

Survey Evaluation of the Malaria Vaccine Decision Making Framework Process

Online interviews in Benin, Burkina Faso,
Ethiopia, Gabon, Ghana, Kenya, Malawi,
Mali, Mozambique, and Tanzania

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EXECUTIVE SUMMARY AND RECOMMENDATIONS

There are more than 15 malaria vaccines now in clinical trials. Given the potential promise of the licensure of a malaria vaccine in the near future, there is much planning, data collection, and many actions required before a country can successfully introduce a malaria vaccine. To this end, in January 2006, the PATH Malaria Vaccine Initiative (MVI) and the World Health Organization Regional Office for Africa (WHO AFRO), in partnership with the Minister of Health of Benin organized a workshop in Cotonou, Benin, to develop a draft framework for decision making regarding a future malaria vaccine. This decision-making framework (DMF) was introduced to six countries before a regional framework was developed, one that can be applicable to any malaria vaccine and by any malaria endemic African country. The regional framework was introduced to four additional countries. USAID, the primary sponsor of the DMF for the last four years, felt now was the right time to evaluate these in-country consultations and to estimate each country's level of preparedness to make a decision about the introduction of a malaria vaccine.

Between September and November 2008, DMF in-country consultation participants with an email address (n=184) were emailed an invitation to participate in the evaluation, a unique username and password, and a letter from USAID encouraging and stressing the importance of their participation. In all, 83 participants responded to the survey and answered at least one question. Each question was analyzed separately and only includes those who answered the question. Thus, those who "skipped" the question are not included in the analysis. We employed this approach to capitalize on all the information available for a given question, even if a participant only answered a few of the survey questions.

Here we provide a brief summary of the findings and recommendations. This is followed by a detailed description of the survey findings.

Key Findings

- The DMF in-country consultations can be largely considered a success. Participants report that the meetings are useful and informative. From an overview of malaria control to the identification and prioritization of country-level data and process requirements, participants say they learned about the data and information necessary for evidence-based decision-making and how to begin to fill any knowledge gaps. A solid majority thought the consultation took place at the right time relative to when a vaccine is likely to be available.
- With the possibility of a malaria vaccine licensure feasible in just a few years and with plans for Phase III trials of RTS,S to commence very soon, it is not surprising to find that a large majority of participants are aware of this product. Most learned at least a fair amount from the consultation but note that the DMF staff did not promote any particular vaccine.

- Participants have different views about how soon their country would make a decision after licensure. However, nearly all agree that a decision would be made within three years of licensure. Many factors could heavily influence a country's final decision, but participants note that efficacy, vaccine safety, and financial sustainability are among the top considerations.
- The DMF Draft Regional Framework earns high marks. Participants say all the issues identified by the framework will be under consideration and will help make a decision about the best course of action for their country.
- There is a general consensus among a large majority of participants that their country is at least somewhat prepared to implement various steps required before a malaria vaccine decision is made. However, no majority or even plurality say their country is very prepared. Nonetheless, the DMF was deemed helpful. A majority of participants attribute at least some of their preparedness to the DMF consultation. A country's experience with past vaccine introductions and its experience with introductions of other malaria interventions also contributed to their preparedness.
- For various types of country-level data, a large majority of participants report that their country is prepared to collect these necessary data to begin the process of filling in the gaps. Eleven data points were addressed in the survey, including malaria-related morbidity and mortality at the province level, the capacity of the national immunization program to accommodate a malaria vaccine, and the economic burden of malaria.
- Opinion of the DMF staff is largely positive. The briefing materials, presentation materials, and clarity of the final meeting report are also viewed fairly positively.

Recommendations

When asked for recommendations, participants resoundingly called for more DMF meetings to support technical development, centralize information, and build rapport and awareness among high-level decision-makers. Participants want more discussion, consultation and technical assistance with respect to acquisition and dissemination of the latest scientific information. Participants provide a thoughtful picture of where countries stand with respect to malaria vaccine preparedness. To start, an underlying issue here is the need for more awareness, particularly among high-level decision-makers. Some comments suggest that there is an understanding of what needs to get done, but some countries remain in a conditional state – that is, participants know “what should get done” but these countries have not moved forward in executing these tasks.

- Participants see a real need for more discussion and awareness at national levels among key decision-makers, policy leaders, and researchers and for additional consultations with stakeholders across government agencies, research institutions, and other relevant organizations.
- There is a very strong call for technical assistance on education and information dissemination on matters related to the efficacy of future malaria vaccines, safety, and cost. In addition, participants have a need for assistance on how best to introduce and supply this information, including follow-up meetings to discuss how best to implement the decision-

making framework. Participants want additional resources to support technical advisory groups in their country, more consultations, and even regular reviews.

- Participants want more coordination and communication between the various ministries within a country and all the stakeholders, including international agencies. Malaria-endemic countries would enhance their malaria vaccine preparedness if there was more consultation and collaboration, according to participants. Centralization of tasks, research, and activities is a theme heard in many participants' suggestions. These centralized sources would be responsible for all relevant activities, including strengthening communication and developing technical partnerships and committees. Participants call on the DMF to provide any related information and to simply share in the form of more frequent meetings, newsletters, email exchanges, and the formation of national and local committees.

I. BACKGROUND AND INTRODUCTION

There are more than 15 malaria vaccines now in clinical trials. Most are in early Phase I testing, but the RTS,S vaccine, developed by GlaxoSmithKline, is projected to begin Phase III clinical testing by early 2009. Clinical data would then be available in 2011 and licensure could follow as soon as 2012 or 2013. Other leading candidates could enter the field as early as 2017.

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Given the potential promise of a malaria vaccine to become a real preventative alternative in the near future to fight malaria along with existing interventions and treatments, there is much planning, data to be collected, and many actions required before a vaccine can be successfully introduced. Policy issues and programmatic issues determine in large part whether a vaccine is introduced. Key decision-makers typically determine whether or not a “vaccine is acceptable from an immunization policy perspective” while the programmatic issues represent the technical feasibility. Both sets of issues must be thoroughly examined before a decision can be made. Learning from recent public health interventions and in some cases multi-year delays, key decision-makers, ministries, and international organizations have a heightened sensitivity to execute the introduction and delivery of a new malaria vaccine with as much forethought as possible.

In January 2006, the PATH Malaria Vaccine Initiative (MVI) and the World Health Organization Regional Office for Africa (WHO AFRO), in partnership with the Minister of Health of Benin organized a workshop in Cotonou, Benin, to develop a draft framework for decision making regarding a future malaria vaccine. The purpose of the framework was to serve as a tool to assist in early preparation for introducing a future malaria vaccine in malaria endemic areas. Health officials from 13 African countries met with multilateral and bilateral partners in Benin to define 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. This project, the Malaria Vaccine Decision-Making Framing Project (DMF), was implemented by the Malaria Vaccine Initiative at PATH (MVI) and WHO and is funded by USAID and the Bill and Melinda Gates Foundation.

Following the meeting in Benin in January 2006, in-country consultations took place in six countries where the generic framework helped to identify issues and the iterative process necessary before a decision can be made about what course of action to take when a malaria vaccine is licensed. The alternatives are: (1) introduce vaccine, (2) conduct a demonstration project before deciding to introduce a vaccine, (3) collect more data before deciding to use a vaccine, (4) wait before introducing, and (5) do not introduce vaccine. These alternatives are sometimes collectively referred to in this report as a “malaria vaccine decision” for ease of reference.

Tanzania	July 18-19, 2006
Kenya	September 12-13, 2006
Gabon	October 10-11, 2006
Mozambique	October 24-25, 2006
Mali	October 31-November 1, 2006
Ghana	December 5-6, 2006
Ethiopia	April 16, 2007
Burkina Faso	February 20-21, 2008
Malawi	April 24-25, 2008

Findings from the first six in-country consultations were used to develop a draft *Regional Decision Making Framework*, which would be applicable to any malaria vaccine and which can be used by any malaria endemic African country. This framework is intended to help key decision-makers make a decision about the best course of action in their country within one to three years of licensure of a vaccine. An additional four countries received in-country consultations after the *Regional Decision Making Framework* was developed. All the DMF consultation countries with the exception of Benin, Ethiopia, and Mali are expected to take part in the Phase III trial of RTS,S.

USAID felt the time was now right to assess the extent to which the DMF is achieving its goals, including the level of preparedness of countries that received consultations, in order to evaluate the advisability of continued support to the DMF. Of particular importance is the need to understand the perceptions on the part of key decision-makers as to the effectiveness of the assistance provided by the DMF as each country evolves in their process toward preparedness.

The purpose of this report is to provide a summary analysis of survey data collected online between September and November 2008 in ten countries among participants of the Malaria Vaccine Decision-Making Framework (DMF) in-country consultations.

