

First malaria vaccine in Africa: A potential new tool for child health and improved malaria control

Every year, malaria claims the lives of more than 400 000 people. Tens of millions more fall ill from a disease that is preventable and treatable. Children under the age of five in sub-Saharan Africa are especially vulnerable, accounting for about two thirds of all global deaths due to malaria.

In recent years, African countries have made tremendous progress in the fight against malaria using core disease-cutting tools such as insecticide-treated mosquito nets, indoor spraying with insecticides and antimalarial medicines. (See page 3: *Proven measures to fight malaria.*)

But in some areas where these approaches have been adopted, malaria illness and death remain stubbornly high. New and complementary tools are needed to further drive down the disease burden with a view to achieving – ultimately – the vision of a world free of malaria.

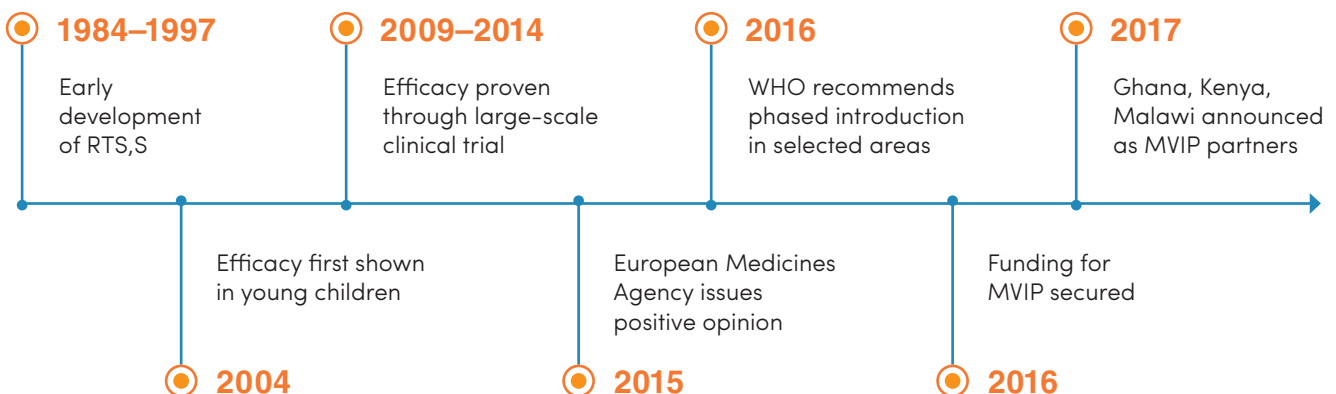
Today, a first-generation vaccine known as RTS,S/AS01 (RTS,S) has the potential to strengthen efforts to control malaria in Africa and save tens of thousands more young lives.

A NEW TOOL WITH PROMISE FOR AFRICA

RTS,S acts against *Plasmodium falciparum*, the most deadly malaria parasite globally and the most prevalent in Africa. The vaccine provides partial protection against malaria among young African children, the population most affected by the disease. Rigorous clinical testing in seven African countries has shown its potential to boost malaria prevention and save lives. (See Figure 1: *Proven results.*)

RTS,S was developed over three decades by GSK, including through a collaboration, begun in 2001, with PATH's Malaria Vaccine Initiative (PATH/MVI) and a network of African research centres.

THE RTS,S JOURNEY: KEY MILESTONES



THE RTS,S MALARIA VACCINE BOASTS A SERIES OF “FIRSTS”

FIRST vaccine to prevent malaria among children

RTS,S is the first and, to date, the only vaccine to show partial protection against malaria in young children. Among children who received four doses in a large-scale clinical trial, the vaccine prevented approximately 4 in 10 cases of malaria and 3 in 10 cases of life-threatening severe malaria over a four-year period.

FIRST malaria vaccine to receive a positive review by a stringent regulatory agency

In July 2015, the European Medicines Agency (EMA) issued a positive scientific opinion of RTS,S, stating that the benefits of the vaccine in preventing malaria outweigh potential risks. The National Regulatory Authorities of Ghana, Kenya and Malawi authorized the RTS,S vaccine for use in pilot areas in May 2018.

FIRST malaria vaccine recommended by global experts for pilot introduction in Africa

Following the EMA decision, and after a thorough review of the clinical trial results, WHO’s top advisory committees for malaria and for immunization – the Strategic Advisory Group of Experts (SAGE) on Immunization and the Malaria Policy Advisory Committee (MPAC) – jointly called in October 2015 for pilot implementation of the vaccine in three to five settings in sub-Saharan Africa.

