



Meningitis
Vaccine
Project



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IMPROVED MENINGITIS VACCINE FOR AFRICA COULD SIGNAL EVENTUAL END TO DEADLY SCOURGE

Successful Vaccine Trial Promises Long-Term, Low-Cost Protection From Epidemics in Africa

GENEVA – The Meningitis Vaccine Project (MVP) today released new data on the performance of a meningitis vaccine in West African children, suggesting that the new vaccine—expected to sell initially for 40 US cents a dose—will be much more effective in protecting African children and their communities than any vaccine currently on the market in the region.

MVP, a partnership between the World Health Organization (WHO) and the Seattle-based nonprofit, PATH, is collaborating with a vaccine producer, Serum Institute of India Limited (SIIL), to produce the new vaccine against serogroup A *Neisseria meningitidis* (meningococcus). The preliminary results of their study, a Phase 2 vaccine trial, reveal that the vaccine could eventually slash the incidence of epidemics in the “meningitis belt,” as 21 affected nations of sub-Saharan Africa are collectively known. The vaccine is expected to block infection by the serogroup A meningococcus, and therefore extend protection to the entire population, including the unvaccinated, a phenomenon known as “herd immunity.”

“When it becomes part of the public health arsenal, this vaccine will make a real difference in Africa,” said Dr. F. Marc LaForce, MVP director. “The vaccine will allow elimination of the meningococcal epidemics that have afflicted the continent for more than 100 years.”

The new meningococcal conjugate vaccine trial, in 12- to 23-month-olds in Mali and The Gambia, shows that the vaccine was safe, and that it produced antibody levels almost 20 times higher than those obtained with the marketed polysaccharide (un-conjugated) vaccine. This means that protection from serogroup A meningococcal meningitis is expected to last for several years.

“This important study brings real hope that the lives of thousands of children, teenagers, and young adults will be saved by immunization and that widespread suffering, sickness and socioeconomic disruption can be avoided,” said Dr. Margaret Chan, Director-General of the World Health Organization.

“Elimination of these epidemics with wide use of the meningococcal A conjugate vaccine is now a likely possibility over the next few years,” said LaForce. “People between the ages of 1 and 29 years of age will be protected by receiving a single dose in large mass vaccination campaigns. The large campaigns are expected to create herd immunity, and eventually, elimination of the disease.”

As a result of the encouraging preliminary findings of this Phase 2 clinical study, SIIL and MVP will proceed with a Phase 2/3 study where the vaccine will be tested in 2- to 29-year-olds—the population that will be mostly targeted by mass vaccination campaigns. Testing will take place in Mali, The Gambia, and at least one other African country. An additional clinical study is planned for this summer in India, where the vaccine will be licensed.

“Serum Institute of India is dedicated to developing safe, effective, and affordable products for the poorest countries in the world,” said Dr. Cyrus Poonawalla, Chairman of SIIL. “These results confirm and extend the observations made last year in our Phase 1 study in India. The new conjugate vaccine has an excellent safety profile in young children, and it is immunologically superior to the polysaccharide vaccine.”

A conjugate vaccine joins (or “conjugates”) sugars from the meningococcal bacterium with a protein, which in turn stimulates immune cells. These cells then produce antibodies to meningitis, protecting the individual from infection. A total of 600 toddlers participated in the Phase 2 study. They were enrolled at two clinical sites in Africa: Center for Vaccine Development (CVD)-Mali and the Medical Research Council (MRC) Laboratories in The Gambia. Dr. Brown Okoko, principal investigator at the MRC site in Basse, said, “The clinical teams at MRC and CVD-Mali identify with the vision, mission, and mandate of the Meningitis Vaccine Project. We are all highly motivated and very proud to be able to contribute to the development of a vaccine that is critically needed in Africa.”

Dr. Samba Sow, principal investigator at CVD-Mali, said, “Some of the families who participated in the study have lost several members of their family to meningococcal meningitis. Those who have not been directly affected know the terrible impact that the disease has on the community. There is a lot of support for the clinical study and the new vaccine in the Bamako community.”

iGATE Clinical Research International, a contract research company in Mumbai, India, is providing data management services.