Recruiting consultation participants and number of interviews conducted

Participants with an email address (n=184) were emailed an invitation to participate in the evaluation, a unique username and password, and a letter from USAID encouraging and stressing the importance of their participation. In all there were 83 persons from government, non-governmental organizations, multilateral or bilateral organizations, academia, media, and health care responded to the survey between September and November 2008. Each question was analyzed separately and only includes those who selected a given response. Thus, those who “skipped” the question are not included in the analysis here. We employed this approach to capitalize on all the information available for a given question, even if a participant only answered a few of the survey questions.

In each of the ten countries, between 3 and 17 opinion leaders were interviewed for a total of 83 interviews.

The margin of sampling error for the full sample (n=83) is ± 8 percent.¹ Results based on smaller subgroups are subject to larger margins of sampling error. In addition to sampling error, the practical difficulties of conducting surveys can also introduce

Country selection and sample sizes

	Number of interviews completed	Number of participants provided	Margin of error (%)
Benin	6	19	36
Burkina Faso	8	18	28
Ethiopia	8	13	23
Gabon	8	20	29
Ghana	11	19	20
Kenya	7	14	28
Malawi	17	29	16
Mali	3	10	58
Mozambique	11	26	24
Tanzania	4	16	49
Total Sample	83	184	8

¹ The sample size varies between n=83 and n=58 depending on the number of respondents who answered a question. For n=58 the margin of error is ± 11 percent. For n=83, if there is an 8 point or more difference in the responses to a question, the difference is statistically significant at the 95% confidence level. For n=58, if there is an 11 point or more difference in the responses to a question, the difference is statistically significant at the 95% confidence level.

error or bias to poll results. Margins of error were calculated with the finite population correction factor. Because of the relatively small sample sizes, country-level findings should be interpreted with great caution.

The overall response rate for the survey was 45 percent. Depending on the accuracy of available contact information, and the type of respondents being targeted, response rates for online surveys range from very low (less than 10%) to very high (70% or greater). Based on PSRAI's experience, the response rate for the current survey falls in the middle to high end of the range of response rates we would typically expect for an online survey of this type. After comparing the available demographic characteristics (organization, title and position) of all the DMF participants and those who responded to the survey, we believe nonresponse is more a function of the respondent not getting the email or being too busy to respond rather than the systematic refusal to participate by any particular type of respondent. In contrast to these overall findings, country-level findings, should be interpreted with great caution, if at all, given the small sample sizes and corresponding margins of error.

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Participants' Background

Most participants have been involved at least somewhat in the decision making process to introduce any new interventions in the national health system. A plurality of participants (43%) say they have been very involved with new interventions and slightly fewer (38%) say they have been somewhat involved. Roughly one in 10 say they have not been too involved (12%) or not involved at all (7%). Nearly all the respondents (96%) say they are at least somewhat knowledgeable about the extent of the malaria problem in their country and three-quarters (76%) say they have been involved at least somewhat in making decisions regarding the malaria control program in their country.

A slim majority of participants (55%) have 11 or more years of experience in their area of expertise. A few (15%) report that they have less than five years of experience and three in 10 (30%) say they have between five and 10 years of experience. Participants' education background is roughly divided between a medical degree (45%) and other advanced degree, such as a PhD or master's degree (47%). A handful of participants (6%) have an undergraduate degree as their highest degree.

Analysis by Country and Participants' Characteristics

A review of the survey data was conducted by country and by participants' characteristics (for example, education and years of experience). No meaningful differences were found and therefore such an analysis is not included in this summary report.

The remainder of this report provides a detailed description of the survey findings.

II. DMF CONSULTATIONS, USEFULNESS AND IMPRESSIONS

Timing of DMF Consultation and Overall Impressions

A primary goal of the DMF in-country consultation is to increase participants’ understanding of the evidence based decision-making process well before a malaria vaccine is introduced. Overall, participants say they found the timing of the consultation about right and the consultation informative and useful.

Participants were asked about the timing of the consultation in their country. Specifically, was the consultation conducted at about the right time, too far in advanced, or not far enough in advance of when a vaccine is likely to be available. A solid majority (70%) report that their consultation was at the right time. A modest minority (25%) say it was too soon while few (5%) think the consultation did not occur far enough in advance.

A series of questions were asked to gauge participants’ impressions of the DMF consultation. These questions ranged from whether the consultation was informative to whether they would recommend participation in the DMF consultation to other colleagues. The responses were solidly positive. Nearly all participants (95%) agree with the statement that the consultation was informative and six in 10 strongly agree. Very few disagree with this assessment.

Every participant agrees that the DMF consultation was useful. A sizable majority (75%) strongly agree that the DMF consultation was useful while the remaining 25 percent somewhat agree.

The DMF consultation encouraged questions from the participants, according to all participants. More than three-quarters (77%) strongly agree with this statement and the remaining participants (23%) agree somewhat.

DMF CONSULTATION TIMING

	N	
At about the right time	76	70%
Too far in advance		25%
Not far enough in advance		5%

DMF CONSULTATION, IMPRESSIONS

THE DMF CONSULTATION WAS INFORMATIVE		
	N	
Strongly agree	76	61%
Somewhat agree		34%
Somewhat disagree		1%
Strongly disagree		4%

THE DMF CONSULTATION WAS USEFUL		
	N	
Strongly agree	60	75%
Somewhat agree		25%
Somewhat disagree		-
Strongly disagree		-

THE DMF CONSULTATION ENCOURAGED QUESTIONS FROM THE PARTICIPANTS		
	N	
Strongly agree	61	77%
Somewhat agree		23%
Somewhat disagree		-
Strongly disagree		-

I WOULD RECOMMEND PARTICIPATION IN DMF CONSULTATIONS TO COLLEAGUES AND OTHER PROFESSIONALS		
	N	
Strongly agree	76	70%
Somewhat agree		26%
Somewhat disagree		3%
Strongly disagree		1%

Participant satisfaction with the DMF overall is highlighted by the overwhelming majority of participants who say they would recommend participation in the DMF consultation to colleagues and other professionals. Fully seven in 10 (70%) strongly agree with this statement and one-quarter (26%) somewhat agree. Just four percent disagree.

Usefulness of Specific DMF Consultation Meeting Topics

The meeting agenda for each DMF consultation was similar across all countries to maintain consistency. Participants rated how useful each topic covered will be in helping them prepare for the malaria vaccine decision.

On the whole, participants found the specific components of the consultation helpful. All consultations began with an overview of the malaria control program followed by an overview of the immunization program. Nearly all (97%) found these overviews useful, including two-thirds (66%) who say they were very useful.

These overviews were typically followed by a presentation regarding the status of malaria vaccine development worldwide along with a description of malaria research in the consultation country. Again, the vast majority of DMF consultation participants found this portion of the consultation to be very (75%) or somewhat (18%) useful. There are a few respondents who did not attend the session or say they are unsure, but no respondent reports that the session was not useful.

Next, the DMF consultation focused on the draft decision making framework developed in Benin. A solid majority of participants (63%) found this segment of the presentation useful, although opinion is split between very useful (32%) and somewhat useful (31%). A notable number (23%) did not attend this session or say they are not sure (8%).

In small group meetings, participants discussed at length what **data** their country needed in order to make a decision about the appropriate use of a malaria vaccine within their health system. This was followed by a discussion about the relative importance of these data and whether they could distinguish data that are “required” from data that would be “nice to have.” A substantial majority of the participants say that both these topics were useful. A solid majority (60%) report it was very useful while 29 percent say it was somewhat useful. Few (5%) state it was not too useful.

USEFULNESS OF TOPIC IN PREPARING TO MAKE A DECISION ABOUT MALARIA VACCINE INTRODUCTION

OVERVIEW OF MALARIA CONTROL AND IMMUNIZATION PROGRAMS

	N	65
Very useful		66%
Somewhat useful		31%
Not too useful		-
Not useful at all		-
Did not attend session		3%

STATUS OF MALARIA VACCINE DEVELOPMENT WORLDWIDE AND DESCRIPTION OF MALARIA R&D

	N	65
Very useful		75%
Somewhat useful		18%
Not too useful		2%
Not useful at all		-
Did not attend session		3%
Not sure		2%

REVIEW OF BENIN DRAFT GENERIC FRAMEWORK

	N	62*
Very useful		32%
Somewhat useful		31%
Not too useful		5%
Not useful at all		2%
Did not attend session		23%
Not sure		8%

*Not asked in Benin

IDENTIFICATION AND PRIORITIZATION OF COUNTRY-LEVEL DATA REQUIREMENTS

	N	65
Very useful		60%
Somewhat useful		29%
Not too useful		5%
Not useful at all		-
Did not attend session		3%
Not sure		3%

Additional small group discussions focused on what country-level **processes** are necessary to make a decision about the use of a malaria vaccine. Discussion also focused on how the data requirements previously identified would be used and who would use them. Further, there was discussion of the relative importance of these processes and whether they are necessary processes versus those that might be “nice to have.” Participants were asked about the usefulness of the identification and prioritization of country-level process requirements. More than two-thirds (69%) say this discussion was very useful and 23 percent say it was somewhat useful. Very few (3%) think it was not too useful.

