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MALARIA VACCINE INITIATIVE

Malaria Vaccines and the Decision-Making Framework for the Possible Introduction of a Malaria Vaccine in Uganda

BACKGROUND TO THE WORKSHOP

While deaths and illness from many diseases can be prevented by vaccines used with other control measures, malaria, for which there is no vaccine, continues to exact a heavy toll on Africa: almost one million African children younger than the age of 5 die from malaria every year. For many years and especially in the last decade, many groups have been engaged in the development of the first vaccine against malaria. However, we may finally be just several years away from having a licensed and effective malaria vaccine available for use in sub-Saharan Africa. A Phase 3 clinical trial of the RTS,S candidate vaccine is ongoing in Africa, and it is hoped that this first-generation vaccine will be available for use within five years or so. In addition, many other potential malaria vaccine candidates are in earlier stages of development. Consequently, malaria vaccines may be added in the future to Expanded Program on Immunization (EPI) schedules as a new intervention to control malaria, complementing current interventions.

Given the complexity involved in decision-making processes, it will be useful to have a tool that will guide the decision on the introduction of a malaria vaccine. The tool will be useful for Ugandan policymakers, providing them with key required information to establish a malaria vaccine decision-making framework. The preparation of the malaria vaccine decision-making framework is a process to minimize the time lag between vaccine licensure and availability. It will ensure that national leaders will be able to make timely, well-informed decisions about the appropriate use of a malaria vaccine in their health systems within one to three years of licensure.

“In Africa, we tend to discuss ‘issues of yesterday’, but the process of the malaria vaccine decision-making framework is different in that it addresses issues of ‘tomorrow’, with an emphasis on planning ahead; for each day we delay, people continue to die.”

In July 2010, the Uganda National Academy of Sciences (UNAS) and the PATH Malaria Vaccine Initiative (MVI) convened a meeting to review the regional malaria vaccine decision-making framework. The purpose was to begin to engage the country in the process of early preparation for a decision on malaria vaccine by highlighting experiences of other countries and experts who had already participated in the development of a malaria vaccine decision-making framework, and to position Uganda to begin developing its own framework. Key stakeholders reviewed the regional malaria vaccine decision-making framework with a view to adapting it to Uganda. Participants prioritized information requirements and outlined future plans for securing that information.

WORKSHOP DESCRIPTION

Held July 28–29, 2010, the Uganda workshop was attended by 47 participants—some of whom will be involved in national decision-making around malaria vaccines—with a diversity of expertise in malaria, epidemiology, policy, finance, pediatrics, infectious diseases, immunology, vaccinology, drug regulation, program management, immunization delivery, health care administration, health economics, vaccine safety, and journalism. In plenary sessions, participants heard from those who had participated in the development of the regional decision-making framework and the process the countries went through to establish the regional malaria vaccine decision-making framework. Several talks framed issues around a similar framework adapted to Uganda, including which data are currently available and where the gaps in information, technical, and policy processes lie. The workshop objectives and activities were to:

- **Understand the country’s health policy decision-making process**, to provide the background for discussions in other sessions, and to update participants on current efforts to develop a malaria vaccine.
- **Learn about the regional malaria vaccine decision-making framework as well as some current studies that could provide the information required for a national decision on a malaria vaccine.** Participants also learned about the experiences of other countries that have gone through the process of using the decision-making framework for planning ahead of the policy decision, and they heard a presentation on the role of malaria vaccines as part of malaria control interventions using a multi-criteria decision analysis (MCDA).
- **Review the malaria vaccine decision-making framework within the context of Uganda.** Participants examined the policy issues relevant to a decision about the need for the vaccine in Uganda; i.e., the malaria disease burden, other available malaria interventions, acceptable malaria vaccine impact, and efficacy, quality, and safety. Participants also considered the technical aspects; i.e., economic and

WORKSHOP OBJECTIVES

THE PROCESS

financial issues, programmatic considerations, and sociocultural issues. They then proposed processes to address these policy and technical issues.

