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Country planning for health interventions under development: lessons from the malaria vaccine decision-making framework and implications for other new interventions

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Traditionally it has taken years or decades for new public health interventions targeting diseases found in developing countries to be accessible to those most in need. One reason for the delay has been insufficient anticipation of the eventual processes and evidence required for decision making by countries. This paper describes research into the anticipated processes and data needed to inform decision making on malaria vaccines, the most advanced of which is still in phase 3 trials. From 2006 to 2008, a series of country consultations in Africa led to the development of a guide to assist countries in preparing their malaria vaccine decision-making frameworks. The guide builds upon the World Health Organization's Vaccine Introduction Guidelines. It identifies the processes and data for decisions, when they would be needed relative to the development timelines of the intervention, and where they will come from. Policy development will be supported by data (e.g. malaria disease burden; roles of other malaria interventions; malaria vaccine impact; economic and financial issues; malaria vaccine efficacy, quality and safety) as will implementation decisions (e.g. programmatic issues and socio-cultural environment). This generic guide can now be applied to any future malaria vaccine. The paper discusses the opportunities and challenges to early planning for country decision-making—from the potential for timely, evidence-informed decisions to the risks of over-promising around an intervention still under development. Careful and well-structured planning by countries is an important way to ensure that new interventions do not remain unused for years or decades after they become available.

Keywords Health policy, policy making, decision making, organizational, developing countries, vaccines, interventions, technologies

KEY MESSAGES

- Insufficient planning for decision-making processes—and a lack of early gathering of data to inform those processes—is a key reason for often long delays between development and availability of new interventions in low- and middle-income countries.
- The PATH Malaria Vaccine Initiative (MVI) and the World Health Organization (WHO) worked with countries years before projected availability of any malaria vaccine to anticipate the country processes and data needed for eventual decisions on use.
- Planning should be cautiously paced to not get ahead of, or over-promise, relative to evidence from the intervention's development progress.

Introduction

An increasing amount of money, US$3.2 billion dollars in 2009 alone, is being spent on research and development for new products intended to address diseases prevalent in the developing world (Policy Cures 2010). Assuming that even a fraction of these funds realizes the goal of creating new health interventions, low- and middle-income countries (LMICs) will face a growing number of decisions on which new interventions to use in the coming decade.

This paper focuses on national decisions to adopt, or not, a new intervention, once it becomes available (i.e. approved by the appropriate regulatory authorities and produced in sufficient quantities by a manufacturer). Such decisions would be distinct from largely regulatory determinations to allow sales of a product through private-sector channels.

National decision-making processes for public policies, and health policies more specifically, have been under study for decades. They can be seen as complex, non-linear processes, balancing evidence, policy alternatives and domestic and international politics (Grindle and Thomas 1991; Walt 1994; Kingdon 1995). Substantial efforts have been made to understand and therefore improve decision-making processes (e.g. DeRoeck 2004; DeRoeck 2005; Gericke *et al*. 2005; Bryson *et al*. 2010; Gessner *et al*. 2010; Grundy 2010; Levine *et al*. 2010a; Victora 2010) and to generate the data needed by countries to facilitate decision-making, including data on burden of disease and on cost-effectiveness of interventions (e.g. Hutubessy *et al*. 2003; WHO 2004; La Force *et al*. 2007; Hajjeh *et al*. 2010; Kim *et al*. 2010; Levine *et al*. 2010b). Countries also need to consider many factors specific to the targeted disease and the characteristics of the intervention, some of which are informed by international organizations and global experts [e.g. World Health Organization (WHO) policy positions; donor funding commitments] (WHO 2002; WHO 2005; Stop TB Partnership and WHO 2007; Bryson *et al*. 2010; Shearer *et al*. 2010). Within countries, there may be questions about co-ordination among different entities, particularly for an intervention that cuts across areas of specialization in public health. One example would be the human papillomavirus (HPV) vaccine that has required collaboration across reproductive health, immunization and school health experts (Katahoire *et al*. 2008).

The track record for adoption decisions and implementation of new health interventions in LMICs suggests that it takes years or decades for many countries to realize the benefits of new public health interventions (Kane and Brooks 2002; Bosman and Mendis 2007; Frost and Reich 2009; Levine *et al*. 2010b; WHO *et al*. 2010). Decisions are likely more complex for a novel, 'first in class' intervention like a malaria vaccine, but less complex for a second-generation or follow-on intervention, such as a new anti-malarial drug that is meant to replace a less effective drug. While detailing the multiple reasons for these delays is beyond the scope of this paper, a recurrent theme has been the need for more thought during the development of a health intervention on what processes and data LMICs would need in order to make timely decisions on whether or not to introduce the intervention.

