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

(November 20th-21st, 2008)

Ouagadougou

Meeting Report

Western 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 in West Africa RBM Network (WARN)

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 Western Africa, with significant contributions from Mr Alan Brooks and Dr Alex Adjagba.

We could not have completed the process without assistance from Mr Ross Brindle 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).

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

Ouagadougou, Burkina Faso (20th-21st November 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) presented to additional countries in 2007-08—Ethiopia, Burkina Faso and Malawi.

The Draft Regional Framework is intended to be a decision-making tool applicable anywhere in the African region. MVI and its partners organized a series of sub-regional consultations with Expanded Programme for Immunization (EPI) and National Malaria Control Program (NMCP) managers to review and validate the data and processes identified in the framework for decision on malaria vaccines. Three meetings were held, encompassing three general regions of Africa:

- The first validation meeting was held February 2008 in Douala during the Central African Roll Back Malaria Network (CARN) meeting.
- The second validation meeting was held August 2008 in Lusaka during the East and Southern African Roll Back Malaria Network (ESA) meeting.
- The third meeting was held November 2008 in Ouagadougou in collaboration with WHO, RBM, and the West African Health Organization.

Meeting Procedures

The WARN meeting was attended by participants from National Malaria Control Programmes and Expanded Programmes for Immunization from the West Africa Regional Network countries—Benin, Burkina Faso, Cape Verde, Cote D'Ivoire, the Gambia, Ghana, Guinea, Guinea-Bissau, Liberia, Mali, Mauritania, Niger, Nigeria, Sierra Leone, Senegal, Togo—as well as active partner organizations in the region—WHO, Roll Back Malaria, and PATH MVI. Representatives from the media were also present. The list of participants and agenda of the meeting are attached in the Appendix.

The objective of this meeting was to validate the Regional Decision-Making Framework (DMF) as a common decision-making tool for the possible introduction of a malaria vaccine in West Africa. It had the following specific objectives:

- Review and discuss issues and challenges in the introduction of new malaria control interventions and new vaccines, including implications for future malaria vaccines.
- Review the Draft Regional Decision-Making Framework.
- Agree on the way forward for the implementation of the Draft Regional Decision-Making Framework for countries and partners.

At the meeting, key stakeholders were asked to discuss issues and challenges in the introduction of new malaria control interventions, review the Draft Regional Decision-Making Framework, discuss whether or not the content is appropriate/sufficient, validate the framework for use as a tool in the West African region, and agree on the way forward for the DMF's implementation.

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

Objective 1: Review and discuss issues and challenges in the introduction of new malaria control interventions and new vaccines, including implications for future malaria vaccines

Introduction
—Dr. M. Jawla, Chair

The Chairperson greeted the participants, thanked them for attending, and welcomed everyone to the meeting.

From research to policy: challenges of introducing new vaccines

—Dr Femi Oyewole, IVD IST West Africa

Dr Oyewole first reminded the assembly that "Introducing new vaccines is one of the four GIVS' strategic areas of work and reviewed the whole vaccine pipeline for vaccines currently in use and to come, summarizing the whole issue of vaccine research questions and how/ when research can answer these questions. He stated clearly the role of donors, partners, and governments with a show case for GAVI current support system.

Dr Oyewole then described all conditions for a smooth vaccine introduction. He went through technical issues, including age, schedule, routine fixed sites or outreach, updating the national policy, updating the tools for data, developing an introduction plan, training, tools and schedule, integration with other activities. Vaccine management issues cover cold capacity needs, sensitivity of the vaccine vial monitor (VVM) etc…

Logistical issues described vaccine bundling according to presentation and logistics policy available to determine storage and storage conditions and packaging. Other issues such as waste management, advocacy and communication, supervision and monitoring, and most importantly surveillance issues, particularly the need to redefine surveillance objectives and strategies to document and show the impact of introduction,

He concluded that these challenges are not constraints, and the efficacy of the vaccines determined the success of introduction.

