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www.genbioconsortium.africa Image source: iStock/Getty



# GROUNDBREAKING MALARIA VACCINE



#### FEATURE ARTICLE OF THE MONTH:

# WHO RECOMMENDS GROUNDBREAKING MALARIA VACCINE FOR CHILDREN AT RISK

The African Genetic Biocontrol Consortium welcomed the news of World Health Organization's recommendation of groundbreaking malaria vaccine.

The African Genetic Biocontrol Consortium was established as an agreement among member organizations committed to contribute and expand Africa's self-determination through research, development, and use of genetic biocontrol approaches to control and eliminate malaria and other vector-borne diseases in Africa.

On October 6, 2021, the World Health Organization (WHO) recommended widespread use of the RTS, S/ASO1 (RTS, S) malaria vaccine among children in sub-Saharan Africa and in other regions with moderate to high P. falciparum malaria transmission. The recommendation was based on results from an ongoing pilot programme in Ghana, Kenya and Malawi that has reached more than 800 000 children since 2019. 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. In recent years, WHO and its partners have been reporting a stagnation in progress against the deadly disease.

WHO 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. RTS,S/AS01 malaria vaccine should be provided in a schedule of 4 doses in children from 5 months of age for the reduction of malaria disease and burden.

Key findings of the pilots informed the recommendation based on data and insights 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 findings include:

#### • Feasible to deliver:

Vaccine introduction is feasible, improves health

and saves lives, with good and equitable coverage of RTS,S seen 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 3 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 3 African countries – the vaccine has a favorable safety profile.



- No negative impact on uptake of bed nets, other childhood vaccinations, or health seeking behavior for febrile illness. In areas where the vaccine has been introduced, there has been no decrease in the use of insecticidetreated nets, uptake of other childhood vaccinations or health seeking behavior 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 for the WHOrecommended malaria vaccine will include funding decisions from the global health community for broader rollout, and country decision-making on whether to adopt the vaccine as part of national malaria control strategies.

**Source:** World Health Organization (2021). WHO recommends groundbreaking malaria vaccine for children at risk. Retrieved from: https:// www.who.int/news/item/06-10-2021-who-recommendsgroundbreaking-malaria-vaccinefor-children-at-risk

# AFRICAN GENETIC BIOCONTROL CONSORTIUM SECOND WEBINAR

### TRANSLATING RESEARCH TO COMMERCIALIZATION OF GENETICALLY MODIFIED PRODUCTS.

On 28<sup>th</sup> October 2021, the African Genetic Biocontrol Consortium successfully hosted its second webinar titled "Translating research to commercialization of genetically modified products." The panelists during this webinar included:

- Silas Obukosia AUDA-NEPAD.
- Kwaku Poku Asante Kitampo Health Research Center.
- Misheck Mulumba Chiarperson AfOHNet.
- Robert Karanja Villgro Africa.
- Julius Ecuru Bioinnovate Africa.

#### The objectives of this webinar were:

- To provide an overview of the status of product development and registration for GM products in Africa.
- To discuss innovation for GM products.
- To discuss business incubation for GM products.
- To discuss system approach towards innovation and entrepreneurship of GM products.

The opening remarks were given by Misheck Mulumba who welcomed the attendees to the webinar by the African Genetic Biocontrol Consortium. He then welcomed the speakers and gave an overview of the program. He finalized by giving the housekeeping rules and then proceeded to introduce the first speaker.

The first speaker was Silas Obukosia who made a presentation on "Status of Product Development and Registration for GM Products in Africa." The general outline of his presentation incorporated event and event approval of crops; product development, registration, and commercialization; GM animals and birds; Gene drive mosquitoes. Silas mentioned that the African Union Agenda 2063 7 aspirations and 20 goals, whereby ABNE contributes to Aspiration 1: A prosperous Africa based on inclusive growth and sustainable development; and Goal 5: Modern agriculture for increased productivity.