Most of the second day of consultations focused on identifying existing data and processes and developing plans for filling gaps for both country-level data requirements and process requirements. Specifically, these discussions focused on how data that do not exist or are under-utilized can be collected or better used.

Other topics included accountability, and the roles and responsibilities of individual countries and whether some data can be developed on a regional basis. A modest majority (56%) say that the DMF consultation was very useful and a notable number (30%) say it was somewhat useful in developing plans to fill gaps in data requirements.

With respect to country-level process requirements or steps, discussion turned to the processes currently planned for and ways to jump start those that are needed but not yet planned. Discussion of roles, responsibilities, and accountability rounded out this portion of the DMF consultation. Similar to the development of plans to fill in data gaps, a solid majority (63%) say the consultation was very useful to develop plans to fill gaps in process requirements. One-quarter (25%) report that it was somewhat useful along with a small handful (8%) who say it was not too useful.

USEFULNESS OF TOPIC IN PREPARING TO MAKE A DECISION ABOUT MALARIA VACCINE INTRODUCTION

IDENTIFICATION AND PRIORITIZATION OF COUNTRY-LEVEL PROCESS REQUIREMENTS		N	64
Very useful			69%
Somewhat useful			23%
Not too useful			3%
Not useful at all			-
Did not attend session			2%
Not sure			3%

DEVELOPMENT OF PLANS TO FILL GAPS IN COUNTRY-LEVEL DATA REQUIREMENTS		N	64
Very useful			56%
Somewhat useful			30%
Not too useful			6%
Not useful at all			-
Did not attend session			3%
Not sure			5%

DEVELOPMENT OF PLANS TO FILL GAPS IN COUNTRY-LEVEL PROCESS REQUIREMENTS		N	64
Very useful			63%
Somewhat useful			25%
Not too useful			8%
Not useful at all			-
Did not attend session			3%
Not sure			2%

Usefulness of Country-Specific DMF Framework

A main product of the DMF consultation is a specific framework customized for each country. Participants report that the framework will be extremely or very useful in helping them prepare to make decisions pre- and post-licensure. Nine in 10 (90%) say the DMF framework developed for their country will be extremely or very useful, including two-thirds (64%) who say that it will be extremely useful prior to licensure. One-quarter (26%) say the framework will be very useful for this purpose while notably fewer (10%) think it will be somewhat useful.

Over eight in 10 (88%) think the framework will be extremely or very useful in decision-making after a malaria vaccine has been licensed, but support is somewhat muted compared to usefulness prior to licensure. A modest majority (55%) say the framework will be extremely useful while one-third (33%) say it will be very useful. Few (12%) say it will be somewhat, not too, or not useful at all.

Participants are less convinced of the usefulness of the framework for vaccines other than malaria. While a large majority say the framework will be useful, participants are roughly split on the framework being extremely useful (33%) and very useful (39%), while almost as many say the framework is somewhat or not too useful (28%) for making decisions about vaccines other than malaria.

Suggestions for Improving DMF Activities

Participants were asked specifically, “In what way could DMF activities be improved?” Numerous suggestions are offered by participants. First and foremost, participants are very adamant that more DMF meetings that would allow more discussion, feedback, and updates would be very beneficial. Participants see these meetings as an important way to share information, especially technical information and updates. The second suggestion is a call for technical assistance. DMF participants want additional resources to support technical advisory groups in their country, more consultations, and even regular reviews. The final suggestion is for assistance in helping countries identify and target appropriate persons at the local and national levels in order to gain their involvement in the issues at hand.

Additional communication can come in many forms. Participants respond with a resounding call for more communication via more frequent meetings and written communication especially among the high-level decision-makers.

“Increase the regularity of the meetings in the future.” (Mozambique)

USEFULNESS OF COUNTRY-SPECIFIC FRAMEWORK

PREPARING TO MAKE THE DECISION ABOUT A MALARIA VACCINE PRIOR TO LICENSURE.

	N	61
Extremely useful		64%
Very useful		26%
Somewhat useful		10%
Not too useful		-
Not useful at all		-

MAKING DECISIONS AFTER A MALARIA VACCINE HAS BEEN LICENSED

	N	60
Extremely useful		55%
Very useful		33%
Somewhat useful		7%
Not too useful		2%
Not useful at all		3%

MAKING DECISIONS ABOUT VACCINES OTHER THAN MALARIA

	N	61
Extremely useful		33%
Very useful		39%
Somewhat useful		20%
Not too useful		8%
Not useful at all		-

“If the DMF activities could be more frequent than it has been.” (Ghana)

“More frequent meetings and consultations and involve more stakeholders such as research and academic institutions, advocacy groups such as Kenya medical associations, Kenya pediatric associations, ministries of finance, planning and office of the president, parliamentary committee on health.” (Kenya)

“More meetings and discussions. More information.” (Benin)

“Regular meetings and feed back.” (Malawi)

“There should be a regular program of updates/meetings to ensure all partners/stakeholders are acting at the same place.” (Malawi)

“Organize a meeting or meetings that bring together researchers and government authorities.” (Gabon)

“Conducting regular meetings with stakeholders. Involving people at the grassroots level.” (Malawi)

“Apart from having a national committee, there is need to have regular meetings to update the countries on the progress of having a vaccine.” (Malawi)

“For better coordination, I would favor physical contact or email. And make the members responsible for taking action.” (Burkina Faso)

“Organize meetings at certain points as the process evolves.” (Burkina Faso)

“In-country stakeholders (Malaria Control program, Immunization program) should take ownership and lead and drive the DMF activities.” (Ghana)

“Encourage more participation and consultation with all key stakeholders.” (Malawi)

“Follow-up committee doing its job, annual meetings to take stock and gain perspectives. Improving communication between the members of the follow-up committee.” (Gabon)

“More dissemination seminars of the processes and outcomes.” (Malawi)

“More information on the next meetings and issues to be discussed to participants way beforehand.” (Ghana)

“Continuous monitoring and meeting with increasing stakeholder inputs.” (Ghana)

Participants’ also provide reasoning for why they would like to participate in more meetings. Namely, that communication facilitates a sharing of information, particularly technical. Participants request more technical information in the form of lectures, meetings to examine lessons learned, clear milestones, and additional resources to support advisory groups in their country.

“After receiving the final report of the meeting, it is my first time to hear about DMF now. Communicate what is underway and keep your network stabilized.” (Ethiopia)

“By introducing a newsletter and other email exchange programs.” (Tanzania)

“Create a liaison bulletin between the countries and those responsible for the DMF.” (Benin)

“More regular communication and information on different steps and stages necessary for accelerating the availability of the vaccine. Improve strategies and instruments for promoting participation of key decision-makers and partners.” (Mozambique)

“More sharing of information.” (Ghana)

“Have internal discussions about the real situation in each country. Identify the weaknesses in the process for vaccine introduction. Hold debates between researchers, the pharmaceutical industry, and political decision makers.” (Mozambique)

“DMF should give participants copies of final reports on countries from the workshop and keep participants updated regularly on the vaccine.” (Ghana)

“Additional resources to support country-level technical advisory groups that are able to act on findings from DMF process in a sustainable way. Identifying the data and processes needed to take a decision is good, but acting to fill the gaps now (before RTS,S licensure) is the more important part of this process.” (Ghana)

“Having clear milestones and outputs of the meetings.” (Tanzania)

“Improve and simplify technical materials.” (Benin)

“Lectures, meetings with the technical malaria group.” (Mozambique)

“More consultations to know country specific needs.” (Malawi)

“Put in place a technical group. Work at national level to follow up about what has been done, what still remains to be done, and what could be done better.” (Benin)

“Provide necessary resources.” (Burkina Faso)

“Organize regular reviews every three or six months to establish what has been done, what still remains to be done, and what could be done better.” (Burkina Faso)

Participants also express a strong need for key decision-makers to be more involved at the local, national, and regional levels. Many decision-makers need to have their understanding of issues related to a malaria vaccine introduction reinforced, according to participants.

