Changes to the National Immunisation Schedule: rotavirus vaccine now added

Contributed by: The Ministry of Health

Changes to the National Immunisation Schedule will soon take effect, with the introduction of rotavirus vaccine, free of charge, from 1 July, 2014. In addition, the Prevenar 13 pneumococcal vaccine, which protects against 13 serotypes of pneumococcal disease, replaces Synflorix, which protects against 10 serotypes. Dr Bryn Jones, Chief Advisor at the Ministry of Heath, expects that the schedule change will have a significant impact on the health of young children: “Thousands of children and their families are affected by rotavirus every year. For most, it’s a few days of unpleasantness, but it can lead to dehydration and hospitalisation. We expect that rotavirus vaccine will save hundreds of children every year from a trip to hospital.”

Infants born from 19 March, 2014 onwards will be aged under 15 weeks when the vaccine is introduced on 1 July, 2014. The eldest infants in this group will have only a brief window in which to have the first dose before they are 15 weeks old. Infants born on or after 20 May, 2014 will be able to have the vaccine as part of their six week immunisations.

An infant who has not been immunised with RotaTeq by age 15 weeks is no longer eligible to be vaccinated against rotavirus.

What is rotavirus?

Rotavirus is a leading cause of gastroenteritis in young children. It can cause rapid onset vomiting and diarrhoea, fever and abdominal pain and can lead to severe dehydration and hospitalisation. Vomiting can typically last for up to three days and diarrhoea up to eight days. Approximately one in every 43 children are hospitalised due to rotavirus before age five years.

Rotavirus is spread through contact with the faeces of an infected child or adult and from surfaces contaminated with the virus, e.g. toys. Careful hygiene for affected children and their carers is recommended to reduce the spread of rotavirus infection.

Adults can be infected with rotavirus, but the symptoms are usually very mild. There is no specific antiviral that can treat rotavirus infection.

From 1 July 2014, infants aged younger than 15 weeks will be eligible for the free rotavirus vaccination, RotaTeq.

The vaccine is given orally at ages six weeks, three months and five months. The first dose of the subsidised RotaTeq vaccine must be given before age 15 weeks (i.e. 14 weeks and six days old at the latest) and the immunisation course must be completed by age eight months (i.e. eight months and 0 days old).
Who is most at risk from rotavirus?
- Infants and children aged under two years
- Infants with a low birth weight who are still under weight
- Infants and children with high-risk medical conditions, e.g. cardiac or renal conditions or diabetes.

What is the RotaTeq vaccine?
RotaTeq (RV5) is a live attenuated, oral pentavalent vaccine which protects against rotavirus gastroenteritis in infants and children caused by five rotavirus serotypes. The vaccine will not prevent diarrhoea and vomiting from other causes of gastroenteritis infections. RotaTeq was first included in the United States’ public immunisation schedule in 2006, and is also on the national immunisation schedules of Australia and a number of other countries. As at December 2013, more than 100 million doses of rotavirus vaccine have been given worldwide.

RotaTeq is available as a single, pre-filled 2.0 mL unit dose in a plastic dosing tube, which is contained in a pouch. The dose of RotaTeq is 2.0 mL, administered orally (see the package insert for administration instructions). Each dose is supplied in a container consisting of a squeezable plastic, latex-free dosing tube with a twist-off cap, allowing for direct oral administration.

The first dose of the funded RotaTeq vaccine must be given before age 15 weeks and the immunisation course must be completed before the infant is aged eight months. Three doses of RotaTeq are required to complete an immunisation course, given at ages six weeks, three and five months. A minimum dose interval of four weeks is needed between each RotaTeq vaccine dose.

Efficacy and safety, including the risk of intussusception (Page 27), has not been studied in infants who received a vaccine dose after age eight months.

RotaTeq does not contain the mercury derivative thiomersal or aluminium.

