

## A Comprehensive Approach to Rotavirus Vaccines

Each year, an estimated 1.3 million children die from severe, dehydrating diarrhea. Rotavirus is the most common cause of severe diarrhea, accounting for two million hospitalizations and more than 500,000 deaths each year, mostly among children in low-resource countries. It is highly contagious and resilient and, regardless of water quality and available sanitation, nearly every child in the world is at risk of infection. Traditional prevention measures are not enough to limit its impact, and vaccination is the best hope for protecting infants against severe dehydration and death from rotavirus infection. Two commercial rotavirus vaccines exist, but they are not yet widely available in or affordable for low-resource countries. PATH is working to address these gaps by increasing access to and effectiveness of existing commercial vaccines and accelerating the development of safe, effective, and more affordable new vaccines. PATH is also pursuing an advocacy strategy to increase awareness of diarrheal disease and how an array of interventions, including vaccines, can save lives.

Based on data from pivotal studies of the commercial rotavirus vaccines conducted in developing countries by PATH and partners, the World Health Organization recommends global use of rotavirus vaccines. More than 20 countries to date have introduced these vaccines in the public sector, mostly in North America, Latin America, and Europe. The GAVI Alliance, a global health partnership that works to increase access to vaccines, has received a number of applications from countries in the developing world that are interested in introducing the vaccines. PATH continues to partner with global health leaders to provide technical support to countries in Africa and Asia preparing for rotavirus vaccine introduction. In addition, PATH is conducting further studies to identify ways to improve or enhance vaccine performance in low-resource settings to maximize their benefits in countries where the burden is greatest.

Because bringing new rotavirus vaccines to the global market is key to improving affordability and ensuring a sustainable supply, PATH is supporting the development of several promising rotavirus vaccine candidates:

- Since 2001, PATH has been part of a collaborative effort to develop and evaluate the 116E rotavirus vaccine, supporting Bharat Biotech International, Ltd. (BBIL) in India to conduct early-stage clinical trials. Currently, the Government of India's Department of Biotechnology, BBIL, PATH, and the Research Council of Norway are working together to assess 116E in a Phase 3 efficacy study with 6,800 infants at three sites in India.
- Several emerging-country manufacturers have licensed the bovine-human reassortant vaccine (BRV) from the US National Institutes of Health for further development. PATH provides a "shared technology platform" for manufacturers actively developing BRV candidates to access a host of technologies, training, methodologies, and material. Since 2007, PATH has also directly supported China National Biotec Group's Wuhan Institute of Biological Products to prepare for Phase 1 and 2 clinical trials of their BRV candidate. In addition, PATH is working closely with Serum Institute of India, Ltd. to prepare for a Phase 3 efficacy trial of their BRV candidate.
- Since 2008, PATH has partnered with Murdoch Childrens Research Institute (MCRI) in Australia to support their development of the RV3 vaccine candidate, beginning with the production of clinical lots in preparation for their Phase 1, 2, and 2b trials. PATH is currently providing guidance on the design and conduct of their Phase 2b trial and on the development of the production process for RV3 by the Indonesian company BioFarma.
- PATH is also assessing several new approaches to rotavirus vaccines that do not use live, albeit weakened, strains of the virus. In 2010, PATH conducted a landscape analysis of early-stage candidates and identified four that it is currently reviewing further for possible advancement to clinical studies in humans.

Finally, PATH is working at both the global and country levels to pursue an advocacy and policy strategy that integrates information about rotavirus and other enteric diseases within the broader public health priority of diarrheal disease control.



pvs@path.org  
www.path.org

MAILING ADDRESS  
PO Box 900922  
Seattle, WA 98109 USA

STREET ADDRESS  
2201 Westlake Ave.  
Suite 200  
Seattle, WA 98121 USA

PATH is an international nonprofit organization that creates sustainable, culturally relevant solutions, enabling communities worldwide to break longstanding cycles of poor health. By collaborating with diverse public- and private-sector partners, PATH helps provide appropriate health technologies and vital strategies that change the way people think and act. PATH's work improves global health and well-being. For more information, please visit [www.path.org](http://www.path.org)