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RESEARCH CONSORTIUM

Evidence Assessment: Summary of a Systematic Review

Who is this summary for?

For Doctors and Health Personal, Administrators and Managers of health facilities and the partners involved in the reduction of newborn mortality.

Vaccines for preventing rotavirus diarrhoea: vaccines in use

Key findings

- In the first two years of life, monovalent rotavirus vaccine prevents more than 80% of severe cases of rotavirus diarrhoea in low-mortality countries, and at least 40% of severe rotavirus diarrhoea in high-mortality countries.
- In the first two years of life, pentavalent rotavirus vaccine reduces severe cases of rotavirus diarrhoea by more than 80% in low-mortality countries and by 40 to 57% in high-mortality countries.

Background

Rotavirus infection is a common cause of diarrhoea in infants and young children, and can cause mild illness, hospitalization, and death. Rotavirus infections results in approximately half a million deaths per year in children aged under five years, mainly in low- and middle-income countries. Since 2009, the World Health Organization has recommended that a rotavirus vaccine be included in all national immunization programmes.

Question

What is the efficacy of rotavirus vaccines approved for use, for preventing rotavirus diarrhoea and death in children up to one and up to two years old in low- and high-mortality countries?

The use of vaccines for preventing rotavirus diarrhoea in Cameroon: Gastroenteritis with rotavirus is the third cause of death in children less than 2 years, with a prevalence of around 40% (Sentinel Survey 2006). Cameroon plans to introduce vaccines against rotavirus in the Expanded Programme on Immunization in April 2014.

Table 1: Summary of the systematic review		
	What the review authors searched for	**What the review authors found**
Studies	Randomized controlled trials (RCTs).	Forty-one RCTs and cluster RCTs met the inclusion criteria for the review.
Participants	Children (age as defined in the trials).	Children (age as defined in the trials).
Interventions	Vaccines approved in any country.	The 41 trials compared a rotavirus vaccine with a placebo. The vaccines tested were rotavirus vaccine 1 and rotavirus vaccine 5.
Controls	Placebo, no vaccination, or other vaccine	Placebo
Outcomes	**Primary outcomes** • Rotavirus diarrhoea: severe (as defined in trial report). • All-cause diarrhoea: severe. • All-cause death • Serious adverse events (that are fatal, life-threatening, or result in hospitalization); e.g. Kawasaki disease. • Intussusception. **Secondary outcomes** • Rotavirus diarrhoea: of any severity. • All-cause diarrhoea (as defined in trial report). • Rotavirus diarrhoea: requiring hospitalization. • All-cause diarrhoea: requiring hospitalization. • Emergency department visit. • Hospital admission: all-cause. • Reactogenicity (capacity to produce an adverse reaction, such as fever, diarrhoea, and vomiting). • Adverse events that require discontinuation of vaccination schedule.	Four trials were safety studies reporting safety outcomes (e.g. serious adverse events and reactogenicity) and generally immunogenicity outcomes as well. The other eight trials reported one or more efficacy and safety outcomes and seven out of those eight reported immunogenicity outcomes also (vaccine virus shedding in stool; conversion from seronegative to seropositive for anti-rotavirus IgA antibodies) .
Date of the most recent search: 10 May 2012		
Limitations: This is a good quality systematic review, AMSTAR = 9/11, due to the wide variety of outcomes it was challenging to pool many of the included studies.		
Citation: Soares-Weiser K, MacLehose H, Bergman H, Ben-Aharon I, Nagpal S, Goldberg E, Pitan F, Cunliffe N. Vaccines for preventing rotavirus diarrhoea: vaccines in use. Cochrane Database of Systematic Reviews 2012, Issue 11. Art. No.: CD008521. DOI: 10.1002/14651858.CD008521.pub3		

Table 2: Summary of Findings

Outcomes	Relative effect (95% CI)	No of participants (studies)	Quality of the evidence (GRADE)	Comments
Severe rotavirus diarrhoea Follow-up: up to 1 year	0.14 [0.07-0.26]	40 631 132 (6)	**high**	One study reported higher efficacy compared to the pooled data. When this study was excluded from the analysis, no heterogeneity was observed on the pooled data
Severe rotavirus diarrhoea Follow-up: up to 2 years	0.15 [0.12-0.2]	32 854 (8)	**high**	
Severe episodes of all cause diarrhoea Follow-up: up to 1 year	0.60 [0.5-0.72]	17 867 (1)	**Moderate**	One additional European study reported on cases of children with severe all cause diarrhoea; this data could not be pooled with the study reporting on number of episodes
Severe episodes of all cause diarrhoea Follow-up: up to 2 years	0.63 [0.56-0.71]	39 091 (2)	**Moderate**	Two additional studies reported on cases of children with severe all-cause diarrhoea; this data could not be pooled with the studies reporting on number of episodes.
All-cause death Follow-up: 2 months to 2 years	1.27 [0.89-1.81]	93 321 (18)	**Low**	
All serious adverse Events Follow-up: 2 months to 2 years	0.9 [0.84-0.95]	91 957 (20)	**Moderate**	
Serious adverse events: Intussusception Follow-up: 2 months to 2 years	0.87 [0.52-1.61]	91 832 (11)	**Low**	

Applicability

In this review 9 of the studies were conducted in USA, 7 in South Africa, 5 in Peru, 4 in Finland, 3 in Bangladesh and in Ghana, 2 in the Philippines, Brazil, Vietnam, Italy, Colombia, Mexico, South Korea, Mali, Belgium and Japan, and 1 each in Canada, Panama, Argentina, Dominican Republic, Costa Rica, Honduras, Panama, China, Thailand, Taiwan, Malawi, Kenya, Venezuela, Nicaragua, Jamaica , Czech Republic, France, Germany, Spain, Austria and Sweden. Some of these settings are representative of low resource settings.

Conclusions

The monovalent rotavirus vaccine efficacy is lower in high-mortality countries; however, due to the higher burden of disease, the absolute benefit is higher in these settings. No increased risk of serious adverse events was detected, but post-introduction surveillance studies are required to detect rare events associated with vaccination.

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