

NINTH GAVI BOARD MEETING



GAVI

**THE GLOBAL ALLIANCE FOR
VACCINES & IMMUNIZATION**

Partnering with The Vaccine Fund

Dakar, Senegal

20-21 November 2002

NINTH GAVI BOARD MEETING

Dakar, 18-19 November 2002

Summary Report

1. Revisiting the GAVI Milestones

Discussion

- The GAVI milestones were developed before the alliance was underway; therefore it is timely to revisit them with an intention of achieving greater clarity and more consistency. For example, different milestones refer to, respectively, 'all countries', 'all developing countries', or 'the poorest countries'.
- The GAVI partners have achieved great progress toward their goal of increasing use of hepatitis B vaccine; the first GAVI milestone, that *'by 2002, 80% of all countries with adequate delivery systems will have introduced hepatitis B vaccine'* will be achieved. In fact, the milestone that *'by 2007 all countries will have introduced the vaccine'* may not be ambitious enough. However, this may depend upon whether the combination vaccines including hepatitis B will become more widely available.
- The challenges we face in reaching the GAVI milestone that *'by 2005, 80% of developing countries will have routine immunization coverage of at least 80% in all districts'*, or the '80/80 goal', are great. It will be important that the work done to analyze and recommend strategies for increasing access will help to establish whether this goal is feasible or should be modified, and how it, or a new goal, could be reached.
- Progress toward reaching the *Haemophilus influenzae* type b milestone, that *'by 2005, 50% of poorest countries with high disease burdens and adequate delivery systems will have introduced Hib vaccine'* is difficult to measure because of uncertainty concerning disease burden in Asia and Central Europe.
- Any consideration of the polio milestone, that *'by 2005, the world will be certified polio-free'* should follow the recommendation of the Global Certification Committee which will meet in March 2003.
- The milestones concerning rotavirus and pneumococcal vaccines, that *'by 2005, the vaccine efficacy and burden of disease will be known for all regions for rotavirus and pneumococcal vaccine, and mechanisms identified to make the vaccines available to the poorest countries'* should be considered by the ADIP teams with a goal of identifying more measurable indicators.

DECISIONS

The Board:

- 1.1 **Requested** more analysis of the milestones, including proposals to make the indicators and denominators more unambiguous and consistent, for

presentation to the GAVI Board at its next meeting. They should be looked at both globally and in terms of the 75 Vaccine Fund eligible countries.

- 1.2 **Requested** the team to develop and propose GAVI milestones concerning yellow fever vaccine and AD syringes, since these are both GAVI priorities.
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2. GAVI Progress Report

Discussion

- The Board noted the remarkable progress that has been made in the first phase of GAVI toward reaching broad consensus on goals and utilizing new and existing systems to encourage increased focus on immunization. In the next operational phase, optimal systems for building upon this progress may look different. There is a big difference between strategies to introduce new vaccines or increase access, and maintaining that increased access.
 - The definition of good vs. poor performance needs to be examined. Is a country which set modest goals and surpassed them a good performer? Is a country which set too ambitious goals and did not achieve them a poor performer? While it is too soon to draw real conclusions, it is good to look at which countries are 'above the line' and which countries are 'below the line' and to ask whether introduction of new vaccines is having a negative impact on provision of basic services. This analysis will be strengthened when countries can be tracked over several years and patterns may emerge.
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DECISIONS

The Board:

- 2.1 **Recommended** that measurement of GAVI's progress should link the financial and other support being provided, and the programmatic impact of this support in countries.
- 2.2 **Requested** the Secretariat to provide a report on which countries had built immunization into their poverty alleviation strategies.
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3. Recommendations from the Independent Review Committee teams

Discussion

- The Board expressed its confidence that both IRC teams – proposals and monitoring – had conducted rigorous and comprehensive reviews and that their recommendations were sound.
- It may be important to develop mechanisms so that issues raised in the reviews, such as countries that make repeated unsuccessful applications, and long delays in

receipt and/or use of funding, are followed up by technical staff of Board members. The noted delays in shipments of vaccines and transfer of funds needs to be analyzed fully to identify reasons for the delays and strategies for overcoming them.

- The monitoring team identified a number of issues that will need to be followed: The apparent lack of ICC involvement in monitoring country progress in many countries; the insufficient information about how immunization services funding is being used; and the general low quality of annual report documentation provided by countries.
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DECISIONS

The Board:

- 3.1 **Endorsed** all of the recommendations of the IRC concerning approval of country proposals and annual reports. The financial implications for the approval of the new country proposals are estimated to be US\$ 9.3 million for 2003-2004, and US\$ 18.5 million for the five-year funding period. The financial implications for the approval of country inception and progress reports are estimated to bring a saving of US\$ 4.5 million for 2003 compared to previously approved support.
 - 3.2 **Requested** The Vaccine Fund Executive Committee to approve the above recommendations, and to provide \$14 million to meet the financial obligations of this decision. With this recommendation, the five-year commitment from the Vaccine Fund is now \$905 million.
 - 3.3 **Approved** the proposal from the IRC to extend eligibility for injection safety support to those countries who currently do not qualify for immunization services support or new and under-used vaccines (currently Nicaragua, Honduras, Cuba, Bolivia).
 - 3.4 **Recommended** that the composition of the IRC monitoring team be strengthened in the areas of immunization program management and health economics; that in the future country reports be pre-assessed by relevant experts in partner agencies; and that the guidelines for annual progress reports be amended based on the initial experience.
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4. Joint session and topics with Executive Committee of the Vaccine Fund

Discussion

- One of the tenets upon which the Vaccine Fund was designed was to increase reliability of vaccine supply, or 'vaccine security', by making longer term purchasing commitments vaccine manufacturers. The GAVI emphasis on results-based funding does not have to be in conflict with this ideology.

- The Board welcomed the commitment from Jacques-François Martin that The Vaccine Fund Executive Committee will always respond to GAVI Board requests within one week.
 - As the Vaccine Fund makes the case for funding from new donors, it will be important to prioritize activities and report on results of efforts to date, while keeping an eye on whether global financing mechanisms distort country priorities. European government Board members may be helpful in securing EU funding for The Vaccine Fund.
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DECISIONS

The Board:

- 4.1 **Endorsed** the proposed approach to long-term funding for vaccines from GAVI and The Vaccine Fund, as outlined by Alice Albright of the Vaccine Fund. In this approach:
 - 4.1 There would be a distinction between commitments for vaccine procurement and financial disbursements to countries.
 - 4.2 Procurement decisions would be made for up to five years on the basis of the current forecast. Both GAVI and Vaccine Fund Boards would approve these procurement decisions at the outset of a procurement cycle.
 - 4.3 The Vaccine Provision Project (VPP) could negotiate long term purchase commitments as needed.
 - 4.4 GAVI and the Vaccine Fund would continue to monitor country progress annually; disbursements of supply would be based on receipt of satisfactory annual progress reports.
 - 4.5 In situations where there is a serious lack of progress and/or non-fulfillment of reporting obligations, the Boards may have to consider discontinuation of support for vaccine supply. This situation would be exceptional and would occur only after extensive consultation with the ICCs to remedy the situation.
 - 4.2 **Requested** the Vaccine Fund to work with the VPP and the GAVI Secretariat to continue analysis and report back to the Board with a proposal that addresses the specific operational issues and mechanics.
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5. GAVI Work Plans, including proposed budgets and discussion of financing

Discussion

- The GAVI Consolidated Work Plan, while representing a tremendous step forward, presenting a basis for efforts to define and build upon GAVI's "added value", remains a "work in progress". Areas for clarification are noted below.

- The reliance on partners to implement is fundamental to the concept of GAVI. However, this complicates efforts to elaborate a credible plan to achieve the GAVI objectives and to hold the alliance accountable for its promised achievements.
- There was concern that the current version of the work plan suggests that GAVI might assume increasing responsibility for implementation at the country level. It is important for GAVI to focus on adding value (vs. substituting for partners' roles); in so doing, GAVI is bound to challenge partners to fulfil their respective responsibilities.
- There is a lack of a clear linkage between the plans for global and regional GAVI activities, and country-level immunization activities. It will be important that further iterations of the work plan reflect input from countries on their perceived needs from GAVI. Developing country board members welcomed the suggestion to provide \$25,000 per year to each Vaccine Fund eligible country ICC to enhance their ability to manage the proposal and monitoring process.
- Broadening the constituency for GAVI, including through an enhanced role for NGOs, may accelerate progress toward improving "access".
- While task forces and regional working group structures have been very important in the initial phase, such as to develop concepts for new initiatives (e.g., financial sustainability plans, the ADIPs) or to generate a short term "surge" of effort, some Board members would like to consider establishing other mechanisms (like the vaccine provision project) for longer term activities that require a substantial budget and clear structures for management and accountability.
- Sources of financial support for the work plans will include a mix of resources from the implementing partners, GAVI donors, and the Vaccine Fund.