Evidence that insufficient planning for country decision-making is a major cause of delays in the use of health interventions is apparent in a number of areas. The GAVI Alliance (GAVI) has pinpointed challenges in decision-making as a key factor in the delay to implement the *Haemophilus influenzae* type b (Hib) conjugate vaccine (Mitchell *et al*. 2005; Hajjeh *et al*. 2010), a vaccine available in the developed world since 1987. The delay led GAVI in 2005 to invest US$37 million in establishing the four-year Hib Initiative. The Initiative provided support to countries wishing to decide if Hib vaccine was a priority for introduction, and programmatic support to countries which had already decided to use it (GAVI Alliance 2004). Reports on the process that is required to change malaria treatment policy suggest that the policy decision process itself takes 1 to 5 years, with an equal length of time for implementation (Williams *et al*. 2004; Mulligan *et al*. 2006; Amin *et al*. 2007; Bosman and Mendis 2007). One estimate suggests that changing treatment is likely to cost roughly US$1 million in today's currency for a reasonably large country like Tanzania (Mulligan 2006). Both GAVI and the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM), the world's largest organizations supporting adoption of new health interventions, recognize the challenges country-level decision-makers face. Proposals to either organization for support must demonstrate the functioning presence of a local partner and government co-ordination mechanism to support decision-making and implementation (GAVI Alliance 2008; GFATM 2010). These requirements would not be called for if those organizations did not recognize the challenges inherent in national decision-making processes.

Variability in the speed of adoption naturally exists between situations and across countries. At the same time, accelerating clinical trials to save 1 or 2 years on timelines to licensure of a new intervention only to have the policy and implementation process add years or decades suggests that more forethought is

needed around national planning processes during intervention development. Product developers, and countries and their development partners, need to plan in advance for new health interventions. This paper lays out a multi-year collaboration designed to anticipate the processes and data that countries would need to make decisions on whether or not to introduce a malaria vaccine. Such work was called for by the Malaria Vaccine Technology Roadmap, a plan laid out by 230 experts representing 100 organizations from 35 countries (Malaria Vaccine Funders Group 2006). The roadmap recognizes that anticipating national decision processes during the vaccine development period is a critical part of making such a novel intervention accessible to those most in need.

The most advanced malaria vaccine candidate (RTS,S) is part-way through phase 3 clinical trials in Africa, the region where an estimated 91% of the nearly 800 000 annual malaria-related deaths occur, almost entirely among children under 5 years of age (Vekemans *et al*. 2009; WHO 2010; Agnandji *et al*. 2011). If all goes well, WHO has indicated that a policy recommendation for RTS,S is possible as early as 2015, and implementation through routine infant immunization programmes in Africa could follow.

This paper describes the decision-making framework which could be used for any upcoming malaria vaccine. The framework was intended to understand what will be needed for national governments of malaria-endemic countries to achieve the following vision: *to make timely and well-informed decisions about the appropriate use of a malaria vaccine within their national health systems within 1 to 3 years of licensure.* It is likely that the framework's first application will be to RTS,S. This paper reports on research to address the following specific questions:

(1) What processes do national experts identify as needing to take place for countries to decide on the use of a malaria vaccine and when do they need to take place relative to the projected availability of a vaccine?
(2) What data do national experts identify as needed for a decision on the use of a malaria vaccine and when would they need the data relative to projected availability of a vaccine?

The paper will go on to discuss the lessons gained from answering these questions for other new health interventions.

Methods

The decision-making framework guide was developed through an iterative process from 2005 to 2008 (Figure 1). A series of 10 consultations, of 1 to 2 days, were convened in African countries with up to 50 participants at each. The consultations included plenary presentations allowing African scientists and immunization, malaria, other government and partner staff, and participants to discuss their shared experiences with taking decisions on the adoption of malaria interventions, vaccines and/or other public health interventions. Participants were also provided with briefing papers on issues related to vaccine development, the adoption of malaria control interventions and new vaccines.

Facilitated break-out sessions, using broad categories drawn from WHO's Vaccine Introduction Guidelines (2005), allowed participants to identify processes and data that would be needed to take a decision to adopt, or not, a malaria vaccine, and when these processes and data would be needed. No similar, generic guidelines were identified by researchers for malaria interventions. Break-out sessions at subsequent meetings used the results of the first meeting as a starting point. Plenary discussions were used to reach consensus on which processes and data points were critical for policy development and implementation decisions, and which were merely helpful. Meeting reports were circulated back to all participants for input prior to finalization and posting to a public website (Malaria vaccine decision-making framework 2011).

Outcomes were analysed to identify consistent findings across two or more country meetings. Outliers were considered according to their merit relative to published and grey literature. Resulting processes and data points were put into a regional decision-making framework guide that was validated through consultations with 30 countries at 1-day, sub-regional meetings of immunization and malaria experts. The process was independently evaluated through an online survey using qualitative and quantitative methods (Princeton Survey Research Associates International 2008).

