

13TH GAVI BOARD MEETING



GAVI

**THE GLOBAL ALLIANCE FOR
VACCINES & IMMUNIZATION**

Partnering with The Vaccine Fund

Washington, DC

6 - 7 July 2004

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Summary Report

1. GAVI Progress Report

- The activities set out in the GAVI Work Plan 2004-05 are on track for the most part, after some initial delays in a few areas due to financial bottlenecks.
 - The progress of GAVI needs to be considered within a context of expectations – to know what goals are being set, what has been done to reach those goals, and how the progress measures against these goals.
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DECISIONS

The Board:

- 1.1 Requested the President of The Vaccine Fund to provide an in-depth presentation at the next Board meeting on its financial situation.
 - 1.2 Welcomed the offer by WHO to report back to the EC at its next meeting on the status of the Vaccine Provision Project.
 - 1.3 Welcomed the development of a global immunization strategy being prepared by UNICEF and WHO in consultation with the wider community, and suggested that the new director of WHO Immunization, Vaccines and Biologicals department (IVB) make a presentation on the progress of the strategy development at the next Board meeting
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2. Recommendations of the Independent Review Committee

- It will be important to look into the reasons why a substantial portion of immunization services support (ISS) funding has not been spent. [The Secretariat is preparing a more in-depth analysis which it will provide to the Board as soon as possible.]
 - As the IRC monitoring team has just finished its most recent review, the official report of the team, including its policy recommendations, will be presented formally to the GAVI Executive Committee for discussion and decision shortly. [Done on 15 July]
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DECISIONS

The Board:

- 2.1 Agreed to recommend to The Vaccine Fund to release US\$ 4,887,500 to fund the proposals recommended for approval by the Independent Review Committee's (IRC) review team.
 - 2.2 Decided to consider how to support low income countries under stress at a future meeting.
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3. The GAVI long-term strategy

- GAVI is strong because of its convening power and the complementary roles of all the partners – most of whom have been involved in immunization for a long time. On the other hand, much of the real power behind the Alliance is the resources of The Vaccine Fund – a new source of funding that the GAVI Board must ensure is additional and spent in the most optimal way.
 - The dual nature of GAVI creates difficulty in identifying its true value and role. GAVI as an alliance has adopted very broad goals related to the entire global immunization arena. The resources in The Vaccine Fund, however, have been used for very specific purposes. Looking to the future, it will be critical to develop and use simple messages that describe the dual nature of GAVI in clear terms.
 - The need for clarity in describing the role of The Vaccine Fund will be especially critical for fundraising activities; the financing requirements of The Vaccine Fund must be put into the context of the global financing requirements for immunization so that its particular added value can be recognized and financing needs of partners can be supported.
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DECISIONS

The Board:

- 3.1 Endorsed the outcome of the EC retreat discussions on GAVI's long-term strategy but requested further work be done to clarify:
 - 3.1.1 The principles, criteria and strategic priorities for the use of Vaccine Fund resources by simplifying the language, reducing the number of items to only the most salient points, and better distinguishing the difference between principles and criteria in the decision-making process.
 - 3.1.2 That time-limited does not mean short-term.
 - 3.1.3 The concept of sustainability.
 - 3.1.4 That the resources of The Vaccine Fund are complementary, building on and supporting what the partners are doing.
 - 3.1.5 That funding to low income countries under stress should continue to be flexible, with channeling through partners as necessary.
 - 3.1.6 How the convergence of the GAVI Secretariat and The Vaccine Fund will affect the messages about GAVI's long-term strategy.
 - 3.2 Agreed that it will need to consider whether to change its mission statement and objectives in light of the agreement on the further clarification of the role of GAVI and The Vaccine Fund.
 - 3.3 Requested the coordinating group on global advocacy to take responsibility for coordinating and improving messaging on GAVI's long-term strategy and dual role, in an iterative process that builds on the discussions and recommendations of the sub-group of the GAVI Board on governance, the WHO/UNICEF global strategy, and other relevant processes as they develop.
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4. Financing

- Increasing the resources available for health from developing country government budgets is as important as increasing overseas development aid.

- The Board welcomed the development of common analyses of the funding gap for reaching immunization-related MDGs. These analyses will be formulated through the IFF planning process (see below) and the WHO/UNICEF global immunization strategy consultative process.
- Fundraising activities will be more effective if partners are consistent in what they say about these strategies and resource needs, and the specific roles of The Vaccine Fund and different partners in the global effort. Messaging needs to be developed as part of the work being undertaken by the coordinating group on global advocacy.

5. International Finance Facility

- If the IFF for immunization goes forward, it will be in effect a launch of the IFF concept, on a limited scale.
- Immunization is a promising area in which to test the concept of the IFF, but many more details are needed, including criteria for funding, disbursement mechanisms, and the financial architecture. There are many assumptions, such as future reductions in vaccine prices and absorption capacity of poor countries; these assumptions require validation.
- The Board will need to know the pros and cons of the mechanism and the potential risks of creating a link to GAVI. The World Bank autumn meetings might provide a good opportunity to gain this knowledge.
- Care must be taken so that an IFF for immunization does not make distortions; with each new vehicle comes the risk of more fragmentation.
It is not yet clear how the money raised by the immunization IFF would be disbursed – these issues are under discussion.

DECISIONS

The Board:

- 5.1 Applauded the leadership of the UK government in designing and proposing the IFF; if the IFF materializes it could have a profound effect on development.
- 5.2 Endorsed further exploration of the IFF for immunization by the 'trio plus two': WHO, UNICEF and The Vaccine Fund, plus the World Bank and the Gates Foundation.
- 5.3 Requested simple, straightforward briefing materials as soon as possible, by the GAVI partners. Advocacy materials should be developed after Board agreement had been reached on an IFF for immunization- project.
- 5.4 Agreed to continue discussing the IFF for immunization with interested donors.
- 5.5 Requested the GAVI EC to have a comprehensive discussion of the immunization IFF at its next meeting.

6. Measles Investment Case

- The document provided as an addendum to the original measles investment case addresses the concerns raised by the Board.
Channeling some of the \$50 million through the GAVI/Vaccine Fund country support mechanism would result in a \$3 million loss in matching grants from the

UN Foundation. However, upholding the GAVI emphasis on bottom-up country application processes would be worth the reduced financial contribution.

DECISIONS

The Board:

- 6.1 Approved option B outlined in the addendum of the measles investment case, namely:
 - 6.1.1 The Vaccine Fund will contribute \$37 million to the UN Foundation for "catch-up" campaigns. This will trigger a \$9.25 million matching grant from the UN Foundation. The relevant countries will access resources for catch-up campaigns through the Measles Partnership.
 - 6.1.2 The Vaccine Fund will make available \$13 million to support implementation of a routine second dose of measles vaccine in selected countries. The relevant countries will access resources for routine second measles dose through GAVI/Vaccine Fund country application mechanism.
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7. EC retreat recommendations on optimal structures and process for GAVI & The Vaccine Fund

- According to the analysis conducted by the Center for Applied Research (CFAR), the financial benefits of convergence would not by themselves justify the move. However, the GAVI EC recommended moving forward on convergence for strategic reasons – improving the performance of The Vaccine Fund and the GAVI Secretariat in supporting the needs of the partners in the alliance. Since the financial costs of convergence are within reason, the strategic justification remains.
 - The Chair of the Vaccine Fund Executive Committee confirmed that it supports the convergence of the Vaccine Fund management and the GAVI Secretariat.
 - At this time it does not make sense to consider merging the two Boards, for legal reasons. This may be considered at a future time.
 - A top priority for the transition teams (see decision 7.2) will be to define the roles and responsibilities of the converged organization.
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DECISIONS

The Board:

- 7.1 Agreed to the 'base case' for convergence described by CFAR, namely:
 - The GAVI Secretariat and Vaccine Fund management structure share common premises
 - The common premises will be located in Geneva
 - Vaccine Fund staff members located in Washington, DC will remain in Washington, DC
 - Both staff organizations report to a single leader
 - Vaccine Fund employees will remain employees of The Vaccine Fund (a private organization) and Secretariat employees will remain employees of UNICEF
 - The entities retain separate boards
 - Staffing levels will be based on the assumption that the Secretariat and Vaccine

- Fund carry out functions consistent with the roles described in the EC retreat report.
- 7.2 Requested two transition teams to carry out the necessary work – one comprised of Board members and one comprised of GAVI Secretariat and Vaccine Fund staff.
- 7.3 Agreed that the staff transition team would be comprised of Bo Stenson of the GAVI Secretariat and Fabian McKinnon of The Vaccine Fund, and would be led by an independent consultant. This consultant would serve as a neutral party in the efforts and provide the considerable staff time necessary to conduct the work required of the transition. Once a new GAVI Executive Secretary is recruited, that person would take over the responsibilities of leading the staff transition team. The staff transition team will review and formulate recommendations to the GAVI and Vaccine Fund Boards on substantive policy issues including, but not limited to:
- Legal issues, including status of staff and implications under UN regulations
 - Organization design and staffing, including an ideal design of the converged entity and staff roles and responsibilities
 - Messaging, including messaging about the converged entity in light of the overall strategy
 - Human resource and operating policies
 - Systems and infrastructure of the converged entity
 - Management of the legal and HR issues of separation and relocation
 - Work plan and budget for transition
- 7.4 Agreed that the Board transition team would be comprised of Pascal Villeneuve of UNICEF and David Fleming or Sylvia Mathews of the Gates Foundation, and be chaired by Chip Lyons, Chair of the Vaccine Fund Executive Committee. The Board transition team will review and formulate recommendations to the GAVI and Vaccine Fund Boards on substantive policy issues including, but not limited to:
- Roles and responsibilities of the converged entity
 - Legal issues oversight
 - Configuration of the Boards and their coordination
 - Oversight of the staff transition team
- 7.5 Requested both the transition teams to report back to the GAVI EC by September or October. The staff transition team will report to the Board transition team as needed.
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8. Investment Case Framework

- The process outlined in the investment case framework is designed to help the GAVI Board make global decisions about where GAVI will invest the resources of The Vaccine Fund in the next phase of GAVI. The framework will come into use once the Board has made the necessary strategic decisions about the long-term goals of the alliance. These long-term goals will be heavily informed by the Global Immunization Strategy currently being developed by UNICEF and WHO in consultation with the broader immunization and health community.
- The investment case framework is not intended to be used by countries that will request new types of support from The Vaccine Fund in the next phase of GAVI. Country support requests will be managed through a modified version of the current country support process.
- The investment case framework describes a complex decision-making process. Some Board members felt this complexity is warranted, considering the large financial implications of these decisions; other Board members felt a more simple

route would be preferred; others were concerned that the role of recipient countries in deciding priority investment is not apparent.

- Most Board members felt that the proposed two-step process of initially inviting and reviewing letters of intent and subsequently requesting full investment cases is not required. Instead, the Working Group could vet ideas for new investment cases.
 - The proposal to provide up to \$50,000 in seed money to an organization or group of partners developing an investment case was positively received, as long as the number of investment cases is limited and the investment cases are actually solicited by the Board.
 - No consensus was reached regarding whether to create a separate review mechanism to make recommendations to the GAVI Board regarding investment cases, or to use existing mechanisms such as the GAVI EC or the Working Group.
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DECISIONS

The Board:

- 8.1 Requested revision of the investment case framework to simplify and streamline the proposal, before it could be approved for use. The Secretariat will work with the World Bank team to provide a revised proposal to the Board at its next teleconference.
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9. EC retreat recommendations on long-term vaccine availability and affordability

- The issues of long-term vaccine availability and affordability are especially pertinent to the discussions on Hib vaccine uptake and the GSK rotavirus vaccine which will soon be available.
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DECISIONS

The Board:

- 9.1 Agreed that UNICEF and the Gates Foundation should convene a small steering group to elicit suggestions from the EC and design a process to review and address procurement concerns.
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10. Hib update

- There are significant challenges in securing the long-term supply of Hib-containing pentavalent combination vaccines. Currently, 13 million doses of pentavalent vaccine are procured annually. This does not represent a significant market to vaccine manufacturers; market competition and price reductions will only come if demand increases.
- The Hib situation will reflect perception of success or failure of GAVI. Strategic supply and procurement approaches are important to develop.
- The dual objectives of affordability, and ensuring that the market is attractive enough for additional producers to invest in vaccine development, must be balanced.

- There is a dearth of disease burden information in developing country settings. In addition, some of the available data are inconsistent. Better collaboration with other pneumonia and meningitis surveillance efforts, such as those being undertaken by the pneumoADIP, could improve the information situation.
 - Given the many programmatic and operational challenges surrounding the introduction of Hib vaccine it is paramount to involve countries in the development of any revised GAVI Hib strategy.
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DECISIONS

The Board:

- 10.1 Agreed to constitute an ad hoc group representing skills and expertise in programmatic, financing, procurement and supplies with representatives from country and global levels. The proposed list of participants (attached) was approved with the addition of the Board members from research institute (Holmgren) and from the technical health institute (King).
 - 10.2 The team will undertake a broader situation analysis and present a report on country information needs and key issues for updating the GAVI global Hib strategy within the next three to four months.
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11. Proposal for bridge financing

- While the proposal does have merits, many Board members raised questions about the reliability of the projections concerning potential 'mature prices' for the vaccines.
 - The GAVI Board could consider advocacy efforts targeted at encouraging the 90 developing to middle income countries not eligible for Vaccine Fund support to introduce the new vaccines, in an effort to increase the size of the market.
 - As new vaccines enter the market it is a given that vaccine prices will be higher than the older, off-patent vaccines that formed the foundation of the EPI programme. It will be necessary to accept the fact that even at higher prices, these vaccines are among the most cost-effective health interventions.
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DECISIONS

The Board:

- 11.1 Agreed to pursue the principle of cost-sharing with countries that are now receiving combination vaccines, after the first five years of support.
 - 11.2 Requested more analysis on options for level of co-payment offered to countries – in addition to 'mature price' – and more consultations with countries and donors, before the proposed direction outlined in the paper can be endorsed. The Financing Task Force, supported by the World Bank, will work with the GAVI Working Group, as appropriate, to develop the revised proposal.
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12. Report of the ADIP Management Committee

- The ADIP Management Committee has reviewed and endorsed the progress of both the Rotavirus and Pneumococcal ADIPs.

- The rapid progress of the new rotavirus vaccines are an exciting development with attention of the two lead companies being focused on the needs of both the developed and developing world. GlaxoSmithKline (GSK) is planning to launch its product first in middle income countries prior to introduction in Europe. Merck & Co, plans to file its product simultaneously in the developed and middle income countries.
 - The Rotavirus ADIP is working with both companies to conduct studies in developing countries, where rotavirus diarrhea has a high mortality/morbidity, as it is uncertain how either product will perform in Vaccine Fund eligible countries.
 - Considering the experience with Hib, reliable disease burden data must be available before considering widespread introduction of rotavirus vaccines in Vaccine Fund eligible countries.
 - WHO is in contact with the Mexican national regulatory authority (NRA) about moving ahead on the pre-qualification process of the NRA, a step needed for the NRA to function as a reference authority. The timeline for the process is unclear.
 - Regina Rabinovitch will from now on represent the Gates Foundation on the ADIP Management committee, replacing Rick Klausner.
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DECISIONS

The Board:

- 12.1 Endorsed the report of the meeting and the progress of the Rotavirus and Pneumococcal ADIPs.
 - 12.2 Requested the Rotavirus ADIP to explore opportunities to participate in testing and pilot introduction of the rotavirus vaccine candidates to, (1) develop necessary data for support of widespread introduction in developing countries including Vaccine Fund eligible countries and (2) address issues of strategic importance to GAVI & The Vaccine Fund such as assessing the feasibility of the vaccine's introduction in poor countries with weak health infrastructure.
 - 12.3 Agreed to establish a small, time-limited group to explore with GSK and Merck (at this stage) the technical, scientific and cost characteristics required for early introduction of rotavirus vaccines in Vaccine Fund eligible countries. Price/volume negotiations would then be conducted with the companies.
 - 12.3.1 The composition of the group is: John Wecker, Rotavirus ADIP Exec. Dir.; Orin Levine, Pneumococcal ADIP Exec. Dir.; Jan Holmgren, Chair of ADIP Mgmt Comm; Kevin Reilly, Member Mgmt Comm; Regina Rabinovich, Gates Foundation; Steve Jarrett, UNICEF Supply Division; Jacques-Francois Martin, The Vaccine Fund, Marie-Paule Kieny, WHO, and Tore Godal, GAVI Secretariat.
 - 12.3.2 The group will need to begin work immediately; its terms of reference will be shared with the Executive Committee and the Board.
 - 12.3.3 The Group will report through the ADIP Management Committee to the full Board at its next meeting.
 - 12.4 Requested UNICEF to clarify why it has not yet signed the Memorandum of Understanding (MOU) with the Rotavirus ADIP at PATH. The UNICEF representative promised to provide the Board with a written update by email, as the information was not available at the time.
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13. Preliminary findings of the evaluation of GAVI immunization services support (ISS)

- The initial analysis was interesting but it will be important to conduct further analysis into the system and its impact. For instance, it might be instructive to look for differences in district-level coverage within countries.
- It is nearly impossible to attribute changes in basic immunization coverage rates to a single cause, considering the interdependency of the health system.
- Some Board members felt that even though the principle of the ISS system is to provide flexible funding it would be helpful if GAVI were to provide countries some guidelines about best use of funds.

14. Improving the country application process and time-limited extension of ISS funding

- The Board could not reach consensus on whether to approve a time-limited extension of ISS funding. Some Board members questioned whether ISS funding fulfills the Vaccine Fund principle of providing a 'step change' to immunization programmes. Further analysis was requested.

DECISIONS

The Board:

- 14.1 Agreed that the Secretariat and the Working Group should continue working on the design of country application process for the second phase of GAVI according to the directions outlined in the document.
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15. Proposed review of GAVI governance processes

DECISIONS

The Board:

- 15.1 Approved the draft terms of reference for the review, with a longer timeframe – the group should report to the Board at its next meeting in December, not before, to allow the necessary consultation and finalization of the recommendations.
- 15.2 Approved the composition of the group. Chair: John Lambert, Chiron. Members: Joy Phumaphi, WHO; Bruno Floury, France; Professor Nymadawa, Mongolia; Sigrun Mogedal, Norway.
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16. Yellow fever stockpile

DECISIONS

The Board:

- 16.1 Endorsed the annual progress report for the yellow fever stockpile.
- 16.2 Requested The Vaccine Fund to release a maximum of \$6 million for the 2005 supply. The Vaccine Fund will need to make the final financial decision, depending on the outcome of the final negotiations between UNICEF Supply Division and the manufacturer.
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17. 2005 Budget for Vaccine Fund Trust Account at UNICEF

DECISIONS

The Board:

- 17.1 Approved the proposed 'bridge' budget in the amount of US\$ 3,592,347 for UNICEF for administration costs in 2005 related to the management of the Vaccine Fund Trust Account at UNICEF and the procurement of vaccine on behalf of the alliance.
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18. Next Board, EC meetings

- The next Board meeting will be in Abuja, Nigeria on 4-5 December (Saturday, Sunday), to be convenient with the High Level Forum on Health being held in Abuja on 2-3 December. Board members are advised to make travel plans soon.
- The next EC meeting will be in early November.

Agenda

Day one

Opening remarks

Ms Marsha Evans, President and CEO, American Red Cross
Dr LEE Jong-wook, GAVI Board Chairperson, WHO Director-General

Progress report

GAVI Progress Report, *Dr Tore Godal*, GAVI Executive Secretary
Report from the Field, *H.E. Dr Jean Yagi Sitolo*, Minister of Health, DR Congo

Independent Review Committee recommendations

Recommendations on funding new proposals, *Merceline Dahl-Regis*, IRC proposal team Chair
Summary of finding from review of country progress reports, *Ciro de Quandros*, IRC monitoring team Chair

GAVI long-term strategy

EC retreat recommendations, CFAR

Financing

EC retreat recommendations, CFAR

International Finance Facility

Progress on development of the IFF, *Beverley Warmington*, Head, International Poverty Reduction Team, UK Treasury
Immunization pilot of the International Finance Facility

Measles investment case

Joy Phumaphi, Assistant Director-General, Family and Community Health, WHO

Investment case framework

Amie Batson, The World Bank

Optimal Structures and Processes for GAVI & The Vaccine Fund

EC retreat recommendations, CFAR

Day two

Long-term vaccine availability and affordability

EC retreat recommendations, CFAR

Hib update

Overview, *David Fleming*, Gates Foundation

Review of country-level decision-making and implementation,
Patrick Zuber, WHO

Long-term procurement issues, *Steve Jarret*, UNICEF Supply Division

Proposal for a time-limited Hib team, *Mercy Ahun*, GAVI Secretariat

Bridge financing

Proposal to explore "bridge" financing, *Steve Landry*, co-chair, GAVI
Financing Task Force

ADIP Management Committee meeting

Report of the ADIP Management Committee, *Jan Holmgren*, Chair,
ADIP Management Committee

Immunization services support (ISS) study

Preliminary finding of the evaluation of GAVI ISS funding, *Grace
Chee*, Abt Associates

Improving country support

**Improving the country application process & time-limited
extension of ISS funding**, *Bo Stenson*, GAVI Secretariat

Proposed review of GAVI governance

**Terms of reference and composition of the team for the internal
review of GAVI governance processes**, WHO

Other matters

**Yellow fever stockpile

**2005 budget for the Vaccine Fund Trust Account at UNICEF

**Proposed date and location of next GAVI Board meeting

**in camera session*

List of annexes

- Annex 1:** GAVI Work Plan Update
- Annex 2:** GAVI Independent Review Committee, Proposal Team Report | 28 May 2004
- Annex 3:** *CFAR* Report on Executive Committee Retreat
- Annex 4:** *CFAR* Optimal Structures and Processes for GAVI and The Vaccine Fund Moving Forward
- Annex 5:** Addendum to the Measles Investment Case
- Annex 6:** Implementing the GAVI Board's Long-term Strategy: Investment Cases
- Annex 7a:** Terms of Reference for Time-limited Hib Team
- Annex 7b:** Proposed Members of GAVI Hib Team
- Annex 8:** Bridge Financing for Select Vaccine Products
- Annex 9:** ADIP Management Committee Meeting Report | 10-12 June 2004, Geneva
- Annex 10:** Country Application/Monitoring Process in the Next Phase of GAVI/The Vaccine Fund
- Annex 11:** Proposal for a Time-limited Extension of Immunization Services Support
- Annex 12:** Terms of Reference for an Internal Review of GAVI Governance Processes and Structures
- Annex 13:** *** *REVISED* *** Interim Annual Progress Report | GAVI Yellow Fever Vaccine Stockpile | July 2004
- Annex 14:** UNICEF Request to GAVI Board for the Vaccine Fund Trust Account Bridge Budget for 2005
- Annex 15:** List of participants
- Annex 16:** Online resources

Annex 1

GAVI Work Plan Update

I Executive summary

After some initial delays in obtaining resources and transferring them to the implementing partners the funding flows are now satisfactory. The early delays have mostly been recovered (with the exception of the Africa Bacterial Meningitis Network) and overall work plan implementation is on track (see next page).