DECISIONS

The Board:

5.1 **Agreed** to the following plan for taking the work planning forward:

5.1.1 **Objective:** To finalize and resource the GAVI consolidated work plan for 2003 (2004).

5.1.2 **Key elements:**

- i) Develop framework for the work plan based on the GAVI added value concept.
- ii) Align the consolidated work plan with GAVI's added value
 - Current work plan elements to focus on added value
 - Exclude those activities that do not contribute to added value
 - Include additional activities that fill gaps
- iii) Analyze the allocation and use of current donor contributions to implementing partners for GAVI "added value" activities.

- iv) Develop the financing mechanisms for unfunded activities.
 - v) Establish management structures and processes that will allow optimization of the use of resources, outcomes and GAVI's added value.
- 5.1.1 **Process:** Board sub-group to work with the GAVI Secretariat to finalize a revised work plan to be submitted to the full Board by the end of January 2003. The Working Group will be consulted throughout the process.
- 5.1.2 **Board sub-group composition:** WHO, UNICEF, Mali, Norway, Netherlands, Gates Foundation, Red Cross, CDC [subsequent to the meeting the World Bank requested to join the sub-group].
- 5.2 **Requested** the Executive Secretary to provide a new proposal for Working Group composition that reflects a more rapid turnover of members while maintaining a consistent and skill-based group, as opposed to a strictly representational group. Increased developing country participation could be sought through the R&D seat.
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6. Accelerated Development and Introduction Plans

Discussion

- Board members that may have had a conflict of interest in the discussions were recused. These were: WHO, CVP-PATH, CDC, Wyeth-Ayerst, CIGB.
 - The present Board members welcomed the presentation by Helena Makela, the chair of the GAVI Board ADIP Sub-Group and stressed the importance of clear 'go' / 'no-go' decision points and further exploration of how to obtain input from industry.
 - Since the Board members had not had enough time to review the proposals, a teleconference was scheduled for 29 November to make decisions on the recommendations.
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DECISIONS

[Reached during the 29 November teleconference.]

The Board:

- 6.1 **Approved** conditionally the rotavirus ADIP proposal from CVP-PATH, pending clarifications in particular in relation to its management.
- 6.2 **Requested** a resubmission of a joint proposal by the two applicants for the pneumococcal ADIP, or alternatively, a full proposal by each which would then be re-reviewed in competition.
- 6.3 **Approved** the committee's recommendation to extend the ADIP timeframe from three to five years; the budget of US\$ 30 million would also be extended to this five-year framework.

- 6.4 **Requested** that all proposals be subject to a final review as soon as possible by the ADIP sub-Group (mid-January 2003 is a likely date), and that its final recommendations be submitted to the GAVI Board soon thereafter.
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7. Human Resources for Immunization

Discussion

- The human resource issue is critical for sustainable immunization and the success of GAVI. However, efforts to address human resources for immunization cannot be conducted in isolation but should be part of a process to improve human resource capacity across the health system.
 - Board members stressed the need to address human resource issues from the country perspective, and that external assistance can be only part of the solution.
 - It might be valuable to examine a number of specific cases that exemplify two distinct categories of countries: 1) countries with good governance and strong leadership; and 2) countries in complex emergencies. It may be that for countries in complex emergencies, a broader health system approach is not feasible.
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DECISION

The Board:

- 7.1 **Requested** that Julian Lob-Levyt, with support of WHO and UNICEF, take the lead in developing an effort that would look at a few specific country examples to examine actual human resource challenges and potential solutions. He will report on his progress at a forthcoming Board teleconference.
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8. Yellow Fever

Discussion

- The Board noted with concern that yellow fever has re-emerged as a disease of considerable public health importance in West and Central Africa and agreed that a major constraining factor for the control of this disease has been the very limited global availability of vaccine.
- While GAVI and the Vaccine Fund currently provide yellow fever vaccine to countries for routine infant use, it would be well within the GAVI priorities of decreasing mortality from vaccine-preventable diseases to provide support for a strategy more suitable to control of yellow fever.

DECISIONS

The Board:

- 8.1 **Approved** the proposal to establish a vaccine stockpile of yellow fever vaccine for preventive campaigns and emergency response activities.
 - 8.2 **Requested** the Vaccine Fund to provide an estimated US\$ 3 million per year – for an initial period of three years (US\$ 9million) – to establish a yellow fever stockpile, with performance and impact to be assessed prior to extension.
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9. Measles

Discussion

- Given the availability of safe, effective and relatively inexpensive measles vaccine and proven vaccination strategies, the current global burden of measles deaths is unacceptable.
 - To reduce measles deaths on a long-term basis, measles mortality reduction strategies including routine immunization and periodic measles supplementary immunization activities, should be part of countries' comprehensive immunization plans, and endorsed by their ICCs.
 - The commitment of the relevant country governments is essential for the success of the efforts and to secure the funds necessary to support them.
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DECISIONS

The Board:

- 9.1 **Approved** the proposal to issue a statement to the media and the public confirming the GAVI Board's commitment to measles mortality reduction and encourage GAVI partners to provide financial support to the cause.
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10. Vaccine Provision Project

Discussion

- There are divergent views on the Board concerning the role of industry in the Vaccine Provision Project. Some consider the industry perspective essential for accurate forecasts and to ensure open lines of communication while others consider the potential conflict of interest to be a significant threat. This issue will need to be further explored.
- As countries become more accustomed to the use of pentavalent DTP-hep B-Hib, vaccine wastage will most likely decrease. However, for forecasting purposes a more generous wastage rate should be considered so that countries do not face stock-outs.

DECISIONS

The Board:

- 10.1 **Endorsed** the report of the Oversight Committee.
 - 10.2 **Endorsed** the forecast methodology chosen while stressing the need for strong involvement of countries in the forecasting process.
 - 10.3 **Endorsed** the use – for forecasting calculations only – of 10% wastage for the 2-dose pentavalent vaccine.
 - 10.4 **Requested** guidance in the next update (30 January 2003) on how to approach manufacturers.
 - 10.5 **Agreed** that Jacques-François Martin should be an additional member of the Oversight Committee in order to contribute his perspective as a former vaccine industry executive.
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11. Vaccine Vial Monitors

- The Board recognized that there are many complex issues related to the adoption of vaccine vial monitors (VVM) but reiterated its conviction that VVMs provide an important safety and quality-control benefit.
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DECISIONS

The Board:

- 11.1 **Requested** that the minutes of the March 2002 meeting with manufacturers be circulated to the Board.
- 11.2 **Recommended** immediate intensive action by appropriate GAVI Partners to accelerate the implementation of VVMs, consistent with ensuring vaccine security.
- 11.3 **Resolved** as an objective that all vaccines supported by the Vaccine Fund will include VVMs after 2003.
- 11.4 **Urged** all national and international agencies procuring vaccines to include VVMs as a requirement latest as of 2004, so the full programmatic benefits of VVMs can be realized.
- 11.5 **Urged** vaccine manufacturers to complete the preparation needed to provide all vaccines with VVMs within a stated time schedule, but no later than end-2003.
- 11.6 **Requested** vaccine industry members of the GAVI Board to provide at its first meeting in 2003 and update on action taken.

12. Access Framework

Discussion

- The Board welcomed the focus on access, recognizing that it constitutes a critical component of successful and sustainable immunization efforts and the success of the Alliance as a whole.
 - In developing new strategies to increase access, is essential to build on experience but to also pursue innovative solutions such as greater involvement of NGOs in strategy development and implementation. Furthermore, solutions must be nationally-driven, as opposed to top-down, and consider the larger health service delivery context.
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13. Next Board meetings

DECISIONS

The Board:

- 13.1 **Agreed** to hold the next Board meeting 18-19 June 2003, venue to be decided.
- 13.2 **Scheduled** a teleconference for Wednesday 18 December 2002 [subsequently changed to 19 December].

