Eighth GAVI Board Meeting

GAVI

THE GLOBAL ALLIANCE FOR VACCINES & IMMUNIZATION

Partnering with The Vaccine Fund

Paris, France

19-20 June 2002

EIGHTH GAVI BOARD MEETING
Paris, 19-20 June 2002
SUMMARY REPORT

1. Report From Asia

Discussion

- There was wide appreciation for the report on the status of immunization in Asia and how countries in the region are accessing support from GAVI and The Vaccine Fund.
- The move toward more accuracy and honesty in terms of reported coverage is welcome.
- ICCs require attention and support; the most appropriate means of achieving that strengthening may be different in different countries. While in some countries an ICC secretariat has worked well, in others this approach might be too formal and not sustainable.
- It is important that the introduction of new vaccines is prioritized rationally, taking account of disease burden and impact on routine coverage, as well as other priorities.
- There is a need to strengthen capacity at all levels. The absorptive capacity of countries is an important factor in the vaccine industry's planning.
- The Board agreed that members should make an effort to attend ICC meetings in their country visits.
- In the future, the Board may consider including presentations from country staff in meeting agendas, as most of the regions have been covered.

2. GAVI Review

Discussion

- The GAVI Alliance faces a transition from its initial emphasis on the development of policies and procedures at global level to a focus on implementation at country level. While a looser alliance approach initially was instrumental to achieve the broad thinking and consensus building, the implementation stage requires more active management.
- The Board welcomed the review of the GAVI Board, Working Group, Secretariat, as an opportunity to clarify relationships, functions, and accountability. This will be key as GAVI and The Vaccine Fund collect evidence of impact in quantitative, economic and social terms.
- The Board agreed that GAVI should retain its current structure but adopt a more businesslike approach. The Board should focus on high-level strategy and key policy issues, delegating more responsibility and accountability to the Executive Secretary, supported by the Working Group and Secretariat.

- One Board member suggested that a Vaccine Fund Board member, rather than its President, should be represented on the GAVI Board.
- One Board member suggested that the Alliance will need to make a decision about whether to fulfill its global mission in the broadest sense, or continue to focus on a limited number of vaccines and immunization service strengthening in the poorest countries (which are a high priority, of course). For example, non-Vaccine Fund eligible developing and middle-income countries currently have no substantive consideration in the discussions, and programs like polio eradication, measles mortality reduction, and neonatal tetanus elimination not fully integrated into the GAVI "tent".

DECISIONS

Regarding management processes (recommendations 1-13) the Board:

1.1 **Approved all recommendations, except those referring to the creation of standing Board sub-groups (see point 2.3).**

1.2 **Requested the Secretariat to prepare a comprehensive, budgeted GAVI workplan for 2003-4, for presentation to the Board at its November 2002 meeting. The workplan should reflect the transition we are facing and be based on individual workplans of the GAVI mechanisms (task forces, Working Group, Secretariat, regional working groups). All GAVI workplans should align with relevant GAVI strategic objectives and milestones, and identify priorities, deliverables, human and financial resources, critical timings, key challenges and GAVI partner commitments and accountabilities.**

1.3 **Decided not to form standing sub-groups of the Board but agreed to form** ad hoc**, task-specific sub-groups as needed.**

1.4 **Adopted the recommendation that the Board should delegate authority and accountability for day-to-day operational decisions to the Executive Secretary, supported by the Secretariat and the Working Group, within the framework of a Board-approved GAVI Secretariat workplan.**

1.5 **Adopted the recommendations that Board documentation should be more concise, clear, provided on a more timely basis, and include more options, as appropriate.**

Regarding Board composition and processes for selection of new seats (recommendations 14 - 22), the Board:

1.6 **The Board will further consider Board composition at its next teleconference. (Board members have been asked to complete a questionnaire on these issues). In order to restrict Board growth, it may be appropriate to allow certain seats to be discontinued once the term of the current representative has concluded.**

1.7 **Requested that the Executive Secretary work with the Chair to solicit all Board members' views on the recommendations concerning the composition of the Board. The Secretariat will provide a synthesis of the feedback in time for the Board to reach agreement during its next teleconference.**

1.8 **Requested the Secretariat to provide a summary of current procedures for selecting new Board representatives, including a description of members' responsibilities and requirements, and make recommendations for streamlining and increasing transparency of the process. Once the summary of the processes used for selection of new Board seats has been accepted and endorsed, it will be made widely available, including being published on the GAVI website.**

Regarding the Working Group (recommendations 23 - 28), the Board:

1.9 Recognized the crucial role of the Working Group in the development and functioning of the Alliance.

1.10 Approved the recommendation that the Executive Secretary, by virtue of position, should chair the Working Group and be held accountable to the Board for its functioning.

1.11 Agreed that the composition of the Working Group will need to diversify to include more non-immunization specific expertise and more people with field-level immunization experience. Recognizing the importance of continuity and links to key implementing agencies, the Working Group should be kept small with a focus on necessary skills, as opposed to being strictly representational. The need for greater participation from developing country governments was stressed.

1.12 Requested the Executive Secretary to submit a concrete proposal for renewal and turnover of the membership of the Working Group in connection with the comprehensive GAVI 2003-4 workplan. Selection of individuals on the Working Group should be made in a negotiation/collaboration process between the Executive Secretary and the concerned agencies.

Regarding the Secretariat (recommendations 29 - 31), the Board:

1.13 Recognized that the staffing of the Secretariat is insufficient for current tasks. As the Secretariat's workload increases it will need to add a limited number of new staff; keeping the Secretariat lean is of high priority.

1.14 Requested the Executive Secretary to submit a skeleton workplan outlining the Secretariat functions, staff needs and staffing priorities in light of the current phase of transition into implementation, so that the Board can take a final decision on additional Secretariat staff at its next teleconference.

Regarding funding arrangements (recommendations 32 - 34), the Board:

1.15 Decided that the funding of the Secretariat, Working Group and Task Forces, and their respective activities, should be based on the comprehensive 2003-4 workplan and budget.

Regarding the Independent Review Committee (recommendations 35 - 40), the Board:

1.16 Approved the recommendations that the Independent Review Committee (IRC) should continue to report, and be accountable, to the Board and that its skill base needs to be expanded to include more health system wide expertise.

1.17 Requested that the Executive Secretary, in consultation with the Working Group and the M&E sub-group of the Implementation Task Force, submit a proposal for a new mechanism to perform the monitoring and evaluation function of the GAVI review process, including assessing progress reports, financial sustainability plans, and mid-term reviews. This separation of functions would ensure that the monitoring and evaluation procedure is pristine and free of conflict of interest.

1.18 Agreed that in the future, the Board should only be requested to review and consider proposals being recommended for approval by the IRC. The Executive Secretary will handle IRC recommendations for resubmissions and conditional approvals.

1.19 Delegated authority to the Executive Secretary to approve minor changes in vaccine volumes, specifications, quantity or presentations, as long as the value of the award does not differ significantly from the financial ceiling originally approved by the Board.

Regarding the relationship with the Vaccine Fund (recs 41 to 45), the Board

1.20 **Agreed with the recommendations that there should be close working relations between the Vaccine Fund, the GAVI Secretariat staff and relevant partners; that the Working Group should continue to include a Vaccine Fund representative; that the Vaccine Fund should be asked to invite the GAVI Executive Secretary to be a member of its Board and Executive Committee by virtue of office. The option of a GAVI Board member to sit on the Vaccine Fund Board was also suggested; and that the President of the Vaccine Fund should have a seat on the GAVI Board (see decision 2.7).**

2. Lessons Learned

Discussion

- The updated analysis of the vaccine industry and the review of the first GAVI procurement process are important contributions to the Alliance as we think about how to better manage our efforts and act as an effective catalyst for improved collaboration between the public and private sector.
- In the future, the procurement process for GAVI and The Vaccine Fund should be based on a single line of reporting and have much more rigorous monitoring and accountability than the current system. It should also, over time, work to develop much more accurate data about demand at country level. The new system could potentially serve middle income countries as well as Vaccine Fund eligible countries.

DECISIONS

The Board:

2.1 **Agreed that an in-depth discussion of vaccine security and the changing vaccine environment and the issues involved in securing adequate vaccine supply from multinational and emerging vaccine producers, and fostering cooperation between them, should be a major topic of discussion at the Partners' meeting.**

2.2 **Approved the new project management structure for the preparation and implementation of the upcoming tender process. In the recommended structure, the project manager would be affiliated with WHO or UNICEF Program Department and be supported by a team made up of partners from WHO, UNICEF Program Division and Supply Division, and the Vaccine Fund. The project manager would report to the GAVI Board, via an oversight committee made up of a developing country government Board member (India) and an OECD country government (tbd), with facilitation / support from the Executive Secretary. This oversight committee will act as a conduit between the procurement project management team and the Board.**

2.3 **Endorsed the proposal from UNICEF and WHO, supported by The Vaccine Fund, that they should move forward with the process of recruiting a GAVI procurement project manager and assembling a team, possibly to be housed in the Geneva office of UNICEF.**

2.4 **Requested that vaccine manufacturers explore how they could engage in the procurement activity without creating conflict of interest.**

2.5 **Requested manufacturers to consider a slight delay of the 2004-06 tender process.**

3. Evolution of the Task Force on Country Coordination (TFCC) into the Implementation Task Force (ITF)

Discussion

- There was general agreement that with GAVI process transitioning from proposal development, review and program initiation to implementation, the TFCC would also need to change its focus and structure.
- The Board recognized the growing importance of the Regional Working Groups, especially as demands on country staff increase with the development of financial sustainability plans and monitoring and reporting systems.
- It may be appropriate for the task force to consider a co-chair, other than WHO or UNICEF, to help lead the coordinating (core) group, and/or the sub-groups.

DECISIONS

The Board:

3.1 Approved the proposed evolution of the TFCC, including the name change to the Implementation Task Force, and the separation into one core group for coordination and two sub-groups to address monitoring and evaluation, and capacity building, respectively.

3.2 Requested that task force's workplan should clearly identify the activities of the task force as well as the implementation roles of the Partners and the links between them. The Board also requested a clear explanation of the additional staff hired to support the country level implementation activities (immunization advisers), including who pays and supervises them.

4. Immunization Financing Database

Discussion

- Board members appreciated the report and encouraged the database development team to continue the effort as it was outlined in the presentation.
- While looking at immunization specific costs for comparative and trend analyses is valuable, it is important to note that to be most effective and sustainable, immunization services must be supported by the larger health system.

5. Financial Sustainability Plan Update

Discussion

- There was enthusiastic support for the work conducted by the Financing Task Force on the development, testing and planning for countries' financial sustainability plans. Countries that prepare these plans could learn important lessons for other areas of health financing.
- It will be important to analyse early countries' experiences to learn how immunization financing decisions apply within the broader health and development context, and to discern the relative benefits of prevention as compared to curative services. However, care should be taken so that the process does not become too complicated and burdensome for countries.

- The process to support countries' development of the plans needs to be integrated into the two-year GAVI workplan and budget; it will be important to think about how this will affect the workload of the GAVI Secretariat.
- GAVI partners at the country level will need contribute to the work on financial sustainability plans, according to their comparative advantage. The Board also noted the important role of the Regional Working Groups in coordinating technical support to countries.
- The outcome of the extended pilot of the financial sustainability plans, including proposed Board actions to address resource gaps, will be presented to the Board in the spring of 2003.

DECISIONS

The Board:

5.1 Approved the proposed system and timeline to support the first 13 countries to prepare financial sustainability plans (FSPs), as outlined in the paper.

5.2 Approved the proposed process for review of the FSPs submitted in the extended pilot phase. The Board will expect a report of the lessons learned at its Spring 2003 meeting.

5.3 Recommended to include the economic context of each country as a component of the FSPs, and that country- and regional-level World Bank staff should be involved in the process.

5.4 Requested an in-depth analysis of the effect of the influx of support from The Vaccine Fund on perhaps two countries, especially as a lesson for other funding mechanisms such as the Global Fund to Fight AIDS, Tuberculosis and Malaria.

6. The Vaccine Fund Draft Strategic Plan and Emerging Policy Issues

Discussion

- The Board supported a longer-term perspective for the Vaccine Fund, beyond the first five-year commitments. To meet future needs, the Vaccine Fund needs to set ambitious fundraising targets. While the environment is receptive to increased investments in health, the Board noted that there is also great demand for these new resources and that it will be important to be realistic.
- In the start-up phase, simplicity was a key concern. The next phase may need to incorporate more flexibility to better respond to diverse country situations.
- The introduction of new vaccines continues to be a high priority for GAVI. In the next phase GAVI may consider using Vaccine Fund resources to introduce available but under-used vaccines such as Japanese encephalitis, MMR, rubella, IPV, and other combination vaccines now being developed.
- While it cannot necessarily assumed that the Vaccine Fund will purchase vaccines against meningococcus A, pneumococcus and rotavirus once they are developed, their status as GAVI priority vaccines indicate that this may indeed become a focus for resources. Looking further into the future, purchase of vaccines against AIDS, malaria and tuberculosis should be considered within the context of The Vaccine Fund.
- A Board member raised concern that as the Vaccine Fund builds its independent brand identity, a drift is occurring between GAVI and the Vaccine Fund. Advocacy

and public awareness efforts on behalf of the Vaccine Fund must not undermine fundraising for other immunization efforts.

DECISIONS

The Board:

6.1 Endorsed the need for ambitious, but reasonable fundraising targets. Considering the substantial needs presented by the Vaccine Fund, the Board recognized that the funding gap is significant.

6.2 Requested that the Vaccine Fund develop a menu of options, reflecting different levels of funding and program implementation, for consideration by the GAVI Board in case the Vaccine Fund's fundraising targets, and/or the countries' program targets, are not fully met.

6.3 Agreed that more Vaccine Fund resources should be used support health infrastructure and capacity-building efforts, and endorsed the proposal to give particular attention to the poorest countries.

6.4 Requested the Vaccine Fund to work with the GAVI Partners to assess the resourcing needs to reach the 80-80 milestone (at least 80% DTP3 coverage in all districts in 80% of developing countries by 2005). A proposal should then be presented to the GAVI Board on how resources could be disbursed to help meet that target. In this context, one option could be to fund operational research that investigates the effectiveness of various approaches, including their efficiency in improving health systems and outcomes.

6.5 Endorsed the clarification of current policy that vaccine commitments to countries are antigen-based. The financial implication of this clarification is estimated to be an additional $625 million over the next 10 years. For example, if a country receives five years' supply of DTP-hepB, it could apply for up to a five years' supply of DTP-hepB-Hib – as long as it finds other funding to cover the costs of the DTP-hepB portion.

6.6 Recommended further policy dialogue, especially at the Partners' meeting, on issues related to the introduction of new vaccines over the coming years, and also about the role and potential of local production in reducing cost and securing supply. The Developing Country Vaccine Manufacturers Network (DCVMN) could play an important role in these discussions.

7. Accelerated Development and Introduction of Priority New Vaccines; ADIPs

Discussion

- There was broad support to the proposed approach to accelerate the development and introduction of priority new vaccines, called ADIPs.
- Of the three proposed hosting arrangements (passive host, active host, GAVI Secretariat), most Board members preferred that the ADIPs are housed in a passive host such as the GAVI Secretariat. The Board agreed that the quality and personality of the team leader is essential.
- The work related to ADIPs would bring GAVI closer to an implementing role; this is not a concern but the ramifications need to be considered.

DECISIONS

The Board:

7.1 Confirmed the importance of having a Steering Group to oversee the work of the ADIPs, with the stipulation that it would include at least one GAVI Board member and report to the GAVI Board.

7.2 Agreed the proposed approach which included several 'go/no go' decision points during the implementation of the ADIP, depending on progress achieved.

7.3 Requested an ad hoc Board subgroup facilitated by McKinsey and consisting of an OECD country (U.K. subsequently selected), Klausner, Lovelace, and India to explore and make recommendations on the best hosting arrangement. If the GAVI Secretariat is chosen as the most appropriate host, an RFP for Host Institutions will not be needed. If the GAVI Secretariat is not deemed an appropriate host, it may be tasked with preparing the RFP. The sub-group will report back to the Board at its next teleconference.

8. Revised guidelines for optimal, effective and catalytic use of resources from "Window 3" of the Vaccine Fund

Discussion

- Window 3 resources may be appropriately used to fund R&D efforts on improved vaccine delivery technology and reduced reliance on cold chain, with the goal of increasing access. Funding should be used to support efforts to reach 80-80 goal, including perhaps operational research addressing issues concerning immunization within the broader health sector context.
- Conflict of interest needs to be even further emphasised in the review process to ensure transparency; in some cases it may be necessary for reviewers to exclude themselves from discussions.

DECISIONS

The Board:

8.1 Approved the guidelines for use of resources from Window 3 to support the ADIP activities, with a ceiling of USD 90 million over three years. Actual funding amounts will be based on the proposed workplans developed by the ADIPs.

8.2 Requested the Executive Secretary to report back to the Board on specific activities, and their budget requirements, that will be needed in the next 6 to 18 months to maintain the momentum gained through the work of the pneumococcal and rotavirus teams – while the ADIPs are being formed.

8.3 Requested additional thinking on intellectual property rights and pricing issues.

9. IRC Recommendations from the 7th country proposal review round

Discussion

- The Board again congratulated the IRC for its excellent and comprehensive work.

DECISIONS

The Board:

9.1 Endorsed all of the recommendations of the IRC concerning approval of country proposals and requested The Vaccine Fund Board to approve the recommendations.

9.2 Approved the proposal from the IRC that East Timor be accepted as eligible for Vaccine Fund support.

10. NGO representative to the GAVI Board

Discussion

- The process for increasing NGO involvement in GAVI outlined by CVP is comprehensive, and it was hoped that it would not deter a strong developing country NGO from applying. Four serious applications to succeed CVP on the NGO seat of the Board had been received by the closing date.
- The Chair of the Board will present a concrete proposal for next steps to take regarding the selection of the CVP successor on the GAVI Board, at the next Board teleconference.

DECISIONS

The Board:

10.1 Decided that the financial contribution (currently $300,000 per year) normally required from GAVI Board member organizations should not be a prerequisite for the NGO representative, but that it will be decided on a case-by-case basis.

11. In Camera session

- The Board agreed to request the Director-General of WHO to serve as Chair of the GAVI Board for a term of two years at the completion of the UNICEF Executive Director's term as Chair in July 2003.
- Noting that the Executive Secretary's contract will expire on 1 July 2003, the Board agreed to establish a process for the selection and appointment of the GAVI Executive Secretary to serve thereafter. It was agreed that the Chair would appoint a sub-group of the Board to oversee the process, and that recruitment should be finalised with sufficient leadtime to allow a smooth transition.

Pre-meeting symposium on Scaling up a joint response between global and national efforts: Summary of Presentations and Discussion

Julian Lob-Levyt presented a summary of the current health and development context:

- **There is an increased international commitment to development, and health in particular. This increase in interest is related to :**
  - **HIPC and Poverty Reduction Strategies**
  - **Globalisation, trade, access to medicines**
  - **HIV/AIDS**
  - **The importance of investing in health, as demonstrated by the Report of the Commission on Macroeconomics and Health**
  - **Millennium Development Goals**
- **This new focus is also translating into increase in resources and innovative partnerships focused on accelerating R&D or delivering health resources. The great challenge is to become more outcome focussed and avoid sterile debates (e.g., on vertical vs. integrated, or categorical vs. systems approaches).**
- **In the donor community, there is a need to bridge the divide between global initiatives and country co-ordination; to set longer term development agendas; to develop an effective response and "lock it in" while there is this strong interest in health; and to enhance capacity (particularly of multilaterals) to provide support at country level.**

Sigrun Mogedal then presented a summary of potential strategies for developing a response:

- **Donors need to take the lead in increasing predictability in funding and partnering; countries need to take the lead in developing systems that respond to and manage benefits of global initiatives.**
- **In the GAVI process there are a number of opportunities to build these bridges:**
  - **Efforts to ensure financial sustainability.**
  - **Link ICC partners and SWAP partners.**
  - **Engage UN and World Bank in bridging with MDGs and PRS.**
  - **Communicate better with civil society / NGO development partners.**
  - **Identify a GAVI partner at the country level that can serve as a communicator between actors.**
  - **Strengthen research at country level to strengthen capacity and inform policy decisions.**

The Board then engaged in a discussion of the points raised:

- **In order to engage in the macroeconomic debate and make the case to Finance Ministers to provide more support, we need to highlight the developmental benefits of vaccination, including future costs averted. This also needs to link into country level priority setting processes.**
- **We need clearer lines of accountability, and measurements of progress against targets, for country health systems and the GAVI alliance.**

- **We have a limited window of opportunity. Some donors may be willing to make longer-term commitments to the poorest countries. However, we need to provide numbers showing how the money we have spent has had an impact. Is this new way of doing business getting the results we have intended?**
- **The lack of skilled and motivated staff is a limiting factor in any effort to improve health outcomes in countries. How do we address this problem, given donors' traditional reluctance to provide recurrent staffing costs?**
- **Finally, it is agreed that GAVI is giving partners an excellent opportunity to explore new strategies, learn lessons, and help to show the way for other similar efforts.**

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REPORT OF THE EXTERNAL REVIEW OF THE FUNCTIONS AND INTERACTIONS OF THE GAVI WORKING GROUP, SECRETARIAT AND BOARD

7 JUNE 2002

Karen Caines, consultant
Hatib N'jie, consultant

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EXTERNAL REVIEW OF THE FUNCTIONS AND INTERACTIONS OF THE GAVI WORKING GROUP, SECRETARIAT AND BOARD

EXECUTIVE SUMMARY AND RECOMMENDATIONS

1. Introduction and approach to the review

This review was commissioned by the Board of the Global Alliance for Vaccines and Immunisation (GAVI) to examine the current operations of the GAVI Board, Working Group and Secretariat and their relationship with partners in the Alliance and with the Vaccine Fund (VF), leading to recommendations to strengthen GAVI's structure and interactions in order to improve its capacity to meet its objectives during the next five years. It also examines the independence and accountability of the Independent Review Committee. The review does not substantively cover Task Forces, Regional Working Groups or ICCs.

The Alliance is a dynamic organism. Fieldwork interviews indicate that at present continued incremental development is likely to be preferable to radical restructuring. GAVI faces a set of strategic issues which lie outside the remit of this review and which will have a decisive bearing on future functions and support mechanisms. There should be a broader review by, say, early 2004 to assess the performance of the Alliance and progress towards its milestones, including regional and country operations and support systems. In the interim, the recommendations below have been designed to allow sufficient flexibility to enable the Alliance architecture to evolve to best effect.

2. Other reports

A seminal report for this review has been GAVI and The Vaccine Fund – Roles and Responsibilities considered by the GAVI Board in October 2001. It proposed that as GAVI develops outcome-based "business plans" to address challenges, needs and issues arising from implementation, it should "consider moving towards basic managerial principles".

This review has taken place alongside four other studies whose findings have important implications for GAVI architecture and interactions:

- *Lessons Learned: New Procurement Strategies for Vaccines (Mercer Management Consulting), due to go to the GAVI Board in June 2002*
- *Project to Accelerate Development and Introduction of Pneumococcal Conjugate and Rotavirus Vaccines (McKinsey & Company), due to go to the GAVI Board in June 2002*
- *A review of GAVI Task Force workplans (John Marshall, consultant), considered by the Working Group in April 2002*
- *Developing Successful Global Health Alliances1 (McKinsey & Company), April 2002.*

[1] Developing Successful Global health Alliances with permission of The Gates Foundation and McKinsey and Company

These studies are strikingly in agreement about the need for the Alliance to ensure that it is operating on the basis of some key "basic managerial principles", as it moves from a strategy phase - requiring broad thinking and consensus building - to a planning and execution phase requiring an active, properly resourced and accountable project management function. Other recommended features include:

- a compelling goal and focused scope, with a clear understanding of the Alliance's added value and what is required to capture this value
- senior champions in partner organizations, an accountable Alliance leader and a focused working team
- clear lines of accountability
- the "minimums" of operational planning including clear partner commitments, performance measures and milestones, and detailed operating and funding plans.

3. Key findings from the review

Within the scope of the limited time and focus, the review has entailed observation of various GAVI processes in operation, face to face interviews, telephone interviews, an email questionnaire of Independent Review Committee members and review of documents and available data. The sections below contain our findings and recommendations. Inevitably they concentrate on what might be done better rather than describe in full what is being done well. They need to be read in a wider context – one that captures the overwhelming tone of approval, enthusiasm and support for GAVI that suffused our fieldwork, that understands how much the Alliance has achieved and how ambitious its goals remain, and that recognises the need for some fine-tuning but is fearful of damaging a delicate organism.

Key recurring themes from our fieldwork interviews are:

- broad satisfaction with GAVI's achievements and a strong conviction that GAVI does add value, even if the work to define that value is not yet complete. "GAVI has brought a level of coordination that never existed before. And a level of resources". "For an entity as young as it is, it is very functional".
- divided views about the need for an external review but a collective warning against major structural change at this stage
- a recognition that GAVI needs to change to match its transition from an initial phase when the emphasis has been on activity at global level to agree policies and procedures, to one of implementation with greater demands at regional and country levels, and greater workloads. "GAVI's performance to date has been stellar but it needs to mature".
- a desire for the Board to spend more time on key strategic issues and less on operational detail. As an example, many interviewees feel the time has come to shape a clear view about the future of the Alliance beyond 2005.The corollary is the need for greater delegation of authority.
- alongside a determination to protect the special nature of the Alliance and to avoid becoming bureaucratic, the felt need for a more managerial approach and greater demonstration of accountability. "There is an increasing recognition that if GAVI is to be more effective, it needs to move from a voluntary group of officials to a more business-like, managed system". At the same time some see an inherent tension in seeking to manage an alliance.

- a concern about GAVI's vulnerability in its reliance on a few highly committed but heavily pressed individuals, some of whom are dealing with GAVI issues on a part-time basis, have other pressing responsibilities within their partner organization, and have career choices to make. This argues for planning for transitions (such as the retirement of Tore Godal) and some greater degree of institutionalisation. At the same time, a strongly-voiced view reminds that GAVI is not an entity in its own right - it is merely a facilitating agent whereas the partners are operational - and that its secretariat should consequently remain "lean".
- a consensus that existing structures can cope with heavy forecast workload, albeit with difficulty.
- a need for more effective communications, and for greater transparency (eg in appointments to the GAVI Board, Working Group and Task Forces; funding, particularly about partners' contributions; and, among some, about decision-making).

4. GAVI Mission, Objectives and Workload

Section 4 describes GAVI's mission, objectives and milestones and the formidable workload facing a range of GAVI components – the Independent Review Committee (IRC), Task Forces, Regional Working Groups and ICCs as well as the Board, Working Group and Secretariat. Country programme management will be increasingly demanding, and tasks will require a wider range of skills. There is no comprehensive outline of the work and budgets of the Secretariat, Working Group and Task Forces.

Recommendation

1. **To ensure a clear focus on shared priorities, assist planning and facilitate accountability, the Secretariat should prepare and the Board approve a consolidated two-year workplan, including budgets and sources of funding, for these GAVI components. The first workplan should be in operation for 2003-2004.**

5. Functions and interactions of the GAVI Board, Working Group and Secretariat

Given the special characteristics and ethos of the Alliance, the challenge is to improve functional effectiveness with the minimum of structural change, and to build on existing informal relationships and understandings. Key issues include handling the growing Board workload, clarifying the authority and accountability of the Working Group and Secretariat, enabling progress in implementing policies to be tracked, improving transparency and putting GAVI in a position to demonstrate evident success. The review's consideration took into account the Roles and Responsibilities paper of October 2001, and the findings of the other contemporary studies mentioned in section 2.

The Board's current *service* function is crucial to the Alliance: harnessing the efforts and resources of partners to achieve a common vision, establishing contacts and fund-raising, creating a high profile for immunization issues, making immunization a centrepiece of global and national socio-economic development agendas and frameworks, and providing advice to other GAVI components. This should remain unchanged. But the review recommends a modified approach to its *control* function, based on greater delegation of specific authorities and a sharper oversight of the accountabilities of the Secretariat and the Working Group.

The Board should retain full authority for:

- approving GAVI's objectives, milestones and overall strategy
- determining major policy issues, including implementation policy issues
- determining GAVI structures, and constituency representation on the Working Group
- nominating the Executive Secretary and holding the post-holder to account
- approving membership of the Independent Review Committee, and determining recommendations of the IRC other than any specifically delegated elsewhere
- making recommendations for funding approval by the Board of the Vaccine Fund
- exercising a challenge and support function in relation to the Secretariat and the Working Group
- exercising an accountability oversight function. It should approve the GAVI consolidated workplan and budget, and workplans and budgets for the Secretariat and for the Working Group; and monitor progress reports and annual performance reports.

For those issues which must be addressed by the Board itself, greater use of Board sub-groups - reporting to the full Board - would allow more detailed consideration of important issues and provide the opportunity to co-opt additional experts as necessary to fill skill gaps. They will usually be ad hoc to deal with one-off issues but there may be benefit in a strictly limited number of standing Board sub-groups, for example

- *an Operations and Review Sub-Group*, providing Board oversight of *inter alia* the GAVI workplan, including monitoring progress towards immunization goals
- a *Country Programmes Sub-Group*, providing Board oversight of activities central to an improved level of success in country programme implementation.

It was proposed during field work that, in the spirit of the Alliance, the precise range of functions and authorities suitable for delegation should not be specified in this report but should be developed participatively, involving members of the Board and other GAVI components, as a follow-up to this review.

The section outlines five possible structural models for future relationships between the Board, Working Group and Secretariat. There is no clear consensus among interviewees on

the issue. The strong preference for retaining a small, administrative Secretariat, the importance of reducing Board overload, the benefits of current working relationships and the need for a clear locus of accountability point to a modified version of the status quo with a single point of authority. The review concludes that this should be the Executive Secretary.

Key recommendations on the functions and interactions of the GAVI Board, Working Group and Secretariat

- *a high-level Board primarily concerned with Alliance strategy, key policy issues and accountability oversight*
- *greater use of Board Sub-Groups for issues which only the Board can address*
- *greater delegation to the Executive Secretary supported by the Working Group and the Secretariat, and also to the Independent Review Committee*

Recommendations

2. **GAVI's high-level Board should be primarily concerned with Alliance strategy, key policy issues and accountability oversight.**
3. **The Board should constitute an ad hoc Board subgroup to consider options for experimenting with greater use of Board subgroups and for specific areas for delegation to other entities of GAVI.**
4. **If the Board decides to establish an Operations and Review Board Sub-Group, it should come into effect in the last quarter of 2002 so as to be able to consider workplans for 2003-4 and proposals for the 2003-2004 biennial budget.**
5. **The Board should retain broadly the current structure, with a lean, predominantly administrative secretariat and a technical Working Group formally chaired by the Executive Secretary. Authority and accountability for day to day operational decisions should be delegated to the Executive Secretary/Chair, supported by the Secretariat and the Working Group. He would be accountable to the Board for the performance of the Secretariat, Working Group and Task Forces, and for ensuring that they work together without overlap or conflict. Task Force Chairs should report to the Executive Secretary who would endorse their appointment. They should continue to attend Working Group meetings.**

6. Management processes, including decision-making

GAVI Board processes

GAVI Board members are generally satisfied with Board processes and decision-making protocols, with the qualification that policy papers have too often been prescriptive, unclear and/or late. In the Working Group there are few formalities about decision taking, and no recourse to voting. Improved communications would help dispel unease in some quarters about lack of transparency.

Recommendations

6. **Documents/proposals for the Board should be timely and more user-friendly, with clear, concise papers and a covering one-pager to highlight the issues, their main implications (including resource implications where appropriate), the recommendation(s) and the action required of the Board.**
7. **Proposals should set out a range of options with sufficient detail of the pros and cons to facilitate genuine Board consideration and decision making.**
8. **Papers for each Board meeting should include a one-page information note, highlighting key events, decisions, discussions, issues arising since the last meeting and forthcoming ones.**
9. **Working Group papers should be circulated sufficiently in advance of the meeting to allow members time to reflect and consult. There should be opportunity for the views of members who are unavoidably absent to be taken into account.**
10. **The GAVI website should be kept up to date.**

Management processes and information

In line with the finding of the McKinsey study of successful global health alliances1 that some "minimums" of operational planning are advisable, GAVI should adopt and use a small number of simple but meaningful management tools to promote efficiency, communication and accountability.

Recommendations /Endorsements

11. **The review endorses the recommendation from John Marshall's consultancy that each Task Force workplan should align directly with the respective GAVI strategic objectives and milestones; be reviewed alongside each other to ensure comprehensive as well as coherent coverage of tasks; and identify priorities, tangible deliverables, human and financial resources, critical timings, key issues and GAVI partner commitments – and accountabilities.**
12. **Similar simple workplans should be produced for the Working Group and Secretariat. With those of the Task Forces, they would form the basis of the overall GAVI workplan recommended in section 4.**
13. **The Secretariat should provide the Board with summary annual reports on performance. The Board must be able to track progress against GAVI milestones. This may well entail the development of intermediate milestones.**

7. The GAVI Board

The emphatic response from fieldwork interviews is that the GAVI Board works well and that, in general, caution should be exercised in contemplating change. Increased representation from developing countries would strengthen the active involvement of beneficiary country governments in GAVI policy making, facilitate the task of effective networking and make consultation more meaningful, strengthen country ownership and leadership, and increase peer pressure to perform better.

There should be a clear, written, easily accessible statement of the processes for the selection and rotation of seats, and a shared understanding about core responsibilities of Board members. Members may sometimes need support in fulfilling them. It is the Board Chair's responsibility to take all necessary action in case of shortcomings.

Ms Bellamy's term of office as the current Chair of the GAVI Board will end in June 2003. There is no clear, shared understanding among Board members about the process which will be followed in selecting the next Chair, or indeed about the pool of potential candidates.

Each Board member (excluding the Chair) is liable for annual Board dues to provide funds for the secretariat and priority tasks, etc, plus associated costs eg for travelling and per diems. This requirement should not be allowed to inhibit good applicants, eg for the forthcoming NGO vacancy.

Recommendations

14. The Board should increase the number of developing country Board members from two to four, to represent

- **West and Central Africa**
- **East and Southern Africa, plus Sudan, Somalia and Djibouti**
- **SEARO/WPRO plus possibly Pakistan, Afghanistan and Yemen**
- **EURO/PAHO.**

15. The Board should invite the President of the Vaccine Fund to become a member to institutionalise the liaison between the GAVI Board and the Vaccine Fund.

16. At least one current rotating seat should be dropped or merged at the end of the present term, to avoid the possibility of the size of the enlarged Board undermining the effectiveness of Board interactions.

17. A note setting out current selection procedures, general criteria for selection and core responsibilities of GAVI Board members should be made publicly available on the GAVI website, along with details of forthcoming vacancies over the following two years.

18. Any invitation letter for nominations or public notice of the forthcoming vacancy should give the Board's general criteria for selection, plus the specific criteria applying to the individual vacancy (eg criteria being applied to ensure technical, geographic or gender diversity). Where a constituency organises its own nominations, the Executive Secretary should provide it with information on both general and specific criteria.

19. The Board's process of consultation on nominations should be fair, transparent, and applied to all constituencies.

20. The outgoing Board member should take responsibility for a seamless handover to his or her successor.

21. The Board should take early steps to confirm the policy and process for the appointment of the next Board Chair, at the end of Ms Bellamy's non-renewable term.

22. The Board should keep under careful review the ability of members, and potential members, to meet annual Board dues of US$ 300,000.

8. The Working Group

The Working Group has been a crucially important element of the GAVI architecture. It has borne an exceptionally, perhaps unacceptably, heavy burden of work. In fieldwork, one repeated concern has been that the recommendations of this review should not damage the effectiveness of the Working Group. It also generated a set of issues about the precise role of Working Group members, the approach to selection and rotation of members, their range of skills and the appointment of the Chair. The general view is that its current composition is acceptable, particularly if more representatives of developing countries are elected to the GAVI Board.

Recommendations

23. Following the Board's determination of the Working Group's place in the future GAVI architecture and the extent to which tasks and authority will be delegated to its Chair, uncertainties about members' roles and responsibilities should be clarified, particularly in relation to constituency representation. This will affect other issues.

24. If the prime emphasis is on ensuring a balance of skills in a functional Group, then there is an argument for the Chair of the Group – or a selection panel - to have a substantial, or even decisive, role in selecting new members. But if the primary intention is representation and liaison, selection should rest with the constituency.

25. Similarly, the argument for rotation is stronger if members carry a significant constituency representation function than if they are primarily selected for their individual skills. If rotation is adopted, the terms of office should be a minimum of three years and a careful transition strategy planned to safeguard the continued high performance of this Group.

26. The Group is strong on immunisation specific skills; current tasks highlight the importance of reinforcing wider sectoral skills and financial understanding.

27. The Executive Secretary, by virtue of office, should chair the Working Group.

28. Appropriate steps should also be taken to mark the appreciation of individuals' work in all the GAVI components, where appropriate by informing their parent institutions.

9. The Secretariat

The Secretariat is a small, close knit team of 7.5 staff, (5 professionals and 2.5 support staff), working with some considerable esprit de corps in handling high workloads to tight timescales. The consensus of Board members remains in favour of a lean secretariat undertaking essentially administrative tasks, but with a strong strategic contribution from the Executive Secretary. They recognise the need for *limited growth* to tackle increased workload. he current GAVI Executive Secretary, Tore Godal, has made an immense personal contribution to the success of GAVI. His term of office, and that of the current Chair, both end in June 2003. The post of Deputy Executive Secretary is vacant.

Recommendations

29. Assuming the rotation of the GAVI Board Chair proceeds as planned at the end of June 2003, the Board should extend the appointment of Tore Godal as Executive Secretary until at least the end of December 2003, to see in the new Chair. The Board should consider this issue under the item for its June 2002 Board meeting on the recruitment process for the Executive Secretary.

30. A substantive Deputy Executive Secretary should be recruited as soon as possible to provide continuity during the change of Executive Secretary. It should be made clear in appointing a Deputy Executive Secretary now that these posts require different and complementary skill sets, and that the Board would not intend to consider the Deputy as a potential successor to Tore Godal.

31. On the basis of present and forecast workload, the secretariat needs three additional staff:

- 1 additional programme officer. He or she should ideally have skills in demography and statistics, and have experience of working in developing countries.

- 1 additional professional to provide capacity for a full-time officer to work on communications, and another to assist the Executive Secretary in support of the Board, Working Group etc. At present these tasks are combined. The new staff member should be recruited on the basis of high-level communication skills.

- 1 additional support person.

10. Funding arrangements

The main mechanism to fund the Secretariat budget is a $300,000 annual contribution from most Board members, yielding a $7.2 million biennial envelope in 2001-2002. At the end of April 2002, contributions totalling $4.3 million for the 2001-2002 biennium were outstanding. Future fee income may fall, if further Board members are exempted. At the same time there will be significant cost pressures in the next two biennia, principally arising from increases in relation to DQAs, progress reports, financial sustainability plans, and mid term reviews. The rationale for which activities are funded from the Secretariat budget is not wholly clear.

In practice, the Secretariat budget covers only a portion of the costs incurred by Task Forces and the Working Group; partners meet other costs, in addition to their wider contributions. It has been impossible in the time available to map the total contributions made by partners, but the sums are substantial. Concern has been expressed about repeated requests for piecemeal donations, sometimes at short notice and involving heavy transaction costs.

Recommendation

32. The recommendation in section 4 for the development of a consolidated, costed and prioritised two year workplan would provide the means for funding requirements to be reviewed and met on a planned, pooled basis. This would help focus on true priorities not distorted by the ready availability of cash or human resource for a 'pet project', and avoid the risk that an important task is not tackled for lack of a committed donor.

33. Within the framework of that overall workplan, it would be important for the Secretariat to have its own workplan and budget, both approved by the GAVI Board.

34. The possibility of regular direct support from the Vaccine Fund for country support activities such as the conduct of DQAs and for capacity building for implementation should be explored with the Vaccine Fund Executive Committee.

11. Independence and accountability of the Independent Review Committee

Review fieldwork suggests no current cause for concern about the Committee's independence to date. IRC members have identified potential concerns which helpfully indicate areas for special vigilance. While no formal decision has been taken, discussions are in hand about the Independent Review Committee reviewing not only country proposals and requests, but also the various reports of the implementation monitoring process. IRC members generally feel that the significant additional demands arising from this will be manageable, albeit with some difficulty. The needs of the implementation phase will call for a wider range of skills on the IRC to address the broader aspects of health systems and capacity development, macroeconomics, health financing and poverty reduction; and systems management, including statistics and evaluation.

Recommendations

35. **The IRC should continue to report, and be accountable, to the Board. Any comments or observations from other GAVI entities or elsewhere should be forwarded to the Board as separate papers. A proposed new Board sub-group, appropriately constituted, could review the IRC's recommendations and exercise the necessary accountability oversight, including maintaining vigilance against threats to the probity of the process. The actual presentation to the Board should continue to be undertaken by the designated spokesperson of the Committee.**

36. **A note on minimum criteria for IRC membership and the process of selection should be approved by the GAVI Board and made publicly available.**

37. **The next two IRC vacancies should ideally be filled by suitable experts in health systems management and financing. Over time, a more appropriate balance of skills and of gender and geographical representation should be achieved through progressive replacement by natural attrition.**

38. **An early decision should be taken on the scope of the IRC's future responsibilities. If it is to cover monitoring and evaluation activities, it should review its current method of work, in consultation with the Secretariat and the Implementation Task Force. The situation should be reviewed again in the last quarter of 2003, in the light of experience gained, particularly in relation to necessary skills and capacity for the tasks on hand.**

39. **Explicit review criteria, particularly on what would or would not constitute a satisfactory progress report, should be agreed and published.**

40. **The Board should delegate to the Executive Secretary authority for handling resubmissions and IRC recommendations for conditional approvals, and forwarding the definitive IRC recommendations to the Board only when the conditions have been fulfilled by the country(ies). The Board may wish to consider further delegation to the Executive Secretary where resubmissions or changes in specification (e.g. change in quantity of vaccines or to polyvalent vaccine) remain within a fixed percentage of the ceiling originally approved by the Board.**

12. Relationship with the Vaccine Fund

GAVI and The Vaccine Fund (VF) are mutually interdependent. To date, the various GAVI organs and the VF have collaborated effectively and relations have generally been supportive and cordial. The complexity of the formal or legal relationships, and the higher transaction costs involved, is a consequence of the decision to establish a separate Vaccine Fund,

compounded by the fact that GAVI is not itself a legal entity. Since there seems no intention to reconsider this model, the formal difficulties will need to be resolved as they arise.

There is a concern that GAVI and The Vaccine Fund may slowly grow apart, particularly if either of the bodies' current executive heads were to change. Examples cited relate to different approaches to the financial sustainability of immunization in poor countries; possible future views on high cost vaccines and the extent to which the Fund should support vaccine research financially; minor irritations around promotional material; and the uncertainties of the future with regards to the long-term vision and forecasting of funding needs. These are fears and challenges, many of which could be addressed by improved communication and action to promote and widen good relationships.

Recommendations

41. The Board should enact the current proposal that the President of the Vaccine Fund should be invited to become a member of the GAVI Board. There is a VF member on the GAVI Working Group. Tore Godal is already a member of the Vaccine Fund Board and Executive Committee. The VF should be asked to offer these positions to any GAVI Executive Secretary by virtue of office.

42. There should be an alignment of GAVI and Vaccine Fund planning horizons, recognising that the Fund cannot afford a hiatus in its fundraising activities.

43. In the absence of strong formal remedies, maintaining an environment of close personal relations will be key. There should be regular liaison meetings between the VF management staff and the GAVI Secretariat (including as appropriate some Working Group representation). The culture should be one of "no surprises".

44. An earlier proposal for common supervision of the two secretariats by the Working Group and the VF Executive Committee should not be pursued. In addition to possible constitutional problems on the part of the VF, it is difficult to see how effective supervision of the Secretariat and Vaccine Fund management can be exercised by bodies on which the heads of both the Secretariat and the VF management sit. But there should be joint sessions of the two bodies, as required, to address problems and key issues.

45. If the Board accepts the recommendation in section 5 for a Board Operations Review Sub-group, part of that Sub-group's remit should be to keep relations with the Vaccine Fund under review.

13. Conclusion

While some see an inherent tension in seeking to manage an alliance, there is in general a recognition that, if GAVI is to be more effective, it needs in the next phase of its evolution to adopt a more business-like approach – without undermining its special nature or anxiety to avoid bureaucratisation. These recommendations have aimed to achieve an acceptable balance.

MAIN REPORT

1. Introduction and approach to the review

This review was commissioned by the Board of the Global Alliance for Vaccines and Immunisation (GAVI) to examine the current operations of the GAVI Board, Working Group and Secretariat and their relationship with partners in the Alliance and with the Vaccine Fund (VF), leading to recommendations to strengthen GAVI's structure and interactions in order to improve its capacity to meet its objectives during the next five years. Full Terms of Reference can be found at Annex A.

These terms of reference have potentially a very broad scope to be covered in limited time. The summary report of the Board's discussion at its seventh meeting in March 2002 emphasised that "the aim of the GAVI Review is to look at the structures and mechanisms developed to pursue the common goals of the Alliance, particularly the Board, Working Group and Secretariat, in order to assess whether they are effectively meeting the objectives" and that "the Review will be most effective if it maintains focus and specificity". The main focus is therefore on those three bodies, plus a specific requirement to examine the independence and accountability of the Independent Review Committee. The review does not cover substantively Regional Working Groups, ICCs or the Task Forces.

Beyond the scope of this review lie some key strategic issues facing GAVI in relation to its future role within the wider global immunization movement. GAVI operates as one of the tools of the global community for providing additional support to immunization in poor countries. The backbone has been, and will continue to be, the efforts of national governments of the developing countries themselves, with support from traditional partners outside GAVI/VF mechanisms.

This wider movement, comprising notably WHO, UNICEF, CDC, funding governments and agencies of the developed world - bilaterals in and outside of GAVI, the World Bank, regional development banks, and other multi-lateral agencies such as the European Community -, the vaccine industry, research institutions and NGOs, continues to provide extensive support to national Expanded Programmes on Immunization. It is mostly these same governments and agencies that support UNICEF and WHO in undertaking not only their normal work in immunization, but also the additional significant demands of their roles within GAVI. The Polio Eradication Initiative - a partnership between developing countries, WHO, UNICEF, CDC and some bilaterals - has built up a formidable workforce in the field.

A key challenge to GAVI is to determine how best to fulfill its important catalytic role, and how to maintain a close linkage to regular immunization and health development activities so as to ensure cost-effectiveness and avoid duplication. Questions to be addressed include:

- what is the long term future of GAVI and the Vaccine Fund beyond 2005?
- how should GAVI relate to other global initiatives such as the Global Fund to fight AIDS, Tuberculosis and Malaria?
- how best can GAVI smoothly and progressively devolve some of its functions back to more traditional mechanisms and agencies, without losing momentum in achieving its objectives?

- what must GAVI do now to strengthen traditional mechanisms and institutions such as WHO and UNICEF?
- how can GAVI best catalyse assurance of an adequate and dependable level of support to these implementing agencies – the absence of which was at least in part one of the reasons for creating GAVI?
- to what extent, and how, can GAVI optimally use the extensive infrastructure established in the target countries by the Polio Eradication Initiative?
- what is the most cost-effective mechanism to channel GAVI/Vaccine Fund resources in support of country implementation over the short term and long term?
- how can GAVI achieve its added value of strengthening partners and partner coordination for sustainable immunization in poor countries?

The Alliance is an evolving organism, and resolution of these issues will have a decisive bearing on the nature of future functions and support mechanisms. It is beyond the remit of this review but the forthcoming biennial meeting of GAVI Partners in Dakar in November 2002 would seem an ideal opportunity to broach some of these fundamental issues.

In the interim, this report reflects the consensus of interviewees that it is too early for a major restructuring of GAVI's Board, Secretariat and Working Group and that, alongside GAVI's catalytic functions, it must maintain and run the core processes of application and performance reporting, with an agenda that gradually includes the introduction of additional vaccines. The report aims to ensure that its recommendations retain sufficient flexibility to enable the GAVI architecture to evolve to best effect. This is very much a snapshot in time. Subject to the outcomes of the questions raised above, we recommend that there should be a broader review by, say, early 2004 to assess the performance of the Alliance and progress towards its milestones, with consideration of its regional and country operations and support systems.

We are hugely indebted to all those who have contributed so much thought and time to the review. Full acknowledgements are in Annex B.