Ongoing work, such as country proposal and monitoring reviews, has not been affected.

For new areas the initial efforts have mostly been to develop tools and guidelines, consult with countries and prepare for later implementation. The experiences from this stage have been important in many respects; the major issues are discussed separately below.

In the work plan area of alleviating systems barriers, discussions and agreements with stakeholders have been delayed. Assessment of barriers in countries is ongoing. As requested the Board will get a specific opportunity to review progress in this area at the December Board meeting.

The indications of interest for an immunization pilot for IFF have resulted in considerable development work. If this project materializes it can be expected to have a major impact for immunization financing.

The overall financing of the work plan is so far proceeding according to plan although some uncertainties remain. At the time of the December Board meeting the overall financing picture should be more clear. No action is proposed at this stage.

A 2004-05 Work Plan overview (as approved by the Board in December 2003) and an overall summary of progress are provided on the next two pages.

Work Plan Overview		Priority Area	Targets
Strengthening service delivery	Health information and monitoring systems	<ol style="list-style-type: none"> 1. DQS methodology and other tools finalized. 2. All countries with failed DQAs have received timely and adequate support 3. DQS systematically used by at least 10 countries 4. HMIS and EPI specific reporting coordinated, where possible 5. Agreement by major health sector stakeholders on joint efforts to address health systems barriers. 6. ICCs strengthened with stronger links to NGOs and higher level national health coordination committees 7. Efforts in 10 high-performing and 10 low-performing countries undertaken, lessons learned, documented and best practices shared. 	
	Contributing to alleviation of system-wide barriers	<ol style="list-style-type: none"> 8. Seven large population countries have made analysis of the barriers and possible solutions, and have agreed with their ICCs on action plans. 9. GAVI and partners have established new policies to support the seven large population countries. 10. Lessons from ADCs applied in the large population countries as appropriate 11. The large population countries are back on track or show tendency of getting back on track in immunization coverage. 	
	Enhanced efforts in large population countries	<ol style="list-style-type: none"> 12. Minimal divergence between vaccine forecasts and uptake. 13. Establish planning processes for vaccines provision, with focus on hepB, Hib and YF and support to other GAVI vaccine initiatives. 	
Ensuring access to vaccines and related products	Procurement / Supply of existing products	<ol style="list-style-type: none"> 14. Technologies for immunization: prioritization reviews, evaluations and advocacy. 15. Monitor the progress towards establishing the public health benefit and demand for rotavirus and pneumococcal vaccines in developing countries. 	
	Development and introduction of new, near-term products	<ol style="list-style-type: none"> 16. All eligible countries that qualify and are interested in GAVI/VF support for ISS, new vaccines and injection safety, will have applied and will have been approved. 17. DQAs conducted in relevant countries. 18. Coverage surveys carried out when needed for allocation of performance-based grants 19. All funded countries have developed their FSPs according to proposal schedule, with lessons learned and experiences shared with countries and partners. 20. All countries assisted to integrate FSPs into their national planning and budgeting processes which may include PRSPs and MTEFs 21. Role of FTF in coordinating partner inputs and assuring funds for financial sustainability work to be transferred to partner(s) with their future roles and responsibilities clearly defined 22. All funded countries have had their FSPs reviewed. 23. New global and country level financing mechanisms developed and tested. 	
Securing long-term financing	Managing process for country support from Vaccine Fund	<ol style="list-style-type: none"> 24. Long-term GAVI/Vaccine Fund resource mobilization (2006 - 2015) plan fully aligned with long term GAVI strategic planning (2006-2015) and new funding. 25. Vaccine Fund resource mobilization level of \$400 million/year achieved by end of 2006 (interim 2005 milestone for this effort is roughly \$325 million/yr). 	
	Financial sustainability	<ol style="list-style-type: none"> 26. Long-term (through 2015) strategic plan, including Vaccine Fund priorities and policies, developed and approved. 27. GAVI 2006-07 work plan developed and approved. 	
Strategic planning & monitoring	Recapitalization of The Vaccine Fund	<ol style="list-style-type: none"> 28. Process to monitor progress of GAVI and respond to emerging needs established and ongoing. 	
	Setting priorities	<ol style="list-style-type: none"> 29. Secretariat: Support for governing bodies, coordination and communication. 30. RWG: coordination of partners efforts in the regions 	
Other	Monitoring progress		
	Alliance coordination		

II Latest information on GAVI work plan implementation

Priority area	Comment
Health information and monitoring systems	On track
Alleviation of system-wide barriers	Target on stakeholder agreements postponed by 6 months. Reduced number of countries -10 instead of 20- in first phase.
Enhanced efforts in seven large population countries	Target on identification of bottlenecks and priority activities for acceleration delayed by 3 months – country analysis will be ready by October.
Adequate supply of existing vaccines	Target 12. Minimal divergence – No decision on VPP. 5-month delay of recruitment of a full-time assistant in WHO to maintain demand forecast. Target 13. Establish planning processes for vaccines provision...: On track. Target 16. All eligible countries...: Generally on track. Based on country demand a brief review of country proposals has been added in the second quarter 2004.
Late stage development and intro new vaccines and technologies	On track
Managing the country support process	The modalities for support to countries to improve reporting quality still not decided. Otherwise on track.
Financial sustainability	On track
Recapitalization of Vaccine Fund	On track
Setting priorities	On track but major new developments such as IFF.
Monitoring progress	African Pediatric Bacterial Meningitis Network activities delayed by 4 months.
Secretariat core costs	On track
RWG coordination	On track

III Major issues

1. The challenges to reach immunization targets in most of the seven large population countries

In 2002, over 50% of the world's 33 million unimmunized children lived in 7 large population countries – Bangladesh, DR Congo, Ethiopia, India, Indonesia, Nigeria and Pakistan. UNICEF and WHO, with other partners (i.e. USAID, Basics, CDC, CVP) have worked with MOH in these countries to initiate joint assessments of the health service delivery and immunization barriers in order to develop a set of actions and resource requirements for coverage improvements.

The actual process was designed by the countries themselves. Most countries included national level workshop and consultative meetings of immunization stakeholders. In one country (Pakistan), an external firm was commissioned to conduct the study to identify barriers to immunization coverage. National strategic plans and annual work plans were used as the main working materials. ICC role was critical to review and endorse the plan.

“Coverage Improvement Plans” (CIPs) endorsed by national ICCs are available for two countries (DR Congo and Bangladesh) and in preparation in two other countries (Ethiopia and Indonesia). Updated Immunization Strategic Plans are in an advanced stage of development for India and Nigeria.

Most country plans consistently presented a long list of barriers, which can be grouped into three categories, i.e.:

i. Programme and Resources Management

- Insufficient and untrained human resources at peripheral levels
- Weak supervision system and poor quality of monitoring data
- Lack of funds for recurrent activities
- Weaknesses in management of funds available

ii. Logistics and Service delivery

- Shortage of cold chain and transport equipment
- Vaccine stock out and unsafe injection practices
- Missed opportunities, invalid doses
- Lack of outreach activities

iii. Creation of Demand for Immunization

- Lack of awareness of immunization quality
- Lack of community participation and user-friendly communication materials

For DR Congo and Bangladesh, select barriers, relevant for the status of programme development, were chosen strategically for the formulation of the CIPs for 2004-05. DR Congo plan aims at expanding access to immunization services through strengthening training for managers and peripheral health workers, expansion of cold chain infrastructure and transport equipment. In Bangladesh, improving the weaknesses of the service delivery system, mobilizing NGOs and effective communication to reduce drop out are the main strategies proposed in the plan.

Apart for US\$ 3 million gaps for DR Congo, the financial resources to cover the needs identified in these 2 complete CIPs are available from local sources (including the immunization services support from GAVI/VF).

Lessons learned so far and next steps:

- National leadership is a key to coordinate the multi-partner efforts. Unfortunately, some countries have fairly weak national immunization teams. Advocacy by GAVI Partners is required to help bridge the gaps and bring to completion the preparation and implementation of CIPs.
- Local immunization partners have the challenging task to ensure that the implementation of CIPs is monitored regularly.
- By October 2004, an analysis of plans from the seven countries will provide further insights on the role of the GAVI Alliance and partners in support of immunization activities in these seven large population countries.

2. Recapitalization of The Vaccine Fund

- The Vaccine Fund has devoted considerable time over the last year to building a fully qualified resource mobilization team which can develop and implement, in partnership with the GAVI Secretariat, effective advocacy and fundraising strategies in donor countries such as Germany, Italy, Japan and Australia. As part of this, we also have strengthened our communications capacity.
- This new team has launched in late February, 2004, the Campaign for Child Immunization with the goal of promoting universal donor support of GAVI and raising on an annual basis by 2006 at least \$400 million. The campaign launch was held in London, subsequent events are planned in Berlin, Rome and Tokyo.
- TVF has produced a best estimate of the cost of funding the GAVI commitments to eligible countries, assuming all do request such support. Our research confirms that the total funding needed for the first phase of GAVI, meaning through 2006, is approximately \$400 million per year, the stated fundraising goal of the Campaign.
- The VF Resource Mobilization Team is now almost completely staffed (with 16 staff). The managers and their assistants are in place, have been properly briefed and are initiating strategies and for GAVI and VF principals in capitals. In all instances, VF regional managers are attempting to inform the national committees for UNICEF of their plans in their territories.
- The Vaccine Fund Board Executive Committee and staff have devoted serious attention to board building over the past year resulting in the addition of three new board members joining the organization's board; Michel Camdessus of France, former Managing Director of the IMF; Dr. Rita Sussmuth of Germany, former President of the Bundestag; and Jocelyn Davis, CPA and financial advisor and former CFO of a major American association.
- The launch of the Global Leadership Council is planned to be held in late February 2005, on/around the first anniversary of the launch of the Campaign.
- Joint efforts between the VF-GAVI has resulted in the annual progress brochure issued in late February, extensive collaboration on development of advocacy and communications strategy, sharing of staffing and budgetary resources and cooperation on development of country-based success stories for advocacy purposes.

3. Challenges for financial sustainability: bridge financing for recently introduced vaccines

From preliminary analyses of national Financial Sustainability Plans and feedback from countries, many countries receiving GAVI/Vaccine Fund support for new antigens will not be able to fully finance these costs when GAVI/VF support ends. Countries and their development partners had assumed vaccine prices would decrease over the GAVI/VF period and that national development partners would provide significant additional funds to support enhanced immunization programs. With increasing and competing demands on limited health budgets, a number of countries are exploring their options including continuing to request increases in support from national partners, selecting less expensive vaccine presentations and, in a few cases, dropping Hib altogether. The FTF has been exploring the potential implications of GAVI/VF providing bridge financing to support countries make an effective transition from GAVI/VF to national and partner financing of new vaccines (being submitted separately to the Board at the July 2004 meeting with the paper, "Bridge Financing for Select Vaccine Products").

4. Process for strategic priority setting including use of investment case framework

The overall plan for GAVI long-term strategic priority setting is being implemented. However, new developments have resulted in major details being added or modified.

Thus a draft investment case framework has been developed by the WB and piloted through the measles investment case. The framework is proposed to be the basis for developing and reviewing strategic priorities (being submitted separately to the Board at the July 2004 meeting with the paper, "Investment Case Framework").

The IFF initiative and its subsequent application to an immunization pilot IFF has been a major undertaking. WHO, UNICEF and The Vaccine Fund have worked in close collaboration with TVF on the development of the IFF Immunization Pilot proposal including the costing of all immunization needs between 2005 and 2015. This will also ensure the availability of data for later discussions on the Investment Case Framework.

If an IFF immunization pilot materializes it will undoubtedly result in significant new financial resources for immunization with subsequent implications for GAVI's strategic priority setting processes.

IV Progress to date

The work plan has only been in force for six months. Most of the action plans under the different targets have started with preparatory and planning activities, development of guidelines and testing of tools. It is therefore little quantitative information to report on. Below follows short statements for areas where specific and quantitative information is available; it is to be seen as illustrative not comprehensive.

Health information and monitoring systems

- The DQS tool has been piloted in 3 countries (Nepal, Morocco and Togo) and the experience will be available by the end of June.
- Staff from all regions have been briefed in the DQS methodology (either at regional meetings or during a briefing on Monitoring Tools held at WHO/HQ Geneva in April 2004).

- All regions are currently preparing plans for DQS implementation in their Region. DQS workshops are being tentatively discussed and planned in EURO (Bulgaria); AFRO (Tanzania); SEARO (Indonesia); and one country in AMRO in 2004.
- All regions have launched the recruitment process for an M&E focal points: AFRO has identified 2 candidates; EURO and EMRO have already filled the positions.
- Digital district-level mapping under development for priority countries
- At regional level, WHO is continuously providing support to countries on DQA follow-up (Annex 1). WHO HQ activities have included a DQA report reviews held with the WPRO Office regarding Lao and Cambodia. A consultant has been identified to provide technical assistance to Mozambique (August 2004); support to Nigeria has been postponed due to competing priorities; partners from 5 local institutions (from 5 different countries) have been briefed on monitoring and data quality issues.

Contributing to alleviation of system-wide barriers

- The process for selecting high- and low performing countries is ongoing, taking into account the significant overload encountered by countries. The tools and the guide were developed and the barriers approach has been piloted in Uganda and Zambia.
- In order to proceed it has been found necessary to facilitate the barrier assessment in countries. Assistance and facilitation is now underway in 9 countries (Uganda, Zambia, Ghana, Sierra Leone, Guyana, Rwanda, Gambia, Lao PDR and Vietnam).
- A special report will be presented to the December Board.

Managing the process for country support from The Vaccine Fund

- Sixteen progress reports were reviewed in the Jan-Feb review. An extra proposal review has been implemented in May with 6 country proposals reviewed. 69 progress reports are expected for the June and October monitoring reviews.
- Seventeen DQAs and three coverage surveys are planned for implementation in 2004. Two companies have been contracted to carry out the 2004 DQA and auditors, including nationals, have been trained.

Financial sustainability

- FTF has put in place a multi-partner global-regional-national system for financial sustainability planning and implementation.
- At the global level, FTF has placed responsibility and oversight for financial sustainability work to a core group of partners who are deeply engaged in financial sustainability planning and implementation.
- Given the workload, the World Bank is recruiting a Global Financial Sustainability Implementation Coordinator to be based at WHO. Expected start date: August 2004.
- 32 Financial Sustainability Plans have been reviewed to date (with 4 countries having been reviewed twice) and 36 plans are expected for review in 2004; some countries have started implementation; 60+ countries will begin implementing FSPs in 2005 (Annex 1.2).

- Financial sustainability planning in China and Indonesia is progressing well; India will not be submitting a financial sustainability planning work to GAVI though the government is costing out its multi-year plan using GAVI financial sustainability planning tools.
- The FTF continues to be committed to linking national financial sustainability work to strategic thinking about broader national and global financing mechanisms.

Monitoring progress

- The ISS evaluation study has been carried out in six countries (Mali, Mozambique, Cambodia, Madagascar, Tanzania and Kenya) and the draft report is under review prior to the Board submission.
- Draft proposals have been completed to measure impact in the areas of wastage, injection safety, yellow fever, hep B and Hib. These proposals have been presented to the M&E sub-group for review and their recommendations are being incorporated into the proposals prior to re-review in June. It is planned that these assessments will start in Q4 2004.
- WHO has provided data analysis for monitoring countries and GAVI global progress, and has highlighted problems of data consistency in GAVI 2004 Progress and Challenges Report. Ongoing discussions between GAVI Secretariat and WHO with the assistance of the M&E sub-group are aimed to resolve this.
- Due to late receipt of funds contracts for the staff of the **Africa Pediatric Bacterial Meningitis (PBM) Surveillance Network**, had to be suspended temporarily for the first part of the year. The team is back on contract although activities are delayed.
- Two microbiologist consultants identified and recruitment process initiated.
- Laboratory external quality assurance (EQA) programme funded for second year (in cooperation with WHO Lyon, AFRO EQA programme in South Africa and AFRO CSR)
- Planning for the launch of Phase 2 (2004-05, GAVI funded) activities at annual meeting including:
 - schedule of visits to all sites,
 - for countries planning to introduce Hib vaccine in the coming years an intensive programme of external quality assurance and technical assistance,
 - review of administrative and technical performance to date (2001-2003, CVP funded)
 - review of Hib vaccine impact in 5 countries that introduced with GAVI-VF support
 - Integration with NetSpear East African surveillance network (Pneumo-ADIP funding) initiated.

V Financing

- Overall the financing of the work plan is materializing as budgeted. Due to a late start there were initial delays in the receipt of funds from the donors which led to some delays in the disbursement from Secretariat to the work plan implementers. Thanks to the timely payment of Board member dues this year we are now back on track and disbursements can be made when required.

- The Secretariat has established a good system for cash flow analysis and efforts to ensure 2005 work plan funding will start early to avoid any liquidity problems for next year.
- The major changes in funding are that the available interim ADIP funding amounts to \$400,000 less than anticipated but that the Canadian contribution of \$1.5 million has been larger than budgeted for. Aventis has made a contribution to the immunization financing database of \$30,000. The original budget of \$200,000 for industry contributions may have been too high. The preparations for the EU contribution of € 3 million are moving ahead although final commitment has still not been received.

Annex 1.1

Update on Follow-up with Countries that Failed their DQAs

VAM, June 2004

AFRO

DQAs

Burkina Faso

Burkina Faso has received long-term support from the Centers for Disease Control to improve their monitoring system.

Cameroon

It is unclear if Cameroon will undertake a coverage survey in 2004 following their failed DQA in 2002. WHO is seeking clarification. In the interim no in-country technical assistance has been given specifically for improving monitoring systems. If Cameroon elects to undertake a coverage survey in 2004, WHO will provide technical assistance.

Côte d'Ivoire

There is a major problem with security in the country. Immunization services are only being undertaken in parts of the country. M&E activities have been suspended for the moment.

Guinea

No information has been received from the regional office or country.

Kenya

Kenya has received long-term technical assistance from CDC. Their monitoring system is much improved and they are convinced that they will pass the DQA this year.

Madagascar

Khadija Mshambachika, AFRO Regional Office met with the Madagascar Immunization Focal Point. Madagascar has agreed to schedule a time with AFRO to be trained on the use of the Data Quality Self-Assessment tool, once the tool is completed in June 2004.

Mozambique

The MOH, Mozambique requested technical assistance after Mozambique failed its DQA in 2002. A consultant will be deployed to Mozambique in August 2004 to:

- Review DQA findings and recommendations with the EPI manager and WHO/EPI Focal Pt in charge
- Explore practical actions to be undertaken (what, where, and when)
- Prepare a plan to address the recommendations

Nigeria

The GAVI Strategic Framework has provided fund for increasing national capacity in the form of a full time WHO staff member. The recruitment process is underway. In the interim period AFRO will deploy a consultant to help with routine immunization in Nigeria.

Nigeria's top priority is polio eradication, so the person recruited will be working on routine monitoring systems within this context.

AMRO

Haiti

There is a major problem with security in the country.

A VAM representative will meet with the PAHO regional counterparts and the Haiti EPI Manager to discuss follow up activities during the forthcoming PAHO meeting:

Prevention Effectiveness: Decision Analysis and Economic Evaluation, June 28-July 1, 2004, PAHO/ Washington, D.C.

EMRO

DQAs

Sudan

The MOH has taken the DQA recommendations into consideration and has accordingly developed an action plan to improve the routine reporting system. Country reports, and country visits conducted by the RWG members have confirmed the progress made in this area. Sudan is ready for an official DQA (planned for 2004).

Yemen

The DQA recommendations were discussed in the national ICC and a decision has been taken to develop and implement an action plan to improve the reporting system. Yemen have requested a cluster survey before the end of 2004 (an official letter was sent to the GAVI Secretariat on the 28th of February 2004). Yemen will then take a second DQA in 2005.

WPRO

A VAM staff member visited the WPRO to hold discussions with the WPRO Regional Adviser on follow up activities to improve monitoring at the regional office and in WPRO countries. These included Cambodia (which has passed the DQA) and Lao (which has failed the DQA). Following these discussions the WPRO Regional Adviser, visited Lao in June 2004 to discuss follow up activities.

Summary Chart

Region	Country	Failed DQA	F/U Activity
AFRO	Burkina Faso	2002	Long-term TA provided by CDC.
	Cameroon	2002	AFRO seeking clarification with the country about whether they will take a coverage survey or a DQA in 2004.
	Côte d'Ivoire	2002	Security problem. M&E activities suspended.
	Kenya	2002	Kenya has received long-term TA from CDC.
	Madagascar	2003	AFRO Regional office met with the Madagascar focal point. A date will be set for DQS training in 2004.
	Mozambique	2002	A consultant to follow up recommendations of the DQA in August 2004.
	Nigeria	2002	Focus on polio. Funding provided for a national staff member under GAVI Strategic Framework to start 2004. In the interim a consultant will be deployed.
EMRO	Sudan	2002	MOH has developed a long-term plan of action. Visit from RWG members to review progress in 2003.
	Yemen	2003	Action plan prepared. Cluster coverage survey requested for 2004.
WPRO	Lao	2003	Visit to Regional office by VAM, visit to country by the Regional Advisor

Annex 1.2

Submission Schedule of Financial Sustainability Plans

Region	November 2002	November 2003	November 2004	November 2005
AFRO			Benin Central African Republic DR Congo Djibouti Eritrea Ethiopia Guinea Lesotho Liberia Mauritania Niger Sao Tome Senegal Togo Zimbabwe	Angola Chad DR Congo Guinea-Bissau Nigeria
WPRO	Cambodia Lao PDR	Viet Nam	China ⁴	
EURO		Armenia Azerbaijan ² Tajikistan Uzbekistan	Albania Bosnia & Herzegovina Georgia Moldova Turkmenistan Ukraine	
AMRO	Guyana ¹	Haiti		Honduras
EMRO		Pakistan ²	Afghanistan Sudan Yemen	Somalia
SEARO			Bangladesh Bhutan India ⁴ Indonesia ⁴ Korea DPR Myanmar Nepal Sri Lanka	
Total Countries (65)	12	16	30 ³	7
FSP Re-submission	0	4	6	
Total FSP Expected	12	20	36	

1. FSP re-submission requested in November 2003

2. FSP re-submission requested in November 2004

3. Total does not include Big 3 countries

4. Special case countries where the FSP may not be developed.

Annex 2

GAVI Independent Review Committee, Proposal Team Report

28 May 2004

The proposal review team of the Independent Review Committee (IRC) met in Geneva from the 24th to the 28th of May 2004 to review country proposals requesting GAVI/Vaccine Fund support.

Outcome of the review

A total of 9 requests were submitted by 6 countries. The proposal team's recommendations are summarized in Table 1, and the financial implications are summarized in Table 2. The Board is requested to review these recommendations and provide its recommendation to the Vaccine Fund Executive Committee.