THE PROCESS

To accomplish the objectives, three activities were undertaken:

- **Key talks and lectures pertinent to the development of the malaria vaccine decision-making framework were presented.**
- **An MCDA was conducted among participants.** This technique was developed to elicit preferences from national policymakers to weigh relevant criteria for priority-setting in health. In this meeting, the MCDA was adapted to focus on malaria control interventions. The primary objective of the MCDA exercise was to assess how Ugandan participants weigh the importance of each criterion listed in the malaria vaccine decision-making framework as part of a decision on introducing a malaria vaccine. The aim of this exercise was to identify data deemed as highly important by participants to establish a framework for introduction of a malaria vaccine.
- **Review and adaptation of the regional malaria vaccine decision-making framework to Uganda.** The framework consists of two parts. The first focuses on the critical data needed by national stakeholders to make a decision about the appropriate use of a malaria vaccine within the health system. The second focuses on the key processes, both global and national, that should take place to facilitate national decision-making about malaria vaccines. Data and processes needed to make decisions about vaccine introduction are identified against the time frame in which decision-makers should gather information and formulate plans. Through plenary discussions, the regional malaria vaccine decision-making framework was reviewed considering the appropriate timing relative to vaccine licensure and identifying which data are currently available and where gaps in information and processes exist.

WORKSHOP FINDINGS

Malaria disease data: Some of the malaria disease data currently used in Uganda—for example, deaths due to malaria per day—are more than 15 years old, and were generated when the population of Uganda was 10 million people. The population of the country has since tripled.

Malaria interventions: The costs of existing malaria interventions are out of reach of the majority of Ugandans. Inappropriate use of available interventions was also highlighted, such as treatment for malaria without proper diagnosis or the current scarcity of drugs in public health facilities (attributed to the rerouting of drugs to

private health facilities). It was proposed that if this problem is addressed, the public sector would then be well-positioned to handle the demand for services.

Impact and coverage of available interventions: There is a need to conduct study to understand the reason of non-use of some of the available interventions. This would help to inform a decision on a malaria vaccine as a possible intervention.

Acceptability arising from efficacy issues: Participants stated that a first-generation vaccine that is even 30 percent effective would make a significant contribution to reduction of the malaria disease burden when it becomes available.

Morbidity data: Data on cause-specific morbidity disaggregated by age group are not readily available in Uganda. However, participants learned that the process of gathering these data had begun.

Efficacy testing in Uganda: Although Uganda is not one of the countries where efficacy trials for the candidate RTS,S vaccine have been conducted, data from tests done in other African countries would suffice.

EPI data in Uganda: There is no information on children who do not come for immunization in Uganda, but there is some information on those who drop out, since their information and contacts are obtained during the immunization process. The pneumococcal vaccine is anticipated to be introduced by the end of 2010, and if Uganda receives its requested support, it will introduce the rotavirus vaccine by 2013.

Financing: The GAVI Alliance and the government of Uganda usually co-finance immunization programs. Financing of new malaria vaccine will be a challenge, and as for any new vaccine, the Ugandan government must first agree to co-finance a malaria vaccine before the Uganda National Expanded Program on Immunization (UNEPI) can present it to the rest of the country as a policy. UNEPI will also need data to back up this proposal.

Programmatic capacity and pharmacovigilance: There is need to assess the country's cold chain handling and delivery system, and pharmacovigilance, as these could have an effect on the possible eventual introduction of the malaria vaccine. One challenge is that whereas the EPI system in Uganda is good, the country's district borders have been changing rapidly. It was suggested that rather than the EPI being planned along district lines, a regional approach with a focus on units would be more appropriate.

Anticipating programmes' needs for vaccine introduction: The EPI process is already in place for other vaccines, and the question is: Will the addition of malaria

vaccine improve or strain the system? And if so, to what extent?

Institutional requirements:

- **Regulatory policy:** A regulatory policy framework for a malaria vaccine needs to be established. In order to do this, the policymakers will need to be convinced. Issues such as its registration and placement on the essential drugs list will need to be worked out.
- **Expanded stakeholder function in UNEPI:** A stakeholder function that goes beyond the scientists is needed as soon as the justification data become available.
- **Engagement of Uganda's National Drug Authority.**
- **Political advocacy:** The need for advocacy is crucial, especially at the political level. Political buy-in (or lack of it) will have a big impact.
- **Updated guidelines and policies:** Uganda needs to update its guidelines and policies to enable smooth introduction of malaria vaccine.
- **Advance knowledge of vaccine cost:** Ugandan decision-makers need to know the costs two years before it is available for introduction to allow for the country to prepare proposals to GAVI, to budget, and to plan. Further, the session was informed that the Ministry of Health in Uganda works on five- and ten-year development plans, and any budget allocation for malaria vaccine should align with the ministry's strategic planning cycles.