Agenda

Monday, 18 November

GAVI Progress

- Refining the global milestones *Olivier Ronveaux*
- Report of the Executive Secretary *Tore Godal*
- Recommendations of the IRC – Proposal and Monitoring *Oleg Benes,
Ciro de Quadros*

Joint session and topics with Executive Committee of The Vaccine Fund

- Rules for disbursement, monitoring and multiyear commitments *Alice Albright*
- Strategic priorities and resource management and development: GAVI and The Vaccine Fund *Jacques-François
Martin*
- Support to resource development by the Partners *Jacques-François
Martin*

GAVI Work Plans

Tore Godal

Tuesday, 19 November

Access Framework: Proposal to Develop a Strategic Framework to Increase Access to Immunization *A. Asamoah-Baah*

Human Resources for Immunization *A. Asamoah-Baah*

Establishment of a strategic stockpile for Yellow Fever vaccine *Paul Fife*

Measles Statement *Deo Nshimirimana*

Vaccine Provision Project *Paul Fife,
Fatoumata Nafou
Traoré*

ADIPs, possible selection of host institutions *Helen Makela,
Raj Shah*

Developing Country Vaccine Manufacturers' Network update *Luis Herrera
Saturnino*

New Board members

In camera

Executive Secretary recruitment *Carol Bellamy*

List of annexes

- Annex 1:** Independent Review Committee outcomes
- Annex 2:** GAVI Secretariat: Interim 2001-2002 report and work plan budget for 2003-2004
- Annex 3:** Proposal to develop a strategic framework to increase access to immunization
- Annex 4:** Human Resources for Immunization
- Annex 5:** Establishment of a strategic stockpile for yellow fever vaccine to accelerate control and contribute to vaccine security
- Annex 6:** GAVI statement on an immunization system strengthening approach to measles mortality reduction
- Annex 7:** Report of the 1st meeting of the GAVI Board Oversight Committee – Vaccine Provision Project
- Annex 8:** Update on the adoption of vaccine vial monitors (VVMs) for all EPI vaccines
- Annex 9:** List of participants

Annex 1

Independent Review Committee Review Outcomes

Recommendations from the Proposal Team

The proposal team of the Independent Review Committee (IRC) met in Geneva from 24 October to 1 November 2002 for the review of country proposals for GAVI/VF support. Seven IRC members participated (See Annex 1.1).

Twenty-five countries submitted proposals for this review, with a total of 42 requests for different types of support broken down as follows:

Immunization services:	5 requests
Injection safety:	21 requests
New and under-used vaccines:	
Introduction of yellow fever vaccines	7 requests
Introduction of hep B vaccines	5 requests
Introduction of Hib vaccines	4 requests

The proposal team's recommendations on the above proposals are summarized in Table 1. The Board is requested to review these recommendations.

The financial implications for 2003-2004 that result from these recommendations on country proposals are estimated to be US\$ 9.3 million (Tables 2 and 3) and the financial commitment for a five year period is estimated to be US\$ 18.5 million.

Update

Including the recommendations from this review, 64 countries will have been approved for support from The Vaccine Fund. For a summary of the approval status of countries eligible for Vaccine Fund support, please see Figure 1.

The overall financial five-year commitment of The Vaccine Fund including the now recommended approvals of new proposals and of requests in the inception/progress reports amounts to US\$ 905 million (including estimated freight cost). For a detailed calculation of estimated five-year commitments by country see Table 4.

With the recommended revision of criteria submitted to this Board meeting for approval, of the 75 countries eligible for GAVI/VF support (GNP/cap US\$ < 1,000) four countries will qualify for Injection Safety Support (Table 5). The remaining six countries have not so far been approved and their status appear on Table 6.

Table 1: Recommendations on reviewed proposals

Country	Requests				
	ISS	INS	YF	hep B	Hib
Azerbaijan		Clarification			
Bangladesh		Re-submission			
Bhutan		Clarification			Conditional
Burkina Faso		Approval			
Cameron		Clarification	Conditional		
CAR	Approval	Clarification	Approval		
Chad	Conditional	Conditional	Conditional		
Congo	Re-submission	Re-submission	Re-submission	Re-submission	Re-submission
Eritrea		Re-submission			
Ghana		Clarification			
Guinea Bissau	Clarification	Conditional			
Kyrgyz Rep		Conditional			
Kenya		Clarification			
Mali		Clarification		Clarification	
Mauritania	Approval			Re-submission	Re-submission
Mozambique		Clarification			
Nigeria			Conditional		
Rwanda		Clarification			
São Tomè		Clarification	Approval	Approval	
Senegal				Re-submission	Re-submission
Somalia		Clarification			
Tanzania		Clarification			
Togo			Conditional		
Turkmenistan		Conditional			
Viet Nam		Clarification			

Table 2: Planned disbursements 2003 and 2004 for proposals recommended for approval (in US\$)

Country	Immunization Services		New and Under-used Vaccines (estimate) ¹		Injection Safety (estimate) ¹		Other support
	1 st tranche Jan 2003	2 nd tranche Dec 2003	2003	2004	2003	2004	
Burkina Faso					294,900	124,000	
CAR	111,400	111,400	79,200	76,900			100,000
Mauritania	97,000	97,000					
São Tomé			14,800	11,600			100,000
<i>Sub-total</i>	208,400	208,400	94,000	88,500	294,900	124,000	200,000
Total			1,218,200				

¹ *excluding estimated freight cost*

Table 3: Planned disbursements 2003 and 2004 for proposals recommended for approval with clarifications (in US\$) *(figures subject to change pending receipt of clarifications)*

Country	Immunization Services		New and Under-used Vaccines (estimate) ¹		Injection Safety (estimate) ¹		Other Support
	1 st tranche Jan 2003	2 nd tranche Dec 2003	2003	2004	2003	2004	2003
Azerbaijan					44,500	36,500	
Bhutan					76,500	68,800	
Cameron					354,300	279,800	
CAR					38,400	40,900	
Ghana					273,800	228,500	
Guinea Bissau	46,300	46,300					
Kenya					575,100	460,100	
Mali			517,800	385,800	231,100	205,800	
Mozambique					334,500	274,100	
Rwanda					136,100	118,100	
São Tomé					3,900	3,300	
Somalia					105,100	102,700	
Tanzania					524,300	440,700	
Viet Nam					1,181,000	972,500	
<i>Sub-total</i>	46,300	46,300	517,800	385,800	3,878,600	3,231,800	
						Total	8,106,600

¹ excluding estimated freight cost

<i>Grand Total of requests</i>	<i>9,324,800</i>
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Table 4. Eligible countries that would qualify for Injection Safety Support if GAVI Board approves to offer this support independently from the other two types of Support.

Country	Comment
Bolivia	National DTP3 coverage above 80%. The Country has not applied for New and Under-used Vaccines Support. Current government and partner financing of hep B and Hib vaccines.
Cuba	National DTP3 coverage above 80%. The country has applied for new and under-used vaccines and received “not approved”. Current government financing of hep B and Hib vaccines.
Honduras	National DTP3 coverage above 80%. The Country has applied for immunization services support and received “not approved”. Current government financing of hep B and Hib vaccines.
Nicaragua	National DTP3 coverage above 80%. The Country has not applied for New and Under-used Vaccines Support. Current government and partner financing of hep B and Hib vaccines.

Table 5. Countries not yet approved for support

Country	Status	Comment
Chad	Conditional for the three types of support	The three requests have been reviewed in October 2002 review.
Congo	Re-submission for five requests of support: Immunization Services, Injection Safety, Vaccines of YF, hep B and Hib	The five requests have been reviewed in October 2002 review. The country is in need of technical assistance.
Mongolia	Re-submission for hep B and Hib	Have indicated intention to apply also for injection safety.
Angola	Not yet applied	Current priority is to focus on polio. Has indicated plans to apply early 2003.
East Timor	Not yet applied	
Papua New Guinea	Not yet applied	Have shown interest to apply in early 2003.
Solomon Islands	Not yet applied	Interest expressed by delegation to WHA 2002.