Summary of approvals to date

The financial implications of these recommendations on country proposals are estimated to be US\$ 4,887,500, for the years 2004-05 with a five-year financial commitment of US\$ 22,516,500. The total 5- year financial commitments from The Vaccine Fund now total US\$ 1,082 million (Annex 2.3).

71 of the 75 countries eligible for GAVI/Vaccine Fund support have applied and 70 have been approved for at least some types of support. Papua New Guinea, Solomon Islands, Nicaragua, Timor Leste have not yet approached GAVI for support.

Table 1: Summary of recommendations by country

Country	Requesting support for	IRC recommendation
Benin	Injection safety	Approval (with clarifications) : To clarify month of introduction in 2005 : transition from hep B to Pentavalent vaccine To correct Tables 7.1 and 7.2 : calculations to be based on identified first dose coverage targets infants, not on total births
	Hib	Approval (with clarifications): To provide specific annual targets of indicators listed under section VII 1& 2 To match targets in Table 6 with those in Table 4
Ethiopia	Hepatitis B	Re-submission
Guinea Bissau	Injection safety	Approval (with clarifications): To provide a work plan of ICC for the next 12 months which takes into account specific targets, indicators of programme appraisal and resource mobilization.
Mali	Hib	Re-submission
Mauritania	Hepatitis B	Approval
Mongolia	Injection safety	Approval
	Hepatitis B	Approval
	Hib	Approval

Table 2: Financial implications in 2004-2005 for proposals recommended for approval (in US\$) (*underlined figures subject to change pending receipt of clarifications*)

Country	New and Under-used Vaccines (estimate)	Injection Safety (estimate)	Other support (one-time vaccine introduction support)
Mauritania	194,000	-	100,000
Mongolia	196,500	47,000	100,000
Benin	<u>4,071,000</u>	<u>136,000</u>	-
Guinea Bissau	-	<u>43,000</u>	-
Subtotal	4,461,500	226,000	200,000
TOTAL			4,887,500

Annex 2.1

IRC Proposal Review Team

Proposal Review – May 2004

Reviewers present:

Dr. Merceline Dahl-Regis
Chief Medical Officer, Ministry of Health, Bahamas

Dr Stanislava Popova-Doytcheva
Scientist, WHO STC
Bulgaria

Dr Grace Murindwa
Principal Health Planner, Ministry of Health, Uganda

Mr Gordon Larsen
Independent Consultant for EPI, UK
(Not participating in decisions on Injection Safety Support for Benin, Guinea Bissau and Mongolia).

Procedure of the review

Each proposal was reviewed by three reviewers. The first reviewer was responsible to take a leading role. The plenary of IRC discussed and made final judgment on recommendations for each component of request. All proposals were decided on a consensus basis, no vote was used.

A strict observation of conflict of interest among members for individual proposal was taken care of. A member was not involved in the discussion of three proposals.

Annex 2.2

IRC Detailed Report on Mongolia

Mongolia

Mongolia applied to GAVI for support for Immunization Services and for New and under-used vaccines (DTP-hep B) in June 2002. With DTP3 coverage >80% the country was not eligible for ISS.

Mongolia was informed that combined vaccines containing the hep B component were not likely to be available until 2004 or 2005 and that in order to receive support from GAVI for NVS the country had to submit an introduction plan for the new vaccine.

Mongolia applied again for DTP-hep B as well as for Injection Safety support in May 2003. As GAVI Board had decided that the IRC would not review new applications for combination vaccines until the requested vaccine would be available within 18 months from the date of the review, Mongolia was advised to either submit a new proposal according to the most recent GAVI guidelines nearer to the date when tetravalent vaccine would be available (keeping contact with UNICEF Supply Division) or apply to GAVI for monovalent hep B vaccine.

Documentation on Injection Safety provided to the IRC did not follow GAVI recommendations and the country was asked to resubmit its application. Mongolia is now applying for introduction of pentavalent vaccine (DTP-hep B+Hib) and Injection Safety support. The ICC has addressed the recommendations made by the WHO EPI Review (2002) and by the IRC.

General comments

Mongolia introduced universal infant immunization with recombinant monovalent hep B vaccine in 1991 starting at birth. The high hep B3 coverage achieved (over 90% since 1998 and over 95% since 2000) and improved injection safety (local production of inexpensive and largely available disposable syringes) together with other social and behavioral changes have contributed to reduction in the acute HBV incidence rate. The Multi-year EPI Plan of Action (1999-2004) set an HBsAg prevalence reduction target (<2% in children below 5 years of age).

Introduction of a Hib-containing vaccine has been discussed by the ICC since its establishments in 2001. National experts consider *H. influenzae* type b an important cause of high acute respiratory infection morbidity (51% of hospital admissions) and accounts for 31% of mortality of children less than 5 years of age (CU5).

Aiming to assess *H. influenzae* type b burden, Mongolia introduced sentinel surveillance of invasive infections and *H. influenzae* laboratory diagnosis in the capital city of Ulaanbaatar where 35% of Mongolian children reside. These activities have been guided by WHO, who also funds lab diagnostics. The incidence of culture confirmed Hib meningitis in 2003 was 31/100,000 children <5 years of age. The majority of cases were 5 to 12 months old. Case fatality ratio of Hib meningitis was 21%.

According to the WHO consultant, “this rate should be considered the minimum incidence of Hib meningitis” in Mongolia. “Adjusting for children who died before reaching hospital or who did not have lumbar puncture, the rate of Hib meningitis is likely to be 39/100,000 CU5. Adjusting for probable meningitis cases that did not have an etiological organism isolated, the incidence of Hib meningitis may be as high as 74/100,000 CU5, a rate comparable to that seen in the United States and some high incidence countries in Africa prior to Hib vaccine introduction.”. Using RAT methodology to estimate overall disease burden, the WHO consultant concludes that Hib is likely to cause 500-1000 cases of pneumonia and meningitis and 70-120 childhood death annually in Mongolia. WHO recommends that if resources can be identified, Hib conjugate vaccine should be introduced in Mongolia.

Specific comments

1. ICC

Chaired by the Vice Minister of Health, the ICC was involved in preparing the application documentation.

2. New and under-used vaccines

According to the Strategic Plan for the Introduction of DTP-hep B-Hib vaccine into Mongolian EPI Programme, it is to be introduced in a phased manner (over 3 years), initially targeting 5 of the 9 district of Ulaanbaatar and 5 provinces, starting from 3 January 2005. Thus, Mongolia is asking GAVI support for 7 years. As it is seen from the ICC minutes and the Proposal, JICA will continue supplying the birth dose of hep B monovalent vaccine. The Pentavalent vaccine is to be given at the same age as the subsequent 3 doses of DPT/hep B monovalent vaccines (6, 10 and 14 weeks). A transition policy and a change-over plan are to be developed by September 2004 (p.22 of the Proposal).

The Strategic Plan is well structured and addresses all remarks and recommendations of the IRC from the May 2003 review (e.g. reducing vaccine wastage, preventing overstocking, situation resulting from phasing in, etc). The ICC states that the country cold chain can accommodate the new vaccine by changing frequency of deliveries of vaccines to and from the national cold store. The fact that Mongolia did not experience cold chain insufficiency during recent mass measles and diphtheria campaigns further supports the ability of country cold chain to accommodate the pentavalent vaccine.

Quantities of the DTP-hep B+Hib vaccine by years of the GAVI support need to be recalculated. Buffer stock will be received only during the phasing in period (2005-2007) for the initial and then for the added vaccine supplies each year.

3. Injection safety

A Rapid Assessment of Injection Practices in Mongolia (September 2001) showed that availability of locally-produced inexpensive standard disposable syringes and their universal use for therapeutic and immunization injections and other invasive procedures has significantly diminished the risk of cross infections with blood-borne pathogens among injection recipients. The assessment found that health care workers are at substantial risk of infection due to unsafe practices (recapping needles, emptying safety boxes and counting injection equipment) despite high awareness of HBV and HIV spread through accidental injuries. Safety boxes are inconsistently used and are often regarded as reusable garbage bins. Open burning in drums/stoves seems to be the

universal method for destruction of used injection equipment. Safety boxes used for collection of injection equipment during outreach visits are usually dumped in open areas.

Auto-disable syringes (ADs) were used only during a recent measles immunization campaign.

The National Policy on Injection Safety is a satisfactory document. It sets a goal of ensuring usage of ADs for any immunization purposes (fixed, mobile, mass campaign) by the end of 2005. The National Policy addresses safe disposal of used injection equipment. All vaccination centers and mobile teams are to be supplied with safety boxes (SBs) by the end of 2004. Mongolia has produced a pilot series of safety boxes.

National experts believe that Mongolia can meet its needs of ADs, disposable syringes and SBs after the ending of GAVI support. However, national policy on destruction of used injection equipment lacks details. Progressive installation of high temperature incinerators is envisaged from 2005 with two facilities in Ulaanbaatar. The document is also not in full compliance with WHO/UNICEF/UNFPA statement (1999). "Bundling" strategy is to be applied in supplying vaccines for not only mass but routine vaccination too.

The Plan of Action (2004-2008) on Injection Safety is a very good document. Activities of the work plan have indicators and targets, permitting progress to be measured. Estimates of items to be provided by GAVI need to be corrected as follows. GAVI/VF policy is to provide injection equipment and SBs for the implementation of the WHO standard immunization schedule (children <12 months of age), i.e. one dose of BCG, one dose of hep B monovalent vaccine, three doses of DPT and one dose of measles vaccine. Mongolia is also eligible for 2 doses of DT (instead of TT given to other countries). New and under-used vaccines are supplied in "bundle". Buffer stock of injection equipment for all antigens except DTP-hep B+Hib is valid for the first year of the support only. "Buffer" ADs will be given for three years for the pentavalent vaccine (during "phasing in").

Conclusion

Mongolia has achieved an enormous progress in less than one year time. The MOH, national experts and ICC members are to be congratulated for producing a good quality application.

Recommendations

Introduction of new and under-used vaccine (DTP-hep B+Hib)-Approval
Injection Safety equipment -Approval

Annex 2.3

Estimate of five-year commitment in US\$ (20 June 2004)

#	Country	Type of support	Prior 5-year commitment as of May 2004	Updated 5-year financial commitment
1	Afghanistan	ISS	7,255,000	7,255,000
		NVS		
		INS	1,619,000	1,619,000
2	Albania	ISS		
		NVS	452,000	452,000
		INS	102,000	102,000
3	Angola	ISS	6,565,000	6,565,000
		NVS		
		INS	1,525,000	1,525,000
4	Armenia	ISS	60,000	60,000
		NVS	437,000	437,000
		INS	54,500	54,500
5	Azerbaijan	ISS	487,500	487,500
		NVS	779,500	779,500
		INS	145,000	145,000
6	Bangladesh	ISS	26,935,500	26,935,500
		NVS	16,536,500	16,536,500
		INS	8,204,500	8,204,500
7	Benin	ISS		
		NVS	2,771,000	20,380,000
		INS		415,000
8	Bhutan	ISS		
		NVS	490,000	490,000
		INS	29,000	29,000
9	Bolivia	ISS		
		NVS		
		INS	665,000	665,000
10	Bosnia & Herz	ISS		
		NVS	359,500	359,500
		INS		

#	Country	Type of support	Prior 5-year commitment as of May 2004	Updated 5-year financial commitment
11	Burkina Faso	ISS	4,410,500	4,410,500
		NVS		
		INS	834,500	834,500
12	Burundi	ISS	2,662,500	2,662,500
		NVS	18,830,000	18,830,000
		INS	428,000	428,000
13	Cambodia	ISS	3,012,500	3,012,500
		NVS	6,129,000	6,129,000
		INS	667,500	667,500
14	Cameroon	ISS	5,557,000	5,557,000
		NVS	8,483,000	8,483,000
		INS	1,108,500	1,108,500
15	Central Afr Rep	ISS	1,837,000	1,837,000
		NVS	730,000	730,000
		INS	156,000	156,000
16	Chad	ISS	2,715,000	2,715,000
		NVS	1,251,500	1,251,500
		INS	421,500	421,500
17	China	ISS		
		NVS	22,753,500	22,753,500
		INS	15,926,000	15,926,000
18	Comoros	ISS	173,500	173,500
		NVS	235,500	235,500
		INS	37,000	37,000
19	DR Congo	ISS	31,298,500	31,298,500
		NVS	11,694,000	11,694,000
		INS	3,238,000	3,238,000
20	Congo Rep	ISS	1,534,500	1,534,500
		NVS	896,500	896,500
		INS	266,500	266,500
21	Côte d'Ivoire	ISS	3,859,500	3,859,500
		NVS	8,057,500	8,057,500
		INS		
22	Cuba	ISS		
		NVS		
		INS		

#	Country	Type of support	Prior 5-year commitment as of May 2004	Updated 5-year financial commitment
23	Djibouti	ISS	271,000	271,000
		NVS		
		INS	32,000	32,000
24	East Timor	ISS		
		NVS		
		INS		
25	Eritrea	ISS	930,500	930,500
		NVS	2,188,500	2,188,500
		INS	147,000	147,000
26	Ethiopia	ISS	19,130,000	19,130,000
		NVS		
		INS	3,091,000	3,091,000
27	Gambia	ISS	489,500	489,500
		NVS	3,387,000	3,387,000
		INS	109,000	109,000
28	Georgia	ISS	341,000	341,000
		NVS	700,500	700,500
		INS	60,000	60,000
29	Ghana	ISS	2,888,000	2,888,000
		NVS	44,121,000	44,121,000
		INS	824,500	824,500
30	Guinea	ISS	2,585,500	2,585,500
		NVS	1,112,000	1,112,000
		INS	645,500	645,500
31	Guinea-Bissau	ISS	423,000	423,000
		NVS		
		INS		123,500
32	Guyana	ISS		
		NVS	1,117,500	1,117,500
		INS		
33	Haiti	ISS	2,171,000	2,171,000
		NVS		
		INS	494,000	494,000
34	Honduras	ISS		
		NVS		
		INS	471,500	471,500

#	Country	Type of support	Prior 5-year commitment as of May 2004	Updated 5-year financial commitment
35	India***	ISS		
		NVS	4,224,000	4,224,000
		INS		
36	Indonesia	ISS	16,362,500	16,362,500
		NVS	13,930,500	13,930,500
		INS	9,707,000	9,707,000
37	Kenya	ISS	11,113,500	11,113,500
		NVS	64,983,500	64,983,500
		INS	1,220,000	1,220,000
38	Korea, DPR	ISS	3,315,500	3,315,500
		NVS	2,565,000	2,565,000
		INS	761,000	761,000
39	Kyrgyz Rep	ISS		
		NVS	1,223,500	1,223,500
		INS	178,000	178,000
40	Lao PDR	ISS	2,251,500	2,251,500
		NVS	3,494,500	3,494,500
		INS	279,000	279,000
41	Lesotho	ISS	517,500	517,500
		NVS	482,500	482,500
		INS	110,500	110,500
42	Liberia	ISS	2,405,000	2,405,000
		NVS	633,500	633,500
		INS		
43	Madagascar	ISS	4,277,500	4,277,500
		NVS	13,801,500	13,801,500
		INS		
44	Malawi	ISS		
		NVS	32,586,000	32,586,000
		INS		
45	Mali	ISS	4,426,000	4,426,000
		NVS	3,267,500	3,267,500
		INS	780,500	780,500
46	Mauritania	ISS	1,062,000	1,062,000
		NVS		925,000
		INS	201,000	201,000

#	Country	Type of support	Prior 5-year commitment as of May 2004	Updated 5-year financial commitment
47	Moldova	ISS		
		NVS	442,000	442,000
		INS		
48	Mongolia	ISS		
		NVS		3,335,000
		INS		109,000
49	Mozambique	ISS	3,291,000	3,291,000
		NVS	15,975,500	15,975,500
		INS	986,000	986,000
50	Myanmar	ISS	7,902,500	7,902,500
		NVS	15,278,500	15,278,500
		INS	1,343,000	1,343,000
51	Nepal	ISS	4,494,000	4,494,000
		NVS	3,751,500	3,751,500
		INS	1,369,500	1,369,500
52	Nicaragua	ISS		
		NVS		
		INS		
53	Niger	ISS	5,027,000	5,027,000
		NVS		
		INS	1,012,000	1,012,000
54	Nigeria	ISS	53,020,000	53,020,000
		NVS	27,829,500	27,829,500
		INS		
55	Pakistan	ISS	32,508,000	32,508,000
		NVS	26,300,000	26,300,000
		INS	9,521,500	9,521,500
56	Papua N G	ISS		
		NVS		
		INS		
57	Rwanda	ISS	3,728,000	3,728,000
		NVS	21,513,000	21,513,000
		INS	406,000	406,000
58	São Tomé	ISS	65,500	65,500
		NVS	166,000	166,000
		INS	11,500	11,500

#	Country	Type of support	Prior 5-year commitment as of May 2004	Updated 5-year financial commitment
59	Senegal	ISS	3,983,500	3,983,500
		NVS	21,438,000	21,438,000
		INS	749,500	749,500
60	Sierra Leone	ISS	2,423,500	2,423,500
		NVS	1,474,500	1,474,500
		INS	312,500	312,500
61	Solomon Isl	ISS		
		NVS		
		INS		
62	Somalia	ISS	3,399,500	3,399,500
		NVS		
		INS	349,000	349,000
63	Sri Lanka	ISS		
		NVS	2,456,000	2,456,000
		INS	622,500	622,500
64	Sudan	ISS	8,968,500	8,968,500
		NVS	4,801,000	4,801,000
		INS	1,828,000	1,828,000
65	Tajikistan	ISS	1,510,500	1,510,500
		NVS	959,000	959,000
		INS	255,500	255,500
66	Tanzania	ISS	8,665,500	8,665,500
		NVS	30,178,000	30,178,000
		INS	1,510,000	1,510,000
67	Togo	ISS	1,945,500	1,945,500
		NVS	1,035,500	1,035,500
		INS	374,500	374,500
68	Turkmenistan	ISS		
		NVS	909,000	909,000
		INS	171,000	171,000
69	Ukraine	ISS		
		NVS	2,388,000	2,388,000
		INS	747,500	747,500
70	Uganda	ISS	11,794,500	11,794,500
		NVS	74,313,000	74,313,000
		INS	1,338,000	1,338,000

#	Country	Type of support	Prior 5-year commitment as of May 2004	Updated 5-year financial commitment
71	Uzbekistan	ISS		
		NVS	3,718,500	3,718,500
		INS	809,500	809,500
72	Viet Nam	ISS		
		NVS	11,650,000	11,650,000
		INS	3,296,500	3,296,500
73	Yemen	ISS	4,342,000	4,342,000
		NVS	44,019,500	44,019,500
		INS	1,238,000	1,238,000
74	Zambia	ISS	2,959,500	2,959,500
		NVS	33,591,000	33,591,000
		INS	762,500	762,500
75	Zimbabwe	ISS	3,220,000	3,220,000
		NVS		
		INS	1,319,000	1,319,000
	TOTAL	ISS	336,572,500	336,572,500
		NVS	638,891,500	660,760,500
		INS	84,872,000	85,519,500
			1,060,336,000	1,082,852,500

Annex 3



Report on Executive Committee Retreat

Washington, DC — June 2-3, 2004

The Executive Committee retreat was intended to facilitate GAVI Board discussions at the upcoming July meeting so that the Board can reach closure on the important strategic issues that it faces. EC discussion focused on four topics, each of which was addressed in a short issue paper. The issue papers were circulated to the Board and written comments from Board members were shared with the EC.

The retreat offered the opportunity for the EC to thoroughly explore a number of important issues facing the Alliance on behalf of the Board. Discussion at the retreat was candid and detailed. Based on that discussion, the EC formulated a number of recommendations to the Board. A summary of the discussion follows. Recommendations can be found in the box at the end of this report.

Long-term priorities and the role of GAVI and Alliance partners (“Strategy”)

About half of the retreat was devoted to the issue of GAVI’s strategy and to developing recommendations for clarifying GAVI’s role and that of its partners in the global vaccination enterprise. The following insights were developed:

GAVI has two basic functions:

- 1) **Vaccine Fund direction:** Providing guidance to The Vaccine Fund on the use of its resources.
- 2) **Working together for greater impact:** Working together as an Alliance towards common immunization goals in order to bring greater synergy and harmonization to the efforts of all partners.

The EC also discussed and elaborated on the specific activities that each of these functions might include.

Vaccine Fund direction

Principles

The EC felt that it would be appropriate for GAVI to recommend that The Vaccine Fund invest only in activities that meet the following principles:

- *Time-limited:* The funded activities will not depend indefinitely on Vaccine Fund support, although the specific scope of the time limit may need to be discussed on a case-by-case basis.
- *Additionality:* The activities are new activities funded by new money.
- *Information available:* Adequate information is available to assess the activities with respect to the criteria below.

- *Unique.* There is no one else positioned to undertake these activities more effectively than GAVI.
- *Catalytic step function.* The activities lead to a step-up functional change in a current situation through innovative processes by fulfilling at least one of the following:
 - Add substantial impact beyond the specific activities that are funded.
 - Have an impact that lasts longer than the funding.
 - Develop innovative models that could be applied more broadly.
 - Are capital investments or one-time expenses that lead to a new level of performance.

Criteria for choosing priorities

The Vaccine Fund does not have sufficient funds to invest in all activities that meet these principles. Therefore, the following criteria are useful for GAVI to prioritize its activities and guide its choices among those activities that meet the above principles:

- *Sustainability.* The activities can, within the timeframe of VF funding, become sustained by other global or local sources of support, or do not need to be sustained in order to have accomplished their catalytic purpose.
- *National priorities.* The activities include some mechanism for countries to determine whether or how to implement the activities based on their needs. In most cases, funds will flow directly to countries unless a strong case for an exception is made.
- *Effective.* Countries have the means to make the activities happen.
- *Cost effective.* The activities provide high return for the investment.
- *Investment case.* The Board is presented with a full analysis and complete documentation of the potential impact of the proposed activities in order to decide whether there is a sound case for investment.
- *Equitable.* The activities include some element of equity within and between countries.
- *Partner commitments.* Alliance partners do not have responsibilities that would preclude their involvement in key required activities.
- *Impact on MDGs.* The activities will positively affect achievement of the immunization-related Millennium Development Goals.
- *Country focus.* Only on an exceptional basis does funding go to another agency or partnership rather than to countries. (Examples of exceptions include the Yellow Fever Stockpile and the, proposed Measles Investment case.)

Strategic priorities

Using these principles to assess current activities, the EC feels the following strategic priorities are important and worthy of VF funding:

- *Scale up of existing vaccines*—where activities are limited to those that meet the above principles, including, for example, measles control activities associated with initial “catching up” but not sustaining ongoing measles activities.
- *Support for underutilized vaccines*—where activities are limited to those that meet the above criteria.
- *Accelerated introductions of vaccines and vaccine technology*—including, for example planning for the introduction of new but not yet licensed vaccines and assessment of the disease burden.
- *Immunization safety*—where activities are limited to those that meet the above criteria.

