

# Effectiveness of rotavirus vaccine in preventing severe acute gastroenteritis in children

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### Abstract

**Question** As rotavirus vaccines enter the scheduled immunization programs in Canada, more and more of the children younger than 1 year of age in my practice are receiving rotavirus vaccines. Is there evidence that rotavirus vaccines are effective in preventing acute gastroenteritis complications such as dehydration and hospitalization?

**Answer** To reduce the burden of illness of rotavirus-induced gastroenteritis, 2 orally administered rotavirus vaccines were licensed in recent years. Large studies documented the safety profiles of these vaccines and several provinces introduced a vaccine as part of their immunization program. Recent data from developed and developing countries suggest that the rotavirus vaccine is substantially reducing morbidity and mortality among children. Initial clinical trials are now being supported by effectiveness data from field studies, showing a 70% to 100% reduction in emergency department visits and hospitalizations of children with rotavirus acute gastroenteritis.

## Efficacité du vaccin contre le rotavirus dans la prévention de la gastro-entérite aiguë grave chez l'enfant

### Résumé

**Question** Les vaccins contre le rotavirus sont progressivement inclus dans les programmes d'immunisation planifiés au Canada et de plus en plus d'enfants de moins de 1 an dans ma pratique reçoivent ces vaccins. Y a-t-il des données scientifiques confirmant que les vaccins contre le rotavirus sont efficaces pour prévenir les complications de la gastro-entérite aiguë, comme la déshydratation et l'hospitalisation?

**Réponse** Pour réduire le fardeau de la gastro-entérite causée par le rotavirus, 2 vaccins administrés par voie orale ont été homologués récemment. Des études de grande envergure ont documenté les profils de sécurité de ces vaccins et plusieurs provinces ont inclus un vaccin contre le rotavirus dans le contexte de leur programme d'immunisation. De récentes données provenant de pays développés et en développement font valoir que le vaccin contre le rotavirus diminue considérablement la morbidité et la mortalité chez les enfants. Les études cliniques initiales sont maintenant corroborées par des données sur l'efficacité tirées d'études sur le terrain démontrant une réduction de 70 % à 100 % des visites à l'urgence et de l'hospitalisation des enfants souffrant de gastro-entérite aiguë due au rotavirus.

Acute gastroenteritis is one of the most common causes of morbidity and hospitalization in North America,<sup>1</sup> and one of the most common reasons for mortality in developing countries.<sup>2</sup> More than 200 000 hospitalizations for dehydration were recorded annually in the United States,<sup>3</sup> with comparable rates in Canada.<sup>4</sup> Prolonged diarrhea and malnutrition are primary causes of morbidity and mortality in the pediatric Canadian Native populations.<sup>4</sup>

Rotavirus is the single most common organism causing acute gastroenteritis in children. Epidemiologic studies show that all children will experience at least 1 episode of rotavirus infection by the time they are 5 years of age,<sup>5</sup> and many children will need hospitalization,<sup>6</sup> especially children younger than 2 years of age.<sup>7</sup>

In recent years considerable effort has been made to develop vaccines for prevention of rotavirus-induced

gastroenteritis. Currently, there are 2 licensed rotavirus vaccines approved in Canada and both are administered orally. One is a monovalent attenuated human vaccine and the second is a pentavalent bovine-human reassortant vaccine. Large international premarketing and postmarketing studies have shown no serious adverse events associated with either rotavirus vaccine, and owing to the recommendations of the National Advisory Committee on Immunization,<sup>8</sup> several provinces have introduced a vaccine as part of their immunization program in the past 2 years.

Recent data from both affluent and developing countries suggest that rotavirus vaccines are making a big difference in morbidity and especially mortality among children.<sup>9</sup> Vaccines reduced the burden of illness, and clinical trial findings are now being supported by effectiveness data. Efficacy of the vaccine in clinical trials

was between 70% and 100% in some countries in Europe and Latin America,<sup>10-12</sup> and close to 70% in developing countries in Africa and Asia.<sup>13,14</sup> Even more compelling are the findings in field studies comparing illness among immunized children to those with no immunization (effectiveness studies).

Two studies from Israel, with an approximate 50% vaccine coverage in 1 large health maintenance organization, 2 doses of the pentavalent vaccine resulted in a 50% reduction in need for a physician visit<sup>15</sup> and an almost 90% reduction in hospitalization.<sup>16</sup> In Australia, with a monovalent vaccine coverage of 73% to 90%, one study group documented a 94% reduction in hospitalizations associated with rotavirus gastroenteritis.<sup>17</sup> A study from Nicaragua, where vaccine coverage exceeded 90% of the population studied, 3 doses of a monovalent vaccine reduced serious illness by close to 80%.<sup>18</sup>

Several studies from the United States, as summarized by Dennehy,<sup>9</sup> reported considerable reduction in complications from acute gastroenteritis in general, and more specifically, illness caused by rotavirus. While the rate of coverage of the vaccine (pentavalent) is largely unknown, between 90% and 100% of severe illness, emergency department visits and hospitalizations were saved.<sup>19-21</sup> The higher the number of doses given to children, the higher the rate of documented reduced complications.

In the most recent prospective case-control surveillance study from 3 US counties,<sup>22</sup> the rate of hospitalizations and emergency department visits was reduced in 74% to 87% of cases, compared with a group that had rotavirus-negative acute gastroenteritis, and was dependent on the number of vaccine doses given. A similar reduction was found when compared with children with acute respiratory illnesses.

As more and more children in Canada are receiving the rotavirus vaccines, similar effectiveness studies are expected. Further information on herd immunity and cost-effectiveness will be needed to ensure comprehensive information on the success of eradicating one of the most common conditions in children. 🌿

#### Competing interests

None declared

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Child Health Update is produced by the Pediatric Research in Emergency Therapeutics (PRETx) program ([www.pretx.org](http://www.pretx.org)) at the BC Children's Hospital in Vancouver, BC. Dr Goldman is Director of the PRETx program. The mission of the PRETx program is to promote child health through evidence-based research in therapeutics in pediatric emergency medicine.

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