Annex 1.1

Independent Review Committee, Proposal Review Team

Dr Sam Adjei

Deputy Director-General, Ghana Health Services, Ghana

Mr Oleg Benes

Epidemiologist, National Center of Preventive Medicine, Moldova
(Not participating in decisions on Azerbaijan and Turkmenistan)

Dr Stanislava Popova-Doytcheva

Scientist, WHO STC
Bulgaria
(Not participating in decisions on Turkmenistan)

Dr Jane Soepardi

Chief Section, CDC & EH, Ministry of Health, Indonesia

Mr Robert Steinglass

Immunization Team Leader, BASICS, USA
(Not participating in decisions on Ghana, Mali, Nigeria, Senegal)

Dr Merceline Dahl-Regis

Chief Medical Officer, Ministry of Health, Bahamas

Dr Viroj Tangcharoensathien *(Chairperson)*

Health Systems Research Institute, Thailand

Recommendations from the Monitoring Team

Executive Report

Summary of Conclusions

The monitoring team of the Independent Review Committee was established to monitor implementation of activities of national immunization programs that have been approved by the GAVI Board for support from The Vaccine Fund. The monitoring team consisted of three epidemiologists and three economists; members are listed in Annex 1.2.

Thirty-eight country reports were reviewed, including 18 inception reports and 20 annual progress reports (Table 1).

Table 1. Summary of outcomes:

Report type	Satisfactory	Satisfactory with clarifications	Insufficient information	Conditional
Inception	9	4	4	1
Annual Progress	10	8	2	-

Note: Full country reports are available on request

Consequence of recommendation:

Satisfactory	Countries will receive the support requested
Satisfactory with clarifications	Country continues to receive support as previously approved. Secretariat follows up to obtain necessary information.
Insufficient information	Country must provide the missing information, meanwhile the country will receive first shipment of vaccine and injection safety materials.
Conditional	Countries will only receive continued support when conditions are lifted. Currently, this applies only to countries receiving Immunization Services support.

Summary Analysis

In general, information contained in the reports indicates that countries are quite committed to implementing their national programs. However, it is the impression of the monitoring team that, with few exceptions, countries do not completely understand the details required of them – in both inception and progress reports.

It is also apparent from the majority of reports that there has been very little, if any, participation of EPI Country Advisors (from WHO and/or UNICEF) in the elaboration and analysis contained in the reports.

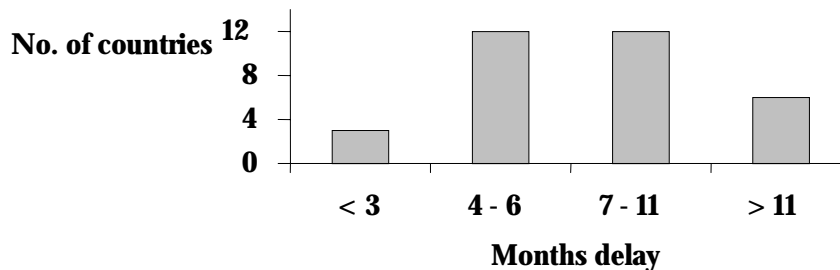
The participation and involvement of the ICCs is also not clear from the information contained in the reports, with very few exceptions.

Major Findings with Policy Implications

a) Delays in disbursement of funds

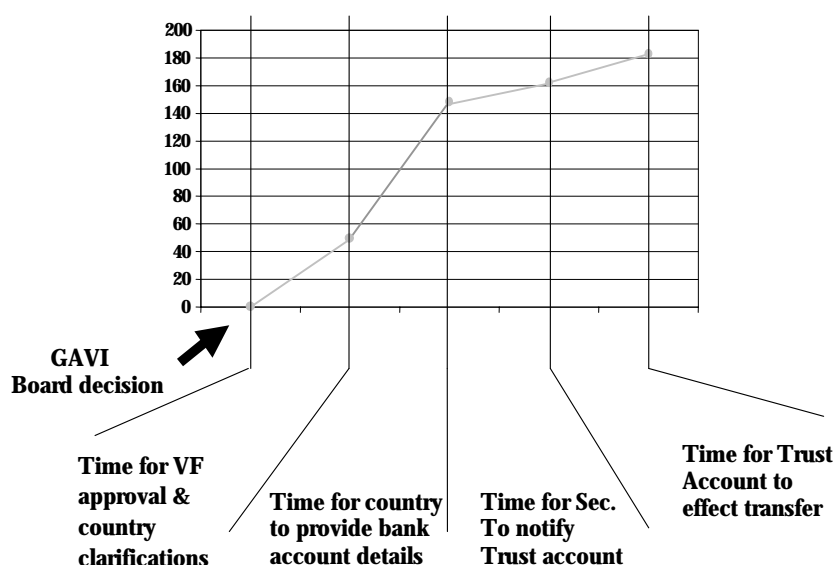
For several countries there was a considerable delay in the disbursement of funds once they were approved by the GAVI Board (Figure 1).

Figure 1: Analysis of delays in ISS disbursement:



The GAVI Secretariat analyzed the 39 countries approved for ISS support in 2000 and 2001. Four countries (Afghanistan, Myanmar, Nigeria and Pakistan) still have not yet received their first disbursement, despite repeated requests for bank account details and country visits (Nigeria and Pakistan) by the GAVI Secretariat. The analysis is therefore focusing on the remaining 35 countries with all information available.

Figure 2: Average # of days taken for 1st ISS disbursement (n = 35 countries)



Details of delays by country are shown in Annex 1.5.

b) Delays in use of funds

Another relatively common issue identified was that in a number of countries there were impediments in the use of the funds by the program manager. In general this seemed due to local financial and banking regulations. It may also be related to the executing agency in each country. However, the reports do not indicate the executing agency in most instances, whether it is the Ministry of Health, WHO, or other.

For this specific issue, the monitoring team recommends that as a matter of policy, further funds not be disbursed until there is a clear demonstration by the country that the funds can be used as soon as they are transferred to the executing agency. The Working Group agrees with this policy.

Analysis of the total ISS funds disbursed by year is provided in Table 3.

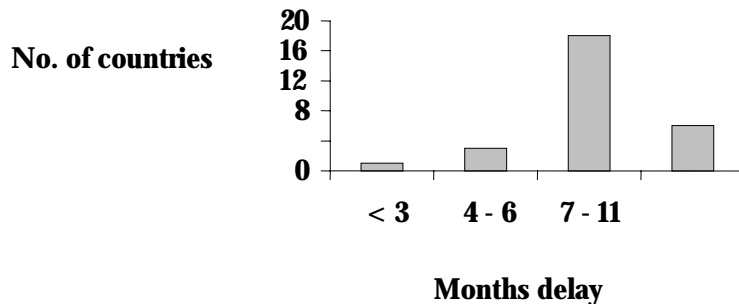
Table 3: ISS funds disbursed by year US\$ Millions

	2000	2001	2002
Reviewed Countries	2.0	4.8	7.8
Countries not reviewed*		1.0	
Total	1.99	5.87	7.86

* Late, unsigned or no response from country

c) Delays in the shipment of vaccines

Delays were also observed in the delivery of vaccines, once the GAVI Board approved proposals. Following is a summary of the interval between Board approval and the reported arrival of vaccines in the 28 countries receiving vaccines from GAVI:



The Vaccine Provision Project will provide an analysis on the reasons for delay. UNICEF Supply Division should provide the exact date in which vaccines have been shipped for a more realistic analysis of this issue.

d) Denominators

The reported size of the birth cohort, or the denominator, was an area that took a considerable time for the monitoring team to sort out. In basically every country, there were considerable changes in the denominators from the original proposal submitted to GAVI. This has an impact on baseline data and targets for subsequent years, which may have a potential impact on the reward system. Some countries provided explanations for these changes, but in most instances the team was either not able to understand or was not able to be convinced of the explanations provided.

The team recommends that for future reviews, a pre-assessment team (WHO led) analyze the denominators and other essential data prior to the review. This will guide and facilitate the decision making process of the monitoring team.

e) Declining population

Some countries presented data suggesting a declining population trend. As this will have a severe impact in the reward system (progress in these countries will not be rewarded), this issue will be taken up by the monitoring and evaluation sub-committee of the ITF.

f) Policy on wastage rates for pentavalent vaccine (DTP/hep B+Hib)

Several countries reported that the present policy wastage rate for the pentavalent vaccine is too low (5%). Among the reasons cited were logistical problems, the number of children immunized outside of the target age group and the drop out rates.

The team could not reach a conclusion on this issue and recommends that a detailed analysis of the use of this vaccine, in different settings and countries, be carried out during the coming year.

g) Impact of review on financial commitments

As a result of the countries' request to adjust supplies of vaccines and injection safety, there is an impact (Figure 3) on the financial commitment for the year 2003. For those countries where the monitoring team has agreed on the adjustment, the impact is a reduction in the commitment for 2003 of US\$ 4.4m. Detailed analysis of this by country is provided in Annex 1.7 & 1.8.