- *Providing ISS funding*—where activities are limited to those that meet the above principles, for example those related to the development, assessment and dissemination of innovative models.
- *Support of value-added activities* identified as part of the work plan process.

The EC further noted that upstream support for R&D on new vaccines does not meet the above principles and should not be funded by The Vaccine Fund.

Finally, the EC noted that GAVI needs a process to make decisions about future investments in a manner that is consistent with the above principles and criteria.

Working together for impact

GAVI also has a role to play help Alliance partners work together to maximize the impact of their immunization-related activities. The EC articulated this role to include the following:

Messaging

The Alliance has a role to play in raising the priority of immunization among donors and developing countries. In playing this role, it needs to do a much better job of coordinating and improving its messaging to emphasize, and clarify some key points for donors and developing countries. These points are articulated below and in figure 1.

- Immunization activities of many types, including maintenance of current activities and new activities, are needed to close the gap with MDG and WFFC goals.
- The VF focuses on a limited set of activities within a wide arena relative to the total immunization enterprise. The success of the global vaccination effort depends on a much broader set of activities of many different players.
- Within the area in which the VF (or any other organization) operates, it does not “own” that arena. It does not fund all of the activities, and does not have a special claim to all of the resources devoted to those activities.
- The EC felt that the Global Immunization Strategy being developed by WHO and UNICEF would serve as an important guide for situating the new strategic understanding of GAVI and the contributions of the VF in the broader immunization context. This was thought particularly relevant to better understanding the gap between current activities and resources and those needed to meet the MDG and WFFC goals. The EC advised WHO/UNICEF to

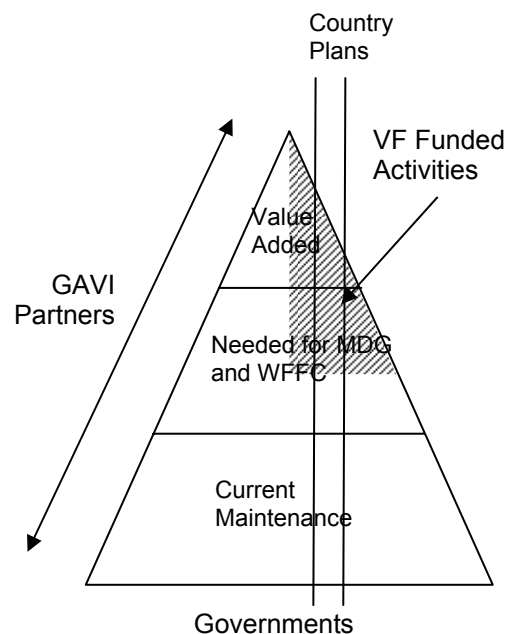


Figure 1

continue the process they have launched ensuring that a strong formal consultative process is undertaken that includes GAVI and the other Alliance partners and the broader immunization community. The Global Immunization Strategy acknowledges the special role that governments play in the execution of strategy and the necessity of its development in a manner that is informed by country needs.

GAVI work plan

The EC felt that a broader value-added Alliance work plan that encompasses the following is also desirable:

- The Secretariat's activities in support of the Board and governance of the Alliance.
- Activities needed to ensure adequate administration and oversight of VF funded programs through the VF EC and Board and UNICEF, which manage the Trust Account.
- Limited additional value added activities of the Alliance.
- Activities that help Alliance partners work in concert for optimal impact on immunization issues.

This work plan needs to be developed in a manner that is:

- Partner generated
- Focused on value added activities
- Focused on activities not done elsewhere

The EC noted in its deliberations that this strategy is not entirely consistent with the existing mission statement or published strategic objectives of GAVI. These statements may need to be reviewed and revised if the Board decides to adopt the strategy as described here.

Optimal structures and processes for GAVI and The Vaccine Fund moving forward (“Governance”)

The large number of questions about the quality of Board support and interaction, the role of the Secretariat, and convergence of the VF and GAVI posed in Issue Paper #2 are, in part, a function of the increasing complexity of GAVI and VF activities in recent years. Some problems are generic difficulties of all alliances.

Governance processes

The EC felt that GAVI should identify a special committee to address the variety of process and structural issues identified in Issue Paper #2 and comments by GAVI Board members and others in reaction to the paper. The GAVI chair should identify a special sub-group, including members of the Board, to prepare a report for the Board with recommendations addressing these issues, including, but not limited to:

- The Board agenda.
- Preparation time for Board members.
- Support for Board members in decision-making and other mechanisms to assure wider engagement of the range of partners in Board processes and decisions.
- Clarity of decision-making at Board meetings.
- The authority of the EC in relation to the Board.
- Management evaluation of Board/EC/Working Group roles and relationships.

- Style of communication between Board/EC/Working Group.

Convergence

The Executive Committee supported proceeding to implement structural convergence of the GAVI Secretariat and the VF in light of the discussion at the retreat clarifying the scope of GAVI's activities in relation to the VF. However, it was agreed that this decision should be contingent on the deliberations of the board, and that those deliberations should be supported by information on the costs and benefits and strategic implications of convergence. The EC requested that in addition to the report on convergence prepared earlier this year, a supplementary report be prepared with the goal of making it available, if possible, for the July GAVI Board. This report should address:

- Issues of messaging of the combined secretariats taking into account the strategy clarification recommended by the EC, and the strategic implications and advantages of reorganizing GAVI and the VF in this manner,
- Cost and savings related to combining staffs, assessing headcount of the combined GAVI/VF staff, relocation costs and office space, and
- Any other information needed to clarify the ramifications of this decision.

CFAR agreed to submit to the Executive Committee by June 11 a plan outlining the work necessary to prepare such a report.

Resource requirements for immunization in general, and GAVI and The Vaccine Fund within that context (“Financing”)

- The EC felt that the Alliance needs a shared understanding of the total funding needed to close the gap between current activities and achieving the WFFC and MDG goals. A shared view is being developed through the IFF planning process and the UNICEF/WHO global immunization strategy process, and other Alliance partners will be consulted in the development of this analysis.
- The EC recognized that Alliance partners will sometimes coordinate and sometimes pursue independent fundraising activities, but all activities will be more effective if they make reference to the same immunization strategy and funding gap.
- Fundraising activities will also be more effective if partners are consistent in what they say about each other's roles in the strategy. Messaging needs to be developed about these roles. (Message about the VF role needs to include principles and criteria developed above)
- Fundraising approaches will need to be flexible as the donor landscape shifts.
- The EC agreed that the IFF is an excellent potential example of the importance of coordination between Alliance partners on fundraising.

Currently, the VF, World Bank, Gates Foundation, WHO and UNICEF are working with some donors to design an IFF immunization pilot and determine whether it is a workable model.

At a later date, it will be important to define how the money will flow to countries and activities. The Alliance will be consulted at that point regarding but it is first important to determine that the IFF is a workable model and will be funded by donors. The EC was not explicit about the scope of Alliance consultation.

Long-term procurement strategy (“Supply”)

The EC discussed and recommended two sets of activities to address the concerns that have been raised with respect to vaccine procurement and long-term supply.

1) Procurement: UNICEF and the Gates Foundation will convene a small steering group to elicit suggestions from the EC and design a process to review and address procurement concerns. This process can begin immediately. It was felt there were a number of specific issues concerning pentavalent and rotavirus vaccines.

2) Hib: Urgent issues also need to be addressed regarding Hib:

- Discussions among several partners have been underway on this, and the Secretariat will coordinate a small group to organize a session at the July Board to highlight these urgent issues.
- The EC felt that following the Board discussion it may be appropriate to charge one or two small group(s) to quickly make recommendations for moving forward.

Recommendations

Strategy

1. The EC recommends that the Board adopt as a revised definition of GAVI’s role the two basic functions as described on pages 1 - 4 of this report, including:

- The *principles* described on pages 1 - 2 to determine the types of activities GAVI will consider for VF funding
- The *criteria* described on page 2 to prioritize and choose among the many different activities that meet the VF principles
- The *strategic priorities* described on page 3 to describe the activities that the VF is currently committed to supporting.
- The approach and components of the *working together for impact* function described on pages 3 - 5, notably:

Coordination and improvement of *messaging*, particularly with regard to describing the roles of GAVI Secretariat, The Vaccine Fund and Alliance partners in the global vaccine effort. In this context, the EC welcomes the effort underway by the WHO and UNICEF, in consultation with Alliance partners, to develop a Global Immunization Strategy
Continued use of a *work plan* for Alliance value-added activities

2. The EC recommends that the Board put in place a process to revise the mission statement and objectives to reflect this understanding of GAVI’s scope. (In this context it may also be necessary for the VF mission and objectives to be revised.)

3. The EC recommends that a process be developed, or the investment case process revised to enable the Board to make decisions about GAVI activities based on the principles, criteria and strategic priorities described above.

Governance

4. The EC recommends that the Chair of the GAVI Board appoint a task force as described on page 5 of this report to address the many complex issues concerning GAVI processes and governance identified there.

5. Pursuant to the report to be delivered on the costs and benefits of convergence, including strategic issues as well as the messaging issues, the EC recommends that the Board move forward with structural convergence between the Vaccine Fund management structure and GAVI Secretariat.

Financing

6. The EC recommends that GAVI adopt a common understanding of the financing gap between current activities and those needed to meet immunization-related MDG goals. This financing gap can be developed using the processes already in place for IFF financing and the WHO/UNICEF global immunization strategy.

7. The EC recommends that a process be developed to ensure that messages about the scope and mission of GAVI and The Vaccine Fund that are developed by the Secretariat, Vaccine Fund or Alliance partners are consistent and reflect the revised understanding described above.

Vaccine supply

8. Pursuant to the presentation on Hib at the July Board meeting, the EC recommends that a small group be appointed to develop recommendations for addressing concerns in this area.

Annex 4



Optimal Structures and Processes for GAVI and The Vaccine Fund Moving Forward

*Recommendations from the EC Retreat and
Supplementary Report to the GAVI Board on Convergence
July 6, 2004 – Washington, DC*

Introduction

The Executive Committee at its June retreat recommended to the GAVI Board that it move forward with structural convergence of the GAVI Secretariat and The Vaccine Fund (VF). This recommendation followed from clarification of the scope of GAVI's activities in relation to the VF, and was contingent on a supplementary report on messaging issues of the combined secretariats, taking into account the strategic implications and advantages of reorganizing the GAVI and VF secretariats, and the costs and savings of combining staffs and relocation.

Subsequent to that decision, the messaging issue was taken up as a separate discussion under the leadership of the Gates Foundation. This report, then, discusses the strategic significance of convergence, as well as its costs and risks. It includes the following:

- Strategic context of convergence
- Strategic risks and benefits
- Operational risks and benefits
- Cost analysis
- Implementation Issues

Strategic context of convergence

The strategic implications of convergence are significantly shaped by the revised understanding of the role of GAVI and The Vaccine Fund, recommended by the EC during its retreat. Key components of that recommendation are illustrated in the figure at the right and described below.

- The VF focuses on a limited set of activities throughout the total immunization enterprise.
- Within the area in which the VF (or any other organization) operates, it does not “own” that arena.

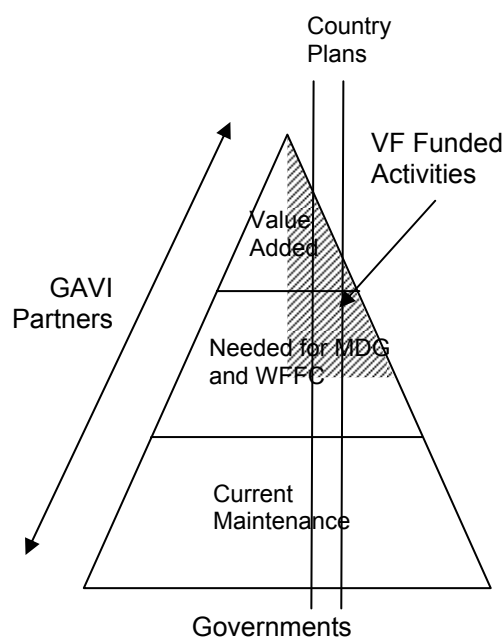


Figure 1

- The Global Immunization Strategy forthcoming from WHO/UNICEF can serve as an important guide for situating the new strategic understanding of GAVI and the contributions of the VF in the broader immunization context.

It is essential to remember that the success of the Alliance, The Vaccine Fund and the GAVI Secretariat make this opportunity possible. Success has led to growth and complexity. Convergence is one response to that complexity. Further much of the success is attributable to outstanding staff and leadership. This opportunity must, therefore, be treated with care so as not to damage the capabilities that have made the Alliance a success to date.

Strategic risks and benefits of convergence

Every reorganization has associated risks and benefits. The table below outlines some potential risks and benefits that convergence poses to GAVI:

Risks

- Disruption to ongoing operations
- Cultural differences may make integration difficult
- Partner concerns about fundraising and advocacy might make it hard for a single leader to serve as a fundraiser
- Partner concerns about the size of the combined entity may reduce the secretariats below effective size

Benefits

- Closer coordination of Alliance and Vaccine Fund activities
- More effective fundraising through closer coordination of fundraising and other Alliance activities.
- Simplified interactions with partners
- Reduced potential for conflict between independent leaders

Benefits and risks turn on whether the Alliance, particularly UNICEF, the WHO, the Board and EC, embraces (or fails to support) the fundraising/advocacy function of The Vaccine Fund. For example, should the Secretariat and VF staff converge under a single roof and single leader, one could imagine the following alternative outcomes.

If partners are uncomfortable with the Executive Secretary of GAVI playing an active and explicit fundraising or advocacy role, convergence could dramatically limit the effectiveness of the GAVI/VF fundraising. Fewer resources would thus be available for Vaccine Fund supported GAVI activities.

If, on the other hand, partners actively embrace a collaborative approach to advocacy and fundraising, including some joint and some separate activities, as envisioned above, convergence could ease and facilitate that collaboration. These joint efforts have the potential to improve the effectiveness of fundraising for the Alliance as well as for partners, bringing more resources to the global immunization enterprise.

Operational risks and benefits of convergence

In addition to these strategic risks, there are some concrete operational risks and benefits of converging the VF with the Secretariat. These include:

	Risks	Benefits
Location	<ul style="list-style-type: none"> • Time and costs to establish legal status of employees may be significant • Some donors may prefer an EU location • Geneva is more expensive than Lyon 	<ul style="list-style-type: none"> • Greater opportunity for VF staff to interact with global health leaders in Geneva
Co-location	<ul style="list-style-type: none"> • Tension between staff with similar roles but different pay scales and benefits packages 	<ul style="list-style-type: none"> • Opportunity to make use of the best resources offered by each entity
Transition	<ul style="list-style-type: none"> • Key staff may not want to move • Costs of transition are significant 	<ul style="list-style-type: none"> • Rationalize skills needed to staff new structure • Long-term costs may be lower if the VF expects to move in the future
Shared Information		<ul style="list-style-type: none"> • Integrated work plan and budget makes strategic thinking easier • More visibility around timing of liabilities can improve investment planning • Greater efficiency carrying out related or sequential tasks

Cost analysis

Subsequent to the request of the Executive Committee, CFAR prepared a cost analysis of the one-time costs of transition and the ongoing savings gained from convergence. To complete this analysis, CFAR served as an "integrator" of information gathered from various sources. In particular, we worked with the financial staffs of the Secretariat and VF to identify and review cost data, and the VF further engaged EY Law to bring expertise on French labor law.

Using a base case, CFAR estimated a range of one-time transition costs as well as ongoing costs under two staffing scenarios. Both of these staffing models are based on current organizational design and functions. The base case assumptions were:

- The GAVI Secretariat and Vaccine Fund management structure share common premises
- Both staff organizations report to a single leader

- Vaccine Fund employees will remain employees of The Vaccine Fund (a private organization) and Secretariat employees will remain employees of UNICEF
- The entities retain separate boards
- Vaccine Fund staff members located in Washington, DC will remain in Washington, DC
- Staffing levels will be based on the assumption that the Secretariat and Vaccine Fund carry out functions consistent with the roles described in the EC retreat
- The common premises will be located in Geneva

Based on these assumptions, we estimated the one-time transition costs and ongoing costs of operation of a combined GAVI/VF staff entity as follows:

Summary of One-Time Costs of Transition (also see appendices G and K)

IN U.S. dollars '000

Location:	Geneva				Ferney Voltaire			
	Number of Ongoing Posts:		Number of Ongoing Posts:		Number of Ongoing Posts:		Number of Ongoing Posts:	
	35 Ongoing Posts		42 Ongoing Posts		35 Ongoing Posts		42 Ongoing Posts	
Item	Minimum	Potential	Minimum	Potential	Minimum	Potential	Minimum	Potential
Total One Time Move	3,664	7,783	3,110	6,353	3,392	7,541	2,838	6,112

Summary of Ongoing Operating Costs (also see appendices H and L)

IN U.S. dollars '000

	Current	Base Case		Ferney Voltaire		Two Leaders	
Item		42 Posts	35 Posts	42 Posts	35 Posts	42 Posts	35 Posts
Total Operating Expenses	17,108	16,198 - 17,671	14,753 - 16,063	16,374 - 16,858	\$14,929 - 15,413	16,606 - 18,279	15,161 - 16,672

The ranges included in these estimates are quite wide, and reflect a significant degree of uncertainty in several key areas, including:

- Design of converged entity—CFAR assumed a high of 42 ongoing posts and a low of 35 ongoing posts (Affects operating expenses and transition costs)
- Some staff may choose not to move (Affects HR transition costs only)
- Separation payments above statutory minimum (These are policy decisions of The Vaccine Fund)
- Cost of living salary adjustments for staff moving from Lyon to Geneva (affects operating costs)
- Choice and cost of space in Geneva (Affects operating expenses and transition costs)
- Ambition of IT integration (Affects transition costs only)
- Choice of integration support (Affects transition costs only)

Based on our understanding of business practices and labor law in France, there are excellent reasons for an organization to consider separation payments above the statutory minimum. Thus, it would be prudent to expect transition costs to be closer to the potential level than to the statutory minimum.

Implementation issues going forward

Should the Board decide to move forward with convergence, there are pressures both to move quickly and to act deliberately and slowly. On the one hand, it would be desirable to undertake many of the difficult convergence decisions prior to the arrival of a new leader, while staff are still under the guidance of leaders they know and trust, and so that the new leader can have an easier entry. In addition, rapid and orderly completion of the transition can help to signal stability to donors. However, there are a number of complex legal issues to resolve particularly regarding the status of the VF and its staff, and a number of decisions to make, all of which may take some time. Some of the most significant decisions to be made include:

- **Staffing.** Who will play what role?
- **Design.** What will the reporting relationships be?
- **Incentives.** What kinds of incentives might be helpful to facilitate the transition?
- **Legal Status.** What legal status will the VF and its employees have?
- **Location.** Find and set up space
- **Technology.** Design and set up the infrastructure (Current system may be inadequate for converged entity.)
- **Accounting.** Will there be one or two accounting systems?
- **Board** configuration and relationship: How will the two governance bodies coordinate?

Given these complex issues, we recommend the immediate formation of two transition teams, one focused on the issues and decisions concerning the convergence of the staff, and the second on the issues concerning the Board. These teams might find it helpful to also seek the guidance of a neutral third party, possibly an expert in mergers or organizational consultant. One possible work plan for a transition process is included in Appendix M. Key early tasks will be an exploration of the legal issues and options regarding the status of the VF and its staff, as well as quick identification and resolution of the issues causing the greatest uncertainty to key staff and donors.

Annex 4.1



Appendices

Appendix A: Process to Estimate Costs

- CFAR served as an 'integrator' of information gathered from various sources over the past month
 - Worked with financial staff of the Secretariat and VF to identify and review costs
 - ◆ VF brought in EY Law to bring expertise in French labor law to the assessment of transition costs and implications of change of location for downstream operating costs
 - Staffing models are based on *current organizational design* and areas of overlap
 - Ranges and scenarios, rather than point estimates, are shown to indicate variance
-

Appendix B: Current Governance of Two Entities

GAVI Board

- 5 Renewable Members (Gates Foundation, UNICEF, WHO, World Bank and VF)
- 11 Rotating Members representing constituencies engaged with immunization enterprise

GAVI EC

- 5 Renewable Members
- 1 Developing Country Representative
- 1 Industrialized Country Representative
- JW Lee - Chair

Vaccine Fund Board

- 3 members representing key institutions (Gates Foundation, VF President and Secretariat)
- 12 Members who bring fundraising potential

Vaccine Fund EC

- 3 members representing key institutions (Gates Foundation, VF President and Secretariat)
 - Chip Lyons - Chair
-

Appendix C: Current Staffing¹

Function	VF Staff Lyon	VF Staff Washington	Secretariat Staff	Total Staff
Leadership and Coordination	5	0	6	11
Resource Mobilization and Communications	11	5	2	18
Finance and Operations	3	5	2	10
Program Support	1	1	6	8
Total	19	12	16	47

¹ includes temporary employees

Appendix D: Current Operating Budgets¹

IN USD 000

Item	Vaccine Fund	Secretariat	Total
Payroll and Benefits	\$5,013	\$2,549	\$7,563
Total Facility and Office Costs ¹	589	330	919
Total Telecom and Data ²	963	40	1,003
Supplies and Equipment	79	60	139
Training and Recruitment ³	408	0	408
Other ⁴	6,186	890	7,076
Total Operating Expenses	\$13,238	\$3,869	\$17,108

1. Secretariat figure includes HR, Admin and IT support services offered by UNICEF. VF figure includes office overhead including security, insurance, furniture and postage and delivery.
2. VF figure includes IT support.
3. Secretariat includes training and recruitment in the total cost for an FTE.
4. Other includes categories that do not change with convergence: professional fees, media production and distribution, events and media, travel and representation, and financial income/expense


¹ VF 2004 Budget and Secretariat 2005 Workplan

Appendix E: The Base Case of Convergence

- The GAVI Secretariat and Vaccine Fund management structure share **common premises**
- Both staff organizations report to a **single leader**
- Vaccine Fund employees will remain **employees of the Vaccine Fund** (a private organization) and Secretariat employees will remain **employees of UNICEF**
- The entities retain **separate boards**
- Vaccine Fund staff members located in **Washington, DC** will remain in Washington, DC
- Staffing levels will be based on the assumption that the Secretariat and Vaccine Fund carry out **functions** consistent with the roles described in the EC retreat
- The common premises will be located in **Geneva**

Appendix F: Staffing Assumptions—Base Case

Function	Total Staff	Potential Efficiency gains	Potential size of converged entity
Leadership and Coordination	11	3-6	5-8
Resource Mobilization and Communications	18	0-2	16-18
Finance and Operations	10	1-2	8-9
Program Support	8	1-2	6-7
Total	47	5-12	35-42



Convergence is only an advantage if you preserve and enhance the value of the two entities. You do not want to cut staff to the point where you reduce effectiveness.