Strategic orientation for malaria control and elimination in the African Region

—Dr Diarra T. WHO/ AFRO

Dr Diarra first put the malaria control and elimination issue into context(RBM 2010 goal and MDGs 2015, April 2008 UN secretary General call for 100 % coverage of interventions etc…) and defined concepts such as malaria control, elimination, eradication, etc..). He explained the strategic approaches and interventions including acceleration of control in high endemicity countries and areas towards universal access to key interventions for impact, expanding of 'Malaria-free' areas and moving to pre-elimination in low endemicity countries and maintenance of malaria-free countries.

Implementation of these interventions depends on various parameters such as partners' coordination and alignment, managerial capacity at country level, surveillance/ monitoring and evaluation, lengthy process between policy adoption and implementation for ACT, low confirmation rate for malaria diagnosis, weak capacity for Indoor Residual House Spraying, low ITN coverage in many countries, gap in term of financial resources for countries and technical partners.

However, existence of effective interventions , strong advocacy at all levels that put malaria high on the international public health agenda ,high political commitment for malaria control in the African Region, increased resources for malaria control are good opportunities of a current environment positive, and should help face these challenges.

In the second part of his presentation, Dr Diarra explored the malaria eradication and elimination question, exposing both the political and technical requirements for such ambition.

Countries' experiences in introducing new vaccines: Introduction of the pentavalent vaccine in Senegal

—Dr. Diallo, EPI/ Senegal

Dr Diallo began his presentation with a description of the situation and a justification of the introduction of pentavalent vaccine. Senegal had a unique combination of EPI performance, immunization system strengthening, political and social commitment, funding opportunities and diseases burden data availability that led to the decision to introduce pentavalent vaccine into EPI.

The introduction plan required that all regions and districts introduced the vaccine simultaneously, old DTC and Hepatitis B vaccines were withdrawn and all children are vaccinated with pentavalent whatever their vaccinal status.

The most critical points to consider concerned vaccine stock (vaccine shortage/ over-stocking, risk of stock lapsing), storage capacity, national affordability and vaccine quality monitoring including National Regulation Authority, WHO/UNICEF.

A communication plan was established in parallel, involving all level communities through media and outreach sessions.

Countries' experiences in introducing new vaccines: Introduction of new control interventions in Ghana

—Dr Owusu Felicia (WHO AFRO) and Dr Aba Baffoe-Wilmot (NMCP Ghana)

The speakers provided first an overview of the malaria disease burden in Ghana and the malaria control strategy (to reduce malaria burden by 75% by 2015) justifying successive introductions of new interventions. They explained that recent major decision included change in the anti-malaria drug policy, introduction of IPTp and subsequent scale up and piloting of IRS. These policy changes required number of steps from formation of Technical Committees, to ensuring availability of the prospective commodity or service including gathering of enough supportive data, consensus building among major stakeholders, sensitization of key personalities and identifiable groups, intensive IE&C.
However, these introductions faced some challenges from which were learned the following lessons: Stakeholder sensitization and involvement is key, Media involvement is paramount, Health worker re-orientation and training is very important, Quality assurance of product and service delivery is equally important, Pharmacovigilance (adverse events monitoring) if medicines are involved , Community involvement from the beginning enhances acceptance of service/product, Intensive and sustained BCC, Supervision , monitoring and evaluation to be well in place, There must be provision for resolution of unanticipated deviations.

Countries' experiences in introducing new malaria control interventions: ACT introduction in Senegal

—Dr M B Diouf NMCP Senegal

Dr Diouf began his presentation with an overview of the malaria epidemiological profile of Senegal. In 2000, parasite resistance against first line treatment (chloroquine) reached 25%, justifying new treatment policies: recommendation to use bitherapy (AQ+SP) for simple malaria and SP for prevention in pregnant women.