Results

Africa Regional Guide to a Malaria Vaccine Decision-Making Framework

The validated regional guide identified 31 processes (26 critical and 5 helpful) and 48 data points (39 critical and 9 helpful). The processes and data were also categorized by accountability; whether they should take place or be generated at international (e.g. global or regional) or national level. Both processes and data points are presented according to a timeline related to product development, from as early as 5 years pre-licensure, to the period around licensure and decisions on use, until 5 years post-licensure if introduced. Figure 2 shows processes at international and national levels. Figure 3 shows data, presented in seven categories based upon the WHO Vaccine Introduction Guidelines (WHO 2005). It reflects data needed for policy development: malaria disease burden; other malaria interventions; malaria vaccine impact; economic and financial issues; and malaria vaccine efficacy, quality and safety. Figure 3 also reflects data needed to inform implementation: programmatic considerations and socio-cultural environment. The frequency of process and data points identified by countries and through the regional validation meetings are presented in Tables 1 and 2.

National processes

An initial step identified during country consultations was to establish national technical working groups with local experts to work on the framework for malaria vaccines prior to availability of the phase 3 data and licensure. When the vaccine is licensed and a decision is being taken, such groups will issue advice to inform the government's policy decision. The guide leaves it up to each country to determine the specific

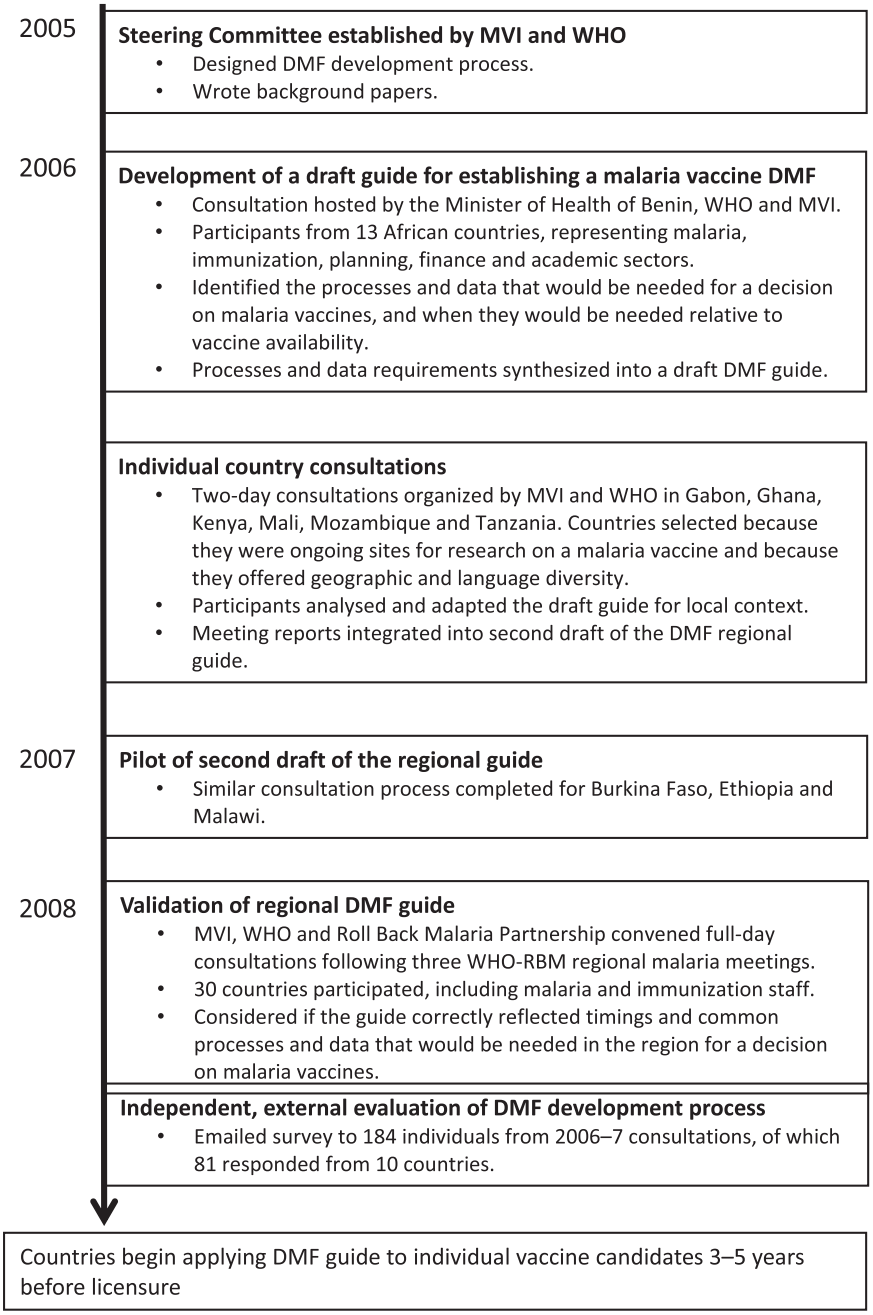

Figure 1 Timeline for decision-making framework (DMF) guide development process *Note*: MVI = Malaria Vaccine Initiative; WHO = World Health Organization; RBM = Roll Back Malaria.

remit and membership of such groups where they are established. Examples of the activities of such groups to date are discussed below. Another critical, early process is the integration of planning for malaria vaccines into multi-year strategic plans, such as for malaria and immunization. Other steps during pre-licensure could include developing communications plans, advocacy and engagement with local private-sector partners. These activities become essential when the vaccine is licensed and a decision on its introduction is being taken. Monitoring vaccine performance, safety, implementation and impact on the health system would take place during the period after introduction. Additional national processes are identified in Figure 2.

