

EMBARGOED for Release: 18:30 EDT 5 August 2010 / 0:01 GMT 6 August 2010

New evidence on rotavirus vaccines in Africa demonstrates significant protection against the most common deadly Form of childhood diarrhoea

New study shows rotavirus vaccination can save lives in Kenya where diarrhoea is the third leading cause of death among children under five

Geneva and Seattle—Data from new clinical studies examining rotavirus vaccines in developing countries of Africa and Asia, published today in *The Lancet*, contribute to a growing body of evidence of the safety, efficacy, and lifesaving potential of vaccines preventing severe rotavirus-diarrhoea.

According to the World Health Organization (WHO), rotavirus diarrhoea is estimated to have caused more than 500,000 child deaths worldwide in 2004. In Asia and Africa, where more than 85 percent of rotavirus-related deaths occur, prevention through vaccination would have a substantial impact on diarrhoea and child mortality.

“The toll of rotavirus in Sub-Saharan Africa is devastating,” said Dr. Fred Were, national chairman, Kenya Paediatric Association. “Rotavirus vaccines can have a powerful impact in our region, saving the lives of tens of thousands of children each year if they are used widely. WHO has recommended that all countries introduce rotavirus vaccines and now it is time for national governments throughout Africa to make rotavirus vaccines available for all of our children.”

The clinical studies conducted in Africa and Asia examined Merck & Co., Inc.’s orally administered, pentavalent rotavirus vaccine RotaTeq®.

The Kenya Medical Research Institute-Centers for Disease Control and Prevention, served as a clinical research site for the African study, along with facilities in Ghana and Mali. Pooled data from these sites estimated that rotavirus vaccination prevented 64 percent of severe rotavirus in the region during the first year of life, when children are at greatest risk for life-threatening diarrhoea. In Kenya particularly, the vaccine prevented 83.4 percent of severe rotavirus during the first year of life.

Earlier this year, the government of Kenya launched a policy reinforcing the comprehensive prevention and treatment recommendations for diarrhoeal disease outlined by WHO and UNICEF, which include zinc supplementation and oral rehydration solution to treat diarrhoea-related dehydration, as well as rotavirus vaccines to prevent severe, life-threatening diarrhoea.

“Rotavirus vaccination will be needed as part of a package of strategies to improve child survival and to achieve Millennium Development Goal 4,” said Anthony Nelson, professor of pediatrics, Chinese University of Hong Kong, and Roger Glass, director of the Fogarty International Center, US National Institutes of Health, in a commentary accompanying the findings. “Some countries that introduced rotavirus vaccines into their national programs early on have already begun to see tremendous benefit.”

More than 5,000 infants in Ghana, Kenya, and Mali were enrolled in the study to evaluate the efficacy of the rotavirus vaccine in low-income, high-burden settings in Africa. Across the African region, vaccination against rotavirus was found to be 64.2 percent effective in preventing severe rotavirus during the first year of life—remaining consistent with findings from previous clinical studies of rotavirus vaccines in Africa over the same time period. Over the course of the two-year study, vaccine efficacy was nearly 40 percent against severe disease. Though this is lower than efficacy demonstrated in developed-country trials, the findings suggest tens of thousands of lives could be saved each year in Africa, given the high burden of diarrhoea mortality, if the vaccines are widely used.

The Asian clinical study, conducted in Bangladesh and Vietnam, found that rotavirus vaccines reduced severe cases by 51 percent during the first year of life. The vaccine was efficacious against severe rotavirus through nearly two years of life, demonstrating 48.3 percent efficacy. More than 2,000 infants in were enrolled in the first-of-its-kind study in low-income, high-burden settings in Asia.

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“These findings support the WHO’s recommendation for expanding use of rotavirus vaccines into the poorest nations in Asia and Africa, where they can be of most benefit,” said Dr. Jean-Marie Okwo-Bele, director, Immunization, Vaccines and Biologicals, WHO. “Such vaccines have the potential to re-energize diarrhoeal control programs around the globe and make major strides toward stopping one of the leading killers of children.”

