



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; more than 250 000 children die from the disease every year. One child dies from malaria every two minutes.

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.

A NEW TOOL WITH PROMISE FOR AFRICA

Today, the world's first malaria vaccine is reaching tens of thousands of African children through a vaccine pilot programme in Ghana, Kenya and Malawi. RTS,S is the first and only vaccine that has demonstrated it can significantly reduce malaria and life-threatening, severe malaria in young African children. The pilot programme is designed to generate evidence and experience about the vaccine in the context of routine immunization. The information and lessons learned will inform a WHO recommendation on broader use of the vaccine across sub-Saharan Africa.

RTS,S acts against *Plasmodium falciparum*, the most deadly malaria parasite globally and the most prevalent in Africa. Rigorous clinical testing in seven African countries has shown its potential to prevent malaria and save lives. (See Figure 1: Proven results.) RTS,S was developed over three decades by GSK, including through a collaboration with PATH's Malaria Vaccine Initiative and a network of African research centres.

Today, the world's first malaria vaccine, RTS,S/AS01 (RTS,S), is being piloted in three African countries. The vaccine is complementary to other proven measures to fight malaria and has the potential to save tens of thousands of young lives.

Above: Elian, shown with his mother Noreen, is the first child to be vaccinated with the malaria vaccine in Kenya. Credit: WHO/N. Thomas



World Health Organization

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

FIRST vaccine to prevent malaria among children

The RTS,S vaccine is the first and, to date, the only vaccine to reduce malaria cases in young children. When given in 4 doses, the vaccine significantly reduced cases of clinical and severe, life-threatening malaria.

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 vaccine has the potential to reduce illness and death in the age group most at risk of death from malaria, and that the benefits of the vaccine in preventing malaria outweigh potential risks. In addition, national regulatory authorities of Ghana, Kenya and Malawi have authorized the RTS,S vaccine for use in pilot areas.

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.



Lusitana is the first in the world to get the malaria vaccine at the launch of the pilot programme in Malawi. Credit: WHO/M. Nieuwenhof

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 widescale use.

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

The Ministries of Health in Ghana, Kenya and Malawi are providing the malaria vaccine at child health clinics in selected areas as part of each country's routine immunization services. The vaccine will be evaluated for use as a complementary tool to prevent malaria in children, as part of a core package of existing preventive, diagnostic and treatment measures.

PROVEN RESULTS

Children receiving 4 doses of RTS,S suffered significantly fewer cases of malaria, including severe, life-threatening malaria, in comparison with those who did not receive RTS,S.

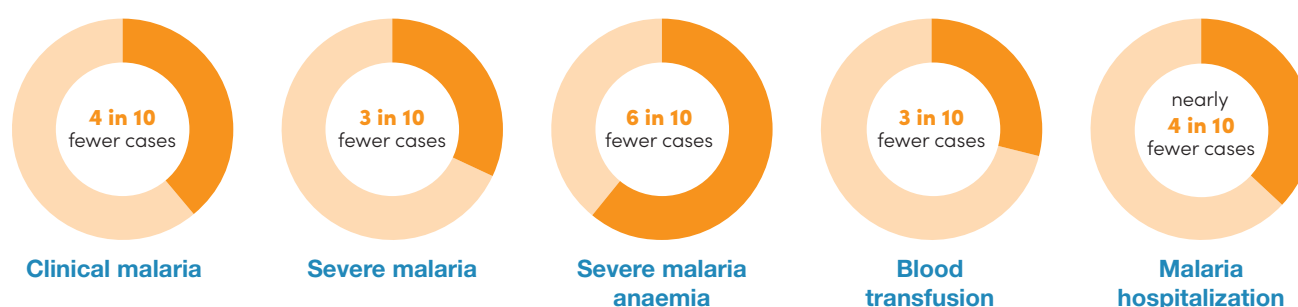


FIGURE 1. Between 2009 and 2014, RTS,S underwent rigorous testing through a large-scale Phase 3 trial. The results were promising: among children aged 5–17 months, the vaccine prevented approximately 4 in 10 cases of malaria (39%). It also prevented about 3 in 10 (29%) cases of severe malaria, a major 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 achieved through the use of long-lasting insecticidal nets (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, intermittent preventive treatment for pregnant women and infants, prompt diagnostic testing, and treatment of confirmed malaria cases with effective antimalarial medicines. In addition, seasonal malaria chemoprevention is recommended in areas with highly seasonal malaria transmission in the Sahel sub-region of Africa. Deployment of these tools has already dramatically lowered the malaria disease burden across Africa, but progress has stalled and reversed in some areas. WHO and partners have called for new tools, such as a malaria vaccine, to help get malaria control efforts back on track.

