Meeting on Malaria Vaccines Development and the Decision-Making Framework for the Possible Introduction of a Malaria Vaccine in Central Africa

(February 25th-28th, 2008)

Douala

Meeting Report

Central Africa

MALARIA VACCINE DECISION-MAKING FRAMEWORK

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Acknowledgements

The PATH Malaria Vaccine Initiative (MVI) would like to acknowledge the many individuals who contributed to this meeting, from the Ministries of Health, WHO, RBM Secretariat and RBM Network in Central Africa.

On the MVI team, Dr. Antoinette Ba-Nguz managed the overall coordination of the Meeting on Malaria Vaccines Development and the Decision-Making Framework for the Possible Introduction of a Malaria Vaccine in Central Africa, with significant contributions from Alan Brooks and Mr Laurent Bergeron.

We could not have completed the process without assistance from Mr Ross Brindle and Ms Kaitlin Christenson from Energetics Incorporated .

We would like to acknowledge all participants, with special thanks to the speakers, partners, and session chairs.

The Decision-Making Framework process is overseen by a Steering Committee. We would like to acknowledge the Steering Committee for their guidance and contributions to the Malaria Vaccine Decision Making Framework process from its inception. During 2008, this Committee included: Dr. Antoinette Ba-Nguz (MVI), Mr. Alan Brooks (MVI), Dr. Carter Diggs (USAID), Professor Dorothée Kinde-Gazard (University of Benin), Dr. Georges Ki-Zerbo (WHO AFRO), Dr. Rose Macauley (WHO AFRO), Dr. Eusebio Macete (WHO), Dr. John Marshall (Consultant), Dr. Kamini Mendis (WHO), Dr. Vasee Moorthy (WHO), Mr. K J Singh (Bill & Melinda Gates Foundation).

We would also like to thank the U.S. Agency for International Development (USAID) and the Bill & Melinda Gates Foundation for funding this process.

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Meeting on Malaria Vaccines Development and the Decision-Making Framework for the Possible Introduction of a Malaria Vaccine in Central Africa

Douala, Cameroon (25th-28th February 2008)

Context

Malaria continues to exert a heavy toll on Africa and almost one million children under five years old continue to die of malaria every year despite the availability of effective malaria control measures.

Over the last decade, the international community has made tremendous progress in accelerating the development of promising malaria vaccines to complement current interventions and to further reduce the burden of malaria. Several African research institutions are contributing to the current vibrant pipeline of malaria vaccine candidates.

Dozens of potential vaccines are being evaluated, and although most are in early development stages, a number of promising candidates are progressing through clinical trials. The leading vaccine candidate, RTS,S, is anticipated to be available as soon as 2012 if remaining clinical trials are successful; other malaria vaccines are likely five or more years behind this timeframe.

Malaria vaccines will likely be delivered through the Expanded Program on Immunization (EPI) as a new intervention to control malaria, building upon and complementing current interventions rather than replacing them. Due to the complexity of the malaria control situation and the anticipated growth of the immunization landscape, decision making about the future role of a malaria vaccine must commence well in advance of actual product availability. Recent experience with new interventions, including insecticide-treated nets (ITNs), artemisinin-based combination therapy (ACTs), and the Haemophilus influenzae type B (Hib) vaccine, has highlighted the importance of early planning.

Background

As research activities continue, there is a need to share information with policy-makers on progress in malaria vaccine development and start to discuss how the decision on the introduction of a malaria vaccine would be made. Experience has shown that there are usually long delays between the availability of a new intervention and its implementation by national health systems due to complex factors involved in policy decisions. Furthermore, a malaria vaccine would complement other malaria control interventions and the decision as whether to introduce it or not will not be straightforward. In addition, numerous new vaccines

are to be introduced over the next 5 years. The countries and decisionmakers will need to keep abreast of progress and possibilities as they arise in order to be able to expedite the use of an effective malaria vaccine once it is available.

Since January 2006, the World Health Organization's Africa Regional Office and MVI, with support from the US Agency for International Development, have been working in partnership with various multilateral and bilateral stakeholders, researchers, and several Ministries of Health, to develop a framework of information that will help countries to make informed decisions about the potential role of a successful malaria vaccine within their national health systems.