How effective is RotaTeq?
RotaTeq prevents rotavirus gastroenteritis for most children, and protects almost all infants and children from severe disease. Since the introduction of rotavirus vaccination in Australia, the number of children aged under five years hospitalised because of rotavirus gastroenteritis has dropped by 70%. A similar response could be expected in New Zealand.

How long does the vaccine protect for?
Studies indicate the vaccine protects for up to three years following the final dose. Young children are therefore protected against rotavirus while they are most vulnerable to dehydration.

Is RotaTeq suitable for all infants?
RotaTeq vaccine is suitable for most infants, however, the following contraindications and precautions should be noted.

Contraindications
RotaTeq should not be given to infants:
- Who have had a severe allergic reaction to a dose of RotaTeq or to any of the vaccine components
- With “severe combined immunodeficiency”
- Who have previously had intussusception

Precautions
There are some infants for whom special consideration is required prior to a decision to give them a rotavirus vaccine. These include infants:
- With acute moderate or severe gastroenteritis – they should be vaccinated when the condition improves
- Who may be immune compromised, or have HIV or who are taking medicines which can affect the immune system, such as steroids (vaccinators should seek advice before administering RotaTeq to these infants)
- With any acute infection or febrile illness – this may be reason to delay immunisation with RotaTeq (Note: rotavirus vaccines can be administered to infants with a mild illness, including gastroenteritis and upper respiratory tract infections).

N.B: This is not an exhaustive list. Please refer to the Immunisation Handbook 2014 and the Warnings and Precautions section of the RotaTeq data sheet before administering RotaTeq.
What if an infant has already had rotavirus?
Infants who have already had rotavirus gastroenteritis should still receive the full course of RotaTeq vaccine. Initial rotavirus infection only provides partial protection against subsequent infection.

What if the infant is still in a neonatal or Special Care Baby Unit?
It is best to vaccinate preterm infants aged over six weeks as they leave hospital. However, if discharge is not anticipated before age 15 weeks, giving rotavirus vaccine in hospital is acceptable. If the standard universal precautions are maintained, administration of rotavirus vaccine to hospitalised infants, including hospitalised preterm infants, would be expected to carry a low risk for transmission of vaccine viruses.

Why are there strict age limits for administering the rotavirus vaccines?
The age limits for initiating (before age 15 weeks) and completing (by age eight months) the vaccine course are recommended because there is insufficient safety data on the use of these vaccines outside this age range.

Why is the age limit 15 weeks rather than 12 weeks as recommended by the data sheet?
The *Immunisation Handbook 2014* recommendation for the first dose of RotaTeq to be given by age 15 weeks is in line with international recommendations and provides an opportunity to vaccinate infants who are late for their first vaccinations.

The Centers for Disease Control and Prevention (CDC) recommends the first dose of either rotavirus vaccine is most effective if it is given before an infant is aged 15 weeks and all doses of rotavirus vaccine should be given before they reach eight months old.

What do we do if an infant aged over 15 weeks is given their first dose of RotaTeq?
Where the first dose is inadvertently given at age 15 weeks or older, the remainder of the series should be completed, but all three doses should be given by age eight months and 0 days. The vaccine is not funded for infants aged 15 weeks or older at the time of their first dose.

Will the RotaTeq vaccine information be collected on the National Immunisation Register (NIR)?
Yes. The NIR and PMS systems are being changed to allow RotaTeq vaccine information to be collected on the NIR from 1 July 2014. Coverage of this vaccine will not be reported against the Health Target until 95% coverage is achieved.

Administering RotaTeq

Can RotaTeq be given with other vaccines, including other live vaccines?
Yes. RotaTeq can be administered at the same time as other scheduled vaccines, e.g. Infanrix-hexa and Prevenar 13.

Live oral vaccines (e.g. RotaTeq vaccines) may be administered simultaneously or at any interval before or after inactivated or live injectable vaccines (e.g. BCG vaccine).

What happens if an infant spits or vomits up a dose of RotaTeq?
If a dose of RotaTeq vaccine is spat up or vomited a repeat dose should not be given. Remaining doses should be administered at the usual recommended ages.

