PRESS RELEASE



Ifakara part of groundbreaking malaria vaccine recommended by WHO

> The Institute participated in initial trials in Tanzania

Key Messages

- 1. Children at risk in Sub-Saharan Africa urgently need protection against malaria and the "RTS,S/ASO1" vaccine recommended by the WHO, which Ifakara took part in developing and evaluating, is a perfect addition to already available approved solutions such as treated mosquito nets and drugs.
- 2. The vaccine will likely have a significant impact in reducing severe malaria and deaths among infants in poor countries in Sub-Saharan Africa.
- 3. This is a transformative addition for Ifakara's quest towards zero malaria in line with both national and global strategies against malaria.
- 4. Efforts should be made to ensure equitable access to the malaria vaccines especially in low-income countries where the social cultural context may impede the optimal uptake.
- 5. Ifakara shall continue to work with other like-minded partners to find solutions to the most important health problems in the global south and the world at large.

October 7, 2021, Dar es Salaam. Ifakara Health Institute is proud to be part of the groundbreaking malaria vaccine known as "RTS,S/ASO1" recommended recently by the World Health Organization (WHO) for children at risk. We at Ifakara consider this as a breakthrough for science, child health and malaria control.

The WHO announced on October 6, 2021 that it recommends widespread use of the RTS,S/AS01 (RTS,S) malaria vaccine among children in sub-Saharan Africa and in other regions with moderate to high malaria transmission. The recommendation is based on results from an ongoing pilot program in Ghana, Kenya and Malawi that has reached more than 800 000 children since 2019.

Read the full announcement here.

In mid 2000s, IFAKARA evaluated the performance and safety of an earlier version of the vaccine in infants in Tanzania, including feasibility of incorporating this vaccine into the standard immunization programs recommended by the WHO. Conclusions of early studies showed the vaccine had a good safety profile and reduced malaria infections in infants.

In later studies, Ifakara, together with the National Institute for Medical Research (NIMR) in Tanzania also took part in a multi-center study which involved a network of over 10 sites in Africa to evaluate the now approved version of the vaccine, RTS,S.

In a quick reaction to the announcement yesterday, a senior researcher at Ifakara who led teams that conducted the RTS,S trials in Tanzania, Dr. Salim Abdulla, said the latest developments added to a rich profile of the Institute in participating and supporting impactful public health reach programs.

Page 1

P.o. Box 74 Bagamoyo Phone: +255232440065 F55-PRE-v19.0

PRESS RELEASE



"Ifakara has over 60 years of experience in researching on malaria. We've have been part of many other impactful studies previously including those culminated in changing policies in Africa and globally on treated mosquito nests and the current first-line malaria drug – ALU," he said.

Commenting on the announcement, the Director Science at Ifakara, Dr. Fredros Okumu, expressed optimism that the vaccine would have great impact in the fight against malaria. "The RTS,S vaccine will likely have a significant impact in reducing severe malaria and deaths, and in that sense, it is a one-of-a-kind transformative addition for our quest to go towards zero malaria with as few deaths as possible," he said.

Dr. Okumu underlined that being the very first vaccine against any parasitic disease, and having been evaluated widely by African scientists, it will also likely inspire new interests in this space and hopefully herald greater commitments to malaria control.

"It should be noted though that the benefits will be accrued only if we continue to strengthen our health systems to enable effective vaccine deployment," he said, stressing: "The WHO endorsement emphasizes that this vaccine, as unique as it is, is only one small component of the arsenal. Countries must continue to focus on other proven interventions, for malaria prevention and case management, as the RTS,S is not itself a silver bullet."

Commenting on the announcement as well, Head of the Interventions & Clinical Trials Department at Ifakara, Dr. Ally Olotu said: "This great achievement should invigorate the efforts to pursue even more efficacious malaria vaccines. As we push for a speedy deployment of the RTS,S vaccine to more vulnerable infants across Africa, we need to capitalize on this success by advocating for more funding in malaria vaccine development."