In January 2006, the PATH Malaria Vaccine Initiative (MVI) and the World Health Organization Regional Office for Africa (WHO AFRO) organized a workshop in Cotonou, Benin, hosted by the Ministry of Health of Benin, to develop a draft framework for decision making on the possible use of a malaria vaccine. Health officials from 13 African countries met with multilateral and bilateral partners in Benin to define the processes and data needed for early decisions on the role of a malaria vaccine in national health systems. The group included participants with expertise in malaria, immunization, research and product development, policy, planning, and finance.

The workshop resulted in a generic framework of the information that countries require to make decisions regarding the use of a malaria vaccine in their national health systems. The information is grouped into categories that correspond to those in the WHO's Vaccine Introduction Guidelines. When applying this framework, national decision-makers will have the data to determine, within one to three years of licensure, the appropriate role for a malaria vaccine in their country. Potential decisions might include:

- introducing the vaccine,
- conducting a demonstration project,
- collecting more data before deciding to use a vaccine, or
- not introducing the vaccine.

A malaria vaccine decision-making framework will be a useful tool to countries, given the complexity involved in national decision-making processes. A framework will not provide a "one-size-fits all" perspective on who should use a malaria vaccine. Instead, it will begin an iterative process to help countries structure how to weigh the many factors and begin to fill gaps in information along the path to making such a decision. The framework aims to allow governments and partners at regional, national, and global levels to better align their planning about the role of a malaria vaccine and, eventually, reach a decision regarding its use.

During the second half of 2006, MVI and WHO collaborated with multiple Ministries of Health to adapt the generic framework in six African countries—Gabon, Ghana, Kenya, Mali, Mozambique, and Tanzania—representing diverse health systems and varying needs for and access to malaria and immunization interventions. In each

country, MVI, WHO, and the Ministry of Health convened a two-day meeting that asked key stakeholders to review the generic framework, prioritize their country-specific information requirements, and outline future plans for securing the information. Each country consultation resulted in the development of a country-specific framework for decision making as well as a country-specific near-term and long-term future plan of action.

In early 2007, the country-specific frameworks were synthesized to create a Draft Regional Decision-Making Framework (DMF). MVI's objective is to work with WHO and Roll Back Malaria and other partners to validate this Draft Regional Framework as a common tool for decision-making across Africa by presenting the framework at different regional meetings. The forum used was the first quaterly meeting of the RBM Network in Central Africa (CARN), held from 25 to 28 February 2008 in Douala, Cameroon.

Meeting Procedures

The CARN meeting was attended by 50 participants from National Malaria Control Programmes and Expanded Programmes for Immunization from the Central Africa Regional Network countries—Angola, Cameroon, Gabon, Centrafrican republic, Democratic Republic of Congo, Sao Tome & Principe and Chad—and from invited countries—Burundi (EARN Network), Comoros and Madagascar (SARN Network), as well as active partners organizations in the region—GMP, WHO-AFRO/IST-Central, WHO-Cameroun, RBM Secretariat-Geneva, Coordination Organization against Endemic Diseases in Central Africa (OCEAC), MSH/RPM+, Population Services International (PSI), Red Cross International Federation, Cameroon Coalition Against Malaria (CCAM), Sumitomo Chemicals, Voices Malaria Advocacy Project African Region, The Boston Consulting Group (BCG), PATH Malaria Vaccine Initiative, PSI/ASF RDC, Islamic Development Bank, Cameroon National Trade and Services Unions Federation (FESCOS-CAM). Representatives from the media were also present. The list of participants and agenda of the meeting are attached in the Appendix.

The last session of the CARN meeting focused on malaria vaccines development and on the DMF with the following objectives :

- Update regional stakeholders on recent developments on malaria vaccines research
- Review the decision-making framework to validate it as a tool for introducing the malaria vaccine in Central Africa

At the meeting, key stakeholders were asked to review the Draft Regional Decision-Making Framework, discuss whether or not the content is appropriate/sufficient, and validate the framework for use as a tool in the Central African region.

Key points discussed during the meeting are summarized below and in the next sections.

Objective 1: Update regional stakeholders on recent developments in malaria vaccine research

Speaker: Dr Antoinette Ba-Nguz

Developing vaccines takes at least 10 years and $500M plus dollars, with a significant risk of failure at each step of development. Following pre-clinical development, a vaccine moves into Phases 1, 2 and 3. Safety is a critical issue at each phase, with growing data on immunogenicity and efficacy by the time of phase 3 regulatory trials. Following regulatory approval, a vaccine enters Phase 4, where post-marketing surveillance continues and the opportunities for effectiveness trials begin.

