



First malaria vaccine:

A potential new tool for child health and improved malaria control in children

THE THREAT OF MALARIA

In recent years, Kenya has made tremendous progress in the fight against malaria through the scale-up of insecticide-treated mosquito nets (ITNs), indoor residual spraying (IRS), and appropriate diagnosis and treatment, using artemisinin-based combination therapies (ACTs).

Largely as a result of these efforts, the proportion of people affected by malaria declined from 11 percent to 8 percent nationally, between 2010 and 2015. However, the burden of malaria remains high in some parts of Kenya. For example, according to the 2015 Kenya Malaria Indicator Survey, 27% of children younger than 15 years were found to be positive for malaria in the Lake Endemic Region.

Overall, the disease is one of the top ten causes of illness and death in the country and a leading killer of children under the age of five. In 2016, malaria caused an estimated 3.5 million infections and just over 10,000 deaths in Kenya, overwhelming the health facility capacity in the Lake Endemic Region. New and complementary tools are needed to further reduce the disease burden.

A PROMISING NEW TOOL

Today, a malaria vaccine—known as RTS,S or Mosquirix™—offers an additional way to protect young children from malaria. The vaccine, where it is available, is part of the package of recommended malaria prevention measures. When used with existing measures, such as ITNs, the vaccine has the potential to save thousands of young lives in Kenya.

Kenya is one of three African countries (alongside Ghana and Malawi) that is carrying out the Malaria Vaccine Implementation Programme with support from the World Health Organization (WHO) and in collaboration with partners, including PATH, a nonprofit organization, and GSK, the vaccine manufacturer.

MALARIA VACCINE IMPLEMENTATION

In Kenya, the Ministry of Health through the National Vaccines and Immunization Programme is leading the phased introduction of the malaria vaccine in parts of the country (the Lake Region) where malaria transmission is highest and where the vaccine is expected to provide the highest benefit.

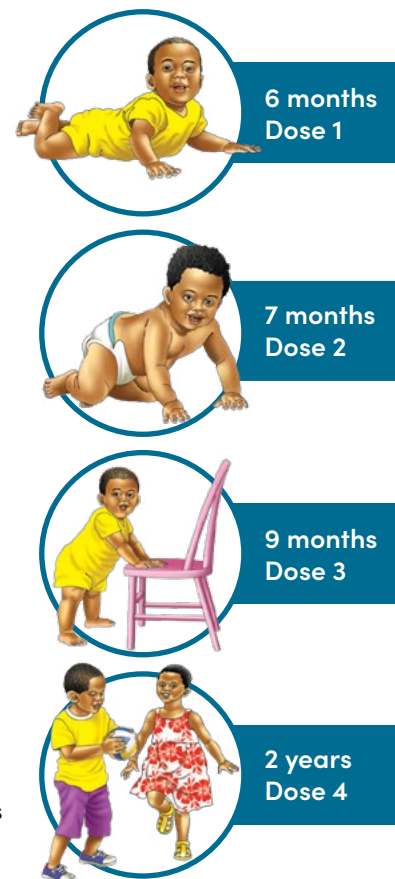
As with other new vaccine introductions, the phased or pilot introduction is providing the National Vaccines and Immunization Programme and participating counties with the opportunity to learn valuable lessons with a view to scaling up to all eligible populations. The aim of this phased introduction is to vaccinate at least 120,000 children per year in the selected areas and to:

- ▲ Determine how best to deliver the required four doses of the vaccine in routine settings (see Figure 1);
- ▲ Assess the vaccine's full potential role in reducing childhood deaths; and
- ▲ Continue to monitor the vaccine for any unwanted side effects.

Vaccines are among the safest and most effective ways to protect children from diseases that could kill them.

FIGURE 1

In Kenya, the vaccine is given at:



To get the most protection, a child who receives the vaccine must get all four doses and continue other practices to prevent malaria, including sleeping under a mosquito net every night and throughout the year.

WHERE WILL THE VACCINE BE INTRODUCED?

The phased introduction is taking place in selected areas where the proportion of people infected with malaria is 20 percent or greater, where coverage for other childhood vaccines is high, and where there are sufficient numbers of children at the right age to receive the vaccine (see Figure 2).

The areas named to be part of the programme include Homabay, Kisumu, Migori, Siaya, Busia, Bungoma, Vihiga, and Kakamega counties. Within the eight targeted counties, some sub-counties have the opportunity to introduce the vaccine into their immunization schedules, while others are expected to introduce the vaccine later.