A first transition step (2003-2005) was to inform stakeholders and partners, reviewing current treatment guidelines and organizing training sessions at district level.
During the second transition stage (2004-2005) funding scheme (Global fund fourth round) and agreement on ACT were found and an introduction plan was elaborated.

The main activities involved in the proper introduction plan included product choice and legal processes such as licensing and Essential Medicines List, product supply, management and distribution, Advocacy sessions and elaboration of introduction plans at districts level, Management of current stock of medicines, workers training, quality control management, pharmaco vigilance system implementation and strengthening of drugs efficacy monitoring
Summarizing the main challenges of this change of policy, Dr Diouf pointed the access to correct diagnosis (confirmation by laboratory tests), the access to treatments at all levels and the assessment of drug needs and utilization monitoring.

Update regional stakeholders on recent developments in malaria vaccine research

—Dr A. Ba-Nguz, MVI

To begin her presentation, Dr. Ba-Nguz provided an overview of the status of malaria vaccine development. She described the mission and goals of the Malaria Vaccine Initiative (MVI) of PATH, and explained that MVI aims to accelerate the development of promising malaria vaccines and ensure their availability and accessibility in the developing world.

Dr. Ba-Nguz then spoke on the origins of and approaches toward malaria vaccine development, summarizing early steps and noting that potential vaccines must target one or more stages of the parasite life cycle; transmission; infection; and/or the disease itself.

Significant scientific challenges remain for malaria vaccine development. Much is not understood about the mix of antigens or targets for malaria vaccines that would optimally stimulate the human immune system, and there are no known correlates of immunity for malaria vaccines. Because of this, candidate vaccines require large trials. Beyond these scientific challenges, malaria vaccine development is also obstructed by the fact that limited financial return can be anticipated from a market located largely in the developing world.

Dr. Ba-Nguz summarized the four stages of clinical trials any vaccine must pass as it is developed:

- Phases I_a and I_b, called "proof of principle," test for safety and immunogenicity in less than 100 people;
- Phases II_a and II_b, called "preliminary efficacy," test for safety, immunogenicity, and efficacy in several hundred people;
- Phase III, called "pivotal licensure studies," tests for safety, immunogenicity, and efficacy in tens of thousands of people; and
- Phase IV, called "post-marketing studies," tests for safety and effectiveness after a vaccine is sold for public consumption.

We are getting closer to a malaria vaccine, Dr. Ba-Nguz explained, through a renewed global commitment with at least three characteristics: increased funding to support research, including on malaria vaccine development; an international scientific community formally committed to working together to advance malaria vaccines from laboratory to clinical trials to implementation; and the Malaria Vaccine Technology Roadmap of 2006.

Dr. Ba-Nguz also spoke about the RTS,S Phase II studies underway in five countries, as of May 2008, and the Phase III studies underway at 11 sites, which are expected to yield results by the end of 2011.

Overall, Dr. Ba-Nguz described the global malaria vaccine development pipeline as "vibrant." Over 90 malaria vaccine development projects are underway; the most advanced candidate, GSK Biologicals' RTS,S/ASO1, is expected to yield a large amount of additional data by the last quarter of 2008 and anticipated to enter Phase III licensure trials in early 2009. RTS,S/ASO1 is anticipated to be submitted to regulatory bodies by 2011. It will be a partially efficacious vaccine and will complement existing measures, rather than replacing them.

Dr. Ba-Nguz concluded by referring listeners to the websites for PATH (http://www.path.org/), MVI (http://www.malariavaccine.org/), and the Decision-Making Framework (http://www.malvacdecision.net/).

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

Introduction to the Draft Regional Decision-Making Framework (DMF)

—Mr Ross Brindle, Consultant for PATH MVI

Mr. Brindle described the development of the DMF from 2006, where it began through the collaborative efforts of partners including WHO, PATH, USAID, the Bill and Melinda Gates Foundation, and MVI.