The RTS,S vaccine in Africa:

4 in 10

malaria cases prevented with 4 doses over 4 years of follow-up

FIRST vaccine recommended by WHO for phased introduction in selected areas of Africa

WHO officially adopted the SAGE/MPAC recommendation in January 2016, recognizing the considerable public health potential of the vaccine while also acknowledging the need for further evaluation before considering its wide-scale deployment.

FIRST malaria vaccine to reach children in Africa through routine immunization in selected areas

Ghana, Kenya, and Malawi will provide the malaria vaccine to young children in selected areas through everyday, public health services. The vaccine will be evaluated for use as a complementary malaria control tool that could be added to (and not replace) the core package of existing preventive, diagnostic and treatment measures.

PROVEN RESULTS

Children receiving four doses of RTS,S experienced significant reductions in malaria and malaria-related complications, in comparison with those who did not receive RTS,S.

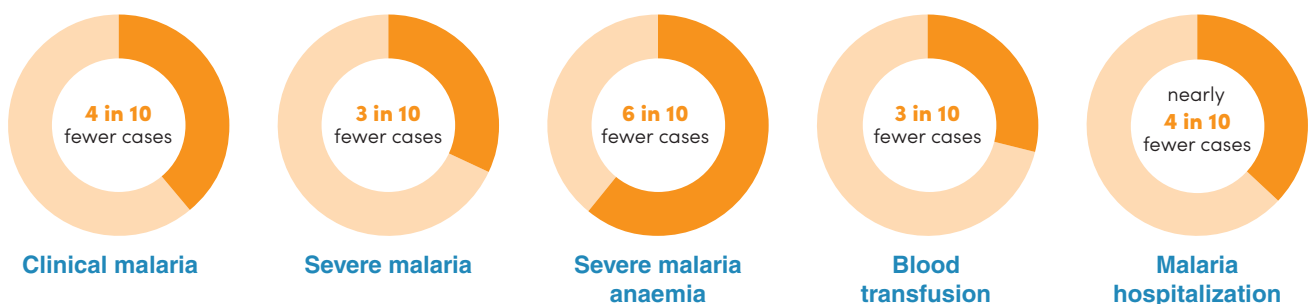


FIGURE 1. Between 2009 and 2014, RTS,S underwent rigorous testing through a large-scale Phase 3 trial. The results were promising: among children aged 5–17 months, the vaccine prevented approximately 4 in 10 cases of malaria (39%). It also prevented about 3 in 10 (29%) cases of severe malaria, a major child killer. Significant reductions were also seen in overall hospital admissions and in the need for blood transfusions, which are required to treat life-threatening severe malaria anaemia. These benefits were in addition to those already seen through the use of LLINs, prompt diagnosis, and effective antimalarial treatment.

PROVEN MEASURES TO FIGHT MALARIA

The WHO-recommended package of tools to fight malaria includes: long-lasting insecticidal nets (LLINs), indoor residual spraying with insecticides, preventive treatment for infants and during pregnancy, prompt diagnostic testing, and treatment of confirmed cases with effective antimalarial medicines. In the Sahel, a sub-Saharan region of Africa, seasonal malaria chemoprevention is recommended in areas with highly seasonal malaria transmission. Deployment of these tools has already dramatically lowered the malaria disease burden in many African settings. The disease burden can be further lowered through the continued scale-up of existing control measures and the addition of innovative tools such as the malaria vaccine.

THE MALARIA VACCINE IMPLEMENTATION PROGRAMME

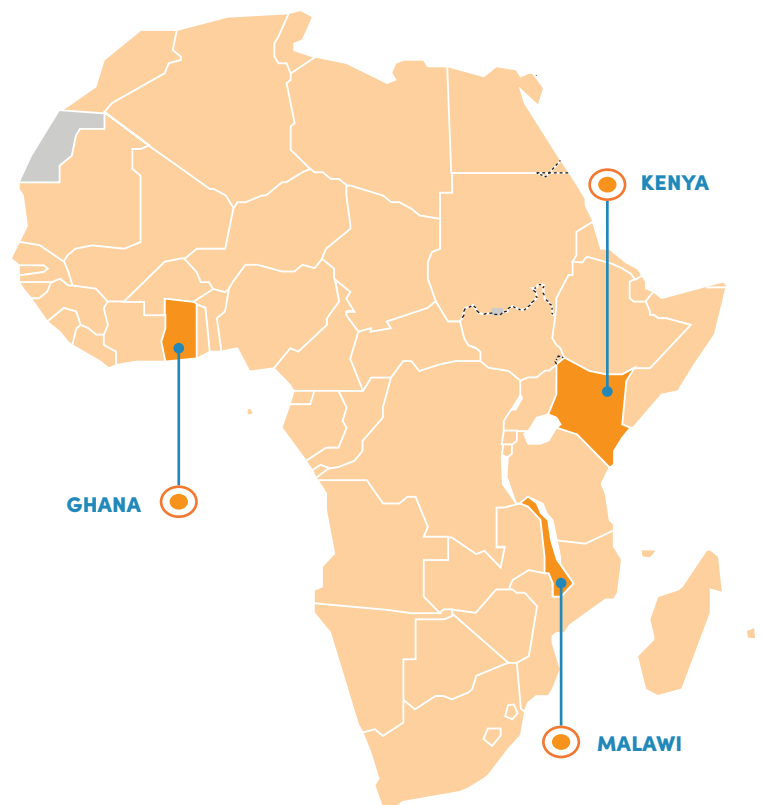
The Malaria Vaccine Implementation Programme, MVIP, was established by WHO to coordinate and support the introduction of the vaccine in selected areas of Africa through country-led routine immunization. The Programme will evaluate the vaccine's public health impact in the context of routine use and inform policy about its potential deployment on a broader scale.