Different groups are currently pursuing dozens of malaria vaccine candidates with a relatively small number of antigens. There is room for greater harmonization in the future.

The Technology Roadmap was a 2005 process to begin further coordination and harmonization across those working on malaria vaccines.

- The most advanced vaccine in the pipeline, the GSK-MVI RTS,S, is targeting only *Plasmodium falciparum*; it has been shown to be 50% efficacious in clinical trials with a follow-up duration of 18 months. Its efficacy is 50 % against severe malaria and 35 % against clinical malaria. RTS,S is a first generation vaccine within a relatively important portfolio. However, it is important to keep in mind that a malaria vaccine would complement the existing arsenal of interventions to fight malaria.

Discussion centered upon:

- detailed information on MVI's portfolio vaccines characteristics,
- number of doses and possibility of booster dose,
- administration regimen and age target,
- potential clinical efficacy,
- suitability to various epidemiological profiles, and
- possibility of a combination/integration with existing EPI vaccines in order to minimize logistical impact on health systems

Objective 2: Discuss and Review the Draft Decision-Making Framework for Introducing a Malaria Vaccine in the Central African region

Draft Regional Malaria Vaccine Decision-Making Framework (DMF)

—Dr Antoinette Ba-Nguz PATH MVI

Historically, it has taken years and decades to introduce new malaria control interventions and vaccines into developing countries. This suggests that advance planning is essential in order to shorten the timeline to 1-3 years between when a vaccine becomes available and when a country takes a decision on whether or not to use the new vaccine.

PATH MVI, WHO, RBM, partners, and countries have worked since 2006 to develop a malaria vaccine decision-making framework that can be used for any malaria vaccine that becomes available. The framework builds upon past experiences in introducing other malaria interventions and new vaccines.

The decision-making framework (DMF) is a tool to help countries' decision makers decide whether or not they will introduce a malaria vaccine as soon as possible after it is licensed. This decision-making process should actually start before the product is licensed. The DMF is not specific for one vaccine (e. g. RTS, S), but rather applies to all malaria vaccines.

The Central Africa DMF document can be found in an annex to this report.

Discussions centered on:

- Vaccine availability, accessibility and utilization: these are crucial questions for the decision making so it is important to have good quality data on these aspects.
- Importance of early planning for introducing a malaria vaccine, particularly because this vaccine needs to be given through EPI. In this context, it is important for all countries to adhere to vaccinal independence: costs related to vaccines and vaccines related of EPI routine programme should be integrated into EPI.
- Importance of the vaccine manipulation, conservation (cold chain), and presentation (lyophilized, mono-dose, etc…).
- Malaria vaccine combination with other antigens was discussed in regard to the potential cold chain and waste management implications. MVI insisted that a collaboration with the manufacturer has been undertaken to match countries stakeholders' recommendations on product profile.

After the presentation of the DMF, participants reviewed the two parts of the framework (data and processes) in breakout sessions and discussed whether or not the data and processes identified in the DMF are sufficient and relevant to guide decisions on introducing a malaria vaccine in Central Africa.

Terms of reference for the group work:

Objectives

- Examine the Draft Decision-Making Framework and reach a consensus on its use as a tool for vaccine introduction in EPI and NMCP programmes in Central Africa.
- Make some recommendations to implement the framework.

Methodology

- Group discussions were facilitated by WHO-AFRO, MVI and the RBM secretariat.
- Each group elected a chair and a rapporteur. Both groups worked on data and then processes. Partners were invited to participate as observers in either group.