Global processes

The framework also identifies important processes to take place at the global level, such as integrating country requirements into product development plans to ensure the programmatic suitability of a vaccine; global advocacy to fundraise for malaria vaccines starting prior to licensure; and development of policy recommendations and guidelines by WHO.

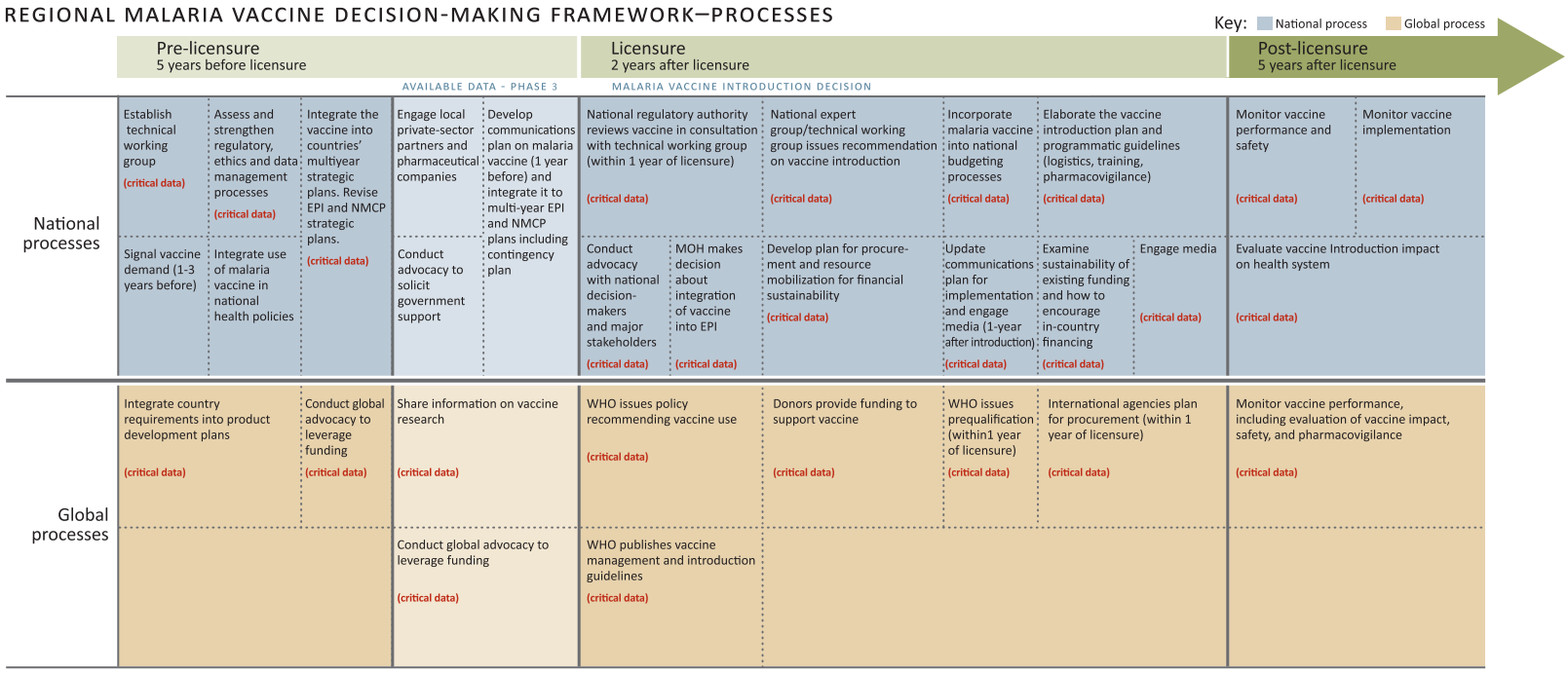

Figure 2 Regional malaria decision-making framework: processes
Notes: MOH = Ministry of Health; NMCP = National Malaria Control Program; EPI = Expanded Programme on Immunization.