He gave a general background of the development of genetically modified organism by giving an overview of development of a gene construct and the tissue culture process. In this regard, he mentioned the six steps of environmental risk assessment that include problem formulation, hazard characterization, exposure characterization, risk characterization, risk management strategies, and overall risk evaluation and conclusions. The pathway of the development of regulatory approval and commercial release of genetically modified seeds include proof of concept, product development, event approval, national performance trials, and commercial release. Silas described a derived variety as a varieties arising from introgression from a recently commercially released variety. He transitioned and mentioned the malaria burden in Africa, whereby the continent accounts for 90% of the cases, especially children under five years. The African Union has called for investment in the development and regulation of the gene drive technology. The WHO guidance document of 2016



and 2020 highlights the phases of development and development from laboratory studies, laboratory population cages, confined field trials, staged open field releases, and post-implementation surveillance.

The next presentation was by Kwaku Poku Asante who gave a presentation on "Translating research to development of world's first-ever RTS, S vaccine for malaria in Ghana." He started by mentioning that progress towards eradication had plateaued and there was need for new tools. Countries will benefit from the deployment of additional tools and technology in the control and elimination of malaria. Vaccination is a proven effective intervention against disease elimination and many more vaccines are in progress. RTS, S/ASO1 also known as Mosquirix is an injectable vaccine developed to protect against P. falciparum malaria in children. RTS, S/ASAO1 is a fusion of repeat regions and T-cell epitopes of P. falciparum circumsporozite protein, hepatitis B surface antigen, and a free protein linked to AS01 adjuvant system and expressed in yeast cell. The vaccine was developed by GlaxoSmithKline. The vaccine triggers the body's own immune system to defend against malaria disease and subsequently prevent the malaria parasite from infecting, maturing, and multiplying in the live, after which the parasite would normally re-enter the bloodstream and infect red blood cells, leading to disease symptoms.

It is noteworthy that the RTS, S malaria vaccine development is a 30-years effort from GSK and successful partnerships. Trials have been conducted in several countries to generate evidence on impact and safety of the vaccine. For instance, phase 2 trials in Ghana established safety, immunogenicity, and adjuvant systems. Results from phase 2 trials indicated that there was 39% reduction in clinical malaria, 29% reduction in severe malaria, 62% reduction in severe malaria anemia, and 29% reduction blood transfusions. In addition, up to 6565 cases averted per 1000 children vaccinated over 4 years. European Medicines Agency issued a positive scientific opinion and concluded that the benefits if the RTS, S/ASO1 vaccine outweigh the risks. WHO recommended phased introduction of the vaccine in moderate to high transmission settings. The objective of pilot evaluation is to deliver the required four doses of the vaccine in routine settings. Post-introduction evaluation indicated that there was a broad acceptance of the vaccine for malaria prevention and control.

An engaging and organic discussion followed that incorporated all the panelists. The link to this discussion can be accessed below under the title "Translating research to commercialization of genetically modified products."

Link: https://www.genbioconsortium.africa/ events/#

#### AFIDEP EDITORS MEETING

### THE AFRICAN GENETIC BIOCONTROL CONSORTIUM PARTICIPATES IN AFIDEP EDITOR'S MEETING

The head of the secretariat made an invited presentation during AFIDEP (African Institute for Development Policy) editor's meeting on 5th October 2021.

The objective of the two-hour breakfast meeting for editor's based in Nairobi was to create awareness on the critical role played by the media fraternity in fostering public conversations on emerging health and their potential in addressing health challenges in Africa. Additionally, the meeting aimed to drum support of editors and subsequently increase dissemination of content on emerging health technologies and their implementation in Africa.

During the breakfast meeting, there was an introduction of editors to emerging health technologies. A panel of experts was then introduced to give specific presentations on the tools being developed on the continent for malaria control and elimination. Malaria, a vector-borne disease still remains a major healthcare burden on the continent. Conventional methods used in the control of malaria are inadequate and the disease burden continues to cause significant number of deaths on the continent. Experts from AFIDEP as well as partner institutions are increasing awareness on emerging health technologies and its potential to mitigate vector-borne diseases' burden on the continent.