The malaria vaccine is nearer than ever before: By 2015, a malaria vaccine with 50% efficacy is expected to be licensed. The DMF was created to assist in vaccine introduction; once the malaria vaccine becomes available, policy decision-making may not be a straightforward process. The DMF takes into account programmatic and policy considerations to promote sound decision making. It is a synthesis of the outcomes from individual countries, incorporating points included by at least half of the countries consulted.

The framework is split into a set of processes and a set of data points. Identified items are further categorized either as critical to reaching a decision or as beneficial but unnecessary. Finally, the items are differentiated into those which the global

community is responsible for generating and those which individual countries or regions are responsible for generating.

The data and processes of the DMF are grouped along a generic timeline, beginning in the pre-licensure period, up to five years prior to licensing and including a point after which the Phase III clinical data is available. The second period begins when a product is licensed by the country, lasting until a decision is made regarding introduction. The final period is the post-licensure or follow-up period, given as approximately five years following the vaccine's introduction. Once established, this generic template enables a country to apply the framework to a specific product by changing the timeline to match the anticipated schedule for that product, once known (presumably during its later development).

Presentation of the Terms of Reference for Group Discussion on the DMF

—Ross Brindle, Consultant for PATH MVI

Mr. Brindle split the participants into three groups, each tasked with reviewing a portion of the Framework and answering a set of questions. Annex 3 details the terms of reference used for group discussions.

Objectives of this session were:

- To determine the data and processes necessary to reach a decision on the potential introduction of a malaria vaccine;
- To reach consensus on the use of the DMF for decision making on the future use of a malaria vaccines; and
- To define necessary "next steps" to properly consider implementation of the DMF.

The conclusions of the group discussion are reported below.

Group A Facilitator: A. Ba-Nguz (PATH MVI) (reported on data from Malaria Disease Burden through Economic and Financial Issues)	Group B Facilitators: R. Brindle (PATH MVI) (reported on data from Malaria Disease burden through Programmatic considerations)	Group C Facilitators: A. Adjagba (PATH MVI)& Dr Kinde-Gazard (RAOPAG) (reported on data from economic & financial issues through socio-cultural environment)
Algeria	The Gambia	Guinea-Bissau
Benin	Sierra Leone	Mauritania
Burkina Faso	Nigeria	Niger
Cap Vert,	Liberia	Senegal
Cote D'Ivoire,	Ghana	Togo
Guinea		Mali

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

Summary of discussions

A. Review of Data

Category of data and data points	Comment
Group A	
Malaria Disease Burden	
BEFORE LICENSURE	
Legend	Unclear
Colors used to demarcate global, local data	colors used to demarcate local, global, required, and unrequired data are difficult to interpret
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
Group B	
This group did not find the data requirements sufficient, choosing to add to or modify several items	
Malaria Disease Burden	
Reported and confirmed clinical cases	To emphasize "admission under age 5" as an important sub-point for "reported and confirmed clinical and severe malaria cases by age group."
AVAILABLE DATA—PHASE III	
Absolute impact	Should data be considered required or desirable? since it is difficult to measure due to ethical constraints on trial design
New data points	"Efficacy" as a global Pre-Licensure point "Safety" and "Efficacy" as Licensure and Decision (2 years) data points.
Adverse events and interaction with other vaccine	Should be considered as *Safety* data points or sub-points?
Donor subsidy	Break "sustainability of donor subsidy" into two bullets: "donor funding" and "national funding," and change the word "sustainability" to "duration."
Many of the DMF data sets will require additional capacity to gather, and should continue to be collected over time.	
Group C did not find the data sufficient	
Sociocultural Environment, Pre-Licensure	
Community expectations towards malaria vaccine in and around clinical trials areas	Add "Acceptability and perception of the disease

	throughout the community"
Efficacy, Quality, and Safety	
Efficacy including impact on: clinical disease, severe disease, anemia, parasitemia	Why impact on anemia, parasites, HIV, and others were all placed in parallel; they suggested that the vaccine's safety data be separated from its efficacy data.
Vaccine price	To be placed in the first frame of Pre-Licensure.
Programmatic Considerations, Licensure and Decision under	
Target groups	Add data on definition of "target" groups
Economic and Financial Issues and *Efficacy, Quality, and Safety*	Do not seem to record data for "conformity with expectations"
Evidence of supply security	Add data on the reliability of the system
Add:	Post-marketing surveillance and safety data
Post-marketing surveillance and safety data	
Public health return on investment	Cost-benefit report