Group A (reported on data)	Group B (reported on processes)
Angola	Burundi
DRC	Comoros
Congo	Madagascar
Gabon	Chad
Sao Tome et Principe	Centrafrique
Cameroon	Cameroon

Review and Discussion of the Data Points Identified for Decision-Making in the draft DMF

Summary of discussions
Group A : Reported on Data

Category of data and data points	Comment
Malaria Disease Burden	
BEFORE LICENSURE	
Number of cases of clinical and severe malaria by age group	Standardize the operational definition
Malaria epidemiology and transmission at district level	Split by epidemiological profile
Cases of malaria in pregnant women and persons with HIV	Split this information in two groups
Other antimalaria interventions	
Impact at national level of existing ant malaria interventions	Should be also measured at provincial level
Sociocultural environment	
Community expectations towards malaria vaccine in and around clinical trials areas	Reformulate: community expectations on clinical trials areas
DATA AFTER LICENSURE	
Malaria Vaccine Impact	
Malaria vaccine coverage	Use a morbidity and mortality indicator for impact study
Public health return on investment	Reformulate: socio-economic impact

Estimate recurrent and hidden costs including post-licensure marketing and surveillance	Reformulate : Recurrent, direct and indirect costs
Efficacy, Quality and Safety	
Post-licensure safety data	Add: efficacy aspect

