

Vaccine confers long-term protection against cholera

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A clinical study published in the *Lancet Infectious Diseases* shows for the first time that an oral cholera vaccine (ShancholTM) provides sustained protection against cholera in humans for up to five years. The study showed the vaccine had a protective efficacy of 65% over a five-year period. The landmark study was a collaboration between scientists from the International Vaccine Institute (IVI) an international organization based in Seoul, and the National Institute of Cholera and Enteric Diseases, (NICED), an institute under the Indian Council of Medical Research (ICMR) of India's Ministry of Health and Family Welfare.

Cholera is a potentially deadly infectious disease that causes profuse, dehydrating diarrhea in children and adults. It is spread through ingestion of contaminated water or food and is commonly found in developing countries that have limited access to clean water and sanitation. There are about 2.8 million cases and 91,000 deaths each year from cholera, mostly in Africa and South Asia.

The oral cholera vaccine (OCV) contains strains of killed cholera bacteria that have been previously shown to be safe in humans and is administered through a two-dose regimen. The vaccine was specifically developed for use in developing countries through a public-private partnership led by IVI with support from the Republic of Korea, Sweden, and the Bill & Melinda Gates Foundation. The partnership involved Shantha Biotechnics (part of the Sanofi group) based in Hyderabad, India; VaBiotech, a state-owned vaccine manufacturer located in Hanoi, Vietnam; and the University of Gothenburg in Sweden.



The vaccine, which is produced by Shantha Biotechnics in India and licensed as ShancholTM, was prequalified by the World Health Organization (WHO) in September 2011.

A Phase III clinical trial was jointly conducted by IVI and NICED in Kolkata, India in 2006 to assess the efficacy of the vaccine. More than 30,000 volunteers from one year old and up were enrolled in the study. A placebo group with a similar number of volunteers was also included.

Previous results from this study had shown that the vaccine provided 66% protection over a three-year period, and the new result shows that such protection is sustained for two additional years. Since vaccine protection does not wane over time, the study has important practical implications in terms of vaccination cost and vaccination strategies in developing countries.

"The study results suggest that this vaccine will protect persons at risk of severe cholera for five years," said Dr. Thomas F. Wierzba, Deputy Director General of Vaccine Development & Delivery at IVI and coauthor of the study. "With protection sustained for five years, we will be able to provide greater benefits to the poor at reduced costs."

Furthermore, the study confirms the use of the vaccine as a powerful and effective tool to prevent and control cholera. "The vaccine is safe, easy to administer, cost effective, and provides protection for up to five years," said Dr. Christian Loucq, IVI's Director General. "The use of the vaccine, combined with other control measures, will make it more feasible for <u>developing countries</u> afflicted by <u>cholera</u> to control a disease that plagues millions of people every year."

The <u>vaccine</u> has already been used to combat outbreaks in Haiti and Guinea, and has been deployed for large-scale use in Bangladesh and Odisha state, India.



Provided by International Vaccine Institute

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