

News Release

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MULTIMEDIA ALERT: Video of Dr. Jacobson is available on the <u>Mayo Clinic News Network.</u>

For Immediate Release

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Mayo Clinic: Rotavirus Vaccine Given to Newborns in Africa is Effective

Vaccine may save thousands of lives annually

ROCHESTER, Minn. — <u>Mayo Clinic</u> and other researchers have shown that a vaccine given to newborns is at least 60 percent effective against rotavirus in Ghana. <u>Rotavirus</u> causes fever, vomiting and diarrhea, which in infants can cause severe dehydration. In developed nations, the condition often results in an emergency room visit or an occasional hospitalization, but is rarely fatal. In developing countries, however, rotavirus-related illness causes approximately 500,000 deaths per year. The findings appear this week in the <u>Journal of Infectious Diseases</u>.

Currently, there is no neonatal rotavirus vaccine available and infants do not receive their first dose of a rotavirus vaccine until they are approximately 2 months old, leaving younger infants at serious risk of rotavirus infection. In the study, the first of two doses was administered within the first 29 days of life (neonatal dosing), and the second dose before 60 days of age.

"For the first time in a large-scale study, we have demonstrated that protection against rotavirus gastroenteritis can be achieved earlier in life," says co-author and pediatrician <u>Robert M. Jacobson, M.D.</u>, of the <u>Mayo Clinic Children's Center.</u> "The next step should be additional studies in neonates to provide earlier protection against life-threatening rotavirus diarrhea. The rotavirus vaccines used in America and Europe are administered later — when babies are 2 to 4 months old — but younger infants also contract the virus in the first two months of life."

Two vaccines serve as standard protection in developed countries, but are not especially effective in African or Asian countries, says Dr. Jacobson. Besides, he says, protection is also needed from birth due to the widespread risk of the virus.

"There is a huge protection gap right now in the first months of life," says Dr. Jacobson. "This study points to a clear and practical solution."

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In Ghana, 998 newborns were selected for the randomized, double-blind, placebo trial from two of the poorest parts of the country. Half received the oral reassortant rotavirus tetravalent vaccine (RRV-TV) in the first two months of life, half received a placebo. Results showed a significant response in parameters of efficacy, safety and immune impact of the vaccine.

The study was funded by the <u>International Medical Foundation</u>. Co-authors include George Armah, Ph.D., University of Ghana; Albert Kapikian, M.D., National Institutes of Health; Timo Vesikari, M.D., Ph.D., University of Tampere, Finland; Nigel Cunliffe, M.D., Ph.D., University of Liverpool, U.K.; D. Bruce Burlington, M.D., Gaithersburg, Md.; and Leonard Ruiz Jr., Ph.D., International Medica Foundation, Rochester.

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