Figure 3: Impact of Review on Financial Commitments US\$ Millions

Support type	Commitment BEFORE Review	Commitment AFTER Review	Difference
Injection Safety	8.4	8.3	-0.1
New Vaccines	65.0	60.7	-4.3
Total impact	73.4	69.0	-4.4

Final considerations

It is clear, from this first meeting of the monitoring team, that there is a need for more active and strong participation by EPI International Country Advisors, ICCs and Regional Working Groups in the process of implementation of national programs and in the preparation and analysis of data presented in the country reports.

The team recommends that:

- a. The GAVI Board emphasize the necessary inputs for the issues referred above with the partners that have advisors deployed in the eligible countries.
- b. The GAVI Board request that minutes of ICC meetings be provided together with Inception and Annual Reports.

The Working Group supports these recommendations.

Annex 1.2

Independent Review Committee, Monitoring team

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Healthcare Economist
MOH
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Annex 1.3

Monitoring team — Summary recommendations

Country	Report Type	Support Type	Recommendation
Afghanistan	IR	ISS	Satisfactory *
Armenia	AR	ISS,NVS,INS	Insufficient Information*
Azerbaijan	AR	ISS,NVS	Satisfactory *
Bangladesh	IR	ISS,NVS	Insufficient Information
Burkina Faso	AR	ISS	Satisfactory *
Cambodia	AR	ISS,NVS,INS	Satisfactory with clarifications*
Cameroon	AR	ISS	Satisfactory *
Cote d'Ivoire	AR	ISS,NVS	Satisfactory with clarifications
Eritrea	IR	ISS,NVS	Satisfactory
Ethiopia	IR	ISS, INS	Satisfactory with clarifications*
Gambia	IR	ISS,NVS,INS	Satisfactory
Georgia	IR	ISS,NVS,INS	Conditional release of ISS
Ghana	AR	ISS,NVS	Satisfactory *
Guyana	AR	NVS	Satisfactory
Kenya	AR	ISS,NVS	Satisfactory with clarifications*
Kyrgyz rep	AR	NVS	Satisfactory *
Lao PDR	AR	ISS,NVS,INS	Satisfactory with clarifications
Lesotho	IR	ISS,NVS,INS	Satisfactory *
Madagascar	AR	ISS,NVS	Satisfactory with clarifications*
Mali	AR	ISS,NVS,	Insufficient Information*
Mozambique	AR	ISS,NVS,	Satisfactory with clarifications
Myanmar	IR	ISS,NVS,INS	Satisfactory with clarifications
Nepal	IR	ISS,NVS,INS	Satisfactory with clarifications*
Niger	IR	ISS	Satisfactory *
Pakistan	AR	ISS,NVS,INS	Satisfactory with clarifications
Rwanda	AR	ISS,NVS,	Satisfactory with clarifications*
Sao Tomé	AR	ISS	Satisfactory
Senegal	IR	ISS, INS	Insufficient Information*
Sri Lanka	IR	INS,NVS	Insufficient Information
Sudan	IR	ISS,INS	Satisfactory with clarifications *
Tajikistan	AR	ISS,NVS	Satisfactory *
Tanzania	AR	ISS,NVS	Satisfactory
Turkmenistan	IR	NVS	Satisfactory *
Uganda	AR	ISS,NVS,INS	Satisfactory
Uzbekistan	IR	INS,NVS	Insufficient Information*
Vietnam	IR	NVS	Satisfactory *
Yemen	IR	ISS,NVS,INS	Satisfactory *
Zimbabwe	IR	ISS	Satisfactory *

* Requested information for next progress report

AR = Annual Progress Report

IR = Inception Report

Annex 1.4

Countries not reviewed

<u>Country</u>	<u>Reason not reviewed</u>
Albania:	No report received
Benin: reviewed	Received substantially after the deadline and too late to be reviewed
Burundi:	Received substantially after the deadline and too late to be reviewed
Comoros: reviewed	Received substantially after the deadline and too late to be reviewed
Guinea:	No report received
Haiti:	No report received
India:	Missing signatures
Liberia:	Received substantially after the deadline and too late to be reviewed
Malawi:	Received substantially after the deadline and too late to be reviewed (requested extension)
Moldova:	Received substantially after the deadline and too late to be reviewed
Nigeria:	Missing signatures
Sierra Leone:	Missing signatures
Zambia:	Missing signatures

These countries will be reviewed in the next round (Jan 2003). This effectively puts ISS funds disbursement on hold. The shipment of vaccine will continue.

Annex 1.5

ISS funds to countries: delay analysis (days)

	A	B	C	D	A+B+C+D
Country	Time for country to provide clarification	Time for country to provide bank details	Time for Sec. To notify Trust Account	Time for Trust Account to effect transfer	Total duration
Armenia	113	127	31	18	289
Azerbaijan	11	71	5	20	107
Bangladesh	116	0	53	14	183
Burkina Faso	4	113	8	15	140
Burundi	17	0	0	7	24
Cambodia	14	39	9	25	87
Cameroon	69	42	0	5	116
Comoros	17	0	0	7	24
Côte d'Ivoire	62	195	47	45	349
Eritrea	67	0	84	24	175
Ethiopia	14	98	3	39	154
Gambia	4	0	7	13	24
Georgia	14	0	0	56	70
Ghana	64	76	1	0	141
Haiti	4	328	2	7	341
Kenya	64	134	1	6	205
Lao PDR	128	0	0	47	175
Lesotho	14	30	13	16	73
Liberia	11	123	0	17	151
Madagascar	64	462	0	3	529
Mali	64	89	8	3	164
Mozambique	64	114	4	0	182
Nepal	14	203	8	30	255
Niger	122	0	29	24	175
Rwanda	64	92	5	3	164
Sao Tomé	11	92	27	49	179
Senegal	122	0	29	24	175
Sierra Leone	4	52	33	22	111
Sudan	67	122	44	61	294
Tajikistan	69	1	8	90	168
Tanzania	64	44	13	1	122
Uganda	11	207	2	5	225
Yemen	55	291	5	21	372
Zambia	116	0	0	2	118
Zimbabwe	6	310	14	17	347
Ave days	49	99	14	21	183
Ave months	1.6	3.3	0.5	0.7	6.1

Annex 1.6

Disbursement of ISS funds by year for all countries (in US\$)

Reviewed Countries	2000	2001	2002
Armenia		15,000	15,000
Azerbaijan		16,500	16,500
Bangladesh		1,785,000	
Burkina Faso		437,000	437,000
Cambodia			334,300
Cameroon		553,500	
Cote d'Ivoire		513,000	
Eritrea			39,300
Ethiopia			964,000
Gambia		32,300	
Georgia			17,000
Ghana	264,500		264,500
Haiti			314,000
Kenya		644,500	644,500
Lao PDR			357,800
Lesotho			37,400
Liberia			305,500
Madagascar	233,500		233,500
Mali	429,000		429,000
Mozambique		231,000	
Nepal			352,300
Niger			435,000
Rwanda	454,000		
Sao Tomé		15,000	15,000
Senegal			123,600
Sierra Leone			90,000
Sudan			768,600
Tajikistan		125,000	
Tanzania	607,000		607,000
Uganda		455,000	455,000
Yemen			283,500
Zimbabwe			318,270
Countries not Reviewed			
Burundi		162,500	
Comoros		13,000	
Haiti		314,000	
Liberia		305,500	
Sierra Leone		90,000	
Zambia		164,000	
Totals:	1,988,000	5,871,800	7,857,570

Annex 1.7

New & Under-used Vaccine Support – Impact on financial commitment immediately following review