Appendix G: Transition Costs Summary—Base Case

In USD 000

Number of Ongoing Posts:	35 Total Ongoing Posts		42 Total Ongoing Posts	
	Minimum Cost	Potential Cost	Minimum Cost	Potential Cost
Item				
Human Resources ¹	\$1,494	\$3,151	\$941	\$1,721
Contract Termination ²	582	582	582	582
Move of Office Furniture and Equipment	159	159	159	159
Adaptation of New Premises	290	960	290	960
IT Costs ³ Merger of GAVI VF systems	100	1,207	100	1,207
Advisor Costs ³	1,039	1,724	1,039	1,724
Total One Time Move	\$3,664	\$7,783	\$3,110	\$6,353

1. Includes relocation expenses, relocation incentives, separation payments.
2. Includes lease termination and termination of service contracts.
3. Includes fees for legal counsel and support for integration teams.

Appendix H: Operating Expenses—Base Case

In USD 000

Item	Current	42 Ongoing Posts		35 Ongoing Posts	
		High	Low	High	Low
Payroll and Benefits	\$7,563	\$7,864	\$7,051	\$6,468	\$5,818
Total Facility and Office Costs ²	919	1,316	656	1,316	656
Total Telecom and Data	1,003	909	909	795	795
Supplies and Equipment	139	125	125	100	100
Training and Recruitment ³	408	381	381	308	308
Other ⁴	7,076	7,076	7,076	7,076	7,076
Total One Time Move	\$17,108	\$17,671	\$16,198	\$16,063	\$14,753

1. Range due to different COLA assumptions.
2. Range due to the difference of location within Geneva and the amount of overhead needed depending on location.
3. Total Telecom and Data, Supplies and Equipment and Training and Recruitment were calculated on a per person basis using current budgets for the two offices of VF and the Secretariat.
4. Other includes categories that do not change with convergence: professional fees, media production and distribution, events and media, travel and representation, and financial income/expense.

Appendix I: Location Variation— Ferney Voltaire

Why consider it?

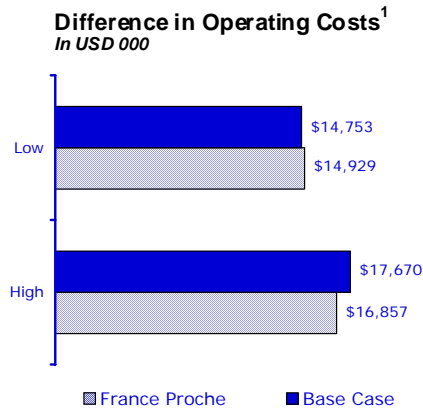
- Avoids some of the legal and immigration issues with Switzerland (and may replace them with others)

How it works

- Secretariat and VF staff co-locate in France, near Geneva

Challenges

- May not capture all the benefits of being in Geneva



1. Differences result from COLAs and Facilities Costs. Difference in Transition Costs is about \$200,000.

Appendix J: Leadership Variation— Two Leaders

Why Consider it?

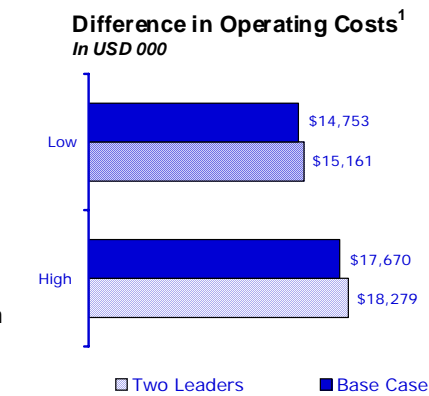
- Swiss Government and partner concerns about “immunity creep”

How it Works

- One leader can be asked to take substantial direction in his/her work from the other while formally reporting to a different board.

Challenges

- It is more complicated to move toward a fully integrated design with two leaders
- There is more opportunity for disagreement between the leaders



1. Differences result from additional leader in Payroll and Benefits and slightly higher per person costs for Total Telecom and Data, Supplies and Equipment and Training and Recruitment.

Appendix K: Comparison of Transition Costs

IN USD 000

Location:	Geneva				Ferney Voltaire			
	35 Ongoing Posts		42 Ongoing Posts		35 Ongoing Posts		42 Ongoing Posts	
Item	Minimum	Potential	Minimum	Potential	Minimum	Potential	Minimum	Potential
HR Costs ¹	\$1,494	\$3,151	\$941	\$1,721	\$1,494	\$3,151	\$941	\$1,721
Contract Termination ²	582	582	582	582	499	499	499	499
Move of Office Furniture and Equipment	159	159	159	159	112	112	112	112
Adaptation of New Premises	290	960	290	960	290	960	290	960
IT Costs—Merger of GAVI VF Systems	100	1,207	100	1,207	100	1,207	100	1,207
Advisor Costs ³	1,039	1,724	1,039	1,724	896	1,581	896	1,581
Indirect Costs of Non-activity ⁴	-	-	-	-	-	31	-	31
Total One Time Move	\$3,664	\$7,783	\$3,110	\$6,353	\$3,392	\$7,541	\$2,838	\$6,112

1. Includes relocation expenses, relocation incentives, separation payments.
2. Includes lease termination and termination of service contracts
3. Includes fees for legal counsel and support for integration teams
4. Cost estimated by the VF

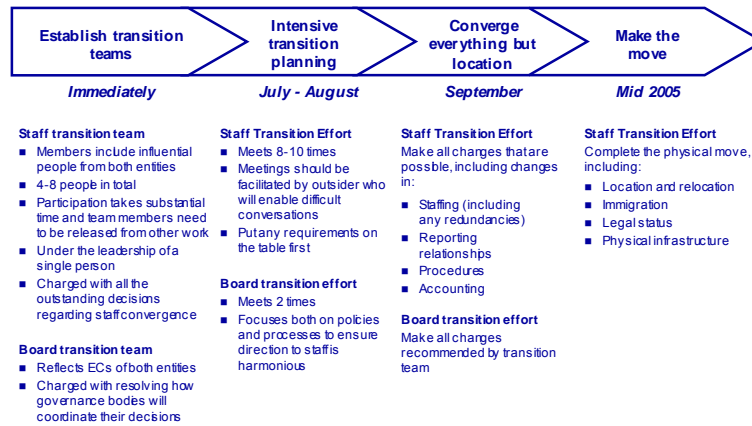
Appendix L: Comparison of Operating Expenses

IN USD 000

Item	Current	Base Case		Ferney Voltaire		Two Leaders	
		42 Posts	35 Posts	42 Posts	35 Posts	42 Posts	35 Posts
Payroll and Benefits ¹	\$7,563	\$7,051 - 7,864	\$5,818 - 6,468	\$7,051	\$5,818	\$7,430 - 8,443	\$6,196 - 7,047
Total Facility and Office Costs ²	919	656 - 1,316	656 - 1,316	832 - 1,316	832 - 1,316	656 - 1,316	656 - 1,316
Total Telecom and Data ³	1,003	909	795	909	795	936	822
Supplies and Equipment	139	125	100	125	100	126	101
Training and Recruitment	408	381	308	381	308	382	310
Other ⁴	7,076	7,076	7,076	7,076	7,076	7,076	7,076
Total Operating Expenses	\$17,108	\$16,198 - 17,671	\$14,753 - 16,063	\$16,374 - 16,858	\$14,929 - 15,413	\$16,606 - 18,279	\$15,161 - 16,672

1. Range due to different COLA assumptions and compensation of 2nd leader.
2. Range due to the difference of location within Geneva and the amount of overhead needed depending on location.
3. Total Telecom and Data, Supplies and Equipment and Training and Recruitment were calculated on a per person basis using current budgets for the two offices of VF and the Secretariat.
4. Other includes categories that do not change with convergence: professional fees, media production and distribution, events and media, travel and representation, and financial income/expense

Appendix M: A Plan to Address these Dilemmas and Decisions



Annex 5

Addendum to the Measles Investment Case

*Submitted to the GAVI Board
by WHO (on behalf of the Africa Measles Partnership)
and the GAVI Secretariat*

During its 6 May 2004 teleconference, the GAVI Board gave conditional approval to a proposal by the Africa Measles Partnership to use US\$ 50 million in Vaccine Fund resources over 5 years for accelerated and sustained measles mortality reduction activities in Africa. There was consensus that the case for GAVI to invest in measles was compelling.

However, some concerns were raised about how to ensure that the investment would:

- a) be **aligned with GAVI/Vaccine Fund's strategic vision**. Indeed, The Vaccine Fund should not be considered as 'just another donor';
- b) capitalize on **front-loading** and be **time-limited**. This implies that the activities proposed for funding make sense as a one time investment, comparable to new antigen introduction or one-time system strengthening;
- c) **provide a "step-change" in immunization** through **innovative processes** that will be sustained by non-Vaccine Fund resources at this new level of performance; and
- d) build on **country-owned** processes that will be amenable to review and accountability mechanisms that characterizes GAVI.

Further, some Board members felt that additional clarification was needed to propose specifically how Vaccine Fund resources would be used and to assure that routine immunization services would be enhanced and not harmed in countries implementing the proposed program.

The Board therefore requested the Director of the WHO Department of Immunization, Vaccines & Biologicals (IVB) and the GAVI Executive Secretary to prepare the present addendum to the Measles Investment Case for circulation to Board members to address Board concerns and to provide options for moving forward. This response was prepared with input from the Measles Partnership as the originators of the proposal submitted to, and approved by, the GAVI Board.

1. Measles mortality reduction and the GAVI/Vaccine Fund strategic vision

Given that measles is the leading cause of vaccine-preventable mortality of children, an investment in accelerated and sustained measles mortality reduction is fully aligned with GAVI's mission "*to protect children of all nations and of all socioeconomic levels against vaccine-preventable diseases*". As outlined in the Statement on an Immunization System Strengthening Approach to Measles Mortality Reduction issued during its 9th Board Meeting, GAVI supports the full implementation of the WHO-UNICEF recommended strategy for measles mortality reduction, including the strengthening of immunization systems and conducting periodic measles supplementary immunization activities. Moreover, measles mortality reduction represents a major step towards the achievement of four of GAVI's six strategic objectives:

- Improve access to sustainable immunization services;
- Expand the use of all existing safe and cost-effective vaccines, and promote delivery of other appropriate interventions at immunization contacts;
- Support the national and international accelerated disease control targets for vaccine-preventable diseases;
- Make immunization coverage a centerpiece in international development efforts.
- In addition, supporting measles mortality reduction activities is completely in line with the Vaccine Fund's mission "*to ensure that every child, everywhere has equal access to life-saving vaccines*".

2. Front-loaded, time-limited, one-time funding

As stated in the IFF proposal, the ultimate case for an early investment (frontloading) is the positive yields in global public goods. The strongest argument for frontloading investment in any immunization activity is the significant humanitarian benefit of a reduction in mortality and morbidity in a manner that reduces overall long-term costs.

In countries with low vaccination coverage for diseases such as measles, it is essential to protect the susceptible population as quickly as possible. This is most effectively done through campaigns. Large "catch-up" campaigns result in protection of the individuals vaccinated directly but also help to protect the unvaccinated by limiting the chances that they will be exposed to the virus. In the case of measles, once the routine system for delivering vaccine is sufficiently robust, the need for and cost of campaigns can largely be replaced by routinely providing a routine "second dose" of vaccine. Early investment in campaigns is therefore particularly effective in saving lives in countries with limited routine delivery systems while the health system can be geared up to do this as part of its routine primary health care service delivery. Further, early investment in building systems if well targeted will limit the need for future campaigns.

There are a number of economic benefits to frontloading investments in measles immunization, including: a) cost savings to the health system of preventing rather than treating measles, especially in epidemic settings; b) improved productivity of households as a result of better health; and, c) general economic gains or returns to investment on immunization. Analyses have demonstrated the cost savings argument, most particularly for measles; numerous reports in the literature support the notion that families/households with healthier children have higher incomes, allocate their resources in healthier ways, and have other benefits. The savings generated for the health system could potentially be reallocated into other cost-effective priority health interventions. Early findings from ongoing studies of the broader economic impact show that

investment in the vaccine preventable disease mortality reduction can be expected to yield an economic rate of return of 10-20 percent or more, similar to that of primary education.

The Africa Measles Partnership fully understands that The Vaccine Fund investment is time-limited for the period 2005-2009 and that no further funding should be expected from this source for this purpose beyond this period. The overall purpose of this "front-loaded" investment is to help high burden countries in Africa rapidly decrease measles morbidity and mortality by facilitating the implementation of a comprehensive, long-term strategy for accelerated and sustained measles mortality reduction.

The Vaccine Fund support would be used primarily to implement "catch-up" campaigns in the 10 African countries that have not yet conducted them. This support will complement ongoing Vaccine Fund efforts to strengthen immunization systems through Immunization Services Support (ISS) funding. As presented in the Measles Investment Case, during the project period efforts will be made to assure financial sustainability of measles mortality reduction activities through national funding and bilateral aid.

3. Provide a "step-change" in immunization through innovative processes: Maximizing benefits, minimizing potential negative impact of measles campaigns on routine immunization

At the GAVI Executive Committee Retreat (June 2-3, 2004) a list of five principles for the use of Vaccine Fund resources were recommended including "catalytic step function" as follows:

"*Catalytic step function*": The activities lead to a step-up functional change in a current situation through innovative processes by fulfilling at least one of the following:

- i. Add substantial impact beyond the specific activities that are funded
- ii. Have an impact that lasts longer than the funding
- iii. Develop innovative models that could be applied more broadly
- iv. Are capital investments or one-time expenses that lead to a new level of performance."

With reference to the Measles Investment Case the following can be highlighted:

- 1) The impact of the proposed activities extend beyond those being funded in several ways including: herd immunity which protects those who remain unimmunized; and the economic savings that result from better health and lower treatment spending.
- 2) These activities particularly the campaigns can result in long-term declines in the rate of measles transmission further extending the benefits described above, both due to immediate reductions in the numbers of susceptibles and longer-term because of the greater efficacy of the vaccine when given to older age groups.
- 3) Providing support to higher performing countries to introduce a routine 2nd dose of measles is a model for longer term sustainability. Moreover, establishing immunization contacts beyond the 1st year of life provides additional benefits in strengthening the ability of health systems to deliver "immunization plus" services (e.g. vitamin A supplementation, anti-helminthics, bednets, etc).

- 4) The text below describes in detail how the one time capital investment requested will lead to new levels of performance both for measles mortality reduction and the overall immunization system.

An investment in measles will result in a rapid and sustained reduction in measles deaths in Africa. With GAVI/Vaccine Fund's additional support and that of other partners, measles mortality in the 35 target countries¹ can be reduced by 85% from current estimates of 332,000 annual deaths, to 52,000 annual deaths by 2009. Since large measles outbreaks will no longer be a regular event, health care workers' time will no longer be diverted to responding to measles outbreaks.

Although measles vaccine has been available for over 40 years, appropriate strategies for its use have only recently become apparent. Experience from many countries has shown that achieving and maintaining reductions in measles deaths will require providing all children with a **second opportunity for measles immunization**.

The need for a second opportunity for measles immunization arises from the highly infectious nature of measles, the fact that 10-20% of nine-month olds receiving vaccine will not be protected (as a result of persisting maternally-derived antibody and other factors), and the fact that only 57% of nine-month olds in target countries currently receive measles vaccine. The WHO/UNICEF comprehensive immunization strategy for sustainable measles mortality reduction was endorsed by the 2003 World Health Assembly.

Almost all industrialized countries and many middle income countries provide children with a second opportunity for measles immunization. Worldwide, more than 150 countries provide children with such a second opportunity, 105 of them through a routine two-dose schedule. The second opportunity for measles immunization can be provided through periodic supplementary immunization activities (in most developing countries) or through a routine two-dose schedule (in countries with well-developed immunization infrastructures). Importantly, supplementary immunization activities have the advantage of reaching children who never received a first dose of measles vaccine. However, many poor countries are not yet implementing this strategy. Not coincidentally, these countries continue to have the highest disease burden and death toll. Thus, measles vaccine can be clearly considered as an underutilized vaccine in the poorest countries.

In addition to the significant decrease in measles deaths expected from the implementation of periodic immunization activities, the project will introduce an additional "step-change" in immunization which will facilitate the sustainability of measles mortality reduction through the initiation of the transition of countries with well-functioning national EPI programmes from periodic follow-up campaigns to a routine two-dose measles vaccination schedule, with the benefit of progressively reducing the need for campaigns. This has the advantage of eventual suspension of the resource

¹ Angola, Benin, Burkina Faso, Burundi, Cameroon, Central African Republic, Chad, Cote d'Ivoire, Democratic Republic of the Congo, Djibouti, Eritrea, Ethiopia, Ghana, Guinea, Guinea-Bissau, Kenya, Lesotho, Liberia, Madagascar, Malawi, Mali, Mozambique, Niger, Nigeria, Rwanda, Senegal, Sierra Leone, Somalia, Sudan, The Republic of the Congo, Togo, Uganda, United Republic of Tanzania, Zambia, Zimbabwe.

intensive implementation of measles supplemental immunization activities in favor of stable budgeting for a universal two-dose schedule.

With careful planning, positive spin-off benefits from measles campaigns will accrue to national EPI programmes in the form of better trained staff (especially in micro-planning, injection safety and monitoring), upgraded cold chain equipment and improved measles surveillance. Additional human resources will be mobilized, including those from the private sector and health care training institutions, to avoid the interruption of routine services during measles campaigns. Further benefits can be realized at no additional cost to national health programs. These potential benefits are outlined below:

- During measles campaigns, key community leaders will place emphasis on the critical importance of achieving and maintaining high routine immunization coverage to sustain the impact of the campaign.
- Partners who support the planning and implementation of campaigns will be encouraged to participate in national Interagency Coordinating Committees for strengthening routine immunization services.
- Information obtained from monitoring and evaluation of campaign activities will be used to identify previously un-reached populations that can be targeted for improved service delivery.

Further potential benefits can be obtained at marginal cost to the immunization program. These benefits include:

- Community agents used for social mobilization activities during the campaign will be recruited to assure ongoing high demand for routine immunization services.
- Measles campaigns will be used as opportunities to periodically reinforce the immunization infrastructure by increasing human resource capacity, strengthening the cold chain and assuring immunization safety and appropriate waste management.

As the WHO/UNICEF guidelines for accelerated measles mortality reduction are developed and revised, efforts will be made to assure that benefits to routine immunization are addressed. These efforts will include advising National Interagency Coordinating Committees (ICCs) to develop review criteria for measles control plans which include such potential benefits.

These additional benefits will undoubtedly contribute towards the achievement of the GAVI global goal of achieving 90% national routine vaccination coverage, with at least 80% coverage in every district.

4. Assuring country ownership of measles mortality reduction activities

Measles remains the leading vaccine-preventable cause of child deaths. Moreover, the disease is highly visible and its burden is well known to mothers, health care workers and policy makers throughout the developing world. There is a very high demand for measles vaccine at the community level throughout Africa. Indeed, greater response to public demand for measles immunization is expected to stimulate trust by the community on health care providers and demand for other vaccines and priority public health interventions.

To assure a sustained reduction in measles deaths, countries need to have a long-term vision and full ownership of the goals, strategies and plans for measles mortality reduction. Efforts will continue to ensure that countries develop comprehensive multi/year national immunization plans which include plans of action for accelerated and sustained measles mortality reduction. These plans will be integrated into strategic plans and budgets of ministries of health and translated into national annual plans to ensure implementation and country ownership.

In summary

The proposal submitted by the Measles Partnership for accelerated and sustained measles mortality reduction fully meets the strategic objectives of the Global Alliance for Vaccines and Immunization, and the Africa Measles Partnership is confident that the present addendum will satisfy the concerns expressed by several members of the GAVI Board:

- Supporting accelerated and sustained measles mortality reduction activities in high burden countries is fully **aligned with GAVI/Vaccine Fund's strategic vision**;
- Providing funding for one-time-only "catch-up" campaigns and transitioning to a routine two-dose immunization schedule is **front-loaded** and **time-limited**;
- Implementing measles supplementary immunization activities will result in a major reduction in measles mortality, and will strengthen immunization services to facilitate a **step-change in immunization through innovative processes**, such as supporting the transition to a routine 2nd dose for measles, that will be sustainable by non-Vaccine Fund resources; and
- Establishing national goals, policies, strategies and plans that are endorsed by Interagency Coordinating Committees will **assure country ownership** and sustainability of measles mortality reduction activities.

GAVI/Vaccine Fund support will result in a massive impact on measles mortality; approximately 1.84 million children's lives will be saved by the project over the period 2005 through 2009. It fully supports GAVI's interest in developing impact and outcome objectives and will be a major asset to achieve the Millennium Development Goal of reducing child mortality. GAVI/Vaccine Fund support will be catalytic by accelerating the pace of progress towards measles mortality reduction through supplemental immunization activities, and increasing the sustainability of those achievements by introducing routine two-dose measles vaccination into a continent where, for all practical purposes, it has not yet been implemented.

Investing in accelerated and sustained measles mortality reduction activities will clearly demonstrate to countries and partners that GAVI and The Vaccine Fund are responding to a public health priority in Africa and are committed to achieving international child mortality reduction goals. Finally, it will demonstrate GAVI's affirmation that "infants and children born in developing countries have the human right to be protected against measles".

Options for channeling Vaccine Fund support for measles mortality reduction

Option A:

As per the Measles Investment Case, The Vaccine Fund contributes US\$ 50 million to the UN Foundation (US\$ 10 million per year for 5 years). Countries will access these resources through the Africa Measles Partnership. All activities will be fully consistent with current WHO/UNICEF measles mortality reduction strategies. This contribution would leverage an additional US\$ 12.5 million matching grant by the UN Foundation for measles mortality reduction activities.

Specifically The Vaccine Fund would contribute to:

- Supporting "catch-up" campaigns in the 10 African countries that to date have not yet conducted them (Central African Republic, Chad, Democratic Republic of Congo, Djibouti, Mozambique, Nigeria, Niger, Sudan, Somalia and Republic of Congo);
- Providing support for periodic "follow-up" campaigns in low-performing countries; and
- Providing support for other appropriate measles mortality control strategies, including transition to a routine two-dose schedule in selected countries which have the capacity of maintaining high levels of routine measles vaccination coverage.

As outlined in the Measles Investment Case, the approximate allocation of these funds would be US\$ 30 million for bundled measles vaccine purchase and US\$ 20 million for selected operational costs, including health care worker training, transport, monitoring and evaluation.

Review Process and Reporting:

WHO/AFRO provides guidelines to countries and countries prepare plans of action for accelerated and sustained measles mortality reduction. These plans are reviewed and approved by the national Interagency Coordinating Committees (ICCs) and are forwarded to the Measles Partnership through WHO. The Measles Partnership is a coordination mechanism for partners to provide support for national plans. These country plans are reviewed by all partners, including WHO, UNICEF, CDC, UNF and the Red Cross. Feedback is provided to countries, usually focusing on increasing operational efficiencies, identifying funding gaps, and inclusion of additional partners. Based on this feedback, countries, in collaboration with ICC partners, are able to revise their applications, accordingly.

The ICC is responsible for providing oversight for the planning, implementation, monitoring and evaluation of measles mortality reduction activities.