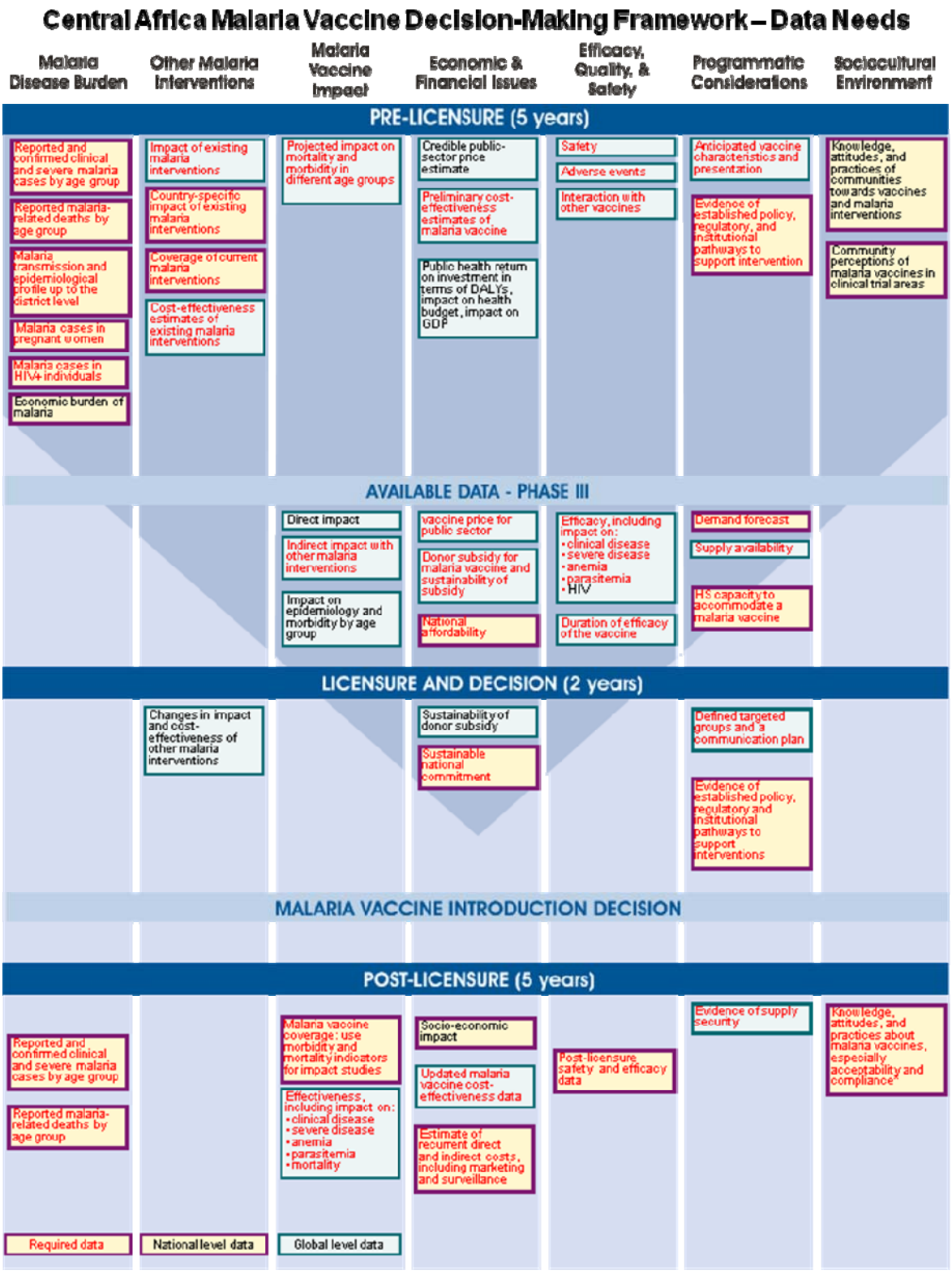
Group B: Reported on Processes

Processes	Comments
PROCESSES BEFORE LICENSURE (including phase 3)	
Integrate country requirements into vaccine development plans (5 years before)	Efficacy and durability are critical
Assess and strengthen regulatory, ethics and data management processes in countries	Responsibility of the National Regulatory Authority (NRA). Strengthen where they exist and encourage NRA creation where they do not exist
Integrate malaria vaccines into countries' multiyear and strategic plans (4-5 years before)	Provided that EPI and NMCP programmes' multiyear plans are revised
Signal vaccine demand (1-3 years before)	Provided that need in vaccines and vaccines goods are informed
Develop a communication plan on malaria vaccines (1 year before)	Integrate this plan into EPI and NMCP programmes' strategic plan, including a contingency plan
Develop plan for procurement and resource mobilization for financial sustainability	Develop a co-financing plan
Incorporate malaria vaccine into national budgeting processes	This is to assure programme sustainability
Elaborate the vaccine introduction plan and programmatic guidelines (within 1 year after licensure)	Depend on national regulatory authority functions
Examine sustainability of existing funding and how to encourage in-country financing	Need to encourage countries to move towards vaccinal autonomy
Vaccine safety and efficacy monitoring	Encourage countries to create pharmacovigilance agencies; Add vaccine quality monitoring up to patient level
Monitor implementation of the vaccine and evaluate its impact on health system	Split in two parts : -Vaccine program implementation monitoring - Assessment of vaccine's impact on the health system

