Vaccine Investment Strategy

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GAVI Alliance Board meeting
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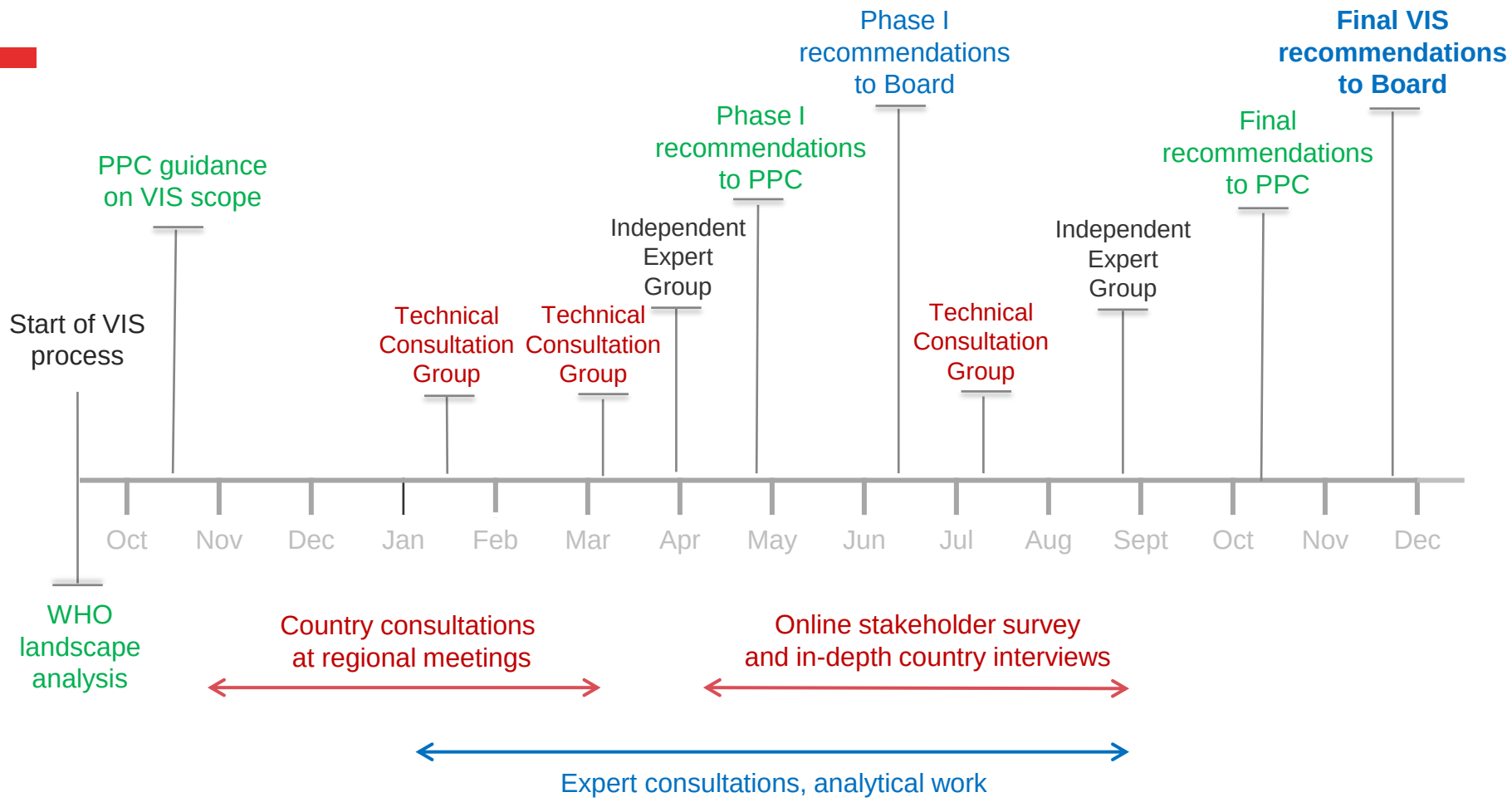
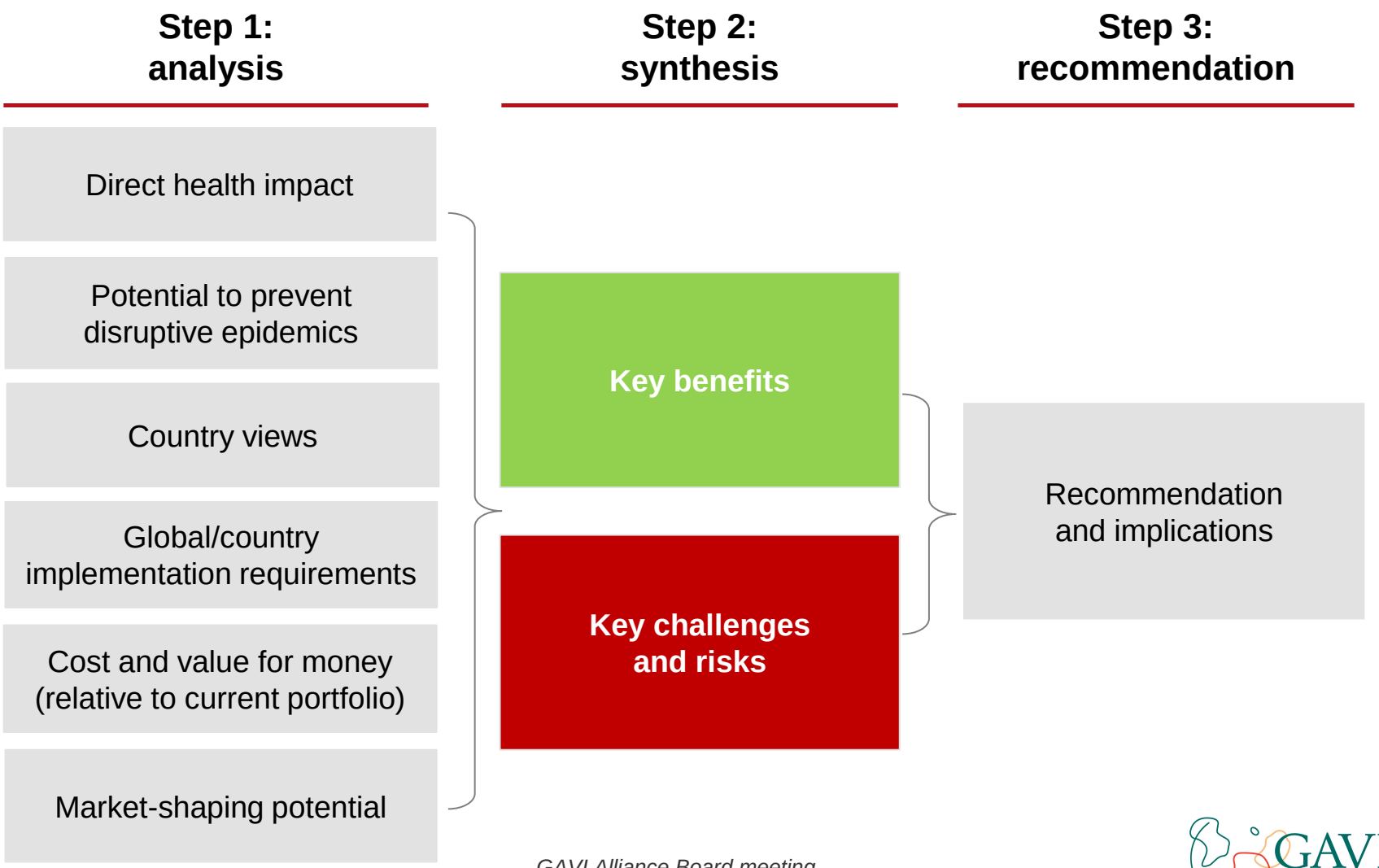
GAVI ALLIANCE