“The plans for the future are quite ambitious,” said LaForce. “With the successful completion of the Phase 2 study, and once funding is secured, we plan to do a demonstration study next year in a hyperendemic country where we will take the vaccine to public-health scale by immunizing the entire population between the ages of 1 and 29. If all continues to go well in testing and during the demonstration study, the new vaccine, which will be priced at about 40 cents per dose, could be introduced in Africa within the next two to three years.”

Meningitis is an infection of the meninges, the thin lining that surrounds the brain and spinal cord. It is one of the world's most dreaded infectious diseases. Even with antibiotic treatment, at least 10 percent of patients die, with up to 20 percent left with permanent problems, such as mental retardation, deafness, epilepsy, or necrosis leading to limb amputation.

The most prominent groups of meningococci are A, B, C, Y, and W135. While groups A, B, and C are responsible for the majority of cases worldwide, group A causes deadly, explosive epidemics every 8 to 10 years predominantly in what is known as the African “meningitis belt,” an area that stretches from Senegal and The Gambia in the West to Ethiopia in the East. The belt has an at-risk

population of about 430 million. The largest epidemic wave ever recorded in history swept across the entire region in 1996–1997, causing over 250,000 cases and 25,000 deaths.

Africa has been relatively spared in recent years, but last year's 41,526 reported cases and the 47,925 cases reported from 1 January to 6 May 2007 bring the fear that a new epidemic wave may have begun in sub-Saharan Africa.

Earlier this year, as an epidemic was raging in Burkina Faso, MVP partnered with Rockhopper TV to produce a documentary on meningococcal meningitis for BBC's *Kill or Cure* series. The film offers a poignant and revealing account of the devastating impact meningitis epidemics have on individuals, families, and communities. The film also takes viewers to Mali where the new vaccine is being tested. The film will be broadcast on BBC World June 8–13, and later available on DVD and the MVP website.

The Meningitis Vaccine Project (MVP - <http://www.meningvax.org>) is a partnership between the World Health Organization (WHO) and PATH. It was established in May 2001 through a US\$70 million seed grant from the Bill & Melinda Gates Foundation. The mission of MVP is to eliminate epidemic meningitis as a public health problem in sub-Saharan Africa through the development, testing, introduction, and widespread use of conjugate meningococcal vaccines.

The World Health Organization (WHO - <http://www.who.int>), the United Nations' specialized agency for health, was established on 7 April 1948. WHO's objective, as set out in its Constitution, is the attainment by all peoples of the highest possible level of health, defined as a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity.

PATH (<http://www.path.org>) is an international, nonprofit organization that creates sustainable, culturally relevant solutions, enabling communities worldwide to break longstanding cycles of poor health. By collaborating with diverse public- and private-sector partners, PATH helps provide appropriate health technologies and vital strategies that change the way people think and act.

Created in 1967, **Serum Institute of India Limited** (SIIL - <http://www.seruminstitute.com>) has emerged as a top supplier of quality vaccines and the world's largest manufacturer of measles vaccine and diphtheria-tetanus-pertussis (DTP) vaccines. Currently, SIIL products are being exported to 150 countries. At least one of two children born throughout the world is administered a measles or DTP vaccine manufactured by SIIL.

The Centre pour le Développement des Vaccins-Mali (Center for Vaccine Development-Mali—CVD-Mali) was created in 2000 under a cooperative agreement with the Malian Ministry of Health and the University of Maryland Center for Vaccine Development. CVD-Mali is headquartered at the Centre National d'Appui à la Lutte contre la Maladie (formerly Institut Marchoux) in Bamako, and it is a division of the Ministry of Health in Mali. The focus of CVD-Mali is to conduct research and provide training in vaccinology and tropical diseases in the country.

The Medical Research Council (MRC) Laboratories (<http://www.mrc.gm>), The Gambia, represents the United Kingdom's major public investment in medical research in developing countries. The unit has been established 60 years ago and works closely with the government of The Gambia. The MRC Laboratories has a long track record of research on vaccines for infectious diseases. Major strengths of the unit include a multi-disciplinary approach, combining field, clinical, and laboratory facilities and excellent relationships with the community.

iGATE Clinical Research International (iCRI - <http://www.igate.com/icri>) is a full service contract research company with offices in India and the United States. iGATE CRI offers clinical trial management services, including clinical operations, central laboratory services, data management and biostatistics, pharmacovigilance, pharmacy and regulatory support, providing India-specific consultancy services to global clients.

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