2. Other reports

This review has taken place alongside a number of other studies whose findings have important implications for GAVI architecture and interactions. We have drawn, with gratitude to their authors, on four specific studies:

- *Lessons Learned: New Procurement Strategies for Vaccines (Mercer Management Consulting)*, due to go to the GAVI Board in June 2002
- *Project to accelerate development and Introduction of Pneumococcal Conjugate and Rotavirus Vaccines* (McKinsey & Company), due to go to the GAVI Board in June 2002
- *A review of GAVI Task Force workplans (John Marshall, consultant),* considered by the Working Group in April 2002
- *Developing Successful Global Health Alliances (McKinsey & Company),* April 2002.

A summary of the findings and recommendations from each study which are most relevant to this review is set out in Annex 3. The studies are available on request from the GAVI secretariat.

The following points, drawn from across the studies, have a general as well as a localised application for the Alliance. In the interests of brevity, this selection is biased to those areas where there is potential for improvement in performance. It should be seen against

the background of the substantial achievements secured by the GAVI partnership in a remarkably short time.

- the wider McKinsey study found that successful global health alliances have a compelling overall goal and a focused scope, with a clear understanding of the alliance's added value and what is required to capture this value[1].
- skilled, credible and committed individuals are needed to drive the alliance forward. These include actively engaged senior champions in partner organizations, an accountable alliance leader, and a focused working team (eg more than 50% dedicated) to provide the horsepower1.
- the need is for a governance structure that provides fast and strong decision-making while involving a large number of people and initiatives. This is assisted by having only one or two primary decision-making bodies, with small numbers of members - "representative" if necessary -, and by a decision-making protocol for the 10-20 most important decisions1.
- the Mercer study notes the ineffectiveness of a loose alliance in *implementing*, as distinct from developing, policy. The strategy phase requires broad thinking, consensus building, and informal participation. Planning and execution require an active, properly resourced and accountable project management function. Both the Mercer and the McKinsey ADIP studies recommend the appointment of a highly competent "project manager", supported by a team as necessary, to provide the leadership required to push forward a challenging plan.
- Mercer's project management model highlights the need for some sort of GAVI-empowered oversight body to create accountability and in recognition that "GAVI's procurement strategy" goes beyond the goals and implementing scope of any one partner.
- orchestration and collaboration are also critical, given the reliance on commitments from part-time partners. But the Mercer study of GAVI procurement noted a lack of lead accountability, overlapping and unclear roles, and inconsistency between partners about priorities. Within the current GAVI operating model, three bodies – the Board, the Secretariat and the Working Group – have coordinating and accountability mandates but lack either the resources or authority to be effective.
- for successful alliances, the "minimums" of operational planning should be in place. These include clear partner commitments (eg people, money, technology); performance metrics and milestones; and detailed operating and funding plans, updated as needed. It can be helpful to track alliance performance in three dimensions: outcome performance, activity performance and relationship performance.
- John Marshall's review of Task Force workplans found little indication of processes that formalise coordination, synergies and avoidance of duplication between the Task Forces, although there are some - but insufficient - informal processes. He recommended that, in future, each Task Force workplan should align directly with the respective GAVI Strategic Objectives and Milestones, and subsequently form the platform for the overall GAVI workplan. The Task Force workplans (and the GAVI workplan) should identify priorities, tangible deliverables, human and financial resources, critical timings, key issues and GAVI partner commitments.

[1] from "Developing Successful Global health Alliances" with permission of The Gates Foundation and McKinsey and Company

3. Key findings from the review

The sections below contain the meat of the review, and our recommendations on specific issues. Inevitably they concentrate on what might be done better rather than describe in full what is being done well. They need to be read in a wider context – one that captures the overwhelming tone of approval, enthusiasm and support for GAVI that suffused our fieldwork, that understands how much the Alliance has achieved and how ambitious its goals remain, and that recognises the need for some fine-tuning but is fearful of damaging a delicate organism. This section summarises the key recurring themes from our fieldwork interviews.

Broad satisfaction with GAVI's achievements

The prime finding is satisfaction with the performance and achievements of the Alliance so far, and of the individuals who contribute to its work. There is a strong conviction that GAVI does add value, even if the work to define that value is not yet complete. "GAVI has brought a level of coordination that never existed before. And a level of resources". "For an entity as young as it is, it is very functional".

Divided views about the need for an external review

We encountered strongly divided views about the need for this review. Some feel that it is too early in GAVI's flowering to be pulling it up to examine the roots. Some would have preferred an internal consideration of the issues among the partners. Others welcome a fresh look. But whatever their view, almost everyone warned against major change at this stage. "There are not compelling problems, there are not major structural issues". One interviewee reminded us of the clinical precept, "first do no harm". We have tried to follow that.

Amoment of transition

GAVI is at a point of transition. It is reaching the end of an initial phase when the emphasis has been on activity at global level to agree policies and procedures, and moving to one of implementation with greater demands at regional and country levels. At the same time, the Board faces new strategic challenges. GAVI infrastructure has grown organically. Partners are strengthening their own efforts in immunization. The Vaccine Fund has assembled a sizeable management team. All these carry implications for the various GAVI elements. "GAVI's performance to date has been stellar but it needs to mature".

A strategic Board and greater delegation

While specific GAVI's strategies are beyond the scope of this review, we should note a feeling amongst interviewees that the Board should spend a higher percentage of its time addressing key strategic issues. As an example, many interviewees feel the time has come to shape a clear view about the future of the Alliance beyond 2005, the next phase of its activities and its future funding.

The corollary is that it should spend less time on operational detail, delegating specific authorities. There are divergent views about whether the Working Group or the Secretariat should be the prime locus of delegated authority. There is also scope for experimentation with more extensive use of Board sub-groups.

A more business-like approach

Respondents are very protective of the special nature of the Alliance and its determination to avoid becoming bureaucratic. And some see an inherent tension in seeking to manage an alliance. Nonetheless "there is an increasing recognition that if GAVI is to be more effective, it needs to move from a voluntary group of officials to a more business-like, managed system". And there is a concern about demonstrating accountability. In part, this requires a more managerial approach, particularly with regard to:

- delimiting activities and developing a longer range and more comprehensive workplan
- identifying and focusing on priorities
- assigning responsibilities and defining accountabilities, without overlaps or structural confusions
- monitoring the performance of the Alliance, as well as that of countries.

Reliance on key individuals and greater institutionalisation

In part also, it turns on human resources. One of GAVI's strengths is the close-knit group of key people across its various elements who have driven it forward. But equally, GAVI's reliance on a few highly committed but heavily pressed individuals makes it vulnerable to change. The proposed retirement in June 2003 of the widely-respected Executive Secretary, Tore Godal, - at the same time as the change of Chair – underlines this point. Many key individuals are dealing with GAVI issues on a part-time basis, have other pressing responsibilities within their partner organisation, and have career choices to make. Planning for transitions, grooming successor "global goal-owners" and some greater degree of institutionalisation must be considered.

At the same time, a strongly-voiced view reminds that GAVI is not an entity in its own right - it is merely a facilitating agent whereas the partners are operational - and that its secretariat is consequently and designedly "lean". There seems to be some ambivalence about GAVI's engagement in implementation. One Task Force representative notes "we are continually oscillating between coordination and implementation".

Heavy but manageable workload

A heavy burden of workload is falling on the Board, the Secretariat, the Working Group, the Task Forces, the Independent Review Committee and increasingly the Regional Working Groups and the ICCs. Future demands are likely to be increasingly onerous. We have concerns on this score. However, the general consensus of interviewees is that the existing structures will cope with forecast workload, albeit with difficulty.

Greater transparency and more effective communications

Recurring comments relate to the need for greater transparency, about for example

- appointments to the GAVI Board, Working Group and Task Forces
- funding, particularly about partners' contributions, in cash and in kind
- and, among some, about decision-making.

This is a substantive issue which should be addressed, but it is also related to the common desire for swifter and more effective communications.

4. GAVI Mission, Objectives and Workload

GAVI Mission and Goals

The Global Alliance for Vaccines and Immunization (GAVI) was created in 1999 with the overriding mission "to fulfil the right of every child to be protected against vaccine preventable diseases of public health concern". Its goal is "to save children's lives and protect people's health through the widespread use of safe vaccines, with a particular focus on the needs of developing countries". GAVI underwrites the goals and objectives set by the World Health Assembly and the World Summit for Children, with particular reference to polio eradication and reduction of measles mortality and morbidity.

The Vaccine Fund (VF), an independent body, was established to help fulfil GAVI's mission (see section 12).

Strategic Objectives

GAVI has six strategic objectives:

- improving access to sustainable immunization services
- expanding the use of all existing safe and cost-effective vaccines, and promote the delivery of other appropriate interventions at immunization contacts
- accelerating the development and introduction of new vaccines
- accelerating research and development for vaccines and related products specifically needed by developing countries, particularly vaccines against HIV/AIDS, malaria and tuberculosis
- making immunization coverage a centrepiece in the design and assessment of international development efforts, including debt relief
- supporting the national and international accelerated disease control targets for vaccine-preventable diseases.

It has also established a set of milestones as minimum global targets to monitor the effectiveness of the Alliance. These include:

1) by 2005, 80% of developing countries should have routine immunization coverage of at least 80% in all districts
2) by 2002, 80% of all countries with adequate delivery systems should have introduced hepatitis vaccine; by 2007 this should have been achieved in all countries
3) by 2005, 50% of the poorest countries with high disease burdens and adequate delivery systems should have introduced Hib vaccine
4) by 2005, the vaccine efficacy and disease burden in respect of rotavirus and pneumococcal disease should be known for all regions, and a mechanism should have been identified to make the vaccines available for the poorest countries.

While GAVI's focus is clearly on the poorest countries, its mission, goals and milestones cover all children in all countries. The specificity of the objectives and milestones, and the need to retain focus on delivering them, remain perhaps the biggest challenge facing the Alliance.

Although the Alliance is still evolving, it has made a remarkable start in raising global awareness of the value of vaccines. It has mobilised significant additional resources for immunization, established a hitherto effective architecture for improving coordination of

the partners and their support to eligible countries, and is promoting the financial sustainability of immunization services.

Workload

Working towards achieving these goals and milestones is a formidable undertaking that is posing major challenges to all components of the GAVI architecture. As GAVI moves through the transition from policy and strategy development to planning and implementation, with simultaneous activities in both phases, each of its entities has to bear significant incremental activities.

Formal meetings of the Board, with heavy agendas, seem likely to continue at the current rate of three rather than the two per year initially anticipated. Board teleconferences have become an almost monthly necessity. GAVI-related work has increasingly become the major component of some Working Group and Task Forces members' day to day work, and many partners have found it necessary to strengthen their immunization teams. Secretariat workload has grown commensurately in relation to processing proposals and monitoring and evaluation documentation. This is, of course, a mark of GAVI's success. A key aim was to focus more effort as well as more attention and more funding on immunization issues. But in reviewing the key GAVI elements of the Board, Working Group and Secretariat, it is important to appreciate the workload demands facing them.

High priorities for the immediate GAVI agenda are such stretching strategic and policy issues as:

- improving access and national capacity development efforts
- vaccine forecasting and procurement management
- financial and political sustainability
- harmonisation and work towards integration with other global disease reduction initiatives
- defining the role of GAVI in middle-income countries
- preparatory work for opening Window 3 of the Vaccine Fund.

The Vaccine Fund's paper on its 10-year strategic options is to be considered at the June 2002 GAVI Board Meeting. This will highlight the call for GAVI to define its own longer term vision and strategic priorities.

Ongoing activities that need to be brought to speedy closure include:

- pushing forward the agenda for realignment with accelerated design and formulation of ADIPs and their management structures
- development, application and revision of Data Quality Audits (DQAs)
- field testing, revision and application of the financial sustainability planning guide
- finalisation of the GAVI Global Advocacy Plan
- development of the guide for the mid-term reviews
- establishment of GAVI databases
- development of the immunization capacity building training programme and training manuals for national staff and their country national level partners.

Work areas that will further add to the existing workload include:

- enlarging the Alliance (more OECD partners, private sector, and Foundations, etc)

- enrolment of the outstanding countries eligible for support from the Vaccine Fund and assessment of new and potential countries
- implementation of decisions on studies such as those currently being undertaken by Mercer, McKinsey, John Marshall and this review
- compilation of "lessons learnt" from the mid-term reviews
- an in-depth evaluation of progress towards the GAVI milestones.

At the same time, programme management and oversight will be particularly demanding in time and effort. The following summary forecast of country proposals, monitoring and evaluation to 2006 - only one element of the Secretariat's provisional medium term work programme and a major programme for the Independent Review Committee – is indicative of the rising workload. Moreover, managing the strategic tasks of the implementation phase - already complicated by the number, complexity and diversity of the VF eligible countries - will demand new skills beyond those normally found in the field of immunization. Nonetheless, the view of those most closely concerned is that, with some modest strengthening in numbers and skills, the tasks will be manageable, albeit with difficulty.

Forecast of GAVI country proposal and monitoring activities 2001-2006

Data source: GAVI Secretariat, May 2002

Activity	2001	2002	2003	2004	2005	2006
Proposals from countries	62	50	45	50	37	20
DQA	8	16	24 (16+8*)	30 (18+12*)	13*	5*
Inception report	24	29	19	-	-	-
1st progress report	-	21	25	19	-	-
Financial sustainability plan	-	13	21	28	10	-
Mid-term review	-	-	34	22	19	-
2nd progress report	-	-	21	25	19	-
3rd progress report	-	-	-	24	25	19
4th progress report	-	-	-	-	24	25
5th progress report	-	-	-	-	-	24
Final review	-	-	-	-	-	24

*asterisked figures indicate estimates of repeated DQAs, following a "not validated" assessment in an earlier DQA. The GAVI secretariat estimates 50% of countries will repeat DQA once, and 25% twice. A more detailed breakdown is given in Annex 8.

Regional Working Groups and ICCs

At regional and country level, the role of the Regional Working Groups (RWGs) and the Inter-Agency Coordination Committees (ICCs) has become larger and more vital. The Regional Working Group concept has been endorsed by the Board, but only as an informal structure. In view of their increasing role in support of country implementation and capacity building, the Implementation Task Force is soon to present to the Board a proposal for formalising RWGs, including adaptable, generic terms of reference defining roles, responsibilities and lines of accountability.

ICCs or their equivalents remain mostly forums of "immunization people", with neither the skills nor status to influence country priorities and resource allocation, either at the macro level or within the health sector itself. Any direct linkages with higher level partnership coordination mechanisms (in the context of CDF/PRSP, SWAps, UNDAF and national MTEFs) are exceptional and mostly tenuous. Various GAVI papers have highlighted inadequacies in country level capacity to absorb effectively the significant resources made available through the Alliance. This, arguably, remains the greatest potential risk to the speedy attainment of the strategic objectives and milestones. Focusing intensive effort towards strengthening ICCs therefore deserves a high level of priority in GAVI.

The need for a consolidated plan

All this constitutes a formidable workload under any circumstances, but poses a daunting challenge for structures that rely essentially on voluntarism within a relatively loosely knit partnership. Moreover, these structures operate in an environment that is in need of more clarity about current and future roles, functions, linkages and lines of accountability.

Capturing the full picture of GAVI's activities, and managing them to good effect, is made difficult because of the absence of any comprehensive outline of the work and budgets of the Secretariat, Working Group and Task Forces.

We therefore recommend as an immediate step the development by the secretariat and approval by the Board of a consolidated two-year workplan for GAVI, including budget and sources of funding. Its prime function will be to ensure a clear focus on shared priorities, assist planning and facilitate oversight and accountability. Such a plan should be developed for the 2003-2004 biennium.

The consolidated plan should be developed within the strategic objectives and priorities set by the Board and its determination of GAVI's future operation within the wider immunization movement. The plan would derive from the biennial plans and budgets of the Secretariat, Working Group, the Task Forces and Regional Working Groups. It should specify workstreams, deliverables and milestones; timescales and accountabilities; and budgets. The budget for each area of work should include amount, sources, and any identified gaps in funding. It should also indicate the dollar value of partners' support activities. To facilitate budget management, the format and budgeting cycle of the host agency should be adopted.

Such a plan should be funded from all sources available to the GAVI, and should go a long way to relieving the understandable irritation felt by some contributing partners about the piecemeal approach to requests for additional funding of GAVI activities.

5. Functions and interactions of the GAVI Board, Working Group and Secretariat

Building on existing relationships

The Alliance needs to become more business-like but it would, in our view, be a mistake to apply rigidly to GAVI management precepts designed for single-entity, centrally-overseen, hierarchically-structured organisations. GAVI is an alliance rather than an organisation, dependent for its success on voluntary cooperation and partners' collective dedication to a vision. Our search has therefore been to identify ways of improving functional effectiveness by building on existing informal relationships and understandings.

In pursuit of this aim, we offer a range of alternative or complementary options designed to do as little violence as possible to the GAVI ethos. At the same time, they recognise that attention has to be paid at this critical stage in the life of GAVI to handling the growing burdens on Board members, clarifying the authority and accountability of the Working Group and Secretariat, enabling progress in implementing policies to be tracked, improving transparency and putting GAVI in a position to demonstrate evident success. With apologies, we - like interviewees - have found it impossible to discuss these issues without recourse to the commonly understood terms, 'management' and 'managerial'.

Key recommendations on the functions and interactions of the GAVI Board, Working Group and Secretariat

- *a high-level Board primarily concerned with Alliance strategy, key policy issues and accountability oversight*
- *greater use of Board Sub-Groups for issues which only the Board can address*
- *greater delegation to the Executive Secretary supported by the Working Group and the Secretariat, and also to the Independent Review Committee*

Board consideration to date: the Roles and Responsibilities paper, October 2001

A seminal paper for this review has been the paper on GAVI and The Vaccine Fund – Roles and Responsibilities (hereafter called the Roles paper) developed by the Working Group and the Secretariat, and considered by the GAVI Board in October and November 2001. Its remit was similar to that of this review: to take stock of GAVI modus operandi to assess whether the entities are fulfilling their roles, whether new mechanisms are needed to address new needs, and how to move the process forward. But it was wider, encompassing the full range of GAVI elements, and explored less detail with regard to the Board, Working Group and Secretariat.

The paper specifies the current functions of all three elements. For the Board, it stresses the importance of drawing members from the highest levels in partner agencies. In terms of interactions with the other GAVI elements, the Board is the overall decision-making authority for the Alliance, appoints the Executive Secretary, decides partners' representation on the Working Group, and monitors the performance of both the Secretariat and the Working Group. The paper does not envisage any substantial change in Board function, though it notes that a number of issues would benefit from more active participation by Board members outside general Board meetings, (for example, providing leadership to promote new funding approaches and strategies on the part of donors, multilateral agencies and lending banks at global level, in order to ensure financial sustainability). The Board should also carry responsibility for issues arising from the alignment exercise,

coordinating efforts with accelerated disease control initiatives and other new health initiatives such as the Global Fund to fight AIDS, Tuberculosis and Malaria.

In relation to the other two GAVI elements under review, the Roles paper states that the Secretariat and the Working Group work very closely together but have distinct roles and responsibilities, with the Working Group performing technical functions and the Secretariat performing administrative functions. But our fieldwork suggests that there is (understandable) confusion about some functions – for example, the coordination and oversight of the Task Forces (see box). And the two bodies are often quoted in tandem, eg "working together, the Secretariat and the Working Group develop the workplans of the Alliance, consolidating the workplans of the Task Forces". It is difficult to tell where accountability rests.

Board Roles and Responsibilities paper, 2001

extract from Secretariat functions:

- coordinates the activities of the task forces
- coordinates and monitors the progress of activities including progress towards the Alliance milestones

extract from Working Group functions:

- coordinates the operations of the task forces and assesses their progress on workplans
- oversees operations of GAVI structures, including involvement in the appropriate task forces

The *Roles* paper sets out three options for their future working relationship:

1: the Working Group and Secretariat as Senior Management Team headed by a CEO. While larger policy and financial decisions would remain at Board level, day to day managerial decisions would be delegated to this team.

2: the status quo, with the Working Group and Secretariat maintaining their "separate" functions.

3: the Working Group as Virtual Secretariat, taking responsibility for all current Working Group and Secretariat functions but with no delegated authority.

The paper recommended option 2, the status quo, for the moment, pending further elaboration of the three options and consideration of "moving towards basic managerial principles". This review was subsequently established.

This review's findings

The contemporary studies cited in section 2 are strikingly in agreement about the need for GAVI to ensure that it is operating on the basis of some "basic managerial principles", particularly in relation to a compelling goal and focused scope, leadership, clear lines of accountability, appropriate skills and capacity, and the "minimums" of operational planning. These "minimums" include clear partner commitments, performance measures and milestones, and detailed operating and funding plans, updated as needed. We agree that these are essential if the Alliance is successfully to handle and track the full scope of its current activities, whatever its future evolution.

During our fieldwork, most GAVI Board members expressed a wish for stronger management processes and we make recommendations about these in sections 4 and 6. But while there was generalised support for 'being more managerial', there was very little for any consequential structural or functional change. And there were some minority views at either end of a spectrum:

- from a conviction that if the Alliance is to add value, it has to be managed to that end, and that this task requires leadership and capacity;
- to an equally strongly felt opposing view that it would be against both the philosophy and the longer term aims of the Alliance to develop any substantial institutional capacity.

There was a similar ambivalence about the role of the Executive Secretary. While there was keen support for his role as facilitator and appreciative recognition of his importance as a strategist, views diverged about the extent to which any GAVI Executive Secretary should play a high-profile directional leadership role.

These are important findings, given that the very success of GAVI to date has been its ability to forge an alliance of interests in which all partners find a sufficient comfort level to participate effectively. We were repeatedly told of the considerable respect and trust which exists among Board members, and in other GAVI components particularly the Working Group and the Secretariat. We have accepted that these strengths should not be compromised. The challenge is to increase effectiveness with the minimum of structural change.

The GAVI Board

The Board has two broad sets of functions: service and control. The GAVI Board's service function is crucial to the Alliance, harnessing the efforts and resources of the partners to achieve common objectives, establishing contacts and fund-raising, creating a high profile for immunization issues, making immunization a centrepiece of global and national socio-economic development agendas and frameworks, and providing advice to other GAVI components. This should remain unchanged.

Given the lack of any significant formal delegation of decision-making, the GAVI Board exercises its control function at a much greater level of detail than the conventional Board tasks of appointing a CEO, approving strategic and resource plans, and reviewing management's major decisions and overall performance. In practice, all issues of any consequence come to the Board. Even so, some Board members feel they have too little opportunity to probe the merits and debate strategy. In part this concern relates to the nature of the submissions (see also section 6). In part it relates to the time and range of expertise needed to deal with the Board's large and complex agenda. Concern has been expressed about the heavy workload the Board Members have had to shoulder over this formative period, and there have been calls for reduced frequency of Board Meetings and conferencing.

Board Sub-groups

One structural solution currently under debate is a greater use of Board sub-groups for those issues which must continue to be addressed by the Board itself. They will usually be ad hoc, to deal with a specific one-off issue (such as those which worked on the China Memorandum of Understanding and the terms of reference for this review). But there may be benefit in a strictly limited number of standing Board sub-groups, for example

- *Operations and Review Sub-Group*
  To be responsible for Board oversight of the implementation of the consolidated GAVI two-year work plan, including monitoring progress towards the immunization goals. It would also, on behalf of the Board, provide oversight of the functioning and operations of the Secretariat and Working Group; and keep under review relations with the Vaccine Fund.
- *Country Programmes Sub-Group*
  To be responsible for Board oversight of activities central to an improved level of success in country programme implementation. These areas include disbursement, procurement and delivery of vaccines and other related supplies, and capacity building. Initial consideration of recommendations and reports from the Independent Review Committee to the Board, as discussed at the May 2002 Board teleconference, should also fall within its terms of reference.

Any such subgroups would report to the full Board, and seek Board approval for proposals.

The arguments against this development are that subgroups would add bodies to a complicated structure, and they would certainly demand more time from those Board members who served on them. The arguments in favour are that they would allow proper Board consideration of important issues, would make better use of Board time and skills and provide an opportunity to co-opt additional experts as necessary to fill skills gaps. Open and appropriate appointments to the subgroups would be a prerequisite.

Action to take forward this proposal will need to be framed within the context of the Board's decisions on review recommendations in general. Subject to that, **we recommend** that the Board should constitute an ad hoc Board subgroup to consider the options for experimenting with Standing Board subgroups, and for the specific areas for delegation to other entities of GAVI (see also below). If the Board decided to establish an Operations and Review Board Sub-group, this might come into effect in the last quarter of 2002 so as to be able to consider workplans for 2003-4 and proposals for the 2003-2004 biennial budget.

Greater delegation

A complementary *functional* solution lies in greater delegation. Under this scenario, GAVI's high-level Board would be primarily concerned with Alliance strategy, key policy issues and accountability oversight.

It has been suggested that it would be most helpful to determine the precise range of functions and authorities suitable for delegation in a participative way, involving members of the Board and other GAVI components, as a follow-up to this review. We therefore **recommend** this.

But **we also recommend** that the Board should retain full authority for:

- approving GAVI's objectives, milestones and overall strategy
- determining major policy issues, including implementation policy issues
- determining GAVI structures, and constituency representation on the Working Group
- nominating the Executive Secretary and holding the post-holder to account
- approving membership of the Independent Review Committee, and determining recommendations of the IRC other than any specifically delegated elsewhere
- making recommendations for funding approval by the Board of the Vaccine Fund

- exercising a challenge and support function in relation to the Secretariat and the Working Group
- exercising an accountability oversight function. It should approve the GAVI consolidated workplan and budget, and workplans and budgets for the Secretariat and for the Working Group; and monitor progress reports and annual performance reports.

Possible structural models

If greater delegation is agreed, the question then is the nature of the structure below the Board, and the locus of delegated authority.

i) the accountable Secretariat

One textbook option is to move towards a more conventional structure with a high-level strategic Board and a larger, highly skilled executive Secretariat under an empowered and accountable Executive Secretary; and to draw on the strengths of the Working Group as a strategy and policy think-tank in support of both. In this option, the Task Force Chairs would report to the Executive Secretary, as would any new project managers, eg ADIT leaders, or a procurement project manager. This would provide both:

- a single clear point of accountability to the Board for delivery of results, in the Executive Secretary; and
- in the secretariat, a stable cadre of personnel with an appropriate balance of skills who would be dedicated full-time to the effective implementation of the consolidated GAVI workplan as approved by the Board. This would help meet concerns about excessive workload on Working Group members, and GAVI's vulnerability to the withdrawal of individuals currently working on key tasks. It would though weaken the direct links with agencies.

One interviewee argued that "as we move ahead, GAVI's engagement will decrease to focus on support to effective country work through strengthened partner collaboration at that level, with looser links at the global level as the Vaccine Fund assumes the global advocacy role for effective resource mobilisation. In the interim, the secretariat should take more of the functions of translating the decisions of the Board into action and to account to the Board".

ii) the hybrid model

We are conscious though of the strength of feeling among Board members about avoiding major change, particularly in the size and nature of the secretariat. This of itself rules out a range of other options.

And we have been impressed by the high regard for the contribution of the Working Group, under the chairmanship of the Executive Secretary. "The Working Group is a very synergistic group of people who intuitively like each other and are very committed to a single purpose. The Working Group is the engine of GAVI". It provides both the working linkages into agencies and institutions, and "the common ground where individual representatives can meet without institutional baggage". Good teams are gold dust. And GAVI has need of high-calibre contributions.

Where there have been occasional questions raised, for example about appointments to the Working Group and oversight of its work, these can be answered by better communication and process management.

An alternative option is therefore to retain broadly the de facto current structure, with a "lean", predominantly administrative secretariat and the Working Group as the dynamo

of Alliance technical activities below the Board. The Executive Secretary would provide the bridge, as head of the Secretariat and Chair of the Working Group, a position which **we recommend** he should hold by virtue of being the Executive Secretary (see also section 8). In this hybrid position, the Executive Secretary would be accountable to the GAVI Board, through its Chair, for the performance of the Secretariat, the Working Group and the Task forces.

In this model too we recommend that the Board should focus on strategy, major policy issues and accountability oversight, delegating clear authority for day to day operational decisions to the Executive Secretary supported by the Working Group and the Secretariat. It should be a specific remit of Working Group members to support the Executive Secretary/Chair in fulfilling his accountability requirements. We have discussed during fieldwork whether it would be practicable to make the Working Group collectively responsible for delegated authority and have concluded that it is not. The line of accountability has to be clear and cannot be shared amongst ten people. But we would also expect any such model to be operated in the participative, facilitative manner which characterises current Working Group relations.

Delegation of authority would take place within a clear strategic framework set by the Board, and detailed workplans and budgets approved by the Board for both the Secretariat and the Working Group.

The appointment of Chairs of the Task Forces should be endorsed by Executive Secretary as Chair of the Working Group. They would report to the Executive Secretary/Chair and should attend Working Group meetings.

As noted above, the Independent Review Committee would continue to report direct to the Board in the interests of independence and probity.

This is in essence similar to the first option of the Board's Roles and Responsibilities paper.

iii) the accountable Working Group

A variant on this option, designed to establish a clear separation of accountabilities between the Working Group and the Secretariat, would be for the Board to establish the Working Group as a formal body, having delegated powers vested in it through an accountable Chair who would report to the GAVI Board through its Chair. In this model, one more commonly found in the public sector than the private, the role of the Executive Secretary would be to provide secretariat support to the WG Chair and the Group as a whole. This option would provide a clear locus for delegation but would increase the workload of Working Group members and sits uneasily with the current role and standing of the Executive Secretary.

iv) the Working Group as Virtual Secretariat

This was one of the three models set out in the Board's 2001 Roles paper. In this option, the Working Group would take responsibility for all current Working Group and Secretariat functions but with no delegated authority. In order to free more time to be involved in the administrative tasks currently conducted by the Secretariat, Working Group members would need to reduce their roles in respective partner institutions, thereby reducing their ability to act as bridges between the Alliance and partners.

v) the status quo

There remains the option of maintaining the *status quo* with minimal delegation, at least in the immediate future. It has served the Alliance to date. But we believe the Board will struggle to cope with the formidable workload briefly described in section 4 without delegating some of the more operational tasks. The time and talents of these very senior

people would be better employed in focussing on strategy, oversight and networking. If the Board does decide in favour of the status quo, we would nonetheless recommend specifying with greater clarity the accountability of the Working Group and the Secretariat.

Recommendation

Our view is that the purity of models (i) and (iii), while perfectly feasible, do not accommodate well to the critical balance of relationships on which GAVI's current success is based. And for the reasons set out above, we believe that seeking to maintain the status quo through the implementation phase will result in overload at Board level. Similar considerations apply to model (iv) which envisages no delegation to a virtual secretariat.

Our recommendation is therefore that the Board should approve in principle option (ii), retaining a lean, predominantly administrative secretariat and a technical Working Group formally chaired by the Executive Secretary. Authority and accountability for day to day operational decisions should be delegated to the Executive Secretary supported by the Secretariat and the Working Group. It would be his responsibility to ensure that the Secretariat and Working Group contribute effectively, without overlap or conflict.

It was proposed during field work that, in the spirit of the Alliance, the precise extent of delegation should not be specified in this report but should be developed participatively, involving interested parties from GAVI entities. We have therefore recommended above that the Board should convene an ad hoc subgroup to consider the options both for standing Board sub-groups and for the specific areas for delegation to other GAVI entities.

We make a recommendation in section 11 about delegating to the Executive Secretary authority for handling resubmissions and IRC recommendations for conditional approvals, and forwarding the definitive IRC recommendations to the Board only when the conditions have been fulfilled by the country(ies). The Board may wish to consider further delegation to the Executive Secretary where resubmissions or changes in specification (e.g. change in quantity of vaccines or to polyvalent vaccine) remain within a fixed percentage of the ceiling originally approved by the Board.

6. Management processes, including decision-making

GAVI Board processes and decision-making protocols

The Board conducts business through regular Board meetings and teleconferences. Extraordinary sessions (for both mechanisms) have so far been the rule rather the exception. Agendas for Board meetings and teleconferences are prepared by the Executive Secretary and approved by the Chair of the Board. Each of the recognised constituencies may raise issues for consideration by the Board, either through the Secretariat or through their representative on the Board.

Background documents are generally prepared by the Secretariat in consultation with other GAVI components and member organizations, as appropriate. The Independent Review Committee prepares its own reports to the Board. Many policy documents, including those originating from Task Forces, are put forward by the Working Group.

The Board is the highest decision-making authority in GAVI. In the spirit of the Alliance, the underpinning philosophy is that it should make decisions by consensus. As a last resort, if consensus is not achievable, there is provision for voting on a one member, one vote basis. This has to date been invoked only once. There are no powers of veto.

The Board agreed at its first meeting that "decisions by the GAVI Board would not override the authority of the governing Boards of each individual partner organization" and were thus "not binding on any Member Organization". A fundamental operating principle

of the Alliance therefore is the dependence on each partner and constituency to ensure the consistency of the policies and decisions of their individual agencies and constituencies with those of GAVI.

The Executive Secretary, as Secretary to the Board, prepares the record of Board meetings and teleconferences, and oversees all follow-up action on decisions and directives of the Board.

Fieldwork suggests a general satisfaction with these arrangements, with the following qualifications:

- there should be greater consultation on the agenda
- several Board members feel that policy papers too often tend to be prescriptive, offering one recommendation rather than a range of options with sufficient detail of the pros and cons to facilitate genuine Board consideration and decision making. The Board has asked for options-based papers in future.
- in the past papers have sometimes been unclear and/or late. Documents/proposals destined for the Board should be timely and more user-friendly, with clear, concise papers and a covering one-pager to highlight the issues, their main implications (including resource implications where appropriate), the recommendation(s) and the action required of the Board.

Below Board level, normal meeting practices in relation to agendas and meeting notes apply. In the Working Group there are few formalities about decision taking, and no recourse to voting. Issues for consideration include:

- ensuring that important Working Group papers are circulated sufficiently in advance of the meeting to allow members time to reflect and consult, and that there is opportunity for the views of members who are unavoidably absent to be taken into account
- redoubling efforts on the vexed problem of communications to dispel an unease in some quarters about lack of transparency. This seems to stem at least in part from lack of easy access to information. We appreciate that the Secretariat has been very hard-pressed. We hope this situation will be eased by the recent engagement of a communications officer on a consultancy basis. In particular the GAVI website should be kept up to date. While we are reluctant to increase Board members' paper mountain, fieldwork interviews suggested that they would find helpful a snappy information one-pager for each meeting, highlighting key events, decisions, discussions, issues arising since the last meeting and noting forthcoming ones.

Management processes and information

We endorse the finding of the McKinsey study of successful global health alliances that some "minimums" of operational planning are advisable. The emphasis here should be on the approval and use of a small number of simple but meaningful tools to promote efficiency, communication and accountability. GAVI's management information processes should not become a paper blizzard of bureaucracy.

The GAVI Board has a strong shared commitment to a common purpose, six strategic objectives and a set of specific milestones. These provide a robust framework for more detailed operational planning and management information.

We have recommended in section 4 the development by the Secretariat and approval by the Board of a consolidated biennial workplan for GAVI, including budget and sources of funding.

In addition we endorse:

- the proposal made during the Board's teleconference discussion on 23 May of the 2002 GAVI workplan that the Board must be able to track progress against the milestones. This may well entail the development of intermediate milestones. This needs to be coordinated with the work of the Implementation Task Force's monitoring and evaluation sub-group.
- the recommendation from John Marshall's consultancy that each Task Force workplan should align directly with the respective GAVI strategic objectives and milestones, and by implication be reviewed alongside each other to ensure comprehensive as well as coherent coverage of tasks. And that those workplans, and the GAVI workplan, should identify priorities, tangible deliverables, human and financial resources, critical timings, key issues and GAVI partner commitments – and accountabilities.

And we recommend:

- the development of similar simple but meaningful biennial workplans for the Working Group and Secretariat. With those of the Task Forces, they would form the platform for the overall GAVI workplan and help the Board and GAVI components ensure a sharp focus on key priorities within limited human and financial resources.
- the provision to the Board of summary annual reports on performance, not least to record learning about what has worked well and what has not to help preserve institutional memory.

7.The GAVI Board

Functions

The functions of the GAVI Board are discussed in section 5; a summary is attached in Annex 4. Proposed functions focus heavily on strategy, key principles and policies, and oversight accountability (including approval and monitoring of GAVI component workplans/budgets)

Composition

The GAVI Board is composed of 15 members from among the Partners, plus a Chair. Membership is considered to be by the relevant agency; individuals sitting on the Board represent their agencies and their constituencies

Four members are renewable, serving renewable two-year terms: WHO, UNICEF, the World Bank, and the Bill and Melinda Gates Foundation.

Eleven members rotate. Their terms will normally be for two years, non-renewable. Non-renewable members hold their seats until their successors are elected. These eleven rotating members are:

- 1 representative of *Foundations*, currently the UN Foundation (July 2000-June 2003) succeeding the Rockefeller Foundation (July 1999-June 2001)
- 1 representative of *industry from developing countries*, currently CIGB, Cuba (January 2001-December 2002)
- 1 representative of *industry from OECD countries*, currently Wyeth-Ayerst (January

2002-December 2003) succeeding Aventis Pasteur (January 2000-December 2001)

- 1 representative of *research institutions,* currently the Institut Pasteur (July 2001-June 2003) succeeding NIH (July 1999-June 2001)
- 1 representative of *technical health institutions,* currently CDC (January 2001-December 2002)
- 1 representative of NGOs, currently the Children's Vaccine Programme at PATH (July 2000-June 2002)
- 2 representatives of *developing countries*, currently:

  - Mali (January 2001-December 2002) succeeding Zimbabwe (July 1999-December 2000)

  - India (January 2002-December 2003) succeeding Bhutan (January 2000-December 2001)

- 3 representatives of *OECD countries*, currently:

  - Norway (January 2001-December 2002)

  - UK (July 2001-June 2003)

  - US (January 2002-December 2003).

  The Netherlands was a member from January 2000-December 2001, and Canada from July 1999-June 2001.

Other global alliances have taken a somewhat different approach to the composition of their Boards. For example, the Global Fund to fight Aids, Tuberculosis and Malaria has 18 voting members, including seven from developing countries and seven donors, plus four ex officio members without voting rights including WHO and UNAIDS. By contrast, the newly-launched Global Alliance for Improved Nutrition (GAIN) has a Board of ten voting members, each representing their constituency rather than their organization (including one representative for bilateral donors and one representative for UN and other multilateral agencies).

But while there are alternatives, the emphatic response from fieldwork interviews was that the GAVI Board works well and, in general, caution should be exercised in contemplating change. One Board member tellingly remarked that "in terms of partnership, GAVI is more successful than other partnerships involving much the same people", with a genuinely shared purpose, some degree of mutual accountability and no sense of domination by any one partner or constituency.

The major question about the composition of the Board relates to the perceived inadequacy of representation from developing countries. The original GAVI Proto-Board recommendation was for one member per constituency, except for developing countries for which two were recommended. However this composition was amended in GAVI's subsequent Guiding Principles document of June 2000 to include three representatives of OECD country governments, but only two from developing countries. While retaining the principle that the Board composition is framed to provide the highest level of profile, political commitment and ability to mobilize global commitment and funding rather than "equal" representation, there now seems to be consensus that the present imbalance should be redressed.

One problem is purely practical. It is the responsibility of Board members to maintain a network amongst their constituencies. The representative of the African developing countries, the Minister of Health for Mali, has said frankly that this is an impossible task to carry out effectively in relation to 36 countries, despite the provision of an assistant funded by the GAVI Secretariat. The immediate burden of work on this member is exacerbated by preparations for the forthcoming Partners' meeting in Dakar in November 2002.

There are in our view powerful arguments in favour of increasing representation from developing countries, particularly as the focus shifts from the development of policy to implementation at country level. It would strengthen the active involvement of beneficiary country governments in GAVI policy making, facilitate the task of effective networking and make consultation more meaningful, strengthen country ownership and leadership, and increase peer pressure to perform better.

The current total of 74 countries eligible for Vaccine Fund support is divided amongst WHO regions thus:

WHO Region	**Current no. of countries eligible for Vaccine Fund Support**
AFRO	**36**
- West and Central	21
- East and Southern	15
EMRO	**6**
EURO	**11**
SEARO	**7**
WPRO	**8** (**7** likely to participate)
PAHO	**6** (**2** likely to participate)
Total for all regions	**74** (**69** likely to participate)

On this basis, consideration should be given to the addition of two further members from developing countries, to yield a total of four representing:

- West and Central Africa
- East and Southern Africa, plus Sudan, Somalia and Djibouti
- SEARO/WPRO plus possibly Pakistan, Afghanistan and Yemen
- EURO/PAHO.

These seats should rotate between countries on a two-yearly basis, with those shared between regions alternating between the regions concerned.

The Board is also to consider a proposal that the President of the Vaccine Fund should become a formal member. This is desirable in order to institutionalise the liaison between the GAVI Board and the Vaccine Fund (see Section 12 below).

However, there is equally a strong view that any change in composition, however desirable, has to be examined carefully in relation to the overall size of the GAVI Board. Factors to be taken into account include the manageability of the Board, issues of communication among Board members and the effectiveness of teleconferences as a means of operating. Options suggested during interviews include:

- providing further support to enable existing developing country members to fulfil their responsibilities for two large constituencies
- having additional developing country representatives attend Board meetings for information without being full members
- adding no more than two members to the GAVI Board
- merging two or more current constituency seats
- substituting additional representatives from developing countries for some existing members.

We recommend that the Board should increase the number of developing country Board members representatives from two to four, and invite the President of the Vaccine Fund to become a member.

The consensus of Board member interviewees is that the current excellent Board dynamics would be hard to maintain if the total size of the Board grew beyond 18 (17 members plus the Chair). **We therefore further recommend** that at least one current rotating seat should be dropped at the end of the present term. Possibilities include amongst others asking the Gates Foundation to represent Foundations and dropping the rotating foundations seat, reducing the number of OECD seats from three to two, and/or merging the seats for research institutions and technical health institutions. We would not recommend dropping the NGO seat. These are hard choices but necessary to safeguard the effectiveness and close relations of the Board.

Selection processes for Board members

While the principle of rotating Board members is well-understood, the process for selecting new members is not. At its Fourth meeting, the Board noted that "the procedures on the turnover of Board members, as outlined in the GAVI Guiding Principles Document, are ambiguous. The Board emphasized that the election of new members is a consultative process based on nominations coming from the constituencies". No revised document has since been produced. Some interviewees remain concerned about an apparent lack of transparency. Only one questioned the principle of the Board itself, rather than the constituencies, electing Board members.

Selection of non-African developing country GAVI Board member

- one of the two developing country representatives, Bhutan, was due to rotate off the GAVI Board in December 2001
- the outgoing Board member and the Executive Secretary wrote jointly in July 2001 to all non-African Vaccine Fund eligible countries to invite nominations supported by the CV of the person nominated and details of the country's commitment to build and strengthen country networks through representation on the Board.
- 9 candidates (7 of them Ministers of Health) were nominated.
- selection was based on previously agreed criteria, covering both organizational and individual factors:

  a) importance, or potential importance, of the institution to GAVI's mission

  b) commitment and availability of the candidate member to GAVI activities, including keeping constituency involved

  c) expertise and experience that will contribute to GAVI Board discussion

  d) technical, geographic and gender diversity in the composition of the Board.
- The GAVI Board teleconference summary report of 25 September 2001 noted that "a proposal was made by a few Board members to accept the nomination of the Indian Minister of Health…The proposal was accepted by all".

The case study in the box details the process followed in selecting India to replace Bhutan in January 2002 as one of the two developing country representatives. But it is not apparent that the processes are broadly consistent across the constituencies, even allowing for inevitable differences.

While the GAVI Board would not want to dictate to constituencies, there should be a clear, written, easily accessible statement of the processes for selection and rotation of each seat.

We recommend that:

- a note setting out current selection procedures, general criteria for selection and core responsibilities of GAVI Board members should be agreed by the Board. It should be made publicly available on the GAVI website, along with details of forthcoming vacancies over the following two years.

- any invitation letter for nominations or public notice of the forthcoming vacancy should give the Board's general criteria for selection, plus the specific criteria applying to the individual vacancy (eg criteria being applied to ensure technical, geographic or gender diversity). Where a constituency organises its own nominations, the Executive Secretary should provide it with information on both general and specific criteria.
- the Board's process of consultation on nominations should be fair, transparent, and applied to all constituencies. The Board should as a minimum consider all nominations received and seek the views of all Board members, even in a teleconference.

Core responsibilities of Board members

There should equally be a clear understanding about core responsibilities of Board members.

We recommend that:

- core responsibilities of GAVI Board members should be spelt out in the note available to potential nominees (see above). This would be reinforced by sharing information and views within the Board on standards and appropriate approaches, eg on involvement of each member's constituency, or on attendance at meetings. The Board has in the past ruled that alternates should not represent absent members, though this does not seem to be observed in practice.
- since demands will vary from constituency to constituency, the outgoing Board member should take responsibility for a seamless handover to his or her successor. Having both attend the Board meeting at the point of handover would help ensure continuity.
- the Chair takes the view that it is her responsibility to ensure that each elected member fulfils his/her commitment to the Board, and to take all necessary action in case of shortcomings.
- members may sometimes need support. For example, in view of the considerable burden of responsibility falling on the Board member representing colleagues in Africa (currently the Health Minister for Mali), the Secretariat funds some short-term staff support and equipment.

The Board Chair

The formal position in relation to the appointment of the Board Chair seems to be that "the Board will select from among its members a Chair whose term will be two years non-renewable" (GAVI Guiding Principles, 3rd Board meeting, Oslo, June 2000; Roles and Responsibilities paper, 6th GAVI Board meeting, Ottawa, October 2001). This supersedes the wording of the 1999 Proto-Board Executive Summary that "the Executive Heads of Board Member Organizations should…act as Chairs of the Board with terms of two years" and the main text "the first objective [of the Alliance] will be achieved by establishing ex officio membership of the Executive Director of UNICEF, the President of the World Bank and the Director-General of the WHO, other Heads of Organizations represented on the Board and by having a rotating chairmanship among them".

It was agreed at the Proto-Board meeting in Seattle in July 1999 that the Director-General of WHO would serve as Chair of the Board for the first two years, and the Executive Director of UNICEF would serve as Chair for the second two-year term. There is no Vice-Chair.

Ms Carol Bellamy, Executive Director of UNICEF, is currently Chair of the GAVI Board. Her (non-renewable) term of office will end in June 2003.

Review interviews with Board members suggest that there is no clear shared understanding about the process which will be followed in selecting the next Chair, or indeed about the pool of potential candidates. Possible proposals suggested by interviewees include the Chairmanship

- reverting to WHO in July 2003
- passing to the World Bank, although there are issues about who from the Bank would actually take the Chair
- rotating around the four renewable member organisations (ie WHO, UNICEF, the World Bank and the Gates Foundation)
- being elected from all Board members, (if a non-renewable member was elected, it would be desirable in the interest of continuity and Board dynamics that his or her term of office as Chair should follow service of a full term as a Board member).

Whatever the earlier position, it is now evident and urgent that the position be clarified. **We recommend** that the Board take early steps to confirm the policy and process for the appointment of Mrs Bellamy's successor.

Given our very limited exposure to the Board in action, we make no recommendation about the preferred options. We simply note that experience has shown the advantage of having a high-profile Chair to attract the attention of a wider audience. And having agency heads as Chairs has been advantageous in terms of stimulating/reinforcing activity on immunisation within the agencies. To that extent, there is an argument in favour of a rotation to the World Bank, provided the issue of representation could be resolved to the satisfaction of the GAVI Board, or a reversion to the Director-General of WHO.

Board fees

Each Board member (excluding the Chair) is liable for annual Board dues of $300,000 per seat to provide funds for the secretariat and priority tasks etc (see section 10). Dues are waived for the two members from developing countries and the developing country manufacturer. The current total fee income is therefore theoretically US$ 3.6m pa (12x$300,000).

The Board will wish to keep under careful review the ability of all other members to meet this sum. The issue arises immediately since, with the rotation of the NGO member at the end of June 2002, it is important that the requirement to fund Board dues and associated costs should not inhibit good applicants. The outgoing NGO member, CVP, estimates that the incoming member should be thinking in terms of costs of $300,000 pa for the Board seat, plus $15,000 pa for travel and per diems, plus $100,000 to support work started by CVP (though this latter would be a matter for the NGO constituency to review).