Country	Vaccine cost BEFORE review	Vaccine cost AFTER review	Difference
<u>Approved Quantities</u>			
Azerbaijan	128,504	140,971	12,467
Cambodia	460,345	582,705	122,360
Eritrea	322,681	376,372	53,691
Gambia	646,361	621,345	-25,016
Georgia	87,080	87,080	
Ghana	7,804,075	6,638,540	-1,165,535
Guyana	221,655	115,613	-106,041
Indonesia	3,436,773	3,436,773	
Kyrgyz Rep.	238,118	176,869	-61,249
Lesotho	43,313	43,313	
Madagascar	2,189,287	1,970,358	-218,929
Myanmar	1,956,872	-2,833	-1,959,705
Nepal	899,371	942,095	42,724
Sao Tomé		14,743	14,743
Tajikistan	151,058	151,058	
Tanzania	4,396,972	4,944,932	547,960
Turkmenistan	149,990	128,206	-21,783
Viet Nam	2,603,506	2,658,015	54,509
Yemen	1,736,995	1,736,995	
sub-total	27,472,956	24,763,152	-2,709,804
<u>Pending Clarifications</u>			
Kenya	12,241,172	10,158,042	-2,083,130
Mali	222,755	740,556	517,801
Armenia	69,022	69,022	
Sri Lanka	292,391	292,391	
Bangladesh	640,143	640,143	
Uzbekistan	697,351	697,351	
Lao PDR	940,075	940,075	
Cote d'Ivoire	1,489,380	1,489,380	
Mozambique	2,558,505	2,558,505	
Rwanda	3,508,594	3,508,594	
Pakistan	6,254,740	6,254,740	
Uganda	8,588,878	8,588,878	
sub-total	37,503,006	35,937,677	-1,565,330
Totals	64,975,962	60,700,828	-4,275,134

Annex 1.8

Injection Safety Support – Impact on financial commitment immediately following review

Country	INS cost BEFORE review	INS cost AFTER review	Difference
<u>Approved</u>			
Indonesia	2,524,038	2,524,038	
Pakistan	2,306,774	2,306,774	
Uganda	339,112	339,112	
Yemen	294,042	294,042	
Uzbekistan	231,625	231,625	
Senegal	215,330	215,330	
Sri Lanka	134,800	134,800	
Lao PDR	46,106	89,924	43,818
Gambia	35,527	23,147	-12,380
Lesotho	34,520	34,520	
Georgia	15,583	15,583	
Armenia	13,960	13,960	
sub-total			31,437
<u>Pending Clarifications</u>			
Cambodia	176,172	176,172	
Ethiopia	821,133	821,133	
Myanmar	546,402	167,726	-378,676
Nepal	179,194	400,276	221,082
Sudan	507,625	507,625	
sub-total			-157,594
Total	8,421,944	8,295,788	-126,157

Annex 1.9

Key policy issues raised by the IRC – Discussed and agreed with the Working Group

I. IRC

1. The IRC wishes to interact with partners on policy and technical issues raised during the reviews. The Secretariat:
 - Will secure broader overlap on the occasion of IRC meetings or WG retreats.
 - Will report back on action taken re policy issues raised previously.

II. Injection safety issues

1. For countries requesting equivalent amount of funds for injection safety because they procure injection safety-related materials by themselves, the country or its NRA is required to provide evidence that such products comply with WHO requirements.
2. The IRC supports recommendations made by the Working Group on extending eligibility for injection safety support to those countries that currently do not qualify for immunization services or new and under-used vaccines (Nicaragua, Honduras, Cuba, Bolivia). For this group of countries, the IRC further recommends that the injection safety guidelines (section 5.7) be revised to include:
 - Profile of the functioning of ICC (Section 5.4).
 - A summary of situation analysis of immunization system.
 - Injection safety plan including situation analysis, national policy and strategies.
 - Budget and financial sustainability when GAVI support ceases.
3. The review process brought up the needs for clarity in the guidelines for application, e.g. common definition of frequently used indicators, or core indicators developed by GAVI to monitor safe injection. To help the countries, the ITF should produce a template of a standard injection safety plan and illustrative targets for indicators [indicators should be well defined and quantifiable]. For the application of injection safety, ICC minutes should be submitted for IRC review to ensure ICC involvement in the process; and provide evidence on the status of implementation of the multi-year plan.
4. Viet Nam requests funding for the equivalent of the cost of AD syringes for 70% of hep B vaccine approved by GAVI. Does this contradict with GAVI bundling policy (vaccine and injection safety)? IRC position supports Vietnam on the ground of government ownership and a single type of AD syringe throughout the country, so as not to confuse health workers and users of immunization services.

III. Introduction of Hib vaccine

1. The IRC needs to be guided by WHO as to whether the country needs to introduce Hib vaccine. Criteria and benchmarks for the assessment of Hib disease burden (e.g. the interpretation of findings if Hib is a public health problem and the need for cost effectiveness assessment) to justify investment in Hib is needed, especially for countries in Asia and Europe.
2. WHO to follow-up to convene a group of experts to address Hib burden issues including methodological aspects and cost-effectiveness, especially in relation to Asia.

Annex 2

GAVI Secretariat: Interim 2001-2002 report and work plan budget for 2003 - 2004

During the past two-year period GAVI has been moving from its start-up phase with establishing policies and organizing the system for Vaccine Fund support to a phase of on-going support and setting up of monitoring systems.

Activities

Proposal Review Process

1. Further developed and fine-tuned the application process, including regular revision of the proposal form and guidelines.
2. Communicated directly with countries to verify and correct information received in the proposals.
3. Managed the operations of the Independent Review Committee (IRC), including seven regular reviews and a number of extra reviews of country proposals.
4. The review process resulted in 69 of 75 eligible countries applying for support, and 64 countries approved for support (including recommendations from the most recent round which have not yet been approved by the GAVI and Vaccine Fund Boards).

Country Monitoring

1. Developed principles, systems and documents for the monitoring processes; includes annual progress reports and immunization data quality audits (DQAs).
2. Distributed the annual progress report requirements to countries; managed the review of 63 annual reports in two years.
3. Managed the implementation of eight DQAs in 2001 and 15 DQAs in 2002 (to be completed by end 2002) including the commissioning of consultancy companies for this purpose.
4. Supported the Financing Task Force to implement the financial sustainability planning process in thirteen countries in 2002; includes preparing for the first review of the financial sustainability plans in early 2003.

Facilitation of Vaccine Fund Resource Disbursements

1. Presented the GAVI Board with the recommendations of the IRC on proposal and annual report reviews, as well as on policy issues.
2. Forwarded the GAVI Board requests to The Vaccine Fund, based on outcome of review of country proposals and annual reports.
3. Facilitated the process to procure and deliver vaccines and injection safety supplies to countries—34 countries by November 2002.
4. Managed process to disburse funds for immunization services support, injection safety and to support vaccine introduction activities to 50 countries.

Alliance Management

1. Organized and managed five meetings of the GAVI Board: London, Ottawa, Stockholm, Paris and Dakar, and numerous teleconferences. Prepared reports of meeting and teleconference outcomes.
2. Organized and managed nine meetings of the GAVI Working Group and weekly teleconferences. Prepared reports of meeting and teleconference outcomes.
3. Managed the first comprehensive work planning cycle for the Alliance resulting in a proposed GAVI work plan for 2003-2004.
4. Organized the second GAVI Partners' Meeting in Dakar, Senegal, in cooperation with the Senegalese Government and Partners at the country level.
5. Managed the GAVI website. Following a consultation with partners, a major upgrade using a consultant has been undertaken to make the GAVI website more functional.
6. Produced eight issues of quarterly electronic newsletter, Immunization Focus.
7. Worked with partners to establish an internet-accessible database of GAVI-related information; this included commissioning consultant, with the aim of having the database running by early 2003.
8. Participated in contacts with donors.

Staffing Situation as of November 2002

Professional staff

Executive Secretary	Tore Godal
Principal Officer, planning & coordination	Bo Stenson
Principal Officer, country support	<i>under recruitment</i>
Senior Program Officer, country proposal reviews	Ivone Rizzo
Senior Program Officer, monitoring	<i>under recruitment</i>
Senior Operations Officer	Umberto Cancellieri
Senior Communication Officer	<i>under recruitment</i>
Associate Board Secretary	Lisa Jacobs

Administrative staff

Secretary to the Executive Secretary	Corina Luputiu
Program Assistant planning & coordination	<i>under recruitment</i>
Program Assistant , country support	Jane Dyrhaug (50%)
Administrative & Budget Assistant	Enyonam Asafo

As the Secretariat follows the Rules and Regulations of the Host Organization (UNICEF), each budget covers two calendar years.

