Planning the introduction of a malaria vaccine: The Regional Decision-Making Framework

MALARIA VACCINE DECISION-MAKING FRAMEWORK

USAID
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mvi PATH
MALARIA VACCINE INITIATIVE

Why should we plan ahead ?

We know from experience that:

- **Licensing a vaccine does not ensure that it is immediately delivered to the most in need:**
  - **Most recent life-saving vaccines (Hep B and Hib) have been introduced to health systems in Africa several years after licensure or recommendation by WHO**

- **Effective malaria control interventions do exist but are yet to be widely accessible**:
  - **Overall in Africa ITNs coverage in U5 less than 20%**
  - **Long process from announcing a new malaria drug policy on ACTs to completing early implementation**

Malaria vaccine decision-making framework

To avoid the usual long delay between the availability of a new intervention and the decision on its use and then its introduction:

What will guide the decision to introduce or not a new tool in the arsenal of malaria control measures ?

Process started in 2005:

- Coordinated by PATH MVI and WHO AFRO
- Sponsored by USAID and the Bill & Melinda Gates Foundation
- Guided by a steering committee made up of malaria and immunization experts

DMF Process -1

7 briefing papers:

- *Malaria control policies;*
- Moving *from development to policy to implementation* of new products in countries where malaria is endemic;
- *Status of malaria vaccines*;
- *Landscape of other vaccines and malaria control options* on the horizon over the next decade;
- *Analysis of the demand for a malaria vaccine*:
- The *return on investment for malaria vaccines*: preliminary estimates of public health impact in Africa
- *Vaccine introduction guidelines from WHO*

DMF Process -2

Regional meeting with 13 countries in January 2006:

- ✓ Data: as pieces of information needed to make a decision about a future malaria vaccine
- ✓ Processes: as steps that should take place in order to facilitate national decision-making about malaria vaccines
- ✓ Relative to the estimated time of availability of a malaria vaccine
- ✓ Both national and global levels

Consultations in 6 countries Country-specific DMF: (Gabon, Ghana, Kenya, Mali, Mozambique and Tanzania) and plan of actions