“Creating infrastructure for implementation and communication.” (Mozambique)

“Involve the relevant focal persons not departments that would establish continuity in the consultations.” (Kenya)

“Involvement of community beneficiaries and consulting with other interested parties (Ministry of Finance and Provincial Directors of Health).” (Mozambique)

“Must highly involve Ministry of Health and in particular National Malaria Control Programme.” (Malawi)

“Quickly install a local DMF team, which will assist the Ministry of Health and the National Anti-Malaria Program.” (Gabon)

“Through the reinforcement of the focal group in Mozambique.” (Mozambique)

“Timing can be better to make sure political hierarchy present.” (Malawi)

“Training of local persons to help disseminate useful information to all levels.” (Ghana)

“Use regional and international forums for dissemination of information.” (Ethiopia)

“In closely working with governments (decision makers and policy makers) and UN agencies like WHO.” (Ethiopia)

“Take into account the availability of resources in the countries.” (Burkina Faso)

“Decentralizing to provincial level in a country.” (Tanzania)

III. ELEMENTS OF THE DECISION-MAKING PROCESS AND THEIR IMPORTANCE

The generic framework for decision making serves as a fundamental tool to assist in early preparation for introducing a future malaria vaccine. The framework identifies many factors that should be considered before a country decides whether or not to introduce a malaria vaccine. The DMF consultation participants find all the considerations in the framework *very* important, at a minimum. Indeed, most of the issues are thought to be *extremely* important factors before deciding what course of action to take once a malaria vaccine is licensed. For many countries it is possible that these considerations could be put to the test within a few years. RTS,S, a malaria vaccine developed by GlaxoSmithKline, is projected to be available in 2012. With the exception of Benin, Ethiopia, and Mali, all consultation countries are expected to take part in the Phase III trial which is set to commence by early 2009.

Knowledge of RTS,S and Role of DMF

Nearly all the participants have heard at least something about the vaccine, though only a plurality (41%) have heard or read a great deal about RTS,S, while 30 percent say they know a fair amount.

Of those who have heard or read about the RTS,S vaccine, a large majority say the DMF consultations taught them at least a fair amount. One-third (33%) report that they learned a great deal about the RTS,S vaccine from the DMF consultation. Slightly more than one-half (52%) say they learned a fair amount about the GlaxoSmithKline vaccine from the DMF consultation.

On the general issue of malaria vaccine introduction, the great majority of participants find the DMF staff neutral and having neither promoted nor discouraged the introduction of a malaria vaccine. Fully eight in 10 (79%) agree that the staff was neutral while a modest but notable minority (21%) disagree.

By similar margins, participants agree that the DMF staff did not promote the introduction of a specific malaria vaccine. Eight in 10 (79%) agree that there

HEARD OR READ ABOUT THE RTS,S MALARIA VACCINE		
	N	
A great deal	63	41%
Fair amount		30%
Not too much		24%
Nothing at all		5%

AMOUNT LEARNED ABOUT RTS,S FROM THE DMF CONSULTATION		
	N	
A great deal	60	33%
Fair amount		52%
Not too much		13%
Nothing at all		2%
*Based on those who heard or read about vaccine a great deal, a fair amount, or not too much.		

DMF STAFF AND ANY BIAS TOWARD A MALARIA VACCINE		
DMF STAFF WAS NEUTRAL, NEITHER PROMOTING NOR DISCOURAGING THE INTRODUCTION OF A MALARIA VACCINE		
	N	
Strongly agree	76	37%
Somewhat agree		42%
Somewhat disagree		16%
Strongly disagree		5%
DMF STAFF DID NOT PROMOTE THE INTRODUCTION OF A SPECIFIC MALARIA VACCINE		
	N	
Strongly agree	61	28%
Somewhat agree		51%
Somewhat disagree		16%
Strongly disagree		5%

was no promotion of a particular vaccine among the staff but with more somewhat agreeing (51%) to this statement than strongly agreeing (28%). Two in 10 (21%) disagree and suggest that the DMF staff did promote the introduction of a specific vaccine.

Projected Decision-Making and RTS,S

Participants have different views about how soon a decision should be made after licensure about the malaria vaccine. But nearly all agree it should be within three years. One-third (33%) say within one year of licensure, another one-third (34%) say between one year and less than two years, and 23 percent say between two years and less than three years. Few (10%) say it is acceptable to make a decision more than three years post licensure.

Factors Contributing to a Malaria Vaccine Decision

If making a malaria vaccine decision, efficacy heads the list of important considerations. All participants say efficacy is extremely or very important. Efficacy of the vaccine is extremely important to 80 percent of the participants and very important to the remaining 20 percent.

No less important a consideration is the safety of the licensed vaccine and any reported adverse side effects. All the participants believe that vaccine safety and the incidence and type of adverse side effects are an extremely important (76%) or very important (24%) consideration.

Participants note the importance of having outside financial support to introduce the vaccine. A sizable majority of 72 percent say that external financing is extremely important while one-quarter (25%) say it is very important. A small number (3%) report outside financing is somewhat important.

It stands to reason that not only are efficacy and safety important, but that these together with cost need to be considered alongside the duration of protection against malaria. Fully seven in 10 (70%) think the duration of a vaccine's protection is an extremely important consideration and the remaining 30 percent say it is very important.

ACCEPTABLE PERIOD AFTER LICENSURE OF A MALARIA VACCINE TO MAKE A DECISION ABOUT MALARIA VACCINE INTRODUCTION

	N	
Within one year of licensure	61	33%
Between one year and less than two years post licensure		34%
Between two years and less than three years post licensure		23%
Between three years and less than five years post licensure		3%
Five years or more		7%

IMPORTANCE WHEN MAKING A MALARIA VACCINE DECISION

EFFICACY OF THE VACCINE

	N	
Extremely important	69	80%
Very important		20%
Somewhat important		-
Not too important		-
Not important at all		-

VACCINE SAFETY AND REPORTS OF ADVERSE EFFECTS

	N	
Extremely important	68	76%
Very important		24%
Somewhat important		-
Not too important		-
Not important at all		-

AVAILABILITY OF OUTSIDE FINANCIAL SUPPORT TO INTRODUCE THE VACCINE

	N	
Extremely important	69	72%
Very important		25%
Somewhat important		3%
Not too important		-
Not important at all		-

DURATION OF PROTECTION

	N	
Extremely important	69	70%
Very important		30%
Somewhat important		-
Not too important		-
Not important at all		-

The cost of purchasing and administering the vaccine also weighs heavily. Nearly all (93%) think this is at least a very important consideration. Indeed, seven in 10 (70%) say the cost of purchasing and administering the vaccine is extremely important followed by 23 percent who say this is a very important factor. Less than one in 10 (7%) think it is somewhat important.

Participants are also concerned about a vaccine's impact on morbidity and mortality among people in different age groups. Two-thirds (67%) say the impact of a vaccine on morbidity and mortality is extremely important. Fully three in 10 (30%) agree that the impact of a licensed vaccine on morbidity and mortality in different age groups is very important.

The interaction of a malaria vaccine with other vaccines already in use concerns participants. Two-thirds (66%) believe this is an extremely important concern and nearly three in 10 (28%) say it is very important. Few (6%) think the interaction of an approved malaria vaccine with other existing vaccines is only somewhat important or not too important.

Once an intervention is introduced, it is understandable that stakeholders would want assurances that the vaccine be sustainable. The long-term financial sustainability of a malaria vaccine is extremely important to six in 10 (60%) participants. More than one-third (35%) find financial sustainability very important. Few (4%) say it is only somewhat important.

Malaria has a huge impact on livelihood since those affected often require periods of bedrest and are unable to engage in daily activities. As such, participants place importance on the cost effectiveness of a malaria vaccine with respect to DALYs (disability adjusted life years), a country's health budget and impact on GDP. Six in 10 (59%) agree that these estimates are extremely important considerations before deciding whether or not to introduce a malaria vaccine. The remaining participants are divided. Two in 10 (22%) say this cost-effectiveness analysis is very important and nearly as many (17%) say it is only somewhat important.

IMPORTANCE WHEN MAKING A MALARIA VACCINE DECISION

COST OF PURCHASING AND ADMINISTERING THE VACCINE

	N	
Extremely important	69	70%
Very important		23%
Somewhat important		7%
Not too important		-
Not important at all		-

VACCINE'S PROJECTED IMPACT ON MORBIDITY AND MORTALITY IN DIFFERENT AGE GROUPS

	N	
Extremely important	69	67%
Very important		30%
Somewhat important		1%
Not too important		1%
Not important at all		-

INTERACTION WITH OTHER VACCINES

	N	
Extremely important	68	66%
Very important		28%
Somewhat important		3%
Not too important		3%
Not important at all		-

LONG-TERM FINANCIAL SUSTAINABILITY OF THE VACCINE

	N	
Extremely important	68	60%
Very important		35%
Somewhat important		4%
Not too important		-
Not important at all		-

COST EFFECTIVENESS ESTIMATES OF THE VACCINE IN TERMS OF DALYS, IMPACT ON HEALTH BUDGET, AND IMPACT ON GDP

	N	
Extremely important	69	59%
Very important		22%
Somewhat important		17%
Not too important		1%
Not important at all		-

Fewer are concerned with how a malaria vaccine would generally impact their current immunization program or their existing malaria interventions. One-half of participants say that the impact of a malaria vaccine on their current immunization program (50%) or on existing malaria interventions (49%) are extremely important considerations. A little more than one-third think these will be very important factors when it comes time to make a decision about whether or not to introduce a malaria vaccine.

