

Malaria pilot vaccine (RTS, S): Benefits and challenges

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Introduction

Malaria is a life-threatening disease caused by parasites that are transmitted to people through the bites of infected female *Anopheles* mosquitoes. It is preventable and curable. In 2017, there were an estimated 219 million cases of malaria in 87 countries. The estimated number of malaria deaths stood at 4,35,000 in 2017. The WHO African Region carries a disproportionately high share of the global malaria burden. Every two minutes a child or baby there dies of the disease. Some children can have up to six bouts of malaria in just one year. In 2017, the region was home to 92% of malaria cases and 93% of malaria deaths. 5 countries accounted for nearly half of all malaria cases worldwide: Nigeria (25%), the Democratic Republic of the Congo (11%), Mozambique (5%), India (4%) and Uganda (4%). *P. Falciparum* accounted for 99.7% of estimated malaria cases in the WHO African Region, as well as in the majority of cases in the WHO regions of South-East Asia (62.8%), the Eastern Mediterranean (69%) and the Western Pacific (71.9%).¹

Vaccination against malaria is a burning issue. Over the past decade, there has been significant progress in malaria vaccine development. Several vaccine candidates are now being tested in Africa, Asia and United states.² The development of a malaria vaccine has faced several obstacles: the lack of a traditional market, few developers, and the technical complexity of developing any vaccine against a parasite. Malaria parasites have a complex life cycle, and there is poor understanding of the complex immune response to malaria infection. Malaria parasites are also genetically complex, producing thousands of potential antigens. Unlike the diseases for which we currently have effective vaccines, exposure to malaria parasites does not confer lifelong protection. Acquired immunity only partially protects against future disease, and malaria infection can persist for months without symptoms of disease.³ 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. The vaccine has been recommended by WHO for pilot introduction in selected areas of 3 African countries.⁴

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. Beginning in 2019, it is the first malaria vaccine provided to young children through routine immunization programmes. Three sub-Saharan African

countries have introduced the vaccine in selected areas as part of a large-scale pilot implementation programme. 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. 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, with significant reductions also seen in overall hospital admissions as well as in admissions due to malaria or severe anaemia. The vaccine also reduced the need for blood transfusions, which are required to treat life-threatening malaria anaemia by 29%. The vaccine took more than 30 years — and more than \$500 million — to develop.⁴

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. Data and information derived from the MVIP will inform a WHO policy recommendation on the broader use of the vaccine. Three countries — Ghana, Malawi and Kenya — are participating in the MVIP. Each of these countries has selected the areas to be included in the pilot programme. 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. In Ghana world's first malaria vaccine was launched in a landmark pilot programme. 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. 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.

The pilot programme is designed to generate evidence and experience to inform WHO policy recommendations on the broader use of the RTS, S malaria vaccine. It will look at reductions in child deaths; vaccine uptake, including whether parents bring their children on time for the four required doses; and vaccine safety in the context of routine use. 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.³ The WHO-coordinated pilot programme is a collaborative effort with ministries of health in Ghana, Kenya and Malawi and a range of in-country and international partners, including PATH, a non-profit organization, and GSK, the vaccine developer and manufacturer, which is donating up to 10 million vaccine doses for this pilot.⁵

Conflict of Interest: None.

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