6.13. Rotavirus vaccine

6.13.1. Epidemiology

Rotavirus is an RNA virus and its outermost layer contains two structural viral proteins: the glycoprotein (G protein) and the protease-cleaved protein (P protein). These two proteins define the serotype of the virus.¹ Currently, the 5 most common G-P combinations identified are G1P[8], G2P[4], G3P[8], G4P[8] and G9P[8], with G1P[8] being the most prevalent combination. These five combinations accounted for around 90% of all human infections in the world. The type of rotavirus does not usually correlate with the severity of the disease.²

Rotavirus is a common cause of gastroenteritis among infants and young children. Severe infection may result in dehydration, electrolyte imbalance, shock and even death. Infection does not confer complete immunity but subsequent infection is usually less severe.³ Rotavirus can also cause gastroenteritis outbreaks in institutions, such as child care centres, kindergartens, hospital wards, elderly homes and correctional facilities.

World Health Organization (WHO) estimated that in 2008, rotavirus gastroenteritis (RVGE)-associated child deaths accounted for about 5% of all child deaths and a cause-specific mortality rate of 86 deaths per 100,000 population aged <5 years. About 90% of all rotavirus-associated fatalities occurred in low income countries in Africa and Asia and were related to poor health care.²

In Hong Kong, according to a local study, from 1 July 1997 to 31 March 2011 9.8% of children aged below 5 years admitted to public hospitals in Hong Kong had primary diagnosis of gastroenteritis-related disorder.⁴ In addition, the overall incidence rates of hospitalisation for rotavirus per 100,000 person-years was 1,071 in children below 2 years and 542 in children below 5 years.⁴

6.13.2. Vaccine characteristics

- **Type**: Live attenuated vaccines.
- **Route**: Oral

Registered rotavirus vaccines in Hong Kong are listed in Table 44. The information is extracted from the website of Drug Office (refer to Annex 2). Primary care providers should refer to product inserts for product description, composition and other pharmaceutical particulars.

Table 44. Rotavirus vaccines registered in Hong Kong. (Information as at November 2018)

<table>
<thead>
<tr>
<th>Name of Product</th>
<th>Ingredients</th>
</tr>
</thead>
<tbody>
<tr>
<td>ROTARIX VACCINE ORAL SUSPENSION</td>
<td>Rotavirus</td>
</tr>
<tr>
<td>ROTATEQ ORAL VACCINE</td>
<td>Rotavirus</td>
</tr>
</tbody>
</table>
6.13.3. Immunogenicity and efficacy\(^2\)

According to the WHO,

- Both rotavirus vaccines have similar efficacy against severe RVGE in countries where a high diversity of strains co-circulates. The interchangeability of the two vaccines has not been studied.
- A number of randomised controlled trials have shown that both rotavirus vaccines are 80%-90% efficacious against severe RVGE in countries with very low child and adult mortality, and 40%-60% efficacious in countries with high child mortality and very high adult mortality. In most cases, vaccination in infancy provides protection against severe RVGE for at least 2 years.
- Breastfeeding and prematurity (<37 weeks’ gestation) do not significantly impair the response to the rotavirus vaccines.

6.13.4. Schedule

- There is no local recommendation on the use of rotavirus vaccine at the population level. Rotavirus vaccine can be considered for personal protection. Primary care providers may provide option and information on rotavirus vaccination, as well as to collaborate with parents to arrive at a shared decision-making on the use of vaccine.

The schedules of selected vaccines are listed here for reference only. Primary care provider should always refer to the product inserts and international guidelines for up-to-date information. Different schedules are adopted in different countries according to their local epidemiology and available vaccines which may not be applicable in other places. Primary care provider should exercise his/her clinical judgment if he/she decides to follow certain schedule.

- According to the manufacturers:
  - Rotarix is administered orally in a 2-dose schedule. The first dose may be administered from the age of 6 weeks. There should be an interval of at least 4 weeks between doses. The vaccination is preferably given before 16 weeks of age, and no later than by 24 weeks of age.
  - RotaTeq is administered orally in a 3-dose schedule. The first dose may be administered between ages 6–12 weeks; the subsequent doses at intervals of 4–10 weeks. The third dose should not be given after 32 weeks of age.

### Table 45. Schedule of rotavirus vaccines according to manufacturers

<table>
<thead>
<tr>
<th>Name of Product</th>
<th>Rotarix Vaccine Oral Suspension</th>
<th>RotaTeq Oral Vaccine</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of doses in series</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Minimum age for first dose</td>
<td>6 weeks of age</td>
<td>6 weeks (up to 12 weeks of age)</td>
</tr>
<tr>
<td>Interval between doses</td>
<td>At least 4 weeks</td>
<td>4-10 weeks</td>
</tr>
<tr>
<td>Maximum age for last dose</td>
<td>24 weeks of age (preferentially before 16 weeks of age)</td>
<td>32 weeks of age</td>
</tr>
</tbody>
</table>
World Health Organization\textsuperscript{2}

- According to WHO position paper on rotavirus vaccines published in January 2013, the first dose of either RotaTeq or Rotarix should be administered as soon as possible after 6 weeks of age, along with DTP vaccination. Because of the typical age distribution of RVGE, rotavirus vaccination of children >24 months of age is not recommended.
- Rotarix and RotaTeq should be administered orally in a 2-dose and 3-dose schedule respectively, with an interval of at least 4 weeks between doses. Rotavirus vaccination can be administered simultaneously with other vaccines in the infant immunisation programme.