B. Review of Processes

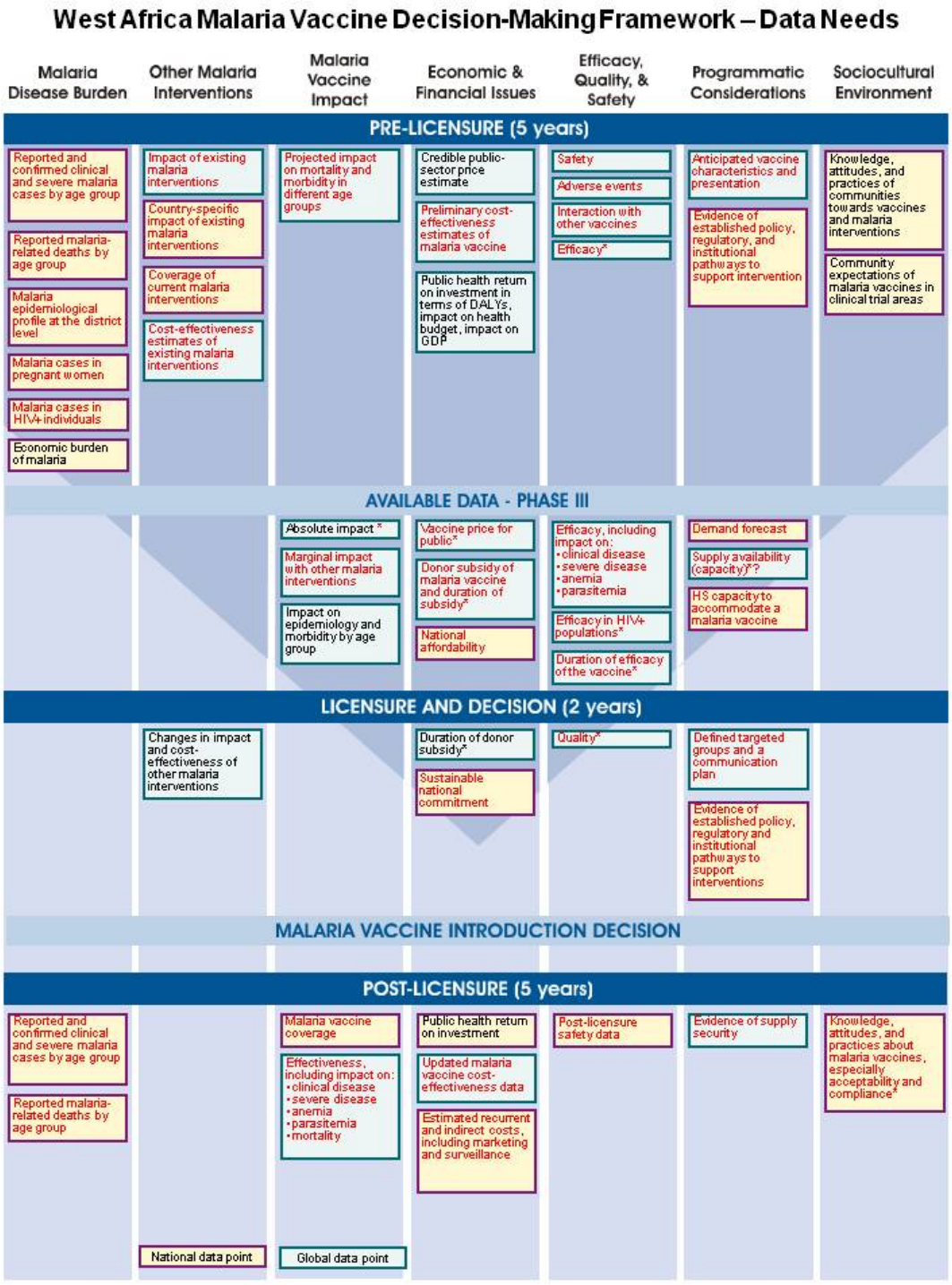
Processes	Comments
PROCESSES BEFORE LICENSURE (including phase 3)	
Group A processes in the DMF were relevant for decision making in the subregion but not sufficient	
At or before the Malaria Vaccine Introduction Decision	DMF must state: "Introduce vaccines into national policies at the country level
	"Take the vaccine into account as part of a country's strategic plan."
at the Malaria Vaccine Introduction Decision	Add: "Develop a plan for the introduction of the vaccine," including logistics, training, pharmacovigilance, and other practical elements of introduction.
After their changes, Group A adopted the document by consensus. They felt that it had certain strengths: The processes described are already known by EPI; the DMF takes into account the data from existing malaria programs; and it is a roadmap that reflects the process of introducing new vaccines. However, they felt that the DMF's main weakness was the "unclear" legend.	
Group B Processes in the DMF were relevant for decision-making in the sub-region; however, they found that the processes were not sufficient.	