IMPORTANCE WHEN MAKING A MALARIA VACCINE DECISION		
IMPACT ON THE CURRENT IMMUNIZATION PROGRAM		
	N	68
Extremely important		50%
Very important		35%
Somewhat important		15%
Not too important		-
Not important at all		-
IMPACT OF EXISTING MALARIA INTERVENTIONS		
	N	70
Extremely important		49%
Very important		37%
Somewhat important		11%
Not too important		3%
Not important at all		-

Suggestions for Specific DMF Activities to help Decision-Making

Participants were asked, “What future DMF activities would help your country in making a decision about whether or not to introduce a malaria vaccine?” Most participants have very specific suggestions. The first is more discussion and awareness building. Participants see a real need for more discussion at national levels among key decision-makers, policy leaders, and researchers and for additional consultations with stakeholders across government agencies, research institutions, and other relevant organizations. The second activity participants would like to see more of is technical assistance. Participants see a need for technical assistance on education and information dissemination on matters related to the efficacy of future malaria vaccines, safety, and cost. In addition, participants have a need for assistance on how best to introduce and supply this information, including follow-up meetings to discuss how best to implement the decision-making framework.

By far the most common suggestions point to a need for more discussion in the form of meetings, consultations with stakeholders and other partners and overall assistance to establish a greater level of awareness and advocacy.

“Any activity that will promote discussion at national level including well publicized and politically supported high level meetings.” (Malawi)

“Conducting of country-specific consultation meetings and dialogue with partners and stakeholders in the country.” (Ethiopia)

“Continued consultation with government and health sector unit and in-country partners, research institutions, universities.” (Kenya)

“Continued dialogue and participation in meetings/consultations.” (Kenya)

“Coordinate activities. Create a structure for implementation. Expand the program at all levels, especially at community level. Develop informational, educational, and communication materials.” (Mozambique)

“Follow-up meeting to update researchers and other stakeholders as well as policy makers.” (Tanzania)

“Further regular updates on the progress of research or licensure for a malaria vaccine. Such updating sessions/meetings will help to make sure people involved in the DMF are on track of new information/progress and also themselves getting prepared at the proper rate/pace.” (Malawi)

“Greater awareness among policy makers will attract more financial support. That way, this vaccine will draw a good part of the financing from the country.” (Mozambique)

“Meeting of key stakeholders to disseminate findings, logistics of introducing the vaccine, costing and cost effectiveness.” (Malawi)

“More information about the latest developments and advocacy with other actors in the health sector.” (Mozambique)

“Supporting us in the data collection and monitoring of the process.” (Malawi)

“To act accordingly with the framework put by the participants with the regional context.” (Ethiopia)

“To have such meetings at the regional level in all the regions with active participation of the local press.” (Ghana)

“Very quickly organize workshops to push countries to fulfill all the recommendations issued in past meetings.” (Gabon)

“Appointing a focal point and having regular meetings.” (Burkina Faso)

“Communications and advocacy.” (Benin)

“Meetings as the phase III becomes available before registration.” (Kenya)

“Encourage the implementation of a local decision making framework, taking into account the important participation of national researchers, to better reassure the local decision makers and populations.” (Gabon)

“Intensive advocacy work at a high level in particular, and at all levels in general.” (Malawi)

Another need often mentioned by participants is technical assistance. Participants say that any new information, ranging from results of the Phase 3 trials when they are complete to general information about the vaccine (efficacy, safety, and cost) would be very helpful. In particular, participants say they would like to have more support in determining the best course of action and more assistance on how best to share information about the benefits of a vaccine.

“Maintain contact with the authorities in the Ministry of Health and provide regular updates on the vaccine development process.” (Benin)

“Having routine visits to the country.” (Mozambique)

“Any activity that will provide concrete evidence on the potency and availability of a malaria vaccine.” (Ghana)

“Complete the research for phase 3 on the vaccine. Publish the obtained results. Implement an intensive educational campaign on the eventual advantages and benefits of the vaccine on morbidity and mortality.” (Burkina Faso)

“Malawi is one of the countries conducting Phase III trials, discussions on the results of this phase will assist in decision making.” (Malawi)

“Future activities should consist of generating missing data on morbidity and mortality as well as socioeconomic data at the household level.” (Burkina Faso)

“Periodic trial results publications, evidence based results workshops.” (Malawi)

“Informative and educational cycles at different levels and with different groups on the profile of the illness and its impact in Mozambique and efficacy of the vaccine, strategies for securing financing and sustainability.” (Mozambique)

“Continue sensitizing different groups about the coming malaria vaccine indicating the vaccine is safe. Starting preparing IEC materials. Assessing the cold chain capacity. Establishing cost effectiveness of the malaria vaccine.” (Tanzania)

“Information on the vaccine in a simple format.” (Mozambique)

“Provision of additional info on new malaria vaccine candidates including cost, efficacy, side effects.” (Ghana)

“Stakeholders meeting to review progress made in data collection and processes required to make a decision. Dissemination of results of phase 3 vaccine trial of the leading vaccine candidate.” (Ghana)

“Some follow-up meetings to discuss local research and data collection on the vaccine issue within these pre-licensure stages.” (Ghana)

“Review of progress made related to data requirements and information sharing with different stakeholders within the country.” (Tanzania)

“Review what has happened since the Benin workshop and current research results.” (Benin)

“Provide regular updates on availability and cost of malaria vaccine. Assist with financial sustainability planning.” (Ghana)

“Put in place a follow-up committee to measure the impact of introducing this vaccine on public health, on the Ministry of Health budget, on the carriers and the modification of the P. falciparum genome. Emphasize the benefits of the vaccine.” (Gabon)

“Regular follow-up with the technical committee on implementing the framework in Burkina Faso (plan for collecting the data, plan for starting the process, plan in short term) and greater awareness among the highest authorities in the Ministry of Health.” (Burkina Faso)

“Updates on progress towards production of a malaria vaccine.” (Mali)

IV. PREPAREDNESS, PROCESS AND DATA

After the consultation, participants were charged with getting their countries prepared. With the exception of Ethiopia, Burkina Faso, and Malawi, where in-country consultations took place between April 2007 and April 2008, roughly two years have passed for the other six countries since their consultations. And although there are at least several years before the first malaria vaccine might even be introduced, there are many tasks and challenges ahead. Sufficient infrastructure, financing, data, and myriad other components are necessary before an introduction of any public health intervention. On the process side, countries need to establish a technical working group, assess and strengthen their regulatory, ethics, and data management processes, and determine how they might integrate the malaria vaccine into their multi-year strategic plan. On the data side, all endemic countries need to collect a wide-range of information. This section examines how well all the countries have progressed in their level of preparedness in the areas of country-level process and data requirements as outlined by the framework.

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Impressions about Country Preparedness

As highlighted throughout the first half of this report, while participants are enthusiastic about the DMF consultations and the framework, they see a strong need for more advocacy, communication, coordination, and technical assistance. Here we find that for both process and data level requirements outlined in the framework, most participants say their country is prepared, but only somewhat prepared. A large majority of participants (76%) say that, given what they know, their country is at least somewhat prepared to make progress toward an evidence-based decision on a malaria vaccine. This confidence, however, is not strong. Fewer than two in 10 (18%) believe that their country is very prepared while a majority (58%) report that their country is only somewhat prepared. A notable minority also say that their country is not too prepared (22%) or not prepared at all (1%).

A substantial majority say these opinions are driven by their country's experience with the introduction of other malaria interventions (89%) and the DMF consultation (85%). Slightly fewer (76%)

COUNTRY PREPAREDNESS TO MAKE PROGRESS TOWARD MAKING A MALARIA VACCINE DECISION

	N	
Very prepared	76	18%
Somewhat prepared		58%
Not too prepared		22%
Not prepared at all		1%

CONTRIBUTION OF (INSERT) ON PARTICIPANTS' RESPONSE THAT COUNTRY IS PREPARED TO MAKE A MALARIA VACCINE DECISION

YOUR COUNTRY'S EXPERIENCE WITH THE INTRODUCTION OF OTHER MALARIA INTERVENTIONS

	N	
A great deal	74	57%
Somewhat		32%
Not too much		5%
Not at all		5%

THE DMF CONSULTATION

	N	
A great deal	72	46%
Somewhat		39%
Not too much		13%
Not at all		3%

YOUR COUNTRY'S EXPERIENCE WITH PAST VACCINE INTRODUCTIONS

	N	
A great deal	74	57%
Somewhat		19%
Not too much		22%
Not at all		3%

say their opinion is shaped by their past experience with vaccine introduction. According to a solid majority of participants (57%), experience with other malaria interventions and with past vaccine introductions contribute a great deal to their opinion. A plurality (46%) say the DMF consultation contributed a great deal toward their opinion about how prepared their country is.