Synthesis into a draft regional framework

Draft Regional Malaria Vaccine Decision-Making Framework

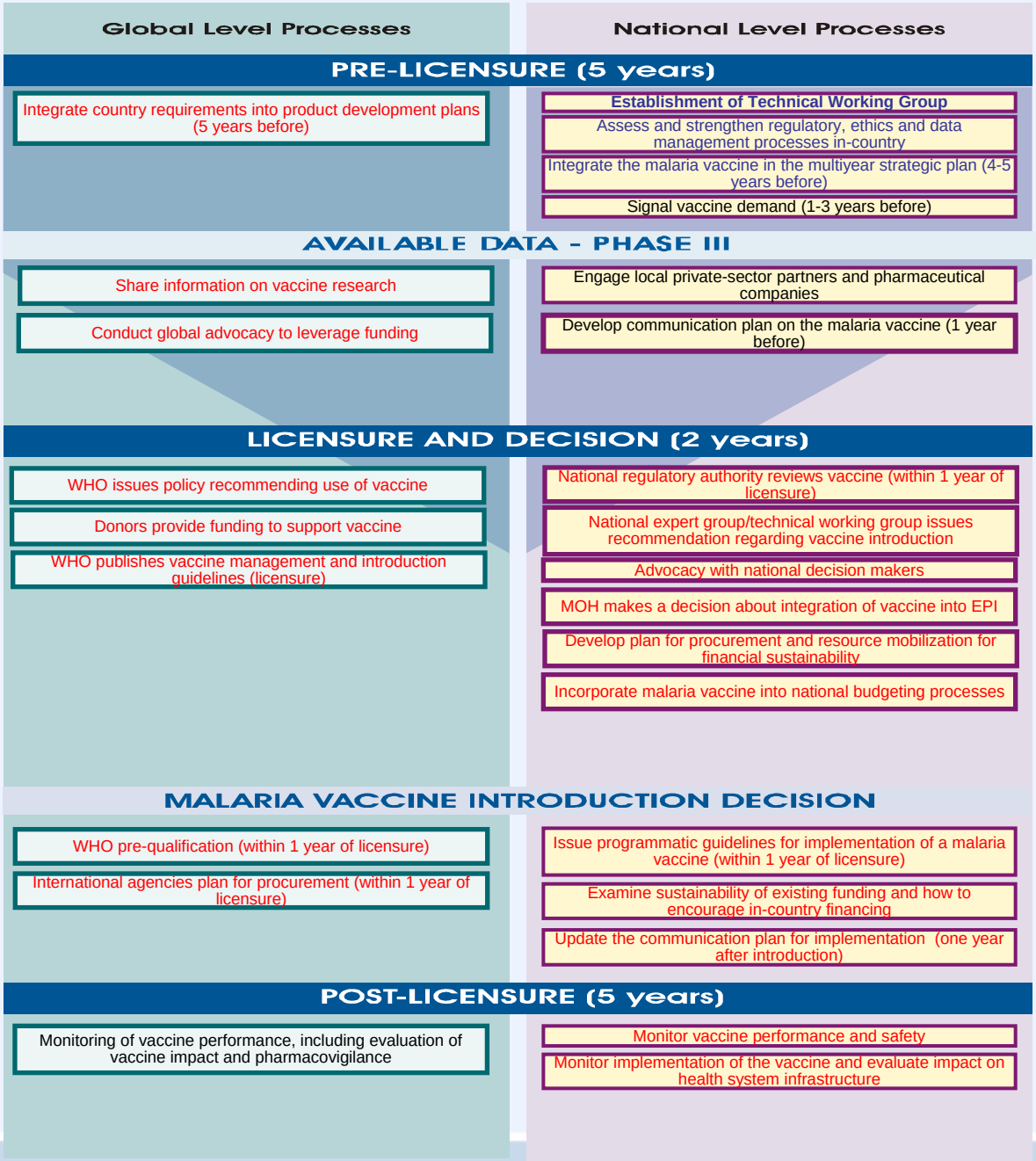
- The first part of framework features **data**, both global and regional, that stakeholders will require to make a decision about the appropriate use of a malaria vaccine within national health systems.

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

Required data | National data point | Global data point

Regional Malaria Vaccine Decision-Making Framework

- The second framework features **processes**, both global and regional, that should take place in order to facilitate decision-making about malaria vaccines.


Global Level Processes
National Level Processes
PRE-LICENSURE (5 years)
Integrate country requirements into product development plans (5 years before)
Establishment of Technical Working Group
Assess and strengthen regulatory, ethics and data management processes in-country
Integrate the malaria vaccine in the multiyear strategic plan (4-5 years before)
Signal vaccine demand (1-3 years before)
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 AND DECISION (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 (within 1 year of licensure)
National expert group/technical working group issues recommendation regarding vaccine introduction
Advocacy with national decision makers
MOH makes a decision about integration of vaccine into EPI
Develop plan for procurement and resource mobilization for financial sustainability
Incorporate malaria vaccine into national budgeting processes
MALARIA VACCINE INTRODUCTION DECISION
WHO pre-qualification (within 1 year of licensure)
International agencies plan for procurement (within 1 year of licensure)
Issue programmatic guidelines for implementation of a malaria vaccine (within 1 year of licensure)
Examine sustainability of existing funding and how to encourage in-country financing
Update the communication plan for implementation (one year after introduction)
POST-LICENSURE (5 years)
Monitoring of vaccine performance, including evaluation of vaccine impact and pharmacovigilance
Monitor vaccine performance and safety
Monitor implementation of the vaccine and evaluate impact on health system infrastructure

Activity/Action	Lead Organizations	Partner Organizations
Incorporate new malaria vaccine into multi-year strategic plan	EPI/NMCP	WHO/UNICEF
Strengthen and reinvigorate ethical review committees and national regulatory bodies	Ministries of Health	Ministry of Research
Establish multisectoral expert/ technical working group	EPI/NMCP/MOH	In-country researchers, WHO/UNICEF, donors
Conduct advocacy with national stakeholders, including media groups	EPI/NMCP/Health Promotion Unit within MOH	Health professionals, media, researchers
Develop communication plans and strategies	EPI/NMCP/Health Promotion Unit within MOH	Health professionals, researchers

