

The Launch of the Malaria Vaccine

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Malaria is a major threat to human life. Malaria has killed and debilitated humans for centuries. Though malaria rates have reduced sharply in the last 20 years, it still sickens hundreds of millions of people and is a leading cause of death around the world. But now, the first-ever vaccine against malaria is being tested in three countries where malaria is a major public health hazard. The results of this vaccine campaign and trial will have a huge impact in how the world approaches malaria prevention in the race to reach a global target of reducing malaria illness and death by 90% by 2030.

In addition to being a major threat to human life, malaria is extremely difficult to control. The unique medium of malarial infection – including both a parasite and the parasite's mosquito host – makes it nearly impossible to eliminate. At present, malaria is controlled through a whole range of different measures, including insecticide-treated bednets, indoor spraying for mosquitoes, removing the breeding grounds for mosquitoes, preventative antimalarial drugs, and identifying and treating malarial infections as fast as possible to reduce the amount of time people can spread the disease.

WHO Ghana welcomed the Ministry of Health's launch of the world's first malaria vaccine in a landmark pilot programme. Top health officials, WHO representatives, community leaders, and mothers and children gathered on 30 April 2019 to officially begin the vaccine rollout. The country-led phased vaccine introduction is supported by WHO and national and global health partners.

Ghana is one of three African countries in which the vaccine, known as RTS,S, will be made available to children up to 2 years of age. Malaria remains one of the world's leading killers, claiming the life of one child every two minutes; most of these deaths are in Africa. In Ghana, about 20 percent of all children have malaria parasites in their blood. "This is a day to celebrate," said WHO Representative for Ghana Dr Owen Kaluwa. "This breakthrough in malaria control caps a 30-year effort to develop a vaccine with proven results to help prevent malaria in young children. The malaria vaccine has the potential to save tens of thousands of children's lives."

The vaccine is a complementary malaria control tool – to be added to the core package of WHO-recommended measures for malaria prevention, including the routine use of insecticide-treated bed nets, indoor spraying with insecticides, and the timely use of malaria testing and treatment.

The vaccine pilot programme includes areas of Brong Ahafo, Central and Volta regions and some districts in Upper East

region. 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 control measures implemented nationwide.

RTS,S/AS01 (RTS,S) is the world's first malaria vaccine that has been shown to provide partial protection against malaria in young children. The vaccine acts against *Plasmodium falciparum*, the most deadly malaria parasite globally and the most prevalent in Africa.¹ The vaccine has been recommended by WHO for pilot introduction in selected areas of 3 African countries. It will be evaluated for use as a complementary malaria control tool that could be added to (and not replace) the core package of WHO-recommended preventive, diagnostic and treatment measures. RTS,S is the first, and to date, the only vaccine to show a protective effect against malaria among young children in a Phase 3 trial. The Phase 3 trial, conducted over 5 years (from 2009 to 2014), enrolled approximately 15 000 young children and infants in 7 sub-Saharan African countries.² The trial sites within these countries represented a range of malaria transmission settings. Among children aged 5–17 months who received 4 doses of RTS,S, the vaccine prevented approximately 4 in 10 (39%) cases of malaria over 4 years of follow-up and about 3 in 10 (29%) cases of severe malaria,³ with significant reductions also seen in overall hospital admissions as well as in admissions due to malaria or severe anaemia. The malaria vaccine implementation programme (MVIP), coordinated by WHO, has been designed to address several outstanding questions related to the public health use of the vaccine.

Specifically, the MVIP will assess the feasibility of administering the required 4 doses of the vaccine in children; the vaccine's role in reducing childhood deaths; and its safety in the context of routine use.

In December 2015, WHO issued a call for expressions of interest from African ministries of health to collaborate in the malaria vaccine implementation programme. Of the 10 countries that responded positively, 3 were selected for the programme based on pre-specified criteria. Key among these was the expressed desire by the ministry of health to engage in the MVIP, and well-functioning malaria and immunization programmes.

Other criteria included: good coverage of recommended malaria control interventions and childhood vaccinations; moderate-to-high malaria transmission despite good implementation of WHO-recommended malaria interventions; a sufficient number of young children living in the malaria-transmission areas where the vaccine will be introduced; strong implementation research or evaluation

experience in the country; and capacity to assess safety outcomes.

Immunization authorities in the 3 countries will specify the vaccination schedule, based on WHO recommendations. A 4-dose schedule is required, with the first dose given as soon as possible after 5 months of age followed by doses 2 and 3 at approximately monthly intervals and the fourth dose near the child's second birthday.

Known side effects include pain and swelling at the injection site, and fever. These side effects are similar to reactions observed with other vaccines given to children. Occasionally, children with fever have seizures. During the Phase 3 trial, an increased risk of febrile seizures was seen within 7 days of the administration of any of the RTS,S vaccine doses. Children who had febrile seizures after vaccination recovered completely and there were no long-lasting consequences. The MVIP is expected to continue through 2022.

RTS,S is not intended to take the place of other malarial control interventions. It is meant to be that last malaria-controlling straw. RTS,S will not be a silver bullet. It is only effective against the *P. falciparum* malaria infections common to Africa, not the *P. vivax* infections found in malarial hotspots in Southeast Asia. It also protects only 39% of children who are vaccinated from malaria. However, reducing malaria infections in four of every ten children is meaningful reduction in death and suffering in its own right. That reduction will also increase the impact of prevention efforts by reducing the number of infected individuals available for mosquitoes to bite and then spread the disease.