

The PATH Malaria Vaccine Initiative

The PATH Malaria Vaccine Initiative (MVI) is a vaccine development program of PATH, a global health nonprofit organization. Established in 1999 and funded primarily by the Bill & Melinda Gates Foundation, MVI works to accelerate the development of malaria vaccines and to ensure their availability and accessibility in the developing world. MVI's vision is a world free from malaria.

Situation

Malaria is a parasitic infection transmitted by mosquitoes. More than one-third of the world's population is at risk of malaria, with about 250 million cases occurring every year. More than 90 percent of these cases are caused by *Plasmodium falciparum*, the most destructive malaria parasite that is found mainly in Africa. Malaria accounts for 40 percent of Africa's public health expenditures and costs that region as much as \$12 billion annually. The disease can damage the nervous system, kidney, and liver, and severe cases can quickly lead to death. Most of the nearly one million annual deaths from malaria are among children in Africa under the age of five years. A malaria vaccine is desperately needed to help prevent these deaths.

While consistent use of effective insecticides, insecticide-treated nets, and malaria drugs saves lives, further reducing the impact of malaria will require additional interventions, such as vaccines. Immunization is one of the most effective and cost-effective health interventions available. Just as it was necessary to use vaccines to control polio and smallpox around the world, vaccines are needed—along with other tools—for an effective malaria-control strategy in Africa and other malaria-endemic regions. Vaccines against common childhood diseases such as polio and measles already save the lives of 3 million to 4 million children every year.

History of MVI

MVI was founded on the premise that while promising vaccine candidates existed, they required assistance to get out of the laboratory and on a path toward clinical trials. Scientists had long demonstrated that immunization against malaria was theoretically possible. However, efforts in this direction were hampered by financial hurdles and the technical complexities of developing any vaccine against a parasite.

When MVI was created, several academic and governmental organizations and pharmaceutical companies had been working on approaches to developing malaria vaccines with the potential to have an impact on malaria. MVI began providing funds as well as logistical and technical support to propel some of these candidates into clinical development.

Progress

Today, MVI maintains a diverse portfolio of preclinical, early clinical, and at least one advanced clinical project. In 2009, four MVI-supported vaccine concepts are under clinical development, including GlaxoSmithKline Biologicals' (GSK Bio) RTS,S, now in its final stage of development. MVI, GSK Bio, and African partners have launched a large-scale Phase 3 trial of RTS,S at sites in seven African countries. If all goes well, RTS,S will be submitted to regulatory authorities and become available for use.

MVI has realigned its research and development (R&D) strategy and further diversified its portfolio to support the long-term goal of eradicating malaria. Thus, in addition to approaches that build on the success of RTS,S, MVI's range of vaccine approaches now includes those that seek to block malaria transmission and those that use weakened, whole parasites to protect against disease. To further support efforts to eradicate the disease, MVI also is increasing its focus on *P. vivax*, the parasite that causes a less severe—but more widespread—form of malaria than *P. falciparum*.

Most new projects come to MVI as preclinical feasibility studies, with only a limited number advancing to full portfolio programs on a clinical track. With 20 feasibility studies underway in 2009, this approach is an effective way to replenish MVI's portfolio and maximize the program's potential for success.

In addition to its direct support for vaccine development, MVI works in a number of other areas. For instance, MVI gives high priority to the development of evaluation technologies to assess the potential efficacy of vaccine components. MVI also works to increase the flow of resources to the field, to define acceptable vaccine product characteristics, to ensure the availability of vaccines once licensed, and to identify the information decision-makers want prior to introducing a vaccine. To accomplish all of this, MVI works closely with many partners, including universities, corporations, intergovernmental organizations, and US Government agencies.

The future of malaria vaccine development is very promising. Despite much progress, however, more resources are still needed for R&D. A recent study by the Australia-based George Institute for International Health showed that in 2007, global spending on malaria vaccine R&D represented about 3.5 percent of the world's total R&D investments in neglected diseases, which is a small fraction of investments in health R&D overall. To build on MVI's successes and reach the goal of having a highly effective malaria vaccine in use by 2025, the world needs many more partners and funders at the table.

THE PATH MALARIA VACCINE INITIATIVE (MVI) is a global program established at PATH through an initial grant from the Bill & Melinda Gates Foundation. MVI's mission is to accelerate the development of malaria vaccines and ensure their availability and accessibility in the developing world. MVI's vision is a world free from malaria. For more information, please visit www.malariavaccine.org.

PATH is an international, nonprofit organization that creates sustainable, culturally relevant solutions that enable 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. PATH's work improves global health and well-being. For more information, please visit www.path.org.