

# New data on rotavirus vaccine from Mexico and Africa show lifesaving impact in the developing world

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For the first time ever, studies in Mexico and Africa, published today in the *New England Journal of Medicine*, demonstrate a reduction in diarrheal disease deaths following rotavirus vaccine introduction in Mexico and vaccine efficacy among impoverished populations in Malawi and South Africa. Both studies underscore the importance of vaccination in achieving significant reduction of severe rotavirus infections among children in the developing world, where disease impact is greatest. Worldwide, rotavirus is the leading cause of severe diarrhea, which takes the lives of more than 500,000 children under 5 every year - with almost half of these deaths occurring in Africa - and causes the hospitalization of millions more.

The findings from these studies informed the World Health Organization's (WHO) recent recommendation that rotavirus vaccines be included in every nation's immunization program. The recommendation is important for Africa which is hit particularly hard by the disease and places rotavirus vaccines among a comprehensive set of other interventions key to stopping diarrheal disease deaths, including access to clean water, proper sanitation and oral rehydration therapies (ORT), breastfeeding, and vitamin A and zinc supplementation.

In an editorial accompanying the studies' results, Mathuram Santosham, Professor of International Health and Pediatrics at Johns Hopkins University, Baltimore, welcomed these studies for supporting the use of

rotavirus vaccines in the poorest countries of the world. "We now have another powerful weapon to add to our armamentarium to combat diarrheal deaths - rotavirus vaccines," wrote Santosham. "Rotavirus vaccine should be introduced immediately in high mortality areas and it should be used as a trigger to energize diarrhea control programs and improve coverage for all the proven interventions for diarrhea."

In Mexico, which in 2006 was among the first countries in the world to introduce rotavirus vaccine, diarrheal disease death rates dropped during the 2009 rotavirus season by more than 65 percent among children age two and under. This demonstrates real-world impact that is crucial as other countries consider rotavirus vaccine introduction. The Mexico study examined the impact of vaccination on diarrheal deaths in Mexican children between 2008 and 2009 following a phased introduction of the orally administered Rotarix™, manufactured by GlaxoSmithKline Biologicals (GSK).

"Mexico had previously instituted interventions, including improved sanitation, use of oral rehydration, breastfeeding, and vitamin A supplementation, but diarrhea-related deaths during the December-to-May rotavirus season still remained high," said Manish Patel, Medical Epidemiologist, Division of Viral Diseases, National Center for Immunizations and Respiratory Diseases, US Centers for Disease Control and Prevention, and co-author of the Mexico study, Effect of Rotavirus Vaccination on Death from Childhood Diarrhea in Mexico. "The reduction in mortality following vaccine introduction points to the importance of immunization against rotavirus as a primary prevention tool in controlling diarrhea not just in Mexico but around the world."

Other findings from Mexico include:

- Among infants younger than 11 months, the target age for

vaccination, diarrhea deaths fell by more than 40 percent; and

- Among children between the ages of one and two, diarrhea deaths fell almost 30 percent, even though only 10-15 percent of this population was eligible for vaccination. This result indicates that vaccination of susceptible young infants may also protect unimmunized children who live in the same community by reducing the exposure of rotavirus to children.

In South Africa and Malawi, the results of a clinical trial showed that the vaccine significantly reduced severe rotavirus disease - by 61.2 percent - in African infants during the first year of life. The African clinical trial specifically focused on the vaccine's performance among infants in high mortality, low-income settings. More than 4,900 infants were enrolled in a clinical trial examining the efficacy of the Rotarix™ vaccine.

"The efficacy of the vaccine coupled with the high rates of rotavirus incidence and severity in low-resource countries point to the dramatic potential rotavirus vaccines hold toward reducing child mortality among the world's most vulnerable populations," said Shabir Madhi, Co-Director of the South African Medical Research Council at the University of Witwatersrand in Johannesburg and author of the African clinical trial study, *Impact of Human Rotavirus Vaccine on Severe Gastroenteritis in African Infants*. "The vaccine can make a significant impact in global public health if investments are made to bring them to all children, particularly those in the world's poorest countries."

The clinical trial was coordinated and co-funded through a partnership between vaccine manufacturer GlaxoSmithKline Biologicals and the Rotavirus Vaccine Trials Partnership (RVTP)—a collaboration between PATH, the World Health Organization (WHO), and US Centers for Disease Control (CDC), funded by the GAVI Alliance. Clinical research sites in South Africa and Malawi conducted the trials.

"Diarrhea is rarely a life-threatening problem in rich countries, but in the developing world it is a leading cause of death in children," said Tachi Yamada, president of the Global Health Program at the Bill & Melinda Gates Foundation. "The world now has an effective vaccine against rotavirus, with the potential to save hundreds of thousands of lives every year. The next challenge is to ensure that rotavirus vaccines reach all those in need."

The GAVI Alliance has launched efforts to support the introduction of rotavirus vaccines in at least 44 low-income countries by 2015. Global health organizations have issued a call to action on diarrheal disease to advocate for adequate funding for rotavirus vaccines to prevent and treat this major cause of severe diarrheal disease. The [vaccine](#) is an important part of a coordinated approach that combines proven strategies for prevention and treatment of diarrhea, such as oral rehydration therapy, exclusive breastfeeding, [zinc supplementation](#), and improved sanitation to achieve the greatest impact on diarrheal disease morbidity and mortality.

Provided by PATH

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