Financing for the MVIP has been mobilized through an unprecedented collaboration between three major global health funding bodies: Gavi, the Vaccine Alliance, the Global Fund to Fight AIDS, Tuberculosis and Malaria, and Unitaid. WHO and GSK are providing additional in-kind contributions, and PATH's activities are also supported by the Bill & Melinda Gates Foundation.

Vaccine introduction

National immunization programmes in Ghana, Kenya, and Malawi will lead the pilot introduction of the malaria vaccine in areas with moderate to high malaria transmission. The aim is to reach approximately 360 000 children per year in the selected areas. The MVIP, working with partners, will evaluate:

- ▲ The feasibility of delivering the required four doses of the vaccine in routine settings;
- ▲ The vaccine's potential role in reducing childhood deaths; and
- ▲ The vaccine's safety profile in the context of routine use.



The boundaries and names shown and the designations used on this map do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted and dashed lines on maps represent approximate border lines for which there may not yet be full agreement.

Through the vaccine roll out, national malaria control programmes will ensure that existing WHO-recommended prevention tools continue to be deployed on a wide scale. Evidence and experience from the pilot programme will inform decisions on the vaccine's potential use on a wider scale in Africa.

Implementation partners

Ministries of Health in each of the pilot countries will lead the vaccine introduction, supported by WHO and in collaboration with in-country and international partners, including PATH, a non-profit organization, and GSK, the vaccine manufacturer. Each partner has clearly defined roles:

Ministries of Health in Ghana, Kenya, and Malawi will lead the vaccine introduction through their national immunization programmes.

WHO is responsible for scientific and technical leadership of the MVIP and will support Ministries of Health as they introduce the vaccine.

PATH provides technical and project management support for the MVIP and is leading studies on healthcare utilization and the economics of vaccine implementation.

GSK is donating up to 10 million doses of RTS,S for use in the MVIP and is leading additional studies to continue monitoring the vaccine's safety and effectiveness in routine use.

With countries in the driver's seat, the malaria vaccine programme will deliver the answers we need on a potential new tool to fight an age-old disease.

Harnessing innovation

After three decades of development, the RTS,S vaccine will soon reach thousands of young children in Africa through country-led immunization programmes. The vaccine takes on a sobering health challenge: even with the significant progress seen since 2000, malaria continues to claim the life of one child every two minutes. Countries and the global health community remain too far from the end point we seek: a world free of malaria.

In April 2017, when announcing the three countries to pilot the RTS,S vaccine, Dr Matshidiso Moeti, WHO Regional Director for Africa, said: "Innovation will enable us to outsmart the malaria parasite." WHO recognizes the considerable public health potential of this innovative tool to prevent malaria, improve child health and save lives. With countries in the driver's seat, the malaria vaccine programme will deliver the answers we need on a potential new tool to fight an age-old disease.



The Malaria Vaccine Implementation Programme (MVIP) is a country-led, WHO-coordinated initiative to assess the feasibility, impact and safety of RTS,S/AS01 in routine implementation in selected areas of Ghana, Kenya, and Malawi. The MVIP brings together ministries of health in the three countries, WHO, and a range of in-country and international partners, including PATH, a non-profit organization, and GSK, manufacturer of the vaccine. More information is available at bit.ly/WHO-MVIP.

WHO acknowledges the generous support of Gavi, the Vaccine Alliance, the Global Fund to Fight AIDS, Tuberculosis and Malaria, and Unitaid for the MVIP, and the significant contributions of the Bill & Melinda Gates Foundation to the development of RTS,S.