



Vaccine Investment Strategy

Working Group Review
Washington DC 29 – 30 September 2008

REPORT

Participants: Julian Lob-Levyt (GAVI), Steve Landry (BMGF), Susanne McKinney (USAID), Ahmed Magan (UNICEF), Anthony Measham (WB), Rudi Eggers (WHO), Vance Dietz (CDC), Deogratias Barakamfitye (former AFRO), Olga Popova (Crucell), Nina Schwalbe (GAVI), Judith Kallenberg (GAVI), Sandy Wrobel (Applied Strategies), Craig Shafer (Applied Strategies)

The working group met in Washington DC to review the methodology and outcomes of the analyses performed as part of the Vaccine Investment Strategy project and to provide guidance and feedback to the Secretariat on a recommendation for the GAVI Board. Overall, the WG commended the process to date, in particular the volume and scope of the information presented, as well as the quality of the analyses performed. The WG felt that the data were of sufficient quality and that sufficient rigor had been applied in the analyses for a GAVI Alliance decision on a relative prioritization of vaccines under consideration. They also noted that given the data limitations, the VIS should be subject to periodic review if there are significant changes to the assumptions.

Terms of Reference:

The WG was asked:

1. To review the underlying assumptions and final outcomes of the analyses leading to cost estimates for vaccine procurement
2. To review the methodology and outcomes of the assessment of non-vaccine implementation costs associated with introduction in GAVI-eligible countries
3. To consider the proposed vaccine prioritization and overall investment plan

VISP Analyses

Demand forecasts

The WG agreed that the methodology used for the VIS project is of a similar approach and scope to that used in previous investment cases. The WG acknowledged that although projections appear somewhat aggressive, they are reasonable to benchmark a maximum investment required by GAVI. Moreover, the WG commented that more ambitious adoption forecasts are a logical consequence of a changing global and country context with many more vaccines available than in the early GAVI years, an increased global recognition of the value of vaccination and a strengthened delivery structure at the country level enabling faster and more efficient uptake of new vaccines.

Implementation costs

The WG commended the assessment of implementation costs as a major step forward for putting GAVI's support for vaccine introduction and procurement costs into a valuable perspective for the Board. The WG approved the method of using the WHO/UNICEF Global Immunisation Vision and Strategy (GIVS) model as a basis for costing the country-level implementation costs and noted that the roughly equal divide between vaccine (procurement) costs and implementation costs is in line with the information presented in countries' Financial Sustainability Plans.

Vaccines and vaccination strategies

The WG confirmed that GAVI would not dictate vaccine policy or strategy for any of the vaccines under consideration, and will rely on SAGE recommendations to move ahead practically.

Cholera

The WG agreed that currently licensed vaccine products are not ideal for implementation in GAVI countries or their value is uncertain due to a lack of consensus in the disease expert community. The WG advised that, while cholera should remain a priority for the GAVI Alliance, the Board should consider alternative investments in operational research to generate further knowledge regarding the most appropriate strategies for cholera vaccines (e.g., revaccination vs. boost). Furthermore, industry should be encouraged to invest in cholera vaccine products that are more appropriate for use the developing world.

HPV

The WG advised that a decision to support HPV vaccines should be contingent upon the upcoming SAGE recommendation. The WG highlighted the additional return on investment in HPV immunisation such as the potential to build a health structure for adolescent girls to deliver comprehensive sexual and reproductive health services. In line with the recommendations of the PATH HPV team, the WG was not in favour of catch-up campaigns for girls between 11 and 14 years old due to the lower cost-effectiveness of immunising a cohort that includes sexually active and therefore, potentially infected individuals who will not benefit from vaccination.

JE

The WG confirmed the importance of controlling Japanese Encephalitis through routine infant vaccination and advised that from an epidemiological perspective, catch-up campaigns in 1 – 15 year old subjects should be included in the strategy (similar to the GAVI-approved strategy for controlling Meningitis). Although typhoid vaccines have the potential to avert more cases than JE vaccines (and therefore a lower cost per case averted), the WG agreed that a number of qualitative arguments give JE vaccines priority given the frequency and severity of the long-term sequelae of the disease. Additionally, multiple safe and efficacious vaccine products are expected by 2011 and immunisation is clearly recommended by the SAGE as the most appropriate and cost-effective means of controlling JE.

Rabies

The WG requested that the mortality figure for rabies was verified given uncertainty around suspect versus actual rabid bites data. The WG felt that more work, such as pilot studies, needs to be done to identify appropriate strategies for preventing rabies. The WG suggested that the Board consider alternative investments in additional operational research to generate knowledge

regarding the impact of GAVI support in accelerating the transition from IM to ID vaccine delivery, where appropriate, which will lower costs significantly.

Rubella

The WG agreed that the impact of rubella should be considered in terms of morbidity. They also noted that Congenital Rubella Syndrome does not always lead to severe anomalies, but rather a spectrum of disabilities ranging from mild symptoms such as deafness in some to much more severe anomalies in others. Given the essential need to maintain high levels (> 80%) of coverage, the WG emphasized that future applications for rubella vaccine support should be scrutinised in particular to assess the capacity of the country's immunisation programme to ensure sufficient coverage.