For her part, Head of Health Systems, Impact Evaluation and Policy department at Ifakara, Dr. Sally Mtenga called on stakeholders in the fight against malaria, including policy makers and development partners, to ensure equitable access to malaria vaccines, especially in low-income countries where the social cultural context may impede the optimal uptake of the vaccine.

"Equitable access to health care is currently a critical agenda globally... there is need to address the social determinants of community acceptance of the malaria vaccine," she said.

Ifakara Chief Executive Director, Dr. Honorati Masanja, expressed his Institute's commitment to continue working with other like-minded partners to find solutions to the most important health problems in the global south and the world at large.

"We advocate for equitable access to various interventions including vaccines that have been approved by WHO. We shall as an institute continue to play a role in developing, testing and validating promising malaria control and other interventions that will improve people's health and wellbeing," he stressed.

Page 2

info@ihi.or.tz | www.ihi.or.tz

Bagamoyo Branch Inside District Hospital P.o. Box 74 Bagamoyo Phone: +255232440065

PRESS RELEASE



Malaria remains a primary cause of childhood illness and death in sub-Saharan Africa. More than 260 000 African children under the age of five die from malaria annually.

More: Ifakara's involvement in RTS,S malaria vaccine development, evaluation

In mid 2000s, IFAKARA evaluated the safety and immunogenicity of an earlier version, RTS,S/AS02D in infants in Tanzania, including feasibility of incorporating this vaccine into the standard WHO Expanded Program of Immunization, in a Phase 2B trial.

The conclusions of these early studies were unequivocal; that the use of RTS,S/AS02D vaccine in infants had a good safety profile, did not interfere with the other EPI vaccines and also reduced malaria infection in the infants.

In later studies, Ifakara, together with NIMR also partnered as a member of a network of 11 other African sites to evaluate the now approved version of RTSS. In these studies, the vaccine candidate prevented a substantial number of clinical malaria cases in young infants and children, when administered with and without a booster.

As a result of these studies, the RTSS vaccine was considered as having great potential for malaria control when used in combination with other effective control measures, especially in areas of high malaria transmission.

The RTS, S/AOS1 is now widely accepted to provide significant protection against both clinical and severe malaria in African children and was already very favorably evaluated by the European Medicines Agency since a few years ago.

WHO Global Malaria Policy Advisory Group, initially proposed that pilot studies be done to monitor feasibility [and safety] when the vaccine is delivered within the existing national immunization programs. In the years following this notice, the vaccine has been given to ~800,000 children in Ghana, Malawi and Kenya. WHO has now finally provided full endorsement that the vaccine is effective and can be used in areas of moderate to high transmission.

More: About the RTS,S vaccine

RTS,S/AS01 (RTS,S) is a vaccine that acts against plasmodium falciparum, the deadliest malaria parasite globally and the most prevalent in Africa. It was created in 1987 by scientists working in GSK laboratories. In early 2001, GSK and PATH—with support from the Bill & Melinda Gates Foundation entered into a partnership to develop the vaccine for infants and young children living in malaria endemic regions in sub-Saharan Africa.

In January 2016, the vaccine was recommended by WHO for pilot introduction in selected areas of 3 African countries. RTS,S is being evaluated for use as a complementary malaria control tool that could

Page 3

info@ihi.or.tz | www.ihi.or.tz

PRESS RELEASE



be added to (and not replace) the core package of WHO-recommended preventive, diagnostic and treatment measures. More about the RTS,S vaccine here.

About Ifakara Health Institute

Ifakara is a leading research organization in Africa with a strong track record in developing, testing and validating innovations for health. Driven by a core strategic mandate for research, training and services, the Institute's work now spans a wide spectrum, covering biomedical and ecological sciences, intervention studies, health-systems research and policy translation. *More about Ifakara*.

CONTACTS

Technical Inquiries:

Dr. Ally Olotu | Head, Interventions & Clinical Trials Department, Bagamoyo +255 718 927 104 | aolotu@ihi.or.tz

Media Inquiries:

#5 Ifakara Street Plot 463 Mikocheni | Kinondoni, Dar es Salaam +255 222 774 756 | 0629 155 157 | communications@ihi.or.tz

Page 4