that a critical process under Malaria Vaccine Introduction Decision was missing:	Plan must include engaging the media to sensitize populations to the malaria vaccine, as a necessary step of any communications planning process.
Whether or not "monitor vaccine coverage and evaluate immunization" should be included as a required, national-level Post-Licensure process.	
countries may choose to conduct additional processes to those described by the DMF, and that exclusion of a process from the DMF does not indicate that countries cannot or should not carry out that process during implementation.	
Group C: add additional processes	
POST LICENSURE	
"advocacy"	added as a process to the first international stage of vaccine implementation,
"incorporate the vaccine into national budgetary processes"	" should be placed after "introduction decision."
"make programmatic guidelines"	To be placed at the bottom of the frame and expanded to include aspects related to business, training, timetables, and logistics.

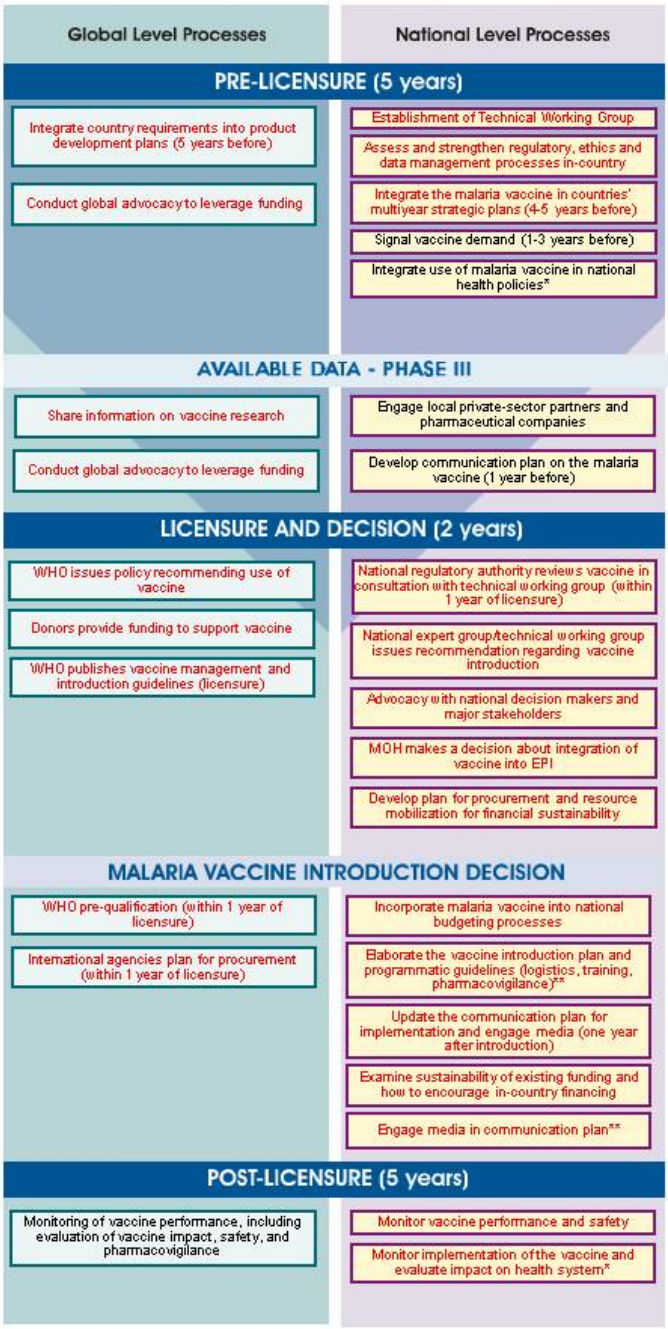
Discussion and Conclusions

The groups discussed their assessments of the data and processes from the DMF and arrived at a consensus on revisions to the DMF and next steps for stakeholder groups. The graphic below shows the revisions to the DMF that participants agreed upon.

Revised version of the draft Regional DMF for West Africa



West 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

Objective 3: Agree on the way forward for the implementation of the Draft Regional Decision-Making Framework for countries and partners

The findings from the groups were endorsed by all participants. The participants agreed upon three types of recommendations: recommendations to MVI, to MVI and its partners, and to NMCPs and EPIs, as follows:

MVI	Conduct advocacy with national authorities to promote adherence to the DMF. If MVI cannot take sole responsibility for advocacy, it should help the NMCPs and EPIs advocate for adherence to the DMF
