

Preparing for a Future Malaria Vaccine in Africa: The Malaria Vaccine Decision-Making Framework

The PATH Malaria Vaccine Initiative (MVI) and the World Health Organization (WHO) have worked with the health ministries of several African countries to develop a tool that will facilitate timely and informed decisions about malaria vaccine introduction into health systems in Africa. Known as the Malaria Vaccine Decision-Making Framework, this tool represents the kind of collaboration and preparation that will help countries avoid the delays seen in introducing lifesaving interventions in Africa.

MVI and WHO launched the Malaria Vaccine Decision-Making Framework process in 2006 with support from the US Agency for International Development and the Bill & Melinda Gates Foundation. The process has involved working with African ministries of health to identify the information that countries need to make decisions regarding the appropriate use of a malaria vaccine as soon as the first is available. Using the WHO guidelines on introduction of new vaccines¹ as a basis, MVI and WHO worked with countries to develop a framework that maps the data and processes required for national leaders to make informed decisions about future malaria vaccine use.

The Potential for Timely Decision-Making

In the past, slow decision making has resulted in a delay between the availability of life-saving interventions and their use in developing-country health systems. In order to avoid the traditional gap, countries and their partners must begin planning now. The most advanced malaria vaccine candidate—GlaxoSmithKline Biologicals' RTS,S—could be available for licensure as early as 2011. By developing a framework to aid decision-making, countries can reduce this time lag for a malaria vaccine and ensure that the intervention is implemented as soon after licensure as possible. The framework can help countries identify their information needs early so that leaders are prepared to make timely and informed decisions.

The Decision-Making Framework

The framework maps **data** and **processes** according to when they would be needed by countries, relative to the timeline for vaccine licensure. The framework accounts for data on:

- National malaria disease burden.
- Impact of other malaria interventions.
- Impact of the future malaria vaccine.
- Economic and financial issues.
- Efficacy, quality, and safety of the future vaccine.
- Programmatic considerations.
- Sociocultural issues.

Processes such as those required for regulatory review of a malaria vaccine also are included. Both data and processes are identified as generated at either the *national* or the *global* levels and are defined as *required* or *not required* in order for a decision to be made.

Progress to Date

Work began in January 2006 on a generic decision-making framework that could be adapted to a specific country's needs. The Minister of Health of Benin, in partnership with MVI and WHO, hosted a workshop where African leaders of malaria and immunization programs and other development partners created the generic tool to aid decision-making. MVI and WHO then consulted with stakeholders from six African countries—Tanzania, Kenya, Gabon, Mozambique, Mali, and Ghana—to adapt the framework to reflect the distinct circumstances of respective health systems. These country consultations engaged representatives from a range of constituencies, including from ministries of health, planning, and finance; WHO, the United Nations Children's Fund, bilateral development partners; malaria scientists; and nongovernmental organizations. Each meeting generated a country-specific decision-making framework, as well as near-term plans to begin working on the framework.

Next Steps

The six country-specific frameworks have since been harmonized and a draft Regional Malaria Vaccine Decision-Making Framework that can be used in any African country has been created. The regional framework will be presented at subregional meeting in Africa in early 2008. The meeting will include a cross-section of the 2006 country meeting participants as well as additional senior decision-makers from the region. The meeting will seek endorsement of the regional framework as a common tool to aid decisions on the possible introduction of future malaria vaccines in African countries. Participants at the meeting will also develop a plan for implementing the regional framework across Africa, including in countries that were not part of the 2006 consultations. MVI and WHO are also working to engage additional African countries in the process to prepare them for making timely decisions on future malaria vaccine use.

For more information about the Malaria Vaccine Decision-Making Framework, please visit www.malvacdecision.net.

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The PATH Malaria Vaccine Initiative (MVI) is a global program established at PATH through an initial grant of \$50 million 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.