Activity/Action	Lead Organizations	Partner Organizations
Strengthen in-country data collection capacity and collect data about malaria disease burden	EPI/NMCP/MOH	In-country research institutions, MOH research units, WHO, Ministry of Research
Conduct economic analyses to determine cost-effectiveness and cost benefit estimates of a malaria vaccine, socio-economic impact of malaria, current EPI/NMCP spending, and cost effectiveness of other malaria interventions	MOH, MVI	WHO, UNICEF, donors, Ministry of Finance
Conduct malaria vaccine need estimates	EPI/PNLP	In-country researchers, MOH
Inform product development plan with outcomes of the DMF meeting	MVI, WHO	
Reinforce communication between researchers and policy decision makers	NMCP/EPI/MOH	

Moving Forward- 1

- Continue consultations with countries:
  - Ethiopia (April 07)
  - Burkina Faso (February 08)
  - Malawi
- Support countries start working on their national DMF and actions plans
  - Technical Working groups in Tanzania, Kenya and Mozambique
- Validation of the draft Regional DMF within the sub-regions:
  - Validation in Central Africa (February 08)

Moving forward-2

GAVI developing investment strategy building upon WHO prioritization

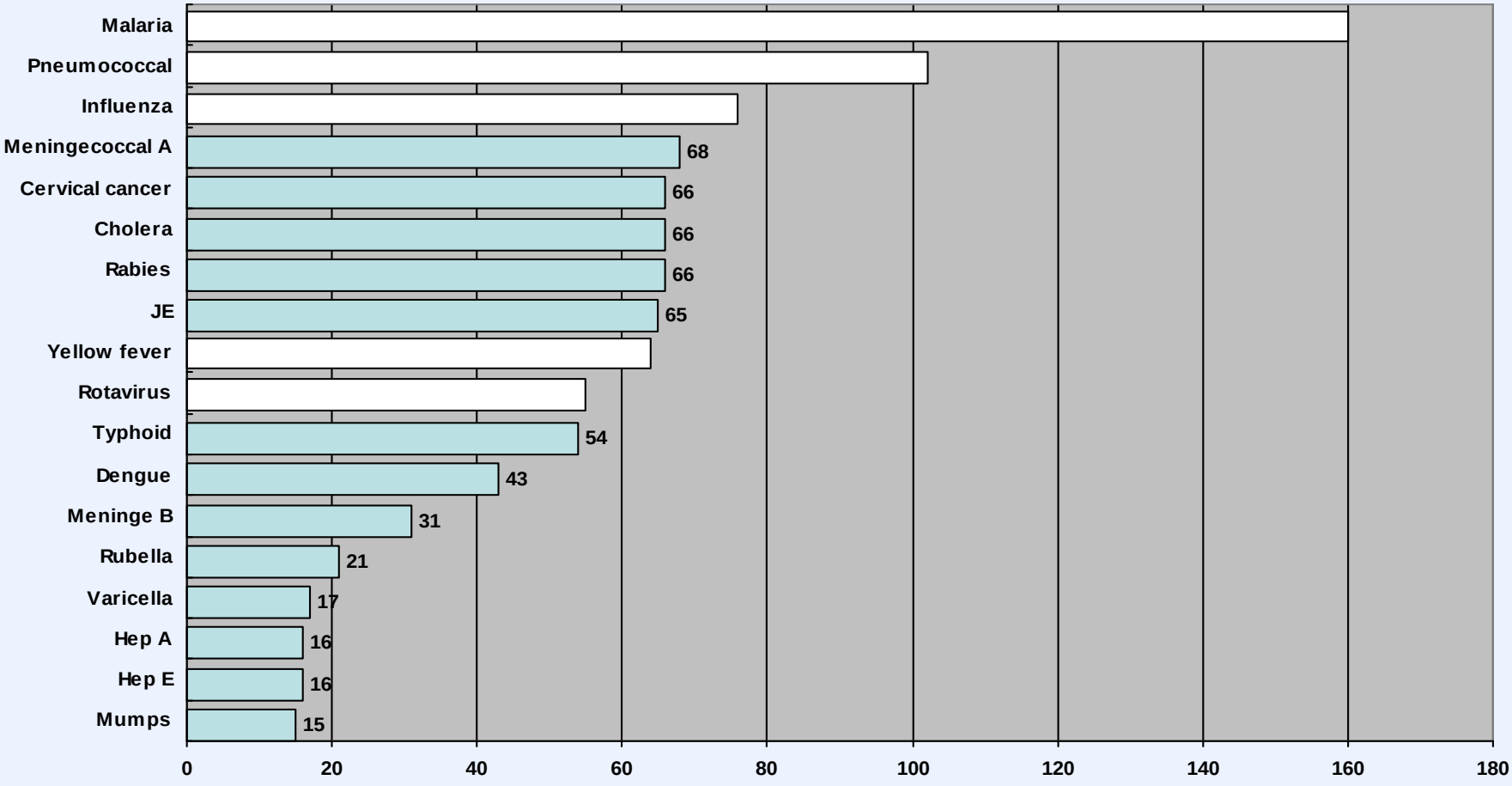
May, 2007 GAVI Board – Considered potential scenarios of over US$3.2B for malaria vaccines over 15 years

