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

In recent years, Malawi has made tremendous progress in the fight against malaria by rolling out proven malaria control measures. These include long-lasting insecticide-treated mosquito nets, indoor residual spraying, and antimalarial medicines. According to the 2017 Malawi Malaria Indicator Survey, the malaria prevalence rate decreased from 43% in 2010 to 24% in 2017. Similarly, malaria-related deaths fell during the same period from 59 per 100,000 people to 20 per 100,000 people, representing a 66% decrease.

Despite these achievements, malaria remains a public health threat, with the whole population at risk. The 2016 Health Management Information System report shows that malaria accounts for more than 30 percent of outpatient visits and 40 percent of inpatient visits. New interventions are needed to complement those currently in use to further drive down the disease burden.

A PROMISING NEW TOOL

Today, a malaria vaccine 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. Parents and caregivers are encouraged to continue using the already existing prevention and control measures along with the vaccine. The vaccine has the potential to save tens of thousands of young lives in Malawi when used with other proven preventive interventions.

MALARIA VACCINE IMPLEMENTATION

Malawi is one of three African countries (alongside Ghana and Kenya) 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.

In Malawi, the Expanded Programme on Immunization (EPI) is leading the phased introduction of the malaria vaccine in some areas in the country where malaria transmission is highest. The 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 reactions.

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 with uptake of other malaria preventive measures, including sleeping under a mosquito net every night.

**Vaccines are among the safest and most effective ways to protect children from diseases that could kill them.**
WHICH AREAS ARE RECEIVING THE VACCINE?

The phased malaria vaccine introduction is taking place in selected areas where:

- The proportion of people infected with malaria is 20 percent or greater;
- Coverage for other childhood vaccines is high; and
- There are sufficient numbers of children at the right age to receive the vaccine.

The vaccine is being given in selected areas in 11 selected districts. The districts are: Karonga and Nkhata Bay (Northern Region); Mchinji, Ntchisi, and Lilongwe rural (Central Region); and Mangochi, Machinga, Balaka, Phalombe, Chikwawa, and Nsanje (Southern Region). Within these districts, the vaccine is being provided in a phased approach.

FIGURE 2

The RTS,S journey: key milestones

- **1984–1997**: Early development of RTS,S
- **2004**: Efficacy first shown in young children
- **2009–2014**: Efficacy proven through large-scale clinical trial
- **2015**: European Medicines Agency issues positive opinion of vaccine
- **2016**: WHO recommends phased introduction in selected areas
- **2017**: Malawi, Ghana, and Kenya announced as implementing countries
- **2018**: Malawi’s PMPB approved the vaccine for use in phased introduction
- **2019**: First malaria vaccine in Malawi in routine settings

KEY MILESTONES

Development of the RTS,S malaria vaccine began more than 30 years ago. Large-scale clinical testing of the vaccine between 2009 and 2014, involving thousands of young children in seven African countries, including Malawi, showed that children who received the vaccine suffered fewer episodes of malaria illness, including severe malaria. Clinical studies in Malawi involved more than 1,600 children in Lilongwe.

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 letter of interest from WHO, Malawi was selected as a pilot implementation country in 2017, due in part to its well-functioning national immunization and malaria control programmes. In 2018, Malawi’s Pharmacy, Medicines and Poisons Board (PMPB) approved the vaccine for use in the phased implementation.
**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 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-related anaemia in the same period (see Figure 3).

**FIGURE 3**

*Potential to boost malaria prevention and save lives*

<table>
<thead>
<tr>
<th></th>
<th>Clinical malaria</th>
<th>Severe malaria</th>
<th>Severe malaria anaemia</th>
<th>Blood transfusion</th>
<th>Malaria hospitalization</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fewer cases</td>
<td>4 in 10</td>
<td>3 in 10</td>
<td>6 in 10</td>
<td>3 in 10</td>
<td>nearly 4 in 10</td>
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**PROVEN MEASURES TO FIGHT MALARIA**

The WHO-recommended package of interventions to fight malaria includes long-lasting insecticidal nets, indoor residual spraying, intermittent preventive treatment for pregnant women, and prompt diagnosis and treatment of malaria. These interventions have already dramatically reduced malaria in many African settings. The malaria vaccine offers an additional way to protect children from malaria and should be used together with other malaria prevention measures for the best protection.
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.