As described in the "Monitoring of process and evaluation of impact" section of the Measles Investment Case document (page 34) WHO and UNICEF are required to submit to UNF one annual progress report based, in part, on country reports to them. UNF then distributes the report to partner donors (which would include GAVI/VF). Semi-annual financial reports to UNF are required from WHO and UNICEF. UNF then distributes the reports to partners; if GAVI/VF awards the funds requested through the UNF, GAVI/VF would receive copies of the same reports.

Strengths:

- Leverage an additional US\$ 12.5 million in matching funds for accelerated and sustained measles mortality reduction;
- Take full advantage of existing and well functioning Africa Measles Partnership; and
- Adding value to GAVI by encouraging other immunization partnerships.

Weaknesses:

- To date, focus of Africa Measles Partnership has been on planning and implementing measles campaigns to provide children with a second opportunity for measles immunization;
- Expands existing GAVI/Vaccine Fund channeling mechanisms; and
- May be perceived as setting a precedent of GAVI/Vaccine Fund providing support for a single disease reduction initiative.

Option B:

Per the recommendation of the World Bank Board member, The Vaccine Fund contributes US\$ 37 million to UN Foundation for "catch-up" campaigns, and makes available using existing GAVI processes US\$ 13 million to support implementation of a routine second dose of measles vaccine in selected countries. The UN Foundation contribution would leverage an additional US\$ 9.25 million matching grant. Countries access resources for catch-up campaigns through the Measles Partnership; countries access resources for routine second measles dose through GAVI/Vaccine Fund country application mechanism.

Ten countries in Africa with low coverage have not yet conducted "catch-up" campaigns (Central African Republic, Chad, Democratic Republic of Congo, Djibouti, Mozambique, Nigeria, Niger, Sudan, Somalia and Republic of Congo). These countries would access Vaccine Fund resources through the Partnership's own process, i.e. the Vaccine Fund contribution would be combined with other donors' contributions. The Measles Investment Case estimated that the total cost for the needed "catch-up" campaigns is approximately US\$ 125 million; The Vaccine Fund is asked to contribute approximately one-third of this, or US\$ 37 million (US\$ 18 million for bundled vaccine supplies; US\$ 19 million for operational costs). By prioritizing and frontloading support for the "catch-up" campaigns, Vaccine Fund resources would thus not be available to for follow-up campaigns in these countries².

Higher performing countries would access routine measles second dose Vaccine Fund support through the current GAVI/Vaccine Fund process. This will help ensure national ownership and inclusion of these long-term activities in national plans. The Measles Investment Case estimated that five countries fall into this category and that the total multi-year commitment to meet the objectives for this group of countries would be US\$ 13 million (US\$ 12 million for vaccine/supplies and US\$ 1 million for operational "start-up" costs).

² The Measles Investment Case estimated \$136 million for measles "follow-up" campaigns of which the Africa Measles Partnership has confirmed commitments of \$55 million, leaving a funding short fall of \$81 million to be filled.

Review process and reporting

For countries requesting support for "catch-up" campaigns, the processes outlined under Option A above will be followed.

For countries requesting support for strengthening routine measles immunization, current GAVI guidelines for application and monitoring processes will be followed, with the usual approval and reporting to the Board.

Strengths:

- Leverage an additional US\$ 9.25 million in matching funds for accelerated and sustained measles mortality reduction;
- Take full advantage of strengths of both GAVI/Vaccine Fund and Africa Measles Partnership;
- Innovative approach for assuring sustainability of measles mortality reduction efforts; and
- Promotes country ownership by providing additional funds for immunization system strengthening.

Weaknesses:

- Lose US\$ 3.25 million in matching funds from UN Foundation.

Summary: Options for channeling Vaccine Fund support for measles mortality reduction

Options

Strengths

Weaknesses

Option A:

- As per the Measles Investment Case, Vaccine Fund contributes US\$ 50 million to the UN Foundation (US\$ 10 million per year for five years)
- Countries will access these resources through the Africa Measles Partnership

- Leverages an additional US\$ 12.5 million in matching funds
- Takes full advantage of Africa Measles Partnership
- Adds value to GAVI by encouraging other immunization partnerships

- To date, focus of Africa Measles Partnership has been on measles campaigns rather than on routine strengthening
- Expands existing GAVI/Vaccine Fund channels
- May be perceived as setting a precedent for GAVI/Vaccine Fund by providing support for a single disease reduction initiative

Option B:

- Vaccine Fund contributes US\$ 37 million to UN Foundation for "catch-up" campaigns, and US\$ 13 million earmarked to support routine second dose in selected countries via GAVI/Vaccine Fund application processes
- The UN Foundation leverages an additional US\$ 9.25 million
- Countries access resources for catch-up campaigns through the Measles Partnership and for support for the routine second measles dose through a GAVI/Vaccine Fund country application mechanism

- Leverages an additional US\$ 9.25 million in matching funds
- Takes full advantage of strengths of both GAVI/Vaccine Fund and Africa Measles Partnership
- Innovatively assures sustainability of measles mortality reduction
- Promotes country ownership through immunization system strengthening

- Loses US\$ 3.25 million in matching funds from UN Foundation
- Requires countries to submit an additional application to GAVI

Annex 6a

Implementing the GAVI Board's Long-term Strategy: Investment Cases

The GAVI Board is now defining the strategic priorities of the Alliance for the longer term (2005-2015). To ensure maximum impact, these priorities will also be translated into Vaccine Fund investment decisions. The GAVI Executive Committee has proposed that Vaccine Fund resources support selected activities in six priority areas or “**windows**”.

- system strengthening,
- scaling up existing vaccines,
- support for underutilized vaccines,
- accelerated introduction of new technologies or vaccines,
- immunization safety,
- support for value –added activities in the agreed GAVI work plan

Once the Board discusses the EC recommendations and decides upon the windows – whether it is the above list or an adaptation – it will need to decide notionally how much should be allocated to each window, based on the amount of funds raised. In making notional allocations to windows, the Board might consider such factors as the expected health impact, equity, relative risk, long-term impact on delivery, technology or access, and fund raising/public relations. The decisions will also need to be consistent with globally-accepted goals, which would serve as a marker to evaluate progress. The Board will then need to make decisions about specific options – i.e., which vaccines or strategies it wants to support within the agreed windows.

To help ensure the Board is presented with comparable and innovative options, the World Bank, in close collaboration with other partners, has developed guidelines for investment cases. The guidelines set out the information required by the Board to make evidence-based and informed decisions. The intention is that people or institutions who would like the GAVI Board to consider using Vaccine Fund resources for a specific vaccine or strategy will use these guidelines to develop their investment cases. In most instances, it is envisioned that once the Board approves an investment case, a new area of funding will become available to countries. Countries will then be invited to apply for these funds through their national applications to GAVI.

The guiding principles used to develop the investment case framework and a possible process and timetable for rolling it out are the following:

- Develop a tool that is based on the Board's list of principles governing use of The Vaccine Fund;
- Keep the investment case preparation and process as straightforward as possible while ensuring sufficient and consistent information is made available to evaluate

requests that target tens or hundreds of millions of dollars at specific strategies and products;

- Structure a process that engages a broad range of immunization partners (e.g. NGOs, academia, governments, bilaterals, multilaterals) to develop innovative options for Board consideration;
- Structure a process and timetable which ensures that once new funding windows are opened, countries can submit a single national application to request support from one or more windows.

The measles investment case piloted the draft guidelines but followed a unique “fast-track” process. The resulting case provides a valuable synopsis of the measles proposal, its costs, potential benefits, risks and implications for sustainability. The measles experience also highlighted the value of clear investment case guidelines to inform partners of the principles and criteria on which the GAVI Board will make decisions.

Based on initial review by the GAVI Board during the 30 March teleconference and further consultation with partners, the investment case guidelines are now in final draft. Pending Board approval, these guidelines would become the basis on which future investment cases are prepared.

Investment cases will be broadly divided into three sections to answer the following basic questions:

- 1) Does the proposal “fit” with the GAVI/Vaccine Fund principles? (see below)
Assuming the proposal does “fit”, then:
- 2) How does this proposal measure up against other investment opportunities?
- 3) How will the proposal be monitored?

In addition to six possible funding windows, the GAVI EC has suggested a set of **principles** to determine whether investments are appropriate for Vaccine Fund support (versus support from other donors in the immunization community) and, if so, **criteria** to determine the relative priority of using limited dollars to support one option over another.

To be considered for Vaccine Fund support the EC suggests an investment case must meet the following **principles**:

- time-limited;
- additional: new activities funded by new money;
- information available: adequate information to assess the activities with respect to criteria below;
- unique: there is no one else positioned to undertake the activities more effectively than GAVI;
- catalytic step function: activities lead to step-up functional change in a current situation through innovative processes by fulfilling at least one of the following – (a) add substantial impact beyond the specific activities that are funded, (b) have an impact that lasts longer than the funding, (c) develop innovative models that could be applied more broadly, (d) are capital investments or one-time expenses that lead to a new level of performance

If an investment case is consistent with the above principles, it would be evaluated based on the following suggested **criteria**, all of which are captured in the proposed investment case guidelines:

- sustainability,
- fit with national priorities,
- effective/implementable,
- cost-effective,
- equitable,
- consistent with partner commitments/mandates,
- high impact on MDGs,
- country focused (e.g. funds directed to governments except in exceptional circumstances)

Based on discussions with several partners, following is a suggested process and timetable for soliciting, evaluating and monitoring investment cases.

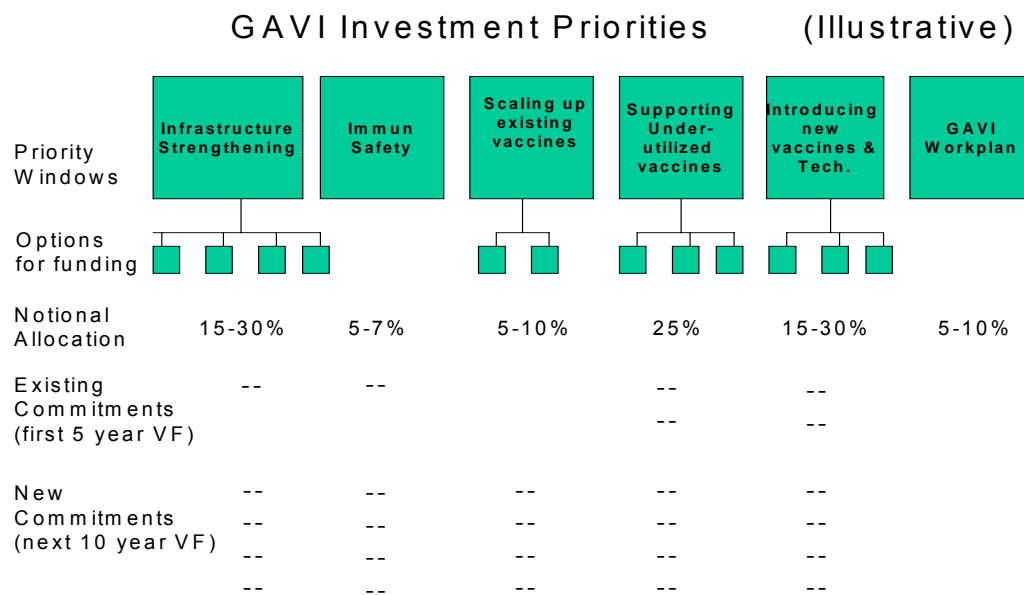
Soliciting investment cases: Following the July 2004 Board meeting, the Board might invite innovative ideas from partners throughout the broad immunization community (e.g. consortia or individual institutions from countries, regional groups, NGOs, academia, bilaterals, multilaterals) for uses of The Vaccine Fund that support governments in meeting the agreed objectives and milestones.

Partners would be asked to submit a short Letter of Intent (LOI) outlining the broad objectives of the investment case, and specifying how the proposal is consistent with the GAVI /VF principles. It is suggested that the LOIs be evaluated by a single independent evaluation panel that would make recommendations to the Board for consideration at the December 2004 Board meeting. If their LOIs are accepted, the Board might consider supporting proposers with US\$ 50,000 to help cover the costs of preparing a full investment case.

Evaluating investment cases: The July 2005 Board meeting would be the opportunity for the Board to make investment decisions within each window based on review of the first round of full investment cases. The Board may wish to consider have periodic request for proposals and reviews every 2-3 years. To support the Board, it would be valuable to establish a small independent evaluation panel. Ideally, this panel would be comprised of neutral colleagues able to assess and make recommendations on each investment case based on its technical merit and fit with GAVI priorities and criteria. The proposed evaluation panel would (a) provide consistent review and feedback to both proposers and the Board members, (b) assist Board members who may not have adequate staffing to review all proposals, and (c) ensure impartial analysis independent of benefits or costs to any single institution. Given that most of the proposals will be for tens if not hundreds of millions of dollars, providing the Board with an independent evaluation seems highly cost-effective and appropriate.

Disbursing funds to countries: Following the global investment decisions of the July 2005 Board meeting, governments would be invited to prepare national applications in which each government highlights its national priorities and specifies requests from the range of approved global investment options.

Monitoring Vaccine Fund investments and impact: Working closely with partners, particularly The Vaccine Fund and WHO, the Bank is exploring a monitoring tool to provide the Board with easy access to information on the overall strategic investment portfolio (see illustrative graphic). This tool will provide the Board with timely snapshots of both the financial status of The Vaccine Fund (e.g. the expected income to The Vaccine Fund, the existing commitments, the impact of new commitments) and the likely programmatic impact of the investment strategies adopted by GAVI (e.g. change in coverage, impact on disease burden, or whatever milestones are decided on by the Board).



Annex 7a

Terms of Reference for Time-limited Hib Team

Context

The first GAVI Board meeting held in October 1999 proposed that *Haemophilus influenzae* type b (Hib) vaccine should be procured for countries which make successful applications in the following regions:

- Africa, Latin America, Middle East and for countries in other regions if supported by epidemiological data

By June 2004, 11 countries have received approval for GAVI Hib vaccine support and nine have already introduced the vaccine as of the end of December 2003. Decision-making for Hib vaccine introduction has been complicated by an unclear disease burden, and by the limited availability of both the desired products and prospects for sustainable financing. There is therefore a need to take a closer look at the key issues in order to provide strategic directions for the way forward.

Composition of team

An ad hoc team is proposed to evaluate the current situation and provide recommendations to the Board on next steps.

The team will be constituted by the Board. It is proposed that recipient countries be adequately represented. Other members should reflect experience in immunization financing, programmatic issues, manufacturing, pricing knowledge, procurement, and supply issues. [Note: a suggested list of individuals for the team will be provided at the Board meeting based on current consultations.]

The team should develop its working agenda in coordination with the Working Group and report regularly on its progress during Working Group meetings or teleconferences.

The area of work should include a situation analysis at global and country level on above issues and strategic directions for the way forward.

Situation analysis

Global level

Key issues which led to inclusion of Hib vaccine in GAVI support:

- Availability of data and geographical variation,
- Procurement strategies and product selection,
- Approach on vaccine financing.

Country level

- Availability of data at country level, (disease burden from local studies, cost effectiveness studies, surveillance issues),
- Public health priorities – competing health priorities, perception on public health significance, health service delivery infrastructure
- Supply and procurement – product selection and availability of supplies
- Vaccine financing – vaccine costs, affordability and sustainability issues
- Impact assessment – program performance, disease occurrence and vaccine effectiveness

Next steps – strategic direction

- Gathering evidence base for decision making through consultation with countries - identifying information needs at country level for decision making and priority setting
- Strategic procurement and financing issues (working with potential suppliers, innovative financing mechanisms)
- Lessons learned for future support of introduction of newer vaccines

Deliverables

Report to the Board (within 3-4 months), proposing an update of the GAVI Hib strategy. The main focus of the report should be on country level issues; global concerns should also be addressed. The report should also propose a structure for the way forward and identify funding sources for proposed activities.

Annex 7b

Proposed members of GAVI Hib Team

Name	Institution	Area of Specialty
David Fleming (Chair)	Gates Foundation	Public Health
George Amofah	Ghana Health Service	Health system financing
Issa Makumbi	Uganda EPI	Country programmatic experience
Patrick Zuber	WHO	Epidemiology (disease burden)
Dr Endang	Independent Consultant, Indonesia	Epidemiology
Stephen Jarrett	UNICEF	Vaccine Procurement
Dr. Pascal Perrin	Aventis	Vaccine manufacturing
Steve Landry	Vaccine Fund	Vaccine financing
Piers Whitehead	Participating based on former work with Mercer Consulting	Economics of vaccine supply
Damien Walker	LSTMH	Cost effectiveness studies
Orin Levine Jan Holmgren	Pneumo ADIP Gothenberg University	Research institute
Shelley Deeks	Health Canada	Technical health institute
Coordination – Mercy Ahun	GAVI Secretariat	Country Review & Progress including financial commitments

Annex 8

Bridge Financing for Select Vaccine Products

This brief provides background information to the GAVI Board as it deliberates on how to sustain the gains that have been made through the introduction of new vaccine products. It focuses exclusively on the financing challenges associated with the introduction of new vaccine products and proposes a new concept for Board consideration called bridge financing. With regard to Hib vaccine, other critical areas such as recognition of local disease burden, documentation of the impact of vaccine introduction, and trends in future vaccine supply and price are discussed elsewhere in the Board agenda.

Starting conditions and initial assumptions

Among other aims, GAVI was formed to accelerate the introduction of new and underused vaccines that could yield important improvements in the health of children today and adults in the future. Recognizing that a key reason for the under-utilization of existing vaccines was their relatively high price, GAVI — through The Vaccine Fund — offered to provide vaccines free to eligible countries for a catalytic, five year period. These have included monovalent hep B, DTP-hep B, DTP-Hib, DTP-hep B-Hib, and Yellow Fever vaccines. Vaccine Fund support for the introduction of new vaccines was originally structured as a maximum of five years of support with no subsequent option to apply for additional funding for the same products.

This strategy was based on two fundamental assumptions:

- 1) Prices of the newly introduced products would decline by the end of the initial funding period, reflecting a combination of increased demand, increased competition in supply and the capture of economies of scale in manufacturing. This assumption was based on historical vaccine price trajectories; and
- 2) Both governments and donors would observe the cost-effective improvements in health associated with the introduction of new vaccines and would then be willing to make significant additional allocations to the immunization program at the national level to sustain those benefits.

Although these assumptions were based on the best thinking at the time, no guarantees or commitments were obtained from any decision-makers. Vaccine manufacturers were not required to commit to lowering prices over time; government officials within Vaccine Fund recipient countries were not required to commit to increasing their spending on immunization or health (or even present a plan for doing so until well after the decision to introduce a specific product had been made), and officials within donor agencies were not asked to make a commitment to increasing allocations for immunization programs or the health sector more broadly.

Assumptions revisited

With 4 years of experience with GAVI and recent documentation from the Financial Sustainability Plans from 21 countries, it is now possible to examine the initial assumptions. Vaccine prices for several products have increased— not decreased— over the initial GAVI/VF period and significant increased donor support for immunization and health overall has not transpired. Reflecting both the lack of dramatic price declines and the lack of substantial new resources allocated to immunization, many countries that introduced the more costly vaccines are facing a financing crisis as the end of the current round of Vaccine Fund support approaches.

Near-term prospects for financial sustainability: Preliminary analyses from national FSPs suggest that countries will be able to sustain the costs of “mature” products such as monovalent hep B and possibly Yellow Fever vaccines. For other products, some countries are making substantial strides towards sustaining new vaccine products and taking advantage of a number of different financing strategies from increasing domestic spending to accessing debt relief and loans/credits. However early findings suggest that—for newer and more immature products where the prices have not decreased as expected—few governments and their partners will be able to fully finance these new vaccines immediately after GAVI/VF support ends. With increasing and competing demands on limited health budgets and in addition to their ongoing requests for additional partner support, countries are exploring selecting less expensive vaccine presentations and, in a few cases, proposing to drop Hib-containing vaccines altogether.

Principles for a solution: Recognizing that assumptions on price declines and donor resource mobilization have not transpired, and that based on current data, future financing is a major problem in many countries, it is important to explore how to ensure that program improvements— that yield significant health benefits—are sustained in the most cost-effective manner while focus is maintained on improving and expanding national immunization programs.

Recognizing further that any strategy for additional financing should provide clear and positive incentives for all actors in moving toward long-term sustainability, the FTF explored with the partners options and implications for further financing. Among the options discussed: provision of an additional 5 years of full funding, a transitional period of co-financing, and no further financing of current products whatsoever. There was unanimous agreement that awarding additional years of full support for current products would undermine both the principles of GAVI/Vaccine Fund and the major strides countries have made towards sustainable financing to date. The group agreed further that providing no further support would result in some countries inappropriately dropping new vaccine products from their programs, thereby thwarting gains that have been made in child health to date. The consensus and preferred direction for ongoing evaluation is a co-financing transitional arrangement “bridge financing” among national governments, national partners and GAVI/Vaccine Fund.

Although much work remains to be done, one promising strategy calls for all countries and their partners to provide the estimated “mature” or “fully competitive market” price, with The Vaccine Fund covering the difference between the market price obtained by UNICEF and the estimated mature price. Prior to making recommendations to the GAVI Board, the FTF proposes to support analyses of total and annual costs of bridge financing; impact of bridge financing on vaccine market and pricing, and on national

programs and decision-making. In addition, there are broader questions as to how bridge financing would be applied (globally or on a country by country basis), negotiated, agreed to, and monitored.

Request to GAVI Board

At this time, the FTF requests GAVI Board guidance on the merits of continued and additional analyses of bridge financing with a view to a full proposal and budget implications for GAVI/Vaccine Fund to be submitted for Board consideration in December 2004. No additional resources from the GAVI budget are anticipated for this analytical work.

Annex 9

ADIP Management Committee Meeting Report

10-12 June 2004, Geneva

Executive summary

Progress with each ADIP team has been according to plan. Early indications suggest that disease burden is high.

Progress in the private sector regarding rotavirus vaccines has been more rapid than anticipated. The two leading companies, GlaxoSmithKline (GSK) & Merck, are fully committed to making the products available early in Vaccine Fund eligible countries. One of the candidates (from GSK) is expected to register in the first country this year.

The Rotavirus ADIP should continue to work with both vaccine manufacturers.

The Rotavirus ADIP should also explore opportunities to participate in testing and pilot introduction of the GSK candidate to address issues of strategic importance to GAVI and The Vaccine Fund. Issues include assessing the feasibility of the vaccine's introduction in poor settings with weak health infrastructure.

The ADIP Management Committee recommends to the GAVI Board the establishment of a small, time-limited group (UNICEF Supply Division/Vaccine Fund/ADIP Management Committee/ADIP Management) to explore with GSK (at this stage) the technical, scientific and cost characteristics required for early introduction of rotavirus vaccine in Vaccine Fund eligible countries. Price/volume negotiations would then be conducted with the company.

Introduction & purpose of the meeting

This 2nd ADIP Management Committee meeting reviewed the progress of the two ADIP projects, pneumo ADIP and rota ADIP, and presented the GAVI Board with an update. It also had a special focus session dedicated to review the rapid development in the field of rotavirus vaccines.

