Evidence Update

Child Health Series *February 2004*

Are rotavirus vaccines effective in preventing diarrhoea?

Rotavirus vaccines tested to date prevent diarrhoea caused by rotavirus. One form of the vaccine has been associated with a rare life-threatening adverse event in post-marketing surveillance data.

Inclusion criteria

Studies:

Randomized controlled trials.

Participants:

Children and adults.

Intervention:

Rotavirus vaccine, including a) live attenuated bovine vaccine; b) rhesus vaccine; c) human attenuated vaccine; versus placebo, or no vaccination.

Outcome measures:

Rotavirus diarrhoea episodes; severe episodes of rotavirus diarrhoea; episodes requiring hospitalisation; episodes of more than four days duration; and adverse events.

Results

- 64 trials involving 21,070 children; 15 trials were adequately concealed.
- **All three groups of vaccines prevent episodes of rotavirus diarrhoea:** rhesus (RR 0.59, 95%CI 0.50 to 0.70); bovine (RR 0.59, 95%CI 0.45 to 0.76); and human (RR 0.42, 95%CI 0.21 to 0.85).
- **All three groups prevented severe episodes of rotavirus diarrhoea:** rhesus (RR 0.42, 95%CI 0.31 to 0.57); bovine (RR 0.38, 95%CI 0.24 to 0.60); and human (RR 0.21, 95%CI 0.13 to 0.35).
- The rhesus vaccine significantly reduced the number of episodes of rotavirus diarrhoea with more than four days duration (RR 0.61, 95%CI 0.42 to 0.87).
- In three trials of the rhesus vaccine intussception was detected, but the power of the study was insufficient to detect a difference in this severe, rare adverse event.
- 4 studies of rhesus vaccine examined all-cause mortality, with no significant difference detected.

Adapted from Soares-Weiser K, Goldberg E, Tamimi G, Pitan OC, Leibovici L. Rotavirus vaccine for preventing diarrhoea (Cochrane Review). In: The Cochrane Library, Issue 1, 2004. Chichester, UK: John Wiley & Sons, Ltd.

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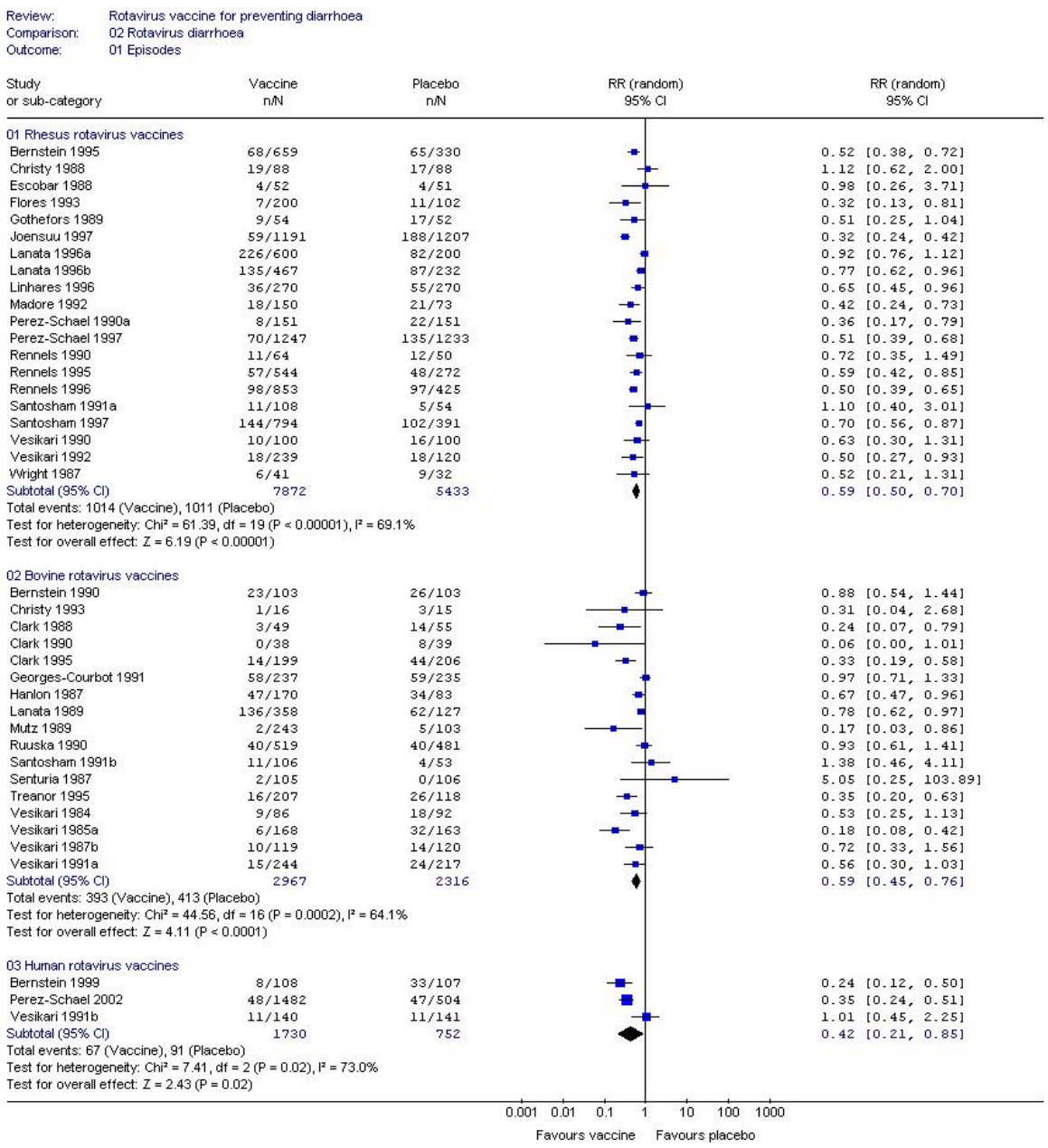

Reviewer's conclusions

Implications for practice:

Rhesus, bovine and human rotavirus vaccines are effective against rotavirus diarrhoea, but the lack of data on mortality and questions over safety has precluded their use in routine clinical practice.

Implications for research:

Large randomised controlled trials, conducted in high, middle and low-income countries to determine the effect on mortality, and safety of the vaccines are needed. The trials should specify death, severe diarrhoea, intussusception and other adverse events as the main outcomes.