Country Preparedness with Respect to Process Level Steps and the Role of the DMF

There is wide recognition that many steps are necessary before a country can make a decision with respect to a malaria vaccine. A large majority of participants say that their country is at least somewhat prepared to implement various steps, but no majority or even plurality say that they are very prepared.

According to DMF consultation participants, the in-country consultation helped them understand *the process* by which a scientifically-based decision can be made about the introduction of a malaria vaccine in their country. The vast majority of participants (96%) report that the DMF consultation was useful, including 73 percent who say it was very useful in understanding the malaria vaccine decision-making process. Very few (4%) say the consultation was not too useful and no respondent reports it was not useful at all.

Overall, DMF consultation countries seem most prepared to establish a technical working group. One-third of participants (36%) say their country is very prepared and a plurality (46%) report their country is somewhat prepared. A handful report that their country has already established or are in the process of establishing a national technical working group.

Again, while a sizable majority (72%) say their country is at least somewhat prepared to strengthen data collection capacity, the degree of preparedness varies. DMF consultation participants are roughly divided with about one-third (33%) who think their country is very prepared and slightly more (39%) who say their country is somewhat prepared. Two in 10 (21%) think their country is not too or not prepared at all and a few (6%) also report that this collection is already complete or underway.

USEFULNESS OF DMF CONSULTATIONS IN UNDERSTANDING THE MALARIA VACCINE DECISION-MAKING PROCESS

	N	
Very useful	78	73%
Somewhat useful		23%
Not too useful		4%
Not useful at all		-

COUNTRY PROCESS-LEVEL STEPS: PREPAREDNESS TO ...

ESTABLISH A NATIONAL TECHNICAL WORKING GROUP

	N	
Very prepared	61	36%
Somewhat prepared		46%
Not too prepared		8%
Not prepared at all		5%
Already implemented		3%
In the process of implementing		2%

STRENGTHEN DATA COLLECTION CAPACITY AND COLLECT DATA ABOUT MALARIA DISEASE BURDEN

	N	
Very prepared	61	33%
Somewhat prepared		39%
Not too prepared		16%
Not prepared at all		5%
Already implemented		3%
In the process of implementing		3%

STRENGTHEN ETHICAL REVIEW COMMITTEES AND NATIONAL REGULATORY BODIES

	N	
Very prepared	61	33%
Somewhat prepared		44%
Not too prepared		15%
Not prepared at all		5%
Already implemented		2%
In the process of implementing		2%

As an important component of infrastructure and feasibility, ethical review committees and national regulatory bodies must be in place. One-third of the participants (33%) report that their country is very prepared and a plurality (44%) say they are somewhat prepared to strengthen ethical review committees and national regulatory bodies. Two in 10 (20%) report that their country is not too or not prepared at all while few (4%) say they are have already established these committees or in the process of doing so.

A large majority of participants say their country is prepared to assess and strengthen their regulatory, ethics, and data management processes. One-quarter (25%) believe their country is very prepared while one-half (51%) feel they are somewhat prepared to handle this task. One-quarter (24%) feel their country is not too prepared or not prepared at all.

By similar margins, three-quarters note their country is ready to reinforce communication between researchers and decision-makers. One-quarter (26%) argue their country is very prepared to reinforce communication while nearly one-half (48%) report they are somewhat prepared to handle this task. Two in 10 (21%) feel their country is not too prepared or not prepared at all to implement this step. Few (5%) say their country has already implemented or are in the process of implementing a program to reinforce communication between researchers and decision-makers.

DMF consultation participants report that their country is least prepared to establish the level of demand for a malaria vaccine. Roughly two in 10 (18%) say their country is very prepared while four in 10 (39%) say their country is somewhat prepared. Just as many (38%) think their country is not too prepared and few (3%) feel they are not prepared at all.

Participants who said their country was very or somewhat prepared to do any of these six country-level process steps were asked the extent to which the DMF consultation contributed to their preparedness. A large majority report that the DMF consultation contributed to this preparedness. About one-quarter (27%) say the DMF consultation contributed to their country's preparedness to a great extent and nearly one-half (49%) say it contributed a moderate amount. One-third (33%) say the

COUNTRY PROCESS-LEVEL STEPS: PREPAREDNESS TO ...

ASSESS AND STRENGTHEN REGULATORY, ETHICS, AND DATA MANAGEMENT PROCESSES

	N	61
Very prepared		25%
Somewhat prepared		51%
Not too prepared		21%
Not prepared at all		3%
Already implemented		-
In the process of implementing		-

REINFORCE COMMUNICATION BETWEEN RESEARCHERS AND DECISION-MAKERS

	N	61
Very prepared		26%
Somewhat prepared		48%
Not too prepared		16%
Not prepared at all		5%
Already implemented		3%
In the process of implementing		2%

ESTABLISH THE LEVEL OF DEMAND FOR A MALARIA VACCINE

	N	61
Very prepared		18%
Somewhat prepared		39%
Not too prepared		38%
Not prepared at all		3%
Already implemented		-
In the process of implementing		2%

EXTENT TO WHICH DMF CONSULTATION CONTRIBUTED TO COUNTRY'S PREPAREDNESS

	N	59*
Great extent		27%
Moderate extent		49%
Small extent		33%
Not at all		-
Other, please specify		2%

* Based on those who indicated that their country was very or somewhat prepared to implement some of these steps, already implemented, or already in the process of doing so.

DMF consultation played a small role in their country's preparedness to implement any of the steps discussed above.

Suggestions for Improving and Implementing Process-level Preparedness

Participants who indicated that their country is not too prepared or not prepared at all to implement some of the steps discussed above were asked, "In your opinion, what steps are necessary to become prepared and who or what organization should take the initiative to implement these steps?" Participants talk about advocacy and increased education targeting high-level decision-makers. These participants' comments suggest that the importance of preparedness has not yet sufficiently reached all areas of government.

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"I think the decision makers and policy makers must be convinced. Therefore, high level advocacy must be done, at all levels: starting from the decision/policy makers down to the technical staff who are the implementers." (Ethiopia)

"Advocacy at the level of key decision makers; Increase awareness among health professionals." (Mozambique)

"Awareness creation. That is people at different levels and professionals INCLUDING DECISION MAKERS and parliament need to be aware that the malaria vaccine is in the market. The impact of the vaccine and safety is important to build community trust. The cost of the vaccine and how much the country needs to pay. To prepare cold chain capacity and data collection tools. The government should take the initiative to implement in collaboration with partners." (Tanzania)

There is also a need for coordination and communication between the various ministries within a country and all the stakeholders, including international agencies, according to participants. Centralization of tasks, research, and activities is the main theme throughout the following participant suggestions. These centralized organizations would be responsible for all relevant activities, including strengthening communication and developing technical partnerships and committees.

"It is necessary to have a central group that coordinates and connects the different operations of the Ministry of Health in the area of public health (Malaria, immunization, and research) and in the area of decision making (cooperation, planning, organization, and management)." (Mozambique)

"Under the leadership of the National Malaria and Immunization Programmes, and with support from partners and research institutions in country, and the go ahead from the Ministry of Health, a technical committee should be set up to initiate the steps required for data collection and regulatory mechanisms and frameworks to be put in place." (Benin)

"Strengthen HMIS in data collection and formation of the national technical committee to oversee the process." (Malawi)

"The Ministry of Health and the Ministry of Scientific Research should form an expert committee to the study the feasibility of different activities." (Gabon)

"Create a mechanism to coordinate between USAID, Ministry of Health and other principally community NGOs to implement the programs." (Mozambique)

"Involve organizations highly involved and specialized for vaccine and funding it. ... There has to be a responsible group delegated to run these activities apart from routine activities like having a consultant. In general, the framework forwarded during the consultative meetings could give us an insight to share responsibilities." (Ethiopia)

*“More centralization. Research institutions in the country (national) in collaboration with WHO.”
(Benin)*

“Both the government (MOH) and other research based organizations/stakeholders need to communicate on a regular basis in preparation for the availability of such a vaccine so as to update each other of new research findings, preparedness of the country for a Malaria vaccine use/accepting and also plan further steps so as to be on the same level/base of knowledge and of work as well.” (Malawi)

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*“MOH should bring together researchers and policy makers at regular intervals to interact.”
(Ghana)*

“Strengthen the local malaria partnership for information sharing and increase transparency in decision-making.” (Mali)

*“More dialogue with a receptive MOH who should be open to new ideas about prevention.”
(Malawi)*

Country Preparedness with Respect to Data Level Steps and the Role of the DMF

As with any public health intervention, a decision to introduce or not a malaria vaccine requires key stakeholders and decision-makers to weigh an enormous amount of data. First, countries need to assess what data need to be collected and then develop an action plan to acquire this information.