One outstanding issue from the previous ADIP management committee meeting was that the rota ADIP/UNICEF/VF MOU is still not signed. The day before the meeting the response from the legal parties at UNICEF/VF arrived following a 2-month waiting period. The ADIP Committee believes that the finalization of the MOU can be achieved though will be actively monitoring the agreement negotiation.

ADIP projects progress reports and management committee recommendations

The 7-valent Wyeth vaccine will be the only vaccine to be available before 2009.

The pneumo ADIP was encouraged to investigate the possibility of early introduction of the 7-valent vaccine in a limited number of countries that specifically express a demand and have an ability to manage the potential risks (e.g. monitoring potential serotype conversion) associated with the vaccine. This introduction should be placed in a long-term perspective envisaging the subsequent introduction of the 9-valent vaccine and should therefore be introduced within the context of intensive surveillance programs. In addition, the ADIP should continue to screen for opportunities within the development portfolios of other manufactures.

Review of the ADIPs' ongoing plans and future ADIP milestones

Both ADIPs reported minimal amendments to the existing plans and presented the committee with detailed justifications where these arose. The rota ADIP is projected to experience a delay in initiating trials in Bangladesh and South Africa. These facts were discussed within the context of the rota ADIP GSK negotiation and RAPID partnership collaboration. Budgets have not been changed and spending proceeded according to the approved plans.

Discussion topics:

A) ADIP Investment Case and Vaccine Fund future financial policies

The Investment Case framework, developed by the World Bank, is perceived as offering a tool that will enable GAVI to ensure successful investment. If approved by the Board the Investment Case Framework could form a basis for an ADIP Investment Case to be presented to GAVI/VF in 2006-2007. The Vaccine Fund should receive in advance the range of calculations including both an ideal and a conservative investment case. This will help to set the budget ceiling as well as to start working on advocacy for rota and pneumo vaccine funding investments.

Producers have indicated that the price for the newly developed vaccines should be expected to be much higher than for the basic vaccines.

Currently several mechanisms of new vaccine financing are under discussion:

- Time-limited 5 year contribution
- Proportional contribution (mature price plus Vaccine Fund contribution)
- Decreasing partial contribution
- Volume induced maturation

ADIPs should suggest to The Vaccine Fund the best way to accelerate the price maturation of pneumo and rota vaccines as well as preferential ways of financing.

ADIPs should prepare plans based on their best assumptions with the understanding that their plans will be competing with other investment projects for Vaccine Fund funding.

The Committee noted that there is an overwhelming necessity to sustain the hep B/Hib in the Vaccine Fund countries' immunization programs before introducing rota and pneumo.

B) *Identification of potential early adopter countries*

Both ADIPs have nearly completed their analysis for selecting potential early adopter countries following regional representation.

The Committee recommends:

- Early adopter country selection should be presented more than is currently the case within the context of long-term ADIP strategy and wide Vaccine Fund countries vaccine uptake
- To choose early adopter countries, ADIPs should liaise with other initiatives and between themselves and take into account the prevailing Hib situation so as not to place an overwhelming burden on the same countries.
- After completing consultation with the regional UN offices, ADIPs should initiate consultations at the country level. The GAVI Secretariat proposed to facilitate this process if deemed necessary.
- The countries, on the recommendation of and with the support of the ICCs, should make the final decision on the choice of introducing new vaccines.

Focus session: rotavirus vaccine. New development and ADIP fit

Rotarix GSK presentation

GSK participants (for this session only):

Walter Vandersmissen, Director, Public Partnerships

Debbie Myers, Director, External and Government Affairs and Public Partnerships

Alain Brex, Director, Business programs, Paediatric Vaccines

Johan Heylen, Associate Director, Life Cycle Management

Progress to date on the clinical development and the regulatory plan of the Rotarix vaccine were presented. Rotarix is a live attenuated, human, monovalent (G1), oral, lyophilized vaccine that has completed the majority of the core elements of regulatory clinical development. The efficacy and safety data are currently under evaluation by the Mexican NRA; conditional to the registration approval the introduction in Mexico is planned in 2004, expected to be followed by the roll-out in other Latin American countries and further registration in Europe.

Currently, the projected timeline of international roll-out of the vaccine after Mexico's approval depends on the speed of the WHO evaluation of the Mexican NRA to obtain a recognized qualification.

GSK expectations from collaboration with rota ADIP were stated as:

- Investigating the possibility to include Rotarix in the GAVI/VF work plan
- Working together towards pilot introduction of Rotarix to selected early adopter VF countries

- ADIP support for Bangladesh and South Africa's Phase III trials
- Access to data on African surveillance
- Working together on awareness of rota disease and communication for rota vaccine health value

Conditional to successful collaboration with public sector the company envisages the possibility of introducing Rotarix to VF countries in 2006.

RotaTeq Merck presentation

Merck participants:

Elaine Esber, Executive Director, Medical Affairs International

Thomas Netzer, Senior Director, Marketing Planning

The clinical progress of the RotaTeq vaccine was presented. RotaTeq is a pentavalent, human/bovine reassortant, liquid, oral vaccine that is in Phase III clinical development, targeting US filing in 2005.

The company reconfirmed their earlier stated commitment to corporate social responsibility for the international and developing countries market as well as a commitment to the notion of differential pricing.

Expectations from collaboration with ADIP were formulated as:

- ADIP championship in PRD and introduction at the developing country level
- Working together on worldwide demand forecast:
 - Including analysis of product profile impact on developing countries
 - demand and forecast of dynamic of the vaccine uptake
 - Future funding. Establishing supply agreements

Conditional to successful collaboration with the public sector the company envisages the possibility of introducing RotaTeq to VF countries. Additional efficacy and vaccine interaction (OPV, wDTP) trials as well as developing countries introduction support will be required.

ADIP Management Committee recommendations for rota ADIP

- Encourage ADIP to continue to work with both vaccine candidate manufactures to maximise the probability of success.
- ADIP should stay open to other competitors that might arise in the field in the next several years.
- ADIP should explore the opportunity to participate in the pilot introduction of Rotarix in Nicaragua and Honduras, recognizing the importance of obtaining real life and large-scale safety and effectiveness data for further strategic decisions.
- The implementation of future efficacy studies in Asia and Africa is a high priority for GAVI to move forward the introduction of rota vaccines into these regions.

- ADIP should put emphasis on developing/preparing clinical trial sites in Africa to meet the standards of international GCP regulations.

The Committee recommends the establishment of a small time-limited group (UNICEF/Vaccine Fund/ADIP Management Committee/ADIP Management) to explore corporate mechanisms to clarify the technical, scientific and price/volume characteristics required for early introduction of rotavirus vaccine in Vaccine Fund eligible countries.

WHO intends to start the Mexican NRA evaluation in October 2004. The ADIP MC expresses the wish that, while of course keeping this process unbiased, WHO will be able to expedite evaluation and if necessary follow-up interventions, recognizing the benefit of early rota vaccine introduction to developing countries.

Functioning of ADIP Management Committee

It was decided that it will be favorable to introduce regular teleconferences (every 2 months) in addition to the Management Committee meetings. Prior to each teleconference, ADIP leaders will submit short progress reports and materials for 1-2 topics in detail.

The tentative schedule for the next meeting and teleconferences is proposed to be:

- Teleconference on 30 August 2004 (4pm Geneva time)
- Teleconference on 14 October 2004 (4pm Geneva time)
- 3rd ADIP Management Committee Meeting from 22-23 November 2004, London, U.K.

Meeting participants

Committee members and members' representatives*: Jan Holmgren, Regina Rabinovich*, Jacques-François Martin, Harry Greenberg, Brian Greenwood, Kevin Reilly, Enkhsaikhan Dashdondog*

Other participants & Observers: Orin Levine, John Wecker, Chris Elias, Mathuram Santosham, Stephen Jarret, Liliana Chocarro, Tore Godal, Irina Serdobova

All participants signed confidentiality agreements. Kevin Reilly has disclosed that he is a Wyeth shareholder, and he will abstain from participating in the Wyeth product introduction discussions.

Annex 10

Country Application/Monitoring Process in the Next Phase of GAVI/The Vaccine Fund

The first phase

The GAVI Partners have followed specific policies for availability of country support from The Vaccine Fund. Only countries with an annual GNI/capita below US\$ 1,000 are eligible. Countries can receive a five year supply of vaccines against hepatitis B, Hib and yellow fever, as epidemiologically appropriate. Untargeted immunization services support (ISS) is provided to strengthen immunization and health systems based on the number of additional children immunized. Safe injection materials for all vaccinations are also available to countries for three years.

The GAVI Partners made a very deliberate decision to provide this support to countries through a bottom-up application process, with an independent peer-review mechanism that makes its recommendations to the GAVI Board for final decision.

Results

In less than four years the GAVI mechanism for country support has resulted in approvals for support to 70 out of the 75 eligible countries (including recommendations to this Board). The total five-year Vaccine Fund commitment to these countries amounts to US\$ 1,083 million. As of April 2004, US\$ 284 million worth of support had been received in countries; with US\$ 188 million for new vaccines, US\$ 57 million in cash payments and US\$ 39 million for injection safety support.

The rapid uptake of vaccine and other support from The Vaccine Fund can be ascribed particularly to the bottom-up application process, to the fact that all eligible countries could apply immediately and to partner support. The speed has ensured predictable and rapid responses to country requests, and the independent review has ensured that decisions are fair and based on evidence rather than on political arm-twisting.

However, the first countries that were approved for support with new vaccines will be faced with high prices for non-mature products at the end of their VF support period. The FTF has therefore prepared a proposal to create bridge financing for these countries (submitted separately to the Board).

Proposed mechanisms and processes for country support in the 'second phase' of GAVI /The Vaccine Fund

The support to countries approved in the first rounds will come to an end in 2005. It is therefore essential to provide early guidelines for countries for the next phase. Based on the Board decision on this paper the Working Group will develop precise guidelines to be communicated to countries and included in the handbook for country support. The

overall eligibility criteria will also be reviewed and any proposed changes will be submitted to the Board.

This document assumes that investment decisions for GAVI/Vaccine Fund support to countries in phase 2 be taken after review of global investment cases relating to different “windows” or investment areas prioritized by the Board. Global investment decisions will then normally be followed by a process of country applications, such as in phase 1. Based on the early experiences some adjustments to the process are recommended, as described below.

Other documents now being presented to the Board propose a time-limited extension of ISS funding and exploration of “bridge” funding for countries that have introduced select new vaccines. It is recommended that countries would not have to undergo a new country application process to qualify for these extensions but that such requests could be considered based on an enhanced progress report to be submitted in 2005.

Country application process

Considering the success of the country support process in the first phase, it appears that the same mechanism can be applied, with minor adjustments, in the second phase of GAVI/Vaccine Fund country support. The main adjustments are:

- A. to require a comprehensive multi-year plan,
- B. to more clearly define the role of national ICCs in implementation and monitoring, and
- C. to strengthen monitoring and more systematically use the experiences from the monitoring process in decisions for additional support.

A. Comprehensive multi-year plans

The Executive Secretary, after consultation with the Working Group, recommends that countries apply for all the support relevant to their national priorities at one time to avoid fragmentation. Countries will be able to choose among options for support based on GAVI Board decisions about which resources will be available within each Vaccine Fund window.

In order to avoid fragmentation and vertical planning and budgeting, countries will be required to base their requests on comprehensive multi-year immunization plans. The new multi-year plans would need to be based on a recent coverage survey and immunization assessment (EPI review), and would include all current components of the immunization programme, any new vaccine(s) and/or immunization strategy(ies) as well as updated financial sustainability plans.

B. Role of ICC

Today the role of the ICCs varies greatly between countries. In many cases it is not obvious that ICC has played the role that was envisaged in endorsing proposals and progress reports and in its general oversight function. The political nature of ICCs and to which extent they are in a position to refuse to sign proposals or reports is also at issue.

There is a need to ensure that the ICCs play a stronger role in general oversight including endorsing proposals and reports, as well as approving changes. ICC endorsement should signal that country plans for new vaccine introduction are appropriate and ready for implementation upon approval, or in any case before disbursement/delivery of support.

In line with the recommendations of the ISS study, the ICCs should also be given a more strategic role in the allocation of ISS funds. It will be essential to use the available technical expertise from WHO, UNICEF and other partners and to coordinate the efforts of immunization advisers with the ICC work, for example through the use of ICC technical sub-groups.

Currently there are several GAVI work plan activities underway aiming at strengthening the ICCs. Knowledge and information gleaned from these activities will feed into the country application process in phase 2.

C. Monitoring information to feed into new proposal reviews

At the outset, it was envisioned that supported countries should undergo a mid-term and final review. The mid-term review was cancelled. It is hereby proposed that the formal GAVI final review also be cancelled and that instead we rely more on the regular immunization assessments that countries undertake as well as on coverage surveys, rather than instituting specific GAVI reviews. Such assessments and surveys are a natural basis for renewing multi-year plans and as such will be required for countries requesting support in phase 2.

It will also be essential to use the information uncovered through the financial sustainability planning process to guide decisions on additional support, i.e., if countries have proven unable to provide evidence for assuming costs of the new vaccines and/or injection safety material already awarded they should not be eligible for approval of additional support.

A FSP amended to include the long-term financial consequences of requested new products should also be required for phase 2 support.

D. Other points to consider

- In order to move the country support process at a sufficient speed two opportunities for application per year are required. This is also necessary to ensure that conditional approvals can be handled within a reasonable time.
- Many countries have experienced delays in the implementation of GAVI/VF supported activities. These delays could be either on the GAVI/VF side – drawn out review, approval and disbursement procedures – or on the country side. In the latter case it could involve administrative problems with financial management and transfers of funds in countries as well as programmatic problems related to the implementation of the immunization services and introduction of new vaccines.

Action to reduce delays for immunization services support should be based on recommendations from the ISS study. Other recommendations from the ISS study may lead to other actions or modifications of the country support processes.

Monitoring in phase 2

In line with suggestions from the Independent Review Committee, the monitoring function should be strengthened to improve annual planning and reporting (further consolidation may be possible). Feedback from the monitoring reviews could be used as a basis for improvements, partners could be asked to provide additional technical support and RWGs could be further involved.

Recommendations

The Executive Secretary, in consultation with the Working Group, recommends that

- Phase 2 support to countries to be based on updated or renewed comprehensive multi-year plans;
- The experiences from the monitoring process be systematically used in decisions on phase 2 support including that countries have to provide evidence that they are assuming the responsibility for the long-term financing of earlier awarded support before being approved for phase 2 products;
- Supported countries not be required to undergo a specific GAVI five-year review as a basis for phase 2 support.

Annex 11

Proposal for a Time-limited Extension of Immunization Services Support (ISS)

GAVI/Vaccine Fund immunization services support

Recognizing that health systems in the poorest countries each have unique requirements, GAVI Partners designed a novel approach to provide funding to support countries' basic immunization services. With immunization services support (ISS) there are no global rules about how the money should be used – the national Interagency Coordination Committee (ICC) is responsible for deciding where the resources are most needed and will be best utilized.

The amount of funding provided in the three-year investment phase is based on the extent to which the country plans to increase immunization coverage. After three years of investment payments, additional funding is only available to countries that have actually reached more children. Immunization coverage data are independently audited to ensure system integrity.

Implementation of immunization services support

Five years of ISS funding (three years of investments and two of rewards) is currently available only to countries with DTP3 coverage below 80%.

In all, 52 countries have been approved for ISS with total commitments of US\$ 337 million over five years, provided the countries actually reach their targets. So far, US\$ 52 million of ISS funding has been disbursed to these 52 countries. The largest amount disbursed for an individual country has been to Bangladesh with US\$ 7.1 million.

By 2003, 16 countries had received three years of ISS investment payments. Eight of those countries achieved immunization coverage gains in 2002 and so were approved by the GAVI Board in December for reward payments totaling US\$ 15 million. The other eight countries had not increased coverage and were not approved for reward payments. However, these countries had recognized their weak performance and decided earlier to delay half of their third investment payment until 2004, to give them more time and resources to achieve coverage increases.

The schedule for subsequent rounds of ISS approvals appears in Annex 11.1.

The ISS study

In order to better understand how the ISS support was used by countries and to get a basis for further decision making, GAVI commissioned a special study. The study was carried out April-June 2004 by Abt Associates and has resulted in preliminary findings

and recommendations based on 2002 immunization figures. When 2003 figures become available the study will be complemented by these and finalized.

The tentative findings – tentative because the ISS mechanism has only been in operation a short time permitting study of only a few countries – show that ISS funds appear to be related to modest improvements in performance in roughly half the countries studied although it has not been possible to attribute changes in performance to ISS funding. Transaction costs appear to be small, countries have put in place appropriate procedures for financial monitoring and the flexibility of the funds allows response to acute problems. In general data quality and completeness was a major problem in most countries although the DQAs appear to have had a significant impact in motivating countries to improve data quality. The presence of a coherent ICC appeared to be a key factor for strategic allocation of funds.

The consultants recommend that GAVI continue to provide ISS funds and continue the approach of un-targeted support.

Discussion

The amount of ISS funds actually disbursed to countries over the past four years (US\$ 52 million) is a relatively small investment. However, this investment has had a major positive impact in establishing GAVI /The Vaccine Fund as a different kind of funder that gives countries freedom to use resources as they need. Most recipient countries appreciate the efficiency of the system and have used the money to fund national priorities.

Early indications are that ISS might be having a positive impact on DTP3 coverage in the countries that receive it. However, it is too soon to tell. More time is needed to give us the opportunity to learn from this funding mechanism. If the principles now being put to the test are successful, they may well be applied to other types of health systems support.

We have seen that in most countries, five years is not long enough to build lasting improvements in immunization services. The proposed extension of the ISS support will only meet a small portion of the financing need. However, by adhering to the GAVI principles of being innovative and time-limited, it is anticipated to have a strong catalytic effect.

Experience shows that the monitoring requirements for ISS, which includes the immunization data quality audits (DQA), have had a strong effect in increasing the attention to reporting systems and instituting change. It will be important to maintain the emphasis on data quality in order to maintain the progress.

The original GAVI access milestone was revised to be in line with the goals of the Children's Summit – 90% national DTP3 coverage or 80% in every district. Furthermore, partners are now discussing 95% national DTP3 immunization coverage as a target for 2015. These are strong arguments for lifting the current 80% DTP3 coverage ceiling.

Extension of ISS

The proposed 5-year extension would not include an investment phase but only be a reward mechanism to provide support based on additional children reached by DTP3 immunization in the previous year.

Calculation of additional children reached will be based on the regular routine immunization reporting system and will require a successful DQA to validate the quality of the information system.

The phase 2 funding would be provided after independent review, and continued funding should be contingent upon the submission of an enhanced progress report and a recent coverage survey, starting in 2005.

If the proposal is approved in principle specific guidelines will be developed by the Working Group for announcement to countries.

Based on partners' best estimates for immunization coverage the 5-year commitment for this extended ISS would be approximately US\$ 127 million, provided all eligible countries (except the three large population countries: China, India, and Indonesia) are approved and ultimately reach their immunization targets. As current estimates end by 2010, and as the individual immunization targets for each country at the end of the second phase are not yet known, the above figure is an estimate.

Recommendations

The Executive Secretary, in consultation with the Working Group, recommends a five-year extension of ISS, based on the same principles as are currently used. This phase 2 ISS would be available to all Vaccine Fund eligible countries (except China, India and Indonesia) and not just those under 80% DTP3 coverage.

Annex 11.1

Timeline of targets/achievements for Immunization Services Support to 72 GAVI/VF eligible countries (Note 1)

	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015
18 countries : Armenia, Azerbaijan, Burkina Faso, Cameroon, Côte d'Ivoire, Ghana, Haiti, Kenya, Liberia, Madagascar, Mali, Mozambique, Pakistan, Rwanda, São Tomé, Sierra Leone, Tajikistan, Tanzania	●—————●														
22 Countries : Afghanistan, Bangladesh, Burundi, Cambodia, Comoros, Eritrea, Ethiopia, Gambia, Georgia, Guinea, Lao DPR, Lesotho, Myanmar, Nepal, Niger, Nigeria, Senegal, Sudan, Uganda, Yemen, Zambia, Zimbabwe	●—————●														
9 Countries : CAR, Djibouti, DR Congo, Guinea Bissau, Korea DPR, Mauritania, Mongolia, Somalia, Togo	●—————●														
3 Countries: Angola, Chad , Congo	●—————●														
<i>Projected to apply for phase 1 support:</i> 3 Countries : Timor Leste, Papua NG, Solomon Isl	●—————●														
<i>Projected for phase 2 support if 80% ceiling is lifted:</i> 17 Countries not eligible for phase 1: Albania, Benin, Bhutan, Bolivia, Bosnia & H, Cuba, Guyana, Honduras, Kyrgyz Rep, Malawi, Moldova, Nicaragua, Sri Lanka, Turkmenistan, Ukraine, Uzbekistan, Viet Nam	●-----●														

Note 1: China, India and Indonesia are not counted in this table because they receive a special consideration for GAVI/VF support

Note 2: Phase 1 —————
Phase 2 -----

Note 3: Table shows years for which support has been approved. Actual disbursement of rewards will normally occur two years after these years.

Annex 12

Terms of Reference For an Internal Review of GAVI Governance Processes and Structures

1. Purpose

To examine the current operations of the GAVI Board and Executive Committee, and the support these bodies receive from the Secretariat and the Working Group, to identify options for optimizing the governance structures and processes of GAVI in order to improve its capacity to implement its longer-term strategy.

2. Context

By many measures, the GAVI Alliance has been very successful in meeting its shared objectives over its first five years. Much of the success can be attributed to high-level and active participation from its Board members in guiding strategic development and implementation.

In July 2003 the Board decided to create an Executive Committee to improve efficiency and facilitate decision-making of the full Board, as the topics being presented to the Board become more and more complex (see Annex 12.1). In creating the EC, the Board decided that its performance should be reviewed after one year of operation in relation to its agreed functions (see Annex 12.2). The Board will need to consider whether the EC is fulfilling its intended purpose, and indeed whether it should continue, and if it is continued, whether its functions, membership, and responsibilities should be adapted.

With the need for a performance review of the EC comes an opportunity to broaden the effort to include other issues related to governance and decision-making in the GAVI Alliance. A paper developed in preparation for the EC retreat in June called Issue Paper #2: "Optimal Structures and Processes for GAVI and The Vaccine Fund", highlighted a number concerns that have been expressed, including:

- Lack of clarity of decisions made during Board and EC meetings and teleconferences and inaccuracies in the reporting of those decisions.
- Agendas that are too full to allow adequate reflection and consideration of the issues.
- The nature, modalities and expected outcome of mutual accountability in GAVI and how they should be effected and evaluated.
- Emergence of factions or sub-blocs within the Alliance and polarization of positions.
- Involvement of the vaccine industry in the EC and other GAVI mechanisms, and how to reduce risk of conflict of interest.