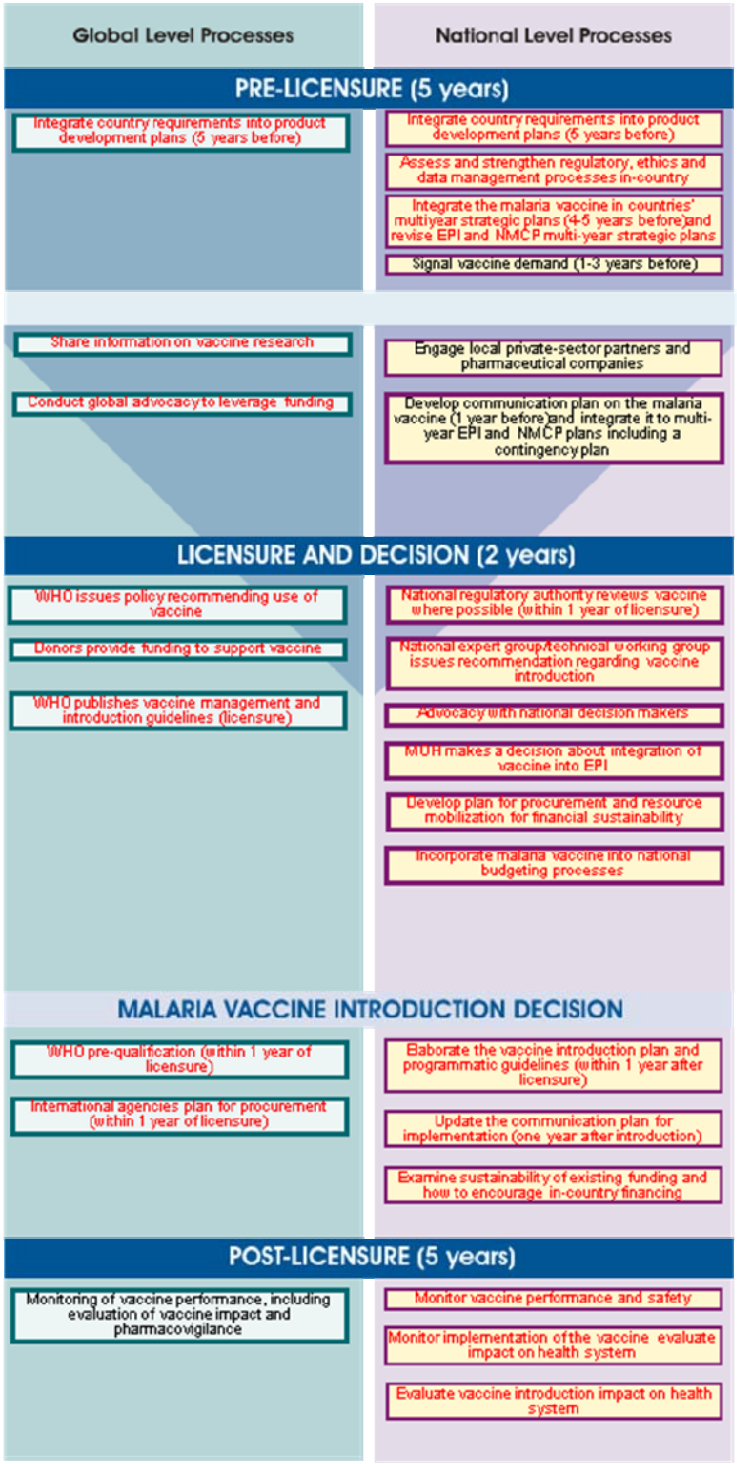
Outcome

- Consensus was reached that all the data and processes identified in the DMF are necessary, relevant and sufficient for Central Africa.
- Amendments made to the DMF:
    - Data: add data on vaccine characteristics (administration mode, waste management, presentation, storage requirements etc…)
    - Processes: add "Strengthen health information system"

Below is the revised version of the DMF for Central Africa


Central Africa Malaria Vaccine Decision-Making Framework – Data Needs
Malaria Disease Burden
Other Malaria Interventions
Malaria Vaccine Impact
Economic & Financial Issues
Efficacy, Quality, & Safety
Programmatic Considerations
Sociocultural Environment
PRE-LICENSURE (5 years)
Reported and confirmed clinical and severe malaria cases by age group
Reported malaria-related deaths by age group
Malaria transmission and epidemiological profile up to the district level
Malaria cases in pregnant women
Malaria cases in HIV+ individuals
Economic burden of malaria
Impact of existing malaria interventions
Country-specific impact of existing malaria interventions
Coverage of current malaria interventions
Cost-effectiveness estimates of existing malaria interventions
Projected impact on mortality and morbidity in different age groups
Credible public-sector price estimate
Preliminary cost-effectiveness estimates of malaria vaccine
Public health return on investment in terms of DALYs, impact on health budget, impact on GDP
Safety
Adverse events
Interaction with other vaccines
Anticipated vaccine characteristics and presentation
Evidence of established policy, regulatory, and institutional pathways to support intervention
Knowledge, attitudes, and practices of communities towards vaccines and malaria interventions
Community perceptions of malaria vaccines in clinical trial areas
AVAILABLE DATA - PHASE III
Direct impact
Indirect impact with other malaria interventions
Impact on epidemiology and morbidity by age group
vaccine price for public sector
Donor subsidy for malaria vaccine and sustainability of subsidy
National affordability
Efficacy, including impact on:
• clinical disease
• severe disease
• anemia
• parasitemia
• HIV
Duration of efficacy of the vaccine
Demand forecast
Supply availability
HS capacity to accommodate a malaria vaccine
LICENSURE AND DECISION (2 years)
Changes in impact and cost-effectiveness of other malaria interventions
Sustainability of donor subsidy
Sustainable national commitment
Defined targeted groups and a communication plan
Evidence of established policy, regulatory and institutional pathways to support interventions
MALARIA VACCINE INTRODUCTION DECISION
POST-LICENSURE (5 years)
Reported and confirmed clinical and severe malaria cases by age group
Reported malaria-related deaths by age group
Malaria vaccine coverage: use morbidity and mortality indicators for impact studies
Effectiveness, including impact on:
• clinical disease
• severe disease
• anemia
• parasitemia
• mortality
Socio-economic impact
Updated malaria vaccine cost-effectiveness data
Estimate of recurrent direct and indirect costs, including marketing and surveillance
Post-licensure safety and efficacy data
Evidence of supply security
Knowledge, attitudes, and practices about malaria vaccines, especially acceptability and compliance*
Required data
National level data
Global level data

Central Africa Malaria Vaccine Decision-Making Framework – Process Needs



Key to Acronyms

EPI	Expanded Program on Immunization
MoH	Ministry of Health
NMCP	National Malaria Control Program
TBD	To Be Determined