8. The Working Group

The Working Group has been a crucially important element of the GAVI architecture. It has borne an exceptionally, perhaps unacceptably, heavy burden of work, sometimes without due recognition by the parent institutions of the individuals concerned.

We recommend in passing that Chairs of the GAVI components such as the Board, the Working Group and the Task Forces should periodically inform the parent institutions of the performance of those individuals making a significant contribution to the work of the Alliance. Appropriate steps should also be taken to mark the appreciation of individuals' work in the Independent Review Committee and the Regional Working Groups.

In fieldwork, one repeated concern has been that the recommendations of this review should not damage the spirit or effectiveness of the Working Group. We hope they have not.

The Board's decisions on levels of delegation and structural relationships will have important implications for the Working Group. These are covered in section 5. A summary of the Working Group's functions is in Annex 4. Fieldwork also generated a set of issues about the precise role of Working Group members, the approach to selection and rotation of members, their range of skills and the appointment of the Chair. These are explored below.

Composition

The parties represented on the Working Group are determined by the Board, who will periodically review the composition and may change its size without exceeding the limit of 10 members.

The GAVI Guiding Principles paper (3rd Board meeting, Oslo, June 2000) states that the Working Group is composed of one representative from:

a) the Bill and Melinda Gates Foundation (covered by Mark Kane) UNICEF (Paul Fife) World Bank (Amie Batson) WHO (Michel Zaffran)

b) OECD partners - currently changing from USAID (Steve Landry)

c) developing countries - Government of Tanzania (Caroline Akim)

d) R&D institutions - Center for Vaccine Development, University of Maryland (Mike Levine)

e) industry – GlaxoSmithKline Biologicals, SA (Walter Vandersmissen)

f) the President of the Vaccine Fund. This has since been amended to one representative of the Vaccine Fund (currently Fabian McKinnon)

g) GAVI's Executive Secretary (Tore Godal).

Task Force Chairs and Secretaries are invited to attend Working Group meetings. Heidi Larson, the chair of the Advocacy task force, has participated in the Working Group since February 2001. Steve Landry will continue to attend Working Group meetings as co-chair of the Finance Task Force. The R&D and Implementation Task Forces are represented among Working Group members, and the secretary of the ITF has attended.

If appropriate and for specific topics, the Chair in consultation with the Working Group may invite an external person to participate without voting rights.

There may be an issue here too about the adequacy of developing country representation. But this is linked to the nature of the role of individual Working Group members (see below). The general view seems to be that the current composition is acceptable, particularly if more representatives of developing countries are elected to the GAVI Board (see section 7).

Roles and skills of members

Both the Board's Guiding Principles and the Roles and Responsibilities papers state that the composition of the Working Group is skill-based and linked to implementation partners and current priority activities.

Fieldwork suggests that some uncertainty exists about where the prime emphasis lies between functional and liaison roles. While they are not mutually exclusive, it would be helpful to achieve some greater clarity since it has implications for:

- *the process for selecting new members*: if the prime emphasis is on ensuring a balance of skills in a functional Group, then there is an argument for the Chair of the Group – or a selection panel - to have a substantial, or even decisive, role in selecting new members. But if the primary intention is representation and liaison, selection should rest with the constituency. We were told that at present the approach varies from case to case.
- *the role and responsibilities of members*, particularly in relation to providing effective liaison with the individual's wider constituency, as appropriate. This in turn raises a question about the respective roles of the GAVI Board and Working Group member in constituency representation. As in the case of the Board, guidance on the role and sharing approaches to fulfilling it would be helpful.
- *the range of skills available*: some members of the Working Group itself feel that it does not have the full suite of skills necessary for the tasks set it. It is currently strong on immunisation specific skills but needs to attract more individuals with wider sectoral skills and experience of health sector development. It is hoped that the new OECD nominee will help meet this need. The advent of financial sustainability plans will increase the importance of financial understanding within the Group. It is, of course, open to the Group to balance skills deficits through the use of consultants or co-optees.

Resolution of these issues is now dependent on the Board's decisions about the Working Group's place in the future GAVI structure, and the extent to which tasks and authority will be delegated to its Chair or the Executive Secretary as its Chair. Our immediate recommendation is that the issues should be clarified and discussed in the light of that decision.

Rotation of members

At present there is no regular rotation of members or bodies. It has though been established as a principle that non-renewable Board member bodies should not simultaneously be represented on the GAVI Board and the Working Group. Hence, when Kevin Reilly of Wyeth-Ayerst was elected to the Board, Jackie Keith - also of Wyeth-Ayerst - left the Working Group and was replaced by Walter Vandersmissen of GSK. Anne Petersen of USAID joined the Board in January 2002 and Steve Landry of USAID is therefore leaving the Working Group. The OECD Group is to provide a nomination. However, Mark Kane has been both a Board and a Working Group member, though he is rotating off the Board at the end of June 2002.

An argument has been made for some form of regular rotation, in line with the Board. There would be less scope than on the Board for changes in the member *bodies*, given that on current understandings six out of ten would be fixed (the four renewable Board bodies, the Vaccine Fund and the Executive Secretary). There could though, if desired, be rotation of *individuals* representing these bodies, save for the Executive Secretary.

Pros and cons include new blood and more opportunities for the involvement of a wider group of partners, versus the importance of continuity in driving forward a complex

agenda, particularly when GAVI is still working its way through a cycle of development. The desirability of rotation is also related to whether members of the Working Group are primarily intended to represent key constituencies and be the link to them (in which case rotation may be more applicable), or whether they are chosen for their individual skills within a carefully balanced Group (in which case it may be less applicable).

This should therefore be considered in the context of the wider decision described above. But we offer two caveats if rotation is adopted. The first is that, to provide continuity for the work in hand, the terms of office should be longer than for the Board. We would suggest a minimum of three years. The second is that a careful transition strategy must be planned before rotation is initiated, to safeguard the continued high performance of this group. A key finding in section 3 was GAVI's vulnerability to the loss of certain key individuals working in its various components.

Chair of Working Group

According to GAVI's Guiding Principles:

- the Working Group will select one of its members as Chair. It is currently chaired by Tore Godal, GAVI Executive Secretary
- regardless of who is Chair, the Executive Secretary will prepare the provisional agenda and will report regularly to the Board about the discussions of the Working Group.

The current arrangement works well because Tore Godal commands widespread respect. But views differ as to whether the Executive Secretary should automatically chair the Group by virtue of his/her position. Arguments in favour include the close working relationship between the Secretary and the GAVI Board Chair, the avoidance of duplication with the reporting requirement already laid on the Secretary, and the fact that the Secretary is well-placed to ensure that Board decisions are followed up, and to feed back Working Group issues to the Board. The argument against seems mainly to be founded on the acceptability of the Secretary as Chair to other Working Group members. If someone other than the Executive Secretary was selected as Chair, he or she should as a minimum attend Board meetings in order to be sufficiently well informed to fulfil the role.

As set out in section 5, **our recommendation** is that the Executive Secretary, by virtue of office, should chair the Working Group.

Funding

Partners cover their own costs, except that the Secretariat pays for the travelling costs and per diems of the developing country representative, and conference/teleconference costs. There is no support from the secretariat budget for Working Group activities.

9. The Secretariat

Functions and workload

The Secretariat is a small, close-knit team, working with some considerable esprit de corps in handling high workloads to tight timescales. We have been struck by its energy and dedication. It is based in the UNICEF office in Geneva.

As discussed earlier, its current tasks are essentially administrative (although at various stages involved in the development and revision of country guidelines), but with a strong

strategic contribution from the Executive Secretary. The consensus of Board members is in favour of maintaining this approach. The recommendations below are framed with that in mind. A summary of its functions is set out in Annex 4, and a detailed specification of future tasks is in Annex 5. With GAVI's shift to implementation, there will be a greater load in process handling of inception/annual progress reports, mid-term reviews and DQAs. Annex 8 sets out the secretariat's forecast of the volume of such items from 2002-2006.

Size and skills for future tasks

There has been a deliberate policy of keeping the secretariat "lean". "*A small secretariat has meant that the major functions of the Alliance are carried out through the partners, thereby further reinforcing their commitment*" (GAVI Secretariat paper: experiences from the early days of GAVI).

Most Board members continue to favour this *modus operandi* but recognise the need for limited growth to tackle increased workload. "*I would be comfortable with 10 [in the secretariat] but not with 20*".

There are at present 7.5 staff, 5 professionals and 2.5 support staff. This core is supplemented by occasional consultants and casual staff. For example, a casual amounting to an estimated 25% of full-time assists with handling photocopying and file preparation for IRC, Board, and Working Group meetings etc. At present, the Secretariat has two short term staff, one working on communications (including the website) and the other on a database of GAVI countries and country reports.

On the basis of present and increasing workload, **we recommend** the engagement of three additional staff (assuming that the Secretariat undertakes an active communications function):

- 1 additional programme officer. He or she should ideally have skills in demography and statistics, and have experience of working in developing countries.
- 1 additional professional to provide capacity for one fulltime officer to work on communications, and another to assist the Executive Secretary in support of the Board, Working Group etc. At present these tasks are combined. The new staff member should be recruited on the basis of high-level communication skills.
- 1 additional support person.

Any significant addition to the technical functions of the Secretariat would entail more staff at a senior level.

Retirement of the Executive Secretary

The McKinsey report on *Developing successful global health alliances* points to the general importance of this post in global health alliances. "The best alliances, including GAVI and IAVI, will recruit an individual leader with the skills, contacts, and personality to make things happen, and structure their role to make them personally accountable for the venture's overall success".

The current GAVI Executive Secretary is Tore Godal. There is acknowledgement on all fronts of Tore's immense personal contribution to the success of GAVI. His nature and breadth of understanding have been fundamental. With retirement now in prospect, he will be a hard act to follow. The post requires an unusual balance of skills: part leader and manager, part diplomat, part technician, part fundraiser. The Board is due to discuss the process of securing a successor at its June 2002 meeting.

While this is starting the replacement process in good time, we have concerns about the overall transition strategy. Tore's current term of office runs to the end of June 2003. This is exactly the same time as the current GAVI Board Chair, Carol Bellamy, ends her (non-renewable) term of office. It would clearly be unhelpful for both to leave simultaneously. Moreover, the post of Deputy Executive Secretary within the secretariat is approved but not filled on a substantive basis.

In the interests of continuity and a smooth transition to a new Chair, we recommend that:

- the rotation of the Chair should proceed as planned at the end of June 2003
- the Board should extend the appointment of Tore Godal as Executive Secretary until at least the end of December 2003, to see in the new Chair. We understand informally that he would be willing to stay on for six months if invited by the Board. His successor should be appointed in time to allow a brief handover.
- a substantive Deputy Executive Secretary should be recruited as soon as possible. He or she would be in post before the end of 2002 and would therefore be well-placed to provide continuity during the change of Executive Secretary. The term of office should be two years in the first instance.

Deputy Executive Secretary

We should also make clear our view that there is an important role to be performed by the Deputy Executive Secretary, in taking responsibility under the Executive Secretary for the internal operation of the Secretariat, secretariat tasks on country programming including monitoring and evaluation (in close collaboration with the relevant Task Forces and partner agencies), and the broad managerial processes we have recommended. This would free the Executive Secretary to focus more on tasks related to GAVI's external environment, and on strategy and policy development. The Board should approve the job description, and the appointment process should involve at least one member of the Board. It should be made clear in appointing a Deputy Executive Secretary now that these posts require different and complementary skill sets, and that the Board would not intend to consider the Deputy as a potential successor to Tore Godal.

In our view, the importance of these tasks, and of securing continuity, overrides the argument that the post should be left open until the next Executive Secretary has taken up post to allow unfettered choice of a key team member.

It has also been suggested that the post of Deputy could be filled by the incoming Executive Secretary, selected early. This is certainly an option which would help meet continuity concerns. But extended handovers, however well-intentioned the parties, can be difficult to handle and create confusion about responsibilities.

10. Funding arrangements

One specific activity was to review the funding arrangements for the Board, Working Group and Secretariat and other bodies such as the Task Forces, to ensure that there are appropriate mechanisms and budgets for funding their priority activities.

This section does not cover those funds which are drawn from the Vaccine Fund or the Trust Account at UNICEF.

Secretariat budget income

The mechanism to provide the income for the Secretariat budget is a $300,000 annual contribution from each Board member, except that the contributions are waived for the two members from developing countries (currently India and Mali) and the developing country vaccine manufacturer. Hence, with 15 Board members of whom 3 are exempted, the current annual income ceiling is US$3.6 million.

In 2001-2002, the secretariat operated within a US$7.2 million biennial envelope, with virement between budget lines and between the two years of the biennium, subject to the endorsement of the Working Group. The Working Group reviewed budgetary revisions twice in 2001, and once to date in 2002.There is an issue about timeliness of payment of Board dues. At the end of April 2002, contributions totalling US$4.3 million for the 2001-2002 biennium were outstanding.

In addition, UNICEF covers costs related to housing the Secretariat. These are estimated to rise shortly to US$170,000, including rent of US$ 90,000 pa later in 2002 when much needed additional space is provided.

Looking ahead to 2003-4, the Board fees income level may come under pressure since the research and development institute members are finding it difficult to meet the full US$300,000, and there is a potential issue about the affordability of the Board dues by the NGO to be selected to replace CVP in July 2002. Conversely, the addition to the Board of the President of the Vaccine Fund as a fee-paying member could restore the balance (see section 7).

Secretariat budget expenditure

The budget lines cover:

- professional and support GAVI Secretariat staff, and short-term professionals and consultancy
- operating costs and secretarial travel
- support to the Task Forces
- reviews of country proposals, verifications (Data Quality Audits), mid-term reviews
- workshops (no expenditure) and Partners' meeting
- contractual work including the website.

The approved budget and estimated expenditure for the 2001-2002 biennium is at annex 6. In this period, c.28% of budgeted income (just over US$ 2 m) is forecast to be spent on staffing, with an underspend of $437,000 largely accounted for by the Deputy Secretary vacancy. Budgeted staff costs amount to one-third of budgeted income.

Forecast expenditure on the review of country proposals and Data Quality Audits (DQAs) constitutes 30% of total planned income. A likely overspend of US$ 1million on these two budget lines together will be covered by the lack of any expenditure in 2001-2002 on mid-term reviews against provision of over US$ 1 million. The secretariat estimates that a balanced budget will be achieved in 2001-2002.

However, there will be significant cost pressures in the next two biennia, principally arising from increases in relation to DQAs, progress reports, financial sustainability plans, and mid term reviews. The 34 initial DQAs forecast for 2003-4 would alone cost about US$ 2 million or 28% of total biennial income at current unit costs, and in addition there may be up to 20 repeat DQAs (*source: secretariat forecast*). Plus 56 mid-term reviews are forecast for the biennium.

The increase in staffing costs will be comparatively modest, even if our recommendations for three additional staff are accepted. Some of the costs are already spent on consultancy and casual staff.

Issues to be addressed therefore include:

i) whether the full range of these activities on proposals and monitoring (say DQAs in particular) should continue to be met from the secretariat budget. The rationale for which activities are funded from the Secretariat budget is not wholly clear.

ii) if the range is unchanged, how the budget can be increased. One option would be to raise the level of annual Board contributions. But current levels already pose problems for some Board members, and fieldwork enquiries suggest that an increase would not be well received.

Moreover, the wider context is that the secretariat budget covers only a portion of the costs incurred by Task Forces and the Working Group. We were told that in principle, each Task Force produces a budget which the Working Group/Secretariat approves in the light of funds available. The secretariat has budgeted expenditure of US$ 600,000 on the Task Forces in 2002. As an example, it will provide the Financing Task Force with US$ 200,000 to finance a coordinator; travel and per diems for members from developing countries, NGOs and academia; and some specific activities.

In practice, partners meet other costs, in addition to their wider contributions. It has been impossible in the time available to map the total contributions made by partners in cash, let alone in kind, but the sums are substantial. They include, as an example amongst many contributions, US$ 1.5m support from the World Bank for country level work, provided through the GAVI Secretariat to the Task Force on Country Coordination (now Implementation Task Force); this in turn helped support the Regional Working Groups. More broadly, the governments of the Netherlands, Norway and Denmark have provided substantial funds to UNICEF and/or WHO for work on immunization as part of their pledge to GAVI/the Vaccine Fund.

As noted earlier, concern has been expressed about repeated requests for piecemeal donations, sometimes at short notice and involving heavy transaction costs. This would be met by **our recommendation** in section 4 for the development of a consolidated, costed and prioritised two year workplan covering the GAVI entities of the Board, Secretariat, Working Group, Task Forces and Regional Working Groups. Its funding requirements, as distinct from partner commitments in kind, could then be met on a pooled basis. This would help assist the Alliance work to a true sense of priorities not distorted by the ready availability of cash or human resource for a 'pet project', and equally avoid the risk that an important task is not tackled for lack of a committed donor. The merits of retaining Board dues should be discussed in this context. Within the framework of that overall workplan, it would be important for the Secretariat to have its own budget based on a workplan, both approved by the GAVI Board.

On the specific point of foreseeable pressures on the Secretariat's budget, **we recommend** that, within the context of this overall plan, the possibility of regular direct support from the Vaccine Fund for country support activities such as the conduct of DQAs and for capacity building for implementation should be explored with the Vaccine Fund Executive Committee.

11. Independence and accountability of the Independent Review Committee

The Independent Review Committee (IRC) is the GAVI body charged with reviewing and making recommendations on country proposals to the Board and, increasingly, on progress reports. Its independence and integrity are therefore crucial. It is composed of nine independent experts in health and immunization, of whom eight are from low- or middle-income countries. They are selected by the Executive Secretary after consultation with the Working Group and partners. All members sign a confidentiality and conflict of interest statement.

In our fieldwork we have found no cause for concern about the Committee's independence to date. We are assured that committee members who have recently been involved in any capacity in the immunization process in countries under review are not present during the deliberations of the review committee, and do not participate in decisions relating to those countries.

We explored the actual process of conducting a review and were satisfied that, at the level of the Secretariat, appropriate steps were being taken to safeguard the independence of the IRC. Although a member of the Secretariat and a technical expert provided by WHO, at the request of the IRC, are available throughout the sittings of the Committee, their only contribution is to provide background information and documents requested by members, or to identify any areas of potential conflict with established GAVI policy. While secretarial support is on standby, the IRC members themselves undertake the actual drafting of reports. The Secretariat assists only in final formatting, editing, printing and distribution of the reports. Appreciation of the quality of the Secretariat's support and their lack of interference was noted in the email questionnaire response.

Since there was no opportune meeting of the IRC during the review, we undertook an email questionnaire, eliciting eight replies from the nine currently active members. A summary of responses is at Annex 7. These responses do not indicate any actual experience of attempts from any source to influence their decisions or compromise their independence.

However, asked about the three most serious threats to their independence, respondents identified *potential* concerns which helpfully indicate areas for special vigilance. They include:

- the possibility, if not the actuality, of interference by some other GAVI element, such as the Secretariat and/or the Working Group. Since the Working Group hears the IRC's report before the Board, it could assume a "gate keeping" role; one IRC member asked that the role of the Working Group be clarified
- the possibility of other interference, say through any intermediating role of WHO Regional Offices (and RWGs) in the review process, or the qualification of country perspectives /documentation by GAVI partners before IRC review
- concerns relating to individual IRC members, whether because of flawed selection processes, the perception that members represent their countries (and are therefore open to domestic influences), involvement - personally or through their agencies - in countries they are to review, or inappropriate engagement in wider GAVI-related activities including conferences
- any expectation of rubber stamp approval of progress reports in the absence of reality checks, members being too remote from actualities in the countries they review
- pressure to reflect GAVI as a success story rather than to seek and solve problems.

Accountability of the IRC

Almost all respondents saw the IRC as accountable to the Board, including for compliance with GAVI policies, with one member qualifying this to the extent that the IRC must maintain its integrity and technical independence. The corollary is that the Board must take responsibility for this accountability oversight.

A paper prepared by the Working Group for the GAVI Board's teleconference on 23 May recognised the consistent and high-quality performance of the IRC and proposed a new procedure under which a new Board Sub-group will first review IRC recommendations and make a presentation to the full Board. In the absence of objections, its conclusions would be considered Board consensus. Such a sub-group, appropriately constituted, could exercise the necessary accountability oversight, including maintaining vigilance against threats to the probity of the process.

Future responsibilities and workload

The Executive Secretary has discussed with IRC members the proposition that the Board will continue to use the Independent Review Committee to review not only country proposals and requests, but also the various reports of the implementation monitoring process.

Forecasts of the schedule for programme monitoring and evaluation over the immediate and medium term (see Annex 8) indicate significant additional demands on the IRC. Members however generally felt that this would still be manageable, albeit with some difficulty. Currently, the working formula is for three members to review each country, with an average output of 3 countries per team per day. While this allows for greater consistency and thoroughness and is supported by Committee members, it may well prove to be unsustainable, given the anticipated workload.

We recommend that the method of work should be reviewed by the IRC, in consultation with the Secretariat and the Implementation Task Force. Options include separating the monitoring and evaluation review process from that for country proposals and requests; and/or increasing the size of the reconstituted IRC.

Skill mix

The expertise of current IRC members is predominantly related to immunization and health systems, with one health economist. The Committee members themselves are clear that the needs of the implementation phase call for the inclusion of a wider range of skills to address the broader aspects of health systems and capacity development, macroeconomics, health financing and poverty reduction; and systems management, including statistics and evaluation.

Recommendations

To maintain the efficiency and independence of the IRC, we recommend that:

- **an early decision is taken on the scope of the future responsibilities of the IRC. If these are to include monitoring tasks, a formal letter of invitation with the revised terms of reference should be issued to each sitting IRC Member. Given the anticipated workload, the method of work should be reviewed by the IRC in consultation with the Secretariat and the Implementation Task Force.**

- **the Executive Secretary, in close consultation with the Implementation Task Force, should develop a note on minimum criteria for IRC membership and the process of selection. Once approved by the GAVI Board, this note should be publicly available.**
- **the next two vacant seats on the IRC should be filled by suitable experts in the new skill areas identified above, giving priority to health systems management and macroeconomics and financing in the first instance. Over time, a more appropriate balance of skills and of gender and geographical representation should be achieved through progressive replacement by natural attrition, in order to maintain the important element of institutional memory within the Committee.**
- **the IRC should continue to report directly to the Board. Any comments or observations from other GAVI entities or elsewhere should be forwarded to the Board as separate papers. The actual presentation to the Board should continue to be undertaken by the designated spokesperson of the Committee.**
- **The Board should delegate to the Executive Secretary authority for handling resubmissions and IRC recommendations for conditional approvals, and forwarding the definitive IRC recommendations to the Board only when the conditions have been fulfilled by the country(ies). The Board may wish to consider further delegation to the Executive Secretary where resubmissions or changes in specification (e.g. change in quantity of vaccines or to polyvalent vaccine) remain within a fixed percentage of the ceiling originally approved by the Board.**
- **safeguards for retaining the independence of the IRC should be kept under scrutiny. Members should be appointed an individual capacity; and vigilance maintained to forestall any potential conflict of interest. The Chair of the IRC should be given a specific mandate in the revised terms of reference to exercise this vigilance. The Board, or its subgroup if one is established, should take responsibility for accountability oversight.**
- **explicit review criteria, particularly on what would or would not constitute a satisfactory report, should be agreed and published.**
- **it should be the function of the ICCs, and Regional Working Groups, to provide the necessary reality checks.**
- **in this fast-evolving environment, the IRC should be reviewed again in the last quarter of 2003, in the light of experience gained, particularly in relation to necessary skills and capacity for the tasks on hand.**

12. Relationship with the Vaccine Fund

As set out in its incorporating documents, the Vaccine Fund (formerly the Global Fund for Children's Vaccines) was organised in response to the establishment of GAVI "*to provide financial support for the purchase of newer and underutilised vaccines and the means to deliver such vaccines to the children of the world" and "to coordinate its charitable efforts with GAVI..[it] intends to provide funds to purchase vaccines for programs that form part of the GAVI members' immunization initiatives*". GAVI and the Vaccine Fund have been inextricably linked from the outset.

It was also emphasised from the outset that GAVI's interests went beyond the financing of underutilised and new vaccines and that the Vaccine Fund (VF) was intended to supplement and not replace the traditional modes and mechanisms of support of immunization in poor countries. This relationship and the place of the VF and GAVI within the broader immunization arena have been constantly emphasised. The benefits of this model of mutual benefit are perceived by most people interviewed to have more benefits than risks so long as the common vision and strategic objectives remain shared.

Nonetheless, the Vaccine Fund is under US law an independent charitable body, with its own Board of distinguished figures serving in their personal capacities. Relationships between the Fund and GAVI structures therefore depend crucially on collaboration and good relationships at Board and working levels. The picture is made more complex by the existence of the Trust Account at UNICEF, established at the request of the GAVI allies to receive and disburse funds for activities consistent with the GAVI immunization goals.

The Relationship Agreement between UNICEF and the Vaccine Fund sets provisions for receiving, disbursing and accounting for funds transferred from the Vaccine Fund on the approval of the Vaccine Fund Board based on recommendations of the GAVI Board. Article IX of the Relationship Agreement calls for use of best efforts to settle disputes amicably. The nature of the collaborative mechanisms between the GAVI Board and the Vaccine Fund Board and disbursements of support to countries were specified in the joint papers of the Fifth Board meeting, London, June 2001 founding on an integrated process of policy development.

In developing these policies and processes, the various GAVI organs and the VF have collaborated effectively and relations have generally been supportive and cordial. The remarkable speed at which country proposals and requests have been processed and approved through the two Boards is indicative of an operational harmony that has contributed to the GAVI Alliance being widely seen as a model for other global initiatives.

However, two sets of concerns emerged during this review. The first relates to the complexity of the formal or legal relationships, such as arose during the drafting of the China Memorandum of Understanding, a complexity compounded by the fact that GAVI is not itself a legal entity. This, and the higher transaction costs involved, is an inevitable consequence of the decision to establish a separate Vaccine Fund. Since there seems no intention to reconsider this model, the formal difficulties will need to be resolved as they arise.

The other set of concerns centres on the risk that GAVI and the Vaccine Fund may slowly grow apart. Examples cited relate to different approaches to the financial sustainability of immunization in poor countries; possible future views on high cost vaccines and the extent to which the Fund should support vaccine research financially; minor irritations around promotional material; and the uncertainties of the future with regards to the long term vision and forecasting of funding needs. The Vaccine Fund is necessarily developing a 10-year strategy while the GAVI Board has yet to determine GAVI's future beyond 2005. The need to work together on the issue of sustainability beyond the current 5-year time horizon is becoming urgent.

It has been suggested that conflicts have so far been averted because of the close rapport between the executive heads of the two entities (Tore Godal as GAVI Executive Secretary and Jacques-Francois Martin as President of the Vaccine Fund) rather than any structural integrity, a situation that may not be sustainable if either individual left.

We should stress that in our view these are fears and challenges rather than concrete areas of serious conflict, many of which could be resolved by improved communication between relevant GAVI components and the Vaccine Fund and action to promote and widen good relationships. This is the more important since the Vaccine Fund secretariat has recently expanded and personal relationships with key GAVI figures have yet to be cemented, and a common culture forged.

We recommend:

- to formalise institutional links, the Board should enact the current proposal that the President of the Vaccine Fund should be invited to become a member of the GAVI Board. There is already a VF member, Fabian McKinnon, on the GAVI Working Group. Tore Godal is a member of the Vaccine Fund Board and Executive Committee. The VF should be asked to offer these positions to any GAVI Executive Secretary by virtue of office.
- there should be an alignment of GAVI and Vaccine Fund planning horizons, recognising that the Fund cannot afford a hiatus in its fundraising activities.
- in the absence of strong formal remedies, maintaining an environment of close personal relations will be key. There should be regular liaison meetings between the VF management staff and the GAVI Secretariat (including as appropriate some Working Group representation). The culture should be one of "no surprises".
- an earlier proposal for common supervision of the two secretariats by the Working Group and the VF Executive Committee should not be pursued. In addition to possible constitutional problems on the part of the VF, it is difficult to see how effective supervision of the Secretariat and Vaccine Fund management can be exercised by bodies on which the heads of both the Secretariat and the VF management sit. But there should be joint sessions of the two bodies, as required, to address key issues and problems.
- if the Board accepts the recommendation in section 5 for a Board Operations Review Sub-group, part of that Sub-group's remit should be to keep relations with the Vaccine Fund under review.

13. Conclusion

In McKinsey and Company's review of global health alliances[1], GAVI is rated one of the best. Our fieldwork interviews found among those involved at Board, Working Group and Secretariat levels a strong conviction that GAVI does add value, even if the work to define that value is not complete.

Its objectives and milestones are extremely stretching. And, in making the transition from strategy development to implementation, it faces a set of major strategic decisions (which generally lie outside the remit of this brief and limited review). On its current plans, it is generating a formidable workload for its partners but also for its inescapable structural components, including the Board, the Secretariat and the Working Group. While some see an inherent tension in seeking to manage an alliance, there is in general a recognition that, if GAVI is to be more effective, it needs in the next phase of its evolution to adopt a more business-like approach – without undermining its special nature or anxiety to avoid bureaucratisation.

Our recommendations have aimed to achieve an acceptable balance. Like other reports being considered shortly by the GAVI Board, we recommend greater use of some basic managerial tools. Examples include workplans and budgets for each of the key GAVI components (particularly the Secretariat, Working Group and Task Forces) which should build into a consolidated, costed and funded GAVI workplan, framed within the Board's strategic objectives and priorities.

[1] from "Developing Successful Global Health Alliances" with permission of The Gates Foundation and McKinsey and Company

We also recommend that its high-level Board should focus primarily on Alliance strategy, key policy issues, accountability oversight and crucial external functions especially in advocacy and alignment. A limited number of Board Sub-groups should help deal effectively with some key issues which only the Board can address. The corollary is that there should be greater delegation. To what or to whom is a matter of debate: we have recommended that it should be primarily to the Executive Secretary supported by the Secretariat and, as its Chair, by the Working Group.

Beyond that, we have made recommendations for improved process handling, for example in relation to selection, briefing and rotation of Board members, and to Board papers and information. These, together with improved communications, should meet concerns about perceived lack of transparency.

We have highlighted the importance of considering some of the more human issues – for example, the critical need to have effective transition strategies for changes in the current Board Chair, the current Executive Secretary and inevitably some of those other individuals whose commitment to GAVI's goals has helped bring GAVI so far so fast. A pervasive impression from our interviews was that close personal relationships lie at the heart of the Alliance's success to date. We do believe that there is need now for a somewhat more structured approach. But we equally believe that good working relationships - between the partners, between GAVI and the Vaccine Fund, between the GAVI elements of the Board, Working Group and the Secretariat and beyond – will remain key to sustained success. And that those two approaches are entirely compatible.

Annex 1

Final Terms of Reference for an External Review of the Functions and Interactions of the GAVI Working Group, Secretariat, and Board

Purpose

The review is being commissioned by the Board of the Global Alliance for Vaccines and Immunisation (GAVI). The purpose of the review is to examine the current operations of the Working Group, Secretariat and Board and their relationships with partners in the Alliance and with the Vaccine Fund (VF), leading to recommendations to strengthen GAVI's structure and interactions in order to improve its capacity to meet its objectives during the next 5 years.

Context

The mission of GAVI is "to save children's lives and protect people's health through the widespread use of vaccines". The strategic objectives are to: improve access to sustainable immunization services; expand use of safe and cost effective vaccines; support national and international accelerated disease control targets for vaccine-preventable diseases; accelerate development and introduction of new vaccines and technologies including R&D for vaccines needed primarily in developing countries; and to make immunization a centrepiece in international development efforts.

GAVI has a dual role – as an alliance of agencies interested in and involved with immunization in developing countries, it provides a forum for coordination of efforts, sharing of priorities and development of common policies. In addition, GAVI determines the policy and use of the additional funds raised for vaccination by the Vaccine Fund.

GAVI was launched in January 2000. As set out in the Guiding Principles adopted in June 2000, its structure includes a Board; a Working Group that is responsible for advising the Board on technical issues and linking with partners and other key agencies; a Secretariat that provides administrative support to the Board and Working Group; an Independent Review Committee; and a series of Task Forces that provide advice and proposals. In addition there is the separate structure of the Vaccine Fund (VF), which has a separate Board and management team. An issues paper on the roles and responsibilities of the various components in the existing GAVI structure was discussed at the GAVI Board meeting in Ottawa in October 2001, and will be provided as one of the key documents.

GAVI has completed some two years in operation and is reaching the end of an initial phase where the focus was on setting policies and procedures for defining how funds would be allocated and used, and supporting and reviewing applications for funding. In the coming years, the GAVI Board wishes to consider how GAVI can best evolve to meet its strategic objectives. In order to fulfil these objectives it is anticipated that the following areas of work will be crucial:

1. management and monitoring of VF funding provided to up to 74 countries to help them improve immunization services, introduce new vaccines and increase safety of injections;
2. monitoring progress in increasing levels of immunization coverage, as well as identifying barriers to increasing coverage and how to address these;

3. monitoring and optimising the impact of GAVI policies and VF support on routine immunization coverage and the broader health systems in low income countries;
4. promoting sustainable financing and delivery of immunization programs;
5. considering whether and how to expand the scope of VF funded activities to include research and development and other new vaccines;
6. identifying GAVI's role with respect to middle income countries;
7. facilitating the alignment of GAVI goals and activities with those of accelerated disease reduction initiatives (e.g. polio eradication, measles burden reduction); with the new Global Health Fund for AIDS, TB and Malaria (GFATM); and national health system development.

The original life span of GAVI and the VF was for 5 years from 2000 to 2005. It is possible that this will be extended and some of the funding commitments already extend into 2006. However, the case for maintaining a separate GAVI, as opposed to integrating with other initiatives or institutions, will be kept under review.

As GAVI moves from start-up to implementation, and in view of the concerns raised in the issues paper on Roles and Responsibilities, the Board has decided to commission a review by external consultants of the Board, Working Group and Secretariat. Terms of reference for this review are set out below.

Outcomes of the review

Provide recommendations about optimal working arrangements, responsibilities, reporting lines and composition to facilitate successful completion of the above areas of work, with a view to ensuring: appropriate staffing; clear roles and reporting arrangements; realistic workloads; maintenance of flexibility; and appropriate use of Board members' time. Where changes are proposed, the recommendations should include concise terms of reference and recommended staffing levels.

Prepare a report and make a presentation to the Board.

Specific Activities

Review the current functions and interactions of the GAVI Board, Working Group and Secretariat; the current roles and responsibilities of each component of this structure; and their relationship with the VF.

In light of the key goals and objectives of the GAVI partnership during the next 5 years (i.e. to 2005 and two years beyond this), review planned activities including current workplans.

Review the composition, staffing, structure and work schedules of the Working Group, Secretariat and Board, including number of members and staff, roles, skills, how they are selected/appointed and the duration of tenure. Evaluate their capacity to meet current and future GAVI management needs. Review the contribution of human resources of partner agencies to these groups, with a view to assessing the sustainability, in the long run, of the concept of a "lean" secretariat.

Review the processes for decision-making and policy setting within GAVI, including the respective roles, relationships between and reporting arrangements of the GAVI global components, task forces, Independent Review Committee; regional working groups; VF Board and management; and partners. Review processes for defining and prioritising issues and agenda items for WG and GAVI Board meetings and teleconferences. Review mechanisms for resolution of conflicting viewpoints.

Review the relationship between the Independent Review Committee (IRC), Working Group and the Board and the conditions that should be created or sustained to ensure the independence of the IRC and its accountability to the Board.

Review the funding arrangements for the Board, Working Group and Secretariat and other bodies such as the Task Forces, to ensure there are appropriate mechanisms and budgets for funding priority activities.

Identify options for reform.

Review Methods

The external review should be conducted by a small team of 2 people who are independent of the existing GAVI Board, Working Group and Secretariat. The consultants should have extensive experience in analysis of institutional arrangements and working of alliances and partnerships. At least one of the team should have an in depth understanding of the international health infrastructure and the partnership context.

The review should if at all possible include interviews with all members of the Board, Working Group and Secretariat; representatives of other GAVI components (Task Forces, etc); and key partners and stakeholders (including a sample of GAVI partners and countries receiving GAVI/VF funding). In addition the consultants are expected to review relevant documents, observe meetings and/or teleconferences, and track decision-making processes.

Timing

The draft report should not exceed 25 pages and should include an executive summary. The draft report will be presented to the Board (probably at a teleconference) and circulated. Comments from stakeholders may be requested by the Board.

The first draft of the report will be delivered to the GAVI Board by end May 2002, and the final report sent to the Board in early June for discussion at its June 2002 meeting. The consultants may be asked to present to the Board.

Management of the review

As agreed in the 26 November 2001 Board teleconference, CDC has taken the lead in defining these TOR with inputs from DFID and WHO. It is suggested that this small group, which has been expanded to include UNICEF, continues to guide the process of identifying the consultants and providing an initial briefing. A member of the Board will assist with the initial briefing and facilitate an initial discussion between the Board and the consultants.

It is envisaged that funding and administrative support for the review will be provided by DFID and WHO.

KEY DOCUMENTS FOR THE REVIEW

The consultants will need to draw on the following key documents:

1. GAVI Board composition, Annex 7.1 of the Third Board Meeting Report
2. GAVI Guiding Principles, Annex 7.2 of the Third Board Meeting Report
3. Overview of the Operations Function in the GAVI Secretariat, Annex 7.3 of the Third Board Meeting Report
4. Relationship between GAVI and the Vaccine Fund, Annex 14.1 of the Fifth Board Meeting Report
5. Collaborative mechanism for disbursement of support to countries, Annex 14.2 of the Fifth Board Meeting Report
6. Country proposal review process - basic principles, Annex 2.1 of the Third Board Meeting
7. Terms of References for Advocacy, Country Coordination and Financing Task Forces, The Proto-Board Meeting Report
8. Terms of Reference for the R&D Task Force, Annex 3C of the Fourth Board Meeting Report
9. Roles and Responsibilities Issues Paper, Board Teleconference Report, Nov 2001
10. Minutes of last 3 Board meetings
11. Minutes/Summaries of Working Group meetings during last 12 months.

Annex 2

Review methodology and acknowledgments

1. Review methodology

This has been a brief but intensive study entailing:

- briefing by an ad hoc group set up by the Board
- observing as many GAVI processes in operation as possible in the timespan of the study, ie the Stockholm Board Meeting, the April and May Board teleconferences, the April meeting of the Working Group and the April meeting of the Implementation Task Force
- field visits to Stockholm, Geneva, Cape Town and Washington DC, Philadelphia, New York and Seattle in the US for face to face interviews with members of the Board, the Working Group, the Secretariat and the Vaccine Fund. An intended visit to Mali could not be arranged at a time convenient to the Minister.
- telephone interviews
- an email questionnaire of the Independent Review Committee
- review of available documents and data, including the secretariat budget
- scrutiny of relevant contemporary studies (see Annex 3), including attendance at the Mercer Management Consulting presentation on its study, *Lessons Learned: New Procurement Strategies for Vaccines*.

The point of reference for the consultants was the Board Chair, Ms Carol Bellamy.

The approach to the study was influenced by the limited worktime allowed for the review and the tight deadline for delivery of the report. This precluded as much follow-up as we would have liked and, in line with the Board discussions in Stockholm, entailed a narrow primary focus on three entities – the Board, Working Group and the Secretariat.

Choice of those to be interviewed face to face was based on selective coverage of the various constituencies, influenced by travel and cost considerations. The field review included interview sessions at the headquarters of each of the four non-rotating constituencies on the Board - the Bill and Melinda Gates Foundation, UNICEF, the World Bank and the World Health Organization. Most Board members were interviewed or consulted, but difficulties in reaching some precluded full coverage. In addition to two early visits to assemble background documents, we spent almost two days interviewing each of the staff of the Secretariat. The full list of those consulted is given below.

Acknowledgements

We are heavily indebted to everyone interviewed, especially members of the Board, for their time and frankness in responding to our many questions. Many had to reschedule engagements to accommodate our tight schedule. And our thanks go to members of the Independent Review Committee for participating in the email questionnaire.

We are particularly grateful to the Chair, Ms Bellamy, for guiding us through the exercise, and to Tore Godal and the staff of the Secretariat for their ready availability to respond to our many requests for additional information.

We also wish to acknowledge with gratitude the cooperation received from the authors of the various reports cited in the report and Annex 3 below : Michael Conway and David Ernst of McKinsey & Company, John Marshall consultant, and Piers Whitehead of Mercer Management Consulting.

List of those interviewed or consulted

1. Mrs Carol Bellamy, UNICEF, *Chair of GAVI Board*
2. Dr Gro Harlem Brundtland, WHO, Geneva, *Board*
3. Dr Yasuhiro Suzuki, WHO, Geneva, *Board*
4. Mr William H Gates Sr, Bill and Melinda Gates Foundation, *Board*
5. Dr David W Fleming, CDC, Atlanta, *Board**
6. Mr James Christopher Lovelace, World Bank, Washington, *Board*
7. Dr Mark Kane, PATH (CVP), Seattle, *Board and Working Group*
8. Dr Julian Lob-Levyt, DFID, London, *Board*
9. Dr Sigrun Mogedal, Norway, *Board*
10. Dr Fatoumata Nafo-Traore, Minister of Health, Mali, *Board**
11. Dr Anne Peterson, USAID, Washington, *Board*
12. Mr Kevin L Reilly, Wyeth-Ayerst/IFPMA, Philadelphia, USA, *Board*
13. Dr Caroline Akim, *Working Group and Independent Review Committee*
14. Ms Amie Batson, World Bank, Washington, *Working Group*
15. Dr Paul Fife, UNICEF, New York, *Working Group*
16. Dr Steve Landry, USAID, Washington, *Working Group*
17. Mr Fabian Mckinnon, Vaccine Fund, *Working Group*
18. Mr Walter Vandersmissen, *Working Group*
19. Dr Michel Zaffran, WHO, Geneva, *Working Group*
20. Dr Tore Godal, Executive Secretary, *GAVI Secretariat, Geneva*
21. Mr Bo Stenson, *GAVI Secretariat,* Geneva
22. Dr Ivone Rizzo, *GAVI Secretariat,* Geneva
23. Ms Lisa Jacobs, *GAVI Secretariat*, Geneva
24. Mr Umberto M Cancellieri, *GAVI Secretariat*, Geneva
25. Ms Corina Luputiu, *GAVI Secretariat,* Geneva
26. Ms Eyonam Asafo, *GAVI Secretariat,* Geneva
27. Ms Jane Dyrhauge, *GAVI Secretariat,* Geneva
28. Dr Sam Adjei, *Independent Review Committee*
29. Dr Robert Steinglass, *Independent Review Committee**

30. Dr Heidi Larson, UNICEF, New York, *Advocacy Task Force Chair*
31. Ms Jacqueline Keith, Wyeth-Ayerst/IFPMA, Philadelphia, USA, *Advocacy Task Force*
32. Dr Alan Brooks, PATH (CVP), Europe, *Financing Task Force*
33. Dr Prosper Nyandagazi, UNICEF, New York, *Financing Task Force*
34. Dr Rune Lea, Norway, *Implementation Task Force**
35. Ms Marion Kelly, DFID, London, *Implementation Task Force*
36. Ms Veronica Walford, DFID Health Systems Resource Centre, London, *Implementation Task Force*
37. Dr G Perkin, Bill and Melinda Gates Foundation, Seattle
38. Ms Sylvia Matthews, Bill and Melinda Gates Foundation*
39. Dr Sally Stansfield, Bill and Melinda Gates Foundation
40. Dr May Yacoob, UN Foundation, New York
41. Mr Jacques-Francois Martin, Vaccine Fund
42. Dr David Nabarro, WHO, Geneva
43. Mr Andre Roberfroid, UNICEF, New York
44. Mr Stephen Jarrett, UNICEF, New York
45. Mr Saad Houry, UNICEF, New York
46. Dr Yves Bergevin, UNICEF, New York
47. Dr Jean-Marie Okwo-Bele, UNICEF, New York
48. Dr Suomi Sakai, UNICEF, New York
49. Mr John Spring, UNICEF, New York
50. Mr Michael Pecho, UNICEF, New York
51. Mr Piers Whitehead, Mercer Management Consulting

*those marked with an asterisk were consulted by telephone

Annex 3

Summary of key relevant points from other current reviews

This review has taken place alongside a number of other studies whose findings have important implications for GAVI architecture and interactions. We have drawn, with gratitude to their authors, on four specific studies:

- *Lessons Learned: New Procurement Strategies for Vaccines (Mercer Management Consulting)*
- *The Pneumococcal Conjugate Vaccine Accelerated Development and Introduction Program (McKinsey & Company)*
- *A review of GAVI Task Force workplans (John Marshall, consultant)*
- *Developing Successful Global Health Alliances (McKinsey & Company)*

The studies are available on request from the GAVI secretariat.

Key findings and recommendations most relevant to our own study are set out below. We should stress that, in the interests of brevity, this selection is biased to those areas where there is potential for improvement in performance. They are to be seen against the background of the substantial achievements secured by the GAVI partnership in a remarkably short time.

Lessons Learned: New Procurement Strategies for Vaccines (due to go to the GAVI Board in June 2002)

This study by Mercer Management Consulting covers both an analysis of the vaccine industry and market, and a review of GAVI's first vaccine procurement round. Key relevant findings and recommendations which relate to the procurement exercise include:

- the ineffectiveness of a loose alliance in implementing, as distinct from developing, policy. The strategy phase requires broad thinking, consensus building, and informal participation. Planning and execution require an active, properly resourced and accountable project management function.
- partner involvement in planning activity shows a lack of lead accountability. Overlap and lack of clarity in roles and responsibilities are embedded in current partner mandates. GAVI partners give different messages about priorities.
- the absence of clear accountability lines results in decision-making processes which may not be fully based on facts.
- within the current GAVI operating model, three bodies – the Board, the Secretariat and the Working Group – have coordinating and accountability mandates but lack either the resources or authority to be effective.
- for the forthcoming procurement round, there is urgent need for a full-time project manager with a project office in an existing institution - either UNICEF PD or WHO since the key issues are programmatic, and a strong in-country presence and links to local deliverers are important. A project management approach should enhance GAVI's impact in avoidance of mixed messages on priorities, cross-functional decision-making and identification of key constraints and policy priorities.

- questions to be resolved include the appropriate oversight body for the project manager: options include the Working Group, a subcommittee of the Board, and/or the host institution.

Project to Accelerate Development and Introduction of Pneumococcal Conjugate and Rotavirus Vaccines (due to go to the GAVI Board in June 2002)

This study by McKinsey & Company was financed by the World Bank, on behalf of GAVI's Financing Task Force, and the Gates Foundation and reported to a Steering Committee comprised of the Gates Foundation, World Bank and Vaccine Fund. The study recommends the creation of Accelerated Development and Introduction Plans (ADIPs) and a supporting organizational set-up composed of a core ADIP team, Steering Group, and Technical review Panel. The core team is charged to develop and drive forward the public-private action plans to ensure rapid development and access to pneumococcal and rotavirus vaccines in developing countries. Its recommendations include the following:

- the most important requirements are leadership, since similar efforts have shown that an accountable driver to push a challenging plan is critical, and orchestration/ collaboration since most ADIP activities are dependent on commitments from part-time partners.
- high management, technical and financial competence is needed to implement a plan spanning several competence areas, and sufficient capacity for the number of parallel workstreams to gain the necessary attention.
- this requires a dedicated full-time team leader, the "pneumo champion" or "rota champion", with high empowerment and accountability, and who can rapidly establish appropriate networks in immunization that can be leveraged in an informal fashion with distinctive leadership capabilities.
- the leader should be supported by a small operational team of a clinical manager, an advocacy manager and a country coordination manager.
- the ADIP-team (ADIT) should have a broad mandate over an upfront funded budget (with funds allocated on some regular basis)
- for efficiency, the team might need to be sited in a host organization, although a start-up would also be considered, and, for guidance and supervision, will need to report to a steering group. There are a number of existing possible host organizations/ structures, each with different advantages and disadvantages (including GAVI/Task Forces, the Vaccine Fund, academia, PATH, WHO, UNICEF, World Bank, CDC and bilaterals) as well as new or less traditional entities. To ensure a transparent and fair process, the GAVI Board should select the host following a competitive Request for Proposal (RFP) process. Questions to be resolved include the GAVI oversight for the ADIT, for example, whether the GAVI Board should delegate management and funding authority to a Steering Group or whether the host agency's internal Board could perform that function.

