

# Vaccination against rotavirus

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## Executive summary

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Health Council of the Netherlands



Rotavirus is a highly contagious disease that causes vomiting and diarrhoea. Young children in particular may become seriously ill and develop dehydration symptoms for which they need to be treated in hospital. There are two oral vaccines against rotavirus on the market. At the request of the Minister of Health, Welfare and Sport, the Committee on Vaccinations of the Health Council of the Netherlands has evaluated vaccination of children against rotavirus. In any case, the Committee recommends vaccinating children with a risk factor (prematurity, low birth weight or congenital abnormality). The Committee also welcomes the inclusion of vaccination against rotavirus in the National Immunisation Programme, bearing in mind, however, that the cost effectiveness of vaccination is unfavourable based on the asking prices of the vaccines.

### **Disease burden due to rotavirus considerable**

The Committee finds that the disease burden resulting from rotavirus is considerable, mainly

due to the large number of young children who end up in hospital due to dehydration symptoms. Each year, the disease causes 2,589 to 4,707 hospital admissions in children up to 5 years of age. If dehydration is not treated on time, shock can occur with severe damage to internal organs, such as the kidneys, liver and brain. However, this risk is usually limited due to timely intervention. Each year, an estimated five to seven children die from a rotavirus infection; these are mainly children who are born prematurely, have a low birth weight or a severe congenital abnormality (risk factors). These children also have a greater risk of developing an infection in hospital, where the virus can rapidly spread.

### **Effectiveness of vaccines sufficient**

The available vaccines, administered orally, are sufficiently effective in reducing the disease burden: vaccination reduces the number of rotavirus infections with severe symptoms and the number of hospital admissions by 85%. In addition, high vaccination coverage (a large

percentage of children are vaccinated) provides group protection. As a result, some of the children who are too young to be fully vaccinated (younger than 3 months) are protected against a rotavirus infection.

### **Slight risk of serious complication**

The disadvantage of vaccination is that it is related to a slightly increased risk of intussusception; a type of intestinal obstruction. If left untreated, part of the intestine can die. Usually, however, an intussusception can be resolved without any residual symptoms. Vaccination against rotavirus is associated with an increased risk of an intussusception in the period of three days to a week after vaccination, especially after administration of the first dose. However, in countries where universal vaccination has been implemented, no increase in the total number of intussusceptions in children up to one year has been observed. In general, the cause of intussusception is often unclear and the association with vaccination is misunderstood. In its assessment, the



Committee assumes a worst-case scenario, that the vaccination actually causes additional intussusceptions. In the Netherlands, this would theoretically lead to an increase of up to four intussusceptions on an annual basis, while without vaccination, approximately 64 intussusceptions would occur in children up to 1 year without vaccination. For a vaccinated child, this would mean that the chance of an intussusception might increase from 1 in 2,857 to 1 in 2,703.

### **Benefit outweighs the risk**

A condition for implementing vaccination against rotavirus is that its benefits outweigh the risks. That is the case, according to the Committee. The greatest benefit occurs when all children are vaccinated: in that case, according to calculations, 1,930 to 3,389 hospital admissions would be prevented per year. Group protection would also occur, so that the group of children that is too young to be (fully) vaccinated would be partially protected against a rotavirus infection. If only risk groups are vaccinated, 254

to 446 hospital admissions would be prevented each year. With both strategies, most of the deaths due to rotavirus would be prevented, possibly five to six deaths a year. The absolute risks, i.e. the potential increase in intussusceptions, are the smallest if only risk groups receive the vaccine. In that case, there might be an additional intussusception once every three years. With vaccination of all children, three to four additional intussusceptions might occur each year.

### **Vaccination is not cost-effective at current vaccine prices**

In assessing the effectiveness of vaccination, a reference value of EUR 20,000 per QALY (Quality-adjusted life year) is used for cost effectiveness. With this reference value, universal vaccination against rotavirus is not cost-effective.

### **Recommended vaccination strategy**

In any case, the Committee recommends vaccinating children with a risk factor

(prematurity, low birth weight or birth defect) against rotavirus. The Committee also welcomes offering vaccination against rotavirus to all children through the National Immunisation Programme. By vaccinating all children, the disease burden due to rotavirus would be the most strongly reduced. This would be beneficial for all children: the number of serious rotavirus infections (and hospital admissions) would decrease significantly. Lasting effects and death due to rotavirus would hardly occur; this benefit mainly concerns children from risk groups. The expectation is that this strategy would also provide protection to some of the children up to 3 months, who are too young to vaccinate fully (with two or three doses). A disadvantage is that the cost effectiveness of universal vaccination is unfavourable at the often used reference value of EUR 20,000 per QALY.

### **Implementation aspects**

To minimise the potential side effects, the Committee recommends administering the first dose of the vaccine as early as possible: at 6 to



8 weeks of age. This would reduce the risk of a vaccination-induced intestinal intussusception, since the baseline risk at that age is smaller than when children are older. Healthcare providers should be well-informed about the importance of timely vaccination. It is also important to inform parents and healthcare providers about the possibility that a child may develop an intestinal intussusception so they can respond alertly to symptoms, preventing the complication from having serious consequences as much as possible. Finally, attention should be paid to monitoring the effectiveness of vaccination and its side effects.



The Health Council of the Netherlands, established in 1902, is an independent scientific advisory body. Its remit is “to advise the government and Parliament on the current level of knowledge with respect to public health issues and health (services) research...” (Section 22, Health Act).

The Health Council receives most requests for advice from the Ministers of Health, Welfare and Sport, Infrastructure and the Environment, Social Affairs and Employment, and Economic Affairs. The Council can publish advisory reports on its own initiative. It usually does this in order to ask attention for developments or trends that are thought to be relevant to government policy.

Most Health Council reports are prepared by multidisciplinary committees of Dutch or, sometimes, foreign experts, appointed in a personal capacity. The reports are available to the public.

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