Table I: Projected income for 2001 – 2002 as of 31 October 2002 (all amounts in US\$)

GAVI Board Member	2001	2002	Total	Paid	To be paid
UNICEF	300,000	300,000	600,000	450,000	150,000
The World Bank	300,000	300,000	600,000	600,000	0
WHO	300,000	300,000	600,000	600,000	0
The Bill & Melinda Gates Foundation	300,000	300,000	600,000	600,000	0
Industrialized country 1 (Norway)	300,000	300,000	600,000	600,000	0
Industrialized country 2 (Canada/United Kingdom)	300,000	300,000	600,000	300,000	300,000
Industrialized country 3 (Netherlands/USA)	300,000	300,000	600,000	150,000	450,000
Developing country 1 (India)	0	0	0	0	0
Developing country 2 (Mali)	0	0	0	0	0
Developing country 3 (Vacant)	0	0	0	0	0
Industrialized country vaccine industry (IFPMA)	300,000	300,000	600,000	287,500	312,500
Developing country vaccine industry (CIGB)	0	0	0	0	0
Foundations (UN Foundation)	300,000	300,000	600,000	300,000	300,000
Research and Development (Pasteur)	300,000	300,000	600,000	0	600,000
Technical Institute (CDC)	300,000	300,000	600,000	300,000	300,000
NGO (CVP)	300,000	150,000	450,000	450,000	0
The Vaccine Fund	0	150,000	150,000	0	150,000
Total	3,600,000	3,600,000	7,200,000	4,337,500	2,562,500

As is indicated in the above, the Secretariat has experienced cash flow problems resulting from delays in receipt of Board member dues. This situation was somewhat alleviated by the carry-over from the previous biennium of \$1,907,549, including \$300,000 received from the NIH (first installment of its \$600,000 balance due). Thus, total income available in 2001-2002 amounts to \$6,545,049 as of October 31, 2002. The Secretariat has received indications of forthcoming payments from USAID and NIH in the amount of \$600,000 in November 2002.

As host of the GAVI Secretariat, UNICEF provides rent and other services that amount to \$170,000 per year – over and above the UNICEF annual \$300,000 contribution to the Secretariat. The Secretariat takes this opportunity to thank UNICEF for this special arrangement.

Table II: Analysis of expenditures versus approved budget for 2001-2002 as of 31 October 2002 (all amounts in US\$)

Budget line	Actual 2001 Expenditures	Estimated 2002 Expenditures	Total (2001 & 2002)	Approved Budget	Variance
1.1 Professional staff ^{a)}	430,000	430,000	860,000	1,241,728	381,728
1.2 Support staff	122,000	166,342	288,342	292,490	4,148
1.3 Short-term Prof. & Consultants	281,525	518,107	799,632	910,782	111,150
1.4 Operating costs	60,786	92,384	153,171	170,000	16,829
1.5 Travel	182,401	200,000	382,401	400,000	17,599
2. Task Forces	348,285	438,807	787,092	900,000	112,908
Review of Country proposals ^{b)}	285,356	450,000	735,356	450,000	(285,356)
Verifications (Data Quality Audit) ^{c)}	593,312	778,457	1,371,769	720,000	(651,769)
Mid-term reviews ^{d)}	0	0	0	1,080,000	1,080,000
Workshops		42,391	42,391	220,000	177,609
Partners' Meeting ^{e)}	0	850,000	850,000	600,000	(250,000)
Contractual Work ^{f)}	326,801	603,046	929,847	215,000	(714,847)
Total	2,630,466	4,569,534	7,200,000	7,200,000	0

- a) The post of Deputy Executive Secretary was not filled during the biennium, resulting in reduced expenditures for professional staff.
- b) When the budget was presented to the Board in November 2000, not enough experience was available to properly assess budgetary requirements for the country proposal reviews.
- c) The above is also valid for the management and implementation of Data Quality Audits. This was done through complex bidding processes in 2001 and 2002. The per country cost of the DQAs was reduced from \$60,000 in 2001 to \$55,000 in 2002.
- d) Mid-term reviews were first postponed and are now proposed to be removed altogether.
- e) Based on the first Partners' meeting in 2000, an amount of \$600,000 was budgeted for the second Partners' meeting. An additional amount of \$250,000 has been required, mainly to cover local costs.
- f) Additional costs under this budget lines were required for the upgrade of the GAVI website (\$67,000), the creation of the GAVI database (\$120,000) and for strengthening of communication activities (\$99,000). Expenses in support of Board activities and the Working Group – mainly travel costs for members from developing countries – are also charged against this budget line (\$272,000).

Table III. Proposed 2003-04 budget (according to work plan) compared to 2001-02 budget (all amounts in US\$)

Budget line	Approved 2001-2002 Budget	Total	Budget line	Proposed 2003-2004 Budget	Total	Variance
1.1	Professional staff	1,241,728	15	Professional staff	2,712,847	1,471,119
1.2	Support staff	292,490	16	Support staff	505,448	212,958
1.3	Short-term-professionals/Consultants	910,782	17	Short-term professionals/Consultants	357,265	(553,517)
1.4	Operating costs	170,000	18	Other support costs	215,000	45,000
1.5	Travel	400,000	19	Travel	600,000	200,000
2	Task Forces	900,000		Task Forces	0	(900,000)
3.1	Review of country proposals		1	Country proposals 389,200		
			2	Financial sustainability plans 299,200		
			3	Annual progress reports 213,200		
		450,000		Total	901,600	451,600
3.2	Verifications	720,000	6	Managing DQAs	2,460,000	1,740,000
3.3	Mid-term reviews	1,080,000		Mid-term reviews	0	(1,080,000)
3.4	Workshops	220,000		Workshops	0	(220,000)
3.5	Partner's meeting	600,000	16	Partner's meeting	650,000	50,000
3.6	Contractual work		10	Timely information 335,000		
			11	Management of the GAVI Board 400,000		
			12	Management of the Working Group operations 205,000		
		215,000		Total	940,000	725,000
			4	Disbursement of funds	0	0
			5	Delivery of vaccines	0	0
			7	Management of rewards	0	0
			8	ADIPs	0	0
			9	Alliance efficiency and effectiveness	0	0
			13	Management of the Vaccine Provision Project	0	0
	Total	7,200,000		Total	9,342,160	2,142,160

Annex 3

Proposal to develop a strategic framework to increase access to immunization

Introduction

In response to the Board request to increase focus on access and equity issues, the Working Group requested a team of immunization experts from among the partners (WHO-HQ, WHO-AFRO, CVP/PATH, and UNICEF) to form an *ad hoc*, time-limited “Access Team” to develop strategies to expand and sustain access to vaccination, defining what would be necessary to achieve the GAVI milestone of achieving 80% DTP coverage in *all districts* in 80% of developing countries by 2005 (hereafter referred to as the 80/80 goal).

The strategic approach presented by the Access Team was generally supported by the Working Group. However the management approaches were felt to lack a broader health sector dimension and did not explicitly address the issue of long-term sustainability.

The Working Group suggested that the Board be requested to consider the possibility of calling on management experts to provide an analysis of the current situation and propose a number of options for Board consideration along the spectrum of integration, i.e., from providing a narrow immunization focus (e.g., a polio-like focus) to a broad sector-wide focus including the full range of health service delivery at the district level. The operational orientation of the Access Team and the strategic thinking of the proposed study would serve to work in complement.

This work will need to draw upon data largely available in WHO and UNICEF and will critically depend upon the GAVI partners for guidance. Such an analysis calls for independence and expertise in analytical approaches to management and investment.

Based on the very positive experience of working with McKinsey Consulting to develop the Accelerated Development and Introduction Plans (ADIPs) for pneumococcal and rotavirus, the GAVI Secretariat, in liaison with the Working Group, has requested McKinsey to develop a proposal along these lines.

Annex 3.1

Access to Immunization: Proposed role for a management consulting firm

I- Objectives

Obtain broad commitment from Partners to contribute to and support an overall effort to improve access to immunization services within the overall health sector.

II- Process

1. Work with all Partners with different implementation skills and perspectives: (e.g., technical, financial, health system, health development, global, regional, national, bilateral, multilateral...).
2. Identify the commonalities and differences in Partners' thinking (e.g. targeted vs. more comprehensive health sector approach) towards achieving the 80/80 milestone and securing its sustainability in the long term, beyond Vaccine Fund support.