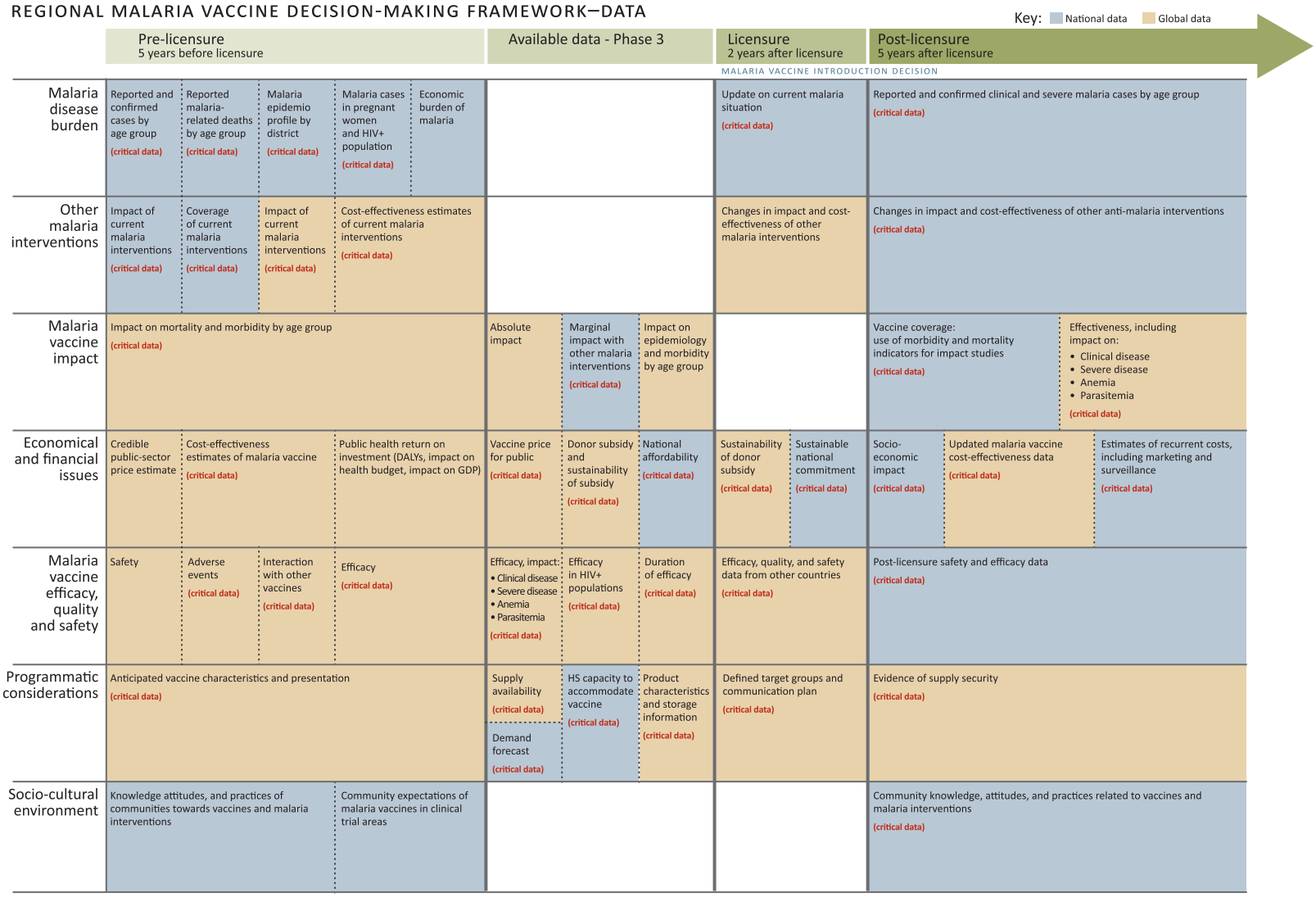

Figure 3 Regional malaria decision-making framework: data
Notes: DALYs = Disability adjusted life years; GDP = Gross Domestic Product; HS = Health system.

Table 1 Frequency of critical process responses from country consultations and regional validation meetings

	Reported in country consultations ($n = 10$)	Reported in regional validation meetings ($n = 3$)
Pre-licensure period		
National		
Establish technical working group	4	2
Assess and strengthen regulatory, ethics and data management practices	5	3
Integrate the vaccine into countries' multiyear strategic plans. Revise immunization and national malaria control programme strategic plans	9	3
Global		
Integrate country requirements into product development plans	10	3
Conduct global advocacy to leverage funding	2	2
Available data – Phase 3		
Global		
Share information on vaccine research	5	3
Conduct global advocacy to leverage funding	3	3
Licensure period		
National		
National regulatory authority reviews vaccine in consultation with technical working group	10	3
National expert group/technical working group issues recommendation on vaccine introduction	9	3
Conduct advocacy with national decision-makers and major stakeholders	8	3
Ministry of Health makes decision about integration of vaccine into immunization programme	8	3
Develop plan for procurement and resource mobilization for financial sustainability	5	3
Incorporate malaria vaccine into national budgeting processes	4	3
Update communication plan for implementation and engage media	9	3
Elaborate the vaccine introduction plan and programmatic guidelines	9	3
Examine sustainability of existing funding and how to encourage in-country financing	2	3
Engage media	2	1
Global		
WHO issues policy recommending vaccine use	9	3
WHO publishes vaccine management and introduction guidelines	9	3
Donors provide funding to support vaccine	9	3
WHO issues prequalification	9	3
International agencies plan for procurement	9	3
Post-licensure period		
National		
Monitor vaccine performance and safety	10	3
Monitor vaccine implementation	9	3
Evaluation vaccine introduction impact on health system	8	3
Global		
Monitor vaccine performance, including evaluation of impact, safety and pharmacovigiliance	6	3

