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History in the making as the World Health Organization recommends a vaccine for children at risk of malaria

Health practitioners around the globe welcomed the World Health Organization (WHO)'s groundbreaking announcement that it would scale up deployment of the first-ever malaria vaccine as a complementary prevention tool for children under five in Sub-Saharan Africa and other regions with moderate to high *P. falciparum* malaria transmission. *P. falciparum* is the deadliest malaria parasite globally, and the most prevalent in Africa.

According to the United Nations Children's Fund (UNICEF), every two minutes [a child under five dies of malaria](#). Many of these deaths are preventable and treatable. In 2019, there were 229 million malaria cases globally that led to 409,000 deaths. Of these deaths, 67% (274,000) were children under five years of age. This translates into a daily toll of nearly 750 children under five, most in Sub-Saharan Africa where an estimated 24 million children were infected with malaria's deadliest form. In addition to being the third most lethal infectious disease for children, malaria infection and the costs of treatment trap families in a cycle of illness, suffering and poverty.

But now the future for children under five in Sub-Saharan Africa and in other regions with moderate to high *P. falciparum* malaria transmission is looking more hopeful. This is because, after more than three decades of research and development, WHO is recommending widespread use of the RTS, S/AS01 (RTS, S) malaria vaccine for children in these regions. The recommendation is based on results from an ongoing pilot programme in Ghana, Kenya and Malawi that has reached more than 800,000 children since 2019.

The RTS, S malaria vaccine is the result of 30 years of work by the pharmaceutical company GlaxoSmithKline (GSK) through a partnership with PATH, with support from a network of African research

centres. The Bill & Melinda Gates Foundation provided catalytic funding for late-stage development of RTS,S between 2001 and 2015.

Financing for the pilot three-country programme has been mobilized through an unprecedented collaboration among three key global health funding bodies: Gavi, the Vaccine Alliance; the Global Fund to Fight AIDS, Tuberculosis and Malaria; and Unitaids.

“This is a historic moment. The long-awaited malaria vaccine for children is a breakthrough for science, child health and malaria control. Using this vaccine on top of existing tools to prevent malaria could save tens of thousands of young lives each year.”

Dr Tedros Adhanom Ghebreyesus, WHO Director-General

Malaria remains a primary cause of childhood illness and death in Sub-Saharan Africa. Each year more than 260,000 African children under the age of five die from malaria. However, in recent years, WHO and its partners had reported stalled progress against the epidemic.

Dr Abdourahmane Diallo, Chief Executive Officer of the [Roll Back Malaria](#) (RBM) Partnership to End Malaria, said: “The WHO announcement is a historic milestone for the global malaria community, and the RBM Partnership congratulates the commitment and efforts of many partners over three decades in reaching this milestone in malaria innovation.”

“For centuries, malaria has stalked Sub-Saharan Africa, causing immense personal suffering,” said Dr Matshidiso Moeti, WHO Regional Director for Africa. “We have long hoped for an effective malaria vaccine and now for the first time ever we have such a vaccine recommended for widespread use. Today’s recommendation offers a glimmer of hope for the continent which shoulders the heaviest burden of the disease and we expect many more African children to be protected from malaria and grow into healthy adults.”

WHO recommendation for the RTS,S malaria vaccine

Based on the advice of two WHO global advisory bodies, one for immunization and the other for malaria, the Organization recommends that:

‘In the context of comprehensive malaria control the RTS,S/AS01 malaria vaccine be used for the prevention of *P. falciparum* malaria in children living in regions with moderate to high transmission as defined by WHO. The RTS,S/AS01 malaria vaccine should be provided in a schedule of four doses in children from five months of age for the reduction of malaria disease and burden’.

Summary of key findings of the malaria vaccine pilots

Data and insights from the pilot projects informed the recommendation, based on findings generated from two years of vaccination in child health clinics in the three pilot countries, implemented under the leadership of the Ministries of Health of Ghana, Kenya and Malawi. The Malaria Vaccine Implementation Programme has been generating evidence and experience on the feasibility, impact and safety of the RTS,S malaria vaccine in real-life, routine settings in selected areas of the three countries.

Findings include:

- Practical to administer: Vaccine introduction is achievable, improves health and saves lives, with good and equitable coverage of RTS, S observed through routine immunization systems. This occurred even in the context of the COVID-19 pandemic.
- Reaching the unreached

- : RTS,S increases equity in access to malaria prevention.
 - Data from the pilot programme showed that more than two-thirds of children in the three countries who are not sleeping under a bed net are benefitting from the RTS,S vaccine.
 - Layering the tools results in over 90% of children benefitting from at least one preventive intervention (insecticide-treated bed nets or the malaria vaccine).
- Strong safety profile: To date, more than 2.3 million doses of the vaccine have been administered in three African countries – the vaccine has a favourable ‘safety profile’.
- No negative impact on uptake of bed nets, other childhood vaccinations, or health seeking behaviour for febrile illness. In areas where the vaccine has been introduced, there has been no decrease in the use of insecticide-treated nets, uptake of other childhood vaccinations or health-seeking behaviour for febrile illness.
- High impact in real-life childhood vaccination settings: Significant reduction (30%) in deadly severe malaria, even when introduced in areas where insecticide-treated nets are widely used and there is good access to diagnosis and treatment.
- Highly cost-effective: Modelling estimates that the vaccine is cost effective in areas of moderate to high malaria transmission.

Next steps (and a word of caution)

The global health community will have to make funding decisions on the vaccine's broader rollout, and countries' will have to decide whether or not to adopt the vaccine as part of their national malaria control strategies. As health budgets are increasingly spread thin over competing priorities, it is all the more important to allocate scarce resources to the most cost-effective uses.

Despite WHO's recommendation, it is unclear whether the new vaccine is the most cost-effective way to save lives in comparison to a wide range of still under-deployed and relatively affordable malaria interventions, such as insecticide-treated bed nets, seasonal malaria chemoprevention, and indoor residual spraying. [Some practitioners](#) are calling for WHO to issue more nuanced guidance that takes different countries' economic and health situations into account: (i) value for money and cost-effectiveness: WHO should base any policy recommendation on thorough cost-effectiveness analysis that considers all evidence available; (ii) who pays? WHO should base any policy recommendation on projected budget estimates; and (ii) a 'one-size-fits-all' approach: WHO should avoid issuing a sweeping global recommendation and instead encourage national and subnational assessments to inform decision-making processes.

Meanwhile, the pilot programme will continue in the three pilot countries to understand the added value of the fourth vaccine dose, and to measure longer-term impact on child deaths.

The Malaria Vaccine Implementation Programme coordinated by WHO is supported by in-country and international partners, including PATH, UNICEF and GSK, which is donating up to 10 million doses of the vaccine for the pilot.

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