A review of GAVI Task Force workplans (considered by the Working Group in April 2002)

This review by John Marshall, consultant, covers the workplans of the four GAVI Task Forces on Advocacy, Country Coordination (Implementation), Financing and Research & Development. Observations and recommendations include:

- the Task Forces are performing a critical role in GAVI's progress and will become increasingly important as the current implementation phase develops. However in many cases they are not equipped to make the optimum contribution necessary.

- the combined activities of the Task Forces cover almost all GAVI's Strategic Objectives. However, there is almost no overt direct link between the Task Force objectives, activities and deliverables and the GAVI milestones per se. In future, each Task Force workplan should align directly with the respective GAVI Strategic Objectives and Milestones, and subsequently form the platform for the overall GAVI workplan.
- there is little indication of formal coordination, synergies and avoidance of duplication between the Task Forces (but some informal processes do exist).
- identification of human and financial resources, critical timings, key issues and GAVI partner commitments is patchy. Deliverables are frequently not specific. Future workplans should define the resources required for each task force to achieve its objectives, and identify how they will be provided. Workplans should give some indication of the priority attached to each main activity, and identify any key dependencies or linkages to other activities, both inter- and intra-Task Force.
- the heavy load borne by some key individuals should be examined and addressed, particularly as sometimes this is not seen as their main responsibility by their employer.
- Task forces should be empowered, with accountability, responsibility and the means and resources to deliver the outcomes required from and accepted by them.
- The Regional Working Groups are a critical element in the Task Force structure and the implementation phase, and need to be adequately resourced (with skills, people and funds).

Developing Successful *Global Health Alliances*, a study by McKinsey & Company (April 2002)

This study for the Melinda and Bill Gates Foundation reviewed more than 30 current health alliances, including GAVI, as well as others during the past 20 years to assess whether alliances are "working" and to identify best practices that can maximize an alliance's chances for success. Relevant findings and recommendations include the following:

- more than 80% of public health alliances appear to be working, in terms of accelerating, improving or reducing the cost of initiatives aimed at reducing disease burdens, in comparison with what could be accomplished on a solitary basis. But a more disciplined approach to structuring and managing these alliances can lead to an even greater impact from the limited resources available.
- successful global health alliances have a compelling overall goal and a focused scope, with a clear understanding of the alliance's added value and what is required to capture this value. GAVI is cited as using its partners' added scale to secure cost benefits.
- it can be extremely useful to quantify the benefits of cooperation in terms of costs, time or effectiveness gains. In assessing the additional costs resulting from being in an alliance, partners are best served by focusing on the basic operating costs of the alliance (ie the quantifiable costs associated with coordinating and convening the partners). Few global health alliances are rigorous in assessing alliance-related costs.
- a number of alliances look for ways to control costs at the expense of overall program effectiveness, eg trying to keep alliance convening, communication and staffing costs down, but in the process severely limiting the upside of the alliance.

- simpler and looser structures are appropriate where the level of integration and coordination is limited. More complex, tighter structures should be used where the potential value is substantial and a higher degree of coordination or integration is required. GAVI is cited as an example of the "secretariat" alliance model, which is somewhat more expensive – both in dollars and management time – to create and maintain compared to looser forms without a "central" coordinating authority entity, and is most appropriate when the partners seek deeper combination gains, a large number of diverse partners are involved, and separation from the parent institutions is desirable.
- to avoid losses in time and efficiency, the "minimums" of operational planning should be in place. These include clear partner commitments (eg people, money, technology); performance metrics and milestones; and detailed operating and funding plans, updated as needed. It can be helpful to track alliance performance in three dimensions: outcome performance, activity performance and relationship performance.
- a governance structure that provides fast and strong decision-making while involving a large number of people and initiatives is assisted by limiting primary decision-making bodies to one or two, with small numbers of members – "representative" if necessary -, and developing a decision-making protocol for the 10-20 most important decisions.
- securing the right mix of skilled, credible and committed individuals to drive the alliance forward is an essential but idiosyncratic task. These include actively engaged senior champions in partner organizations, an accountable alliance leader, and a focused working team (eg more than 50% dedicated) to provide the horsepower of the alliance and create the individual motivation, accountability, and esprit de corps to make alliances succeed. The study notes that "the best alliances, like GAVI and IAVI, will recruit an individual leader with the skills, contacts and personality to make things happen and structure their role to make them personally accountable for the venture's overall success".[1]

[1] from "Developing Successful Global Health Alliances" with permission of The Gates Foundation and McKinsey and Company

Annex 4

Functions of the GAVI Board, Working Group and Secretariat

The following represent review proposals for the core functions of the key GAVI structures based on adaptations of the Roles and Responsibilities Board discussion paper.

Board Functions:

The GAVI Board is the governing body of the Alliance and expresses the highest political commitment of partners.

The Board:

- shapes strategic vision and direction for the Alliance (ultimate decision-maker)
- provides high level policy decisions stimulating GAVI partners to adopt new approaches and behaviours (e.g. alignment)
- approves, reviews and updates joint objectives and milestones
- determines GAVI structures, and constituency representation on the Board and Working Group
- nominates the Executive Secretary, submits its name to the host organization for appointment, and holds the post-holder to account
- approves membership of the Independent Review Committee, and determines recommendations of the IRC other than any specifically delegated elsewhere
- makes recommendations for funding approval by the Board of the Vaccine Fund
- notes and monitors the commitments of Partners to undertake certain strategies and activities
- contributes, through its members, to fundraising and advocacy activities
- exercises an accountability oversight function. It should approve the GAVI consolidated workplan and budget, and workplans and budgets for the Secretariat and for the Working Group; and monitor progress reports and annual performance reports.
- resolves issues among partners.

Secretariat Functions:

The Secretariat:

- services the Board, including:
  - working with the Board Chair to finalize meeting dates, locations and agendas
  - preparing documentation for presentation to the Board
  - preparing all correspondence with Board members
  - drafting and publishing the reports of the meetings and teleconferences

  - working with constituencies to nominate new members
  - coordinates and monitors the progress of activities including progress towards the Alliance milestones
- arranges the Partners' Meeting every two years
- manages the review of country proposals, including:
  - working with the partners to identify Independent Review Committee members
  - preparing documentation for the review
  - correspondence with members; hosting the 10-day proposal review sessions two to three times per year
  - drafting and managing correspondence with countries regarding the outcome of reviews
- providing human resource and financial support to developing country health ministry members
- services the Working Group, including:
  - managing all teleconferences and meeting
  - drafting meeting and teleconference agendas and reports
  - prepares and disseminates consistent documentation on GAVI policies and procedures
  - manages the website and quarterly publication.

Working Group Functions:

The Working Group facilitates the development and implementation of the decisions and policies of the Board.

The Working Group:

- communicates major Board decisions such as new Fund policies and country proposal decisions to partner constituencies at the regional and national levels
- acts as a bridge between the Alliance and operations of individual organizations ensuring operations are consistent with GAVI objectives
- under the Chair of the Executive Secretary:
  - monitors progress to identify issues arising from Partners (including task forces, regional working groups, countries) that require Board decisions
  - develops policy and operational policy issues for Board decisions
  - identifies important structural issues for Board decision
  - supports the Executive Secretary/Chair in coordinating the operations of the task forces and assessing their progress on workplans
- performs any other functions entrusted to it by the Board.

Annex 5

Workload of the GAVI Secretariat

Analysis of Future Workload

This analysis of the future workload of the secretariat and its staffing consequences is based on the assumption that the GAVI Board will prefer to operate on the basis of a lean secretariat and that the Secretariat will remain responsible for its range of functions. We have also assumed that it will play an active role in communications. With the exception of the Executive Secretary, the secretariat will therefore be mainly concerned with administrative coordination and support functions. It indicates new tasks and where there are likely to be significant changes in workload in current tasks, without change of function.

To cope adequately with this forecast level of workload, we recommend that the secretariat should be increased by three additional staff, two of them professional staff and one support staff (see section 9). We note here that the Board had at its decision 6.1 of the Fourth meeting, Noordwijk, November 2000, already agreed that "because of its increasing workload, the Secretariat "consider adding a limited number of additional staff as needs arise".

The main areas of activity for the Secretariat are as follows:

1. Servicing the Board and the Broader Alliance

1.1 Servicing GAVI Board Meetings and Teleconferences
Continuous work that is likely to increase in both volume and analytic content

1.2 Biennial Meeting of GAVI Partners
We anticipate no change in work load over the medium term.

2. Support to Other GAVI Structures

Working Group, Independent Review Committee, Task Forces, Regional Working Groups, Inter-Agency Coordination Committee

3. Joint GAVI/Vaccine Fund (VF) Coordination

Moderate additional work will be incurred as the Joint Committee of GAVI and VF Secretariats convenes regularly.

4. High Level Advocacy at Global, Regional and Country Levels

4.1 Participation in Global, Regional and Country High Level Meetings

4.2 High Level Consultation with Partners and Potential Partners

We envisage an increase in activities

5. Programme Oversight

5.1 Development of guides and operations management tools
Work involved should decrease progressively as guides/tools become routine management instruments and all eligible countries in implementation mode.

5.2 Review of Country Proposals, Requests, Inception, Annual and Mid-term Reports. We envisage a significant increase peaking in 2004 and falling back to current levels in 2006/2007. This scenario will however not hold should there be a major increase in new vaccines for developing countries or significant changes in immunization technology.

The country level implementation phase of GAVI related activities will continue to generate significant increase in work load related to monitoring and evaluation of country programmes.

Year	Total no. of activities	Data quality	Financial sustainability audits	Mid-term reviews plans	All other progress reports
2002	79	16	13	-	50
2003	144	24	21	34	65
2004	148	30	28	22	68
2005	110	13	10	19	68
2006	97	5	-	-	92

We envisage an input of 30% time of each of 3 Programme Officers

5.3 Management of DQA Contracts
20% each of staff time of Principal Programme Officer and Programme Officer

5.4 Data Base on Countries and Country Reports
80% time of 1 Programme Officer plus 10% time of Senior Programme Officer envisaged

6. Communications

We envisage 1 full-time equivalent of staff time

7. General Administrative Functions

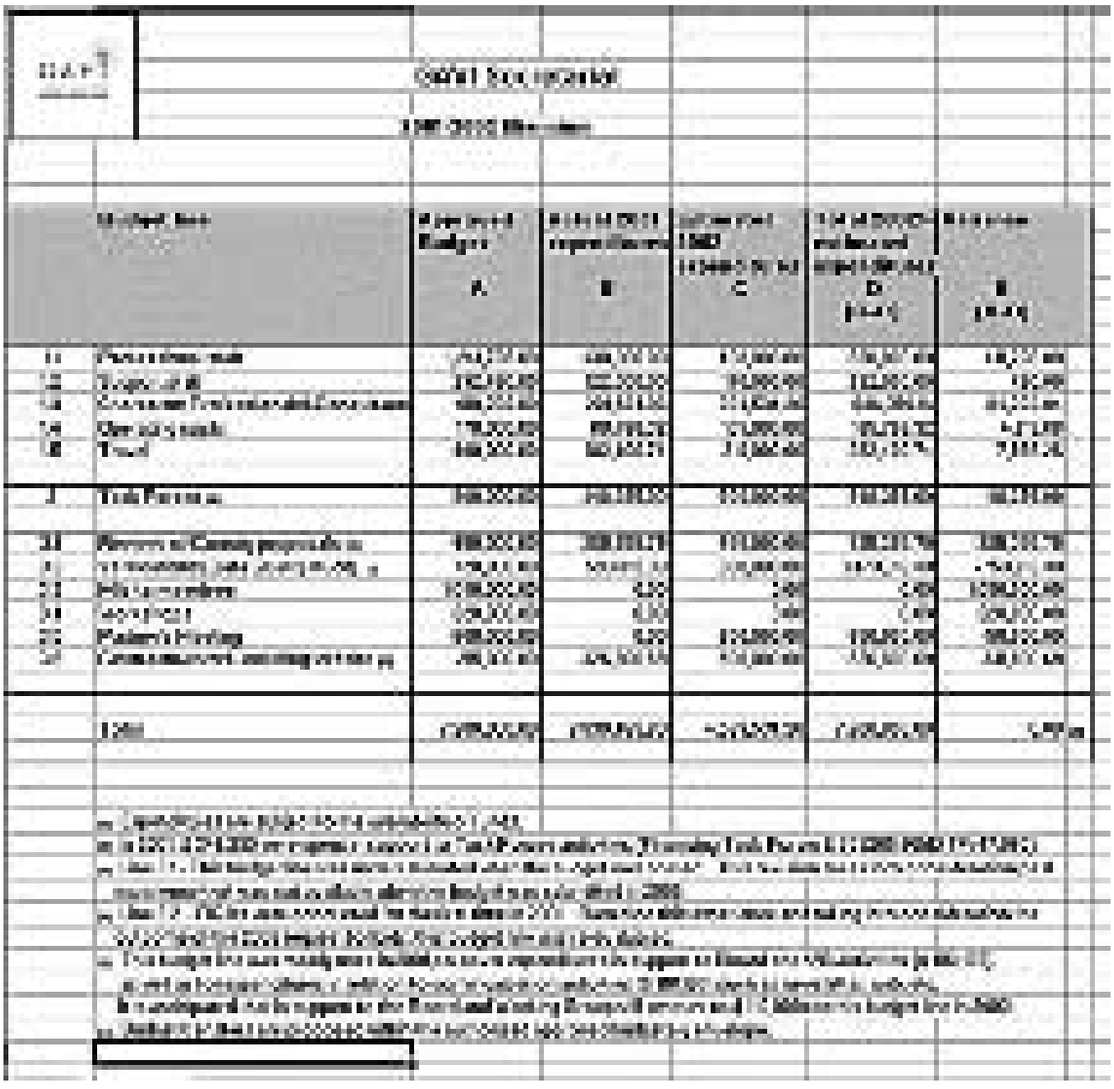
Management and administration functions are envisaged to increase and involve:

Executive Secretary and other technical staff

100% time of Senior Operations Officer and 100% Secretary (Operations).

Annex 6

GAVI Secretariat Budget 2001-2002



Annex 7:

Independent Review Committee questionnaire summary

The Independent Review Committee (IRC) is charged with the responsibility of reviewing proposals from GAVI-eligible countries seeking Vaccine Fund support. It has nine members, most of them from developing countries.

The terms of reference for this review included reviewing the relationship between the Independent review Committee, Working Group and Board and the conditions that should be created or sustained to ensure the independence of the IRC and its accountability to the Board. Section 11 of the main report discusses these issues.

As part of this work, a structured email questionnaire was developed to elicit the views of committee members. The questionnaire was issued on 27 April 2002 and by 7 June, eight of the nine members had responded to the questionnaire.
A summary of actual responses is attached below.

E-mail Questionnaire of Independent Review Committee

Replies received	8/9
1. Do you consider that the IRC, as currently composed, is fully equipped with the necessary range of skills to undertake not only current tasks but the full scope of the new monitoring role and its related functions?	**No :** 5/8 **Yes:** 3/8
2. If "no", what specific skills/ competences would need to be added (in descending order of priority)	• health economists (x 3 replies) • finance (x 2 replies) • monitoring/evaluation • waste management • technical expertise/pre-assessment of country proposals/ reports on specific issues (injection safety, financial sustainability plans, demographic data). Tracking planned activities/indicators/targets from approved applications to allow monitoring progress. The extent of additional assistance may vary, depending on the IRC's role in the monitoring process
3. Please provide a brief justification for each choice [in 2]	• health economists are needed, given tasks on financing sustainability, macro-economic perspective. IRC has only 1 health economist, other members are all program managers with expertise in EPI program operations • finance: interpretation of financial sustainability plans (FSPs), guidance to GAVI/countries, advice to agencies on support needed • monitoring : assessment of progress reports, contribute to GAVI thinking on use/limits of monitoring & evaluation, advice to agencies. But NB one comment: the role of the IRC should be mainly in assessing the functioning of the ICC, identification of communication and programmatic problems requiring additional assistance. The IRC will be less appropriate for monitoring purposes being far from the field. • waste management: interpretation of safe injection plans and continuing needs etc. • IRC members have different experience of specific issues. A specific/standardized technical expertise pointing on weak and strong parts would be helpful in making a final decision.

4. In the light of your experience of the recent review of inception reports, do you think the likely future workload of IRC members – including the growing demands of the monitoring process - will be manageable?	**Yes:** 0 **Yes, with difficulty:** 7/8 **Not manageable:** 0 **Cannot answer:** 1/8 - need clarification of what is expected of IRC on monitoring
5. If not manageable, how can such problems be overcome?	**Not applicable :** 7/8 • RWGs and sub-regional RWGs should be more involved in reviewing annual progress reports • a less formal process
6. What, if any, are the 3 most serious threats to the independence of the IRC?	• 1 respondent: no potential threat • 1 respondent: no threats at the moment • possible interference by the Working Group, but no pressure felt on IRC decision. "Frank discussion and different opinion between the IRC and WG is acceptable but I feel no pressure on IRC independence" (one member). The Working Group hears the IRC's report before the Board and potentially has a gatekeeping role; role of WG to be clarified (another member) • conflict of interest by IRC members: independence safeguarded in 1st 6 rounds • potentially interference by Secretariat but none seen. Secretariat highly appreciated in this regard • attrition and loss of institutional memory • selection of new IRC members • not maintaining 3 reviewers for each proposal which allows a more standardized review of proposals/reports. A reviewer can cope with no more than 3 countries per day, in different positions as 1st, 2nd, 3rd reviewer. • rubber stamp approval of progress reports (compounded by distance from field) • pressure to present GAVI as a success rather than seek/solve problems • (potential) conflict of interests in using IRC members on Agency assignments related to GAVI • an intermediary role by WHO Regional Offices • if individuals on the IRC are perceived to be representing their countries • any formal qualification by GAVI partners of country perspectives/documentation before IRC review • the quality/standardization of assessments /reports/plans • narrow experience of different countries/health infrastructure environment

7. What, if any, are the essential steps that have to be maintained/introduced to safeguard the independence of the IRC?	• strictly watch for conflict of interest; preserve existing policy on conflicts of interest • the individuality of IRC members needs emphasis • maintain no channel of communication between IRC members and the country; communication is solely the responsibility of the secretariat • support services from the secretariat • relationship and feedback from the Working Group (one member). Discussion with the WG has been helpful in past to test out IRC recommendations, but should be seen in that light only. • develop more detailed review criteria/formats (one member). Explicit criteria for unacceptable progress and inception reports (another member) • specify the role of RWGs v IRCs in review of annual reports • external expert opinion helpful but guard against judgement beyond requested facts • information sharing with stakeholders (eg vaccine suppliers) • direct briefing on new GAVI policies from Agencies as spokesmen for GAVI Board, as well as from GAVI secretariat in future • no body or organ between the IRC and the Board • consider no longer using IRC members on GAVI applications, conferences, progress reports
8. Do you regard the IRC as directly accountable to the GAVI Board?	**Yes:** 5/8 **No:** 1/8 **In-between yes and no:** 2/8 • No because the IRC maintains its integrity and technical independence, yes because IRC has to be accountable to GAVI Board policy direction, not because the Board appoints the IRC. • Yes, but…mediated through WG
9. If no, to which body (or to which additional body) is the IRC accountable?	• GAVI secretariat • IRC is accountable to all countries, to give the fairest, unbiased opinion and recommendations based on technical merits of the applications and ensure all applications treated similarly. Specific role for the Chair
10. Any other comments	1/8 • need a more defined mechanism/forum to share technical insights with partner agencies face to face (eg on last round IRC had 10-12 policy suggestions, but not clear WHO/UNICEF technical staff will hear them)

ANNEX 8 : Timetable of GAVI activities for monitoring and evaluation of Countries in 2002-06 (May 2002)

#	Round	Country	Month of 1st disbursement		2002				2003							2004						2005							2006					
			Cash	Vaccines	DQA	Inc Rep	1st Pr Rep	FSP	DQA	Inc Rep	1st Pr Rep	FSP	MTR 1st half	MTR 2nd half	2nd Pr Rep	DQA	1st Pr Rep	FSP	MTR 2nd half	2nd Pr Rep	3rd Pr Rep	DQA	FSP	MTR 1st half	MTR 2nd half	2nd Pr Rep	3rd Pr Rep	4th Pr Rep	DQA	3rd Pr Rep	4th Pr Rep	5th Pr Rep	Fin Rev 1st half	Fin Rev 2nd half
1	1	Cambodia	Feb-02	May-01			X	X	X					X	X						X							X				X		X
2		Côte d'Ivoire	Jul-01	Jul-01	X		X	X						X	X						X							X				X		X
3		Ghana	Dec-00	Oct-01	X		X	X					X		X						X							X				X	X	
4		Guyana		Jul-01			X	X						X	X						X							X				X		X
5		Kenya	Feb-01	Sep-01	X		X	X					X		X						X							X				X	X	
6		Kyrgyz Rep		Mar-01			X	X					X		X						X							X				X	X	
7		Lao PDR		Jul-01			X	X	X					X	X						X							X				X		X
8		Madagascar	Dec-00	Sep-01	X		X	X					X		X						X							X				X	X	
9		Malawi		Oct-01			X	X						X	X						X							X				X		X
10		Mali	Dec-00	Apr-02	X		X	X					X		X						X							X				X	X	
11		Mozambique	Jan-01	Mar-01	X		X	X					X		X						X							X				X	X	
12		Rwanda	Dec-00	Dec-01	X		X	X					X		X						X							X				X	X	
13		Tanzania	Nov-00	Oct-01	X		X	X					X		X						X							X				X	X	
14	2	Armenia	Sep-01	Jun-01			X					X		X	X						X							X				X		X
15		Azerbaijan	Mar-01	Jun-01			X					X	X		X						X							X				X	X	
16		Bhutan								X							X	X						X		X				X				
17		Haiti	Oct-01		X		X					X		X	X						X							X				X		X
18		Liberia	Apr-01	Oct-01	X		X					X	X		X						X							X				X	X	
19		Pakistan		Jul-01	X		X					X		X	X						X							X				X		X
20		Sâo Tomé	May-01				X					X		X	X						X							X				X		X
21		Uganda	Jul-01	Jan-01	X		X					X	X		X						X							X				X	X	
22	3	Burkina Faso	Jul-01		X		X					X		X	X						X							X				X		X
23		Cameroun	Jul-01		X	X	X					X		X	X						X							X				X		X
24		Sierra Leone	Jun-01				X					X		X	X						X							X				X		X
25		Tajikistan	Aug-01	Nov-01	X		X					X		X	X						X							X				X		X

#	Round	Country	Month of 1st disbursement		2002				2003							2004						2005							2006					
			Cash	Vaccines	DQA	Inc Rep	1st Pr Rep	FSP	DQA	Inc Rep	1st Pr Rep	FSP	MTR 1st half	MTR 2nd half	2nd Pr Rep	DQA	1st Pr Rep	FSP	MTR 2nd half	2nd Pr Rep	3rd Pr Rep	DQA	FSP	MTR 1st half	MTR 2nd half	2nd Pr Rep	3rd Pr Rep	4th Pr Rep	DQA	3rd Pr Rep	4th Pr Rep	5th Pr Rep	Fin Rev 1st half	Fin Rev 2nd half
26	4	Albania		Oct-01		X					X	X		X						X							X				X			
27		Afghanistan				X			X									X	X															
28		Bangladesh	Dec-01	Apr-02		X			X		X	X		X						X							X				X			
29		Eritrea		Dec-01		X					X	X		X						X							X				X			
30		Nigeria			X	X			X									X	X															
31		Turkmenistan		Oct-01								X		X																					
32		Uzbekistan		Aug-01		X					X	X		X						X							X				X			
33		Viet Nam		Nov-01		X					X	X		X						X							X				X			
34		Yemen				X			X									X	X															
35		Zambia	Oct-01			X			X		X	X		X						X							X				X			
36		Zimbabwe				X			X		X							X	X	X							X				X			
37	5	Benin		Mar-02		X					X							X	X	X							X				X			
38		Burundi	Dec-01			X			X		X	X		X					X	X							X				X			
39		Comoros	Dec-01			X					X	X		X					X	X							X				X			
40		Ethiopia				X			X		X							X	X	X							X				X			
41		Gambia	Dec-01			X					X	X		X					X	X							X				X			
42		Georgia	Feb-02			X					X							X	X	X							X				X			
43		Guinea		Apr-02		X			X		X							X	X	X							X				X			
44		Lesotho	Feb-02			X					X							X	X	X							X				X			
45		Moldova				X					X							X	X	X							X				X			
46		Myanmar				X			X		X							X	X	X							X				X			
47		Nepal				X			X		X							X	X	X							X				X			
48		Niger				X			X		X							X	X	X							X				X			
49		Senegal				X			X		X							X	X	X							X				X			
50		Sri Lanka				X					X							X	X	X							X				X			
51		Sudan				X			X		X							X	X	X							X				X			
52	Extra	China				X					X							X	X	X							X				X			
53		India				X					X							X	X	X							X				X			
54		Indonesia				X					X							X	X	X							X				X			
SUB-TOTAL					16	29	21	13	16	1	25	21	11	23	21		1	20	22	25	24			1		1	25	24		1	25	24	11	13

Estimate of additional activities

8	8 new countries with proposals approved in June 2002[1]						8						8	8	8						8		8				8				
6	6 new countries with proposals approved in November 2002 [1]						6						6	6						6		6	6				6				
4	4 new countries with proposals approved in June 2003[1]						4						4	4						4		4	4				4				

Estimate of repeated DQAs[2]

	50% of first DQA								8							8						9										
	25% of first DQA															4						4							5				
	SUB-TOTAL								8	18						30	18	8				13	10	8	10	18			5	18			
	GRAND TOTAL	16	29	21	13	24	19	25	21	11	23	21	30	19	28	22	25	24	13	10	9	10	19	25	24	5	19	25	24	11	13

Notes:

[1] The GAVI secretariat estimates that of the 20 countries not yet approved, 5 will not request GAVI support (Cuba, Honduras, Bolivia, Nicaragua and Solomon Islands). They also estimate that 3 other countries (East Timor, Yugoslavia and Syria) will become eligible (with GNP/cap < US$ 1,000). There are therefore 18 additional countries which could be approved for GAVI support.

[2] The Data Quality Audit will be repeated the following year in those countries that have a "not validated" result. The GAVI secretariat estimates 50% of countries will repeat the DQA once and 25% twice.

[3] Acronyms: DQA (Data Quality Audit); Inc Rep (Inception Report) Pr Rep (Progress Report); FSP (Financial Sustainability Plan); MTR (Mid-Term Review); Fin Rev (Final Review).

Lessons Learned

New Procurement Strategies for Vaccines
Final Report to the GAVI Board

June 28, 2002

MERCER
Management Consulting

Lessons Learned

New Procurement Strategies for Vaccines:

Executive Summary

1. This paper summarizes the findings of a study commissioned by the Vaccine Fund and the GAVI Financing Task Force Procurement Sub-group to examine the first procurement of vaccines by GAVI and the Vaccine Fund.
2. The study had two components: (1) building a fact base around the global vaccine market including the suppliers, market segments and economics, and determining the implications of this market structure for GAVI's procurement strategy; and (2) analyzing the actual implementation of GAVI/The Vaccine Fund's first procurement of vaccine and recommending enhancements going forward.
3. The study process, analyses and findings have been extensively reviewed with representatives of UNICEF, WHO, the Vaccine Fund and the Procurement Sub-group of the GAVI Financing Task Force.

The context for GAVI/Vaccine Fund Procurement

4. Demand profile and trends

- The global market for vaccines has grown at a 10% annual rate since 1992, from $2.9bn to $6bn. This growth is forecasted to continue.
- The growth is driven predominantly by high-income country demand for higher priced vaccines, not volume.
- The market remains characterized by strong value/volume skews. High-income country demand represents 82% of industry revenue, but only 12% of volume.
- Increasingly, high-income country immunization schedules are diverging from those in low and middle countries. This trend threatens one of the bases for tiered pricing, whereby high-income and low-income countries bought the same products, but high-income countries' pricing covered most of the production costs. Historically, tiered pricing has been critical to affordability and broad access.

5. Vaccine production economics

- Vaccine production economics are highly volume sensitive, with an average 60% of costs fixed at the plant level and 25% fixed on a per batch basis. Scale is therefore a major cost driver.
- Whilst there is wide variation in the costs to produce different vaccines, many of the factors explaining these differences are subject to buyer influence. For existing vaccines, multidose presentations and making appropriate use of those lower cost suppliers that are both economically viable and meet quality standards enhances affordability. For newer vaccines, influencing batch size decisions during plant scale-up (e.g. size or number of fermenters) will also enhance affordability.
- By comparison, differences in vaccine cost attributable to manufacturing processes (e.g. testing regimes and direct labor) are relatively minor. However, reliance on purchased (versus in-house manufactured) components (e.g. CRM protein for conjugates) and the inclusion of high numbers of antigens in combination products have a significant impact.

6. Supplier trends

- For the multinationals[1] , profitability has risen significantly since 1992, driven by proprietary products and technology substitution in high-income markets.
- As a consequence, R&D investment has also risen significantly, and is now at pharmaceutical industry levels. We estimate the five industry leaders spent over $750m on R&D in 2000.
- Since 1992, the number and scale of WHO-prequalified producers in low and middle-income countries has increased.
- These producers, termed in this paper "Emerging Suppliers[2] , have a large cost advantage over OECD-based producers, but typically lack significant R&D or process development capability. In consequence, their production is largely limited to older products.

7. Implications for GAVI/The Vaccine Fund's procurement strategy priorities

- GAVI's procurement strategy and implementation influences (positively or negatively) the engagement and decisions of vaccine suppliers.
- GAVI needs the engagement of both multinational and emerging suppliers to meet its conflicting procurement objectives of affordability and access to new/newer vaccines

→ Low-cost emerging suppliers can provide affordable pricing on mature products.

→ Large multinational suppliers, with significant R&D capabilities and process know-how, are better equipped to make available new or recently developed vaccines.

- GAVI's procurement priorities should therefore comprise the following:

→ Maintaining / enhancing large multinational supplier engagement, to ensure access to new/newer products.

→ Seeking to expand the number of economically viable and high quality emerging suppliers, to increase competition for basic pediatrics and accelerate access to products as they mature.

→ Ensuring multi-dose presentations continue to be produced, as presentation is a key factor in affordability and access regardless of supplier type.

- Whereas GAVI and its partners are a significant and profitable customer for emerging suppliers, GAVI has little leverage in terms of revenue or profit with the multinationals.
- Given GAVI's objectives and lack of leverage over the multinationals, the procurement strategy needs to be designed and managed to increase multinational supplier engagement. These measures will also solidify emerging supplier engagement.

→ Providing for appropriate returns.

→ Creating credible and predictable demand (in part through firm contracting)

→ Working in a collaborative and open fashion with suppliers.

→ For new products, focusing (from a product and supplier perspective) to maximize leverage and minimize costs.

[1] Aventis Pasteur, Chiron, GlaxoSmithKline, Merck, and Wyeth
[2] Includes Green Cross Biofarma, Serum Institute of India,

8. Review of 2000-2001 Procurement Activity

- During the first procurement, the Alliance successfully allowed for appropriate returns, creating "pull" incentives that have accelerated competition in DTP-based combinations. This competition will result in reduced prices for these products in due course.
- However, opportunities were missed to demonstrate credible and predictable demand and to work in a collaborative and open fashion with suppliers

→ The mismatch between 2001 supplier awards (98 million doses) and actual offtake (18 million doses) was especially problematic in this regard.

- Shortcomings of the first GAVI effort, relative to a procurement strategy which would fully support GAVI's objectives, are attributable to:

→ Extreme pressure of time: fourteen months from conception to award.

→ An excessive focus on financing as the key constraint, with inadequate and late attention to program and supply issues.

→ The ineffectiveness of a loose alliance in implementing (vs. developing) policy, with unclear and overlapping roles and a lack of accountability.

→ Significant discomfort with suppliers as partners in the effort

9. Lessons Learned and Recommendations

- Our recommendations to address these shortcomings going forward are:
- Pressure of time. In any context, preparing for the introduction and introducing a new vaccine is a multi-year effort. This is especially true for low-income country immunization, given that decision-making is complex with multiple actors, programmatic strength varies, and change places an additional burden on constrained resources at country, donor, agency and supplier levels.
- Reflecting these facts, GAVI must start planning now for the next wave of vaccine introduction several years hence.
- GAVI and the Vaccine Fund should therefore engage with partners to define the next wave of initiatives, consistent with the likely resource levels available and other calls on those resources.
- GAVI and the Vaccine Fund have a key role to play in ensuring that consistent messages on priorities are sent to suppliers, potential donors and countries and that constrained resources are aligned against these priorities.
- Excessive focus on financing. Preparing for and introducing a new vaccine is a multidisciplinary effort. Success depends on contributions from program (advocacy and delivery), supply and financing. Further, there are inter-dependencies between these disciplines, requiring strong coordination and communication.
- Each required discipline is represented in the Alliance: Program (UNICEF PD, WHO, low-income countries), Supply (UNICEF Supply Division, industry) and Financing (the Vaccine Fund, World Bank, donors). The Alliance is therefore well positioned to facilitate multi-disciplinary and coordinated planning and implementation.
- Therefore, we recommend that GAVI implement a multi-disciplinary approach to planning and managing the introduction of vaccines and ensure that a strong coordinating mechanism is in place.

- The ineffectiveness of a loose alliance in implementing. Multi-disciplinary implementation and coordination is a challenge even within one organization with a single objective. A loose alliance with complex objectives faces an even greater challenge.
- The challenge of ensuring effective implementation, coordination and decision-making in such circumstances is most often addressed in our experience by using a project management model, the key components of which are:

→ Responsibility for integrated decision making and outcome is vested in a single entity and individual within that entity (the project manager).

→ Each required discipline is represented on the project team and relevant experts are accountable for a component of the overall project. Individual representatives draw on the resources of their institution to achieve the goals of the project.

→ Team members are accountable to the project manager, and the project manager is accountable to a project oversight body.

→ A properly constituted project oversight body should be small and should include a mix of senior staff from engaged partners and representatives of partners not directly involved in the project team to ensure objectivity.

→ Project management tools, such as workplans, timelines, milestones and measurement of deliverables to ensure progress and accountability are essential.

- The composition of each team, the choice of project manager and the membership of the oversight body are functions of the specific goals and critical issues of each project. The selection of the appropriate institution(s) to fulfill all of these roles should depend on both relevant expertise and a willingness to be accountable to the GAVI Board for performance.
- We recommend that GAVI should institute a project management model for the planning and implementation phases of key initiatives such as vaccine procurement and introduction.
- We further recommend that GAVI and the Vaccine Fund pilot the project management approach with the upcoming 2004-6 procurement round.
- The key objective is to produce an accurate, product-specific, forecast that enhances the credibility of demand and commands sufficient confidence amongst partners to allow the majority of GAVI's vaccine to be procured on a firm contract basis.
- Given that programmatic issues ultimately determine forecast accuracy, we suggest the Project Manager function reside in an agency with a strong program focus: either UNICEF PD or WHO.

→ Either UNICEF PD or WHO should have lead responsibility for program issues within the project team.

→ UNICEF SD should have lead responsibility for supply.

→ The Vaccine Fund should have lead responsibility for finance. Firm contracting for vaccine transfers offtake risk from suppliers to purchasers. Therefore the Vaccine Fund will also have a particular responsibility, given its fiduciary responsibility to donors and fundraising, for satisfying itself that the planned firm commitments are prudent.

→ It is worth emphasizing that no one agency has all the skills and resources to deliver within each of these foundations. It is therefore the responsibility of each lead agency to draw upon and team with other agencies to meet the project's and GAVI's objective.

- GAVI should create or instruct an oversight body to monitor progress and hold the project manager and the relevant individuals and institutions accountable for performance. This oversight body should include representatives from the engaged institutions as well as representatives from institutions outside the core project team.
- Each member of the project team should have indicators and milestones to measure performance and progress. These indicators and milestones should be defined in advance with the oversight body and team members. As examples:

→ For the project manager, forecast accuracy, proportion of firm contracting, meeting project deadlines, meeting supply needs to achieve coverage targets.

→ For the program function, country by country and overall forecast accuracy, both as to product and timing.

→ For the finance function, proportion of firm contracting, financing return, uptake of firm offtake.

→ For the supply function, realized accuracy of availability and pricing assessments, delivery reliability, timeliness, frequency and content of information shared with industry, and pricing trends over time.

- There is an urgent need to move forward with this initiative as soon as possible.

→ A tender/RFP is due to be issued in Q3 of this year for 2004-2006, and we understand that little preparatory work has been done to date.

→ Even with prompt action by GAVI partners, we are concerned that this Q3 target date may not allow sufficient time for the partners to ensure accurate, transparent forecasting, implement new strategies like firm contracts and establish indicators to measure performance across the 3 disciplines.

→ We therefore recommend that GAVI consult with industry to determine if a later deadline for RFP/tender issuance can be set without jeopardizing supply. We believe industry will, in general, be supportive of efforts to improve the robustness of forecasts and the predictability of demand.

→ Given timelines, there is an urgent need to move forward with this promptly.

- Significant discomfort with suppliers. We believe it is in GAVI's interest that suppliers have as good insight, as early as possible, into the Alliance's plans and preferences. Lead times in the vaccine industry, whether for product development, capacity investment or production, are relatively long. Further, capacity at some major suppliers is increasingly constrained and so early indications of demand are essential.
- We therefore recommend that GAVI ensure that information on demand, product preference and future needs is shared with industry, unless there is a well-defined reason not to do so. Further, GAVI should ensure that bilateral meetings are held with industry when key decisions need to be made or there is a major development.

Piers Whitehead
Vice President
Mercer Management Consulting, Inc.
3 Embarcadero Center, Suite 1670
San Francisco, CA 94111

(415) 743-7888
piers.whitehead@mercermc.com

Andrew Pasternak
Principal
Mercer Management Consulting, Inc.
10 South Wacker Drive, 13th Floor
Chicago, Illinois 60606

(312) 902-7012
andy.pasternak@mercermc.com

Project Context

The Procurement Sub-Group of the Financing Task Force of the Global Alliance for Vaccines and Immunization ("GAVI") and the Vaccine Fund engaged Mercer Management Consulting to evaluate GAVI's vaccine procurement strategy and the implementation of that strategy in GAVI's first two years of existence. Further, Mercer was asked to recommend changes, where applicable, in GAVI's procurement strategy and implementation approaches that would better support GAVI's strategic objectives. The project began in mid-February 2002 and ran until mid-May.

The study was led by the authors of this paper and culminated in a series of presentations in May and June of 2002 to the GAVI Financing Task Force, the Procurement Sub-group, and concluding with the GAVI Board at its June 2002 meeting. The audience across these presentations included a broad cross-section of GAVI partners, including the World Health Organization, UNICEF Supply Division, UNICEF Program Division, the World Bank, the Vaccine Fund and the Gates Foundation. We have solicited the input of these and other partners in the development and communication of these findings and recommendations.

Project Objectives

The terms of reference for this study laid out the following two major objectives and deliverables:

- A description and fact base of the global vaccine market (size, segmentation, trends, supplier economics and key dynamics); the implications of the current state of the market for GAVI's procurement strategy priorities and the ability of that strategy to achieve public sector goals; and resulting procurement options for GAVI and the Vaccine Fund.
- An evaluation of GAVI's first set of procurement activities, recognising that actual deliveries to countries only commenced in the last twelve months, and therefore a full cycle of procurement and use has yet to be completed. This included a mapping of key processes and roles and responsibilities; identification of procurement strategy, organizational or process-related shortcomings that detracted from the effectiveness and desired outcome of the effort; and recommendations for changes going forward.

Methodology

In arriving at our findings, we have drawn on three sets of sources:

- A comprehensive review of publicly available data, including immunisation coverage and schedules, company annual reports and websites, the general and specialist press and GAVI Board Meeting and Task Force minutes. It is noteworthy that, given the open nature of the Alliance, we did not have access to any proprietary information from GAVI partners from either public or private sectors.
- A wide-ranging interview program, covering GAVI stakeholders and participants in the procurement process; major suppliers and customers; experts and regulators. We are grateful to all those who found time to contribute their thoughts and insight to our efforts.
- Mercer's own proprietary vaccine expertise and models, including the 1993 study for UNICEF Supply Division and subsequent work for a variety of public and private sector clients. No client-confidential material has been included in our findings.

The context for GAVI/Vaccine Fund Procurement

Demand profile and trends

We estimate the global vaccine market was approximately $6 billion in revenues in 2000, as compared with $2.9 billion in 1992, when Mercer conducted its study for UNICEF Supply; this represents an average annual growth rate of 10% in nominal terms (i.e. before adjusting for inflation) over the eight year period. This growth can be expected to continue, and likely accelerate, given both the recent focus on bioterrorism risks and

the early stage of introduction in 2000 of some of the antigens driving revenue growth, such as Meningitis C and Pneumococcus.

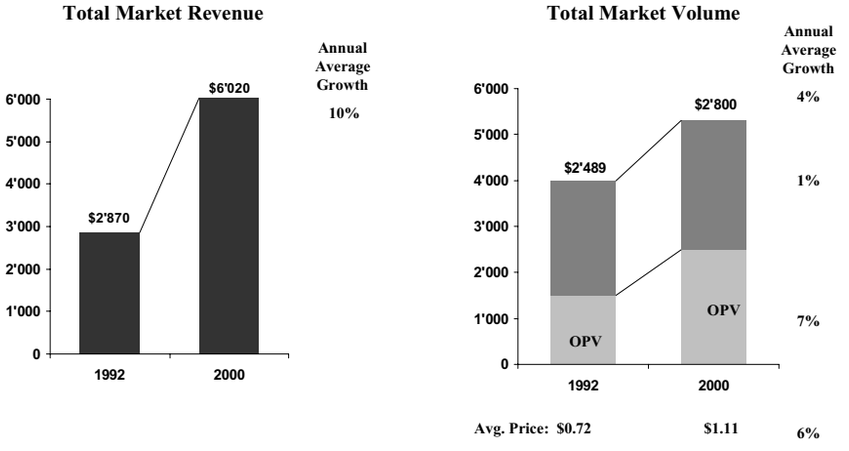
We estimate total worldwide volume to be 5.3 billion doses, as compared with 4.0 billion doses in 1992. The majority of volume growth is attributable to the worldwide polio eradication effort, with volume of all vaccines excluding oral polio vaccine increasing at only a 1% rate during the 1992-2000 period. Note that our definition of doses is filled vaccine. A multivalent vaccine represents one dose, regardless of the number of antigens it contains.

Most of the revenue growth, therefore, has been driven by an increase in average vaccine pricing rather than by increased volumes. We estimate that the average price per dose across all vaccines increased 6% annually to $1.11 in 2000 from $0.72 in 1992. Significant volume/value skews continue to characterize the global vaccine market from a buyer perspective; high-income countries represent $4.9 billion, or 82%, of the total market in terms of revenues, but only 12% of the total market in terms of volume.

Understanding volume and revenue growth requires that one consider the distinct product segments within the global vaccine market. The first distinction is between vaccines intended primarily for adults and those for primarily pediatric use. Within pediatrics, our segmentation criteria is product lifecycle – in general, products earlier in their lifecycle are proprietary and are characterized by a less competitive supply base; as in most markets, such conditions result in restricted availability and relatively high pricing. Relatively mature or basic products have more competitive supply bases, and in many cases are produced not only by companies in the OECD but also by emerging suppliers based in low/middle income countries. Notably, the earlier the product is in its lifecycle, the more likely that product is to be purchased exclusively by high-income countries3. Adult/travel and proprietary pediatrics are primarily or exclusively purchased by high-income countries, whereas several enhanced pediatric vaccines are purchased by all buyer segments and basic pediatrics are purchased primarily by low/middle income countries.

Vaccine market: Growth

Revenue growth has been driven by modest volume gains and higher average prices.



Source: Mercer analysis, 1992 Vaccine Report.
Note: 2000 OPV volume includes UNICEF (1200MM), UNICEF estimated local procurement in China and India (600MM), PAHO (340), and other

Product Segments and Example Vaccines

Basic Pediatrics	Enhanced Pediatrics	Proprietary Pediatrics	Adult/Travel
• OPV • BCG • TT • DTP • Measles 2000 Revenue: $680MM	• IPV • DTaP • Hepatitis B • Hib • MMR 2000 Revenue: $2.0 billion	• Pneumococcal and Meningococcal conjugates • Varicella 2000 Revenue: $1.7 billion	• Hepatitis A • Yellow Fever • Typhoid • Influenza 2000 Revenue: $1.7 billion

Illustrative of the lifecycle-based differentiation in supply bases and pricing, proprietary products, all of which have been brought to market in the last seven years, and two of which (pneumococcal conjugate and varicella) are each currently produced by a single supplier, had an average price per dose in 2000 of $35. These levels contrast with an average price per dose of $12 and $0.15 for enhanced pediatrics and basic pediatrics, respectively.

Due to their relatively high pricing, three proprietary products – pneumococcal conjugate, meningococcal conjugate and varicella represented $1.7 billion, or nearly 30%, of the total vaccine market spend in 2000, on only 1% of the total market volume. Since they did not exist in 1992, these three products represent over 50% of the absolute revenue growth in the vaccine market since 1992. Consistent with historical experience, these products have been developed for, and are exclusively purchased by, high-income countries.

The success of these products has served as a strong "signal" to suppliers: significant increases in revenue and profits4 can be achieved through the development of new products for high-income countries targeting previously unserved needs. This strategy is analo-

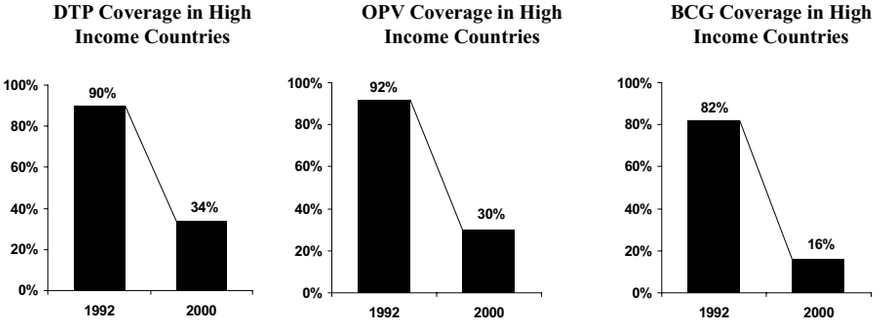
gous to the predominant "blockbuster drug" strategy which has underpinned much of the commercial success of the large pharmaceutical companies in the recent past.

The second factor driving the growth in revenue terms of the vaccine market is two technology substitutions in high-income country markets – acellular pertussis for whole cell pertussis in diphtheria-tetanus combinations, and injectable polio vaccine for oral polio vaccine. For example, DTaP is now specified in the majority of high-income immunization schedules, covering 66% of high-income birth cohorts, which were covered by whole cell pertussis combinations in 1992. While these substitutions are volume-neutral, they typically result in significantly higher pricing compared to the products they replace. As a result, the market for enhanced pediatrics has doubled, increasing to $2.0 billion in 2000 from $1.0 billion in 1992.

By contrast, the size of the market in revenue terms for basic pediatrics has decreased by 40% during the last 8 years to $680 million in 2000, in spite of the significant volume increases driven by polio eradication. This reflects the decline of high-priced, high-income country demand for these products. This decline is attributable to multiple factors: technology substitution with enhanced pediatrics, the increasing prevalence of combinations (e.g., MMR versus measles monovalent) and the more targeted use of BCG (i.e., during tuberculosis outbreaks) in high-income countries. Thus, the schedules of high-income countries and low/middle income countries are increasingly divergent.

Demand divergence

Low and middle income markets increasingly represent the sole source of demand for basic pediatric vaccines.



Source: Mercer analysis, 1992 Mercer report, WHO coverage statistics

Schedule divergence has significant implications for the cost and availability of vaccines for low/middle income country demand. Historically, low/middle income country demand has benefited from tiered pricing for a given product; in the 1993 study, we found that high-income country pricing for a given product could be 250 times higher than low income country pricing (as achieved by UNICEF Supply). This degree of price tiering has historically been enabled by three conditions:

- The existence of both high-income country and poor/middle income country demand for a common vaccine. As a result, relatively high prices paid by high-income countries cover suppliers' fully-loaded costs and profit requirements, enabling low/middle income countries to achieve marginal pricing, defined as prices

which cover direct costs but do not fully cover fixed costs.

