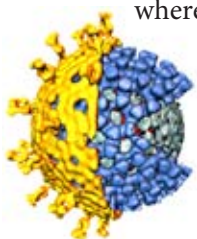




Equal protection against a childhood threat

Each year, more than half a million children die from diarrheal disease caused by rotavirus. Over 90 percent of these deaths occur in developing countries,



where access to simple, lifesaving interventions is limited. The virus is found everywhere, regardless of hygienic conditions, and almost all children suffer a rotavirus infection by five years of age. New vaccines offer the best hope for reducing its global burden, but for many children in the world's poorest countries, they remain out of reach.

The PATH Rotavirus Vaccine Program, a partnership with the World Health Organization and the US Centers for Disease Control and Prevention, was established in 2003 with funding from the GAVI Alliance. The program aims to dramatically reduce the typical 10- to 15-year timeline between introduction of new vaccines in wealthy countries and their availability in the developing world through a strategic set of technical activities.

Measuring global rotavirus disease burden

- Surveillance networks in Asia, Africa, Eastern Europe, Latin America, and the Middle East measure the burden of disease and track the prevalence and diversity of rotavirus strains.
- Surveillance data is an important resource for decision-making at country and regional levels.
- Ongoing surveillance allows for evaluation of vaccine impact once it has been introduced in-country.

Determining vaccine efficacy and safety in developing countries

- Clinical trials of Rotarix[®], in partnership with GlaxoSmithKline.
South Africa: Immunogenicity, dose range, age of administration, and interaction with oral polio vaccine (Phase 2, completed in 2005); safety and efficacy (Phase 3, ongoing); safety, reactogenicity, and immunogenicity in HIV-positive infants (Phase 2, ongoing).
Malawi: Safety and efficacy (Phase 3, ongoing).
Bangladesh: Immunogenicity, dose range, and reactogenicity (Phase 2, completed in 2006).
- Clinical trials of RotaTeq[®], in partnership with Merck & Co., Inc.
Bangladesh and Vietnam: Safety and efficacy (Phase 3, scheduled to begin in early 2007).
Kenya, Ghana, and Mali: Safety and efficacy (Phase 3, scheduled to begin in early 2007).

“GAVI and its partners are laying the groundwork for the introduction of next generation of vaccines, while building political support for their introduction.”

— Michel Zaffran, GAVI Deputy Executive Secretary



The introduction of rotavirus vaccines into Nicaragua's public sector health program in October 2006 marked the first time in history that a vaccine has been introduced in a GAVI-eligible country in the same year that it was approved in the industrialized world. At an event to launch nationwide rotavirus immunization, Nicaraguan president Enrique Bolaños administers the ROTATEQ[®] vaccine manufactured by Merck & Co., Inc.

Communicating the value of rotavirus vaccines

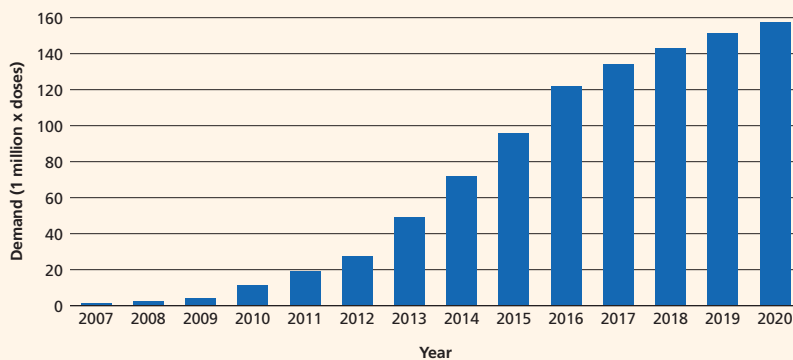
- Up-to-date information on rotavirus disease burden facilitates informed decision-making among key stakeholders at global, regional, and national levels.
- PATH's Enhanced Diarrheal Disease Control Initiative presents rotavirus vaccines in the context of both new and traditional interventions to inform policy decisions on the effective management of diarrheal disease.
- Engaging local child survival organizations in Latin America and Asia increases awareness of the lifesaving potential of rotavirus vaccines and fosters culturally relevant strategies for child survival.

Generating information on the health economics of rotavirus vaccination

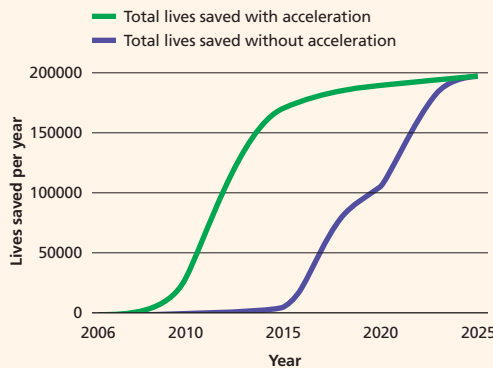
PATH and its partners are developing resources to help decision-makers evaluate the cost-effectiveness of rotavirus vaccines. A primary consideration for the introduction of any new technology is whether its cost justifies the anticipated benefit. Vaccine cost includes the price of the product, as well as the resources required to distribute it. The potential benefit is the number of children whose lives are saved or health improved, as well as the related reduction in medical expenses.

Manufacturers also need information to justify an investment in vaccine production for the developing world. PATH helps by forecasting the demand for vaccine over time so that manufacturers are able to better predict the market and offer an affordable price. This information also helps justify investment by international funders like the GAVI Alliance, which approved the "Investment Case" submitted by PATH's Rotavirus Vaccine Program in late 2006.

Forecasted demand, 2007-2020.



Lives saved per year.



PATH/Kathy Neuzil

Clinical trials are an essential step to determining the safety and efficacy of rotavirus vaccines in developing country populations. Participating in a study PATH is conducting in collaboration with GlaxoSmithKline, a mother in Malawi cradles her infant as a health worker provides drops of Rotarix®, the manufacturer's oral rotavirus vaccine.

For more information

For more information about PATH's Rotavirus Vaccine Program, visit www.rotavirusvaccine.org, or contact rvpinfo@path.org.



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