Participants consider the consultations helpful in learning about what data and information should be collected and analyzed before making a malaria vaccine decision. Nearly all participants (97%) found the DMF consultation very (73%) or somewhat (24%) useful. Very few (3%) say the consultation was not too useful and no respondent reports it was not useful at all in learning about what data and information needs to be gathered and analyzed to make a decision.

USEFULNESS OF DMF CONSULTATIONS IN LEARNING ABOUT WHAT DATA AND INFORMATION NEEDS TO BE GATHERED AND ANALYZED TO MAKE MALARIA VACCINE DECISION

	N	78
Very useful		73%
Somewhat useful		24%
Not too useful		3%
Not useful at all		-

Developing plans to collect necessary data and actually completing these tasks are challenging but necessary steps toward informed decision-making. Participants were asked how prepared their country is to begin the process of filling in gaps for various types of country-level data. Overall, a handful report that their country has already collected or are in the process of collecting the necessary data. Slightly more state that their country is not too or not prepared at all to fill the gaps. A large majority, however, do believe that their country is prepared to collect data. However, a plurality note that their country is somewhat prepared rather than very prepared to begin the process of filling in country-level data gaps.

There is no one type of country-level data for which participants report being notably better prepared or are particularly lacking. Participants were asked to rate their level of preparedness on a variety of measures addressed in the DMF.

Roughly three-quarters report that their country is very or somewhat prepared to fill in data gaps in malaria-related morbidity and mortality at the province level (77%), clinical and severe malaria cases by age group, i.e., inpatient or hospitalized cases (74%), and malaria-related deaths by age group (73%). In each of these cases, a plurality state that their country is somewhat prepared while three in 10 report that their country is very prepared.

Similarly, about seven in 10 participants report that their country is prepared to measure the capacity of the national immunization program to accommodate a malaria vaccine. Participants are roughly split though on their perception of level of preparedness, with as many saying very prepared (33%) as somewhat prepared (36%). Three in 10 (29%) say their country is not too or not prepared at all to measure the capacity of the national immunization program to accommodate a malaria vaccine.

COUNTRY-LEVEL DATA: PREAPAREDNESS TO FILL IN GAPS

MALARIA-RELATED MORBIDITY AND MORTALITY AT PROVINCE LEVEL

	N	66
Very prepared		29%
Somewhat prepared		48%
Not too prepared		12%
Not prepared at all		3%
Already collected		5%
In the process of collecting		3%

CLINICAL AND SEVERE MALARIA CASES BY AGE GROUP (INPATIENT OR HOSPITALIZED CASES)

	N	66
Very prepared		32%
Somewhat prepared		42%
Not too prepared		15%
Not prepared at all		2%
Already collected		8%
In the process of collecting		2%

MALARIA-RELATED DEATHS BY AGE GROUP

	N	67
Very prepared		30%
Somewhat prepared		43%
Not too prepared		18%
Not prepared at all		-
Already collected		6%
In the process of collecting		3%

CAPACITY OF THE NATIONAL IMMUNIZATION PROGRAM TO ACCOMMODATE A MALARIA VACCINE

	N	67
Very prepared		33%
Somewhat prepared		36%
Not too prepared		25%
Not prepared at all		4%
Already collected		-
In the process of collecting		1%

IMPACT AND COVERAGE OF EXISTING MALARIA INTERVENTIONS

	N	67
Very prepared		21%
Somewhat prepared		51%
Not too prepared		15%
Not prepared at all		9%
Already collected		-
In the process of collecting		4%

A bare majority of participants state that they are only somewhat prepared to determine the impact and coverage of existing malaria interventions (51%) or to estimate how many people would need to be vaccinated (51%). Almost as many who say their country is very prepared say their country is not too or not prepared at all.

A large majority of seven in 10 (72%) report that their country is at least somewhat prepared to collect evidence of established approaches that support intervention, such as current policies and regulations. Many more, however, note that their country is somewhat prepared (58%) rather than very prepared (14%). Three in 10 (29%) say that their country is not too or not prepared at all.

A modest majority of participants (56%) say their country is very prepared (13%) or somewhat prepared (43%) to fill in gaps related to the public's knowledge, attitudes and practices toward vaccines and malaria interventions. Four in 10 (41%) say that their country is not too or not prepared at all.

Preparedness levels are somewhat lower on the remaining measures asked about in the survey. Countries are prepared to fill in gaps related to measuring the prevalence of malaria among pregnant women and HIV positive individuals according to exactly one-half (50%) of participants. Almost as many (44%) say their country is not too or not prepared at all. A handful (6%) say their country is in the process of collecting this data.

According to participants, countries are less prepared to measure the economic burden of malaria in terms of DALYs (disability adjusted life years), the health budget, or GDP, or the cost of purchasing and administering a licensed vaccine. A modest or solid majority report that their countries are not too or not prepared at all to collect economic data (55%) or data on cost (67%). A sizeable minority (42%) do report, however,

COUNTRY-LEVEL DATA: PREPAREDNESS TO FILL IN GAPS

ESTIMATES OF HOW MANY PEOPLE WOULD NEED TO BE VACCINATED

	N	67
Very prepared		21%
Somewhat prepared		51%
Not too prepared		16%
Not prepared at all		6%
Already collected		-
In the process of collecting		6%

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EVIDENCE OF ESTABLISHED APPROACHES THAT SUPPORT INTERVENTION, SUCH AS CURRENT POLICIES AND REGULATIONS

	N	66
Very prepared		14%
Somewhat prepared		58%
Not too prepared		23%
Not prepared at all		6%
Already collected		-
In the process of collecting		-

PUBLIC KNOWLEDGE, ATTITUDES, AND PRACTICES TOWARDS VACCINES AND MALARIA INTERVENTIONS

	N	67
Very prepared		13%
Somewhat prepared		43%
Not too prepared		31%
Not prepared at all		10%
Already collected		-
In the process of collecting		1%

PREVALENCE AMONG PREGNANT WOMEN AND HIV POSITIVE INDIVIDUALS

	N	66
Very prepared		12%
Somewhat prepared		38%
Not too prepared		35%
Not prepared at all		9%
Already collected		-
In the process of collecting		6%

ECONOMIC BURDEN OF MALARIA IN TERMS OF DALYS, THE HEALTH BUDGET AND THE GDP

	N	66
Very prepared		15%
Somewhat prepared		27%
Not too prepared		32%
Not prepared at all		23%
Already collected		2%
In the process of collecting		2%

COST TO PURCHASE AND ADMINISTER THE VACCINE

	N	66
Very prepared		9%
Somewhat prepared		23%
Not too prepared		47%
Not prepared at all		20%
Already collected		2%
In the process of collecting		-

that their country is ready to collect data on the economic burden of malaria while nearly one-third of participants (32%) say their country is prepared to collect data regarding the cost to purchase and administer a vaccine.

Participants who said their country was very or somewhat prepared to collect any of the 11 types of country-level data were asked the extent to which the DMF consultation contributed to their preparedness. A substantial majority (71%) say that the DMF consultation contributed to a great or moderate extent their country's preparedness to collect the data addressed above. By contrast, nearly three in 10 (28%) say the DMF consultation played only a small or no role at all in their country's preparedness.

EXTENT TO WHICH DMF CONSULTATION CONTRIBUTED TO COUNTRY'S PREPAREDNESS

	N	66*
Great extent		26%
Moderate extent		45%
Small extent		26%
Not at all		2%
Other		2%

* Based on those who indicated that their country was very or somewhat prepared to collect some types of data, already collected, or already in the process of doing so.

Suggestions for for Improving and Implementing Data Preparedness

Participants who indicated that their country is not too or not prepared at all to collect the data addressed above were asked, "In your opinion, what are the most important steps your country should take to become prepared?" and to indicate "who or what organization should take the initiative to implement these steps." Participants' responses provide a thoughtful picture of where countries stand with respect to malaria vaccine preparedness. To start, an underlying issue here is the need for more awareness, particularly among high-level decision-makers. One participant cautions that since the vaccine is unavailable *now*, there is no sense of urgency. Yet, we know from past experience that now is the time to prepare. Thus, an effort must be made to emphasize the importance of getting prepared now, particularly through proper data collection.

