



**WHO Recommends Global Use of Rotavirus Vaccines**  
*Decision Could Help Protect Millions of Children in Africa and Asia  
from Lethal Diarrheal Disease*

Geneva and Seattle, June 5, 2009 — The World Health Organization has recommended that rotavirus vaccination be included in all national immunization programmes in order to provide protection against a virus that is responsible for more than 500,000 diarrheal deaths and two million hospitalizations annually among children. More than 85 percent of these deaths occur in developing countries in Africa and Asia. This new policy will help ensure access to rotavirus vaccines in the world's poorest countries.

The new recommendation by the WHO's Strategic Advisory Group of Experts (SAGE), extends an earlier recommendation made in 2005 on vaccination in the Americas and Europe, where clinical trials had demonstrated safety and efficacy in low and intermediate mortality populations. New data from clinical trials which evaluated vaccine efficacy in countries with high child mortality has led to the recommendation for global use of the vaccine. This is reported in the *Weekly Epidemiological Review* published on June 5, 2009.

“This is a tremendous milestone in ensuring that vaccines against the most common cause of lethal diarrhea reach the children who need them most,” noted Dr. Thomas Cherian, Coordinator of the Expanded Programme on Immunization, WHO Department of Immunization, Vaccines, and Biologicals.

The GAVI Alliance, vaccine manufacturers, and the public health community made an unprecedented commitment to understand how these vaccines would work in developing-world conditions. The clinical trial, funded in part by GAVI and conducted by PATH, WHO, GlaxoSmithKline (GSK), and research institutions in high-mortality, low-socioeconomic settings of South Africa and Malawi, found that rotavirus vaccine significantly reduced severe diarrhea episodes due to rotavirus.

“This WHO recommendation clears the way for vaccines that will protect children in the developing world from one of the most deadly diseases they face,” said Dr. Tachi Yamada, President of the Global Health Program at the Bill & Melinda Gates Foundation. “We need to act now to deliver vaccines to children in Africa and Asia, where most rotavirus deaths occur.”

In 2006, the GAVI Alliance added rotavirus vaccines to its portfolio of vaccines for which it provides financial support to developing countries, underscoring GAVI's

commitment to reduce the traditional 15- to 20-year lag between the introduction of new vaccines in wealthy countries and their availability in the developing world. Today, WHO's global recommendation paves the way for low-income countries in Africa and Asia to apply to GAVI for introduction of rotavirus vaccines— just three years after new rotavirus vaccines became available in the US, Europe, and Latin America.

“The GAVI Alliance welcomes this exciting recommendation,” said GAVI CEO, Dr. Julian Lob-Levyt. “It represents another important step in our ability to achieve significant impact on under-five deaths in the world's poorest communities and make progress towards the Millennium Development Goals. We are extremely excited about the potential to offer African and Asian countries funding to introduce rotavirus vaccines.”

Because oral vaccines can have variable efficacy in different populations, it was important to demonstrate vaccine performance in high-mortality settings. The studies in Africa were conducted among populations with high infant and child mortality, poor sanitary conditions, high diarrheal disease mortality, and high maternal HIV prevalence.

“The new evidence and the WHO recommendation are major breakthroughs for the health of our children,” said Dr. Oyewale Tomori, Vice Chancellor of Redeemer's University, Nigeria, who has served as Regional Laboratory Coordinator for the World Health Organization (Africa Region). “Too many of our children are dying from rotavirus and other causes of diarrhea. We urgently need these lifesaving vaccines against rotavirus.”

The clinical trial investigators from Malawi and South Africa will present and publish their data on the GSK Rotarix™ vaccine later this summer. Clinical trial sites in Bangladesh and Vietnam—along with sites in Ghana, Mali, and Kenya—evaluated the performance of Merck's rotavirus vaccine, RotaTeq®, and data are expected in Fall 2009. While efficacy data from Asian countries are forthcoming, SAGE recommended rotavirus vaccines for all populations, including Asia, since available evidence indicates that efficacy data can be extrapolated to populations with similar mortality patterns, regardless of geographic location.

Because there are many causes of diarrheal disease, SAGE emphasized the importance of providing rotavirus vaccination in the context of a comprehensive diarrheal disease control strategy, including improvement of water quality, hygiene, and sanitation; provision of oral rehydration solution and zinc supplements; and overall improved case management.

WHO, UNICEF, and other GAVI partners are working together in a new accelerated and integrated approach to combat rotavirus diarrhea and pneumonia, the two biggest vaccine-preventable diseases which together account for more than 35 percent of all child deaths each year, the majority of which are in the developing world.

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**Further information**

African and Asian leaders applaud WHO recommendation on rotavirus vaccines:

<http://www.rotavirus.org/files/who-rotavirus-support-Asia-Africa-leaders.pdf>

Weekly Epidemiological Record: <http://www.who.int/wer/2009/wer8423.pdf>

SAGE: <http://www.who.int/immunization/sage/en/index.html>

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