Australia\textsuperscript{5}

The recommended rotavirus vaccination schedule in Australia:

- Rotarix is recommended for use in a 2-dose course (at 2 and 4 months of age).
- RotaTeq is recommended for use in a 3-dose course (at 2, 4 and 6 months of age).

Table 46. Age limits for dosing of oral rotavirus vaccines recommended in Australia\textsuperscript{5}

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Doses</th>
<th>Age of routine oral administration</th>
<th>Age limits for dosing</th>
<th>Minimum interval between doses</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Rotarix</strong></td>
<td>2 oral doses (1.5ml/dose)</td>
<td>2 and 4 months</td>
<td>1st dose: 6-14* weeks, 2nd dose: 10-24* weeks, 3rd dose: Not applicable</td>
<td>4 weeks</td>
</tr>
<tr>
<td><strong>RotaTeq</strong></td>
<td>3 oral doses (2ml/dose)</td>
<td>2, 4 and 6 months</td>
<td>1st dose: 6-12† weeks, 2nd dose: 10-32† weeks, 3rd dose: 14-32† weeks</td>
<td>4 weeks</td>
</tr>
</tbody>
</table>

* The upper age limit for receipt of the 1st dose of Rotarix is immediately prior to turning 15 weeks old, and the upper age limit for receipt of the 2nd dose is immediately prior to turning 25 weeks old.
† The upper age limit for receipt of the 1st dose of RotaTeq is immediately prior to turning 13 weeks old. The 2nd dose of vaccine should preferably be given by 28 weeks of age to allow for a minimum interval of 4 weeks before receipt of the 3rd dose. The upper age limit for the 3rd dose is immediately prior to turning 33 weeks old. For infants receiving their 2nd dose after reaching 29 weeks of age and before turning 33 weeks of age, this 2nd dose will also be their final dose.

United States\textsuperscript{3}

The recommended rotavirus vaccination schedule in the United States according to the Advisory Committee on Immunization Practices (ACIP):  

- The vaccine be administered as a series of either two or three oral doses, for Rotarix and RotaTeq, respectively, beginning at 2 months of age. The vaccination series for both vaccines may be started as early as 6 weeks of age. Subsequent doses in the series should be separated from the previous dose by at least 4 weeks.
- The ACIP recommendations state that the maximum age for the first dose of both vaccines is 14 weeks 6 days. This is an off-label recommendation for RotaTeq since the approved maximum age for the first dose of that vaccine is 12 weeks. The minimum interval between doses of both rotavirus vaccines is 4 weeks. The maximum age for any dose of either rotavirus vaccine is 8 months 0 days. No rotavirus vaccine should be administered to infants older than 8 months 0 days of age. This is an off-label recommendation for both vaccines, because the labelled maximum age for
Rotarix is 24 weeks, and the labelled maximum age for RotaTeq is 32 weeks.

6.13.5. **Contraindication and precaution**

**Contraindication:**
- History of a severe allergic reaction following a prior dose of vaccine or to a vaccine component including latex (latex rubber is contained in the Rotarix oral applicator)
- Infants with severe combined immunodeficiency syndrome
- History of intussusception

**Precautions:**
- Altered immunocompetence other than severe combined immunodeficiency syndrome
  - Limited data do not indicate a different safety profile in HIV-infected versus HIV-uninfected infants
- Acute, moderate or severe gastroenteritis or other acute illness.
- The decision to vaccinate if a precaution is present should be made on a case-by-case risk and benefit basis.

**Information for answering some common questions:**
- Infants with pre-existing gastrointestinal conditions (such as congenital malabsorption syndromes, Hirschsprung’s disease or short-gut syndrome) who are not undergoing immunosuppressive therapy should benefit from receiving rotavirus vaccine. It was considered that the benefits outweigh the theoretic risks. However, no data is available on the safety and efficacy of rotavirus vaccine for infants with pre-existing chronic gastrointestinal conditions. The product information for Rotarix indicates that the vaccine is contraindicated in those with history of uncorrected congenital malformation of the gastrointestinal tract that would predispose to intussusception.6
- No dietary restriction (including breastfeeding) is needed before or after administration of rotavirus vaccine.1
- Infants living in households with pregnant women or immunocompromised people can be immunised.1
- Rotavirus vaccine may be administered at any time before, concurrent with, or after administration of any blood product, including antibody-containing products. (Also see Chapter 3.2)
- It is not recommended to readminister a dose of rotavirus vaccine to an infant who regurgitates, spits out, or vomits during or after administration of vaccine. No data exist on the benefits or risks associated with readministering a dose. The infant should receive the remaining recommended doses of rotavirus vaccine following the routine schedule (with a 4-week minimum interval between doses).1
6.13.6. Adverse events following immunisation (AEFI) 3

**RotaTeq**
- Diarrhoea 18.1%
- Vomiting 11.6%
- Also greater rates of otitis media, nasopharyngitis and bronchospasm

**Rotarix**
- Irritability 11.4%
- Cough or runny nose 3.6%
- Flatulence 2.2%

The Global Advisory Committee of the WHO concluded that available data suggest both Rotarix and RotaTeq exhibit a good safety profile, but may be associated with an increased risk of intussusception after the first dose of vaccine in some populations.7

**References**


Disclaimer: The contents of the module on immunisation will be updated regularly in order to provide the latest evidence-based recommendations for reference by healthcare professionals. However, they are subject to updates and not considered exhaustive. Concerted efforts from experts in various fields are vital.