Formal decision anticipated in 2008 of role of malaria vaccines in future financing scenarios

Discussions commencing on coordination between GAVI and GFATM

WHO vaccine prioritization – preliminary results

(WHO SAGE, Nov 2007)



Weighted priority score based upon expert opinion

Moving forward-3

Estimates of impact, cost, & cost-effectiveness

- Malaria vaccines, even considering a conservative scenario of vaccines with partial efficacy, are anticipated to be cost-effective and generate significant public health benefits.

Estimates of impact, cost, & cost-effectiveness

Swiss Tropical Institute modelling:

- Base case of a vaccine with 52% efficacy against infection, similar to what has been seen with RTS,S the most advanced malaria vaccine, based upon data from Tanzania
- An estimated 942 lives per 100,000 population could be saved over a 20 year period.*
- Therefore in Malawi it could prevent approximately 116,000 deaths over 20 years (9% of infant deaths)

***Extrapolated from:** TEDIOSI, F. G. HUTTON, N. MAIRE, T. SMITH, A. ROSS, AND M. TANNER. PREDICTING THE COST-EFFECTIVENESS OF INTRODUCING A PRE-ERYTHROCYTIC MALARIA VACCINE INTO THE EXPANDED PROGRAM ON IMMUNIZATION IN TANZANIA. *Am. J. Trop. Med. Hyg.,* 75(Suppl 2), 2006, pp. 131–143

Estimates of impact, cost & cost-effectiveness

Swiss Tropical Institute modelling:

- The cost per fully-immunized child of using a malaria vaccine ranges from $4.73 to $34.43*, for vaccine price ranges of $1 to $10 per dose
  - For Malawi, could be $2.3 million up to $16.9 million per year at 90% coverage
- Cost-effectiveness for vaccine $1-$10/dose**
  - $450-$3,500 per death averted
  - $12 to $96/DALY averted

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Review of the global data and processes

