Gavi’s Vaccine Investment Strategy

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Vaccine Investment Strategy (VIS)

Evidence-based approach to identifying potential new vaccine priorities for Gavi support

- Evidence review, analyses, stakeholder consultations, independent expert advice

2008 VIS:
- HPV, rubella, JE, typhoid

2013 VIS:
- Expanded support for yellow fever campaigns
- Time-limited contribution to global cholera stockpile
- Learning agenda: rabies and cholera studies to fill evidence gaps
- Malaria vaccines to be re-assessed in 2015/16
VIS process (phase 1)

1. WHO ‘landscape analysis’ of vaccines in scope: anticipated licensure within next 5 years
2. Development of prioritisation criteria through Gavi stakeholder consultations
3. Assessment of vaccines against criteria
4. Development vaccine shortlist for in-depth analysis

2013 vaccines considered:

<table>
<thead>
<tr>
<th>Existing vaccines not supported by GAVI</th>
<th>‘Pipeline’ vaccines</th>
<th>Potential expansion of GAVI vaccine support</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cholera</td>
<td>Malaria</td>
<td>DTP (booster)</td>
</tr>
<tr>
<td>Hepatitis A</td>
<td>Dengue</td>
<td>Hepatitis B (birth dose)</td>
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<tr>
<td>Hepatitis E</td>
<td>Enterovirus 71</td>
<td>Measles (additional campaigns)</td>
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<tr>
<td>Influenza</td>
<td></td>
<td>Meningococcal (additional serotypes)</td>
</tr>
<tr>
<td>Mumps</td>
<td></td>
<td>Yellow Fever (additional campaigns)</td>
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<tr>
<td>Poliomyelitis</td>
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<tr>
<td>Rabies</td>
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## Evaluation criteria and indicators

<table>
<thead>
<tr>
<th>Category</th>
<th>VIS Criteria</th>
<th>Phase I Indicator</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health impact</td>
<td>Impact on child mortality</td>
<td>U5 future deaths averted, 2015 – 2030</td>
</tr>
<tr>
<td></td>
<td>Impact on overall mortality</td>
<td>U5 future deaths averted per 100,000 vaccinated population</td>
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<tr>
<td></td>
<td>Impact on overall morbidity</td>
<td>Total future deaths averted, 2015 – 2030</td>
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<tr>
<td></td>
<td></td>
<td>Total future deaths averted per 100,000 vaccinated population</td>
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<tr>
<td></td>
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<td>Total future cases averted, 2015 – 2030</td>
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<td></td>
<td></td>
<td>Long-term sequelae</td>
</tr>
<tr>
<td></td>
<td>Impact on overall mortality</td>
<td>Epidemic potential of disease</td>
</tr>
<tr>
<td>Supplementary considerations</td>
<td>Global or regional public health priority</td>
<td>Presence of global / regional (UN) resolution on elimination or eradication</td>
</tr>
<tr>
<td></td>
<td>Herd immunity</td>
<td>Herd immunity threshold</td>
</tr>
<tr>
<td></td>
<td>Availability of alternative interventions</td>
<td>Current use of alternative interventions for effective disease control (prevention and treatment) and potential for scale up</td>
</tr>
<tr>
<td></td>
<td>Socio-economic inequity</td>
<td>Disproportionate impact on one gender</td>
</tr>
<tr>
<td></td>
<td>Gender inequity</td>
<td>Disproportionate impact on one gender</td>
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<td></td>
<td>Disease of regional importance</td>
<td>Burden concentrated in a subset of GAVI countries within the same region</td>
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<td>Implementation feasibility</td>
<td>Capacity and supplier base</td>
<td>Capacity to meet GAVI demand and # of manufacturers by 2020</td>
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<td>GAVI market shaping potential</td>
<td>GAVI demand (by volume) as % of global demand</td>
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<tr>
<td></td>
<td>Ease of supply chain integration</td>
<td>Packed volume (cm3)</td>
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<td>Ease of programmatic integration</td>
<td>Alignment with other vaccine schedules and significant change in health worker practices/behavior required</td>
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<td>Vaccine efficacy and safety</td>
<td>Vaccine efficacy (as defined by clinical endpoints) and safety</td>
</tr>
<tr>
<td>Cost and value for money</td>
<td>Vaccine procurement cost¹</td>
<td>Total procurement cost to GAVI and countries, 2015 - 2030</td>
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<td>In-country operational cost</td>
<td>Incremental in-country operational costs per vaccinated person</td>
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<td>Procurement cost per event averted²</td>
<td>Procurement cost per death / case averted</td>
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1. Procurement cost includes vaccine, syringe, safety box, and freight  
2. Scoring based on cost per future death averted
Methodology for vaccine evaluation

1. Identify vaccination scenarios

2. Develop demand forecast

3. Develop impact estimates

4. Develop cost estimates

5. Assess other disease/vaccine features
Methodology for vaccine prioritisation

6. **Populate scorecards**
   - Health impact
   - Cost
   - Implementation feasibility
   - Other considerations

7. **Compare vaccines against selected criteria**
Consultations identified 5 key criteria to drive initial prioritization in phase I

- Health impact (mortality and morbidity) most important
- Also consider epidemic diseases and value for money