Data to inform policy development

Malaria disease burden

During country consultations, experts indicated that data reflecting trends in malaria indicators at district-level would be essential, as would age-stratification given that a vaccine may not target all ages.

Other malaria interventions

Local data on the coverage, impact and cost-effectiveness of other malaria interventions, as well as from international organizations, were identified as critical before introduction of a vaccine. It is critical to have updated estimates after introduction to understand the relationship between the vaccine and ongoing investments in other preventive, diagnostic and therapeutic interventions.

Malaria vaccine impact

Age-specific estimates of vaccine impact from international organizations would be important in the policy decision process. After introduction, local data on changes in mortality and

Table 2 Frequency of critical data responses from country consultations and regional validation meetings

	Reported in country consultations ($n = 10$)	Reported in regional validation meetings ($n = 3$)
Pre-licensure period		
Malaria disease burden		
Reported and confirmed cases by age group	10	3
Reported malaria-related deaths by age group	10	3
Malaria epidemiology profile by district	7	3
Malaria cases in pregnant women and HIV+ population	5	3
Other malaria interventions		
Impact of current malaria interventions	10	3
Coverage of current malaria interventions	7	3
Cost-effectiveness estimates of current malaria interventions	9	3
Malaria vaccine impact		
Impact on mortality and morbidity by age group	9	3
Economical and financial issues		
Cost-effectiveness estimates of malaria vaccine	9	3
Malaria vaccine efficacy, quality and safety		
Adverse events	9	3
Interaction with other vaccines	4	3
Efficacy	5	1
Programmatic considerations		
Anticipated vaccine characteristics and presentation	9	3
Available data – Phase 3		
Malaria vaccine impact		
Marginal impact with other malaria interventions	9	2
Economical and financial issues		
Vaccine price for public	8	3
Donor subsidy and sustainability of subsidy	9	3
National affordability	7	3
Malaria vaccine efficacy, quality and safety		
Efficacy, impact: clinical and severe disease, anaemia and parasitaemia	8	3
Efficacy in HIV+ populations	4	3
Duration of efficacy	9	3
Programmatic considerations		
Supply availability	8	3
Demand forecast	5	3
Heath system capacity to accommodate	4	3
Product characteristics and storage information	3	1
Licensure period		
Malaria disease burden		
Update on current malaria situation	2	1
Economical and financial issues		
Sustainability of donor subsidy	7	3
Sustainable national commitment	10	3
Malaria vaccine efficacy, quality and safety		
Efficacy, quality and safety data from other countries	1	2
Programmatic considerations		
Defined target groups and communication plans	5	3

(continued)

Table 2 Continued

	Reported in country consultations ($n = 10$)	Reported in regional validation meetings ($n = 3$)
Post-licensure period		
Malaria disease burden		
Reported and confirmed clinical and severe malaria cases by age group	7	3
Other malaria interventions		
Changes in impact and cost-effectiveness of other anti-malaria interventions	2	1
Malaria vaccine impact		
Vaccine coverage: use of morbidity and mortality indicators for impact studies	10	3
Effectiveness, including impact on clinical and severe disease, anaemia and parasitaemia	8	3
Economical and financial issues		
Socio-economic impact	10	3
Updated malaria vaccine cost-effectiveness data	9	3
Estimates of recurrent costs, including marketing and surveillance	5	3
Malaria vaccine efficacy, quality and safety		
Post-licensure safety and efficacy data	10	3
Programmatic considerations		
Evidence of supply security	4	3
Socio-cultural environment		
Community knowledge, attitudes and practices related to vaccines and malaria interventions	6	3

morbidity indicators as well as impact studies from other countries will be essential to reinforce the decision.

Economic and financial issues

The most data points, nine critical and two helpful, were identified for economic and financial issues. Cost-effectiveness estimates of the malaria vaccine should be available as early as the pre-licensure period. Early indication of the price and impact on national health budgets; amount and sustainability of donor subsidies; and indications of country affordability and sustainability were identified as key elements that would be taken into account in the policy development process. If introduced, it is essential that international partners provide updated estimates of cost-effectiveness, and that countries generate data on socio-economic impact as well as recurrent costs such as for surveillance.