Decisions on which sub-counties would receive the vaccine initially and which ones would introduce the vaccine later took various factors into account, including the burden of malaria and vaccine coverage.

These factors were included in a computer model to generate numbers that indicated whether a given sub-county would introduce the vaccine at the beginning or later. The selections were made randomly to give each sub-county an equal opportunity. The county health leadership participated in the randomisation event that was led by the County Executive Members for Health.

The sub-counties that are expected to introduce the malaria vaccine later will serve as comparison areas to help health officials evaluate the programme. The evaluation is meant to inform decisions on the vaccine's potential use on a wider scale in Kenya and elsewhere across Africa where malaria is a public threat.

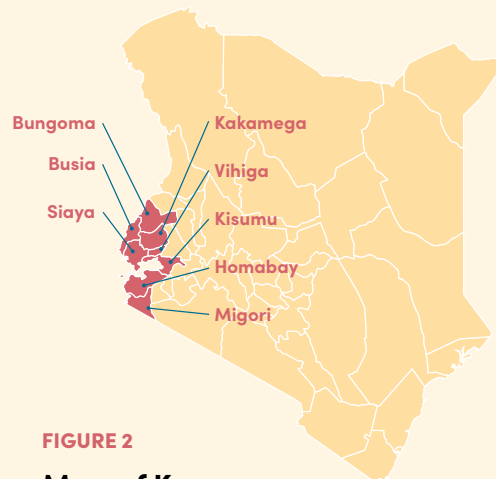


FIGURE 2

Map of Kenya, with targeted counties

MALARIA VACCINE IMPLEMENTATION (CONTINUED)

The phased introduction is allowing the National Vaccines and Immunization Programme and partners to:

- ▲ Strengthen monitoring and evaluation for timely decision-making and planning.
- ▲ Support capacity building and training for health care workers to reduce the number of unvaccinated children and to strengthen the 2nd year of life platform;
- ▲ Strengthen pharmacovigilance and safety surveillance through a newly established Kenya National Vaccine Safety Advisory Committee and through strengthened data reporting of adverse events;
- ▲ Bolster logistical support for immunization through cold chain equipment expansion and distribution;
- ▲ Strengthen advocacy communications and social mobilization as well as community engagement for immunization.

Phased introduction of the malaria vaccine is also providing an opportunity to strengthen county health systems. Target counties are working with the National Vaccines and Immunization Programme to introduce the malaria vaccine in the same manner that they introduce other routine vaccines.

KEY MILESTONES

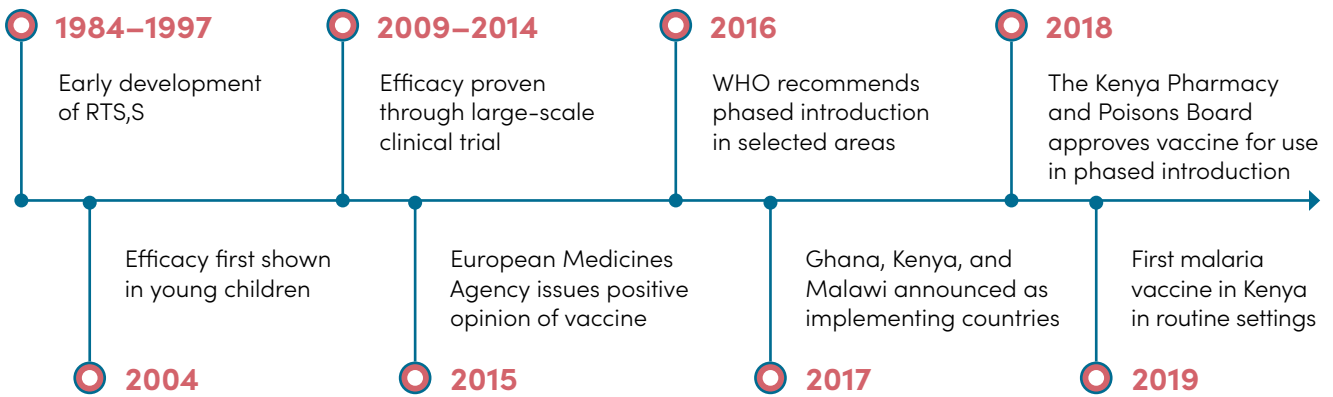
Development of the RTS,S malaria vaccine began more than 30 years ago (see Figure 3). Large-scale clinical testing of the vaccine between 2009 and 2014, involving thousands of young children in seven African countries, including Kenya, showed that children who received the vaccine suffered fewer episodes of malaria illness, including severe malaria. Clinical studies in Kenya involved more than 4,000 children at three sites (Kombewa, Siaya and Kilifi). The studies in Kenya were run through the Kenya Medical Research Institute (KEMRI) through collaborations with the U.S. Centers for Disease Control and Prevention (CDC), Wellcome Trust, and the Walter Reed Army Institute of Research.