THE MALARIA VACCINE IMPLEMENTATION PROGRAMME

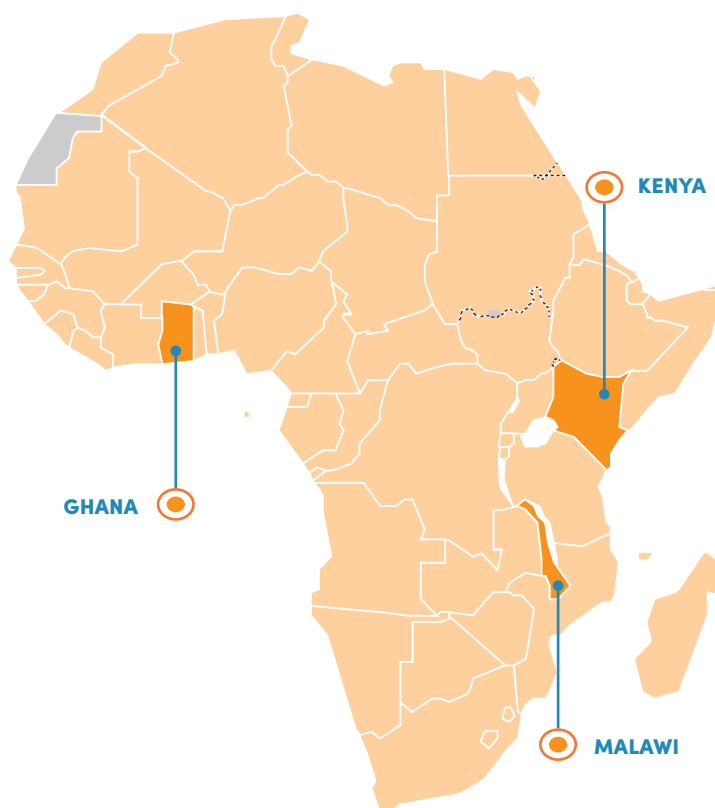
The Malaria Vaccine Implementation Programme, MVIP, was established to support the country-led introduction of the RTS,S vaccine through the routine immunization programmes in selected areas of Africa. The vaccine's public health impact in the context of routine use will be evaluated to inform policy on its potential deployment on a broader scale.

Vaccine introduction and evaluation

Pilot introductions of the malaria vaccine by national immunization programmes in Ghana, Kenya and Malawi are underway in selected areas with moderate to high malaria transmission. The aim is to reach approximately 360 000 children per year in the selected areas across the three countries. The MVIP will evaluate:

- ▲ The feasibility of delivering the required 4 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.

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.



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.

Implementation partners

Ministries of health in each of the pilot countries are leading 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:

WHO is responsible for coordination of the MVIP and provides scientific and technical leadership for the programme; WHO also supports the 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.

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**.

Harnessing innovation

After three decades of development, the RTS,S vaccine is reaching tens of thousands of young children in Africa through country-led immunization programmes.

When announcing the historic launch of the RTS,S vaccine in Africa, which took place in Malawi in April 2019, WHO Director-General Dr Tedros Adhanom Ghebreyesus said: "We have seen tremendous gains from bed nets and other measures to control malaria in the last 15 years, but progress has stalled and reversed in some areas. We need new solutions to get the malaria response back on track, and this vaccine gives us a promising tool to get there. The malaria vaccine has the potential to save tens of thousands of children's lives."

WHO recognizes the considerable public health potential of this innovative tool to prevent malaria, improve child health and save lives as part of a package of proven measures to fight malaria. The malaria vaccine pilot programme will deliver the answers we need on a potential new tool to fight an age-old disease.



Abigail Blessing, with her mother, holds her child health book that marks her first dose of the malaria vaccine, in Ghana. Credit: WHO/F. Combrink

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—WHO Director-General
Dr Tedros Adhanom Ghebreyesus



The Malaria Vaccine Implementation Programme (MVIP) is a WHO-coordinated initiative to assess the feasibility, impact and safety of RTS,S/AS01 in country-led 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 <https://bit.ly/30vfCPy>

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.