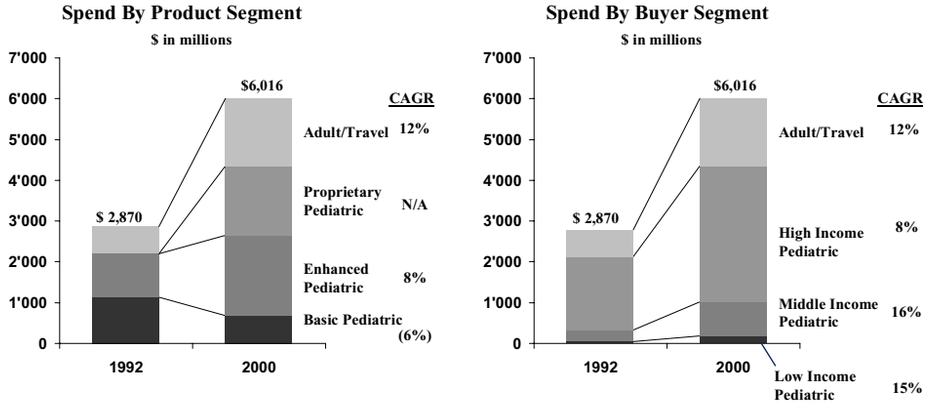
- The existence of significant excess capacity relative to high-income country demand.
- The willingness of certain suppliers and government customers to accept radically different pricing for different segments of demand.

Schedule divergence means that the first enabler of price tiering is increasingly threatened. Divergence requires low/middle income pricing to increasingly justify (and therefore cover) the fully loaded costs and required profit of the capacity dedicated to this product; otherwise, availability of the vaccine becomes jeopardized and potentially compromised. Therefore, while price tiering continues across products based on lifecycle, price tiering is less prevalent for a given product. As we will discuss in the next section, capacity constraints amongst the multinational suppliers threaten the second enabler of the traditional tiered pricing / marginal capacity paradigm.

Given the product segment trends discussed above, it is unsurprising that most of the market revenue growth is attributable to high-income demand, both for pediatric and adult/travel vaccines. Whilst low and middle income demand is in fact growing faster in percentage terms, the absolute impact of this growth is modest, given that it represents only 18% of the market by value.

Market growth: Revenue

High income markets buying proprietary, enhanced or adult products have driven vaccine revenue growth.



Source: Mercer analysis, 1992 Vaccine Report.

Vaccine Production Economics

Production Process & Economics Overview

At a high level, vaccine production represents two sets of sequential activities: bulk production (growing cell lines/fermenting and harvesting) and filling (blending, formulating, filling and lyophilizing, where applicable). To conduct these activities, vaccine manufacturers incur certain expenses, such as labor, animals for testing, and depreciation on equipment and facilities, utilities, vials and packaging materials, among others. Throughout this document, we exclude research and development and selling/marketing expenses from the definition of production costs.

Vaccine production economics are characterized by high operating leverage. The majority of costs are either fixed regardless of volume (on average, 60% of total costs) or "semi-variable" (25% of total costs) – that is, fixed at the batch level or filling lot level, regardless of batch size or filling lot size. Only 15% of costs are truly variable, meaning that they fluctuate in direct proportion to the volume of individual doses produced.

We do not believe there has been a significant increase in the costs of vaccine production since 1992, after making allowance for the effects of inflation. Companies have significantly increased their spending on R&D, which we do not consider a production cost. In addition, there has been an increase in the effort and thus expense associated with regulatory compliance. However, our research and analysis does not suggest that this is significant overall, and may have been offset by productivity gains elsewhere.

Vaccine cost behavior

Production costs can be grouped into three different categories, based on behavior.

Cost Category	Average Cost Contribution[1]	Definition	Examples
Variable Costs	15%	• Unit cost is constant • Cost increases directly with increased volume	• Vials, stoppers, labels, packaging, in-sourced components
Semi-Variable Costs	25%	• Batch cost is constant, regardless of number of doses • Cost per dose falls with an increase in batch size	• Labor (production and testing) • Animals
Fixed Costs	60%	• Cost is independent of volume • Cost per dose falls with increased number of doses produced	• QA and admin. labor[2] • Depreciation • Other manufacturing overhead

Determined by:
Vaccine-Specific Characteristics
Company-Specific Characteristics
Factor Costs

[1] Average contribution to cost per dose for three major European suppliers; fixed costs exclude R&D and sales.
[2] R&D and sales labor are also fixed costs, but are excluded from the analysis of production costs.

Vaccine Cost Drivers

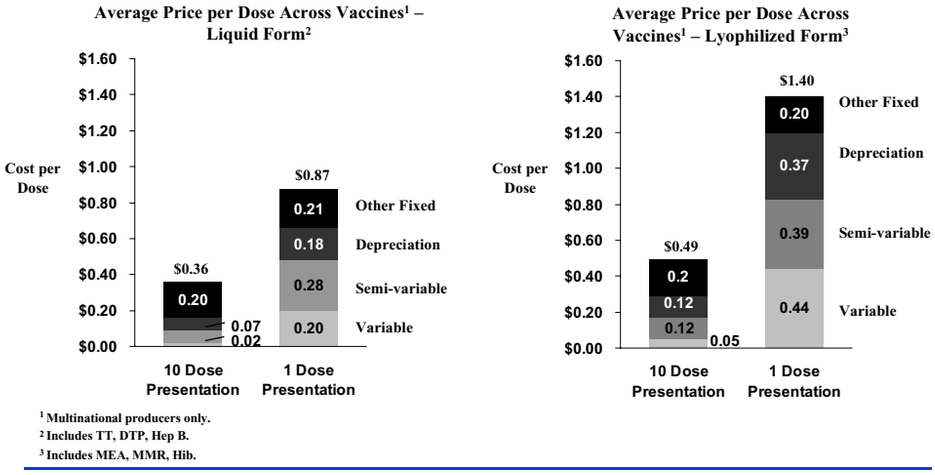
The cost to produce a vaccine varies significantly, ranging from $0.05 per dose up to $3-$4 per dose. There are six factors that drive the variation in these production costs. These factors are:

1. *Presentation:* the number of doses per vial
2. *Scale of Operations:* the total volume of production over which fixed costs are amortized
3. *Supply Policy for Vaccine Inputs:* whether antigens and carrier proteins are produced in house by the supplier or purchased from another supplier
4. *Supply Base Location:* whether the production (and required labor) is located in a country with relatively high or relatively low wage rates
5. *Vaccine Batch Size:* The number of doses in a bulk production batch for a given vaccine
6. Vaccine Production Characteristics: The amount of time, labor intensity and testing regimen required to produce a given vaccine

1. *Presentation* Presentation is customer-defined; that is, the buyer specifies the presentation, not the supplier. Single dose presentations are significantly more costly to produce than multi-dose presentations because presentation is the key determinant of filling lot size. This is attributable to increased filling labor requirements, higher vial costs per dose and a greater depreciation burden due to higher filling capacity requirements (6-7x versus 10 dose presentations). In an OECD supplier context, single dose presentations add approximately $0.50 per dose to the cost of a liquid vaccine, and $0.90 to the cost of a lyophilized vaccine.

Presentation effect

Single dose presentation drives higher variable and semi-variable filling costs and increased depreciation burden, particularly for lyophilized vaccines.



[1] Multinational producers only.
[2] Includes TT, DTP, Hep B.
[3] Includes MEA, MMR, Hib.

Scale of operations, supply policy for vaccine inputs and supply base location are all supplier-specific factors. The influence of these factors on the price paid by a buyer for a vaccine is therefore within the control of the customer to the extent that the customer can choose among suppliers to satisfy its product needs.

2. *Scale of operations* The impact of manufacturer scale can be illustrated by comparing the US multinationals with the European multinationals. U.S. multinationals are higher-cost producers relative to European multinationals because of the former's overall lower volume levels (fewer than 100 million doses annually versus over 1 billion doses for certain European multinationals). We estimate the impact of this scale differential at $0.82 per dose. Much of this scale differential is attributable to European supply of OPV for polio eradication.

3. *Supply policy for vaccine inputs* The importance of supply policy for vaccine inputs reflects two trends. Since 1992, these trends have reduced the extent to which any major vaccine producer is self-sufficient in terms of all the components it requires to manufacture its products. These trends are the growth of combinations and the growth of conjugate vaccines, which require a carrier protein. As a consequence, vaccine manufacturers have entered into contractual arrangements with other suppliers to gain access to the antigens and carrier proteins required for their suite of products; for example, GSK sources diphtheria toxoid and tetanus toxoid bulk requirements from Chiron.

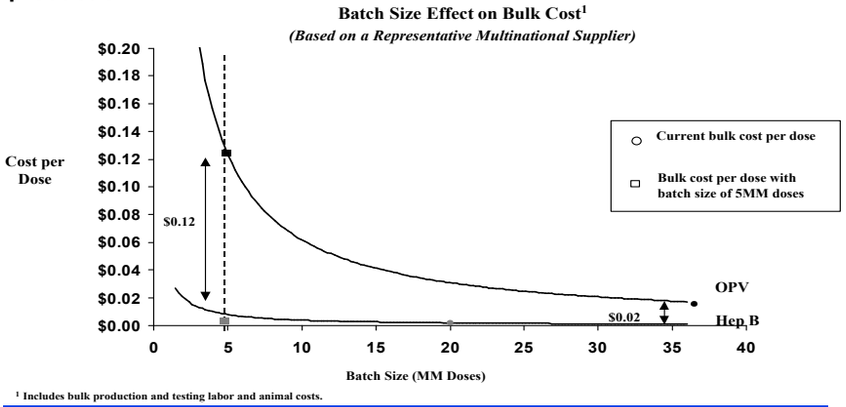
While we are not privy to the terms of these supply arrangements, two factors, supported by anecdotal evidence, suggest that these supply arrangements have a significant impact on economics. First, outsourcing a component reduces operating leverage, since it converts what is primarily a fixed cost activity (in-house production) into a variable cost. The marginal cost of vaccines with significant outsourced components will likely therefore be higher than those produced entirely in-house. Second, we believe the likely impact of these arrangements is generally to increase the absolute cost of the vaccine in question. There is no law of economics that dictates that this should be true: if the outsourced supplier is a more efficient producer than the customer, the decision to outsource might actually reduce cost. Finally, each arrangement will be unique and reflect the negotiating positions and strategies of the parties involved. However, an outsourcing arrangement introduces a second party requiring a commercial return and a second set of plant fixed costs and overhead to cover. Anecdotally, it is clear that these deals have had the effect in the short term of limiting both availability and competition in the DTwP-based combination market.

4. Supply base location All OECD suppliers are significantly higher cost producers than large emerging suppliers, as wage rates for pharmaceutical labor in lower income countries such as India and Indonesia are less than 10% of comparable wage rates in high-income countries. Location translates into a $0.12 per dose advantage (for multidose vials) on average in labor costs alone for such emerging suppliers. This differential will be much higher for single dose presentations.

5. Vaccine batch size The bulk batch size is a significant driver of variation in cost between vaccines. Since the cost to manufacture and test a bulk batch is largely fixed, an increase in batch size results in lower per dose costs. Batch size is largely determined at the time of manufacturing scale-up. Once a plant is in place, there are two ways in which bulk batch size can be increased. One is by adding capacity, a process that requires incremental capital, may disrupt production and certainly requires regulatory approval and GMP certification. The second is to wait and allow the experience effect to drive yield improvements and consequent increases in effective batch size. Although recombinant hepatitis B appears to have experienced very rapid and dramatic improvements in yield, the available data suggests that for most other vaccines, this process takes many years to reach the kind of batch sizes desirable for the international public sector, given the scale of demand and affordability requirements. Given the difficulties of increasing batch size once a plant is built, the most desirable route to both capacity and relative affordability is to influence batch size at the time of scale-up, either through being considered part of the "core" market, or perhaps through early commitment to purchase.

Batch size effect

The cost impact of batch size, typically fixed at the time of scale-up, varies by vaccine and diminishes at higher absolute scales of production.



[1] Includes bulk production and testing labor and animal costs.

6.Vaccine production characteristics These are entirely beyond the control of the buyer and do vary across vaccines. These differences result from differing testing and labor requirements, antigen combinations and production process cycle times, which in turn drive cost differences. However, after normalizing for the five customer and supplier-specific drivers of cost, differences in cost attributable solely to varying production methods are relatively small. As an illustration, the most expensive vaccine to produce at the bulk stage is OPV. However, the large batch sizes and the fact that it is manufactured by high scale producers in predominantly multi-dose presentations results in a fully loaded production cost we believe to be the lowest of any vaccine manufactured by OECD producers.

In summary, buyers can significantly impact the cost of production and resulting pricing they receive based on the choices they make with respect to suppliers, presentations and, for new vaccines, the timing of commitment to purchase. Therefore, a buyer seeking to enhance affordability can do so by buying in multi-dose presentations, purchasing in significant quantities from a limited set of suppliers (to reduce overhead per dose) and doing business where appropriate with lower-cost emerging suppliers.

Supply Base and Trends

There are five segments of vaccine producers in the market today.

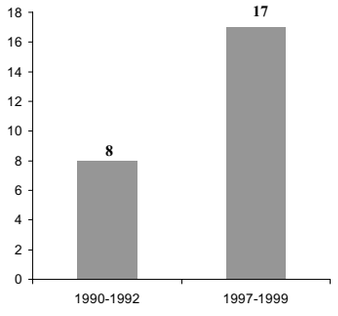
	U.S. Multinationals	European Multinationals	OECD Locals	Emerging Suppliers	Developing Country Locals
Product Range	Narrow	Broad	Narrow	Narrow - Moderate	Narrow Low-High
Scale	Low	High	Low	Moderate-High	Low-High
Customer Focus	Mostly high-income	All buyer segments	Mostly in-country moderate income buyers	In-country and other low-	All in-country
R&D Activity	High	High	Low	Low-Moderate	Low
Example Suppliers	Merck, Wyeth	Aventis, GSK, Chiron	SSI, CSL, Powderject	Serum Institute of India, Biofarma, Green Cross	State-owned producers in China, Egypt, Vietnam

U.S. and European multinationals experienced near double-digit revenue growth during the 1992-2000 period, resulting primarily from the sale of adult/travel, proprietary and enhanced pediatric products to high-income buyers. The success of this strategy has driven significant investments in research and development; we estimate that the vaccine businesses of Merck, Wyeth, GSK, Aventis and Chiron spent in excess of $750 million in 2000 on research and development. We believe that this represents a significant increase, both in absolute terms and as a percentage of sales, over the level of R&D investment in 1992. Spending as a percentage of sales is now at a level consistent with the broader pharmaceutical industry, and the fruits of this investment are feeding through, both in terms of new product introductions and development pipeline.

Significant increases in R&D

Enhanced profitability and the application of pharmaceutical and biotech business models have greatly expanded investment in R&D.

Number of New U.S. Vaccine Licenses Granted



Current Development Pipeline

- **Nearly 350 vaccines in various stages of development[1]**
  - **188 in pre-clinical phase, 158 in clinical trials**
- **Pipeline contains increasingly complex vaccines**
  - **Genetically engineered recombinants (e.g., HIV, herpes simplex virus, diabetes, fertility)**
  - **Conjugates (e.g., group B streptococcal)**
  - **Combinations (e.g., DTaP/Hib/IPV/HB, 9- and 11- valent pneumococcal conjugate)**

R&D spending on vaccines among multinationals likely exceeds $750m annually: pharmaceutical levels[2]

[1] As of 2000. 2. 16% of sales
Sources: NIH 2000 Jordan Report, "Vaccines", CDC.

These increased research and development expenditures notwithstanding, we believe that as a group, the profitability of the multinational producers is now higher than it was in 1992. As an illustration from public data, GSK's Belgian subsidiary (which represents the majority of its vaccine operations) reported an operating margin of 33% for 2000, as compared with 26% in 1992. This increase occurred despite a nearly five-fold expansion in R&D on a revenue base that grew by a much lower 50% over the period.

However, the observed strategies being pursued by U.S. and European multinationals differ significantly. U.S. multinationals appear focused on point innovation, concentrating their business and R&D efforts on a small number of proprietary products with high profit margins. These companies have demonstrated (e.g., tetanus) that they are willing to drop mature products from their portfolio, as competition increases and profitability drops to unacceptably low levels. Conversely, European multinationals have built and are continuing to develop comprehensive "suites" of product, enabling them to serve a wide range of buyers with both monovalent and combination products; for example, Aventis and GSK are currently the only providers of pentavalent and hexavalent products in the world.

Emerging suppliers have significantly enhanced their scale and product breadth since 1992. Given their cost advantages,, they represent an attractive low price supply source for basic pediatrics, and have benefited as a result. However, these suppliers do not currently have experience in developing new products, and generally lack the R&D infrastructure and process know-how (e.g., conjugation) possessed by multinationals. Therefore, the key challenge for emerging suppliers is accessing / developing technologies that are of interest to low and middle-income countries, either as direct buyers or through agencies such as PAHO, UNICEF and GAVI.

Implications for GAVI/The Vaccine Fund's Procurement Strategy Priorities

GAVI and the Vaccine Fund seek to balance three objectives in procurement: affordability, supplier investment in capacity and relevant R&D. The tension between these objectives is obvious: investment, whether in capacity or R&D, tends to follow profitability, whereas affordability translates to lower prices and lower profitability.

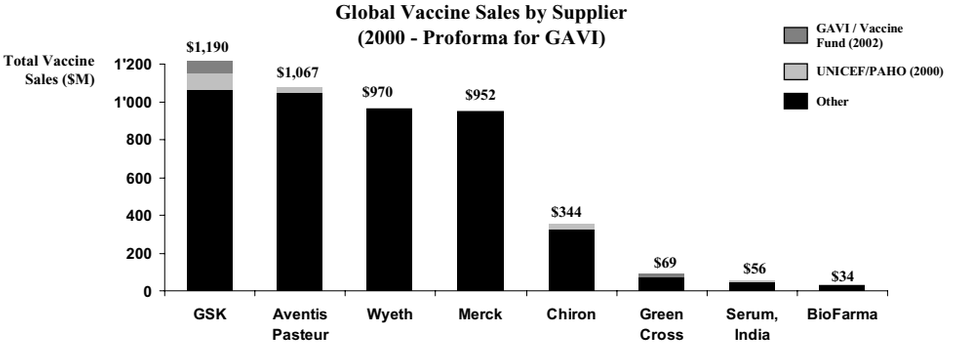
Given this mix of objectives, both large multinational and emerging suppliers are potentially important to meeting GAVI's overall objectives. Emerging suppliers provide GAVI with a low-cost and potentially high-volume sourcing option, and one over which GAVI can exert significant influence, given the importance of the GAVI market for these suppliers. Large multinationals, on the other hand, possess the R&D capabilities, product pipeline and range, and process know-how which are critical to providing product options that, while not lowest-cost, may afford significant programmatic and public health benefits.

Not only do these different types of suppliers have very different things to offer GAVI, but they are also likely to see GAVI/Vaccine Fund demand – and low and middle income demand generally – as very different commercial opportunities for them. Even with the Vaccine Fund, low-income country demand represents a relatively small and marginally profitable opportunity for multinational suppliers. We should note, however, that whereas procurement of mature vaccines from the multinationals is at marginal prices (i.e. prices which do not cover fully-loaded production costs), we believe that the newer (combination) vaccines purchased by the Vaccine Fund are at prices that allow OECD suppliers a significant profit margin.

By contrast, for emerging suppliers, international public sector procurement, even of mature vaccines, is both a major part of the business (up to a third of revenues) and is profitable on a fully loaded cost basis. This difference in economic importance and value for mature vaccines is reflected in UNICEF's sourcing of these products. In 1992, UNICEF bought no vaccine from emerging suppliers. In 2000, such suppliers fulfilled over 50% of UNICEF's non-OPV needs. Emerging suppliers have responded by significantly expanding capacity to meet the needs of this source of demand.

Supplier perspective: Revenue

Developing country demand is modest for the multinational players, but can be significant for emerging suppliers.



	GSK	Aventis Pasteur	Wyeth	Merck	Chiron	Green Cross	Serum, India	BioFarma
UNICEF/PAHO Share	8%	2%	0.2%	0.01%	9%	6%	32%	2%
+2002 GAVI	14%	2%	0.2%	0.4%	9%	29%	32%	3%

Source: Analyst reports, Company 10K, Lit search, CDC, UNICEF.
Note: UNICEF purchase data is for 2002

Given the relatively low economic importance of developing country markets to multinational suppliers, it is legitimate to ask whether these manufacturers are engaged and committed to low-income country immunisation. We believe there is evidence that they are, but also that it is important for procurement policy to recognise the pressures on this commitment. As evidence, it is worth acknowledging that the multinationals were

critical historically to broad access to mature vaccines, and continue to be critical to the polio eradication effort. Further, all five (Merck, Wyeth, GSK, Aventis and Chiron) have contributed time and resources to GAVI and responded to its RFP. European multinationals are making investment decisions in capacity that can only be explained by a strategy to serve markets outside the core high-income countries. (E.g., GSK's acquisition of Human and Aventis' investment in building Hepatitis B capacity). Finally, in interviews, all of these suppliers expressed a commitment to serving developing country demand.

We see three pressures on this commitment. The first is absolute capacity constraints. As discussed above, excess capacity was a key enabler of broad access via tiered pricing for the basic pediatric vaccines. We do not recollect having a single conversation with a manufacturer in 1992 around capacity limits. This situation has changed. Since 1992, multinational suppliers such as Aventis and Chiron have specialized and rationalized their bulk and filling operations to increase overall utilization rates, which reduces capacity relative to overall demand. In addition, the shift to a single-dose presentation preference among high-income country buyers has significantly increased the demands on filling and lyophilizing capacity. As an example, we estimate that the U.S. Centers for Disease Control's shift to single-dose presentations has doubled the filling capacity required to serve this customer. The removal of thimerosal from vaccine production, as strongly encouraged by the FDA and other regulatory bodies, will further increase demand for single dose presentations and thus will exacerbate filling capacity constraints.

The second is opportunity cost. International public sector demand is increasingly competing for bulk quantities of antigens that can be used in many different products. For example, the diphtheria toxoid component of GSK's DTP-Hep B combinations for GAVI is also used in its DTaP and DTaP combinations sold to high income country buyers; the tetanus toxoid component is used not only for these other products but also as a carrier protein for its Hib products. Faced with capacity constraints , suppliers are likely to allocate antigens based on the absolute and relative profitability of buyers and products.

The third is regulatory pressures and regulatory divergence. Schedule divergence has increased the production of vaccines not marketed in the country of manufacture, which in turn raises a number of regulatory oversight issues. More pressing, perhaps, is the fact that the needs, and priorities, of high-income countries are different from those of low-income countries. The requirements and concerns of OECD regulators reflect (as they should) the needs of the populations they serve. As an example, regulatory action on thimerosal will both add to capacity constraints (as above) and threaten the ability of the multinationals to supply multi-dose vials, a key enabler of affordability.

To summarise, the different types of suppliers have different roles to play in support of GAVI's objectives. The GAVI market also represents very different levels of commercial importance and priority for the different suppliers. Given these factors, procurement policy should seek to:

- Ensure access to capacity of existing vaccines and encourage R&D in other desired products from the multinationals
- Broaden the number of viable emerging suppliers to facilitate competition

To achieve these procurement priorities vis-à-vis multinational suppliers for existing vaccines, GAVI and the Vaccine Fund need to demonstrate and provide:

- Appropriate returns for suppliers
- Open, collaborative relationships
- Credible and predictable demand

These components will also enhance emerging supplier engagement, albeit that it is less fragile, and consequently there is less of an imperative to provide them.

Providing *appropriate returns* better positions GAVI to access capacity in an environment where all buyers are competing for constrained resources but other buyers are highly profitable. The purpose of open and collaborative relationships with suppliers is to facilitate production planning and minimize costs to serve GAVI, as well as to enhance the credibility of end demand by demonstrating a robust planning process.

Perhaps most important, *demonstrating credible and predictable demand* creates confidence for suppliers that procurement awards will translate into actual purchases and that production to meet these awards will be consumed. Predictable demand is essential, given the long lead-times of vaccine production often taking upward of a year before product is ready to ship. Demand credibility can be achieved through a number of means: past record (previous credibility), information sharing, demonstrating a well-thought out execution plan and rigorous forecasting process (current credibility) and contractual commitments (guarantees).

However, to encourage research and development in products valued by, and potentially dedicated to, developing countries, GAVI and the Vaccine Fund need to provide in addition:

- A credible, profitable market today
- Focus, both in terms of priority and suppliers, to maximize the potential commercial opportunity (and therefore leverage) of a new product

Review of 2000-2001 Procurement Activity

In assessing the activities associated with the Alliance's first procurement of vaccine, we have sought to answer three questions:

- What worked well / what was achieved?
- Was the procurement process aligned with the required procurement priorities as defined in the section above?
- Did the alliance function effectively from a process and executional perspective?

There were significant positive outcomes resulting from this first procurement. GAVI partners, in a new alliance, executed against the first major GAVI initiative. Second, GAVI achieved access to a relatively new product dedicated to developing country demand in large quantities (2003 supply of 41 million doses of DTP-Hep B and DTP-Hep B-Hib per year). In the context of low-income country demand, this is a unique accomplishment, at least on this scale. Third, GAVI achieved low pricing for these combination products when compared to other relatively early lifecycle products: for example, the price achieved for the pentavalent combination is close to half the average OECD price for monovalent HIB, and less than 20% of OECD prices for new products.

Perhaps most important, the signals the procurement sent, both in terms of desired product and a willingness to depart from marginal pricing seem to be acting as a "pull mechanism" for additional future capacity for desired products. We are aware of seven initiatives being undertaken by both multinational and emerging suppliers to build capacity for DTP (whole-cell pertussis) combination products with Hepatitis B and/or Hib. In effect, GAVI has accelerated the product lifecycle for DTwP-based combinations, which will result in increased capacity and competitiveness in the future for these products and thereby enhance affordability.

Review of 2000/2001 procurement activity

As a result of GAVI activities, there are significant efforts to expand DTwP-based combination capacity.

Supplier Plans for DTwP-Based Combinations with Hep B and/or Hib

Supplier	Product	Timing/Status
• GSK	• DTP capacity in Hungary for combinations	• Additional capacity available in 2004
• Aventis-Pasteur	• Hep B and combinations	• 2006 for monovalent, 2008 for combinations
• Chiron	• DTP-Hib	• In production, availability from August, 2002
• Chiron/Green Cross	• DTP-Hep B-Hib	• Available by 2005
• Serum Institute of India	• DTP-Hep B, DTP-Hep B-Hib	• In clinical trials on quadrivalent, pentavalent 3-5 years away
• Biofarma	• DTP-Hep B, DTP-Hep B-Hib	• 2-3 years away on quadrivalent, 5 years away on pentavalent
• Chendu	• DTP-Hep B	• In clinical trials

Source: Company interviews, WHO

Finally, GAVI was able to complete this process very quickly – fourteen months from start to finish – which served to accelerate the introduction of Hepatitis B and Hib in the poorest countries and accordingly save lives.

Measured against the criteria defined above (appropriate returns, open relationships and credible demand), the performance of the Alliance was more mixed. On the one hand, we believe that the pricing achieved for the combination products does allow the supplier a return, and this represents a clear break with the historic marginal pricing paradigm. Whilst this may be controversial to some, it is important to evaluate this investment by the Alliance against three factors:

- The impact on supplier behavior and thus the product lifecycle, discussed above, and its ramifications for future capacity and affordability.
- The impact on the achievement of program goals which would have been harder or more expensive (including country delivery costs) to achieve by other means.
- The recognition that, given schedule divergence, the marginal pricing paradigm (which has set expectations of what vaccines "cost" for low income countries) is increasing irrelevant.

Against the other two criteria, open relationships and credible, predictable demand, the 2000/2001 procurement activity must be considered a missed opportunity.

At the outset, there was a wide expectation and desire that GAVI/Vaccine Fund procurement would break with past practice and make contractual commitments to purchase (as opposed to "gentlemen's agreements"). This did not happen, and given the accuracy of actual offtake versus forecast to date, this is on balance a good thing. We believe that committed contracting is a potentially valuable tool to enhance demand credibility and predictability. However, to avoid wasting financial resources, it must be supported by a forecast of offtake in which partners have a high degree of confidence and which ultimately accurately reflects demand.

Second, the forecast and the RFP outputs and process were not as helpful to suppliers in supporting capacity and production planning as they could have been. Data shared with suppliers was exclusively at the antigen, rather than product, level ("number of children to be immunized") even after significant information on country product preference was available. Further, country-level demand data was not shared with suppliers as it became available. Although country applications are public documents, significant research was done as part of the forecast effort into country demand and product preference and not shared.

As we see it, the rationale for not sharing this information fully was twofold. As regards product preference, it was decided to procure using a RFP process. The reasons for this decision were understandable in the context, given that procurement and demand creation were running in parallel. Therefore, product preference information was not shared to avoid biasing responses to the RFP. However for both practical and philosophical reasons, the Alliance gave primacy to meeting country preferences wherever possible. The position that countries should drive product selection is inconsistent with a RFP process that is product-agnostic with a view to seeking innovative manufacturer responses.

The second rationale was concern over how suppliers would use the information, and in our view reflects residual discomfort with suppliers as GAVI partners. Country by country product preference and demand was not shared, at least in part, to avoid triggering supplier competitive marketing activities in countries.

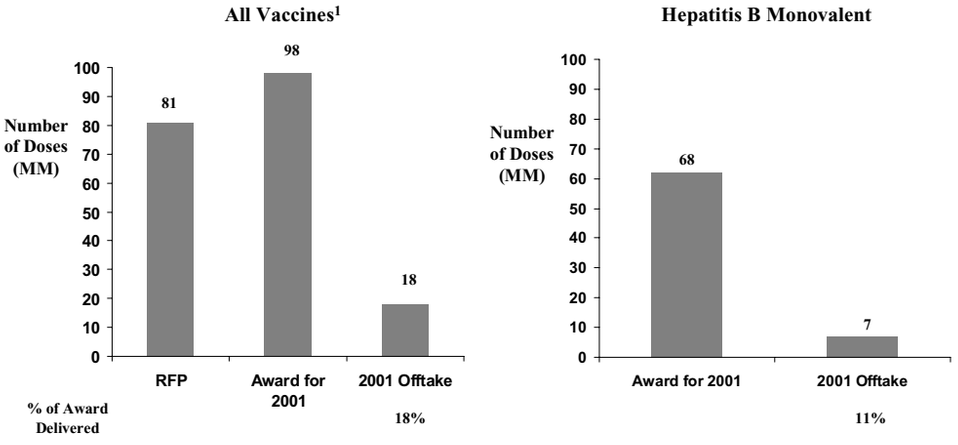
Going forward, it seems to us that more should, be done to ensure that suppliers are aware earlier of both evolving product preference and likely demand, even if only in the aggregate. Whilst it is clear that procurement itself (supplier selection, competitive offers, decision-making) needs to be confidential, we believe that transparency of process and data leading up to procurement significantly enhances both demand credibility and likely capacity availability. Further, the multi-disciplinary and transparent nature of the country application process ought to act as a brake on inappropriate marketing activity.

Third, and perhaps most important, to date actual offtake has fallen well short of awards to suppliers. In 2001, the Alliance purchased 18% of the doses (counting pentavalent as two doses) it awarded. The difference is even more marked for monovalent Hepatitis B, where 2001 offtake was only 11% of award. A number of factors explain much of this shortfall. Some countries delayed introduction, so the gap will narrow as they come online, although from a supplier perspective, this delayed volume should probably be considered permanently lost. Two large countries determined that, given the lack of availability of combinations, they would prefer to delay introduction rather than utilize monovalent product. Obviously, given the pressure of time and the new ground being broken, some inaccuracy was unavoidable. In our view, however, one should not lose sight of the fact that there was no uptake scenario in which offtake would not fall well short of award, given that:

- The volume forecast incorporated in the RFP was based on the "high" case, and
- The awards in aggregate exceeded the volumes in the RFP by 17 million doses, because of the need to accept or reject manufacturer offers, including volumes, in their entirety.

Review of 2000/2001 procurement activity

Forecasting, RFP issuance and awards did not support the objective of credible and predictable demand.



Source: RFP (August 14, 2000), UNICEF Supply Division self-assessment, UNICEF Supply Division website.
[1] Includes Hep B and Hib volumes, based on number of antigens (e.g., DTP-Hep B-Hib counts as 2 doses).

One possible explanation for this mismatch might be that, under the circumstances prevailing at the time, the RFP/Award process was required to serve two somewhat contradictory objectives. On the one hand, it was intended to ensure supply of vaccines to countries approved by the GAVI Board and funded by the Vaccine Fund: a classical definition of procurement. On the other, it may also have had the intent of establishing product and capacity availability and willingness to supply. Regardless of explanation, the gap between award and offtake does not support the objective of credible and predictable demand. Although we believe that direct financial losses by suppliers have been minimal (e.g. inventory carrying cost), we would suggest the Alliance should consider buying all the vaccine awarded in 2000, even if delivery takes place after 2003. Bearing in mind the economics of vaccine production, prices offered are inextricably linked to volumes, and the Alliance should try and recognize this fact in its purchasing behavior.

Whilst far less serious in its impact, we would also suggest that the credibility of the procurement process suffered somewhat from the communication of requirements or product preferences which were not reflective of the supply reality and the Alliance's negotiating position. This is not necessarily to question the validity of these requirements or preferences. Rather it is to observe that having mandatory requirements which then have to be ignored because of the supply situation, or preferences (e.g. single dose, pre-filled syringes) which do not take account of capacity and perhaps affordability considerations, does not enhance the credibility of the procurement process. Again, it seems to us that there is some telescoping of intent here, mixing strategic aspiration into a more tactical process.

We have already cited some issues around the depth of openness and collaboration that was achieved with suppliers. In general, we believe these issues are significantly less important than those which relate to creating credible demand. It is also worth noting that many of the suppliers to whom we spoke felt that the relationship that now exists between the international public sector and the supply base is much improved since 1992. Some suppliers expressed frustration with the quality or timeliness of communication, whether around product preference or changes in direction, for example, around the decision not

to use the supplier selection criteria. Perhaps most important, GAVI partners and The Vaccine Fund do not speak with a single voice to the suppliers: this can lead to mixed messages, a lack of clarity around authority to take decisions, and the impression of disagreement or competition amongst partners.

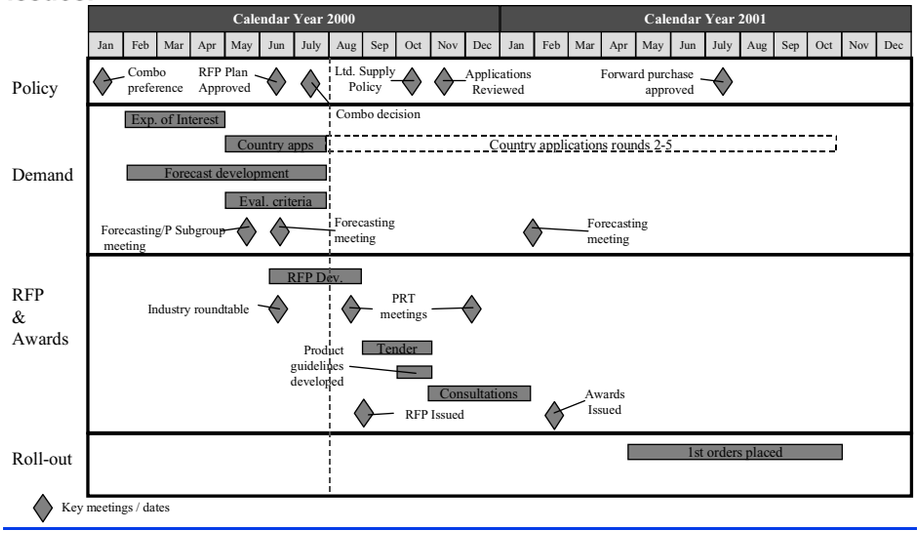
Turning to the internal functioning and execution capability of the Alliance in support of procurement, it is important to reiterate that an incredible amount of work was done in a very short period of time and in an entirely new context. That said, there were significant process shortfalls, which both affected the quality of the outcome and created some frustrations amongst partners. The process followed in support of procurement had significant sequencing, redundancy and hand-off issues. Further, as at the end of 2001, Hepatitis B coverage is significantly below the goal, largely for reasons outside the control of procurement, but nonetheless with significant implications for purchasing as discussed above.

On examining the process which was followed, our first observation is that the timeline required that vaccine order awards be made before demand (as defined by the country application process) was fully, or even largely, complete. The need to run procurement in parallel with demand creation drove a requirement for a separate and additional forecasting process, drawing on the country applications but also supplementing that data with direct country research. The incomplete status of the country application process also required that UNICEF SD conduct a separate country consultation in late 2000 and early 2001, both to establish product preferences for those countries which had not completed the application process and to advise of supply constraints for certain combination products.

In addition to the parallel processing requiring duplicative activity, the supplier evaluation criteria developed by the procurement sub-group were simply never used, on the advice of UNICEF SD's Procurement Reference Team.

Review of 2000/2001 procurement activity

The timeline of activity shows significant sequencing and redundancy issues.



Overall, there were significant changes, both additions and deletions, to the process followed once the RFP process proper started in late July 2000. The RFP was significantly redrafted, the country consultations executed and the evaluation criteria dropped. Whilst

the necessity for these steps is largely clear to us, it seems that with the benefit of hindsight, more attention should have paid earlier in the process to:

- Establishing the country product and volume requirements
- Understanding the supply situation for the products likely to be required

In the event, three semi-independent processes established country product and volume requirements: country applications, the forecast and the consultation. In aggregate, from a procurement and forecasting perspective, these yielded the disappointing outcome for 2001 described above. On the supply side, although UNICEF SD advised in early 2000 that combinations might be in short supply, the product availability picture was not quantified until responses to the RFP were received, and the RFP ended up serving two purposes: information collection and a statement of intent to purchase.

In order to understand, and learn from, the shortcomings of the Alliance's first procurement, it is important to identify the root causes of issues. We see four:

1. Pressure of time played a key role, as discussed above.
2. We believe that financing, as opposed to program or supply issues, was perceived to be the key constraint to introduction of new vaccines in low-income countries.
3. Loose alliances face effectiveness issues when called upon to implement, as opposed to develop, policy.
4. Finally, we perceive there to be significant residual discomfort with suppliers as partners in the effort.

In the section which follows we expand on these four themes, and recommend steps we believe the Alliance should take to ensure that the lessons of the first procurement are learned.

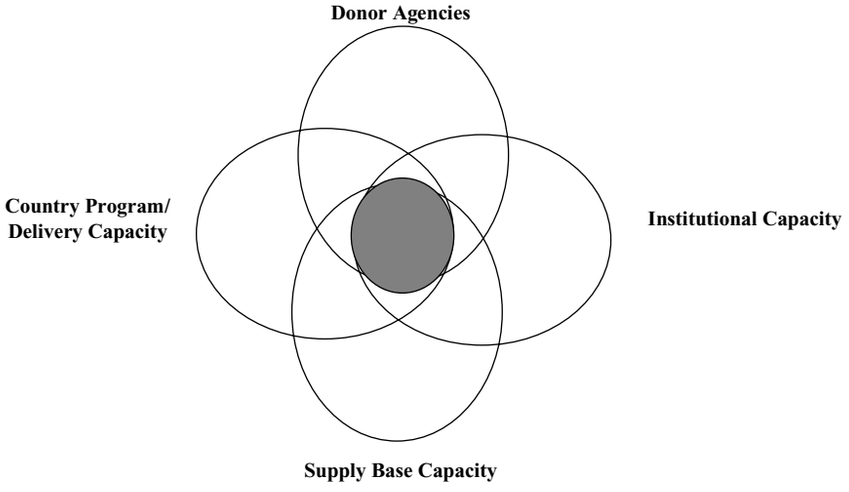
Lessons Learned and Recommendations

A significant proportion of the issues raised by GAVI and the Vaccine Fund's first procurement can be attributable to the very short period of time allowed to define and create demand, ensure delivery capability and procure vaccine. By way of comparison, the UK, a rich country with a strong, centralized, immunization system took five years to introduce Meningococcal C Conjugate, albeit this time period included the need for industry to develop a vaccine. From a supply perspective, up to five years is required to create capacity, if additional or new capacity is required.

Now that the Alliance has "won its spurs", and is in the implementation phase of its first major initiative, we would recommend that it define as soon as possible the next wave initiative, and start planning for its implementation. Without a strong lead from the Alliance in this area, there is a risk that each individual agency pursues its own priorities, an outcome that has three major risks. First, it will not allow cross-functional planning, which we believe to be essential to successful introduction. Second, any low-income country immunization effort draws on the same finite agency, supply, country and funding resources. A set of priorities inconsistent with the resource available will overload these resources and will not result in effective implementation. Finally, conflicting messages around priorities to the supply base is unlikely to result in timely capacity or R&D investments. This is an area where the Alliance clearly has an additive role over individual agencies.

Lessons learned

By definition, GAVI relies on shared resources to achieve its objectives, so strategy needs to take account of all claims on these resources.



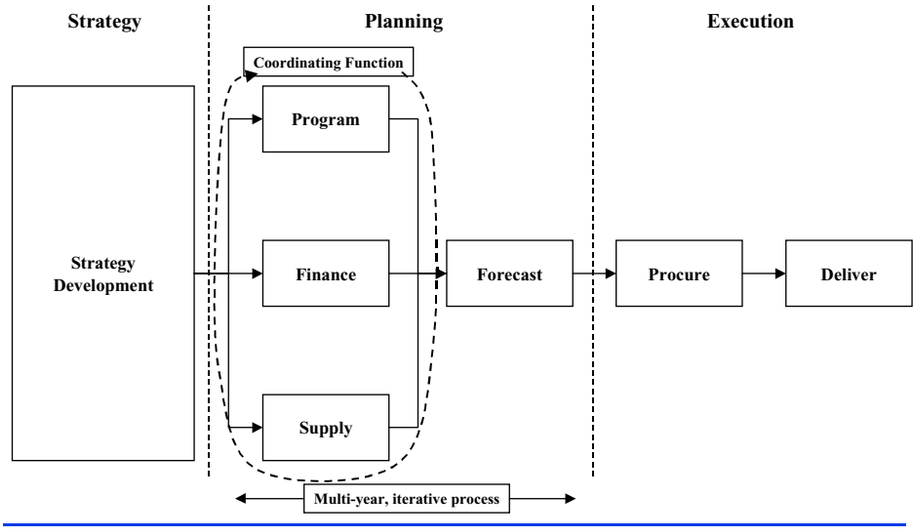
We therefore recommend that GAVI and the Vaccine Fund engage with partners as soon as possible to define the next wave initiative, consistent with the likely resource levels available and other calls on those resources.

In terms of the constraints on introducing new antigens in developing countries, it is important to preface our observations with the caveat that the scope of our work was limited to procurement. In this regard, whilst there were elements of the procurement activity which resulted in less than ideal results, as noted above, the outcomes in terms of vaccine supply and pricing were satisfactory. Given the timeline, no amount of creative procurement activity could resolve the combination capacity constraint. The main flaw in the process which was followed from a pure procurement perspective (as opposed to forecasting) was how late in the process the capacity constraint was identified, which may have had an undesirable knock-on effect on country uptake of monovalent product. Indeed, looking at the process which was followed, it is striking how late supply issues were considered, and how limited the resources devoted to understanding country and program issues were.

Based on these considerations, and again taking the UK introduction of Meningococcal C as a template, the key lesson from this is that successful introduction of a new antigen is fundamentally a multi-disciplinary task. The three disciplines involved are program (including advocacy and the creation of in-country demand), finance and supply. Once a strategy is set to introduce a given antigen, these three disciplines need to work together closely and in a coordinated fashion to plan the introduction. The forecast that is used to support procurement is a composite of all three disciplines: what real demand exists, what can be paid for and what can be supplied. Given that these questions are inter-dependent, and decision-making based on any one is unlikely to produce an overall optimum outcome, there is a need for a strong coordinating and integrated decision-making entity to sit above the three individual disciplines in this process.

Lessons learned

Introducing a new vaccine is a three phase, multidisciplinary effort



Again, since no one agency or GAVI partner encompasses all the disciplines required to assure the successful introduction of new antigens, there is clear value-add to the role GAVI should play, including ensuring that the coordinating function is in place.

We therefore recommend that, going forward, GAVI implement a multi-disciplinary approach to planning the introduction of antigens and ensure that a strong coordinating mechanism is in place across these disciplines.

Implementing policy across disciplines and ensuring cross-functional decision making is a significant challenge in most organizational contexts. Private sector companies invest significant effort in structures and processes to try and ensure that these challenges are met. This challenge is even greater in the context of a predominantly public sector alliance, which may host a range of legitimate, but competing, objectives and where there is not a single chain of command, indeed where the structure is consciously a loose one.

Nonetheless, we believe that such coordination is essential if GAVI is to be an effective implementer, as opposed to developer, of policy. In policy development, broad thinking, informal participation and redundancies are all desirable so long as they do not threaten the desired outcome of a clear and shared strategic direction. Once the focus shifts to implementation, however, clarity of roles, coordination and accountability become important.

Based on our analysis of the procurement activity, the Alliance needs a different operating model for planning and implementation (as opposed to policy-setting) activities. We would make the following observations. First, there are three bodies within the Alliance (the Board, the Secretariat, and the Working Group) which have, in theory, a mandate to coordinate partner activity and hold partners accountable. In practice, however, none of these bodies currently has either the resources or authority to be fully effective.

Second, partner involvement in planning activity, at least as it relates to procurement, showed a lack of clarity around roles and responsibilities. For example, on a self-reported basis, no partner claims lead responsibility for forecast development, or advising coun-

tries on vaccine choice. Two partners claim lead responsibility for procurement strategy development. As well as the loose nature of the Alliance, some of this lack of clarity and overlap is embedded in the Board mandates to partners and Task Forces. For example, UNICEF Supply is responsible for "procurement implementation", without the scope of this responsibility being spelt out. The Financing Task Force has a broad set of responsibilities, including procurement-related responsibilities, without it being clear how the FTF work links to others with procurement mandates.

We further believe that the absence of clear responsibilities and accountabilities means that the Alliance risks making operational decisions which are not fully fact-based. Not only does this increase the risk of making mistakes, it also means that decisions, even if right, can be hard to defend. In the procurement context, we would cite two examples. The first is the Alliance's preference for combination vaccines. This preference was determined before the supply constraints were fully appreciated. Further, it emerged, so far as we are aware, without any cost/benefit analysis, trading off the additional procurement spend against rapidity of introduction, capacity to deliver and in-country program savings. Similarly, the decision to communicate to suppliers a preference for a doses per vial reduction seems not to have been taken with any supporting analysis of cost/benefit.

One of the ways in which the private sector addresses the challenge of cross-functional execution and decision making is to appoint an individual or entity whose responsibility it is to ensure these things happen. Each function is accountable to this individual or entity for meeting their individual goals in a timely fashion, and also for contributing their expertise to integrated decision making. We call this the project management approach.

The key components of a project management approach are:

- Responsibility for integrated decision making and outcome is vested in a single entity and individual within that entity (the project manager).
- Each required discipline is represented on the project team and relevant experts are accountable for a component of the overall project. Individual representatives draw on the resources of their institution to achieve the goals of the project.
- Team members are accountable to the project manager, and the project manager is accountable to a project oversight body.
- A properly constituted project oversight body should be small and should include a mix of senior staff from engaged partners and representatives of partners not directly involved in the project team to ensure objectivity.
- Project management tools, such as workplans, timelines, milestones and measurement of deliverables to ensure progress and accountability are essential.
- Team composition, and project manager selection are a function of the specific situation and key constraints.

We believe such an approach will significantly enhance GAVI's effectiveness as an implementer of policy, as well as improving the quality of operational decision-making.

We therefore recommend that GAVI institute a project management model for the planning and implementation phases of key initiatives.

Turning to relationships with industry, we have already discussed our view that more information could and should have been shared earlier with suppliers. We see three separate issues relating to engagement with industry: the engagement "model", confidentiality and conflict of interest, and partner responsibilities. Taking each in turn:

We believe that GAVI risks overemphasizing multilateral engagement with industry at the expense of bilateral engagement. Whilst both types of engagement have value, industry

often has competitive and competition law concerns with the multilateral model. It is also clearly important to maintain a level playing field for suppliers. In this context, we would observe that it is not safe to assume that industry representation at a meeting (one company) means that all companies will be made aware of the contents of the meeting.

On conflict of interest and confidentiality, we believe that in the 2000/2001 activity, these areas of concern were defined too broadly. Specifically, demand and product preference information should be shared and updated, and there is a cost to not doing so. On the other hand, procurement decision-making is clearly not a place where industry can participate, and individual companies have a right to expect that their commercial discussions and negotiations with customers will remain largely confidential.