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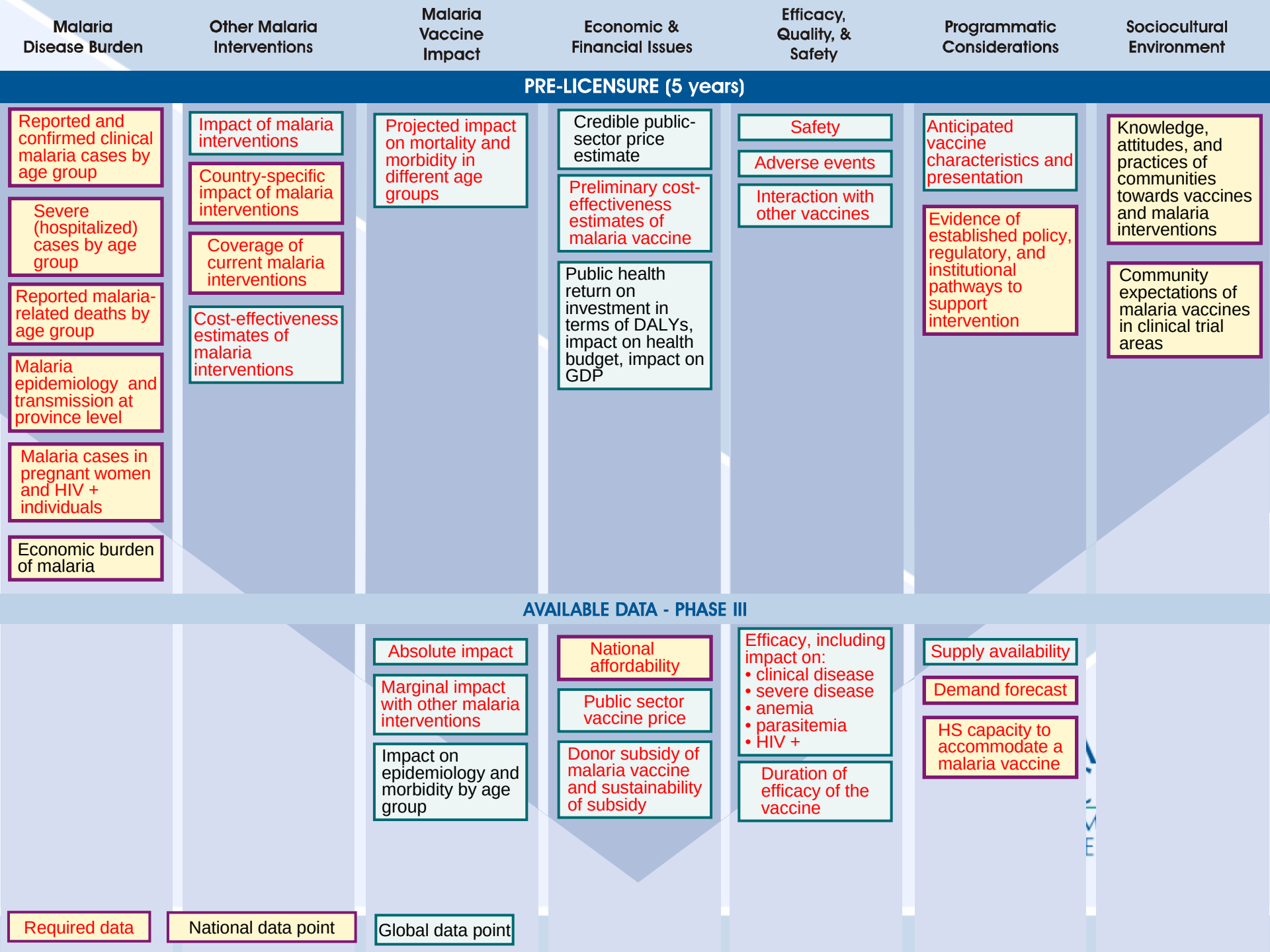
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Coverage of current malaria interventions
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Projected impact on mortality and morbidity in different age groups
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• parasitemia
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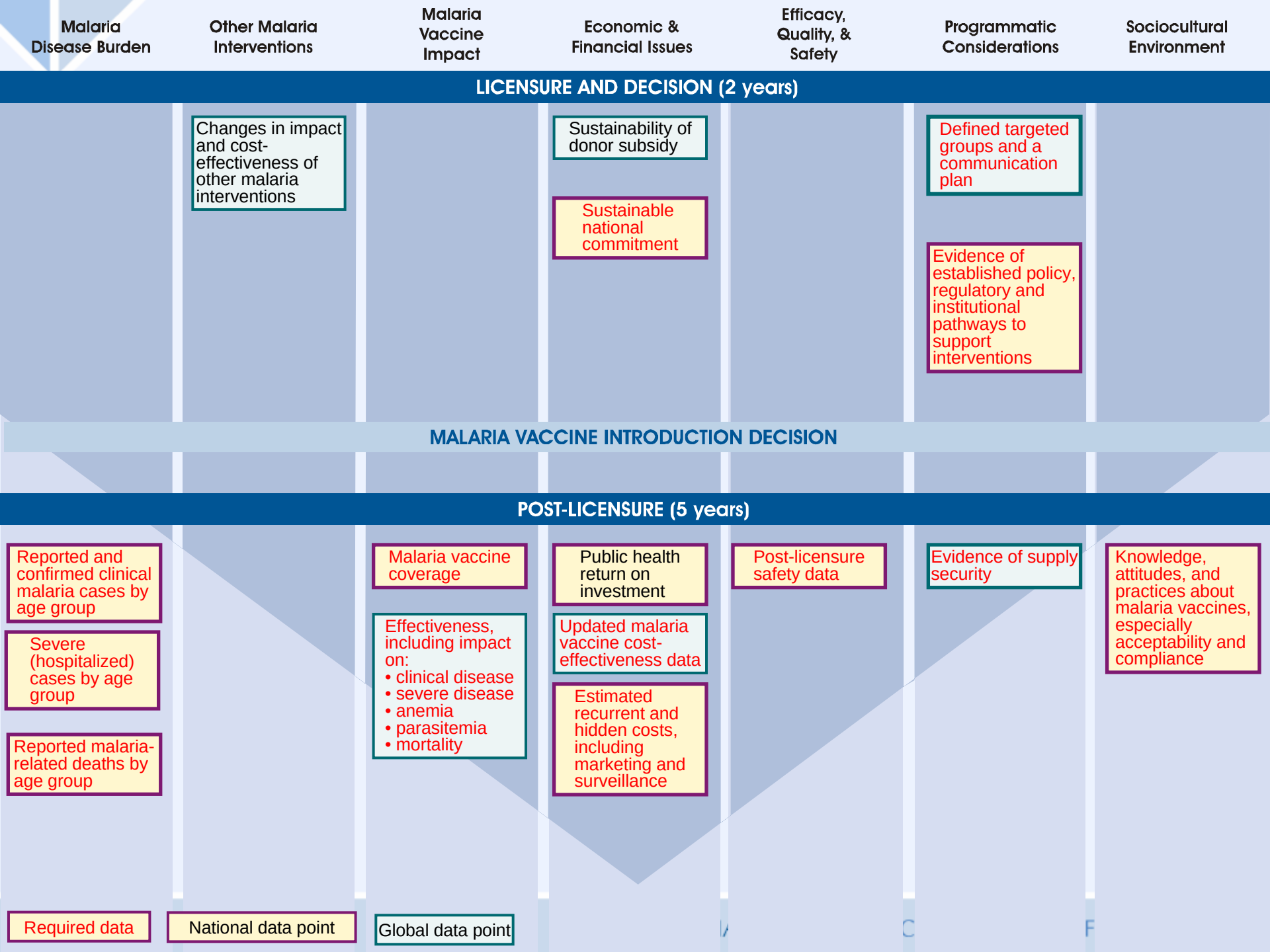
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• mortality
Public health return on investment
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WHO publishes vaccine management and introduction guidelines (licensure)	Advocacy with national decision makers
	MOH makes a decision about integration of vaccine into EPI
	Strengthen human resources, infrastructure to deliver vaccines as well as national surveillance systems
	Incorporate malaria vaccine into national budgeting processes
	Develop plan for procurement and resource mobilization for financial sustainability

Global Level Processes	National Level Processes
MALARIA VACCINE INTRODUCTION DECISION	
Reinforce regional and national capacities, such as the establishment of a regional quality control laboratory	Issue programmatic guidelines for implementation of a malaria vaccine (within 1 year of licensure)
WHO pre-qualification (within 1 year of licensure)	Examine sustainability of existing funding and how to encourage in-country financing
International agencies plan for procurement (within 1 year of licensure)	Update the communication plan for implementation (one year after introduction)
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Monitoring of vaccine performance, including evaluation of vaccine impact and pharmacovigilance	Monitor vaccine performance and safety
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