Typhoid

The WG agreed that the majority of the available vaccine products are not ideal for implementation in GAVI countries due to a limited duration of protection which may require revaccination of the entire cohort every 3 years. The WG requested that the mortality impact figures for typhoid vaccines are revised to avoid the recounting of deaths averted every 3 years by revaccinating the same cohort. The WG expressed a strong preference for the conjugate vaccine product (currently in late stages of development) which could be administered through routine vaccination strategy. However, in light of the prospect of only one available conjugate vaccine product, the WG also noted that sole source supply is not ideal for the GAVI market.

Resource requirements

The WG noted that significant resources would need to be raised to implement all 6 vaccines and thus prioritization was critical. The WG also noted that for some vaccines, onetime investments such as catch up campaigns might be better supported by other donors. In light of an expanded vaccine portfolio, the WG advised that the capacity of the GAVI Secretariat would probably need to be strengthened over time, to ensure efficient management of GAVI's increasingly complex country support processes.

Vaccine prioritization

The WG then evaluated the following metrics and qualitative considerations across the 6 vaccines to determine the relative value of each vaccine within the portfolio for the period 2009 - 2020. Where applicable, these metrics were evaluated separately for different components (e.g. routine immunization and campaigns) of the vaccination strategies for each respective vaccine:

- Vaccine readiness (extent to which there is consensus within the disease expert community on whether introduction in GAVI-eligible countries was appropriate given the current state of knowledge around safety, effectiveness and feasibility of the available vaccine products and their recommended or associated implementation strategies)
- Deaths averted
- Deaths averted < 5 yo
- Cases averted
- Total vaccine cost
- GAVI cost per death averted
- GAVI cost per case averted
- Country implementation cost
- Public health impact, including severity and long term sequelae

Portfolio Recommendations

The WG noted the tremendous potential public health impact of all vaccines/diseases under consideration. They strongly recommended that those disease not prioritized in this exercise be considered for alternative investments, specifically operational research to help build the evidence base for how these diseases could be addressed in future investment strategies.

The WG deemed cholera vaccines not ready for GAVI support on the basis of the relatively low effectiveness of the available vaccine products, challenging vaccination strategies and the relatively low return on investment in terms of cost per death averted. This disease area, along with any others not prioritized for this exercise, should be considered for investment in operational research.

On the basis of the aforementioned evaluation, the WG was of the view that the Board should consider three potential investment options, differing in price for GAVI and eligible countries, and in the number of additional vaccines to be introduced. Although the Working Group believes that either options A or B would be acceptable, it expressed a preference for option B.

Option A

The WG was of the view that the GAVI Board should, at minimum, consider support for HPV, JE and Rubella vaccines in 2009 – 2020 and consider additional investments in the other vaccines on the basis of sufficient resource availability. HPV, JE and Rubella are proposed as priorities for three main reasons: 1) these diseases have a significant impact on public health in GAVI-eligible countries, 2) there is broad consensus in the disease expert community around the optimal vaccination strategies for the available vaccine products in GAVI-eligible countries, and 3) safe and effective vaccines that are appropriate for GAVI eligible countries are available now or will be available within the next 2 years.

Option B

A second portfolio should include typhoid, because of the major public health impact of typhoid fever in developing countries (estimated mortality of 216,000 – 600,000 per year, estimated morbidity of 16 – 33 million cases per year) and the significant impact of vaccination in terms of cost per case averted.

Option C

The third option should also include rabies and catch-up campaigns for rubella as these would add significantly to 1) the number of deaths averted (rabies) and 2) the rapid impact on controlling CRS.

The working group requested that the team finalize analyses for the 3 portfolio options for final consideration at a teleconference planned for 6 October.

Additional recommendations

Separately, the WG noted that the following policy issues should be reviewed by the GAVI Secretariat following the Board's decision on the VIS:

- Detailed implementation plans for rolling out the introduction of vaccines approved by the Board in October

- The need for an adjusted demand forecast based on the Board's decision to support selected vaccines (i.e. GAVI support decision will impact demand)
- GAVI's eligibility policy on vaccine support, i.e. the scope of financial GAVI support if countries are already partly procuring the vaccine or procuring a non-recommended product

Working Group Teleconference, 6 October 2008

Participants: Steve Landry (BMGF), Susanne McKinney (USAID), Osman Mansoor (UNICEF), Anthony Measham (WB), Mahima Dalta (Biological E Ltd, India), Deogratias Barakamfitye (former AFRO), Olga Popova (Crucell), Nina Schwalbe (GAVI), Judith Kallenberg (GAVI), Sandy Wrobel (Applied Strategies), Carol Marzetta (Applied Strategies), Craig Shafer (Applied Strategies)

In a subsequent teleconference on 6 October the WG reviewed updated analyses for typhoid, rabies and rubella and endorsed the 3 portfolio options. The WG expressed a preference for portfolio B, given adequate resources are available.