In terms of partner responsibilities, we would suggest the following. It is potentially damaging for the Alliance to send mixed messages or to give the impression of internal competition to suppliers. Therefore, within a specific initiative, the partner with lead supply responsibility, and by extension, the project manager have responsibility for supplier liaison. On broader strategy priorities, it is less important that there be a single point of contact, so long as the Alliance has clearly defined and communicated the strategy and the role and timing of individual antigens within it.

We therefore recommend that GAVI ensure that information on demand, product preference and future needs is shared with industry, unless there is a well-defined reason not to do so. We further recommend that GAVI require that project teams schedule bilateral meetings with industry when key decisions need to be made or there is a major development.

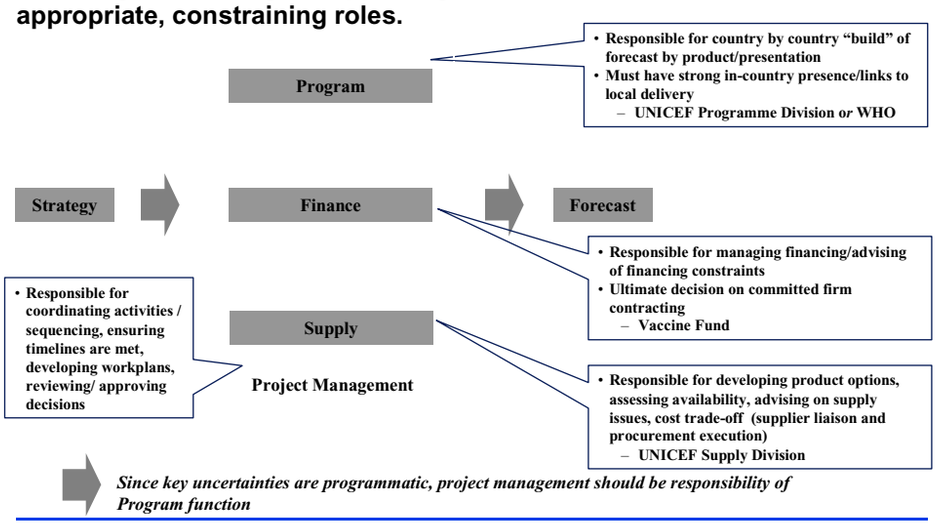
The most immediate challenge facing the Alliance on the supply/procurement side is the upcoming procurement round for 2004-2006, for which an RFP is due in the third quarter of 2002. We believe that this round represents both an opportunity and a need for GAVI partners to utilize the project management approach we described above. Specifically, there is a need to create a forecast to support this procurement. The most visible issue with the 2000/2001 procurement activity was the weakness of the forecast. This weakness damages credibility of demand, damages the credibility of the Alliance as a paradigm shift and does not support the goal of firm contracting. However, we understand that little has been done to date to improve on the forecast that already exists.

We therefore believe there is an urgent need to move forward with this effort, the first issue being the selection of the project manager. Whilst all three functions (supply, finance and program) need to be involved as described above, project management lead should reside in an institution which has insight and resources to address the key constraints. This will vary from situation to situation, but in this circumstance, we perceive the key issue to be developing a more robust understanding of the status and likely evolution of country uptake. Hence the project management lead should reside in an institution which has strong country presence and links to government, and therefore either UNICEF PD or WHO.

Within the project management structure each function should have a lead partner: WHO or UNICEF PD for program, the Vaccine Fund for finance and UNICEF SD for supply. These partners are at liberty (and, indeed, will need) to recruit other partners to assist as appropriate, but are accountable for the performance of their function to the project manager. The project manager should be accountable to an entity designated by the GAVI Board. This oversight body should be small, but should include representatives of Agencies not directly involved in the project team to ensure objectivity.

Lessons learned

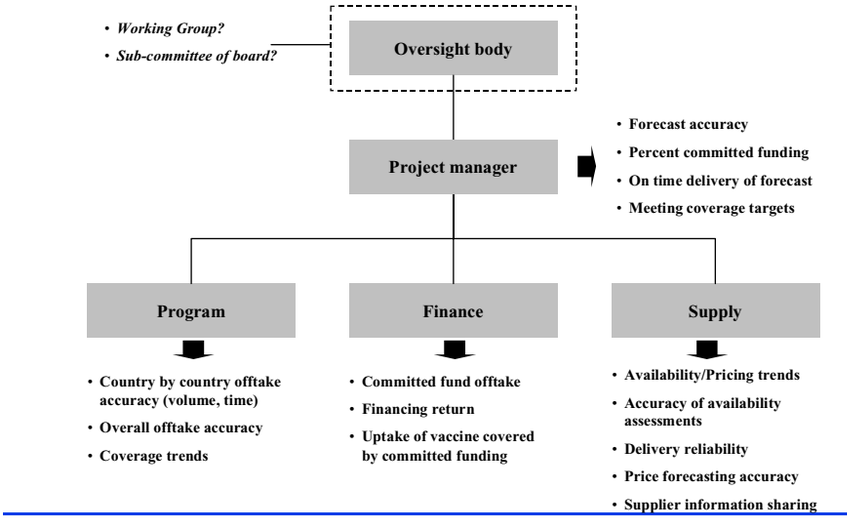
Forecasting needs to be driven from the country level, with supply and financing functioning in supporting, communication, and, where appropriate, constraining roles.



Accountability and measurement are critical to the success of a project management approach. A suggested structure and potential performance measures are shown below.

Lessons learned

Lines of accountability and metrics need to be established for all involved parties and endorsed by the GAVI board.



Immunization Financing Database: UPDATE

Background: The GAVI Financing Task Force (FTF) is responsible for increasing the understanding of the reasons behind inadequate funding for vaccines and immunization services in the poorest countries and identifying strategies to improve the capacity of governments and external donors to finance these needs.

To help fulfil its role, the FTF has recognized the importance of developing a comprehensive database on immunization spending and financing. Such a database would yield new insights about donor and government financing patterns for immunization and strategies for long-term financial sustainability. By providing baseline and trends on immunization spending and financial flows, it will contribute to the long-term evaluation of the influence of GAVI and The Vaccine Fund on immunization financing at the national, regional and global levels. Moreover, the immunization financing database will help address policy and programmatic concerns such as assessing the relationship between funding patterns and program performance and efficiency, and assist in the provision of guidance to countries on how to most effectively use additional financial support for immunization.

Development: In November 2001 and under the auspices of the GAVI Financing Task Force, a team of technical experts from World Bank, USAID (Abt Associates), CVP (Abt Associates), UNICEF, WHO and PAHO was brought together to develop the immunization financing database. To date, initial work has consisted of collecting and assessing the quality of existing data, developing tools and methods to strengthen future data collection, and designing the basic database structure for a publicly available database on immunization expenditures and financing.

Challenge: The key challenge of this work has been to address the comparability and quality of the existing data from the wide variety of data sources available. Over the past two years, the GAVI and Vaccine Fund application process has been seen as an unprecedented opportunity to collect consistent and comparable baseline country level information on immunization financing and expenditures. Although baseline expenditure and financing estimates are now available for 58 countries, it has been difficult to evaluate their accuracy and reliability. The baseline estimates are often incomplete and inconsistent in methodologies or when compared to other sources of information (such as a recent in-depth costing study). The reliability of the information provided by countries through the GAVI and Vaccine Fund application process is weak as a result.

Lessons Learned: The shortcomings in the country-provided information is the combined result of a clear lack of capacity to report financial information at both the national and regional levels, and the lack of any clear guidance and support to countries to report consistent, comparable and high quality data. Looking into the future, it will be important that the review process for countries' Financial Sustainability Plans gives due attention to assessing and providing feedback to countries on the completeness and accuracy of the financial information provided.

Key Findings: Existing country-reported information, although imperfect, does however convey several clear messages:

1. Vaccine Fund contributions represent a substantial share of total routine immunization expenditures in many countries and the introduction of new vaccines will represent a financial challenge for many countries, especially countries that introduce the pentavalent vaccine.

2. There is considerable variation in the basic cost structure and levels of spending across countries –- even countries of similar income and coverage levels. This implies the need to better understand the sources of this variation for future analyses from the Financial Sustainability Plans.

3. The data clearly demonstrate substantial year-to-year variability in the levels of financial resources available to the national immunization program, suggesting that multi-year funding commitments could be useful to reduce volatility and to advance the aim of long-term sustainability.

4. Finally, early and still tentative results seem to suggest that GAVI and the Vaccine Fund are not displacing existing resources from immunization, although better quality data in the future will ascertain the validity of these findings.

Next Steps: In light of the clear data comparability and quality issues that the database development group has identified and systematically analysed, the FTF has placed its emphasis on ensuring the success of the second opportunity to collect high quality information on immunization expenditures and financing through the GAVI Financial Sustainability Plans. Efforts have been made to strengthen both national and regional capacities to report this information through the development of standardized methodologies, guidelines and tools, and to strengthen the capacity of countries to better report this information through existing data collection mechanism such as the UNICEF-WHO Joint Reporting form.

Conclusion: In summary, by taking the fullest (yet appropriately cautious) advantage of existing country-reported data, and by making every effort to strengthen reporting of financial information in the near future through the Financial Sustainability Plan process, the database is compiling extremely useful information that has not been previously available to countries and global and regional partners. The database effort – the result of the combined work of GAVI's partners – represents one more "global public good" under the Alliance's auspices.

Update on plans and process to support countries in developing their Financial Sustainability Plans

Background

From the outset, ensuring the sustainability of improved immunization programs into the future has been a top GAVI priority. At its third meeting in Oslo, Norway in June 2000, the Board decided to offer countries the opportunity to extend the total five-year award of vaccines over and up to a maximum of eight years—if the countries gradually phase in government and partner funds to cover the cost of a portion of vaccines—thereby encouraging countries to plan for a smooth transition to national and partner funding of vaccines.

To facilitate long-term national planning and permit countries to manage their vaccine allotment over a five- to eight-year time frame, Ministers of Health in each country approved for Vaccine Fund support will be informed of the total five-year vaccine commitment in terms of vaccine doses. This will further reinforce the relationship between financing and program targets.

Issue 1. What is the proposed process and strategy for supporting countries in developing their plans and for capacity building?

Beyond the provision of FSP Guidelines and related tools and information, the FTF is working with the GAVI Regional Working Groups (RWGs) to develop targeted support to regions and countries. Among the support requested to date: short and long-term national and international technical assistance and financial sustainability orientation and technical training workshops (please see attached table).

The FTF is currently working with the Africa Sub-Regional Working Groups to organize a set of two "hands-on" orientation workshops in July. The workshops will give both managerial- and technical-level personnel in national governments and partner agencies a significant head start in developing a plan of action for the preparation of the FSP that is consistent with existing national planning processes. This will include steps to identify government or local partner staff and resources which would support the process, regional resources available, and if necessary, short-term technical assistance from the global level where needed.

Furthermore, the FTF is working with the RWGs to map out institutional and financial expertise at country level in order to further mobilize existing national capacity. Where such expertise does not exist, capacity building will be explored with partners support. The FTF will continue to work with RWG representatives and with each country point of contact to ensure that all countries have the requisite support to prepare FSPs. The FTF will capture the lessons learned from the 13 pilot countries.

Recognizing the importance of planning for financial sustainability planning and the management effort that will be required over the next two years and beyond, the FTF is recruiting a full-time global coordinator to work through the RWGs to provide and organize support for countries. A detailed outline of proposed technical support for FSP development for all countries that have received awards from GAVI and The Vaccine Fund will be submitted to the Board in November 2002.

The Board is requested to consider and provide feedback on the process for support and capacity building as outlined above.

Issue 2. How can the development and implementation of the FSPs fit within the broader health context?

Immunization services are but a small part of the larger health systems and just as the health sector competes with many other sectors for limited public resources, any changes in the public sector—from the introduction or expansion of a Sector Wide Approach (SWAp) to debt relief to civil service reform—will have both implications and opportunities for the immunization program. From the outset, investments in strengthening immunization services from The Vaccine Fund have been designed to be system-neutral and flexible, and are entirely consistent across all health sector planning and budgetary processes. The FSP has been designed to build on—and contribute to—on-going discussion about national and health sector priorities and mechanisms. The challenge now is to monitor how this is actually working.

While it is still early in the process, preliminary indications from the FSP pre-tests suggest that the work conducted for the FSP is already being integrated directly into national planning and budgeting processes including PRSP/HIPC, and is compatible with countries undergoing health sector reforms. Bringing in national institutions with health finance expertise, as outlined above, and engaging high ranking personnel in ministries of health and finance that deal with broad issues of health financing, will be essential to strengthen and secure this link.

To adapt the FSP process to the broader health systems context will be a continuous challenge and further reflection and discussion will undoubtedly be needed.

Based on the findings of the extended pilot, the FTF will explore potential Board actions to ensure that FSPs fit within the broader health context and present proposals to the Board in Spring of 2003.

Issue 3. How will partners address the resource gaps that are identified through the FSP process?

There is no one unified response that is expected on the part of partners when a country identifies a resource gap. Through the FSP process and the resultant plan itself, countries and partners will have a clear data-driven appreciation of likely future resource gaps and develop a range of realistic and specific strategies and actions that are likely to lead toward financial sustainability. These strategies may include any or all of the following: advocating for and obtaining greater commitments from national and/or sub-national governments, including use of funds freed by debt relief; advocating and obtaining greater commitments from external financiers in the form of both grants and loans; obtaining greater efficiencies in the delivery of services and/or procurement of inputs; and ultimately, if no other solution can be found, scaling back program targets to better match realistic funding levels. Ideally, both the country-level and the larger-scale (through the immunization financing database) analyses of resource requirements will lead to multi-partner commitments of multi-year support.

It is expected that on a country level, through the Inter-agency Coordinating Committee (ICC), the FSP process will stimulate partner agencies to participate actively in the development of these strategies. On a global level, it is expected that GAVI will promote an on-going discussion of the possible magnitude and duration of coordinated international support for immunization through bilateral, multilateral, and pooled (e.g. Vaccine Fund) strategies. Financial sustainability will likely be attainable through a mix of these approaches, applied over a medium-term timeframe.

The FSP process coincides with a general trend of growing health budgets both from internal and external sources. It is therefore essential that the FSPs link up to these broader initiatives. GAVI Partners, in particular national governments, bilateral agencies and the World Bank, can be instrumental in establishing these ties.

Based on the findings of the extended pilot, the FTF will explore potential Board actions to address resource gaps and present proposals to the Board in Spring of 2003.

Issue 4. How will the FSPs be reviewed?

Based on an extensive consultative process among technical-level staff at GAVI partner agencies, it is proposed that the review of the FSPs be conducted in a fully supportive spirit. The FTF Sustainability Group proposes that the objectives of the review of the FSPs should be to determine if a sound process has been initiated that will increase the likelihood of long-term sustainability of immunization programs through improved planning and management and combined increases in government and funding partner commitments. This will be accomplished by (a) identifying major financing and capacity challenges; (b) documenting national efforts to address those challenges; and (c) determining the assistance required to implement the FSPs.

Modeling the FSP review on the application review process (with slight modifications), it is planned to include the following aspects:

- First, a pre-screening review by experts, to be identified by the FTF, to ensure compliance with the required elements described in the FSP Guidelines. If deemed incomplete, the plan will be returned to the respective Ministry of Health with clear instructions for revision and resubmission in time for the next IRC review.
- Second, a check of the consistency and validity of the financial information reported in Tables 1 and 2 (using both internal consistency checks and external data sources that have been collected as part of the Immunization Financing Database (IFD)). If data issues are identified, these will be resolved with technical discussions between GAVI partners (particularly the IFD development team) and national officials. These first two steps are expected to take place in time for the next IRC review.
- Third, a review by the Independent Review Committee (IRC), augmented with financing expertise, applying the criteria of clarity, comprehensiveness, technical rigor, involvement of stakeholders and feasibility of the plan. For each country required to submit an FSP, in January 2003 the IRC will recommend to the GAVI Board one of the following three actions:

(1) For countries submitting FSPs that describe a process that is likely to lead to a sustainable program, the IRC comments will be provided to government and partners, and support will be arranged through national partners and RWGs to assist the country with implementation of the FSP.

(2) For countries submitting FSPs that are not deemed to be technically sound, the IRC comments will be provided to government and partners, and support will be arranged through national partners and RWGs to assist the country with revision of the FSP.

(3) For countries failing to submit an FSP, a letter will be sent to the government from the GAVI Board chair (copied to the RWG) and to national ICC partners (from the relevant GAVI Board member) indicating that a plan has not been submitted, requesting an explanation, and reiterating offers of technical support.

Because of the intensity of the current roll-out process, and the active interest observed to date, the FTF Sustainability Group expects that very few, if any, countries will fail to submit an FSP.

The Board is requested to consider and provide feedback on the above process for reviewing the FSPs.

Accelerated Development and Introduction of Priority New Vaccines:

The case of pneumococcal and rotavirus vaccines

Executive Summary

Background: On behalf of GAVI, the Gates Foundation and World Bank sponsored a study by McKinsey & Company to explore strategies to accelerate the introduction of pneumococcal and rotavirus vaccines. McKinsey and Company has worked closely with a broad range of GAVI partners and particularly the pneumococcal and rotavirus vaccine teams. McKinsey has reported to a Steering Committee composed of the Gates Foundation, the Vaccine Fund and the World Bank.

Accelerated Development and Introduction Plans (ADIPs): Historically vaccines have been introduced in developing countries 10 to 15 years after their first launch in industrialized countries. This long delay is unnecessary and results in an unacceptable loss of life. There are a number of strategies to assure supply of the new vaccines ranging from working with multinational firms, to working with local manufacturers to develop and produce new vaccines, to acquiring intellectual property rights, to building greenfield capacity, to waiting for better/cheaper technology. However, to ensure supply is as early as possible, the only viable option is to work with multinational firms that have late stage products that will be available in 2006-2008.

Demand uncertainty was cited as the single largest barrier to the rapid development and adequate supply of the new vaccines to Vaccine Fund eligible countries. However, other barriers, such as price erosion between middle income and low-income (Vaccine Fund eligible) countries will be important for manufacturers given the likely desire for parallel introduction. The solution to demand uncertainty is a comprehensive, target-oriented plan for introduction that is backed by adequate funding (termed an Accelerated Development and Introduction Plan (ADIP). These plans build on the lessons learned by GAVI partners from introducing other vaccines such as hepatitis B and Hib.

Draft ADIPs have been developed, building on the substantial work of the pneumococcal and rotavirus communities. These ADIPs define critical actions to "Establish" the value of the vaccine, to "Communicate" this value of to the key decision leaders, and to "Deliver" the value by ensuring supply and delivery systems are in place. Manufacturers and public sector partners have reviewed and commented on the structure and substance of the draft ADIPs. They have applauded the framework and content noting it is target-oriented, feasible, prioritized, transparent, and allows progress to be measured. The reviewers also noted ways to further strengthen and streamline the ADIPs once the responsible implementing teams are in place.

The ADIP effort is designed to improve supply and demand certainty through interactive planning and implementation by both public and private sector. Activities conducted in developing countries will, as a matter of preference, be carried out by trained nationals or through the training of nationals during the implementation of activities.

The ADIP effort will generate commitment and trust, first through a transparent fact-based plan and later through actual delivery against the milestones in that plan. Predictable demand will help ensure supply at the lowest workable price.

Proposed Structure: All of the private and public sector partners interviewed reinforced the importance of empowering a dedicated team, responsible for ensuring the coordinated and timely implementation of ADIP activities. They noted that credible and dynamic

leadership teams must be recruited and provided with upfront funding to work with partners around the world to conduct development activities, ensure front line advocacy and ensure supply and delivery systems. The suggested team structure is designed to respond to the specific activities within the ADIP plan and the overarching need to coordinate different partners.

McKinsey recommends that small, dedicated teams be established for rotavirus and pneumococcal vaccines, with oversight from a steering group and technical support from expert review panels. To ensure sufficient management support, administration capacity and credibility, the teams should be hosted in an existing or new organization.

The small, dedicated teams would be accountable, target-driven and responsible for leading the process and coordinating the work across the scientific, financial, advocacy and implementation phases. It is advised that the ADIP teams be overseen by a small, high level steering group comprised of 5-6 individuals. The GAVI Board may consider delegating authority to the steering group to review and approve the ADIP plan and budget and to evaluate the teams' use of resources and progress toward milestones. The steering group and ADIP teams would, of course, be accountable to the GAVI Board. The ADIP teams should have access to technical review panels on an as needed basis to provide advice on technical RFPs and/or to help review proposals. A competitive RFP process is recommended to identify the optimal host. If Window 3 of the Vaccine Fund is opened, it is suggested that the GAVI Board recommend the release of envelopes of funding on a semi-annual or annual basis to the ADIP teams with detailed budget oversight by the steering group. This structure and funding pattern would ensure effective and timely use of funds while also empowering the ADIP teams.

Implications of establishing an ADIP team: While McKinsey strongly recommends establishing the proposed ADIP teams, it should be noted that the proposed process will require roughly 9-12 months before the teams are operational. If the Board approves the RFP approach, the Secretariat and Working Group could draft an RFP for Board approval by September; agencies wishing to submit proposals would then require 60 days to respond to the RFP; a selection committee could be convened in December 2002 for a recommendation for final decision by the Board in January 2003. At this point, the host agency would begin hiring staff, a process that can take anywhere from 2-6 months. During this 9-12 month period, an interim process modelled on the independent review panel would be required to maintain the momentum and ensure early activities are initiated as planned. If desired, the Secretariat and Working Group could work out the detailed arrangements.

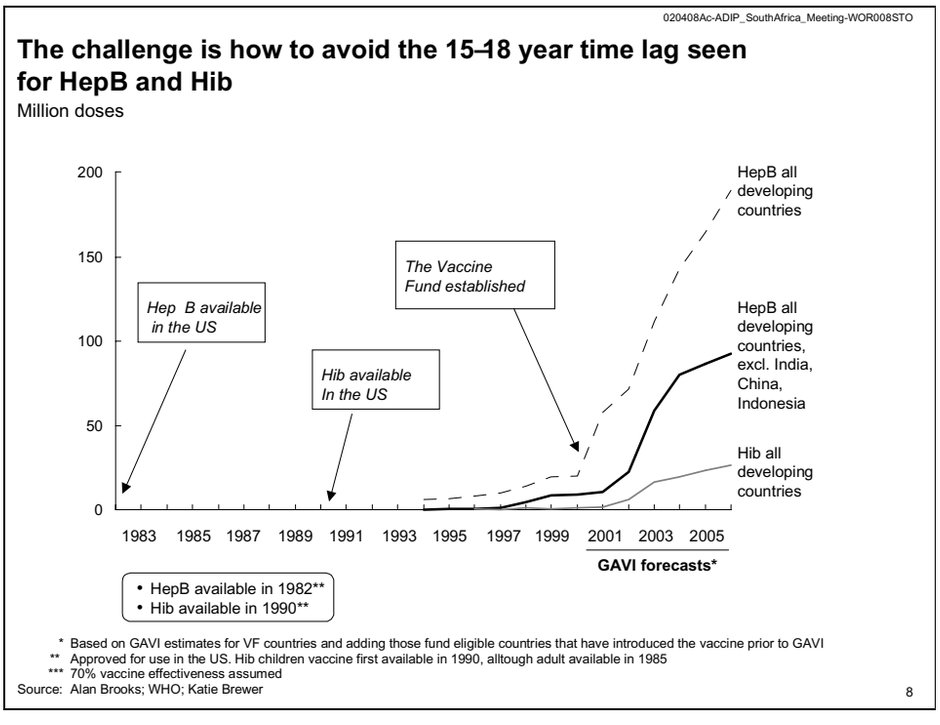
Accelerated Development and Introduction of Priority New Vaccines:

The case of pneumococcal and rotavirus vaccines

BACKGROUND AND INTRODUCTION FOR THE PROJECT

GAVI's objective is to accelerate the development and introduction of priority vaccines into developing countries. Streptococcus pneumonia and rotavirus, which together kill nearly 2 million children each year, have been identified as GAVI priorities[1]. On behalf of GAVI, the Gates Foundation and the World Bank commissioned a study by McKinsey & Company to explore strategies to accelerate the introduction of pneumococcal and rotavirus vaccines into developing countries. Through the course of the project, McKinsey & Company has worked closely with a broad range of GAVI partners, particularly the pneumococcal and rotavirus vaccine teams[2]. McKinsey has reported periodically to a Steering Committee composed of the Gates Foundation, the Vaccine Fund and the World Bank.

To understand new vaccine introduction, the cases of Hepatitis B and Hib vaccine uptake were explored. These vaccines had low uptake initially, due to a combination ---f supply and demand factors, including fears about long-term sustainable funding (for both) and, in the case of Hib, a lack of local disease burden data and a subsequent under-appreciation of the potential value of the vaccine. Based on this experience, it is likely that without public/private effort, neither pneumococcal conjugate nor rotavirus vaccine will launch in the developing world before 2010-2012, and even then, uptake would be expected to be slow.

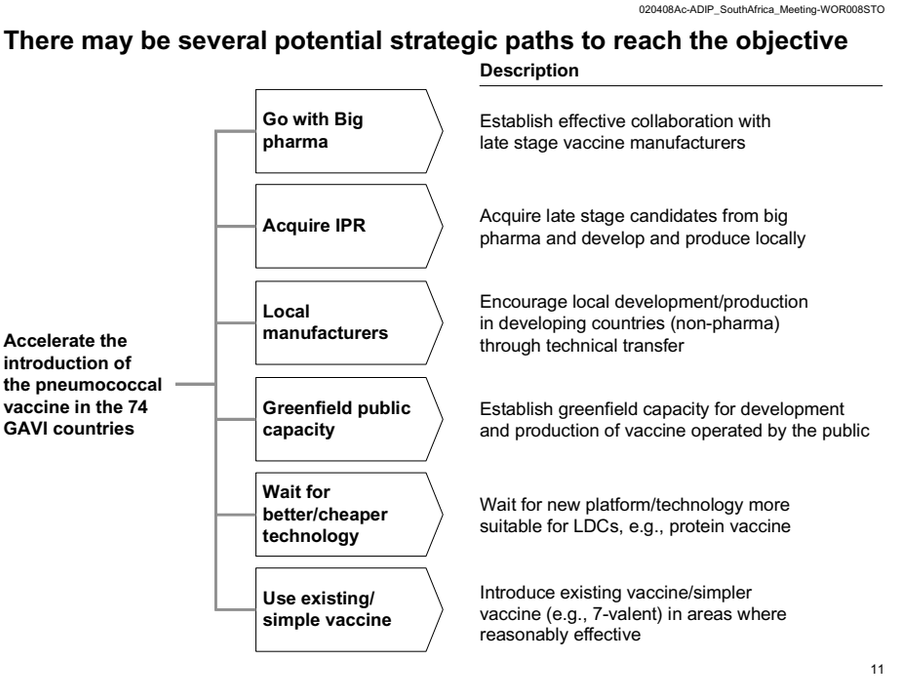


[1] With meningococcal.

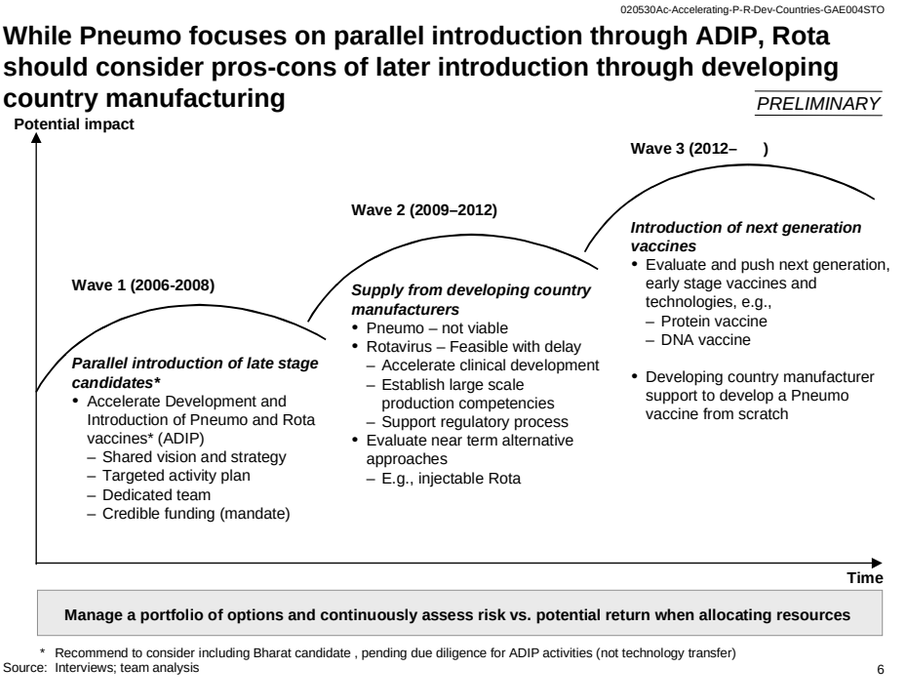
[2] For, pneumococcal vaccine: Drs. Orin Levine (NIH/CDC), Thomas Cherian (WHO), Jay Wenger (WHO). For rotavirus vaccine: Drs. Roger Glass (CDC), Umesh Parashar (CDC), Joseph Bresee (CDC). Alan Brooks (PATH) has been very helpful in developing the forecasts.

Vaccine development and introduction is characterized by long-lead time for manufacturers, governments and public health partners. Manufacturers must invest years in the development of the products and scale up their production capacity. Unanticipated demands requiring greater capacity will take years to fulfill. Therefore, a delay in predicting developing country demand will have dramatic effects on the timeliness of available supply. In many cases, a "vicious cycle" comprised of uncertain demand, insufficient supply, and high prices has prevailed. Working to assure supply is one way to break this cycle which then helps increase the certainty of demand which then further raises the certainty of supply and thereby lower prices.

There are a number of strategies to assure supply of pneumococcal and rotavirus vaccines. Potential options range from securing supply from multinational firms with late-stage products, to working with local manufacturers to develop and produce new vaccines, to acquiring IPR, to building greenfield capacity, to waiting for better/cheaper technologies.



An effective development plan will include multiple strategies to ensure accelerated introduction and uptake over time. However, given GAVI's objective of accelerating the introduction of these vaccines into developing countries, the most viable immediate option for early access to pneumococcal conjugate and rotavirus vaccines is to work with multinational firms already holding late stage products (Phase III or beyond). This option would allow introduction in countries beginning around 2006; all other options would delay access until at least 2009-2012. However, other strategies must continue to be monitored. A phased approach whereby initial efforts focus on multinationals to yield near-term results, while mid to long-term efforts establish the framework/relationships to facilitate other options (e.g. local production, or access to new, better technology) is one way to ensure a targeted, prioritized approach.



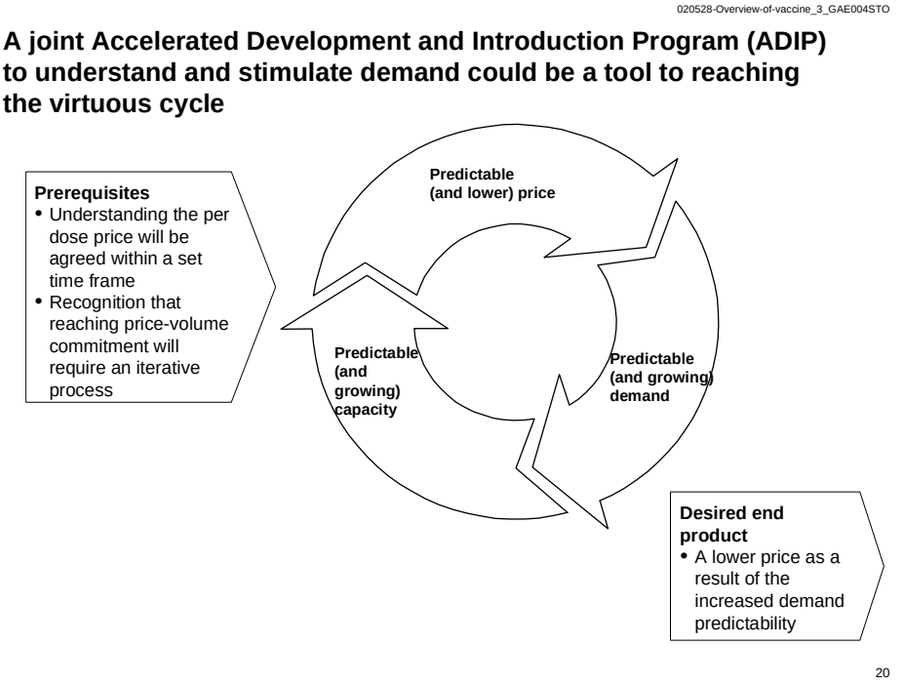
To identify priority activities for the initial phase focused on early access to products from the multinationals, McKinsey analyzed barriers faced by multinationals that inhibited their investment in the late-stage development, production and scale-up of pneumococcal conjugate and rotavirus vaccines. In-depth consultations with the manufacturers as well as numerous other public and private sector experts indicated that demand uncertainty is the most important barrier[3]. Demand uncertainty is the very real risk to a manufacturer of not knowing when governments and or donors will purchase and introduce the product. As seen in the cases of Hep B and Hib, introduction did not occur for at least fifteen years after licensure in industrialized countries. This delay represents a tremendous cost to a manufacturer who has invested in licensing and producing a product for the developing world market. As a result, first wave efforts have focused on strategies to reduce demand uncertainty.

[3] Recognizing that other barriers, such as price erosion between middle income and low-income (Vaccine Fund-eligible) countries will be important for manufacturers given the likely desire for parallel introduction.

ACCELERATED DEVELOPMENT AND INTRODUCTION PLANS (ADIPs)

The proposed solution to reduce demand uncertainty is a comprehensive, target-oriented plan for introduction that is backed by adequate funding (termed an Accelerated Development and Introduction Plan (ADIP). ADIPs are based on a phased approach which addresses demand uncertainty (i.e. through working with governments to collect local impact data), ensure supply (i.e. by working with manufacturers early), and funding (i.e. by engaging governments and donors early as they debate priorities and resource allocation). ADIPs are designed so that the activities necessary for successful uptake are already underway when governments begin the difficult process of deciding to introduce a new vaccine, and as manufacturers begin the lengthy development and scale-up process. Beginning these activities early helps alleviate the concern for manufacturers that demand will not exist, and the concerns of the public sector that the vaccines will be unaffordable and unavailable. The ADIP effort is therefore designed to improve supply and demand certainty through interactive planning and implementation by both the public and private sectors.

If executed successfully, the ADIP effort should turn the "vicious cycle" of demand uncertainty, inadequate supply, and high prices into a virtuous cycle of predictable supply, demand and (lower) prices.



DEVELOPMENT OF THE ADIPs

All manufacturers and many public sector partners have expressed excitement around an accelerated transparent vaccine introduction plan, including a much higher degree of public and private collaboration.

Accelerated Development and Introduction Plans (ADIPs) have accordingly been developed for both the Rotavirus and Pneumococcal vaccines[4]. The current "first generation" ADIPs are based on the work of the GAVI Pneumococcal and Rotavirus teams and provide target-oriented plans for how to accelerate introduction in Vaccine Fund eligible countries by 2006/2008. For rotavirus vaccine this will represent a near-parallel introduction in both developing and developed markets.

The ADIP plan is based upon a proven framework organized around three necessary components: establishing, communicating, and delivering value, where value is the public health value associated with the vaccine. The ADIP effort will generate commitment and trust, first through a transparent fact-based plan, and later through actual delivery against the milestones in that plan.

The ADIPs are modeled on a business framework with activities to establish the value of a vaccine, communicate that value, and ensure delivery (supply, etc.). They are specifically designed to be continually reviewed, updated, and revised to incorporate new learnings as they emerge from the process. ADIPs are "living documents" of activities to be implemented by multiple stakeholders, across many geographical regions, and with several vaccine suppliers (both from global and local manufacturers)[6].

The current plans provide a comprehensive picture of the vision/objectives, strategy, activities, and budgets. Future iterations should seek even greater engagement of country representatives, donors, and manufacturers.

A very beneficial outcome of the ADIP process has been the constructive, transparent and solution-oriented relationship that has been reinforced between the public sector partners and the manufacturers. Manufacturers have remarked that this spirit of collaboration, which recognizes each sector's strengths, is an improved way of working together. Successful implementation of these ADIPs will lay the foundation for collaboration in future vaccine introductions.

THE MAIN ELEMENTS OF THE ADIPS

The ADIPs are structured around four areas essential to the successful introduction of the vaccines: (1) a coherent vision and strategy for introduction, supported by (2) a broad activity plan to reach the target number of doses, and (3) a budget that covers costs for the activities and administration, and (4) a description of the organizational requirements and oversight needed to drive implementation.

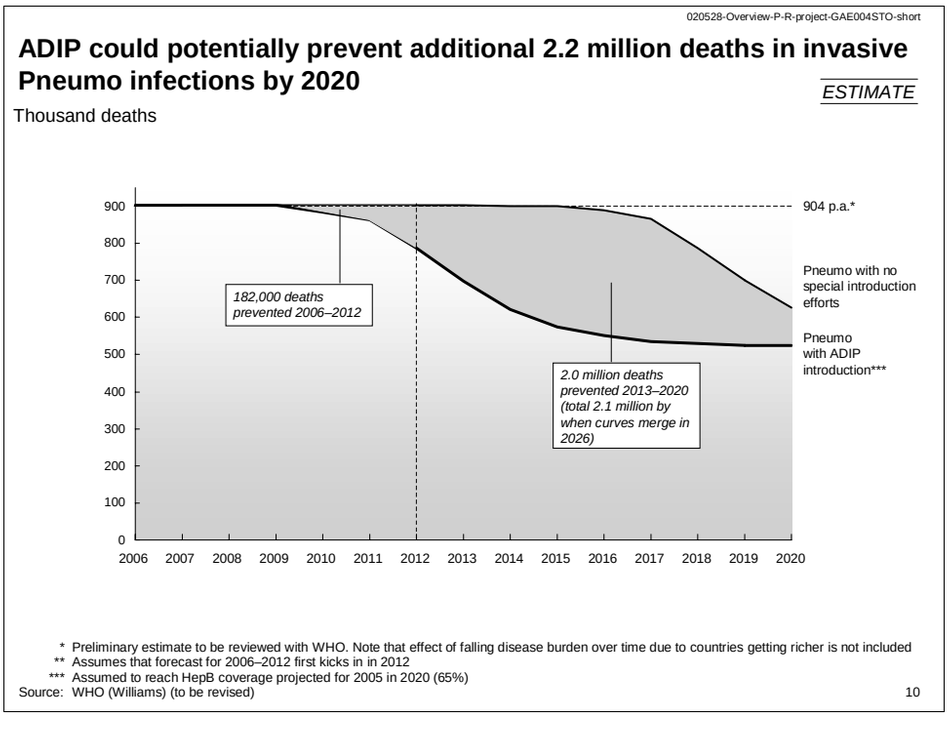
[4] The material presented at the February 20 meeting is attached, and outlines the more detailed background and rationale for the ADIPs

[6] The term local manufacturer in the document refers to manufacturers that are located in developing countries, and that do not seek licensure in USA/Europe. They may, however, export vaccines to other developing countries.

1. Vision and strategy

As discussed above, given GAVI's goals to accelerate the development and introduction of rotavirus and pneumococcal vaccines, focus has been on multinational manufacturers with vaccines in late stage clinical development. For pneumo, these are GSK and Wyeth and for rota, GSK and Merck. The remainder of this memo thus focuses primarily on the identified processes to accelerate the development and ensure the supply from these manufacturers. However, opportunities to develop alternative supply options or new technology platforms must be explored, as part of the medium to long-term planning. Given the complexity of producing multivalent conjugate, the timing of local production of pneumococcal conjugate is uncertain and distant; local producers have neither the technology nor the specific candidates. Similarly, the pneumo protein vaccine, currently in pre-clinical phase, will not likely represent a viable opportunity for at least ten years. For the Rotavirus vaccine, however, local production will be more feasible since drug candidates exist and production technology is simpler and better known. China, Indonesia, and India all have products in development which they hope to have licensed for national use between 2007-2009.

Based on a best estimate that the pneumococcal conjugate and rotavirus vaccines will be available in 2006/2008, the pneumococcal and rotavirus teams, in consultation with experts, have established preliminary targets for the number of children in Vaccine Fund eligible countries who might reasonably be immunized during the 2006-2012 time frames. The current, preliminary target is to immunize approximately 10 million children (30 million doses) for pneumo, and around 30 million children (90 million doses) per year for rotavirus. The long-term (by 2020) impact of investing in an Accelerated Development and Introduction Plan for pneumococcal will be to bring forward the year of introduction by 6 years, resulting in 2.2 million deaths prevented as a result of the faster introduction. For rotavirus, the long-term effect of the early introduction will be to prevent 1.1 million deaths.

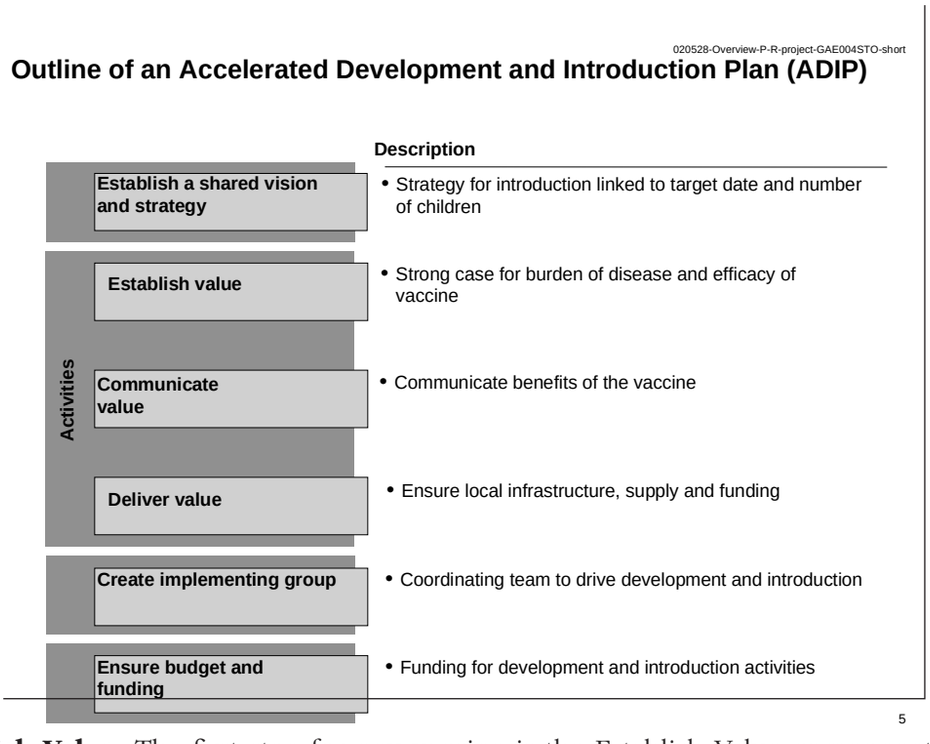


Iterative discussions with national governments and donors about their introduction plans will guide prioritization of activities, and will shape the overall rollout strategy which is based on national and regional plans. For example, some have suggested that Rotavi-

rus efforts should initially focus on the hotbed area in India, Pakistan and Bangladesh, before expanding to increase the impact. Clearly strategic trade-offs between countries and regions will have to be managed to maximize impact. These trade-offs must be based on disease burden and vaccine efficacy data; the collection of which are primary activities of the ADIP effort.

2. Activity plan

The activity plan in the ADIP is organized around three areas: establishing, communicating, and delivering the value. Establishing the value depends on building the evidence about the impact of the vaccine based on the safety, efficacy, and disease burden in the target regions/countries. Importantly, these activities must be linked to a communication strategy to ensure that the right information reaches the decision makers and influencers in a timely fashion. In parallel, appropriate support must be provided to enable the countries to deliver the vaccine to the end users and to the manufacturers to ensure adequate supply and appropriate price. We review each of these areas in more detail below.



Establish Value: The first step for any vaccine is the Establish Value component in the activity plan. Establishing value includes understanding and detailing the research program to (1) assess the burden of disease and (2) assess the impact of the vaccine.

Assess the burden of disease. As identified in previous studies[7], and confirmed through numerous interviews with health ministers from Vaccine Fund eligible countries, awareness of disease burden is the single most important factor for considering introduction of new vaccines. Local disease burden studies generate national and regional data critical to engage local opinion leaders and pediatricians. Working with experts in their communities, the Pneumococcal and Rotavirus teams have begun to prioritize these local studies to match the expected uptake of the vaccines. This prioritization effort includes identifying potential local partners with capacity to perform the studies as well as estimating the cost and timing of studies.

[7] Princeton survey research associates, for USAID and Gates Children Vaccine Program at PATH , December 1999

Assess the impact of the vaccine. Significant investments are required to establish efficacy of the late stage vaccine candidates in developing countries. Differences in serotypes/strain distribution, total disease burden, nutrition, and other factors between populations in developing and industrialized countries, drive the need for such safety and efficacy trials. In addition, trials could be required to test alternative regimens (e.g., two, three or four doses for pneumo) and monitor field impact of the vaccine. Currently the ADIPs include a prioritized list of necessary vaccine trials at the regional level, without defining which manufacturers will supply the vaccine. Based on further discussions with manufacturers, the detailed design and location of such trials will be defined.

Communicate value: The burden of disease and potential impact of a vaccine has to be communicated through a coherent communication strategy, targeting the appropriate audiences through the right channels. The ADIPs outline the early thinking on the necessary components of a communication plan to key national and international audiences. The ADIPs also outline what messages and channels might most effectively reach each target group. Additional work is required to flesh out a detailed communication strategy, including an assessment of needed data and messages from the studies, and initial activities to begin building critical networks of opinion leaders.

The communication strategy must also address negative issues. In interviews, Ministers of Health noted that negative press exists in developing as well as in industrialized countries; for example, about the risk of intussuseption linked to rotavirus vaccine. The future ADIP team must prepare an effective and coordinated response to counter potentially negative publicity.[8]

Deliver Value: To successfully introduce the vaccines, long-term vaccine supply must be assured, and national immunization systems must be able to deliver the vaccine to the end users. A strong national delivery system is a critical factor in each government's decision to introduce a new vaccine.

Ensuring vaccine supply. A successful national immunization program relies on a reliable supply of vaccine which is consistent with forecasted number of doses and product profile. Agreements between public procurement agents (acting on behalf of The Vaccine Fund eligible countries) and manufacturers can take several forms, from firm purchasing guarantees to more open agreements. The ADIP team should work with appropriate experts to determine what model is most appropriate.

Ensuring funding. Credible donor support over time is a major concern of most developing countries. Even when short term financing is secured, countries may not introduce a vaccine if this financing is not sustainable. This is one factor explaining the slow uptake of a fairly costly vaccine such as Hib. Understanding national plans for sustainability and, within that, how donors allocate funds, is therefore important.

Funds needed. Annual funding needs for rotavirus and pneumo depend, of course, on price and uptake volumes. Assuming some 20 million children are vaccinated in 2012 for Pneumococcal and some 30 million are vaccinated against Rotavirus, funding requirements would be around USD 300-600 million for pneumo (price USD 5-10) and USD 100-200 million for Rotavirus (price USD 1-2). Compared to the Hib and Hep B vaccine procurement costs of some USD 65-100 million, it is evident that substantial additional funding commitments from the donor community are required. According to some estimates, in-country costs for adding another vaccine to the existing delivery system are roughly USD 1-2 million. Historically, local budgets finance all or most of the delivery

[8] Based on interviews conducted with Ministers of Health/Health ministry representatives in Cape Town April 11-12 with Uganda, Rwanda, Mozambique, Malawi, Kenya, Swaziland, Indonesia, Ghana, Cote d'Ivoire, Mexico, and Ukraine

costs, whereas external financing usually supports the procurement of the vaccines early in their introduction.

Funding of vaccine purchase. Few Vaccine Fund eligible countries fund their newly introduced Hep B and Hib vaccines. However, several governments anticipate an increase in the national budget for immunization (in some countries from debt relief) as a result of the successful (albeit delayed) introductions of Hep B and Hib. It is unclear how much of these funds will be used for vaccines, versus strengthening the delivery system, and what portion of these funds will be used for new vaccines like pneumococcal and rotavirus.