	Develop an utilization document to implement the framework
	Make the final framework available and circulate it to the Ministries of Health
MVI and Other Partners	Provide technical support for the collection of data (i.e., on malaria-related mortality) by requesting support from research institutions in the US.
	Provide financial support for the collection of data (i.e., on malaria-related mortality) by requesting support from donors and partners.
NMCP and EPI of each country	Conduct advocacy with national stakeholders on the Decision-Making Framework and its use for decision making in the sub-region.

Participants agreed on both national and global next steps. They agreed that the next steps on a national level will include continued data collection on the burden of malaria. Furthermore, support to countries to begin implementing the DMF must be provided. Support must also be provided to country-level modeling of malaria vaccine impact, in the case that the countries have the necessary data to work from.

Participants agreed that after this meeting, a report will be developed to summarize meeting results, and a final DMF tool for use across Africa will be produced. A strategy document for DMF implementation will also be developed, and a technical review by WHO Geneva, WHO AFRO, and technical experts will be conducted.

On a global level, work must continue to support DMF data and process needs. Financing must be pursued from the Global Fund and GAVI, and GSK must be informed of the desired product profile for the upcoming vaccine. Stakeholders must also continue to share information about the progress of RSTS,S through clinical trials.

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 countries in Western 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 Western Africa.

