First malaria vaccine:

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

THE THREAT OF MALARIA

Ghana has made tremendous progress in the fight against malaria by rolling out proven malaria control measures, including long-lasting insecticide-treated mosquito nets, indoor residual spraying, proper diagnosis, and effective chemoprevention with antimalarial medicines.

Malaria still remains a major health threat. People in every part of the country—roughly 30 million men, women and children—are at risk of malaria, and 20 percent of all children have malaria parasites in their blood. There were an estimated 11 million suspected cases of malaria in Ghana and 5.5 million confirmed cases in 2018. New tools are needed to complement those currently in use to further drive down the disease burden.

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

FIGURE 1

In Ghana, the vaccine is given at:





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 available, does not replace existing malaria control interventions. Parents and caregivers are advised to continue using the other interventions in addition to the vaccine. The vaccine has the potential to save tens of thousands of young lives in Africa when used with other proven prevention tools.

Ghana is one of three African countries (alongside Kenya and Malawi)that is carrying out the Malaria Vaccine Implementation Programme (MVIP) 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 Ghana, the Expanded Programme on Immunization (EPI) is leading the phased introduction of the malaria vaccine in targeted parts of the country where malaria transmission is highest. This phased introduction is meant to allow the programme to learn about the impact of the vaccine on preventing severe malaria and deaths in children and about whether parents bring their children on time for all four doses (see Figure 1). There is also close monitoring for any adverse events following immunization.

The aim is to vaccinate at least 120,000 children per year for three years in the selected areas and to:

- Determine how best to deliver the required four doses of the vaccine in routine settings;
- ▲ Assess the vaccine's full potential role in reducing childhood deaths; and
- ▲ Establish the vaccine's safety profile in the context of routine use.



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 night.

WHERE WILL THE VACCINE BE INTRODUCED?

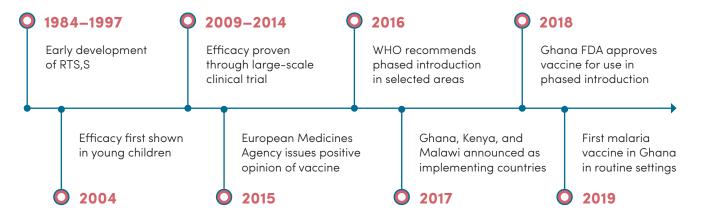
The phased malaria vaccine introduction is taking place in selected areas where the proportion of people infected with malaria is 20 percent or greater, where coverage for other childhood vaccines is high, and where there are sufficient numbers of children at the right age to receive the vaccine. Areas recommended for seasonal malaria chemoprevention are not eligible at this early stage.

The programme includes areas of Brong Ahafo, Central and Volta Regions. Within these regions, some districts are receiving the vaccine, while others are expected to receive the vaccine at a later date. The remaining districts and regions are continuing to benefit from other malaria interventions implemented nationwide. Assignment of districts into those that receive the vaccine and those that do not was through a random computer-run selection that gave each district an equal opportunity of being selected for the vaccine.

The districts that are not yet receiving the vaccine are serving as comparison areas to help health officials evaluate the programme. This evaluation is meant to inform decisions on the vaccine's potential use on a wider scale in Ghana and elsewhere across Africa where malaria is a public health threat.



FIGURE 2 The RTS,S journey: key milestones



KEY MILESTONES

Development of the RTS,S malaria vaccine began more than 30 years ago (see Figure 2). Large-scale clinical testing of the vaccine between 2009 and 2014, involving thousands of young children in seven African countries, including Ghana, showed that children who received the vaccine suffered fewer episodes of malaria illness, including severe malaria. Clinical studies in Ghana involved more than 2,500 children at two sites—Agogo and Kintampo.

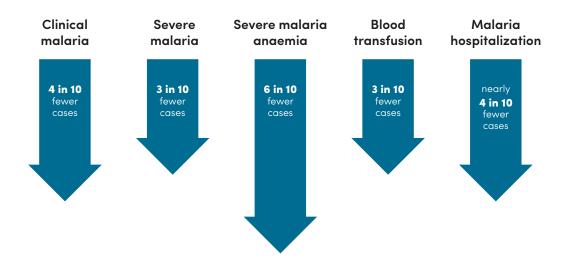
The malaria vaccine has been found to have an acceptable safety profile. In July 2015, the European Medicines Agency, a stringent medicines authority, issued a positive scientific opinion of the vaccine, stating that its benefits in preventing malaria outweigh potential risks. In 2016, WHO recommended 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 a call for expressions of interest from WHO, Ghana was selected as a pilot implementation country in 2017, due in part to its well-functioning national immunization and malaria control programmes. In 2018, the Ghana Food and Drugs Authority approved the vaccine for use in the phased introduction.

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 in the same period (see Figure 3).

FIGURE 3 Potential to boost malaria prevention and save lives



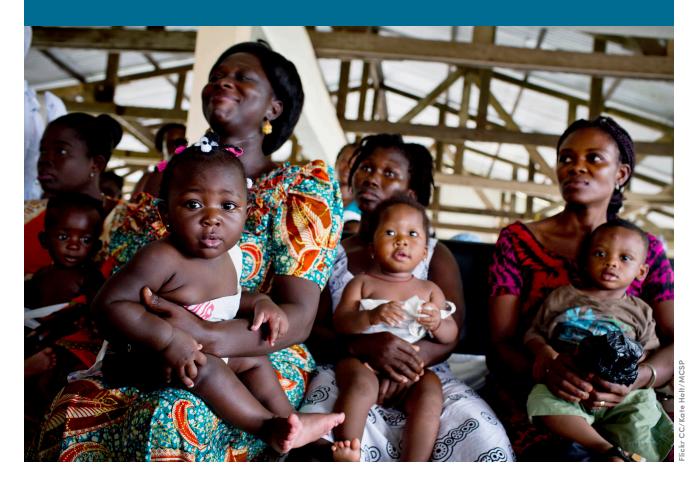
PROVEN MEASURES TO FIGHT MALARIA

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 FDA Ghana for use in the phased introduction.
- ▲ Is the first malaria vaccine recommended by WHO for phased introduction.
- ▲ Is being given, for a start, in some areas in Ghana with moderate to high levels of malaria.



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. The 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.