The following general guidelines for oral administration of vaccines may avoid the spitting or vomiting up of a dose of RotaTeq:

1. Give RotaTeq at the beginning of the visit while the infant is settled and before administering injections or other procedures.
2. Make every effort to aim the vaccine dosing tube down one side and towards the back of their mouth. Do not put the dosing tube so far back that it causes the infant to gag.

There are no restrictions on the infant’s consumption of food or liquid, including breast milk, either before or after vaccination with RotaTeq.

Are there any concerns around nappy changing after rotavirus immunisation?
Contacts of vaccinated infants should observe careful hygiene measures when changing their nappies.

Shedding of vaccine virus in the stool is possible and therefore the vaccine virus could then be transmitted to unvaccinated individuals. There are no known concerns, but there are also
no data to confirm the safety of these vaccines for immune-compromised people, e.g. children with HIV.

**What side effects are there from the vaccine?**

Like all vaccines and medicines, RotaTeq can cause side effects in some infants. These are usually mild and resolve without intervention. Common side effects include fever, mild diarrhoea or vomiting in the week after vaccination.

Serious side effects are possible, but are very rare. These include severe allergic reaction and intussusception.

Please report any adverse events following immunisation with RotaTeq to the Centre for Adverse Reactions Monitoring CARM. This can be done via the electronic adverse drug reaction reporting tool, which includes a specific vaccines tab.

**Intussusception – how common is it?**

Intussusception is a condition where one part of the bowel slides into the next (like a telescope) and causes obstruction. The cause is unknown, but some cases may be triggered by an infection. There is a small additional risk of intussusception after receiving rotavirus vaccination. The risk is highest in the week after vaccination with the first dose. Intussusception is treated in secondary care. In approximately one-third of cases surgical intervention is required. Most infants recover completely with no further problems. However, intussusception can reoccur in up to 10% of cases. The additional risk of intussusception after vaccination has been estimated as between 1 – 6 infants in every 100,000 infants vaccinated. The overall benefits of vaccination far outweigh the very small risk of intussusception.

The signs of intussusception include severe crying and abdominal pain. Infants might pull their legs up to their chest as if they have colic. Infants may also vomit or have blood in their faeces. The faeces can often have the appearance of “redcurrant jelly”, which is a mix of mucus, cells and blood. The classic sign on examination is a “sausage-like” mass in the right upper quadrant, with a corresponding emptiness in the right lower quadrant. However, this is often difficult to detect if the infant is unsettled, the abdomen is tense or if the condition has been present for a longer period of time.

**RotaTeq vs. Rotarix**

**What is the difference between RotaTeq and Rotarix?**

Both RotaTeq and Rotarix are orally-administered live-attenuated vaccines offering protection against rotavirus. RotaTeq protects against five viral protein types G1−4 and P, and Rotarix protects against one viral protein type G1.

These two vaccines are manufactured differently and the number and timing of doses is different. For further details refer to the Immunisation Handbook 2014.

**How many doses of RotaTeq do infants who have already begun a course of Rotarix need?**

An infant who has received two doses of Rotarix does not require any additional doses of RotaTeq vaccine as they have completed the course for this vaccine. Rotarix is purchased as two doses together, so it is unlikely that many infants will have had one dose of Rotarix and need to complete with RotaTeq. There is no data available on the interchangeability of Rotarix and RotaTeq. A complete course with one vaccine is preferable but, if necessary, a course that contains both vaccines is preferable to an incomplete course.

An infant who has received only one dose of Rotarix should complete their vaccination with two doses of RotaTeq providing that:

- There is a minimum of four weeks between doses; and
- Dose three is completed by age eight months and 0 days

Although there is no data available on the interchangeability of the vaccines, there are not expected to be any safety concerns if an infant starts on one vaccine and completes on another, provided that the upper age limit and inter-vaccine interval are adhered to.