

# Saving children's lives from deadly rotavirus diarrhea

## PATH's comprehensive approach to rotavirus vaccines

Each year, more than half a million children die from severe, dehydrating diarrhea. The most common cause of severe infantile diarrhea—accounting for approximately one-third of these deaths and millions of hospitalizations—is rotavirus. More than 90 percent of rotavirus-related deaths occur among children in poor countries.

Rotavirus is highly contagious and resilient. Regardless of water quality and available sanitation, nearly every child in the world is at risk of infection. Traditional diarrheal disease prevention measures are not enough to limit its transmission, and vaccination is the best way to prevent severe rotavirus illness.

Oral, live attenuated rotavirus vaccines exist, but they remain out of reach for many in the developing world. PATH works in several ways to address these gaps: increasing access to and improving the performance of existing rotavirus vaccines; demonstrating rotavirus vaccine impact and cost-effectiveness; collaborating with vaccine manufacturers to develop new rotavirus vaccines and improve formulations; conducting clinical trials to demonstrate rotavirus vaccine safety and efficacy; and accelerating the development of safe, effective, and affordable new rotavirus vaccines. PATH also conducts advocacy to increase awareness of diarrheal disease more broadly and the array of interventions, including vaccines, needed to save lives.

### FACILITATING USE OF CURRENT VACCINES

Based on data from pivotal studies conducted in developing countries by PATH and partners, the World Health Organization recommends global use of rotavirus vaccines. To date, more than 80 countries have introduced these vaccines in the public sector. Gavi, the Vaccine Alliance offers support for the introduction of rotavirus vaccines in low-income countries, and nearly 40 countries have introduced the vaccines with Gavi's help so far.



PATH/Mike Wang

Over the past decade, PATH has partnered with global health leaders to provide key evidence, technical assistance, and advocacy and communications support to countries in Africa and Asia that are preparing for rotavirus vaccine introduction with support from Gavi. Today, PATH continues to generate and disseminate information on the burden of rotavirus and the potential and observed impact of safe and efficacious rotavirus vaccines in countries where they are needed most.

In parallel with accelerating access to current rotavirus vaccines, PATH is also dedicated to improving or enhancing their performance in low-resource settings to maximize their benefits. Several factors may impact the efficacy of rotavirus vaccines in low-income countries, such as the age of administration, co-administration with other vaccines, maternal antibodies, nutrition deficiencies, exposure to other pathogens, higher prevalence of coinfections, or wide varieties of rotavirus strains. PATH has conducted a range of studies to identify and evaluate these factors, along with potential ways to address them. PATH also builds on and disseminates this evidence to provide national health ministries with the tools and data they need to optimize rotavirus vaccination strategies.

Another way that PATH facilitates the use of current rotavirus vaccines is by collaborating with vaccine manufacturers to improve their formulations. For example, PATH is working with a Vietnamese vaccine manufacturer to assist with the development of a liquid formulation of its rotavirus vaccine, which is licensed and marketed domestically. The new formulation and product presentation could help ease distribution and administration logistics. To support the broader field, PATH hosts an annual meeting for manufacturers actively developing new rotavirus vaccines to share and discuss common issues and practices around vaccine development.

Finally, PATH works with partners to help inform vaccine introduction efforts through health economic analyses related to rotavirus vaccine impact and cost-effectiveness. PATH's work in this area focuses on strengthening global- and country-level knowledge based on new data and illustrating the broader benefits of rotavirus vaccination. This includes updating global rotavirus vaccine impact and cost-effectiveness estimates in light of new disease burden estimates. In addition, PATH conducts workshops to provide updated health economic tools and technical assistance to countries in Asia, Eastern Europe, and Africa.

#### DEVELOPING NEW ROTAVIRUS VACCINES

PATH also supports the development and licensure of promising new rotavirus vaccines, because bringing new vaccines to the global market is critical to improving affordability and ensuring a sustainable supply. For instance, PATH was part of a collaborative effort to develop and evaluate *ROTAVAC*<sup>®</sup>, which obtained licensure in India in early 2014 based on positive Phase 3 efficacy study results. PATH continues to back several other promising rotavirus vaccines in the pipeline.

Several emerging-country manufacturers have licensed the live attenuated bovine-human reassortant rotavirus vaccine (BRV) from the US National Institutes of Health for further development. PATH is working closely with Serum Institute of India, Pvt. Ltd. to conduct a Phase 3 efficacy trial of its pentavalent BRV candidate. The three-year trial, launched in May 2014, is being conducted with 7,500 infants at six study sites across India. In addition, PATH is assisting China National Biotec Group's Wuhan Institute of Biological Products to prepare for initial clinical trials of its BRV candidate.



PATH/Doune Porter

PATH is also evaluating non-replicating rotavirus vaccine candidates to be administered by injection, which may offer a promising alternative approach for improving protection through rotavirus vaccination for children at greatest risk. Encouraging results are currently moving PATH's most advanced candidate through pivotal clinical studies in South African adults, toddlers, and infants.

#### RAISING AWARENESS THROUGH ADVOCACY

The Defeat Diarrheal Disease (DefeatDD) Initiative is a PATH advocacy effort that focuses on prioritizing diarrheal disease within the broader global health arena. Through its website ([www.DefeatDD.org](http://www.DefeatDD.org)), social media channels, and campaigns using a range of advocacy tools, DefeatDD aims to regain attention for diarrheal disease and to unite often-fragmented efforts on specific interventions (vaccines, oral rehydration solution, breastfeeding, zinc treatments, improved hygiene, and safe drinking water) into a coordinated and compelling case for integrated approaches to prevent and control diarrheal disease.

PATH also serves as a core partner of the Rotavirus Organization of Technical Allies (ROTA) Council, a team of scientific authorities who promote the use of rotavirus vaccines as part of a comprehensive approach to addressing diarrheal disease. PATH provides input and support to the ROTA Council's collaborative efforts to supply scientific and technical evidence to key policymakers to accelerate the introduction of rotavirus vaccines in high-burden countries.



[www.path.org](http://www.path.org)

PATH is the leader in global health innovation. An international nonprofit organization, we save lives and improve health, especially among women and children. We accelerate innovation across five platforms—vaccines, drugs, diagnostics, devices, and system and service innovations—that harness our entrepreneurial insight, scientific and public health expertise, and passion for health equity. By mobilizing partners around the world, we take innovation to scale, working alongside countries primarily in Africa and Asia to tackle their greatest health needs. Together, we deliver measurable results that disrupt the cycle of poor health. Learn more at [www.path.org](http://www.path.org).

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