Vaccine Investment Strategy: evidence-based process to identify new priority vaccines

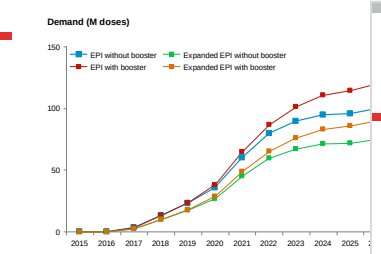


Assessment framework for shortlisted vaccine investments



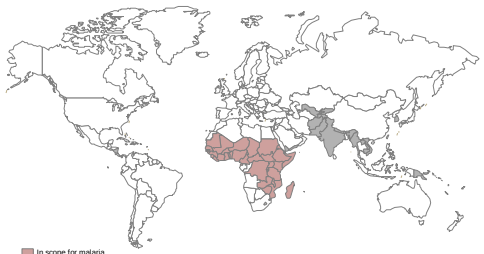
Detailed vaccine assessments

Cumulative demand estimated to be 760M – 1.2B doses through 2030



Note: includes introductions in African countries only (both vaccine licensure and a WHO recommendatic
likely to be restricted to Africa; vaccine indication for use in Asia is not expected in the near term); Includ
from countries that graduate from GAVI support during 2015-2030 (following GAVI supported introductior