In July 2015, the European Medicines Agency, a stringent medicines authority, issued a positive scientific opinion of the vaccine, stating that its benefits in preventing malaria outweigh potential risks. In 2016, WHO recommended phased implementation of the vaccine in selected areas of Africa, following the joint advice of global advisory committees for malaria and immunization.

After responding to calls for expressions of interest from WHO, Kenya (together with Malawi and Ghana) was selected in April 2017 to take part in the Malaria Vaccine Implementation Programme, due in part to its well-functioning national immunization and malaria control programmes. In May 2018, the Kenya Pharmacy and Poisons Board (PPB) approved the phased introduction of the vaccine.

FIGURE 3

The RTS,S journey: key milestones

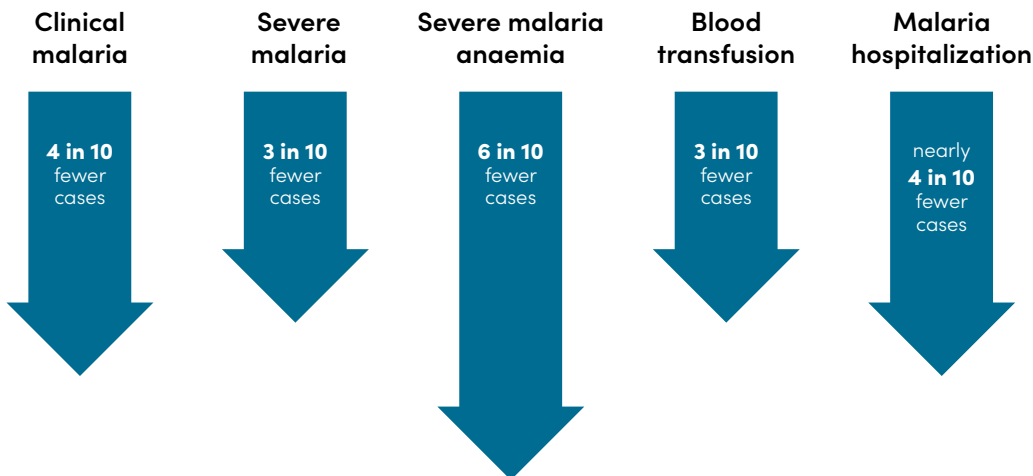


PROVEN RESULTS

The malaria vaccine acts against the most deadly and most common malaria parasite in Africa, *Plasmodium falciparum*, and was developed for young children because they are at highest risk of dying from malaria. Clinical testing showed that the injectable vaccine prevented about 4 in 10 cases of malaria and about 3 in 10 cases of life-threatening, severe malaria over a four-year period. There were also significantly fewer hospital admissions and blood transfusions that are required to treat life-threatening malaria anaemia (see Figure 4).

FIGURE 4

Potential to boost malaria prevention and save lives



PROVEN MEASURES TO FIGHT MALARIA

The WHO-recommended package of tools to fight malaria includes long-lasting insecticidal nets, indoor residual spraying with insecticides, intermittent preventive treatment in pregnancy, and seasonal malaria chemoprevention. These tools have already dramatically reduced malaria in many African settings. The malaria vaccine, where it is available, offers an additional way to protect children from malaria and should be used with other malaria prevention tools for the best protection.

QUICK FACTS

The malaria vaccine:

- ▲ Offers an additional form of protection against malaria when used with other prevention tools.
- ▲ Is used with existing preventive, diagnostic, and treatment measures for malaria.
- ▲ Was developed for young children, because they are at highest risk of dying from malaria.
- ▲ Reduces the number of times a child gets sick with malaria, including life-threatening malaria.
- ▲ Has been approved by Kenya's Pharmacy and Poisons Board for use in the phased introduction.
- ▲ Is the first malaria vaccine recommended by WHO for phased introduction in areas in Africa.
- ▲ Is being given, for a start, in some sub-counties in Kenya with moderate to high levels of malaria.



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