Funding of the delivery systems. The costs associated with introducing the new vaccines will be significant. Importantly, most countries bear the full responsibility of such costs (although with donor support), and thus place heavy weight on how new vaccines impact the delivery system. Understanding the impact of Pneumococcal and Rotavirus (on cold chain, storage, transportation systems, personnel training, etc.) is critical for country level decision-makers to implement these vaccines. Raising the national and international funds needed to strengthen delivery will require a compelling and broad communication effort. Many countries receive substantial financial support, some through unspecified multi-donor funds supporting the health sector. For example, Ghana has a USD 30 million budget for the five-year health plan, funded by the government, private sector, donors, and investment funds. A decision to invest in a new vaccine must be supported by these fund investors.

3. Budget requirements to implement the ADIPs

In addition, as the activity plans to establish, communicate, and deliver the value are refined, corresponding budgets will be developed. Currently the budget is focused on activities to establish the value (e.g. development activities). As activities on communicating and delivering the value are defined, corresponding budgets will be established..

Budget requirements for development activities have been summarized in the ADIPs based on the prioritized activity plan. Current budgets 2002-2006 outline requirements of roughly USD 50 million for pneumo, and USD 20 million for rotavirus (in addition to the USD 8 million already secured). Parallel clinical vaccine trials (projected at USD 11 million per trial) represent the largest cost. Disease burden studies are projected at USD 25,000-100,000 per study. The 2007-2012 budget is primarily for monitoring trials and maintenance of clinical networks to continuously measure vaccine impact. It should be emphasized that these budgets cover a fairly broad range of activities and thus represent an upper limit for funding requirements. Further streamlining of the clinical plans and budget needs to take place once an ADIP team is established and this streamlining will likely reduce funding needs for the clinical program.

4. Organizational requirements

All of the private and public sector partners interviewed have reinforced the importance of empowering a dedicated team, responsible for ensuring the coordinated and timely implementation of activities. They noted that a credible and dynamic leadership team must be recruited and supported with up-front funding. The team's mandate will be to drive the rapid development, introduction and uptake of the vaccine. The team will work with partners around the world to implement development activities, ensure front line advocacy and ensure supply and delivery systems. The suggested ADIP team structure is designed to respond to the activities that will be implemented by different partners across regions. To ensure sufficient management support, administration capacity and credibility, the team

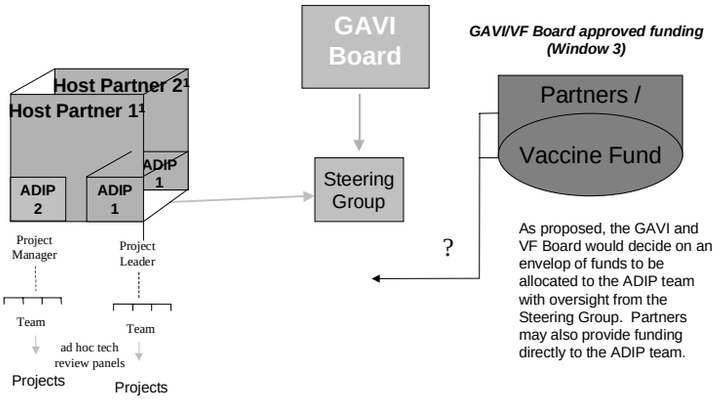
should be hosted in an existing or new organization that can facilitate ADIP work. We outline suggested requirements for such a host organization, but do not put forward a recommendation on which organization is preferred. This selection process would best be done through a competitive RFP, in which interested organizations submit proposals to a GAVI selection committee[10], outlining how they would incorporate and support the team in their organization.

Below we have several recommendations on a structure for the team, requirements for the host agency, and how activities might be organized in the interim period.

Structure of core ADIP team

We recommend that small, dedicated ADIP teams be established for rotavirus and pneumo, and that a Steering Group and a Technical Review Panel support them. These recommendations are outlined in more detail below, and a proposed organizational chart is included:

Recommended ADIP Management Structure



[1] Note: Host partner may be an existing or new entity.

1) The Proposed ADIP Team: The ADIPs will be managed by a small, accountable, target-driven team that is responsible for leading the process and coordinating the work across the scientific, financial, advocacy and implementation phases. It is suggested that this team ultimately consist of roughly four people: One leader with strong leadership/ management skills, a clinical manager responsible for coordinating the multi-partner efforts to implement the research agenda, an advocacy manager responsible for working with the community to create awareness and demand, and a program manager responsible for working with the community to address introduction issues. As the workplan will be staged, the hiring may also be staged since certain positions, such as the program manager, may have less intensive duties during the initial 1-2 years.

2) Steering Group: It is strongly advised that the ADIP teams be accountable to a small, "Board-like" Steering Group comprised of 5-6 stakeholders including the host agency, and, for example, 1-2 primary funders, the Executive Secretary of GAVI, and 1-2 other experts with strong management oversight experience. This Steering Group would have decision-making authority delegated by the GAVI Board to approve the ADIP plan and budget and to evaluate the teams' use of resources and progress toward milestones. The Steering Group may also be delegated the oversight of the budget, especially if funds are provided

[10] We recommend that the selection committee be no more than five people, with no conflict of interest (e.g. vaccine manufacturers and all agencies submitting proposals) but with experience with the different organizations and/or managing public-private partnerships.

for Window 3. The Steering Group would be responsible for input into, and formal or informal approvals of, proposed ADIP team members that are not identified during the RFP process. The Steering Group would report to the GAVI Board. It has been suggested that one Steering Group be established for both the pneumococcal and rotavirus ADIPs to encourage learning and interaction across the ADIPs.

3) Independent Technical Review Panel: It is suggested that each ADIP have access to ad hoc independent technical panels to both review technical RFPs and score technical proposals for funding. To ensure flexibility to address the evolving issues, the composition for each review panel will be determined by the scope of the RFP or proposals to be reviewed. GAVI may wish each ad hoc review panel to include a GAVI Task Force observer (selected based on the scope of the work) to liaise back with the task force workplan. In cases with potential for conflicts of interest, the Steering Group will approve the composition of the ad hoc panel.

The proposed ADIP structure provides not only strong oversight but also leadership and a transparent review of progress, and is therefore an effective tool for using Window 3 resources. Access to resources from a source such as Window 3 would also empower the ADIP process and team, dramatically improving the public sector's ability to achieve its goal of early introduction. If the Board approves Window 3, it might then authorize an envelope of funds to be released on a semi-annual or annual basis to the ADIP team. The use of these funds would be overseen by the ADIP Steering Group for priority activities outlined in the transparent, prioritized ADIP. With the approval of the Steering Group, the ADIP team would fund activities, in some cases based on a competitive RFP with advice from a specially constituted Technical Review Panel.

Requirements of the "host" organization

To ensure efficient administration and support, it is advised that the ADIPs be hosted by an organization capable of providing rapid, flexible, and appropriate support to the ADIP team. The host agency would need to outline how it would provide appropriate administrative and organization support including HR systems for rapid and flexible hiring of staff, rapid preparation of travel and meetings, systems allowing for rapid contracting with both public and private partners, and robust financial management systems for the ADIP team's budget, including paying on contracts. Given the recommended structure, this host organization must be able to accommodate the ADIP team's reporting to an external Steering Group. It is suggested that the host agency be selected by a competitive RFP process with transparent selection criteria that allow for comparisons of the strengths and weaknesses of each of the proposals in priority areas. Given the practical considerations, a small review panel comprised of a combination of Board members and some individuals with expertise in running public-private partnerships who do not have conflicts of interests (e.g. not a manufacturer with a relevant product or an agency submitting a proposal) would evaluate the proposal and provide scores based on the weighted criteria.

Maintaining the momentum

Although it will take some time to establish the ADIP teams, it is important that the current momentum not be lost. If the ADIP momentum is slowed down there is a risk that the public sector will miss the opportunity to influence the manufacturers' decision process and thus not be able to ensure that capacity is scaled up in time for early introduction. There is a further risk that established milestones for disease burden and surveillance studies will not be met, thus delaying the time when governments are able to make decisions and credible demand forecasts can be established.

If the Board approves the ADIP approach and team structure, it is likely to take 9-12 months before an ADIP team is operational. This is because of the following probable timing of steps. If the GAVI Board approves the concept of an RFP, the Secretariat/Working Group can then draft the RFP document for Board approval in September. Any organization that wishes to submit proposals would have sixty days in which to respond. Proposals could be reviewed in December, and a recommendation on the host agency reviewed and decided upon by the Board in January. At this point, the designated host agency could begin the hiring process which might take anywhere from 2-6 months. To maintain this momentum, we recommend that the current rotavirus and pneumococcal teams which have played a pivotal role in developing the ADIPs continue to perform the planning and coordination activities in the interim period to ensure that all activities are high quality and consistent with the targets set in the ADIP.

FURTHER REFINING THE ADIPS

The ADIPs for pneumococcal and rotavirus vaccine have been discussed with Wyeth, GSK, and Merck. The R&D communities for pneumo and rotavirus have been actively involved in developing the respective plans and the GAVI Working Group, Task Force on R&D, and Task Force on Financing have reviewed and commented on the findings. Valuable feedback on how to bring the plans forward to next generation has been provided from all these sessions. Key points are described below.

Manufacturers' feedback

Manufacturers felt that to be successful, the plans required an even stronger prioritization of activities, for example, allocating scarce resources based on where coverage and deaths prevented are greatest per dollar spent[11]. In response to this feedback, the team has included some preliminary perspectives on investment-payback that could guide further thinking.

For manufacturers, the implied clinical workload seemed high relative to the available financial and human resources. Manufacturers suspect that the program can probably be streamlined by reviewing the clinical objectives in light of the market needs, uptake ambition, and what is feasible. For example, current rotavirus introduction activities are planned in all seven major regions with little phasing. An alternative approach would focus on highest disease burden areas (e.g., India/Pakistan/ Bangladesh) and then extend to other areas. A critical review of the budget allocation seems required, which should be based on how countries are strategically targeted and sequenced. Importantly, all manufacturers have offered to involve their clinical personnel and leverage their in-house knowledge to help streamline the program.

Manufacturers had two primary pieces of feedback on forecasts. First, manufacturers noted that initial forecasts appear reasonable, but somewhat optimistic, especially given the slow uptake of the Hib vaccine. It was noted that there are substantial challenges in forecasting demand at this stage, given the uncertainties around price, product profile and limited understanding of decision criteria to use and fund the vaccine by the countries and donors. Second, the manufacturers noted that forecast estimates would be more credible if they included middle-income markets, as these markets will likely be among the first to adopt the new vaccines. The forecasts will, of course, need to be refined by the ADIP

[11] Note that most Latin American countries fall outside the Vaccine Fund eligible countries, and that only small countries such as Bolivia, Nicaragua and Cuba are included in the forecast. However, the wealthier middle income countries in the region may be among the earliest adopters of the new vaccines.

teams as they work with countries and partners and gain more insight into the decision processes and decision criteria across user countries and donors, as well as a better fact base is established on cost-effectiveness per country.

Public sector feedback

Most public sector experts believe that the ADIP can provide a prioritized approach for an integrated and accelerated introduction effort. In the short term, it is accepted that the ADIP, which is in essence an introduction plan, will focus on the late stage manufacturers which represent the only viable path to introduce the vaccines at the earliest possible date (in this case 2006/2008). However, several public sector representatives see the focus on late stage manufacturers/products as narrow and therefore risky. They note that more attention is needed on technical transfer to local producers as they may represent a significant supply opportunity particularly for rotavirus vaccine.

The current ADIPs have very detailed development plans and budgets, however communication and delivery plans and budgets need to be further defined.

Health ministers from developing countries have noted the importance of a well-designed plan to provide national data. A national clinical plan would include pediatric networks to gather the disease burden data and at the same time create advocacy in this important group. Government health and finance officials should also be involved to ensure health economic analysis to support introduction decisions. All emphasized that it would be critical to quickly begin activities to accelerate the introduction.

CONCLUSION

The current Accelerated Introduction and Development Plans represent an important step towards achieving GAVI's goal of rapid, successful introduction of the pneumococcal and rotavirus vaccines into developing countries. The plan reflects key learnings from the introduction of other vaccines and also attempts to leverage the unique opportunity provided by the collaboration and resources of GAVI and The Vaccine Fund. Accordingly, the current ADIPs include activities to simultaneously build demand, ensure supply, and guarantee funding in as transparent and efficient manner as possible. We believe that this strategic, phased approach represents the best hope towards achieving GAVI's goals.

Presentation by The Vaccine Fund on its Draft Strategic Plan and Emerging Policy Issues

June 2002

Jacques-François Martin

Mission

The mission of The Vaccine Fund is:

> "to mobilize resources for, champion, monitor the results of, and help sustain the Global Alliance for Vaccines and Immunization's (GAVI) programs to protect the children of the world's 74 poorest countries from vaccine-preventable disease."

Strategic Objectives

The Vaccine Fund has four strategic objectives, which flow from the specific aims of its mission:

1. Mobilize resources to achieve immunization sufficiency and sustainability.
2. Achieve recognition of and support for The Vaccine Fund's mission so as to maximize the value of its brand.
3. Manage The Vaccine Fund for efficiency and accountability for results.
4. Ensure with GAVI partners a secure supply of all relevant vaccines that are accessible to all target countries.

The Vaccine Fund and GAVI

The strategic objectives of The Vaccine Fund must be understood in the context of the GAVI program for the development of national immunization capacity, supply of underused vaccines, provision of safe injection materials, and the potential introduction of future vaccines such as those against meningococcus, rotavirus, pneumococcus and, further in the future, HIV, TB and malaria.

The central objective of The Vaccine Fund is resource mobilization. The Vaccine Fund's capacity to mobilize resources on a sustained basis is directly dependent on its ability to account for the effective use of its resources – particularly of the results achieved on the ground by governments and other GAVI partners – and to communicate effectively. Therefore, the Vaccine Fund will continue to work with the GAVI partners to ensure the necessary flow of information on country-level performance.

One of the key strategic advantages of the Vaccine Fund is its multiyear commitments from donors, allowing a potential for multiyear commitments from the Fund to national governments and to vaccine manufacturers. This advantage has been amply illustrated in the way suppliers are now responding to the strategic directions taken by the GAVI and Vaccine Fund Boards; capacity for producing hepB- and Hib- containing combination vaccines is being scaled up by a number of manufacturers.

The first commitments to the Vaccine Fund were considered in terms of five years; now the Fund must develop its strategic plan for the next five years. As the Vaccine Fund relies upon GAVI for its technical and policy directions, the GAVI Board needs to start looking

beyond the first five years for the next set of GAVI milestones so that the Vaccine Fund can calculate its future needs and the funding gaps.

Planning and Supporting Financial Sustainability

Resources provided by The Vaccine Fund to countries' immunization programs are designed to encourage a catalytic effect within a broader national effort that aims for immunization sustainability. As such, Fund resources should be considered in the context of a combination of resources generated by an increased commitment to immunization by all actors.

The Vaccine Fund and GAVI are collaborating closely in supporting countries in the development and implementation of countries' financial sustainability plans. These plans are meant to facilitate the ability of countries to focus their planning of immunization financing requirements and to seek and secure additional funding from the broadest possible array of sources, including the governments' own budgets, bilateral and multilateral donors, NGOs, development loans and other funding mechanisms.

This synergistic approach to identifying long-term funding will reinforce the perception among recipient countries, as well as donors, that The Vaccine Fund resources constitute a catalytic global public good that, seeking a multiplier effect, is intended to result in long term sustainable financing for immunization within health systems. Indeed, consultations thus far suggest that long-term commitments through the financial sustainability plans (national and international) will be essential in securing continued funding commitments from governments to the Vaccine Fund.

Defining the Current Endpoint of Vaccine Fund Support

Before looking toward the next phase of Vaccine Fund support to countries, it is essential to reach agreement on the endpoints of current support. In other words, what are the exact financial commitments from The Vaccine Fund to eligible countries based on current GAVI policies? The first phase of the funding requirements (2002-2006) has been calculated using the following assumptions (reflecting the current GAVI Board policies and commitments):

- Performance-based support to immunization infrastructure (shares derived from additional children immunized), be paid over five years.
- Support to introduce under-used vaccines defined as hepatitis B, Hib, and/or yellow fever (YF) vaccines (where recommended for use according to burden of disease), as well as associated AD syringes and disposal boxes, for a period of five years.
- Support for China, India and Indonesia with a cap of $40 million per country over the five years.
- Provision of safe injection materials – AD syringes and safety boxes – for all vaccines given to infants, according to the standard EPI schedule, for a period of three years.

It should be noted that current policy for under-used vaccine support from The Vaccine Fund does not stipulate a final date for applications or implications of re-applications for the introduction of new antigens. For example, a country that began receiving the pentavalent DTP-HepB-Hib and yellow fever vaccines in 2001 will no longer be eligible to receive these vaccines from The Vaccine Fund after its five-year allotment is depleted. On

the other hand, a country that began receiving the tetravalent DTP-HepB vaccine in 2001 may want to add the Hib antigen to its routine immunization schedule at some point in the future. Currently, there is no policy to indicate whether this country would be able to apply, say, in 2006 to The Vaccine Fund for five years of financing for Hib, even if it has already received five years' worth of support for DTP-HepB.

Following are policy options for the GAVI Board to consider in order to clarify the current endpoint of Vaccine Fund support:

1. The Vaccine Fund would pay only for the additional cost of the Hib antigen for five years; the country would be required to assume the cost of the DTP-hepB component. The financial implications would be an estimated additional $625 million[1].
2. The Vaccine Fund would pay for five years' supply of DTP-HepB-Hib, even if a country has already received five years' supply of DTP-HepB. The financial implications would be an estimated additional $825 to $925 million.
3. The Vaccine Fund would only pay for five years' worth of vaccine, regardless of when a new antigen is introduced in a country, i.e., a country may receive only two years' supply of DTP-HepB-Hib if they have already received a three years' supply of DTP-HepB. This is basically the current practice, so financial implications are in line with current commitments.

The Vaccine Fund has used Option 1 as a basis for its calculations of resource needs for HepB and Hib for years 2006-2011, using country-identified DTP3 coverage targets outlined in the following table. The table excludes China, India and Indonesia as they are funded on a different basis (however, these countries will significantly increase immunization rates with hepatitis B vaccine).

	2001	2006	2011
Birth cohort in 71 countries	44.9 million	48.9 million	49.7 million
DTP3 immunized children	27.0 million	41.0 million	41.0 million
Hepatitis B immunized children	1.8 million	20.8 million	38.9 million
Hib immunized children	0.5 million	8.9 million	23.0 million

Identifying Potential Scenarios for Future Vaccine Fund Support

In order to provide a ten-year framework for the development of the funding requirements, the Vaccine Fund has also explored a number of scenarios for future GAVI policies. These scenarios are based on the original vision that the Vaccine Fund would support the introduction of other priority vaccines, beyond the first three priority vaccines of hepatitis B, Haemophilus influenzae type b and yellow fever. In addition, concerns have been expressed that the Vaccine Fund should increase its financial commitments to infrastructure.

It must be stressed that these proposals are merely options for consideration by the GAVI Board. It is recognized that more detailed work is necessary to better define those options identified as high priority by the Board, or to identify additional options, such as catch-up campaigns with priority vaccines, that currently fall outside the GAVI policy framework.

[1] Calculations assume that Hib is not made available in Asia, in consideration of current data; if disease burden studies ultimately indicate appropriateness of Hib vaccine in Asia, estimated financial implications may double.

Additional support for immunization infrastructure

There seems to be wide agreement that the countries need more resources than are currently provided through the share system to strengthen their health infrastructure in order to reach the GAVI immunization goals. It might be advantageous to consider increasing this type of support sooner rather than later.

However, as previously stated, The Vaccine Fund is designed to be catalytic and should not replace other sources of funding. Furthermore, care must be taken to encourage financial sustainability and not undermine governments' efforts to secure more sustainable sources of funding for their health systems. The GAVI Board will need to weigh these issues as it considers how to provide countries with more financial support to strengthen infrastructure. Options to consider include, but are certainly not confined to, the following:

1. Extend current share system by providing an additional one to two years of shares, so that instead of providing $20 for each additional child reached, The Vaccine Fund would provide $40 to $60, paid out over two to three years.
2. Target additional resources to the poorest countries.
3. Link contributions to successful development of financial sustainability plans and their implementation.
4. Other mechanisms for supporting infrastructure.

Further analysis and exploration of options and mechanisms is required should the Board decide to pursue increasing Vaccine Fund support to infrastructure.

Fundraising target for additional infrastructure support – **$640 million**

Introduction of important new vaccines

Acceleration of the development of vaccines against meningococcus A, pneumococcus and rotavirus have been identified by the R&D Task Force and endorsed by the GAVI Board as priorities. While it is not assumed that The Vaccine Fund would purchase these vaccines if and when they are developed, their status as GAVI priority vaccines indicate that this may indeed become a focus for resources.

In addition, other vaccines are available today but are not used in many of the poorest countries. These include, but are not limited to, Japanese encephalitis, MMR, rubella, IPV, and other combination vaccines now being developed. Looking further into the future, vaccines against AIDS, malaria and tuberculosis should be considered within the context of The Vaccine Fund. Finally, technologies to improve delivery of vaccines may be developed within the next ten years.

While precise scenarios for the future purchase of vaccines are difficult to predict, it is essential to have a long-term view, considering the timeline manufacturers need in scaling up production. Within the next two years the GAVI Board will need to consider the 'next generation' of vaccines targeted for support from The Vaccine Fund.

Fundraising target for additional vaccine and technology support – **$2.5 billion**

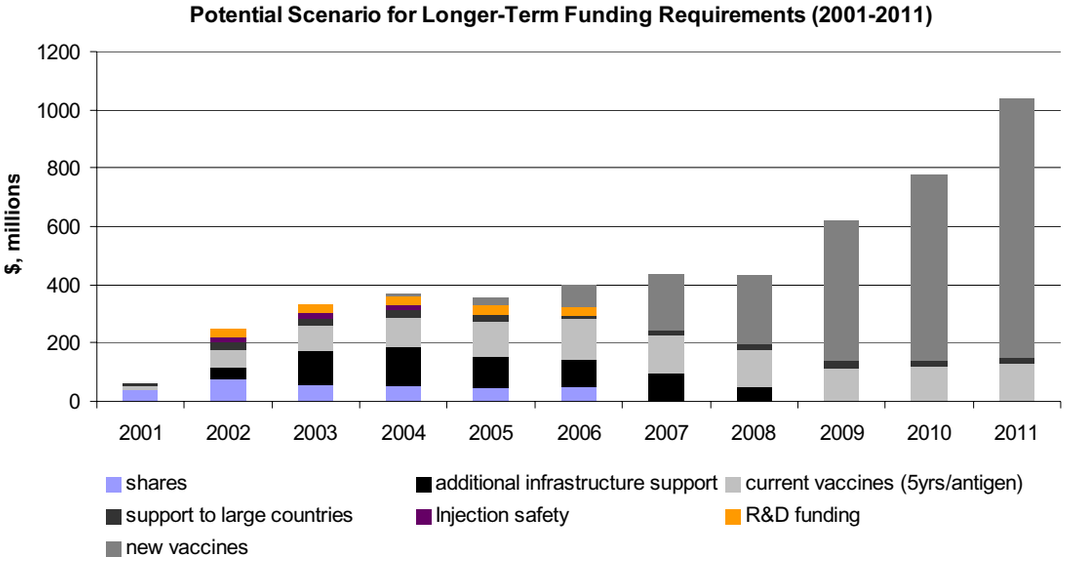
Other support

Other categories of additional support not covered under current GAVI policies are:

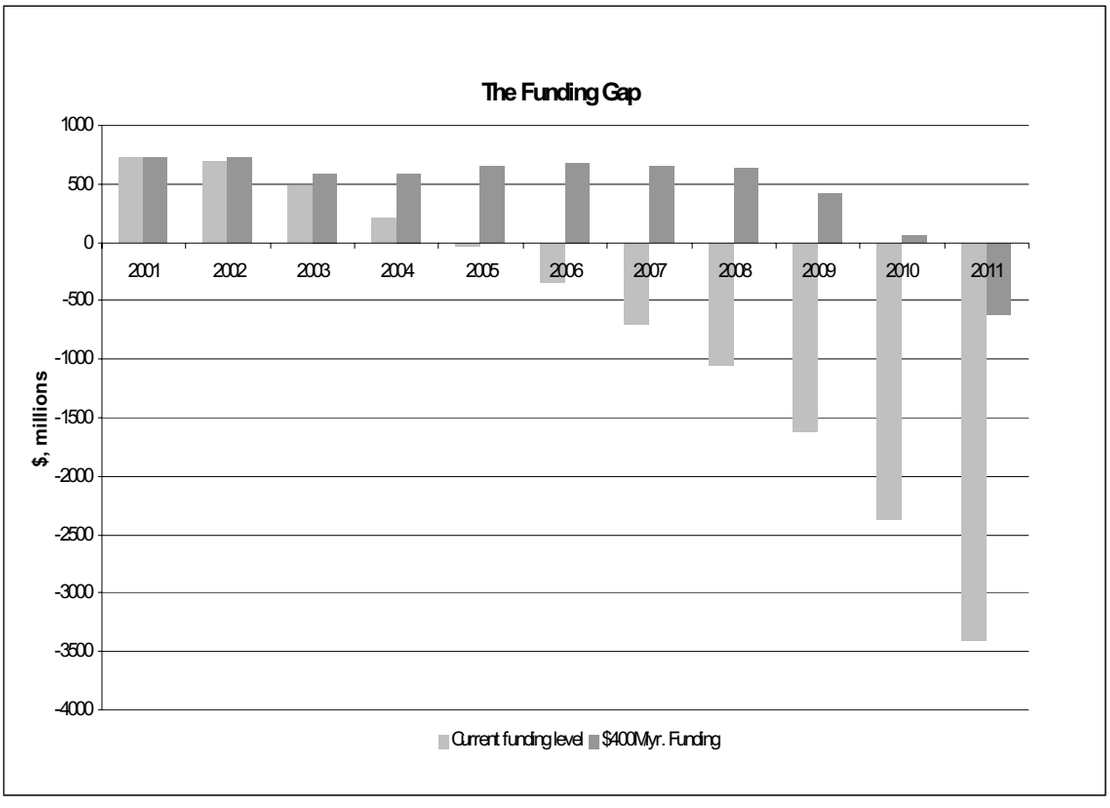
- Provision of $30 million per year for five years for vaccine development activities contributing to the development of new vaccines or of technology that enhances immunization in the target countries.
- Additional support for larger countries in the period 2007-2011.

Fundraising target for other support – **$350 million**

Based on the above scenarios, the potential funding needs for the period 2001-2011 are illustrated below:



Based on the above needs, we have assumed an annual fundraising target of $400 million. If this fundraising target is met, The Vaccine Fund will face a funding gap starting in 2011. This is illustrated in the graph below.



All of the scenarios outlined in this paper are dependent upon the actual performance of country immunization programs. If the countries exceed, or do not meet, their targets, the funding needs and gaps will need to be adjusted.

Similarly, GAVI priorities for utilizing resources from the Vaccine Fund could evolve, as more field experience is gained and the relative impact of current investments are assessed. The GAVI Board will clearly need to develop criteria and a prioritization process for identifying, evaluating and comparing different policy options so that Vaccine Fund resources can be applied in the most effective and advantageous manner.

REVISED Guidelines for Optimal, Effective and Catalytic Use of Resources from "Window 3" of The Vaccine Fund

Introduction

Focused Research and Development (R&D) projects play a key role in addressing glaring gaps in the equitable access to priority vaccines needed to immunize the world's children against vaccine-preventable infections. As discussed in the GAVI Board Meeting in Stockholm in March 2002, the GAVI research agenda needs to be focused on implementation – support the research that is required to get more vaccines to more children in the shortest time. In addition, the involvement of developing country researchers and manufacturers is essential in the GAVI research agendas.

Accelerating the development and introduction of new generation pneumococcal vaccines, live oral rotavirus vaccines and meningococcal* conjugates that include group A into the world's least developed countries will enhance **Equity.** The "vaccine technologies" projects (currently under selection) will expand **Access** by improving the practicality and efficiency of immunization.

Accelerated research, development and introduction plans

Under auspices of the GAVI Task Force on R&D (in conjunction with GAVI partners such as WHO, the Bill and Melinda Gates Foundation, Rockefeller Foundation and NIH), leaders of the global research communities involved with pneumococcal, rotavirus and meningococcal vaccines from industrialized and developing countries have drafted plans to accelerate research, development and introduction of these vaccine products into immunization programs of developing countries.

The preliminary business plans drafted by the GAVI (mainly public sector) partners were converted by McKinsey Consultants (in conjunction with GAVI partners) into comprehensive definitive Accelerated Development & Introduction Plans ("ADIPs"). Among the various approaches taken to manage R&D in international health, a consensus has emerged around this ADIP approach.

GAVI has a number of mechanisms at its disposal to assure that high priority research and development activities are successfully resourced and completed. Window 3 is a new mechanism that will work catalytically with other available mechanisms that include:

- Partners working in a coordinated fashion to increase efficient use of existing resources
- Individual partners assuming responsibility for specific high priority tasks or activities, according to their interest, expertise and funding capacity
- Individual partners directly financing others to carry out all or part of the Accelerated Development & Introduction Plans

Guidelines for Use of Window 3 Funds

Window 3 funds will complement existing resources and function as an advocacy tool

Window 3 will co-fund ADIPs in conjunction with support from other partners and donors. Window 3 funding will thus serve as an advocacy tool in two distinct ways. First, financial support from The Vaccine Fund sends a strong message about the global priority accorded

to the activities and projects to be supported. Second, some prospective donors are interested in supporting GAVI's R&D objectives. For such donors, Window 3 of the Vaccine Fund assures a conduit to channel their contributions to further the R&D objectives of GAVI.

Types of activities that should be supported

The prioritized tasks and activities that will be supported by Window 3 are integral components of Accelerated Development & Introduction Plans for vaccines specifically targeted by the GAVI Board, beginning with the three vaccine priorities (pneumococcal, rotavirus and meningococcal vaccines) and potentially expanding to include future vaccine technologies. (Note – Since the meningococcal conjugate vaccine agenda has already been substantially funded, it is not included in this exercise.)

It is anticipated that Window 3 funds may be used to support any critical ADIP activity (e.g., Research & Development, Advocacy, Implementation). However, initially, two activities that are particularly critical to move the ADIPs forward are:

- epidemiologic measurements of the burden of pneumococcal, rotavirus and meningococcal vaccine-preventable disease, and
- clinical trials that assess the safety, immunogenicity, practicality, efficacy and effectiveness (including cost effectiveness) of the vaccine (and vaccine technologies) in target populations in developing countries.

These activities are very well suited as a basis for institutional and individual capacity building in developing countries – a major consideration for GAVI R&D activities. Efforts will be made to ensure that qualified capacity will be developed during such studies and trials.

Disease burden studies generate the evidence base to guide countries in prioritizing vaccine introduction. Disease burden data do not favor manufacturers of individual products but benefit all partners, public and private.

In contrast, support for clinical trials of specific products might benefit manufacturers of particular products. To minimize any implications stemming from use of Window 3 funds on competition in industrialized country markets, ADIP teams will:

- Wherever possible, engage multiple manufacturers as partners rather than a single manufacturer.
- Be transparent in all funding, allowing all firms to respond to public advertising of requests for proposals.
- Limit funding to clinical trials that are structured so there are minimal or no direct licensing benefits in industrial country markets. In situations where both an obvious industrial market benefit may arise because of the design of the clinical trial and the level of Window 3 funding surpasses the level of > US$ 5 million (over a period of three years), then an analysis of the potential commercial benefits and the appropriate returns to the public sector will be required. These returns to the public sector may include, for example:
- Negotiating in advance an appropriate and "affordable" price for the Vaccine Fund eligible countries.
- Negotiating in advance a guarantee that a certain number of doses of vaccine will be made available for Vaccine Fund countries.

- Negotiating access to the patents and (or) a transfer of technology if the manufacturer chooses not to develop the product or not to manufacture sufficient quantities to supply the Vaccine Fund countries.

The portfolio of activities within each ADIP represents a balance of "downstream" activities as well as some activities involving products that are further upstream in the development pipeline but that may have specific advantages over the further developed products with respect to use in developing countries.

Other priority activities required to accelerate the introduction of these new vaccines and technologies into public health use in developing countries, such as investment in additional production capacity to meet the needs of developing countries, will be handled separately and brought to the GAVI Board on a case-by-case basis.

Once disease burden and clinical trials have been completed, the commitment of affected countries to invest in the use of these vaccines can be addressed.

Management

The proposed management structure of the Accelerated Development & Introduction Plans is described in detail in a separate document.

Minimizing conflicts of interest

To avoid conflicts of interest with respect to the status of individual manufacturer's products, experts from industry will not serve as members of the Independent Review Panels when studies of specific products are to be considered. Industry members may participate in the review of projects related to disease burden measurement or other activities that are generic and not related to specific products.

All members of the Independent Review Panels will fill out a form in which they must declare equity holdings, paid consultancies, collaborations, etc. that might be construed as constituting a potential conflicts of interest with projects that will be under review.

Rapidity of transfer of funds

The transparent, target-oriented ADIP contains prioritized activity plans. The proposed ADIP structure provides an efficient oversight and disbursement mechanisms for funds. As proposed, an envelope of funds (allocated on a semi-annual or annual basis) would be disbursed to the ADIP team. A steering group is proposed to provide oversight to the ADIP team, its plan, budget and progress toward ADIP milestones. Within the detailed and transparent ADIP, the steering group would authorize use of the funds by the ADIP team.

Commitment of The Vaccine Fund to purchase specific products

The commitment of Window 3 resources to support clinical research within an ADIP involving a specific vaccine or vaccine technology product does not necessarily obligate The Vaccine Fund to procure that vaccine or product in the future. It is anticipated that support of clinical trials of specific pneumococcal, rotavirus or meningococcal vaccine products or vaccine technologies by Window 3 of The Vaccine Fund will generate invaluable information about the use of those products in developing countries. In general, however, once these products become licensed, the actual procurement of vaccines or related products by The Vaccine Fund will take place through the same transparent, competitive procurement process that currently exists for other vaccines purchased by GAVI. Neverthe-

less, should it become obvious that development of the vaccine or modifications of the vaccine or technology for developing country use (e.g., changes in vaccine formulation to include additional serotype antigens) is contingent upon some level of future guaranteed purchase by The Vaccine Fund, such situations will be handled separately and brought to the GAVI Board on an individual case basis.

The amount of funds from Window 3 to be allocated annually

It is proposed that the total allocation of funds from Window 3 of The Vaccine Fund shall not surpass US$ 30 million per year for the first three years. After three years, Window 3 will be reviewed and the ceiling may be increased or decreased. Precise apportionment among the projects will depend on the activities prioritized in each Accelerated Development & Introduction Plan and the degree of direct financing from partners.

Evolution of the Task Force on Country Coordination (TFCC)

June 2002

Background

In its third year of existence, the TFCC encountered a shift in activities from simply providing assistance to countries to complete their applications to The Vaccine Fund, to coordinating technical support in the implementation phase of the initiative. The Board, recognising this move toward implementation, requested a clarification of the role of the TFCC at the Fifth GAVI Board meeting.

In response to this request the TFCC commissioned a review and as a result has developed a new set of objectives, new Terms of Reference and structure, and a proposal to change its title to "Implementation Task Force".

Proposed new structure, modus operandi, objectives and responsibilities

1. Management structure (see Figure 1 for organigram)

To improve efficiency, management, and expedite decision-making, it is proposed that the new task force should consist of a Core Group comprising of similar membership as the TFCC with two sub-groups for Monitoring and Evaluation and Capacity Building. Regional Working Groups (RWGs) will provide the critical liaison with the ICCs and partners at the country level. Core Group members will be assigned a role in one of the sub-groups. The sub-groups will report to the Core Group to endorse activities. Regional Working Group focal points will sit on the Core Group and on the sub-groups.

The ITF will be chaired by WHO (Coordinator V&B/EPI). WHO will also provide secretariat to the Task Force. It is also proposed that the Monitoring and Evaluation sub-group be headed by WHO and that the Capacity Building sub-group be headed by UNICEF.

2. Modus operandi

National governments have responsibility for reaching immunization targets as set out in their 5-year strategic plan. The ICC partners support countries in this task and the ICC facilitates coordination, identifies needs, and links to broader health sector development issues based on review of annual country results and workplans. The ITF (through the RWGs) facilitates and supports these activities.

Workplans at global and regional level coordinate activities to increase coverage, improve capacity building and carry out monitoring and evaluation. Global level workplan activities are followed up during the bi-weekly sub-group conference calls and monthly Core Group conference calls. The ITF Chair and Secretariat provide feedback to RWGs on budgets and planned activities and in addition, RWGs share the minutes of their meetings in an Information Update and provide feedback to the bi-annual ITF meeting on country-level activities and lessons learned. The progress report and workplan of the ITF will be sent to the Working Group on a bi-annual basis.

3. Objectives and Responsibilities

3a. Coordination

- To coordinate GAVI partner activity at global, regional and country level.
- To support regions and countries to improve access to sustainable immunization services; meet accelerated disease control targets; and to attain the GAVI 80:80 milestone.
- To coordinate a global "think tank" function and provide feedback and advice to the GAVI Working Group and Board, and to countries, on issues arising from GAVI country-level strategic objectives, and on those issues detrimental to a country's successful achievement of GAVI milestones.
- Provide timely and innovative inputs and regional/country feedback to the GAVI Working Group and Board on issues arising from the implementation of GAVI country-level strategic objectives.

3b. Monitoring and Evaluation

- To review annual progress toward GAVI strategic objectives and milestones.
- To coordinate technical assistance to regions, sub-regions and countries on improving data collection, management and use of data at district level.
- To advise on the content and format of the GAVI/Vaccine Fund country monitoring and reporting tools (Annual Progress Report, DQA, MTR, etc) and organise their field tests.
- To design the evaluation of the GAVI performance-based reward mechanism and investigate alternative mechanisms (development of a set of qualitative indicators).
- To finalise the development and selection of core indicators (with the Capacity Building sub-group).
- To monitor the impact of the GAVI process on the broader health system.

3c. Capacity Building

- To develop a framework for capacity building as the basis for a common global approach and set of principles for partner agencies (in collaboration with the Financing Task Force on issues of financial sustainability).
- To identify the highest priority capacity building gaps in immunization systems.
- To map global and regional activities to better understand and harmonize partner activities and address relevant gaps.
- To ensure consistency and coordination of capacity building initiatives against globally defined principles.
- To develop, through Regional and Sub-regional Working Groups, a country-level self-administered methodology for assessing national capacity for immunization, based on the core indicator set.
- To provide support to the financial sustainability activities directed towards capacity building at country or regional level.

3d. Role of Regional Working Groups – a critical function

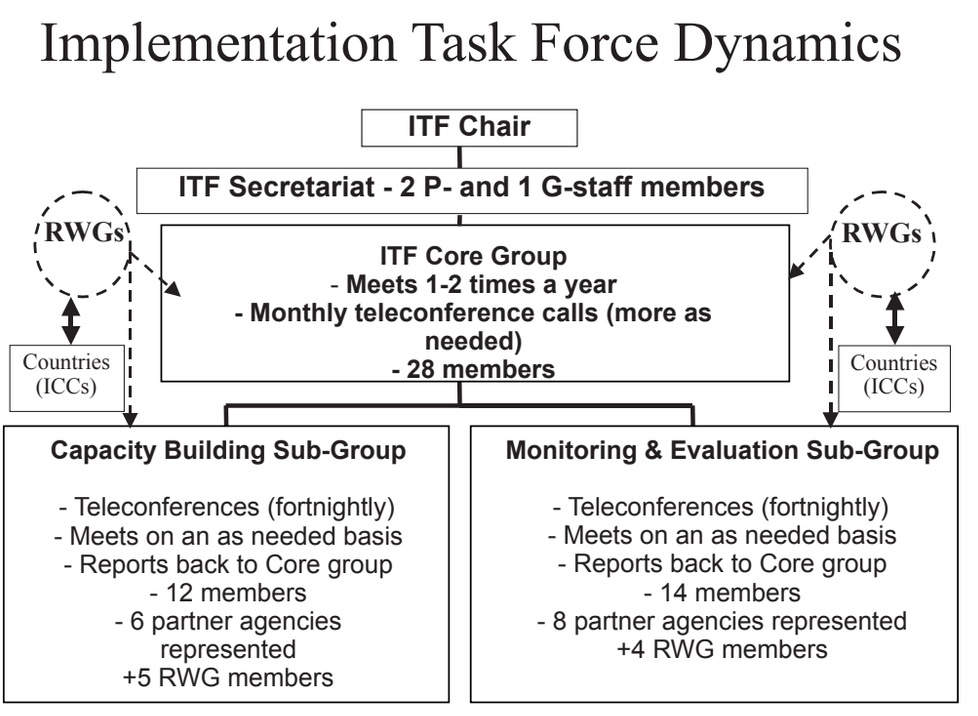
The RWGs are an integral part of the implementation process and have demonstrated a critical role in coordinating partner activities, supporting Interagency Coordinating Committees and providing technical assistance. However, RWGs do not replace the policy-making role of existing regional bodies such as Technical Consultative and Technical Advisory groups. As a result of their work, RWGs have recruited 22 Immunization Advisers in a corresponding number of countries to carry out GAVI-related activities. Regional Working Groups have held frequent meetings to review country progress and ensure that technical support is available to countries. In addition, RWGs also have a new role in providing assistance during the financial sustainability planning process.

As the role of the RWGs develops it will be necessary to build their skill and resource base so that they are able to provide the results expected of them—this will require an increased budget (currently estimated to be in the order of an additional $1.2 million from May 2002 to June 2003).

Annexes attached

ITF Structure.

Figure 1



Recommendations from the Seventh Round of Country Proposal Review

The Independent Review Committee (IRC) met in Geneva from 23-31 May 2002 for the seventh review session. Eight IRC members participated (see page 11).

Nineteen countries submitted proposals for this review, with a total of 32 requests for different types of support—

- Immunization services 7 requests
- New and under-used vaccines 10 requests
- Injection safety 15 requests

The IRC's recommendations are summarized by country on page 3, and appear in greater detail in pages 5-10. The Board is requested to review these recommendations.

The financial impact of these recommendations is estimated to be US$ 18.9 million in 2002-2003 (Tables 2 and 3), and would commit the Vaccine Fund to an expenditure of approximately US$ 70.7 million over five years.

If the recommendations from this review are carried forward, 60 countries will have been approved for support from the Vaccine Fund since GAVI's inception. For a summary of the approval status of countries eligible for Vaccine Fund support, please see Figure 1 (page 16). The overall financial five-year commitment of the Vaccine Fund, including the now recommended approvals, will amount to US$ 902 million. For a detailed calculation of estimated five-year commitments by country see Table 4 (page 12-14).

UPDATE

Out of the 74 eligible countries (GNP/cap US$< 1,000), four countries do not qualify for support under the current criteria (Table 5, page 15). The status of the remaining ten countries that have not yet been approved is shown on Table 6 (page 15)—only four of the eligible countries that qualify for assistance have failed to apply.

ADDITIONAL RECOMMENDATION

A proposal is being prepared for the Board regarding additional countries and territories that may now be eligible for support. In the meantime, the IRC proposes that East Timor, as a newly independent country with a GNP/capita below US$ 1,000, be immediately accepted as eligible for Vaccine Fund support.

Table 1. SUMMARY OF RECOMMENDATIONS BY COUNTRY

COUNTRY	immunization services	new and under-used vaccines	injection safety
Albania			Re-submission
Azerbaijan			Conditional
Bosnia & Herzegovina		Approval (hepB)	
Comoros		Appr clar (hepB)	Appr clar
Congo DR	Appr clar	Appr (YF)	Appr clar
Djibouti	Approval		Appr clar
Korea DR	Approval	Appr clar (hepB)	
Kyrgyzstan			Conditional
Lesotho		Approval (hepB)	Appr clar
Malawi			Conditional
Mali		Conditional (hepB)	Conditional
Mauritania	Conditional	Re-submission	Approval*
Mongolia	not eligible	Re-submission	
Nigeria		Conditional (YF)	
Pakistan			Appr clar
Rwanda			Re-submission
Somalia	Approval		Re-submission
Togo	Appr clar	Conditional (YF)	Appr clar
Uzbekistan			Approval

*** = (only effective after approval for other support)**

Table 2: Financial implications in 2002 and 2003 for proposals recommended for approval (in US$)

Country	Immunization Services		New and Under-used Vaccines (estimate)		Injection Safety (estimate)	
	1st tranche Aug 2002	2nd tranche Dec 2003	2002	2003	2002	2003
Bosnia & Herzegovina	-	-	22,200	90,700	-	-
Congo DR	-	-	-	595,500	-	-
Djibouti	32,700	32,700	-	-	-	-
Korea DPR	297,200	297,200	-	-	-	-
Lesotho	-	-	-	47,700	-	-
Mauritania	-	-	-	-	70,400	65,700
Somalia	304,500	304,500	-	-	-	-
Uzbekistan	-	-	-	-	173,800	312,000
Sub-total	634,400	634,400	22,200	733,900	244,200	377,700
Grand Total					**3,484,600**	

Table 3: Financial implications 2002/2003 for proposals recommended for approval with clarifications (in US$) ***(figures subject to change pending receipt of clarifications)***

Country	Immunization Services		New and Under-used Vaccines (estimate)		Injection Safety (estimate)	
	1st tranche Sep 2002	2nd tranche Dec 2003	2002	2003	2002	2003
Comoros	-	-	-	29,100	13,700	12,400
Congo DR	2,930,600	2,930,600	-	-	-	1,391,800
Djibouti	-	-	-	-	11,100	10,800
Korea DPR	-	-	-	207,300	-	-
Lesotho	-	-	-	-	-	46,500
Pakistan	-	-	-	-	3,657,500	3,108,700
Togo	350,600	350,600	-	-	129,500	122,800
Sub-total	3,281,200	3,281,200	-	236,400	3,811,800	4,693,000
Grand Total					**15,303,600**	

Annex A

Proposals recommended for approval

BOSNIA AND HERZEGOVINA
New and under-used vaccines (hepB)

CONGO, DEMOCRATIC REPUBLIC
New and under-used vaccines (YF)

DJIBOUTI
Immunization services

KOREA, DEMOCRATIC PEOPLE'S REPUBLIC
Immunization services

LESOTHO
New and under-used vaccines (hepB)

MAURITANIA
Injection safety (supplies)
only effective after approval for other support

SOMALIA
Immunization services

UZBEKISTAN
Injection safety (supplies)

Annex B

Proposals recommended for approval with clarifications

COMOROS
New and under-used vaccines (hepB)
- to justify the wastage rate which is higher than 25% in 2003

Injection safety (supplies)
- to provide targets for training health workers

CONGO, DEMOCRATIC REPUBLIC
Immunization services
- to complete budget tables in annex 1 of the application according to GAVI guidelines,
- to review DTP and TT coverage targets, in particular from 2001 to 2003, to ensure that they are realistic

Injection safety (supplies)
(same clarifications as for immunization services)
- to complete budget tables in annex 1 of the application according to GAVI guidelines,
- to review DTP and TT coverage targets, in particular from 2001 to 2003, to ensure that they are realistic

DJIBOUTI
Injection safety (funds)
- to confirm that AD syringes for all vaccines (including BCG) and safety boxes are secured for three years, indicating source and amount of funding.

KOREA, DEMOCRATIC PEOPLE'S REPUBLIC
New and under-used vaccines (hepB)
- to confirm the readiness of the cold chain to prevent freezing of hepatitis B vaccine

LESOTHO
Injection safety (supplies)
- to provide targets for monitoring progress toward injection safety and waste management.

PAKISTAN
Injection safety (supplies)
- to provide targets which will be used for monitoring progress on injection safety and waste management,
- to revise the number of surviving infants, and
- to provide realistic targets for vaccination

TOGO
Immunization services
- to explain how to achieve the targets for immunization

Injection safety (supplies)
- to provide more realistic vaccination coverage targets and revise tables 6.1-6.4

Annex C

Proposals recommended for conditional approval

AZERBAIJAN
Injection safety (supplies)
- to revise the plan of action including targets, indicators, timeline, more detailed activities and waste management
- to provide the 2002 Decree on national policy
- to calculate supplies for safety injection consistent with Table 4 of the application form as previously approved.

KYRGYZSTAN
Injection safety (supplies)
- to provide a national policy on injection safety (or a plan to develop one) and a detailed action plan on injection safety and waste management according to current GAVI guidelines.

MALAWI
Injection safety (funds and supplies)
- to provide a national policy on injection safety (or a plan to develop one) and an improved action plan on injection safety and waste management.