Malaria vaccine efficacy, quality and safety

The guide for the decision-making framework on malaria vaccines outlines a number of data that would be required from vaccine developers for countries to develop a policy: efficacy against clinical and severe disease; anaemia; and parasitaemia. Impact on mortality was identified as an outcome of interest, but not essential as a trial endpoint. If introduced, local data on vaccine safety would be essential.

Issues to consider for implementation

Programmatic considerations

Information on anticipated vaccine characteristics and storage requirements would be needed as early as the pre-licensure period, as would be data on supply availability. National demand forecasts and data on the national health system's ability to accommodate the vaccine (e.g. implications for the cold chain) were identified as critical in the period prior to licensure. Communications plans become increasingly important after a decision to adopt, as does ongoing evidence of a secure vaccine supply.

Socio-cultural environment

Country experts identified the need for data on community knowledge, attitudes and practice related to vaccines and malaria before introduction, but it became critical during the introduction period.

Summary findings of the external evaluation

Participants gave high marks for the development process for the decision-making framework guide, with 90% indicating that the guide will be extremely or very useful for the preparation process prior to vaccine licensure, while 88% indicated it would be extremely or very useful for making decisions after a vaccine is licensed. In addition, 77% indicated it would be extremely or very useful when considering the decision-making process for other vaccines; 79% felt that the meeting facilitators were neutral (neither promoting nor discouraging introduction of a malaria vaccine).

Interestingly, 70% indicated that the timing of the preparation of the decision-making framework guide was about right, 5% indicated it was already too late and 25% felt it was too early. The recommendations received from participants called for similar meetings to support technical development and

central co-ordination of the information identified in the decision-making framework guide.

Discussion

The research described above demonstrates that it is possible to plan for national decision-making for a new intervention and that African health officials value this process. The research also shows that developers, partners and countries should begin to consider requirements for decisions at least 3 to 5 years before an intervention is anticipated to be approved by the appropriate regulatory authorities. The actual timing of a decision relative to licensure, as well as the ultimate process, will vary among countries and interventions. Use of a guide developed jointly with countries to establish the decision framework should increase the likelihood of timely, evidence-based decisions, but will not guarantee such an outcome.

After the Africa regional guide was validated by countries in 2008, MVI engaged a number of malaria and immunization programme managers within African health ministries, and other national stakeholders, in a discussion on how to start working on the requirements that will guide a decision on a possible first-generation malaria vaccine. Burkina Faso, Ghana, Tanzania and Uganda organized technical working groups to co-ordinate the process. The focus of the working groups is to assemble the evidence needed for a policy formulation and ensure systems are in place for a smooth decision-making process. Under the guidance of each group's chair, they develop annual or bi-annual work plans, and members may choose to carry out the planned activities within their own institutions or they may seek services elsewhere. Composition and their modes of operating vary, but common features include: (1) They are linked to an existing group within the malaria control or immunization programmes; (2) Members are from Ministries of Health, research institutes and universities, and partner organizations (e.g. WHO country offices); (3) They are officially established by the senior management at the Ministry of Health: and (4) They report to an existing advisory body to the Ministry of Health. In Ghana and Burkina Faso, the co-ordination is led by the National Malaria Control Program and WHO. In the two other countries, the co-ordination is led by local, parastatal research institutions.

The process for the malaria vaccine decision-making framework benefited from a commitment to create a guide, building upon existing WHO guidelines, that was generic to any malaria vaccine to come, and a focus on all vaccines under development instead of only one potential product (WHO 2005). Only after the guide was validated was there discussion of its application to specific products. The guide adapted the WHO guidelines for introducing new vaccines. This suggests that the requirements for malaria vaccines are not completely unique, but that the general requirements need specificity to the context of malaria vaccines. Some aspects need emphasis while others will not. For example, there was relatively little data from developing countries on the epidemiology and burdens of disease that could be prevented by Hib, rotavirus and pneumococcal conjugate vaccines, while malaria is relatively well studied. Therefore, the question was not if malaria was a problem but how would a vaccine perform in different epidemiological settings and what would be its additional benefit in the context of other interventions. This contrasts to Hib and pneumococcal diseases where there are no widely available, preventive measures other than vaccines.

The iterative nature of such a process creates an important forum for those who may not normally collaborate, for reasons that may include different specialties in public health and splits between researchers and implementers, academia and government (DeRoeck 2004; Amin *et al*. 2007). By creating a forum with a shared technical task, each group is able to apply its unique skills to the shared technical challenge, which also strengthens and prepares messages informing policy. A shared process was particularly important for bridging the long-established disciplines of malaria and immunization, similar to the challenge identified previously for HPV vaccines. Such a challenge may not be faced by other vaccines or those working only in the malaria community.