37 countries in scope for malaria (Africa)



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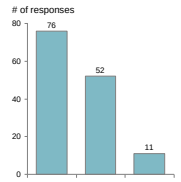
Country openness to new schedule and awareness that vaccine cannot replace other interventions

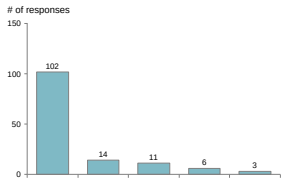
Respondents positive on ability to add new visits for 5-17M age group

Question: Please indicate the statement(s) that most closely apply in your country



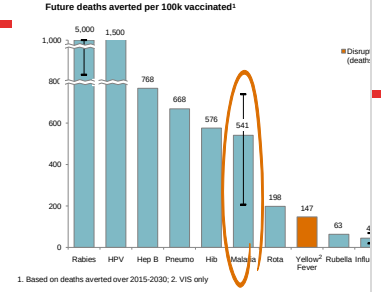
Respondents emphasized that vaccine could not displace other malaria interventions

Question: Please indicate the statement(s) that most closely apply in your country



Source: 2013 GAVI Phase II country consultation survey
Note: question only posed to 136 respondents ranking malaria as first or second priority for introduction

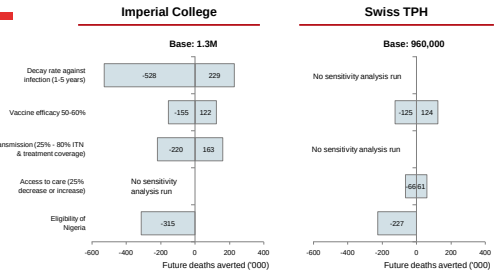
Malaria vaccine may have impact comparable to Hib



1. Based on deaths averted over 2015-2030; 2. VIS only

Note: Model outputs shown for Expanded EPI with booster scenario, for illustrative purposes; error bars
lowest value generated by malaria sensitivity analyses and are driven by decay rate of protection; point
midpoint of Imperial and Swiss TPH models

Vaccine duration of protection is biggest sensitivity of high impact



Note: For illustrative purposes base case is shown as expanded EPI with booster scenario (midpoint between Imperial College and Swiss TPH model outputs)

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Implementation would require managing possible global supply shortage and communication needs

	Area of focus	Unique implementation requirements	Unique costs
Global level	Policies and processes	▪ WHO position TBD; few required GAVI policy changes currently foreseen; coordination with the GFATM required	▪ N/A
Global level	Supply	▪ Account for supply constraints through 2020 (impact likely small)	▪ No direct costs
Country level	Health workforce	▪ HR/training requirements for RTS,S similar to those for vaccines already in health system	▪ N/A
Country level	Social mobilisation, education, communication	▪ Manage risk to program credibility if efficacy lower than other vaccines in use (eg, rota) ▪ Additional training/social mobilisation/programmatic investments for initiating new routine visits for immunisation (expanded EPI scenario only)	▪ Cost accounted for in operational costs¹
Country level	Supply chain infrastructure and logistics	▪ Requirements for RTS,S similar to those for vaccines already in health system	▪ N/A
Country level	Surveillance	▪ No unique surveillance requirements	▪ N/A
Country level	Planning, coordination, integration	▪ Expanded EPI scenario would require infrastructure to support at least one additional touch point ▪ Manage potential for older (not eligible) age groups to present for vaccination (implications for forecasting in intro year) ▪ Coordinate with malaria control program to ensure vaccine does not undermine the use of other malaria interventions	▪ Focused organizational effort

1. Expected to be covered by GAVI Vaccine Introduction Grant, MoH, partners

Unique but manageable | May not be manageable in short term / within current GAVI model

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Yellow fever: fund additional campaigns

ASSESSMENT

- Continued risk of outbreaks in Africa
- WHO: additional mass campaigns to cover remaining unvaccinated populations in high-risk countries
  - Future populations protected through routine YF use

