus vaccine may be associated with a very small increased risk of intussusception within 7 days of vaccination (up to 6 cases of intussusception per 100,000 first doses of vaccine).

The main symptom of intussusception is severe abdominal pain that comes and goes. Each episode tends to last 2 to 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, leading to dehydration.

Intussusception can be life threatening and requires prompt medical treatment.

Because of the potential risk of intussusception, 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.

Risk of intussusception following administration of Rotarix vaccine

Prescribing information includes intussusception as a possible side effect. Poelaert and others (2018) reported that in England, the rotavirus vaccination programme results in around 21 intussusception cases annually but Atchison and others (2016) found that it prevents around 50,000 hospitalisations for gastroenteritis, so its benefit or risk profile remains strongly positive.

Parents or guardians should be advised to contact their doctor immediately if their infant develops symptoms of intussusception as described previously or develops severe vomiting or abdominal pain and passes what looks like redcurrent jelly in their stools.

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 of age, it will be more difficult to ascertain, if the child develops intussusception, whether this was due to the vaccine or was naturally occurring.

Infants with pyloric stenosis, necrotising enterocolitis, hirschprungs disease or recent abdominal surgery (for example hemicholectomy, hernia repair or gastroschisis repair)

These are not contraindications for rotavirus vaccine. Infants for whom the vaccine is contraindicated include primarily those with a previous history of intussusception or those who have a malformation of the gastrointestinal tract that could predispose them to intussusception. Parents should be given information about intussusception at the time of vaccination and told to seek immediate help if their child becomes unwell during the first 3 weeks after receiving the rotavirus vaccine. Uncorrected or corrected hernias are not a contraindication to rotavirus immunisation. Other contraindications are listed earlier in this document.

Swimming following vaccination

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

Administering the vaccine to infants who have recently received an antibody containing blood product (for example a blood transfusion or HBIG)

The Advisory Committee on Immunization Practices (ACIP) advise that:

> “Rotavirus vaccine may be administered at any time before, concurrent with, or after administration of any blood product, including antibody-containing products, following the routinely recommended schedule for rotavirus vaccine (previous recommendation: defer vaccination for 42 days after receipt of an antibody-containing product, if possible).”

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 2 doses of rotarix vaccine, they have 2 opportunities to make a protective immune response to the vaccine.

Rotavirus vaccine and infants who are receiving anti-reflux medications, including antacids

The manufacturers SmPC for Rotarix vaccine advises that there are no restrictions on the infant's consumption of food or liquid, either before or after vaccination, and it does not report any interaction between reflux medicines and Rotarix vaccine. Infants taking these medications should receive the vaccine as scheduled.

Further information

All resources relating to the rotavirus vaccination programme can be accessed on the Rotavirus vaccination programme for infants page on GOV. These include:

- rotavirus training slide set
- protecting your baby against rotavirus – flyer
- protecting your baby against rotavirus – leaflet
- algorithm with process for checking SCID screening results

Marketing authorisation holder's Summary of Product Characteristics.

Medicines and Healthcare products Regulatory Agency (MHRA) – for reporting adverse reactions.

Immunisation against infectious disease, rotavirus Green Book chapter.

PHE Patient Group Direction (PGD) for Rotarix vaccine.

Guide to immunisation for babies up to 13 months of age.

Information on diarrhoea and vomiting on NHS.UK.

Oxford Vaccine Knowledge Project.

Information on laboratory-confirmed cases of rotavirus infection.

Public information materials produced by the British Society for Immunology.

Acknowledgment

This document was originally developed from work completed by NHS Education for Scotland as a national training resource to support the introduction of rotavirus vaccine into the infant vaccination schedule. Their permission to adapt it for use in England is gratefully acknowledged.

About Public Health England

Public Health England exists to protect and improve the nation's health and wellbeing, and reduce health inequalities. We do this through world-leading science, research, knowledge and intelligence, advocacy, partnerships and the delivery of specialist public health services. We are an executive agency of the Department of Health and Social Care, and a distinct delivery organisation with operational autonomy. We provide government, local government, the NHS, Parliament, industry and the public with evidence-based professional, scientific and delivery expertise and support.

Public Health England
Wellington House
133-155 Waterloo Road
London SE1 8UG
Tel: 020 7654 8000

www.gov.uk/phe
Twitter: @PHE_uk
www.facebook.com/PublicHealthEngland

Prepared by: [Immunisation and Countermeasures Division, PHE]
For queries relating to this document, please contact: [immunisation@phe.gov.uk]

Published September 2021
PHE gateway number: GOV-9819

PHE supports the UN Sustainable Development Goals