"I think the MVI objectives and DMF consultation recommendations should first and foremost get the attention of decision makers/policy makers of the country. Therefore a lot of advocacy work has to be done at high level. It is after the policy/decision makers are well convinced that preparations are started. Some of the data mentioned are already part of the routine HMIS." (Ethiopia)

"More sensitization within the country as to the importance of the use of data in the decision making framework for the introduction of the vaccine. The fact that the vaccine is not ready makes it not appear to be urgent, and the country is concentrating on other malaria control interventions for the moment. Good sensitization on the progress with the development of the vaccine (marketing) and advocacy will help." (Benin)

Some comments suggest that there is an understanding of what needs to get done, but some countries remain in a conditional state – that is, participants know "what *should* get done" but have not moved forward in executing these tasks. Notably, Ethiopia, Burkina Faso, and Malawi were among the last to have in-country consultations (i.e., they were conducted between April 2007 and April 2008). Participants provide some very specific suggestions for next steps, particularly in Ghana.

"Important and essential data for the introduction of malaria vaccine need to be given due emphasis and initiatives should be taken by FMOH, Regional Health and Districts/world health offices and other actors and partners in public health system in the country." (Ethiopia)

“Information collection is not part of the current routine. One would need to create an information collection system for both demographic and health data. This would require collaboration between the Ministry of Health and the Ministry of Finance and Economics.” (Burkina Faso)

“The most important steps to be taken include: strengthening HMIS so as to capture reliable malaria data disaggregated by age.” (Malawi)

“Certain logistics are necessary to collect the data. The Minister of Health should find the means and the funds necessary to train their personnel (hospital staff) and buy the materials with the goal of collecting the data that are needed, including the most remote village.” (Gabon)

“Determine what data needs to be collected. Prepare records of the effect. Determine responsibility of analysis for the same. The Ministry of Health should lead this whole process with technical support from other organizations that are involved in this subject.” (Mozambique)

“Development of a plan of introduction (PNLP and PEV). Broad information and training. Resource mobilization. System of vaccinovigilance.” (Benin)

“Prepare the personnel who are currently preoccupied with malaria prevention activities 2. Take them through the process (training) since many of them have little info concerning the process; Organization: Division of Malaria Control, Ministry of Health. Research Organizations eg. Kenya Medical Research Institute; Universities eg. University of Nairobi.” (Kenya)

“1. Improve the capacity to diagnose malaria to identify the real clinical malaria cases 2. Enable the hospitals to carry out diagnostic tests for other diseases, such as bacterial meningitis or HIV, which could be misdiagnosed as malaria. 3. Evaluate the impact of prevention strategies that contribute to reducing malaria (mosquito nets, etc.).” (Mozambique)

“1. Financial support to deploy data collection tools 2. Training/refresher training of data managers in the context of IDSR 3. Collaboration with WHO EPI teams for data handling and analysis.” (Gabon)

“Become aware, plan, budget and collect the missing or needed data. Various stakeholders/organizations would need to be involved, under the leadership of the government.” (Benin)

“Country should have a task team to review relevant information available for decision making on vaccine introduction, do cost benefit analysis. Present findings to policy makers, start the discussions on financial sustainability with MOH and Ministry of Finance. Update this information as and when more current global information become available. Assess the current EPI system to determine whether it can take on another vaccine.” (Ghana)

“Train statisticians and epidemiologists at all levels to collect accurate data on morbidity and mortality and also to have “accurate” estimates of the population (number of children) that would need the vaccination.” (Ghana)

“1. Build capacity for data collection at the peripheral level. 2. Establish an automated data collection system rather than manual compilation, i.e. use computers. This must be done by the Ghana Health Service.” (Ghana)

“Many malaria cases still do not pass through health care facilities especially in the rural areas. Therefore the data collected at facilities may not be representative of all the scenarios there are. Well established Civil Society organizations should be used.” (Ghana)

As noted earlier, participants believe in more consultation and collaboration between national and international organizations. No different here. Malaria-endemic countries would enhance their malaria vaccine preparedness if there was more consultation and collaboration, according to DMF participants.

“The Malaria Control Program in collaboration with other stakeholders should take the initiative and leadership to address gaps in the collection of some types of data.” (Malawi)

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“Human capacity building. MOH in consultation with training and research organizations to take initiative.” (Malawi)

“Put in place a management structure to coordinate research for better readability of government decision makers.” (Gabon)

“USAID and the Ministry of Health need to create a strong partnership to improve coordination with other programs or NGOs that are fighting malaria.” (Mozambique)

“The effort of your organization in collaboration with WHO, UNICEF, and NGOs engaged in similar role should work with the Federal Ministry of Health and its stakeholders locally, regionally and globally.” (Ethiopia)

“Involve organizations who are already doing research. More than the Ministry of Health and Population alone.” (Malawi)

“As the profile of the vaccine to be used is not known, it will not be easy to say whether the country is prepared or not. ... Collaboration with partners will assist to address some constraints like financial and technical. Each partner has areas of expertise.” (Tanzania)

A few participants give suggestions for how the DMF can provide leadership and even plans to collect very specific data.

“The DMF should meet and look at the data that we need and identify strategies of obtaining that data and also identify lead organizations in different areas of data collection depending on the relevance of the organizations to different areas.” (Malawi)

“Convene a DMF follow-up technical meeting to monitor what exists and what is needed to ensure the country will be ready when the vaccine is ready. Establish a DMF working group co-chaired by EPI and NMCP.” (Mali)

“MVI should, in collaboration with the researchers, identify and the Malaria Control Program comply with this process so that the data on efficacy will be taken care of as quickly as possible.” (Burkina Faso)

V. DMF STAFF, IMPRESSIONS

As detailed throughout this report, participants show great appreciation for the DMF consultation and framework. This high opinion extends to the DMF staff and the written materials they produced for the briefing, in-country consultation presentations, and final meeting report.

Participants were asked to rate the DMF staff's helpfulness and knowledge. Nearly all regard the DMF staff as helpful (93%) and knowledgeable (97%). More than one-half (54%) strongly agree that the DMF staff is helpful and another 39 percent somewhat agree. Participants show even more enthusiasm over the staff's knowledge. Three-quarters (74%) strongly agree with the statement that DMF staff is knowledgeable while slightly less than one-quarter (23%) only somewhat agree. Few people disagree with either statement.

The DMF Steering Committee prepared seven briefing papers, which were distributed to participants before the in-country consultation. These reports provided current information about malaria vaccines and provided context for decision-making. Nine in 10 (90%) participants say the materials were easy to understand. A plurality (49%) somewhat agree that the materials are easy to understand while four in 10 (41%) strongly agree. Only a handful of participants disagree.

Each in-country consultation had presentations over the course of two days. These presentations always included overviews of a country's malaria control program, immunization program, and in malaria vaccine research and development. As noted at the start of this report, an overwhelming majority of participants find these presentations useful. With respect to the presentation materials, nearly all the participants (95%) agree that the materials are easy to understand. Notably, a slim majority (53%) somewhat agree with this

IMPRESSIONS OF DMF STAFF

THE DMF STAFF WAS HELPFUL

	N	76
Strongly agree		54%
Somewhat agree		39%
Somewhat disagree		5%
Strongly disagree		1%

THE DMF STAFF WAS KNOWLEDGEABLE

	N	62
Strongly agree		74%
Somewhat agree		23%
Somewhat disagree		3%
Strongly disagree		-

DMF MEETING MATERIALS AND PRODUCTS

DMF BRIEFING MATERIALS WERE EASY TO UNDERSTAND

	N	76
Strongly agree		41%
Somewhat agree		49%
Somewhat disagree		9%
Strongly disagree		1%

DMF PRESENTATION MATERIALS WERE EASY TO UNDERSTAND

	N	62
Strongly agree		42%
Somewhat agree		53%
Somewhat disagree		5%
Strongly disagree		-

DMF FINAL MEETING REPORT SUMMARIZED THE ACTIVITIES AND FINDINGS WELL

	N	57
Strongly agree		63%
Somewhat agree		37%
Somewhat disagree		-
Strongly disagree		-

DMF FINAL MEETING REPORT WAS CLEAR

	N	58
Strongly agree		53%
Somewhat agree		45%
Somewhat disagree		2%
Strongly disagree		-

statement while four in 10 (42%) strongly agree.

Participants were asked two questions about the accuracy and clarity of the final report. Overall, a substantial majority of participants say the report presented a good clear summary. A solid majority of more than six in 10 (63%) strongly agree that the final report summarized the activities and findings well. A little more than one-third (37%) somewhat agree with this statement. A slim majority (53%) strongly agree that the DMF final meeting report was clear. Almost as many (45%) somewhat agree that the final report was clear.