RECOMMENDATION

- Fund additional campaigns from 2015 (~USD140M)
- Secretariat to review planning / funding process, including risk assessment mechanism, in coordination with WHO

Cholera: make catalytic investment in global stockpile

ASSESSMENT

- Disruptive epidemics, inequitable burden
- Low global demand and severe supply shortage relative to estimated need

RECOMMENDATION

- Enlarge stockpile to fight outbreaks, gain experience with vaccine use, shape the market
- Insufficient evidence for broad rollout through recurring, preventive campaigns in endemic settings: re-evaluate in next VIS

Rabies and maternal influenza: re-evaluate in next VIS

RABIES

- Operational feasibility and effectiveness of GAVI support for rabies vaccines unclear
- Re-evaluate in next VIS, and
- Fund observational study to fill critical knowledge gaps and catalyse progress
  - Mitigate risk of preserving status quo

INFLUENZA

- Limited evidence base for impact beyond pregnant woman
- Data forthcoming on effects on foetus and infants
- Re-evaluate in next VIS

Malaria: re-assess investment case in 2015/16

ASSESSMENT

- A leading cause of death in young children, strong demand
- Bednets and spraying can prevent up to 55% of deaths
  - Vaccine targets remaining burden; complements other malaria control interventions
- Analysis: incremental impact in Africa ≈ Hib/rotavirus
- Expert Committee: supportive based on preliminary data

RECOMMENDATION:

- Note reasonable case for support based on current analysis; await final trial data
- Back to PPC/Board for decision in 2015/16

Programme funding implications of recommendations

- 2014-2020: ~$200M for YF and cholera
  - 2% of vaccine spending
- 2016-2020: ~$300M for malaria; US$ 230M/year from 2021
  - Pending future Board approval

Projected programme costs in US$ millions (vaccine + introduction grant + operational cost)

Budget period:	**2014-2015**	**2016-2020**	**2021-2030**
Cholera stockpile	26	89	-
Yellow fever campaigns	14	95	31
Subtotal	***40***	***184***	***31***
Malaria	-	287	2,274
Total VIS incl. malaria	***40***	***471***	***2,305***
Current GAVI portfolio*	***3,014***	***6,895***	***~10,000***

*Based on demand forecast version 8

The PPC and, where appropriate, the AFC and the EC recommended to the GAVI Alliance Board that it:

- Decide to support new yellow fever vaccine campaigns and request the Secretariat to develop a process for the funding of individual campaigns on the basis of robust risk assessments.
- Approve a contribution to the global cholera stockpile for use in epidemic and endemic settings and to that end:
  - Endorse a net increase in programme budgets for the global cholera stockpile by US$ 114.5 million for the period 2014-2018. (This endorsement would constitute acknowledgement of such budget amounts as an indication of potential future expenditures but would not constitute a funding approval, decision, obligation or commitment of the GAVI Alliance or its contributors.);
  - Approve a net increase of near-term programme liabilities for the global cholera stockpile (a sub-component of endorsed programme budgets) by US$ 8.5 million for 2014;
  - Note the opportunity for the GAVI Alliance to generate impact data based on the use of the cholera stockpile in emergency settings.

The PPC and, where appropriate, the AFC and the EC recommended to the GAVI Alliance Board that it:

- Approve an assessment of the feasibility of GAVI support for rabies vaccines (to be evaluated in the next Vaccine Investment Strategy process). A funding request for the outsourced assessment will be included as part of the Business Plan in 2015.
- Note that based on the current assessment there is a reasonable case for GAVI support for a malaria vaccine, and that the Board will consider opening a window if and when the vaccine is licensed, recommended for use by the joint meeting of the WHO Strategic Advisory Group of Experts and the Malaria Programme Advisory Committee (expected in 2015) and WHO pre-qualified, taking into account updated projections of impact, cost and country demand as reviewed by the PPC.

The PPC and, where appropriate, the AFC and the EC recommended to the GAVI Alliance Board that it:

- Note the potential public health impact of vaccinating pregnant women against seasonal influenza and the need to assess the emerging evidence of impact of vaccination on neonates, but decides not to open a funding window for influenza vaccines at this time.
- Approve an amount up to US$ 1.5 million to be added to the 2014 Business Plan to implement the Board's VIS decisions through Secretariat and partner activities as described in section 5.2 of Doc 07.

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