Accelerating Vaccine Development to Save Lives

SITUATION

Malaria is a parasitic infection transmitted by mosquitoes. Over one-third of the world's population is at risk, with up to 500 million cases occurring every year. The resulting disease can damage the nervous system, kidney, and liver; severe cases can quickly lead to death. Most of the 1 – 2.7 million deaths from malaria are of children in Africa under the age of five.

> "The malaria epidemic is like loading up seven Boeing 747 airliners with people every day, then deliberately crashing them into Mt. Kilimanjaro." Dr. Wen Kilama, African Malaria Network (AMANET)

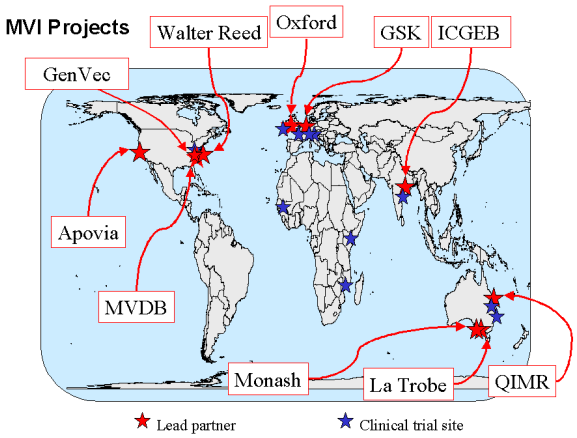
Consistent use of effective insecticides, insecticide-treated nets, and malaria drugs saves lives. Ending deaths from malaria will require new interventions, such as malaria vaccines. Just as it was necessary to use vaccines in addition to effective drugs to control the two most common kinds of meningitis in the U.S., vaccines will be needed as part of an effective malaria control strategy in Africa. Vaccines against common childhood diseases such as polio and measles already save the lives of three to four million children every year. And immunization is one of the most cost effective health interventions available.

HISTORY

PATH's Malaria Vaccine Initiative (MVI) is a highly focused vaccine development program launched in 1999 with a $50 million grant from the Bill & Melinda Gates Foundation. MVI was created with the recognition that while a malaria vaccine is urgently needed, traditional market forces are insufficient to prompt the substantial investment necessary to aggressively develop vaccines against a disease that primarily affects people in developing countries. In September 2003, the Gates Foundation announced an additional $100 million investment in MVI.

MISSION AND VISION

MVI seeks to accelerate the development of promising malaria vaccines and ensure their availability and accessibility in the developing world. MVI's vision is a world in which people no longer suffer or die from malaria.



PROGRESS

MVI has ten vaccine development partnerships that span five continents. To date, MVI's projects have eight vaccine formulations in the vial, with seven of those in clinical trials and additional trials being conducted with combinations. Clinical trials of two of the vaccines have taken place in Africa. Additional trials are expected to begin over the next several months.

PATH
A catalyst for global health

CLINICAL TRIALS IN AFRICA

Pediatric clinical trials in Mozambique and The Gambia
MVI is working with GlaxoSmithKline Biologicals (GSK), the Hospital Clinic of the University of Barcelona, Centro de Investigaçao em Saude de Manhiça (CISM), and Mozambique's Ministry of Health to evaluate GSK's advanced malaria vaccine candidate in children. The vaccine was previously shown to be safe and efficacious in clinical trials with adults in The Gambia and Kenya. Phase 1 trials in The Gambia (with the Medical Research Council) and Mozambique showed the vaccine to be safe in children. A Phase 2 trial in Mozambique confirmed the vaccine's safety and demonstrated that the vaccine can protect children against malaria.

Clinical trial in Kenya
MVI has partnered with the Walter Reed Army Institute of Research (WRAIR), the Kenya Medical Research Institute (KEMRI), GSK, and the U.S. Agency for International Development (USAID) to evaluate WRAIR's MSP1 vaccine candidate in Kenya. The vaccine was previously evaluated for safety in U.S. civilian and military volunteers. Following favorable results in a Phase 1 adult trial in Kenya, the vaccine's safety has now been evaluated in children, with results expected by the end of 2004.

CLINICAL TRIALS IN DEVELOPED COUNTRIES

Europe and United States
Apovia Inc., a San Diego and Germany-based biotechnology company, has conducted Phase 1 clinical trials in Germany, the U.S., and U.K. of three different versions of its candidate vaccine, MalariVax.

United States
MVI has partnered with NIAID's Malaria Vaccine Development Branch (MVDB) to accelerate process development and pre-clinical testing of several blood- and sexual-stage malaria vaccine candidates. The AMA-1 candidate and two versions of MSP-1[42] are being evaluated in Phase 1 clinical trials in the U.S.

United Kingdom
The partnership with the University of Oxford and Oxxon Pharmaccines has developed and is now evaluating in human volunteers a series of malaria vaccines based on Oxxon's "prime-boost" technology.

DEVELOPMENT AND MANUFACTURING

Australia
MVI helped develop three innovative partnerships in Australia—Monash University and Progen Industries; Queensland Institute for Medical Research, Cooperative Research Centre for Vaccine Technology (CRC-VT), and Progen Industries; and LaTrobe University, CRC-VT, and GroPep Ltd. The partners are moving forward five vaccine constructs designed to reduce the severity of malaria in children. The current focus is to optimize the formulations and devise methods for cGMP manufacture before taking them into clinical trials.

India
MVI is working with the International Centre for Genetic Engineering and Biotechnology (ICGEB) in New Delhi, India, to develop a vaccine against *Plasmodium vivax*. This development effort includes Bharat Biotech International Ltd. (Hyderabad), which will manufacture the vaccine under cGMP for pre-clinical testing followed by initial safety trials in adults.

United States
MVI's newest vaccine development partnership is with GenVec, Inc., and the U.S. Naval Medical Research Center to develop and test multivalent, multi-stage malaria vaccines using GenVec's adenovirus vector technology.