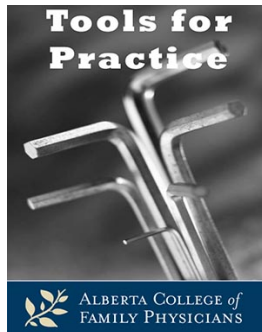


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Rotavirus Vaccine: A shot to get off the pot(ty)

Clinical Question: What are the benefits and risks of the rotavirus vaccine?

Bottom-line: In developed countries, rotavirus vaccine prevents serious diarrhea for one in 22 and reduces hospitalizations for one in 100. There does not appear to be an increase in intussusception rates.

Evidence:

- For monovalent and pentavalent rotavirus vaccine (RV1 and RV5, respectively)
 - Systematic Review (RV1: 29 Randomized Controlled Trials (RCTs), 101,671 infants; RV5: 12 RCTs, 84,592 infants), vaccine versus placebo in developed (western) countries.¹ Statistically significant results at two years:
 - Any rotavirus diarrhea:
 - RV1: Relative Risk (RR) 0.33 (95% confidence interval, 0.21-0.50).
 - RV5: RR 0.36 (95% confidence interval 0.25-0.50).
 - Placebo rate ~9%, vaccine rate ~3%.
 - Number Needed to Treat (NNT) ~17, either vaccine.
 - Severe rotavirus diarrhea, NNT ~50, either vaccine.
 - RV1 (no or too little data from RV5):
 - Any diarrhea, NNT ~40.
 - Any severe diarrhea, NNT ~22.
 - Hospitalizations, NNT ~100.
 - Mortality: No difference.
 - Limitations: Inconsistent definition of 'severe diarrhea' in trials (varies from rotavirus diarrhea scales to hospitalization requiring rehydration therapy).
 - Safety:
 - Reactions to immunization similar between vaccine and placebo: rates were fever (38-41%), diarrhea (7-25%), vomiting (13-17%).^{1,2}
 - No increase in intussusception in RCTs or subsequent surveillance/observational data.¹⁻⁵

Context:

- Rotavirus transmission is fecal-oral and fomites (including toys) with a 1-5 day incubation.⁶
- An estimated 80% of children have rotavirus gastroenteritis by age five.⁷
 - One in 62-312 children are hospitalized for rotavirus.⁶
 - Most (90%) Canadian cases occur December-April and 63% affect children <2 years old.^{8,9}
- Licenced oral vaccines include:
 - RV1 (Rotarix®; GlaxoSmithKline): Live attenuated, human monovalent rotavirus, two oral doses (two and four months).
 - RV5 (RotaTeq®; Merck): Live human-bovine reassortment, pentavalent rotavirus, three oral doses (two, four, and six months).
- Publicly funded in British Columbia, Alberta, Saskatchewan, Manitoba, Ontario, Quebec, Prince Edward Island, Northwest Territories, and Yukon.
- Approximately \$165-\$200 per vaccine series.

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Disclosure:

Authors do not have any conflicts to disclose.

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