Appendices

Annex 1: Agenda

20 November 2008
Chair: Ghana
Rappoteurs: Mali, Sierra Leone

Time	Activity		Facilitator / Presenter
11:30–12:00	Introduction to the session		Chair
12:00–12:30	**Key note presentation** ***From research to policy: challenges of introducing new vaccines*** ***Strategic orientations for malaria control and elimination in the African region***		Dr. S. Fall Dr. T. Diarra
12:30–13:00	Countries' experiences in introducing new vaccines Countries' experiences in introducing new malaria control interventions Discussion		Dr. Diallo, EPI/Senegal NMPC: Senegal-Ghana
13:00–14:30	Lunch		
14:30–15:15	Update on progress for malaria vaccines Introduction to the draft regional decision making framework for malaria vaccines (DMF)		Dr A. Ba-Nguz PATH MVI Ross Brindle (consultant for MVI Facilitator)
15:15–15:30	Presentation of the ToRs for group discussion on the DMF		Ross Brindle (consultant for MVI Facilitator)
15:30–16:00	Group discussion on the draft DMF		Participants
	Group A:	Algeria, Benin, Burkina Faso, Cap Vert, Cote D'Ivoire, Guinea	
	Group B:	The Gambia, Ghana, Liberia, Nigeria, Sierra Leone	
	Group C:	Guinea Bissau, Mali, Mauritania, Niger, Senegal, Togo	
16:00–16:15	Tea/Coffee Break		
16:15–	Group discussion on the draft DMF		Participants

17:00		
17:00–17:30	Rapporteurs' / Facilitator's Meeting	Rapporteurs and Facilitators

21 November 2008
Chair: Ivory Coast
Rappoteurs: general

08:00–08:30	Administrative announcement	Secretariat
08:30–10:00	Plenary on group discussions	Participants-facilitators
10:00–10:15	Tea/Coffee break	
10:15–11:30	Recommendations and way forward	President
11:30–12:30	Main achievement of the meeting, next steps and recommendations on the joint plans	Secretariat
12:30–12:45	Presentation and amendment of the general report of the meeting	Dr. D. Gbenou and Dr. A. Coulibaly
12:45–13:00	Closing ceremony	

Annex 2: Participants List

Name	Title/organization
Benin	
Dr Yacoubou Imorou	NMCP Coordinator—Benin
Dr Celestin Ganse	C/EPI
Dr Dina Gbenou	NPO/MAL
Dr Nouratou Rego	C/EPI
Burkina Faso	
Dr Sosthene Zombre	NPO/MAL
Dr Laurent Mouyenga	NMCP-Burkina Faso
Dr Victor Nana	NMCP-Burkina Faso
Dr Placide Gbedonou	WHO/IST-WA/IVD
Dr Femi Oyewole	WHO/IST-WA/IVD
Dr Beranger Keman	EPI-Burkina Faso
Cap Verde	
Dr. Moreira Antonio	NMCP – Cap Vert
Cote D'Ivoire	
Dr Moise San Koffi	NMCP-Cote d'Ivoire
Dr Adama Coulibaly	NPO/MAL
Dr Siguiofota Coulibaly Ouattara	C/EPI
The Gambia	
Dr Malang Fofana	NMCP-Gambia
Dr Mamo Jawla	NOP/MAL
Dr Yamudow Jawla	C/EPI
Ghana	
Dr Aba Baffoe-Wilmot	NMCP Coordinator-Ghana
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Annex 3: Terms of Reference for Group Discussion on the DMF

A. Review of the data and processes

1. Data:

Objective: Determine the data necessary to reach a decision on the potential introduction of a malaria vaccine

Review the data outlined in the DMF and discuss if:

a. They are relevant for decision making in the sub-region?
b. There is any which is not and why?
c. They are sufficient?
d. If not what are the most critical data for decision in the sub-region which are missing

2. Processes:

Objective: Determine the processes necessary to reach a decision on the potential introduction of a malaria vaccine

Review the processes outlined in the DMF and discuss if

a. They are relevant for decision making in the sub-region?
b. There is any which is not and why?
c. They are sufficient?
d. If not what are the most critical processes for decision in the sub-region which are missing

B. Draw a conclusion:

Objective: Report and reach consensus on the use of the DMF for decision making about the future use of a malaria vaccines.

1. Is the DMF a valid tool to guide the decision on malaria vaccine in West Africa
2. What are the strengths of such a tool
3. What are the limitations

C. Make recommendations to countries and partners for the use of the DMF

Objective: Define next steps necessary to properly consider implementation of the DMF.

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
- 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

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