Recommendations

Participants at the meeting also made recommendations for the DMF implementation as follows:

- Reinforce partnerships for resources mobilization (GAVI, CARN, local partners
- Inform countries and local and national partners on the DMF and its further plans (Inter Country Coordination agencies, Country Coordination Mechanism)
- Countries to implement pharmacovigilance systems
- Continue to organize joint meetings: NMCP-EPI and EPI-NMCP

Conclusion:

During this meeting, the most recent results from the trials on the malaria vaccine candidate RTS,S were disseminated to regional stakeholders. Information was also shared on the status of research on other malaria vaccines.

The draft Decision making Framework was presented to EPI and NMCP managers from eleven countries in the Central Africa subregion. Participants have reviewed the data and processes identified and made suggestion to make it a valid common tool for decision on the introduction of malaria vaccines in Central Africa.

Next Steps:

In 2008 and beyond, MVI and its partners anticipate similar consultation with other sub-regions in Africa for the revision and validation of the DMF.
With guidance from the Steering Committee, MVI will continue to work with WHO, RBM and other stakeholders in African countries to gain insight into the Regional Decision-Making Framework, as well as develop plans for its implementation.

Appendices

Agenda
28th February 2008

Time	Topic	Facilitator/Speaker
9.00 – 9:15	Opening Welcome remarks	WHO /Cameroun
Objective 1: Discussion on the Decision-Making Framework as a tool for introducing malaria vaccines in Africa		
9:15 – 9:45	Presentation of the draft Decision Making Framework (DMF)	WHO/PATH-MVI
9:45–10:00	Presentation of the ToR for group discussion	PATH-MVI
10:00–11:15	Group discussion: Review of the DMF	participants
11:15–11:45	Coffe/tea break	
11:45–13:00	Group discussion: Review of DMF (follow-up)	participants
13:00–14:30	Lunch	
14:30-16:00	Plenary discussion and consensus	chair
Objective 2: Agree on an action plan for implementation of regional decision-making framework.		
16:00-16:30	Recommendations to countries and partners on DMF implementation	Chair
16:30	Conclusions and wrap-up	Chair

Participants List

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Steering Committee

A steering committee of experts provided technical input into content development for the Malaria Vaccine Decision-Making Framework. The members of the 2009 Steering Committee include:

- Dr. Antoinette Ba-Nguz, Program Officer for Africa, MVI
- Mr. Alan Brooks, Director Policy and Access, MVI
- Dr. Carter Diggs, Senior Technical Advisor, USAID
- Professor Dorothée Kinde-Gazard, University of Benin
- Dr. Georges Ki-Zerbo, Malaria Regional Advisor, WHO AFRO, Malaria Control Programme
- Dr. Rose Macauley, WHO AFRO, Vaccine Preventable Diseases
- Dr. Eusebio Macete, WHO Initiative for Vaccine Research (IVR) and Centro de Investigación en Salud de Manhiça (CISM)
- Dr. John Marshall, Consultant to PATH
- Dr. Kamini Mendis, WHO Global Malaria Programme
- Dr. Vasee Moorthy, WHO IVR
- Mr. Gerard Cunningham, Bill & Melinda Gates Foundation

Briefing Paper Summary

Members of the Steering Committee produced seven briefing papers to provide input into the Workshop on a Malaria Vaccine Decision-Making Framework held in Cotonou, Benin in January 2006. These papers summarize current knowledge that is likely to inform future malaria vaccine decision making. The topics of the briefing papers are as follows:

- Analysis of the Demand for a Malaria Vaccine: Outcome of a Consultative Study in Eight Countries
- The Return on Investment for Malaria Vaccines: Preliminary Estimates of Public Health Impact in Africa
- Vaccine Introduction Guidelines from WHO

- Malaria Control Policies: Pathways for Decision Making
- Landscape of Other Vaccines and Malaria Control Options on the Horizon Over the Next Decade
- Status of Malaria Vaccines: Development Process and the Product Pipeline
- Moving from Development to Policy to Implementation of New Products in Countries where Malaria is Endemic: Historical Context for a Malaria Vaccine

Copies of these papers are available at www.malvacdecision.net.

Contact Information

For further information the Malaria Vaccine Decision-Making Framework process, please see www.malvacdecision.net or contact:

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