In 2009, WHO reviewed the data, along with other studies conducted in developed and developing country settings, and recommended that every country include rotavirus vaccines in its national immunization program. In countries where diarrhoea causes more than 10 percent of death among children aged five years and younger, introduction is strongly recommended. According to WHO estimates, rotavirus claimed more than 7,500 lives in Kenya in 2004. Annually, diarrhoeal disease causes 20 percent of deaths among children under five years of age in the country.

“The evidence is clear—immunization against rotavirus is one of the best ways to protect millions of children from severe, fatal diarrhoea,” said Dr. Tachi Yamada, president, Global Health Program, Bill & Melinda Gates Foundation. “Funders and political leaders must now ensure we can deliver the vaccines to the children who need them most.”

“These studies add further evidence that rotavirus vaccines are powerful weapons in saving the lives of the world’s most vulnerable children. Yet because of insufficient funding, these vaccines are only included in the routine immunization programs in a handful of the world’s poorest countries,” said Julian Lob-Levyt, chief executive officer of the GAVI Alliance, which is campaigning to raise funds to reach its target of supporting the introduction of rotavirus vaccines in at least 44 low-income countries by 2015. “It is in the lowest-income countries, where access to healthcare is most limited and the disease burden heaviest, that these vaccines are most desperately needed.”

Where rotavirus vaccines have been introduced—both in developed and developing countries—studies show major reductions in rotavirus hospitalizations and deaths. Recent findings from Mexico indicate that following vaccine introduction in 2006, diarrhoea-related deaths dropped during the 2009 rotavirus season by more than 65 percent among children aged two years and younger. In Nicaragua, the first developing country to introduce rotavirus vaccine, the vaccine prevented 60 percent of severe cases and cut hospital admissions and emergency room visits in half. More broadly, researchers also are finding that vaccination may indirectly benefit unvaccinated children by limiting the number of circulating infections, suggesting a herd immunity effect, in which the potential impact of vaccination extends beyond that predicted by efficacy studies.

This expanding evidence base emphasizes the important role rotavirus vaccines can fill within an integrated set of interventions critical to preventing and treating the many causes of diarrhoea. Proven, complementary interventions to address the other causes of diarrhoea include access to clean, safe water, improved hygiene, and sanitation. Oral rehydration solution, breastfeeding, vitamin A, and zinc supplementation are proven and effective diarrhoea treatments. As part of its recommendation, WHO encouraged delivery of rotavirus vaccines within a comprehensive approach that utilizes all the tools available against diarrhoeal disease.

The clinical studies were coordinated and co-funded through a partnership between vaccine manufacturer Merck and the Rotavirus Vaccine Program—a collaboration between PATH, WHO, and the US Centers for Disease Control and Prevention, funded by the GAVI Alliance.

“The WHO called for these studies to determine how rotavirus vaccines would perform in the places with the greatest need today,” said Dr. Kathleen Neuzil, senior clinical advisor for vaccines, PATH. “Oral vaccines are known to perform differently in different settings, and the latest findings reinforce that rotavirus vaccines can have a major public health impact in Africa and Asia—much larger than we saw in the United States and Europe. The disease burden is just that much greater.”

The GAVI Alliance has undertaken a major campaign urging donors to provide sufficient funds to support rotavirus vaccine introduction. It will hold a funding meeting on October 6, following the September summit in New York on progress towards achieving the Millennium Development Goals. GAVI will underline that achieving Millennium Development Goal 4 will be impossible without widespread immunization against rotavirus and pneumococcal disease.

To request a copy of the study articles, please contact Tony Kirby at Tony.Kirby@Lancet.com. For more on rotavirus, please view: <http://www.path.org/media/common-disease-promising-solution.php>. Go to www.defeatDD.org to learn

more about the tools available to stop diarrhoea. To view this press release online, please visit <http://www.path.org/news/pr100805-rotavirus-evidence-Kenya.php>.

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