One valuable outcome of research to plan early for decision-making is the voice that countries can have. The process provides a structured means for countries to provide their input to those developing interventions. By identifying critical processes and data and by assigning responsibility to the international level, countries are signaling their expectations of developers and international organizations. The process identifies areas, such as the product profile, in which countries would like to explicitly inform the work of developers, and it helps countries understand when such contributions are possible (i.e. years before an intervention is available.) Identifying the elements for which countries feel they should be held accountable informs and strengthens national planning capacity and management processes, and provides a means for local researchers to collaborate and seek complementarities in their research.

Researchers will need to consider sought-after data in light of its feasibility. Some types of data, for example re-stratifying age-specific malaria mortality data which is typically aggregated and reported for all children under 5, may not be difficult. Others may come from modelling or extrapolation from other countries. Prioritizing the data as critical vs helpful was intended to help prioritize data collection efforts.

The process of developing a guide to describe the malaria vaccine decision-making framework also illustrated some of the challenges inherent in planning for decisions on an intervention that is still under development. The most significant challenges relate to the time constraints of national staff in light of current programme priorities, to risks of interventions failing in late development and to over-promising by developers, each of which are elaborated below.

LMIC health system managers are typically pulled in multiple directions, responding to the immense challenges faced every day. It is essential to find an appropriate balance, not asking for too much time focused on interventions not yet available, while seeking concrete input to ensure that future interventions will meet programme needs. Because of the many time constraints, concrete planning activities will generally require a local organization or part of the government to fill a secretariat and co-ordination role. This was described in the previous section.

Planning in advance also means helping programme staff and collaborators at country level understand that a new intervention, particularly a novel one, could fail at any time. Time spent on a new intervention is invested 'at-risk'. For example, a safety concern might arise during late clinical trials or efficacy may not be seen in certain populations, stopping development of the intervention such that time invested might be considered partially wasted.

Development timelines, and to a lesser extent final intervention characteristics, are notoriously difficult to predict. Countries need to understand that timelines are rarely shortened, and that they are more typically lengthened by years.

The challenges considered in the previous paragraphs can be mitigated by transparency, education and care in not letting decision planning activities get ahead of accumulated scientific evidence. Taken together, these three challenges necessitate a cautious, carefully planned approach when discussing future health interventions with national decision-makers.

Another challenge is to properly contextualize discussions on a new health intervention relative to existing health interventions targeting the same disease, to other interventions of the same modality (e.g. drugs, vaccines) and to priorities within the wider health system (WHO 2005; Stop TB Partnership and WHO 2007). A novel intervention like a malaria vaccine will enter a complex arena of existing malaria control measures, and an environment of multiple new vaccines being considered by countries. In some cases, interventions may replace existing ones (e.g. an improved medication), although perhaps it is more cautious to assume a new intervention will co-exist for at least some time with others. For this reason, those supporting early planning should be well-versed in other interventions, not be seen to be pushing a single product onto countries to the exclusion of other approaches.

The basic processes and lessons described above are relevant for novel health interventions under development. Second-generation or follow-on interventions may not require the same level of research over multiple years. Precedents and advisory bodies may already exist (Gessner *et al*. 2010). Data may already have been collected on many essential aspects. However, a structured approach to confirm the processes and data needed, and the relevant timelines, remains a valuable step during the development period of an intervention.

Such exercises do not guarantee that policy decisions will be based only on evidence and all countries will go through a predictable process. Political decisions in some situations will triumph other factors (Kingdom 1995). It is recognized that decisions are influenced by many political, societal and institutional factors. Experts consulted in the development of the guide highlighted that global level advocacy must begin early and that local implementation of strategies for advocacy, communications, and outreach to private-sector and pharmaceutical companies should start well before a decision would be taken.

A structured approach provides clear insights into what data countries will need for a decision (DeRoeck 2004). It informs the work of those developing an intervention, allowing the clinical activities to respond to questions for public policy as well as regulatory requirements. It is a capacity building and health systems strengthening exercise creating a pool of expertise to inform government decisions after the intervention is available, while allowing greater clarity on roles and responsibilities for different stakeholders and parts of government.

The outcome of the decision planning process may lead to the decision to adopt, or not, the intervention. Countries with timely 'no' decisions help international funding bodies, procurement agencies and manufacturers as they do their own long-term planning. Countries that are undecided can be the most challenging for these bodies.

Conclusion

This paper argues for the importance of early planning for country decisions on new health interventions. Malaria vaccines provide one example of an approach and multiple lessons, identified above, should be considered for other new interventions. While there is always a risk that an intervention under development fails, a small amount of time invested in planning for its possible use has the promise to pay off immensely down the road. This paper seeks to determine which planning steps are appropriate and reasonable to take prior to intervention availability. It argues that such an approach holds promise for better public health decisions and greater public health impact through accelerated and informed decisions on the use of a new intervention once available.

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Conflict of interest

AB and ABN declare that they have no conflicts of interest regarding this work.

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