- Unequal preparedness among Board members to consult, discuss and decide upon critical issues.
- The role of the EC in relation to the Board and the decision-making responsibility of the EC.

After its meeting in June the GAVI EC felt that the GAVI chair should identify a special committee to address the variety of process and structural issues identified in the paper, and comments by GAVI Board members and others in reaction to the paper. The GAVI chair was asked to identify a special sub-group, including members of the Board, to prepare a report for the Board with recommendations addressing these issues.

3. Outcomes of the review

The reviewers should:

Provide recommendations on the following issues, among others, as defined by the team:

- The Board agenda.
- Preparation time for Board members.
- Support for Board members in decision-making and other mechanisms to assure wider engagement of the range of partners in Board processes and decisions.
- Clarity of decision-making at Board meetings.
- The authority of the EC in relation to the Board.
- Management evaluation of Board/EC/Working Group roles and relationships.
- Style of communication between Board/EC/Working Group.

Prepare a report and make a presentation to the Board at its December meeting.

4. Review Methods

In order to increase the likelihood of partner buy-in and ownership of the process, it is recommended that a subgroup of the Board conduct this management review. In addition, advice from an external expert on governance issues might help to provide creative solutions and objective problem-solving.

The following are suggested to be members of the management review subgroup:

- One international organization
- One developing country
- One industrialized country
- One industry
- One Working Group member

[Note: a suggested list of individuals for the subgroup will be provided at the Board meeting, based on current consultations.]

The Chair of this subgroup should be a Board member who is impartial, analytical and results-oriented, and who has varied experience with a number of Boards or alliances.

The review should if at all possible include interviews with all members of the Board, Working Group and Secretariat; past Board members and others integrally involved in the Alliance.

5. Timing

The review is expected to start in September with submission of a draft report by end October. The subgroup would report at the December 2004 Board meeting.

Annex 12.1

Excerpt from the Summary Report of the 11th GAVI Board Meeting

Washington, DC – 15-16 July 2003

4. Improving Board Operations

- An Executive Committee of the GAVI Board could help to improve efficiency and facilitate decision-making of the full Board, as the topics being presented to the Board become more and more complex.
- The current two-year term of rotation may be too short for rotating members to fully build their constituencies and contribute to the GAVI Board.

DECISIONS

The Board:

- 4.1 Approved the creation of a GAVI Board Executive Committee, to include all five renewable members (WHO, UNICEF, the World Bank, the Vaccine Fund and the Gates Foundation) and one rotating member each from developing and industrialized country governments. Based on consultations with Board members subsequent to the meeting, USAID (Anne Peterson) and Mozambique (Francisco Songane) have been elected as the first two rotating members of the Executive Committee.
- 4.2 Decided that the performance of the EC should be reviewed after one year of operation in relation to its agreed functions, as outlined in terms of reference developed during the meeting which can be found in the revised Proposal for improved GAVI Board operations.
- 4.3 Endorsed the proposal that other Board members should be consulted and participate in Executive Committee deliberations on specific topics as necessary.
- 4.4 Decided that involvement of Board members – and not alternates – will be essential for the Executive Committee to be effective.
- 4.5 Approved the extension of rotating Board member terms from two to three years.

Annex 12.2

GAVI Board functions

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

- reviews, approves and updates joint objectives and milestones;
- considers the recommendations of the Independent Review Committee and approves support for country immunization programs, requests funds to be disbursed by The Vaccine Fund;
- notes and monitors the commitments of partners to undertake certain strategies and activities;
- approves budgets of the Secretariat and any task force that might be established by the Board;
- contributes, through its members, to fundraising and advocacy activities;
- nominates the Executive Secretary and submits its name to the host organization for appointment;
- shape strategic vision and direction for the Alliance (ultimate decision-maker);
- provides highest level policy decisions stimulating GAVI Partners to adopt new approaches and behaviors (e.g. alignment);
- resolves issues among partners.

GAVI EC functions¹

Report on proposed strategic priorities to the full Board and make recommendations regarding their adoption.

- a) Based on approved priorities, guide and oversee the process of strategic planning and the development of the GAVI work plan.
- b) Report to the full Board on key ongoing strategic and operational issues facing the Alliance.
- c) Report to the full Board on progress and outcomes, ensuring alignment with strategic objectives and values in a transparent manner
- d) Review and act on recommendations of the IRC on country proposals, and request payments from The Vaccine Fund between full Board meetings.
- e) Report to the full Board on any major issues or conflicts arising from a systematic review of Alliance strategies and plans vis à vis the strategies and plans of The Vaccine Fund.
- f) Be responsible for any other functions delegated to it by the full Board.

GAVI Working Group functions²

The Working Group will facilitate the implementation of the decisions and policies of the Board through;

- Communicating major Board decisions – such as new Fund policies and country proposal decisions – to partner constituencies at the regional and national levels.

¹ From Proposal for improved GAVI Board operations, 11th GAVI Board meeting, Washington, DC.

² From “GAVI and The Vaccine Fund – Roles and Responsibilities”, prepared the GAVI Working Group and adopted by the GAVI Board, November 2001.

- Acting as a bridge between the Alliance and operations of individual organizations ensuring operations are consistent with GAVI and partner objectives
- Monitor progress to identify issues arising from partners (including task forces, regional working groups, countries) that require Board decisions
- Prepare background documentation for Board to make decisions – preferred practice is to provide more than one recommendation
- Oversee operations of GAVI structures, including involvement in the appropriate task forces, and identify important structural issues for Board decision.

Annex 13

*** REVISED ***

Interim Annual Progress Report GAVI Yellow Fever Vaccine Stockpile

July 2004

1. Background

At its Dakar meeting on the 18-19th November 2002, the GAVI Board approved the establishment of a yellow fever (YF) vaccine stockpile to be loaned for outbreak response and used for preventive campaigns. The approval was for 6 million doses each year for an initial period of 3 years. In order to clearly outline the procedures for the establishment, use and replenishment of the stockpile, a series of meetings and videoconferences were held with representatives from The Vaccine Fund, WHO and UNICEF Supply Division (SD) at the beginning of 2003. Consequently, the procedures were agreed upon and written in a document titled "*The Yellow Fever Vaccine Stockpile: Procedures for Establishment, Use and Replenishment of the Yellow Fever Vaccine Stockpile Supported by GAVI and The Vaccine Fund*", which also outlines the roles and responsibilities of each agency.

In summary, the document states the following operational procedures and responsibilities:

- The annual stockpile of 6 million doses will be accumulated by the manufacturer at the beginning of the year.
- In the event of a YF outbreak during the year, vaccine from the stockpile may be released and shipped to affected countries. WHO, as part of the YF sub-group of the International Coordinating Group for Provision of Meningococcal Vaccines (ICG) coordinates the assessment of country documentation and requests for emergency support. According to the ICG mandate, the use of the stockpile is prioritized for the countries that are not able to find either the vaccine or the funds to purchase it for a prompt outbreak response. If the outbreak is verified and these conditions are met, WHO requests from UNICEF SD to allocate YF vaccine from the stockpile.
- Vaccines used for this purpose are expected to be replenished before the end of the calendar year, so that the total amount of annual stockpile is available for use in preventive campaigns. The availability of replenished vaccine will depend on the time funding is received, the quantity to be replenished and the production plans of the manufacturers.
- At the beginning of the following year, all remaining vaccine in the stockpile will be released for shipment and used in preventive campaigns in the countries identified by WHO and UNICEF as being at high risk for yellow fever.

- As these planned campaigns will deplete the stock in hand, the following year's stockpile should be already accumulated and ready to be loaned for outbreak response.

The experience with the YF stockpile in 2003 and in the first half of 2004 is summarized in this report.

2. Accumulation of the stockpile

2003 stockpile: Once the procedures were agreed upon, The Vaccine Fund transferred the funds to the Vaccine Fund Trust Account at UNICEF in May 2003, and the process was initiated. The first 6 million doses were successfully accumulated by Aventis by the end of August 2003.

2004 stockpile: The 2004 stockpile was not accumulated by January 2004 as originally planned. It is expected to be available according to the following schedule given by the manufacturer:

- 2,000,000 doses by the end of May 2004
- 1,000,000 doses by the end of June 2004
- 3,000,000 doses by the end of July 2004

A number of factors contributed to this late accumulation including:

- A delay in the request to The Vaccine Fund for approval and transfer of funds in 2003, causing UNICEF SD to start negotiations with the manufacturer only at the end of October.
- Manufacturing problems in Aventis causing delays in vaccine production
- Unplanned vaccine demands of Aventis by several Latin American countries due to YF outbreaks at the end of 2003.

3. Utilization and replenishment of stockpile for outbreak response

2003 stockpile: After the stockpile was established in July/August 2003, a YF outbreak occurred in Sierra Leone in September 2003. A response campaign was started using an emergency vaccine stock existing in the country. In addition, 150,000 doses of YF vaccine from the stockpile were used to carry out the campaign as planned. Several contacts were made with potential donors by WHO at country and HQ level to replenish this vaccine, but no pledge was obtained. Consequently, the balance of stockpile was 5,850,000 doses at the end of 2003. The duration of the 2003 stockpile contract was extended from January 2004 to May 2004.

2004 stockpile: In January 2004, an outbreak in Colombia occurred and an emergency supply of 1,000,000 doses of vaccine from 2003 stockpile was shipped to the country to meet the immediate need. Another YF outbreak occurred in Liberia in February 2004, requiring 495,000 doses of vaccine from 2003 stockpile for the outbreak response. Because the 2004 stockpile was not yet accumulated, the scheduled shipment for one of the preventive campaigns had to be postponed in order to respond these outbreaks.

Regarding the replenishment of the vaccine used for Liberia outbreak, a fund-raising proposal was written and widely disseminated to potential donors by both WHO HQ and UNICEF. Two pledges from Ireland and Norway were received. Subsequently, UNICEF HQ transferred US\$ 150,000 for replenishment to Supply Division in May

2004. The Colombian government has not yet transferred the funds for the replenishment of 1,000,000 doses of vaccine.

4. Utilization of stockpile for preventive campaigns

2003 stockpile: Given the design of the stockpile, the first year was dedicated to planning and preparation activities for the preventive campaigns that would take place early next year, using the vaccine stock of 2003. WHO and UNICEF agreed on the prioritization criteria to select the countries to conduct preventive campaigns using vaccine from the stockpile:

- 1) Evidence that populations to be vaccinated are at high risk for YF – based on best available epidemiological, entomological and immunization coverage data.
- 2) The introduction of YF vaccine as part of routine infant immunization.
- 3) The implementation of case-based surveillance for yellow fever.
- 4) The ability to mobilize part or all funds needed for the operational costs of the preventive campaign.
- 5) The ability to implement a safe and effective preventive campaign.

As a result of the evaluation using these criteria, Senegal and Guinea were identified to implement preventive campaigns in 2004. Planning missions were carried out by WHO to both countries by the end of May 2003. Detailed micro-plans were developed with the Ministry of Health where data on persons already vaccinated in the entire country was obtained, and the population targeted for vaccination in each high-risk district was calculated. The countries have been allocated 3,000,000 doses of YF vaccine each from the stockpile. The micro-plans also included a detailed budget required for the campaign (excluding the cost of bundled vaccine). Partners in those countries were met and sensitized on the importance of the preventive campaigns in the control of yellow fever, and the need to mobilize funds for the operational costs of the campaigns.

2004 stockpile: As per the stockpile agreement, all remaining doses from 2003 were to be released to be used in preventive campaigns no later than during the first month of 2004. The delayed accumulation schedule in 2004 contributed to postpone the shipment of a part of previous year's stock for preventive campaigns, as otherwise there would be no vaccine in hand until June 2004 to be used in the event of a YF outbreak.

In January 2004, Senegal received 3,000,000 doses of bundled YF vaccine from the 2003 stockpile to use in the campaign. In the meantime, Ministry of Health has decided to extend the campaign to cover all the susceptible population in the country, and is considering purchasing an additional 3,000,000 doses of vaccine. Following a government change in April, Senegal is currently waiting for the political decision to mobilize necessary funds for the campaign.

The vaccine for Guinea was divided into two shipments, in order to maintain a minimum supply in the stockpile in case of an outbreak. As mentioned earlier, delay in accumulation of 2004 stockpile has prevented Guinea to receive all vaccine at the beginning of the year. In May 2004, the country received 1,350,000 doses of bundled YF vaccine from the 2003 stockpile. Pending the replenishment from PAHO/Colombia, the remaining 1,650,000 doses are estimated to be dispatched by mid to end July 2004. The country is in the process of raising the operational costs needed for the campaign.

Currently WHO is in the process of identifying countries to conduct preventive campaigns in 2005.

Annex 13.1

Draft Letter from GAVI Executive Secretary to The Vaccine Fund

Mr Jacques-François Martin
President
The Vaccine Fund
36 Quai Fulchiron
69005 LYON

..... June 2004

Dear Jacques-François,

Request to approve allocation of funds for the third year (2005) of yellow fever vaccine stockpile

We would like to formally request Vaccine Fund approval for the allocation of US\$ 6,046,080 to purchase 6 million doses of yellow fever vaccine to stockpile for the year 2005. The actual claim to release the transfer of funds to the Vaccine Fund Trust account at UNICEF will be made by Ms Marilena Viviani in UNICEF New York.

The cost of the 6 million doses in 20-dose vials is higher than the initial estimated cost made in May, 2002 of US\$ 3,000,000. This difference is mainly due to the increase in vaccine price, as the manufacturer will only supply YF vaccine in 10-dose vials in 2005 due to the upgrading of manufacturing facilities. Aventis has confirmed that the 2005 price of a 10-dose vial is US\$ 0.88 per dose, compared to the 2004 price of 0.45 per dose. Please note that in addition to the vaccine cost, the above amount includes the associated safe injection equipment and delivery costs.

It is also noted that the stockpile can only be arranged with Aventis at this time due to the fact that Aventis is the manufacturer that can handle properly a stockpile given the production size, warehouse capacity and capacity of response in emergency situations. No other manufacturers can offer these capabilities at this point in time.

An interim report on the use of the stockpile is attached for your information. Once the stockpile of 2003 has been depleted, a detailed report of its use will be provided to the GAVI Board at its December 2004 meeting.

We would be happy to provide you with further details on the use of the yellow fever vaccine stockpile upon your request.

Yours sincerely,

Dr Tore Godal
Executive Secretary
Encl.

cc: Members of the GAVI Board and Working Group
Vaccine Fund Executive Committee
Ms Alice Albright, Vaccine Fund
Mr Terry Brown, Ms Marilena Viviani, UNICEF New York
Mr Stephen Jarrett, Ms Shanelle Hall, UNICEF Supply Division
Mr Umberto Cancellieri, GAVI Secretariat

Annex 14

UNICEF request to GAVI Board for the Vaccine Fund Trust Account bridge budget for 2005

Background

In 2000, UNICEF agreed to manage the Vaccine Fund Trust Account on behalf of GAVI in order to facilitate financial transactions aiming to strengthen immunization services, procure new vaccines for 75 GAVI eligible countries and provide support for research of new vaccines. By end of 2003, a total of US\$ 497.7 million has been approved for disbursement of which US\$ 383.4 million has been disbursed through the Vaccine Fund Trust Account. In terms of procurement, 59,186,428 doses of vaccines were supplied with 55,224,000 auto-disable syringes and 595,850 safety boxes. The Third GAVI Board approved a budget of US\$ 9.1 million to UNICEF for the period **2000-2004** to support incremental activities related to the management of the Vaccine Fund Trust Account.

This document is proposed to the GAVI Board to approve a budget for **2005**. The budget requested for 2005 will serve a bridge to complete UNICEF transactions of biennium 2004-2005. Subsequently, next requests will be on biennium basis in order to maintain the continuity in managing the Trust Account and comply with UNICEF procedures.

Management of the Vaccine Fund Trust Account

The roles and responsibilities for the management of the Trust Account are those **approved** by the Third GAVI Board in June 2000. They are organized under two main functions addressing the following GAVI windows: procurement of new and underused vaccines, disbursement of funds for strengthening immunization services and for ADIPs¹.

The procurement function consisted primarily of planning and delivery of vaccines and immunization devices funded by GAVI/Vaccine Fund. New developments such as safe injection support and the yellow fever stockpile were added to procurement activities during the GAVI implementation process (2000-2004). To secure vaccine availability from manufacturers, firm contracting for long-term period has been initiated. For vaccine quality, funding support is provided to WHO for manufacturers pre-qualification and quality assurance of new vaccines.

The function of funding management consists in the receipt of funds from donors to the Trust Account and funds disbursement based on GAVI/Vaccine Fund Board approval.

¹ For details see Annex 6 of the Third GAVI Board Report: Incremental activities related to the Management of Global Fund for Children's Vaccines Working Capital Account.

The complexity of work has steadily increased with the number of transactions and volume of total funds being disbursed. Regular accounting reconciliation and reporting on financial transactions and quarterly financial forecasting allow The Vaccine Fund to plan funds disbursement to the Trust Account.

The coordinating function ensures that interaction between partners, donors and recipient countries is effective in relation with financial transactions and procurement activities performed by the Trust Account for the implementation of GAVI/Vaccine Fund related activities. One role of the Management of the Trust Account is to coordinate fundraising activities for immunization and monitoring of relationships with donors within GAVI framework.

Resources requirements for 2005

The requested budget of US\$ 3,592,347 for 2005 represents needs for staff and administrative costs to manage the Vaccine Fund Trust Account activities. The budget remains in the line with the previous approved budget of 2004 and the increase for 2005 covers the normal increase in staff cost and no additionality.

The management of the Vaccine Fund Trust Account involves directly four divisions of which some staff funded from the Vaccine Fund Trust Account budget are directly involved in these activities.

The budget below shows a breakdown of needed funds per division to manage Trust Account related activities for GAVI/Vaccine Fund.

The GAVI Board is requested to approve the budget of US\$ 3,592,347 for the Management of the Trust Account at UNICEF for 2005 as a bridge budget.

HQ Divisions	2005 Budget
<i>Supply Division</i>	2,046,450
<i>Programme Division</i>	306,164
<i>Division of Financial and Administrative Management</i>	219,829
<i>Coordination Programme Funding Office</i>	409,904
<i>Staff Termination Fees</i>	250,000
<i>Support to Vaccine Quality with WHO</i>	360,000
TOTAL	3,592,347

Annex 15

List of participants

Host Organization, Board Members, Working Group Members and Observers

*** Board Member*

**Working Group Member*

HOST ORGANIZATION

AMERICAN RED CROSS

1. Ms. Marsha Evans, President and Chief Executive Officer
2. Mr. Gerald Jones, Vice President, International Services
3. Dr. Mark Grabowsky, Senior Technical Advisor

WHO

4. **Dr. LEE Jong-wook, Director-General & Chair
5. **Ms. Joy Phumaphi, Assistant Director-General, Family and Community Health
6. *Ms. Tracey Goodman, Technical Officer
7. Dr. Rudi Eggers, WHO AFRO
8. Dr. Patrick Zuber, Project Leader, Accelerated Vaccine Introduction

UNICEF

9. Mr. Kul Gautam, Deputy Executive Director, UNICEF
10. **Dr. Pascal Villeneuve, Chief Health Section
11. *Dr. Jean-Marie Okwo-Bele, Senior Health Adviser and Team Leader, Immunization Activities
12. Mr. Stephen Jarrett, Deputy Director of Supply Division
13. Ms. Heidi Larson, Senior Communication Officer
14. Mr. Peter Mason, Office of the Executive Director

THE WORLD BANK

15. **Dr. Jean-Louis Sarbib, Senior Vice President, Human Development
16. *Dr. Tony Measham, Consultant
17. Ms. Amie Batson, Senior Health Specialist

BILL & MELINDA GATES FOUNDATION

18. **Dr. Richard Klausner, Executive Director of Global Health
19. Dr. David Fleming, Director of Global Health
20. *Dr. Sally Stansfield, Associate Director for Global Health
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22. **Mr. Jacques-François Martin, President and Chief Executive Officer
23. Mr. Charles J. Lyons, President, US Fund for UNICEF & Member of the Vaccine Fund Board

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28. Dr. Steve Landry, Senior Director, Program Financing
29. Ms. Vanina Laurent, Chief, Office of the President
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31. **Dr. Khandaker Mossarraf Hossain, Minister of Health and Family Welfare
32. H.E. Syed Hasan Ahmad, Ambassador of Bangladesh in Washington
33. Mr. Shahidul Islam, Political Counsellor, Embassy of Bangladesh, Washington

CONGO, DEMOCRATIC REPUBLIC OF

34. H.E. Dr. Jean Yagi Sitolo, Minister of Health
35. Dr. Mbuya Mbayo, EPI Director

MOLDOVA

36. *Mr. Oleg Benes, Medical Epidemiologist, National Center of Preventive Medicine

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37. **Dr. Francisco Ferreira Songane, Minister of Health

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47. Ms. Fern Leathers, UK Treasury
48. Ms. Beverley Warmington, UK Treasury

UNITED STATES OF AMERICA

49. *Ms. Susan McKinney, Advisor for Immunisation; Maternal and Child Health, USAID
50. Dr. Murray Trostle, USAID

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BRAC

51. *Dr. A. Mushtaque R. Chowdhury, Director of Research and Evaluation Division, Bangladesh

PATH

52. Dr. Mark Kane, Director, Children's Vaccine Program, USA

RED CROSS

53. **Dr. Muctaru A. S. Jalloh, National President, Sierra Leone Red Cross Society

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54. **Dr Suresh Sakharam Jadhav, Director, Serum Institute of India

INDUSTRIALIZED COUNTRIES

55. **Mr. John Lambert, President, Chiron Vaccines
56. Mr. Rudi Daems, Executive Director, Policy and Corporate Affairs, Chiron Vaccines
57. *Dr. Elaine Esber, Executive Director, Merck – Vaccine Division

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60. Professor Myron M. Levine, Director, University of Maryland School of Medicine, U.S.A.
61. Ms. Ruth Levine, Center for Global Development, Washington
62. Dr. Rebecca Prevots, Epidemiologist, National Institute of Allergy and Infectious Diseases, National Institute of Health/NIH, U.S.A.

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64. Dr. Stephen Hadler, Chief, Routine Immunization, Centers for Disease Control and Prevention, U.S.A.
65. Dr. Vance Dietz, Leader of Strengthening Childhood Immunization Team, Global Immunization Division, Centers for Disease Control and Prevention, U.S.A.

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- 76. Ms. Corina Luputiu, Assistant
- 77. Mr. Bo Stenson, Principal Officer, Alliance Co-ordination
- 78. Ms. Anne Winter, Principal Officer, Advocacy and Communications

Annex 16

Online resources

GAVI Work Plan: http://www.vaccinealliance.org/General_Information/About_alliance/workplan/0405workplanindex.php

Investment Case Guidelines: http://www.vaccinealliance.org/Board/Board_Reports/13_board_icframework.php

Report of the 13TH GAVI Board meeting (*includes presentations and background documents*): http://www.vaccinealliance.org/Board/Board_Reports/13th_Board_Summary.php

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