- Verify additional benefits and implementation feasibility
- In phase II, the full scorecard will be (re)considered to inform final prioritization

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**VIS process: phase 2 (~6 months)**

1. Further, in-depth assessment of shortlisted vaccines
2. Comparison with current Gavi portfolio to determine value-add
3. Independent expert validation of analyses
4. Country consultations
5. Development of investment recommendations

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**Malaria vaccine may have impact comparable to Hib**

Future deaths averted per 100k vaccinated

- Vaccine duration of protection is biggest sensitivity of high impact

**Vaccine implementation would require managing possible global supply shortage and communication needs**

- Policies and processes
  - WHO position TBD; few required GAVI policy changes currently (e.g., coordination with the GFATM required)
- Supply
  - Account for supply constraints through 2020 (impact likely small)
- Health workforce
  - HR/training requirements for RTS,S similar to those for vaccines already in use (e.g., immunization programs)
- Social mobilization, education, communication
  - Additional training/social mobilization/programmatic investments (e.g., for initiating new routine visits for immunization expanded EPI scenario only)
- Country level
  - Requirements for RTS,S similar to those for vaccines already in use
- Supply chain infrastructure and logistics
  - No unique surveillance requirements
- Surveillance
  - Expanded EPI scenario would require infrastructure to support at least one additional touch point
- Planning, coordination, integration
  - Expanded EPI scenario would require infrastructure to support at least one additional touch point
  - Focused organizational effort

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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 5-15M age group
  - 60% agree/have no concerns
  - 30% agree with constraints on schedule and no effect on other interventions
  - 10% disagree/require some constraints

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**Note: question only posed to 136 respondents ranking malaria as first or second priority for introduction**
VIS lessons learned

• VIS process led to a set of defensible investment recommendations and consensus among key Gavi stakeholders

• **Success factors**: robust evidence-base; clear decision framework and full transparency of the process; active stakeholder engagement and consultation; independent expert validation of analyses

• Multi-step process with many qualitative and quantitative inputs; **methodology evolved** in the course of the process

• Evaluation criteria formed a framework to help facilitate comparison and prioritisation; **ranking difficult**: no single algorithm can do justice to the diverse considerations relevant for prioritisation

• Limited focus on **DALYs** and inability to conduct comprehensive **CEA**

• Critical and consistent **evidence gaps** for some vaccines: missed opportunities?
VIS 2008: Typhoid update

- 2008 VIS recommended a one-time catch up campaign targeting children 1-14 yo + routine immunisation of infants
  - Assumptions: A TCV was expected to reach WHO PQ status in 2011; 24 countries projected to apply for typhoid vaccine support

- Taking stock:
  - Timeline of lead conjugate (Bharat) PQ unclear
  - Demand uncertainties
  - SAGE review of TCVs in 2017/2018

- Potential way forward: refresh investment case for typhoid in parallel to new VIS strategy
  - Need to better understand (and generate) demand; engage with research community pre-2018
VIS 2013: Malaria / rts,s next steps

Gavi Board requested an updated assessment following conclusion of trials and SAGE recommendation

- Updated demand scenarios, impact estimates and comparison with impact of current Gavi vaccines
- Updated cost and value for money estimates
- Preliminary implementation approaches in coordination with the Global Fund (application process, M&E, etc.)

- December 2015 / June 2016: Gavi Board review of options for a possible role in supporting rts,s implementation
VIS 2013: updates on VIS learning agenda

Cholera

- *Evidence gaps*: lack of vaccine effectiveness data for targeted vaccination strategy, unsure of demand and impact and programmatic feasibility
- **Decision**: global cholera vaccine *stockpile contribution* for epidemic response + *research* investment to understand role of OCV in endemic settings

Rabies

- *Evidence gaps*: lack of understanding of burden, lack of ability to predict demand; equity and feasibility issues related to whether Gavi would need to support Rabies Immunoglobulines (risk issue), sustainability issues
- **Decision**: investment in *research* on feasibility of Gavi support for rabies vaccines
Three work streams under learning agenda to inform VIS 2018

- **Cholera**: Cost-efficient strategies for OCV use in endemic settings
- **Rabies 1**: Evaluate the feasibility and logistic requirements of increasing access to post-exposure prophylaxis rabies vaccination in existing programmatic experiences
- **Rabies 2**: Estimate (vaccine-preventable) rabies burden and vaccination impact in endemic Gavi countries
Planned activities for learning agenda

Cholera
1. Mass campaign in 1-14yo in endemic setting in Bangladesh; focus on feasibility/coverage
2. 5-year and age-specific VE and impact in Haiti (TBC)

Rabies
1. Prospective burden and impact measurement in Chad, Mali, Cote d’Ivoire
2. Leverage existing country data to strengthen disease burden estimates and descriptive analysis of existing program management, with a focus on Asian countries
Next steps for VIS 2018

- Explore typhoid conjugate vaccine research engagement
- Implement learning agenda for cholera and rabies
- Monitor other vaccine developments (influenza, RSV, etc.)
- Q4 2015 / Q1 2016: partner meeting to plan for VIS 2018
  - Process and timelines
  - Metrics and inputs
  - Scope of potential investments
  - Key evidence gaps/needs
THANK YOU