Uganda also will require:

- World Health Organization prequalification for the product to be purchased.
- Support from the GAVI Alliance.
- Formation of a technical working group, which is fundamental before a product is adopted in Uganda.

JOINT STATEMENT ABOUT THE WAY FORWARD

It was agreed that Uganda needs a multi-sectoral standing committee on malaria vaccines, consisting of nine members with UNAS as the focal point, and with membership from health research institutions, the Uganda Bureau of Statistics, and UNEPI, among others. This committee would be chaired by Dr. James Tibenderana (Malaria Consortium, Uganda), and it would be set up within three months, with its first meeting scheduled for February 2011.

NEXT STEPS

Participants agreed on these next steps to facilitate the standing committee's activities:

- UNAS would formulate a policy statement from this meeting within two months.
- UNAS would draft a report of this workshop within two weeks.
- MVI would facilitate the launch of the committee.

MEMORABLE QUOTES

“Let us all be realistic about how long it will actually take to get a malaria vaccine licensed. If we underestimate or overestimate, we might not plan appropriately. Let us also remember that licensure can take a long time. This is not meant to make you lose hope; rather, we need to look at a time frame that is closer to how long it has taken other new vaccines to get licensed.”

Dr. Mercy Ahun, Managing Director, Programme Delivery, GAVI Alliance

“As this workshop progresses, I would humbly request you to keep in mind the critical role this academy can play in convening all the stakeholders in vaccines and immunization in Uganda to continue the crucial dialogue we are beginning today. What you should know right from the beginning is our academy's dedication and commitment to improving Ugandan lives through vaccines and immunization.”

Prof. Paul E. Mugambi, President, Uganda National Academy of Sciences

“As scientists and policymakers, we should not begin a lengthy decision-making process after the vaccine becomes available. Rather, we should prepare in advance. So if we prepare, but for some reason a vaccine is not available as expected, we will have lost nothing because we will be heading for the next one or whatever comes up. But if we fail to prepare, and fortunately a malaria vaccine is available and effective, we will have lost time tremendously.”

**Dr. Antoinette Ba-Nguz, Senior Program Officer for Africa, Policy and Access,
PATH Malaria Vaccine Initiative**

UGANDA NATIONAL ACADEMY OF SCIENCES

Staff on the activity:

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The mission of UNAS is to advance the ability of Uganda to address its most serious health challenges by (1) engaging in a series of scientific activities designed to elucidate potential evidence-based solutions to pressing national and regional health concerns; (2) enhancing the general capacity of UNAS to provide relevant and useful scientific policy advice; and (3) building Uganda's appreciation of and demand for advice from the academy.

Like many other academies of science, UNAS is an autonomous body that brings together a diverse group of scientists from the physical, biological, and social and behavioral sciences. These scientists work together in an interdisciplinary and trans-disciplinary manner to achieve their main goal of promoting excellence in science by offering independent, evidence-based advice for the prosperity of Uganda. The success of any academy lies in the strength and expertise of its membership and its ability to mobilize scientific experts to continually advise policymakers. For more information, please visit www.ugandanationalacademy.org.

PATH MALARIA VACCINE INITIATIVE

The PATH Malaria Vaccine Initiative (MVI) is a global program that was established at PATH through an initial grant from the Bill & Melinda Gates Foundation. MVI's mission is to accelerate the development of malaria vaccines and ensure their availability and accessibility in the developing world. MVI's vision is a world free from malaria. For more information, please visit www.malariavaccine.org.

PATH is an international, nonprofit organization that creates sustainable, culturally relevant solutions that enable communities worldwide to break longstanding cycles of poor health. By collaborating with diverse public- and private-sector partners, PATH helps provide appropriate health technologies and vital strategies that change the way people think and act. PATH's work improves global health and well-being. For more information, please visit www.path.org.

Copies of the full report will be posted on the above websites when finalized.

The workshop was supported by the PATH Malaria Vaccine Initiative through a grant from the United States Agency for International Development.

Detailed information on this workshop and follow-up activities can be obtained from the UNAS Secretariat: A4 Lincoln Flats, Makerere University Main Campus, PO Box 23911, Kampala, Uganda, Tel: +256-414-533-044, Fax: +256-414-533-044, Email: info@unas.or.ug / unas@infocom.co.ug.