MALI

New and under-used vaccines (hepB)

- the ICC to discuss and endorse DTP3 coverage, in view of conflicting figures,
- if DTP3 coverage meets the eligibility criteria of >50%, then Mali will need to provide an introductory Plan in accordance with current GAVI guidelines.

Injection safety (funds)

- to provide a detailed plan of action for safe injection and waste management according to current GAVI guidelines.

MAURITANIA

Immunization services

- to revise the multi-year plan to reflect the findings and recommendations of the review of the EPI program, in keeping with current GAVI guidelines, and using DTP3 coverage in 2001 as the baseline.

NIGERIA

New and under-used vaccines (YF)

- to justify yellow fever coverage target (in relation to measles coverage target)
- to provide the cold chain rehabilitation plan and to update progress made on rehabilitation
- to revise the introduction plan of yellow fever vaccine in a manner that reflects the phased achievements of the cold chain rehabilitation.

TOGO

New and under-used vaccines (YF)

- to provide an introduction plan for yellow fever vaccine

Annex D

Proposals recommended for re-submission

ALBANIA

Injection safety (supplies)

In the resubmission, Albania needs to provide a detailed plan of action for injection safety and waste management according to current GAVI guidelines.

MAURITANIA

New and under-used vaccines (HepB and Hib)

In the resubmission, Mauritania needs to provide an introduction plan according to current GAVI guidelines.

MONGOLIA

New and under-used vaccines (hepB)

In the resubmission, Mongolia needs to provide an introduction plan according to current GAVI guidelines. If Mongolia wishes support for Hib vaccine there is also a need to establish and demonstrate the burden of disease.

RWANDA

Injection safety (funds)

In the resubmission, Rwanda needs to provide a detailed plan of action for injection safety and waste management according to current GAVI guidelines.

SOMALIA
Injection safety (funds)
In the resubmission, Somalia needs to provide a detailed plan of action for injection safety and waste management according to current GAVI guidelines.

Annex F

Independent Review Committee, Seventh Round

Dr. Sam Adjei,
Deputy Director-General, Ghana Health Services, Ghana

Dr. Caroline Akim,
Project Manager, Expanded Programme on Immunization, Ministry of Health, Tanzania (not participating in decision on Tanzania)

Dr. Abdallah Bchir
Professor, School of Medicine, Monastir, Tunisia
(not participating in decisions on Djibouti and Somalia)

Mr. Oleg Benesh
Epidemiologist, National Centre of Preventive Medicine, Moldova
(not participating in decisions on Albania, Azerbaijan, Bosnia & Herzegovina and Uzbekistan)

Dr. Peter Figuroea
Chief Epidemiology and AIDS
Jamaica (not participating in decision on Somalia)

Dr Stanislava Popova-Doytcheva
Scientist, WHO STC
Bulgaria (not participating in decisions on Albania and Bosnia & Herzegovina)

Mr. Robert Steinglass
Immunization Team Leader, BASICS, USA
(not participating in decisions on Congo DR, Mali and Nigeria)

Dr. Viroj Tangcharoensathien (Chairperson)
Health Systems Research Institute, Thailand

Estimated five-year commitment in US$ to 60 countries *(June 2002)*

PENDING OUTCOME OF BOARD DECISIONS ON 7TH ROUND REVIEW

Numbers in italics indicate that clarifications are needed from country

Country	Surviving Infants	Baseline DTP3 coverage	Immunization Services (5yrs)	Injection Safety (3yrs)	5 years Vaccine Support	Vaccine presentation	Other support	Total 5yr commitment
1 Afghanistan	901,328	31%	7,255,000					7,255,000
2 Albania	60,000	97%		R	465,000	(A) hepB, (C) Hib	100,000	565,000
3 Armenia	36,118	63%	30,000	***61,000***	397,000	HepB	100,000	588,000
4 Azerbaijan	106,250	72%	266,000	C	711,000	HepB	100,000	1,077,000
5 Bangladesh	3,662,915	67%	26,935,000		47,254,000	hepB	100,000	74,289,000
6 Benin	240,517	61%			2,763,000	hepB & YF	100,000	2,863,000
7 Bhutan	15,902	88%			349,000	DTP-hepB 2003	100,000	449,000
8 Bosnia & Herzegovina	39,633	85%		R	423,000	hepB	100,000	523,000
9 Burkina Faso	456,000	42%	4,410,000	C	R			4,410,000
10 Burundi	261,669	57%	2,662,000	414,000	14,204,000	DTP-hepB+Hib 2003	100,000	17,380,000
11 Cambodia	480,000	65%	3,012,000	727,000	4,623,000	DTP-hepB	100,000	8,462,000
12 Cameroon	457,000	48%	5,556,000		C			5,556,000
13 China	19,107,468	93%		16,008,000	21,789,000	hepB	800,000	38,597,000
14 Comoros	21,376	67%	165,000	***40,000***	***179,000***	hepB	100,000	484,000
15 Congo DRC	2,425,327	31%	31,298,000	***3,766,000***	9,858,000	YF	100,000	45,022,000
16 Côte d'Ivoire	468,276	56%	3,859,000		6,464,000	DTP-hepB	100,000	10,423,000
17 Djibouti	24,061	46%	289,000	***35,000***				324,000
18 Eritrea	97,846	56%	30,000		1,768,000	DTP-hepB	100,000	2,798,000
19 Ethiopia	2,532,519	45%	19,130,000	3,565,000				22,695,000
20 Gambia	51,840	74%	489,000	***150,000***	3,167,000	hepB & DTP-Hib	100,000	3,906,000
21 Georgia	50,776	61%	341,000	68,000	529,000	hepB	100,000	1,038,000

Country	Surviving Infants	Baseline DTP3 coverage	Immunization Services (5yrs)	Injection Safety (3yrs)	5 years Vaccine Support	Vaccine presentation	Other support	Total 5yr commitment
22 Ghana	779,359	73%	3,359,000		37,914,000	DTP-hepB+Hib&YF	100,000	41,373,000
23 Guinea	288,702	57%	***2,585,000***	R	944,000	YF	100,000	3,629,000
24 Guyana	20,414	83%			1,127,000	DTP-hepB+Hib	100,000	1,227,000
25 Haiti	262,500	59%	2,171,000	R	R			2,171,000
26 India	24,460,000	55%			4,138,000	hepB(2002-03) [1]	100,000	4,238,000
27 Indonesia	4,570,828	90%		R	16,228,000	hepBUniject	100,000	16,100,000
28 Kenya	1,285,300	64%	11,113,000		69,783,000	DTP-hepB+Hib&YF	100,000	80,996,000
29 Korea DPR	441,096	62%	3,315,000	835,000	***2,799,000***	hepB	100,000	7,049,000
30 Kyrgyz Rep	98,637	99%		C	10,876,000	hepB,Hib2003	100,000	10,976,000
31 Lao PDR	180,000	56%	2,251,000	251,000	3,898,000	DTP-hepB	100,000	6,500,000
32 Lesotho	64,324	56%	517,000	***114,000***	475,000	hepB	100,000	1,206,000
33 Liberia	147,540	23%	2,804,000		499,000	YF	100,000	3,403,000
34 Madagascar	588,315	57%	4,277,000		11,639,000	DTP-hepB	100,000	16,016,000
35 Malawi	393,539	83%		C	28,668,000	DTP-hepB+Hib	100,000	28,768,000
36 Mali	409,000	48%	4,100,000	C	1,515,000	(C)DTP-hepB&(A)YF	100,000	5,715,000
37 Moldova	41,100	98%		R	451,000	(A)hepB&(R)Hib	100,000	551,000
38 Mozambique	691,967	73%	3,291,000	R	12,088,000	DTP-hepB	100,000	15,479,000
39 Myanmar	1,271,239	70%	7,902,000	2,012,000	13,635,000	hepB	100,000	23,649,000
40 Nepal	727,764	72%	4,494,000	722,000	12,139,000	***DTP-hepB***	100,000	17,455,000
41 Niger	506,284	23%	5,027,000	R				5,027,000
42 Nigeria	4,608,972	38%	53,020,000		C			53,020,000
43 Pakistan	4,787,000	58%	33,900,000	***10,088,000***	28,273,000	hepB	100,000	72,361,000
44 Rwanda	326,886	57%	4,108,000	R	20,254,000	DTP-hepB+Hib	100,000	24,462,000
45 Sao Tome	5,651	79%	30,000		R			30,000
46 Senegal	418,091	52%	3,983,000	949,000	R			4,932,000
47 Sierra Leone	198,918	23%	2,353,000	***379,000***	C			2,732,000
48 Somalia	270,769	30%	3,399,000	R				3,399,000
49 Sri Lanka	322,366	99%		606,000	2,252,000	hepB2003	100,000	2,958,000

Country	Surviving Infants	Baseline DTP3 coverage	Immunization Services (5yrs)	Injection Safety (3yrs)	5 years Vaccine Support	Vaccine presentation	Other support	Total 5yr commitment
50 Sudan	1,029,179	64%	8,969,000	2,141,000				11,110,000
51 Tajikistan	155,283	65%	1,138,000	R	1,005,000	hepB	100,000	2,243,000
52 Tanzania	1,279,401	74%	6,499,000		23,747,000	DTP-hepB	100,000	30,346,000
53 Togo	84,383	43%	***1,945,000***	***389,000***	C			2,334,000
54 Turkmenistan	94,818	96%		R	879,000	hepB	100,000	979,000
55 Uganda	968,155	54%	9,343,000	***1,470,000***	50,518,000	DTP-hepB+Hib2002	100,000	61,431,000
56 Uzbekistan	533,484	95%		904,000	4,224,000	hepB	100,000	5,228,000
57 Viet Nam	1,598,518	93%			13,524,000	hepB	100,000	13,624,000
58 Yemen	592,436	74%	4,342,000	***1,009,000***	34,384,000	DTP-hepB+Hib	100,000	39,835,000
59 Zambia	427,524	75%	2,959,000	***781,000***	24,124,000	DTP-hepB+Hib	100,000	27,964,000
60 Zimbabwe	380,394	78%	3,220,000		C			3,220,000
TOTAL	**86,806,957**		**303,041,000**	**47,484,000**	**546,943,000**		**5,200,000**	**902,440,000**

Key: **A** = approved **C** = conditional approval **R** = re-submission = Did not apply

[1] Current financial commitment for India is limited to two years, while waiting for a second proposal for additional three years of support.

Table 5. Eligible countries that do not currently qualify for support

Country		Comment
Bolivia		Has not applied and do not intend to apply. Current government and partner financing of hepB and Hib vaccines
Cuba		Has applied and received not approved. Current government financing of hepB and Hib vaccines
Honduras		Has applied and received not approved. Current government financing of hepB and Hib vaccines.
Nicaragua		Has not applied and do not intend to apply. Current government financing of hepB and Hib vaccines

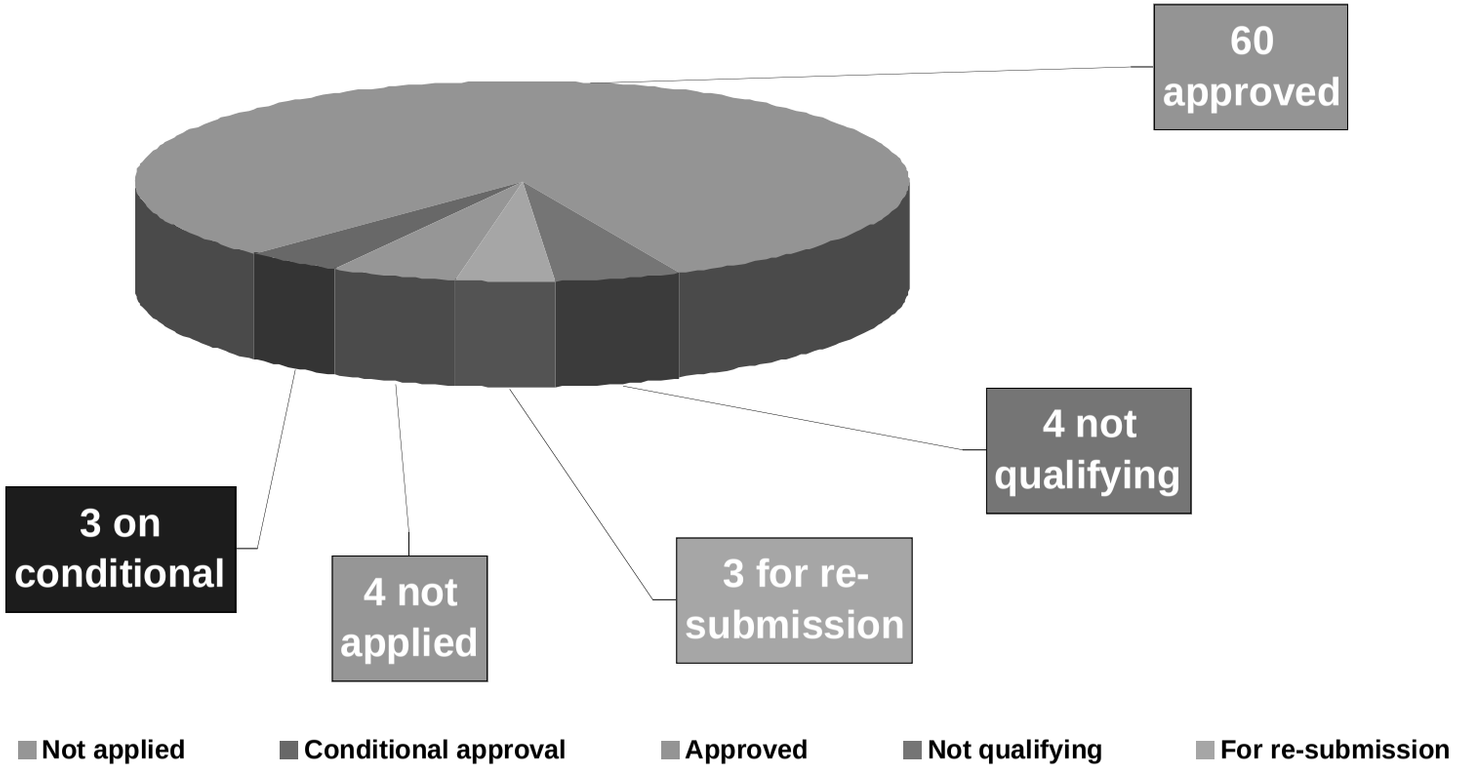
The GAVI Board has decided that in no case will the Vaccine Fund replace government funds.

Table 6. Countries not yet approved for support

Country	Status	Comment
Central African Republic	Re-submission for immunization services	Technical assistance requested. Have indicated plans to apply — no date confirmed
Chad	Re-submission for immunization services	Technical assistance requested. Tried to re-submit in May 2002 but did not manage in time
Guinea-Bissau	Conditional for immunization services	
Mauritania	Conditional for immunization services re-submission for hepB approval for injection safety	Approval for injection safety only takes effect upon approval for other type of support
Mongolia	Re-submission for hepB and Hib	Have indicated intention to apply also for injection safety
Ukraine	Conditional for hepB	Response is expected shortly and will be reviewed without delay
Angola	Not yet applied	Current priority is to focus on polio. Has indicated plans to apply early 2003
Congo	Not yet applied	Had indicated plans to apply in May 2002
Papua New Guinea	Not yet applied	Have shown interest to apply in early 2003
Solomon Islands	Not yet applied	Interest expressed by delegation to WHA 2002

Figure 1 : Status of countries* requesting support

**** 74 eligible countries with GNP < 1***



NGO Representative to the GAVI Board

Background

The Children's Vaccine Program at PATH has been the first NGO representative to the GAVI Board. CVP at PATH's term ends this fall. As the NGO representative, CVP at PATH has contacted you about the Global Alliance for Vaccines and Immunizations (GAVI) and the important role that NGOs have in providing lifesaving vaccines to the poorest members of society. We have organized several international meetings to bring NGOs interested in immunization together and to strategize for a more synergistic involvement of NGOs in immunization and GAVI related activities. Through this process, we have received an incredible amount of feedback and support from the NGO community and have worked hard to convey your ideas, concerns and enthusiasm to the GAVI Board. Because of this, we now have a better idea of the next steps needed to progress toward these goals as well as the necessary momentum to pursue this challenging task.

CVP at PATH's term as your representative to the GAVI board ends in November 2002. Therefore, we are seeking a replacement for this position; an NGO that is dedicated to immunization and the GAVI mission, and to serve as the NGO Representative to the GAVI Board for the next two year term, November 2002 until November 2004.

Representatives to the GAVI Board

The current representatives and their respective term periods are listed below:

- The Bill and Melinda Gates Foundation
- UNICEF
- WHO
- The World Bank Group
- Developing Country Government- Mali, 2001-2002; India, 2002-2003
- Developed Country Governments-Norway, 2001-2002; United Kingdom, 2001-2003; United States-2002-2003
- Foundations—UN Foundation 2001-2003
- Non-governmental Organization-The Children's Vaccine Program at PATH, 2000-2002
- Research and Technical Health Institutions- Institut Pasteur, 2001-2003; CDC-2001-2003
- Vaccine Industry from Developed Country- Wyeth-Ayerst Global Pharmaceuticals, 2001-2002;
- Vaccine Industry from Developing Country- Center for Genetic Engineering and Biotechnology (CIGB), Cuba, 2001-2002

Terms of Reference

The position of NGO representative to the GAVI Board is a volunteer position, and the NGO will not be paid by GAVI for participation. The GAVI Board meets two times a year. The Board will provide travel and lodging expenses for the NGO representative to participate in these meetings.

Responsibilities of NGO Representative

1. Act as a liaison between GAVI and NGOs. Represent the views and concerns of each side while working to improve immunization and NGO activity in this field.
2. Work closely with the proposed GAVI NGO Forum (see Attachment A) to represent the concerns of NGOs to the GAVI Board.
3. Work to strengthen NGO participation in Regional Working Groups (RWGs) and Inter-agency Coordinating Committees (ICCs).
4. Expand NGO activities to include the participation of local, in-country NGOs.
5. Identify and assist in the development of tools to assist NGOs in immunization and GAVI related activities.
6. Work to facilitate greater cooperation and understanding between NGOs and governments.
7. Assist interested NGOs in different regions (Japan, Australia, North America and Europe) in targeted activities as necessary in the given economic, political and social climates.
8. Maintain contact with over 150 international PVOs/NGOs identified by CVP at PATH to keep them informed and engaged in NGO activities relating to immunization and GAVI.

Qualifications and Selection Criteria

Based on the work that has been done to engage NGOs in GAVI and immunization, there are several activities that the new NGO representative will be expected to continue. These activities require that the NGO possess certain qualities and meet specific criteria. In addition to these activities already identified, the NGO representative will be expected to use its own unique talents and expertise to enhance NGO representation on the GAVI Board. Qualifications and selection criteria for the NGO representative include:

1. Strong history and record in the field of child health and immunization.
2. Demonstrated partnerships with other organizations on both the international and local level. Collaboration-building ability and strong ability to work well with numerous partners.
3. Ability to represent concerns, issues and ideas of NGOs to the GAVI Board.
4. Ability to represent concerns, issues and ideas of the GAVI Board to the NGO community.
5. Sensitive to the concerns of NGOs in the field. A willingness to include all NGOs regardless of their mission (i.e. political or religious beliefs).
6. Diplomacy skills.
7. Ability to work with large number of partners from different sectors: government, pharmaceuticals, foundations, bilaterals/multilaterals, research and technical institutions.
8. Demonstrated record of networking and outreach with NGOs on all levels.
9. Intent to dedicate at least one full time staff member to NGO activities.
10. Willingness and ability to raise funds for NGO activities in immunization.

Application Process

In addition to the qualifications and selection criteria outlined above, each applicant must submit an application, which can be found on the next page. Applications must be returned to Kim Kelly (CVP at PATH) NO LATER than Wednesday, June 19th, 2002. Applications will be reviewed by CVP at PATH and a recommendation to the GAVI Board will be made. The GAVI Board will announce its decision later in the summer, and the new NGO Representative will assume its responsibilities starting in November, 2002.

APPLICATION FOR GAVI NGO REPRESENTATIVE

Name of NGO:

Person Filling out Application:

Title:

Contact Information:

Please answer the following questions. Answers should be no longer than one page each, type written.

QUESTIONS:

1. How would your organization reach out to represent indigenous NGOs based and working in developing countries?
2. How much budget will your organization commit to represent NGOs to the GAVI Board and How many full time equivalent staff will be assigned to this task?
3. How would you carry forward the development of the GAVI NGO Forum (see Attachment A)?
4. What additional activities or approaches can you foresee undertaking during your period in office?
5. Describe the special strengths your organization will bring to GAVI and any similar partnerships and collaborations you are currently involved in with other NGOs or other organizations.

Fax, send or email you application to:

The Children's Vaccine Program at PATH

C/o Kim Kelly

1455 NW Leary St.

Seattle, WA 98107

Tel: 206-285-3500 ext. 2449

Fax: 206285-6619

Email: kkelly@path.org

Attachment A

Proposed GAVI NGO Forum

One of the strongest recommendations to come from the CVP-lead meetings of NGOs is the need for a GAVI NGO Forum. We have designed this forum, and expect the new NGO Representative to further its development.

The function of this Forum is to assist the NGO representative in its efforts to:

- Engage and represent the interests and concerns of the NGO community to the GAVI partners.
- Promote more active involvement of NGOs in GAVI, especially through their respective Regional Working Groups.
- To take the decisions of the GAVI Board back to their more local constituencies.

This group should have twelve members and two co-chairs. One international NGO will be selected from each of Africa, Eastern Mediterranean (including N. Africa), North America, S.E. Asia, Europe and the Western Pacific. Each of these international NGOs will be paired with an indigenous NGO from a GAVI country in each of the six regions. Thus, the twelve members will be half international NGOs and half NGOs from developing countries.

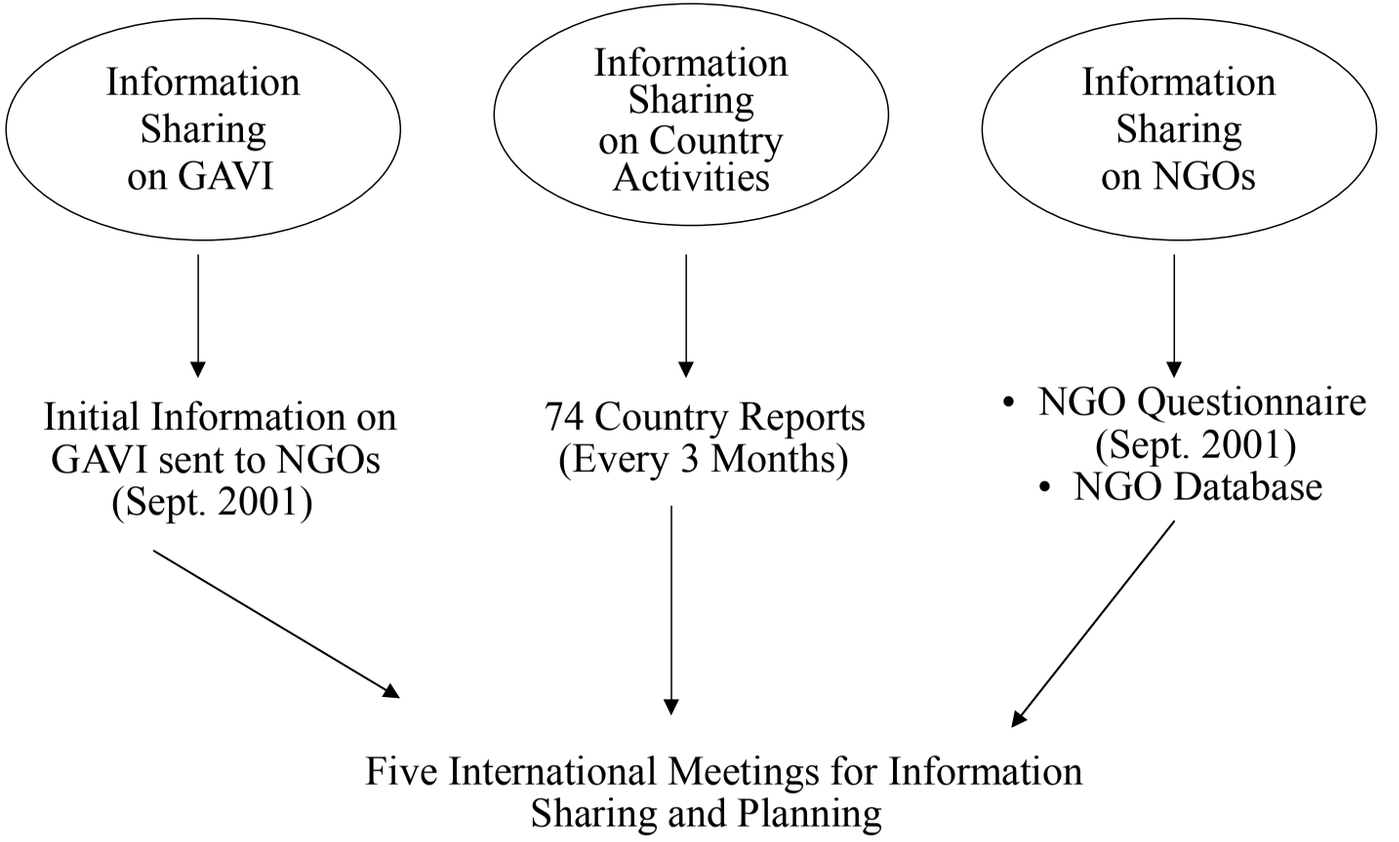
The representative to the GAVI Board will chair the group. For continuity and to maintain the momentum of the work, the co-chair will be the previous representative to the GAVI Board (CVP at PATH for the coming period).

The normal term of office on this group will be two years. After two years, when a new NGO will be selected to represent NGOs on the GAVI Board representative, the previous representative will be made co-chair.

For continuity at the outset all NGO members of the Forum will serve for two years. Following that, one-third (four NGOs) will be replaced by four new NGOs following the same rules as above. The procedure will be repeated every year.

The group will normally meet three times each year with one meeting in each of the host countries of the indigenous NGO. In the event that an NGO cannot attend any of the meetings, substitutes will be accepted.

CVPs Strategy to Increase NGOs Involvement in GAVI and Immunization Activities



Information Note to June GAVI Board Meeting

June 1, 2002

Proposal for November Board Agenda Item:

WHO/UNICEF Human Resources for Immunization

Introduction:

A paper entitled "Alignment of GAVI Objectives and Accelerated Disease Control (ADC) Initiatives", was presented at the 5th GAVI Board Meeting (London, June 21-22, 2001). The analysis was well received and a number of Board decisions were taken (see Annex 1).

This note provides an update on the activities that WHO and UNICEF are undertaking in response to the Board decision 8.4. Specifically, it summarizes the preparation of a joint human resources plan for immunization and proposes that this plan be discussed in detail at the November 2002 GAVI Board meeting.

Background:

At the request of the GAVI Board, a consultation with immunization stakeholders was undertaken during 2001 to investigate the synergy between GAVI objectives and the accelerated disease control (ADC) initiatives (polio, measles, maternal and neonatal tetanus (MNT), vitamin A).

There was stakeholder consensus that one of the greatest assets of the ADC initiatives was the infrastructure that had been established, particularly that of polio eradication. The importance of retaining this infrastructure for the benefit of all immunization objectives was strongly voiced. The human resources infrastructure was identified as the most important to GAVI goals and most fragile in terms of financing beyond 2003.

The GAVI Board agreed with the analysis, noting the need to better understand the health systems strengthening and capacity building implications of the human resources infrastructure. Accordingly, the Board issued the following decision:

8.4 recognized the importance of a human resources infrastructure for immunization and requested that UNICEF and WHO together develop for consideration by the Board an immunization human resources plan (i.e. minimum staff by country) and costing based on the current human resources, including those that are ADC-funded.

Preparation for November Board Meeting:

WHO and UNICEF have undertaken a program of work to establish the rationale for, and cost of, a long-term human resource plan for immunization, which builds on the ADC experiences and opportunities.

1. Immunization Roles and Responsibilities: WHO and UNICEF have established their respective immunization roles at the global, regional and country levels as the basis for long-term human resource planning. A summary table identifying each agency's responsibility by immunization activity is currently being prepared.

2. Survey of WHO Polio-funded Staff: WHO has conducted a survey of the 1,015 polio-funded technical staff who were stationed around the world as of October, 2001 to: (i) evaluate skills and document the "non-polio immunization" activities that polio-funded staff are engaged and (ii) assess the risk to GAVI objectives should these staff be phased out after polio-free certification. Preliminary data found that 91% of international, and 100% of national, polio-funded staff were involved in "other non-polio" immunization activities, which constituted as much as 44% of their time. Further analysis is ongoing.

3. Survey of UNICEF Immunization Plus-Funded Staff: UNICEF has conducted a global survey to assess the number and type of staff working on Immunization Plus and staff time spent on Immunization Plus related issues. Initial analysis of data shows: (i) 135 staff are funded through Immunization Plus funds. This comprises 51 international staff, 59 national officers and 25 support staff, distributed across 43 Country Offices, 5 UNICEF Regional Offices and Headquarters; (ii) several hundred additional staff at field level are involved in Immunization Plus activities as part of their broader responsibilities.

4. Analysis of Current and Future Human Resources: WHO and UNICEF have compiled data on their existing health and immunization staff and their future human resource requirements for immunization through 2006. Detailed information on staff costs has also been collected. Both agencies are in the process of creating human resource databases to enable the further analysis of staffing patterns by key indicators such as health systems performance, economic status, and immunization coverage. WHO and UNICEF are working with WHO's Health Systems staff to ensure that the strengthening of national health systems drives this analysis.

By September 2002, this program of work will result in a WHO/UNICEF Human Resources Plan for Immunization that provides the following:

- Number and type of staff required by country and region through 2006;
- An analysis of how staffing patterns correlate to health system performance;
- A costing of the human resources requirements for immunization through 2006.

Next GAVI Board Meeting:

Given the importance of human resources to achieving GAVI goals, WHO and UNICEF propose a detailed briefing on this work to the GAVI Board at their November 2002 meeting.

Annex 1

GAVI Board Decisions re: Alignment with accelerated disease control initiatives (21-22 June 2001, London)

8.1 approved the establishment of a new objective and milestone:

Objective: To support the national and international accelerated disease control targets for vaccine-preventable diseases.

Milestone: By 2005, the world will be certified polio-free.

and requested that the Working Group consult with partners to identify appropriate disease outcome indicators (polio, measles, MNT and vitamin A);

8.2 approved the proposed direction to work towards integration of all immunization initiatives by placing renewed emphasis on GAVI's first objective to "improve access to sustainable immunization services".

In practice, this will mean that as soon as possible and no later than 2003, all countries' annual work plans, and subsequent multiyear plans, reflect an approach that incorporates routine services, accelerated disease control, introduction of new vaccines, and vitamin A supplementation within the context of the health system. Targets in the national plans would need to match available resources. For this approach to work, it would have to be technically and financially supported by all partners at all levels, especially through their participation in national and regional Inter-Agency Coordinating Committees (ICC's) and regional working groups;

agreed to consider a revision of all GAVI objectives, milestones, and indicators to support the full operationalization of this strategic direction, at an appropriate time in the near future.

requested that, over the next few months, the Working Group further elaborate on the framework for this strategy and its implications for the national workplans and ICCs, and regional and global activities;

8.3 approved a revision of objective #2§ as follows: "Expand the use of all existing safe and cost-effective vaccines, and promote delivery of other appropriate interventions at immunization contacts";

8.4 recognized the importance of a human resources infrastructure for immunization and requested that UNICEF and WHO together develop for consideration by the Board an immunization human resources plan (i.e. minimum staff by country) and costing based on the current human resources, including those that are ADC-funded.

/Current GAVI objective #2 is: Expand the use of all existing safe and cost-effective vaccines

Update on Haemophilus influenzae type b (Hib) conjugate vaccine introduction and Hib disease burden in Asia

Current status of Hib introduction globally

Global demand for Hib vaccine has increased steadily since 1997 – in late 1996, 26 countries had introduced Hib conjugate vaccines into their routine national immunization program, while by May, 2002, over 90 countries had introduced the vaccine (see figure below).

Demand has been slowest in the poorest countries. In 2001, only 5% of countries with a GNP of less than US$1000 had introduced the vaccine, compared with 75% of countries with a GNP greater than US$12 000. Since then, the Vaccine Fund has approved funding for Hib vaccine for 11 countries (as of March 2002).

Hib in Asia

As of June 2002, Hib vaccine was routinely being used in several Pacific Island countries but no mainland Asian country had introduced Hib vaccine as a routine infant immunization. Until recently, the available data were limited, of questionable quality, and showed relatively low incidence rates.

Recently, 4 studies of the incidence of Hib meningitis were conducted in Asia-Pacific countries: South Korea, China, Vietnam, and Thailand. Preliminary reports of these studies (including 3 coordinated by the International Vaccine Institute, and one in which CVP/PATH collaborated) showed that while Hib was the most common cause of bacterial meningitis in children less than 5 years old, the incidence of all causes of bacterial meningitis was lower than expected, with rates of Hib meningitis between 3 and 10 cases/100,000 children – markedly lower than rates observed from the US, Europe, Africa, and Latin America (range: 15-50/100,000).

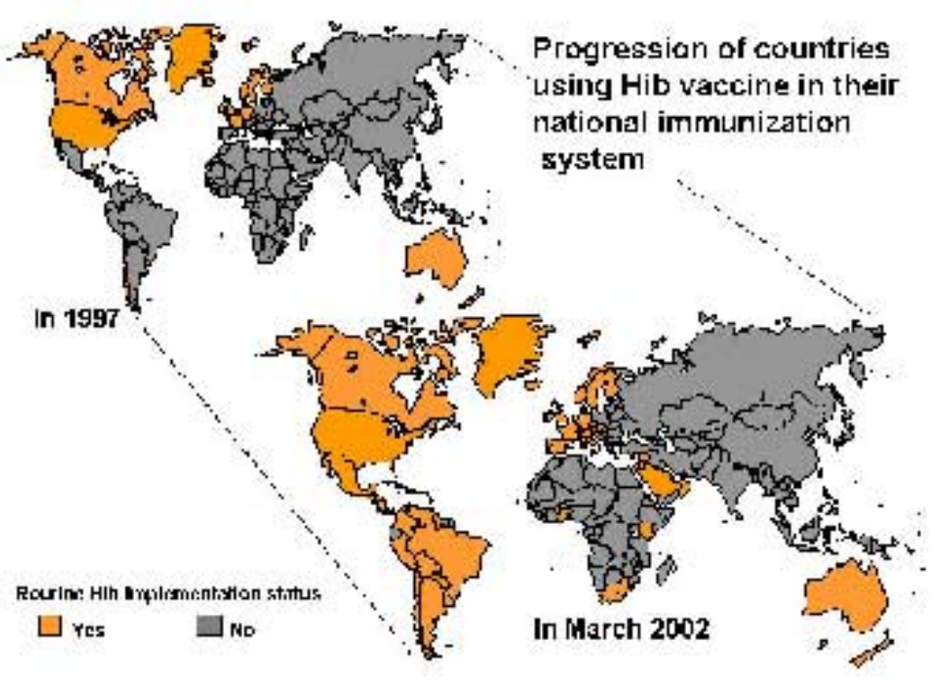
These studies represent a major improvement over previous studies but these studies are not representative of all of Asia and do not address the issue of Hib pneumonia burden. Asia is a large and heterogeneous region. These studies were conducted in areas of Asia with low childhood mortality rates and high access to care including antibiotics. No comparable studies have been done in south Asia (e.g., India). Studies from Papua New Guinea, Pacific Island countries, and the Philippines show a high incidence of Hib meningitis, reaffirming the importance of not treating "Asia" as a single entity. Ongoing trials of Hib vaccine in rural Lombok, Indonesia, and in urban Dhaka, Bangladesh should provide valuable data on the burden of Hib pneumonia by the end of 2003.

Nevertheless, assuming there is a relatively lower rate of Hib disease in Asia, what are the implications for global, or regional policies? The current WHO recommendation provides for exactly this scenario, by recommending a decision be made based on public health priority (disease burden) and national capacity to support the program. The goal of GAVI partners including WHO in this area is, and should continue to be, provision of technical assistance to countries to facilitate rational decision-making.

A related question is whether a specific Hib meningitis incidence be set, below which the Vaccine Fund would not support vaccine purchase. Experience with GAVI applications suggests that irrational requests for Hib vaccine are uncommon. In general, countries with low perceived Hib disease burden have not requested Vaccine Fund support for Hib vaccine.

Therefore, in line with the general GAVI concept of responding to expressed country needs, it may be more appropriate for GAVI partners to enhance demand estimating procedures, and base allocation on improved demand estimates. Continued work with countries to improve availability and use of burden and cost effectiveness data for decision-making on new vaccine introduction will build country capacity in this critical area.

The Board will be presented with more information on Hib disease burden in Asia as it becomes available.



Update of MVP activities
GAVI Board Meeting
Paris, June 2002

Over the last 100 years, meningitis epidemics have caused enormous suffering in Sub-Saharan Africa, with an at-risk population of over 250 million. The Meningitis Vaccine Project (MVP), a partnership between the Program for Appropriate Technology in Health (PATH) and the World Health Organization (WHO) was created through core funding from the Bill & Melinda Gates Foundation and has the following goal:

> **"To eliminate epidemic meningitis as a public health problem in Sub-Saharan Africa through the development, testing, introduction and widespread use of conjugate meningococcal vaccines."**

The project is working with two vaccines. One is a heptavalent EPI vaccine (DTPw, HepB, Hib, mening A/C) with Groups A/C glycoconjugate antigens that is being developed by Glaxo-Smith-Kline (GSK). MVP's role in this product development is to support clinical trials of this polyvalent vaccine in Africa.

The second MVP vaccine is a Group A conjugate vaccine for use in mass immunization campaigns and as an EPI antigen. This vaccine has no commercial market outside of Africa and would not be developed without the support of the MVP. Debate about the composition of this mass vaccination campaign vaccine has consumed an important part of the project's work over the last two months. Until this year Group A meningococci have accounted for about 85 percent of all cases of epidemic meningitis in Africa. In 2001 studies by the Pasteur Institute indicated that a sizable fraction of isolates from Burkina Faso were Group W135. This year, a sharp outbreak of Group W135 disease occurred in Burkina Faso and MVP through its investment in enhanced meningitis surveillance helped document this outbreak. It is not possible to predict what will happen to Group W135 next year but a review of meningococcal isolates in Africa by WHO showed that, except for Burkina Faso, Group A continues to be, by far, the principal cause of epidemic meningitis in Sub-Saharan Africa. After thorough discussion MVP has chosen to develop a monovalent conjugate A product because this vaccine would be the simplest to develop, would have the shortest time to market, would have a major public health impact and could be produced and sold at a price low enough to be sustainable.

When MVP was created it was thought that a big pharma company would produce this vaccine but after extensive negotiations large vaccine manufacturers have chosen not to continue as possible partners with the MVP. One important reason was the inability to protect big pharma from "all risk". Hence, since January 2002 MVP has devoted considerable effort exploring alternative strategies for the production of a monovalent A vaccine. Three critical components were identified in this new model: (1) sources of high quality Group A polysaccharide (PS) and tetanus toxoid (TT); (2) development and transfer of a conjugation method and (3) identification of a commercial manufacturer capable of conjugation, blending, packaging and fill/finish/lyophilization.

A contract manufacturer has agreed to develop the technology for the production Group A PS, including the provision of appropriate seed banks and quality assurance and monitoring protocols as well as furnish the project with vaccine grade A PS. The company is highly regarded and received an excellent evaluation from MVP consultants. Several sources of highly purified TT have been identified and these manufacturers can easily supply the

project's needs. In addition, a company with a major interest in pediatric vaccines has been identified to develop and transfer conjugation techniques.

After extensive due diligence that included in-depth technical, managerial and financial reviews a developing country manufacturer has been selected to be MVP's manufacturing partner. The company has a deep technical and managerial base as well as facilities that could accept a conjugate meningitis A project relatively easily. The company wants to broaden its experience with conjugate vaccines and views a partnership with MVP as a sound business decision. The vaccine product will be licensed in the country of manufacture and will meet European regulatory standards. The goal of the project is to have initial large demonstration projects in 2006 and beginning in 2007 25 million doses of vaccine available annually for 10 years at a price of $US 0.40 per dose.

The major change in program direction from a large contract with a big pharma company to a network of partners will substantially increase the management demands for MVP at least until the vaccine is licensed. A new management and staffing plan is being developed at MVP that will begin with a detailed product development plan that is expected to be finished by September of this year. New staff will be required in business development, technology transfer, clinical trials and regulatory issues. The project's work must also be seamlessly organized with country regulatory standards so that introduction of vaccine will be smooth. Lastly, and perhaps most importantly, attention also needs to be paid to current African immunization programs and their difficulties with access, cold chain etc. The public health impact of a conjugate meningococcal vaccine will depend upon the quality of the infrastructure. As the project matures beyond product development increased investment at the regional and country level will be necessary.

Participants List

Board Members	
Chair	1. **Ms. Carol Bellamy**, Executive Director, UNICEF
Host & Research and Development Board member	2. **Prof. Philippe Kourilsky**, Director General, Institut Pasteur, Paris
Bill & Melinda Gates Foundation	3. **Mr. Richard Klausner**, Executive Director of Global Health, Bill & Melinda Gates Foundation, U.S.A.
Governments: Developing countries	4. **Dr. C. P. Thakur**, Minister of Health and Family Welfare, India
Governments: Industrialized countries	5. **Dr. Sigrun Mogedal**, Senior Adviser, NORAD, Norway
	6. **Dr. Julian Lob-Levyt**, Chief, Health & Population Department, Department for International Development (DFID), U.K.
	7. **Dr. E. Anne Peterson**, Assistant Administrator for the Bureau for Global Health, U.S. Agency for International Development (USAID), U.S.A.
NGO	8. **Dr. Mark Kane**, Director, Children's Vaccine Program at PATH, U.S.A.
Technical Health Institute	9. **Dr. David W. Fleming**, Deputy Director for Science and Public Health, Centers for Disease Control and Prevention (CDC), U.S.A.
The World Bank	10. **Mr. James Christopher Lovelace**, Director, Health Nutrition and Population, The World Bank, U.S.A.
UNICEF	11. **Dr. Paul Fife**, Health Adviser, UNICEF
Vaccine industry: Developing country	12. **Dr. Luis Saturnino Herrera Martinez**, Director-General, CIGB, Cuba
World Health Organization	13. **Dr. Daniel Tarantola**, Special Adviser to the Director-General of WHO and Director, Vaccines and Biologicals, WHO
United Nations Foundation	14. **Dr. May Yacoob**, Program Director, Population and Health, United Nations Foundation
The Vaccine Fund	15. **Mr. Jacques-François Martin**, President, The Vaccine Fund, Lyon
GAVI Working Group	16. **Ms. Amie Batson**, Senior Health Specialist, Health, Nutrition and Population Unit, The World Bank 17. **Dr. Tore Godal**, Executive Secretary, GAVI Secretariat 18. **Dr. Steve Landry**, Technical Advisor, Child Survival, Population, Health and Nutrition, USAID, U.S.A. 19. **Ms. Heidi Larson**, Senior Communication Adviser, UNICEF 20. **Dr. Mike Levine**, Director, Center for Vaccine Development, University of Maryland School of Medicine, U.S.A. 21. **Mr. Fabian McKinnon**, Executive Vice President, Operations, The Vaccine Fund, Lyon

GAVI Working Group	22. **Mr. Walter Vandermissen**, Government Affairs Director, GlaxoSmithKline Biologicals, S.A., Belgium 23. **Mr. Michel Zaffran**, Program Manager,Vaccines & Biologicals, WHO
Reviewers	24. **Ms. Karen Caines**, Consultant, Department for International Development (DFID), U.K. 25. **Mr. Hatib Njie**, Consultant, Department for International Development (DFID), U.K.
Observers	26. **Dr. Abdallah Bchir**, Member of the GAVI Independent Review Committee 27. **Dr. Yves Bergevin**, Chief of Health, UNICEF 28. **Ms. Michele Boccoz**, Executive Vice President, Institut Pasteur, Paris 29. **Ms. Phyllida Brown**, GAVI consultant, Editor Immunization Focus 30. **Dr. Brent Burkholder**, Regional Adviser Vaccines and Biologicals, WHO Regional Office for South-East Asia 31. **Dr. Stephen L. Cochi**, Director, Global Immunization Division, National Immunization Program, CDC, U.S.A. 32. **Mr. Michael Conway**, McKinsey & Co. 33. **Ms. Liv Elden**, Senior Executive Officer, Ministry of Foreign Affairs, Norway 34. **Dr. Christopher Elias**, Director, PATH, U.S.A. 35. **Ms. Jacqueline Keith**, Assist.Vice President, Wyeth-Ayerst Labs, U.S.A. 36. **Ms. Marion Kelly**, Specialist in Child Health, DFID, U.K. 37. **Dr. Marie-Paule Kieny**, Director, Initiative for Vaccine Research, WHO 38. **Mr. Steve Jarrett**, Deputy Director, UNICEF Supply Division 39. **Dr. Rune Lea**, Senior Adviser, NORAD, Norway 40. **Ms. Ruth Levine**, The World Bank Group, GAVI Financing Task Force 41. **Mr. Patrick Lydon**, WHO, GAVI Financing Task Force 42. **Dr. Masami Sakoi**, Deputy Director, Ministry of Health and Welfare, Government of Japan 43. **Prof. Tilek Meimanaliev**, First Deputy Minister of Health, Kyrgyzstan 44. **Dr. Bernard Morinière**, Senior Medical Epidemiologist, IFRC, Geneva 45. **Ms. Violaine Mitchell**, Co-ordinator, GAVI Financing Task Force 46. **Mr. J.V.R. Prasda Rao**, Secretary, Family Welfare, Government of India 47. **Mr. Sanjeev Ranjan**, Private Secretary to Minister of Health, India 48. **Mr. Raj Shah**, Chief Policy Analyst, Senior Economist, Bill and Melinda Gates Foundation, U.S.A. 49. **Mr. Osamu Tasaka**, Director, International Affairs Planning Office, Ministry of Health, Labour and Welfare, Japan 50. **Ms. Veronica Walford**, Consultant, DFID, U.K. 51. **Mr. Piers Whitehead**, Vice President, Mercer Management, U.K. 52. **Dr. Marijke Wijnroks**, Health Adviser, Ministry of Foreign Affairs, Netherlands
GAVI Secretariat	53. **Ms. Lisa Jacobs**, Communication Officer 54. **Ms. Corina Luputiu**, Senior Secretary 55. **Mr. Bo Stenson**, Principal Officer

Annex E: List of Presentations

Presentations may be viewed and downloaded from the GAVI website: www.vaccinealliance.org

Update on Immunization and GAVI Activities in Asia

Dr. Brent Burkholder, Regional Adviser Vaccines and Biologicals, WHO Regional Office for South-East Asia

External Review of Functions and Interactions of the GAVI Working Group, Secretariat, and Board

Ms. Karen Caines, Consultant, Department for International Development (DFID), U.K.

Mr. Hatib Njie, Consultant, Department for International Development (DFID), U.K.

Lessons learned: New procurement strategies for vaccines

Mr. Piers Whitehead, Vice President, Mercer Management, U.K.

Task Force on Country Coordination: Proposed Evolution

Mr. Michel Zaffran, Program Manager, Vaccines & Biologicals, WHO

Immunization Financing Database: Review of Progress

Ms. Ruth Levine, The World Bank Group, GAVI Financing Task Force

Mr. Patrick Lydon, WHO, GAVI Financing Task Force

Supporting National Efforts to Improve Financial Sustainability of Immunization Programs

Dr. Steve Landry, Technical Advisor, Child Survival, Population, Health and Nutrition, USAID, U.S.A.

Accelerating Pneumococcal and Rotavirus vaccine to developing countries

Mr. Michael Conway, McKinsey & Co.

Outline of the guidelines developed by the R&D Task Force for opening "Window 3" of The Vaccine Fund

Dr. Marie-Paule Kieny, Director, Initiative for Vaccine Research, WHO

Original: English

For information
and/or to obtain copies of this document,
please contact:

GAVI Secretariat
c/o UNICEF
Palais des Nations
CH-1211 Geneva 10
Switzerland

Tel: +41 22 909 5019
Fax: +41 22 909 5931
E-mail: gavi@unicef.org
www.vaccinealliance.org

Printed: October 2002