

A tool for informing policy decisions on malaria vaccines

The Malaria Vaccine Decision-Making Framework

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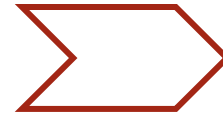
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WHO vaccine introduction guidelines

- Key policy issues

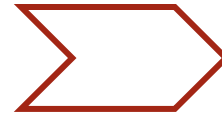
- Public health priority
- Disease burden
- Efficacy, quality, and safety
- Other interventions (other vaccines)
- Economic and financial issues



**Immunization policy
decision**

- Key programmatic issues

- Vaccine presentation
- Supply availability
- Programmatic strength



Technical decision

A framework for deciding on malaria vaccines

- Series of consultations with malaria, immunization, finance, and regulatory experts from over 30 African countries
- An outline of the types of data on which policymakers will base their decision and the processes required to allow the decision to be made
- A definition of:
 - The time for collecting the data and for putting in place the processes relative to the vaccine development and licensure
 - Before the vaccine is licensed (launch of Phase 3 trial; availability/publication of data)
 - When the vaccine is licensed and a decision taken
 - After the vaccine is introduced
 - The level of responsibility involved: country or global level

Regional Malaria Vaccine Decision-Making Framework: Data needs

Malaria Disease Burden	Other Malaria Interventions	Malaria Vaccine Impact	Economic & Financial Issues	Efficacy, Quality, & Safety	Programmatic Considerations	Sociocultural Environment
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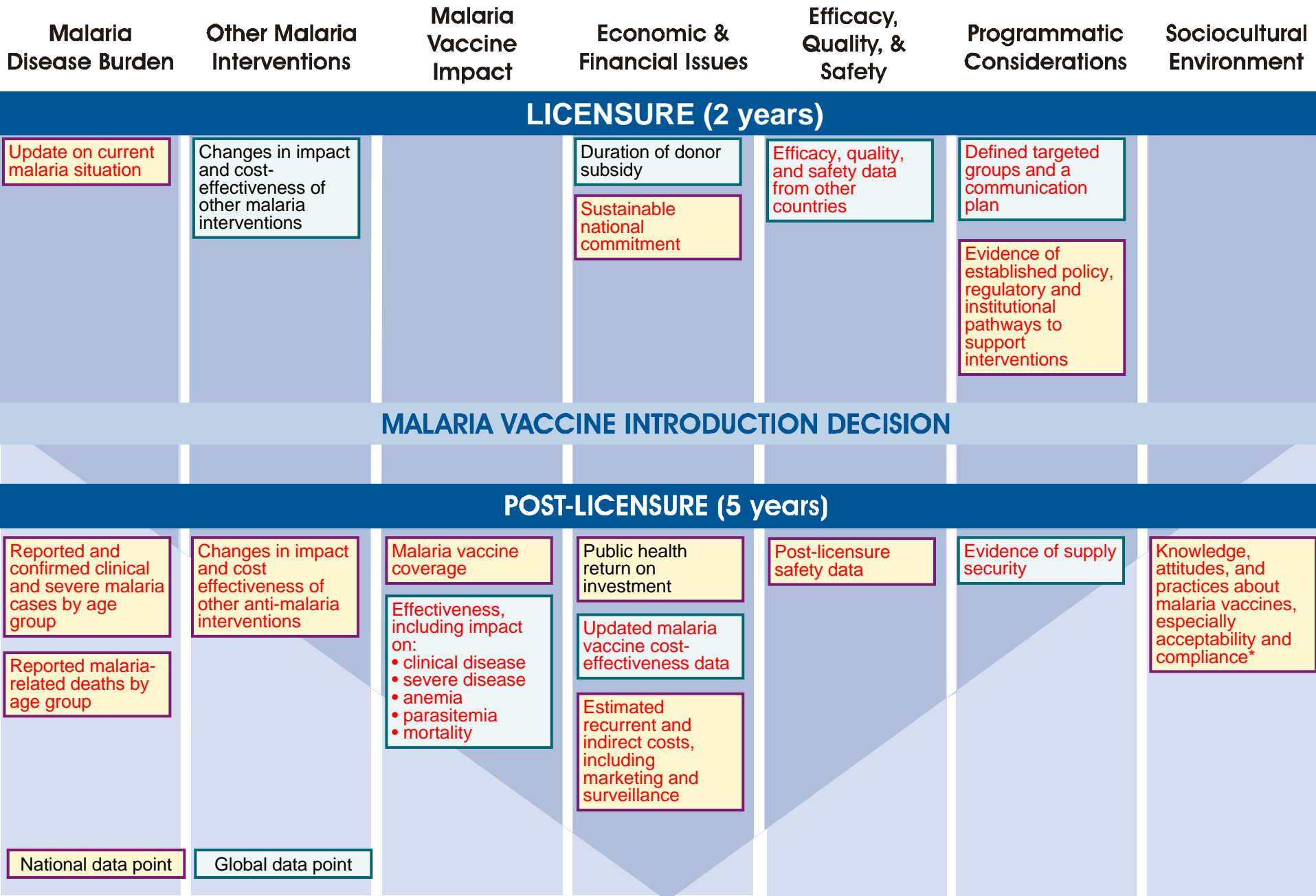
PRE-LICENSURE (5 years)