Dr. Willy Tonui, the head of the African Genetic Biocontrol Consortium, gave a presentation on "Regulatory framework for gene drive research in Africa." The general point of focus of the presentation was on the policy and legal regulatory frameworks relating to gene drive for malaria control in Africa. In addition, there was discussion on ongoing efforts to address the gaps in the regulatory framework, as well as efforts to strengthen technical capacity for regulating gene drives research on the continent. The laws and regulations on gene drives are derived from international laws and country laws, for instance, the Cartagena Protocol in Biosafety. However, the release of gene drives will be made on a case-bycase basis after a comprehensive environmental risk assessment. Further, clear communication and public engagement, especially of the affected communities is essential. There are positive developments for gene drive research on the continent, whereby the AU High-Level African Panel on Emerging Technologies pointed out that it is imperative to comprehensively examine gene drive technology in mitigating the threat of malaria.

In conclusion, Dr. Willy Tonui reiterated the mission of the consortium, which is to expand Africa's selfdetermination of the course of research, development, and use of genetic biocontrol approaches for animal, public health and for conservation of wildlife and the environment in Africa.



### EMERGING TECHNOLOGIES AND THEIR POTENTIAL FOR IMPROVING HEALTH IN AFRICA

On regulatory framework for gene drive in Africa countries, Nigeria is the only country in the world that has amended their act to include emerging issues in biotechnology (Biosecurity, Gene Drive, Gene Editing and Synthetic Biology

#### Dr. Willy Tonui

Chairman and Executive Director. Environmental Health and Safety (EHS Consultancy)





Editors Breakfast Meeting Hilton Hotel, Nairobi 7:00am (EAT) Sehtp\_Africa







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# THE STEERING COMMITTEE MEETING CONFERENCE

# THE AFRICAN GENETIC BIOCONTROL CONSORTIUM HOSTED THE STEERING COMMITTEE MEETING CONFERENCE AT HILTON DOUBLE TREE HOTEL, NAIROBI

The African Genetic Biocontrol Consortium hosted the steering committee members in its first ever physical meeting at the Double Tree by Hilton Hotel. The meeting ran from Monday the 25th of October to Thursday the 28th of October 2021.

In attendance were the members of the Steering committee and the Secretariat:

- Dr. Misheck Mulumba Member representing the African One Health Network (AfOHNet).
- Jacqueline Kado Member representing the Network of African Science Academies (NASAC).
- Dr. Fayiz Abakar Member representing the Africa Biological Safety Association (AfBSA).
- Emma Orefuwa Member representing the Pan-African Mosquito Control Association (PAMCA).
- Dr. Elijah Juma Member representing the Pan-African Mosquito Control Association (PAMCA).
- Dr. Willy Kiprotich Tonui, PhD, EBS Head of the Secretariat.
- Willy Kibet Scientific and Technical Coordinator.
- Kimberley Terik Communications Coordinator.
- Willy Kipyegon Langat Administration and Finance Manager.

The Consortium functions under a shared governance system which is handled through the Steering Committee drawn from representatives of the Member Organizations as mentioned. The Steering Committee is the decision-making body of the Consortium. During the 4-day meeting members of the secretariat along with the steering committee



representatives discussed the progress made by the consortium secretariat since its inception on 30<sup>th</sup> November, 2020. This was a time to share ideas, evaluate and celebrate the various achievements made by the secretariat. The event coincided with the second webinar event hosted by the consortium secretariat on Thursday October the 28th 2021. The theme of the event was "Translating Research to Commercialization of Genetically Modified Products." An event which is part of a four-part series titled "The Needs and Requirements for Testing Genetic Biocontrol Technologies in Africa." The event on the 28th of October was moderated by Dr. Misheck Mulumba chairman the steering committee members.



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