<p>Reported and confirmed clinical and severe malaria cases by age group</p> <p>Reported malaria-related deaths by age group</p> <p>Malaria epidemiological profile at the district level</p> <p>Malaria cases in pregnant women</p> <p>Malaria cases in HIV+ individuals</p> <p>Economic burden of malaria</p>	<p>Impact of existing malaria interventions</p> <p>Country-specific impact of existing malaria interventions</p> <p>Coverage of current malaria interventions</p> <p>Cost-effectiveness estimates of existing malaria interventions</p>	<p>Projected impact on mortality and morbidity in different age groups</p>	<p>Credible public-sector price estimate</p> <p>Preliminary cost-effectiveness estimates of malaria vaccine</p> <p>Public health return on investment in terms of DALYs, impact on health budget, impact on GDP</p>	<p>Safety</p> <p>Adverse events</p> <p>Interaction with other vaccines</p>	<p>Anticipated vaccine characteristics and presentation</p> <p>Evidence of established policy, regulatory, and institutional pathways to support intervention</p>	<p>Knowledge, attitudes, and practices of communities towards vaccines and malaria interventions</p> <p>Community expectations of malaria vaccines in clinical trial areas</p>
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AVAILABLE DATA - PHASE III

<p>National data point</p>	<p>Global data point</p>	<p>Absolute impact</p> <p>Marginal impact with other malaria interventions</p> <p>Impact on epidemiology and morbidity by age group</p>	<p>Vaccine price for public sector</p> <p>Donor subsidy of malaria vaccine and duration of subsidy</p> <p>National affordability</p>	<p>Efficacy, including impact on:</p> <ul style="list-style-type: none"> clinical disease severe disease anemia parasitemia <p>Efficacy in HIV+ populations</p> <p>Duration of efficacy of the vaccine*</p>	<p>Demand forecast</p> <p>Supply availability</p> <p>HS capacity to accommodate a malaria vaccine</p> <p>Info. on product characteristics and storage</p>	
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Regional Malaria Vaccine Decision-Making Framework: Data needs



Regional Malaria Vaccine Decision-Making Framework: Process needs

Global Level Processes

National Level Processes

PRE-LICENSURE (5 years)

Integrate country requirements into product development plans
(5 years before)

Conduct global advocacy to leverage funding

Establishment of Technical Working Group

Assess and strengthen regulatory, ethics and data management
processes in-country

Integrate the malaria vaccine in countries' multiyear strategic plans
(4-5 years before)

Signal vaccine demand (1-3 years before)

Integrate use of malaria vaccine in national health policies

Conduct advocacy to solicit government support

AVAILABLE DATA - PHASE III

Share information on vaccine research

Conduct global advocacy to leverage funding

Engage local private-sector partners and pharmaceutical companies

Develop communication plan on the malaria vaccine (1 year before)

LICENSURE (2 years)

WHO issues policy recommending use of vaccine

Donors provide funding to support vaccine

WHO publishes vaccine management and introduction guidelines
(licensure)

National regulatory authority reviews vaccine in consultation with technical
working group (within 1 year of licensure)

National expert group/technical working group issues recommendation
regarding vaccine introduction

Advocacy with national decision makers and major stakeholders

MOH makes a decision about integration of vaccine into EPI

Develop plan for procurement and resource mobilization for financial
sustainability

Regional Malaria Vaccine Decision-Making Framework: Process needs

Global Level Processes

National Level Processes

MALARIA VACCINE INTRODUCTION DECISION

WHO pre-qualification (within 1 year of licensure)

International agencies plan for procurement (within 1 year of licensure)

Incorporate malaria vaccine into national budgeting processes

Elaborate the vaccine introduction plan and programmatic guidelines (logistics, training, pharmacovigilance)

Update the communication plan for implementation and engage media (one year after introduction)

Examine sustainability of existing funding and how to encourage in-country financing

POST-LICENSURE (5 years)

Monitoring of vaccine performance, including evaluation of vaccine impact, safety, and pharmacovigilance

Monitor vaccine performance and safety

Monitor implementation of the vaccine and evaluate impact on health system*

Partnership for acting upon the framework

- Strong partnerships across expertise areas and organizations
 - Formalized collaboration between immunization and malaria control programmes
 - Joint planning
 - Collaboration with malaria vaccine researchers
 - Share critical information needed prior to licensure
- Establishment of a Technical Working Group or other coordination mechanism
 - Works systematically towards a planned decision on malaria vaccine
 - In place in Ghana, Burkina Faso, and Tanzania

Conclusions

- Important to reinforce and maintain use and accessibility to current malaria control interventions
- Critical to prepare the evidence on whether to introduce or not a new tool such as a malaria vaccine
- Framework facilitates a comprehensive, systematic, and coordinated approach to decision-making, within a reasonable timeframe, for a timely policy decision



Thank you

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MALARIA VACCINE INITIATIVE