III- Deliverables

1. Using existing data, especially from WHO and UNICEF, consolidate knowledge base:
 - assess baseline coverage for all antigens,
 - review national plans and targets,
 - review strategies,
 - identify drivers of successes and gaps.
2. Present a range of feasible scenarios/options – related to the level of integration with the overall health sector – to achieve the 80/80 milestone and their implications, covering as a minimum:
 - health and economic impact of achieving the target,
 - sustainability,
 - implications for timing of achievement,
 - cost of implementation,
 - human resources requirements,
 - resource flows.
3. Review existing management and coordination mechanisms at country, regional and global levels; suggest ways to help integrate and optimize the contributions of partners, including recommendations for :
 - roles and responsibilities of partners,
 - accountability systems.

IV – Management of the study

The consulting firm will report to a reference group composed of WHO, UNICEF, 1-2 other GAVI Board members (to be discussed) and the Executive Secretary of GAVI, with WHO as the lead Partner in the management of this study. The Executive Director of the Health Technologies and Pharmaceuticals (HTP) cluster will represent WHO on this reference group and will keep the GAVI Board updated as required. A full-time consultant familiar with both WHO and GAVI (Karen Caines) and working from the

office of the HTP Executive Director will facilitate the work of the reference group and liaise with the Working Group and Task Forces as required. This will be in addition to the consultant (Robin Biellik) contracted and working out of the office of the Director of Vaccines and Biological to serve as technical reference for information specific to immunization.

IV – Financing of the study

The Government of Norway, WHO, UNICEF and The Vaccine Fund have all expressed interest in contributing to the financing of the study. If there is still a funding gap after all potential donors have been approached the GAVI Secretariat may be able to contribute additional resources.

V – Issue of sole sourcing

According to WHO management, McKinsey's strong interest in and understanding of the GAVI goals and structures gleaned through its past involvement in the Alliance, and its vigorous work in preparation of this proposal, makes a strong case for sole sourcing. WHO would therefore explore this possibility through its contract review process.

Annex 3.2a

Executive Summary – Access to Immunization Proposal

Prepared by McKinsey Consulting for the GAVI Board

GAVI has identified the need to further explore the options and requirements to increase access to immunization in line with the 80/80 goal. This memo summarizes the key points of a proposed study addressing this question. Our proposal builds on a series of discussions over several months with the GAVI Working Group, Secretariat and the *ad hoc* “Access Team”.

Brief summary of the current situation

Early immunization appears to be one of the most cost effective health interventions available (See Exhibit 1). Especially for populations in highly burdened areas, access to immunization has a large beneficial impact on children’s health, secondary benefits on the general population’s health and longer-term economic benefits. To date, the relationship between the need, cost and impact of increased access to immunization is not fully established. However, increasing immunization coverage dramatically is likely to be costly, but also attainable. The impact in terms of lives saved is expected to be very significant, perhaps on the order of 1 in 20 children dying from preventable diseases today in the unvaccinated population. Thus, GAVI and its Partners have committed to the 80/80 goal and are working to reach it. Achieving the 80/80 goal is recognized to be a difficult challenge with a number of barriers needed to be overcome. These barriers currently cause a number of countries to achieve vaccination levels well below the 80% goals. Some observers suggest that alternative strategies may be required to reach and sustain vaccination rates at target levels.

Study approach and deliverables

The proposed study seeks to develop a robust and realistic strategy for achieving GAVI’s goals, and it will be conducted in such a fashion as to build commitment from GAVI partners to support the effort to improve access to immunization services. The estimated length of the study is 4 months. The study will be conducted in three phases with clear deliverables as outlined in this proposal:

Phase 1-Situation analysis. The situation analysis will function as a starting point and aim at establishing a common understanding of the current coverage situation and its evolution in a “base case”. There are four key deliverables in phase 1: (1) an assessment of the baseline coverage levels, (2) review of the status and content of national plans and targets, (3) review of current strategies to increase access and (4) assessment of the key barriers to successfully increase access. To establish the situation analysis, existing data available at WHO, UNICEF, and the GAVI Secretariat will be reviewed and supplemented through interviews with country representatives, stakeholders and experts (See Exhibit 2).

Phase 2-Establish scenarios/options and evaluate pros/cons to achieve the 80/80 goal. Scenarios or options are defined as different potential approaches to reach the 80/80 goal. Scenarios will differ regarding the level of integration of coverage improvement with the overall

health sector, but they also discriminate in important dimensions such as human and financial cost/impact, resource flows, time trade-offs, attractiveness for stakeholders and ease of national/sub-national level implementation. The scenarios and their evaluation represent the key deliverable for phase 2. The scenarios will be established in collaboration with GAVI Partners and the evaluation will integrate different perspectives and Partners' thinking (e.g. targeted vs. more comprehensive health sector approach). Each scenario will have specific requirements that will be discussed with Partners (e.g., level of GAVI spending, focus of GAVI spending, and partnerships with other health initiatives) (See Exhibits 3 & 4). At the end of this phase, the GAVI Board will be expected to provide guidance to the project team in terms of which approach should be developed more fully in phase 3.

Phase 3-Synthesis and implications for strengthening management structures at global, regional and country level to help integrate and optimize the contribution of partners. Phase 3 will (1) synthesize the conclusions from prior phases, (2) suggest ways for GAVI to strengthen existing management structures and models for collaboration among Partners and stakeholders and (3) recommend management systems and reporting procedures to facilitate the approach selected. Over the course of the two phases above, the team will have talked to many countries, stakeholders and experts. These conversations will provide a platform to understand the current roles, models and policies of these players. The scenarios developed in phase 2 will also function as discussion material with stakeholders and their feedback will inform GAVI about preferred approaches and strategies (See Exhibit 5). All of these activities will be undertaken in close coordination and collaboration with WHO, UNICEF and other GAVI Partners. From McKinsey, Michael Conway and Paul Jansen would lead our effort. Michael has extensive experience in the healthcare industry and he has worked with GAVI on the ADIP program. Paul is a leader of McKinsey's global non-profit practice and works with several health related public institutions. A full time project manager and two associates with appropriate health, strategy, and analytical experience would support them. The team will access McKinsey experience from related public health projects and our local office capabilities as needed throughout the course of the project.

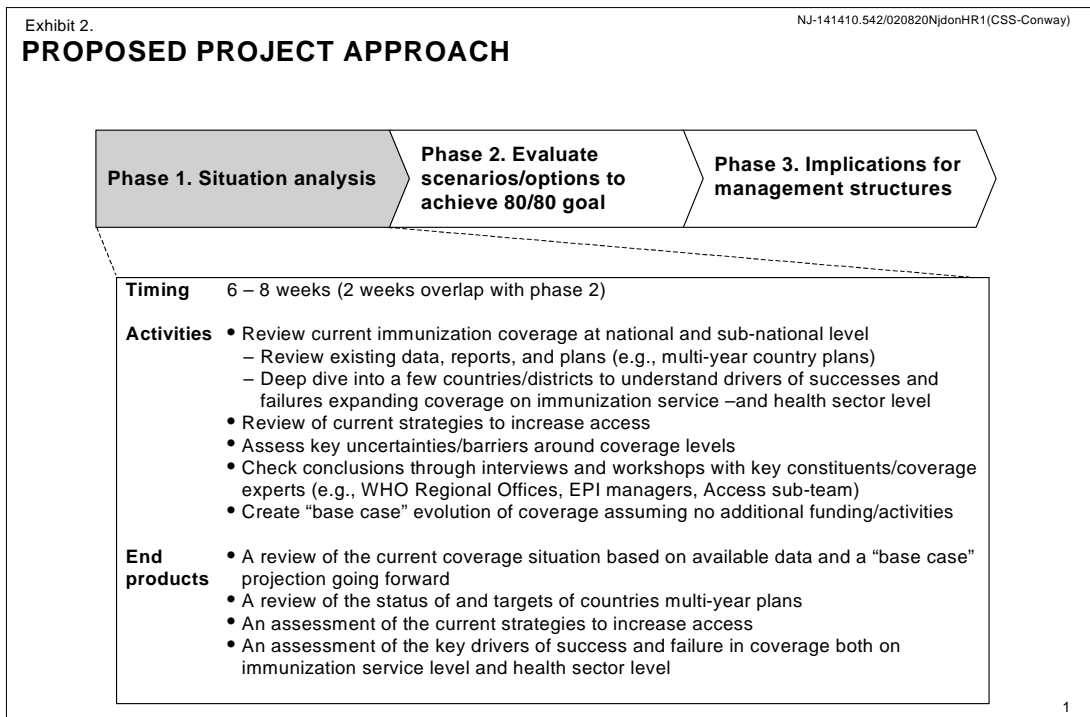
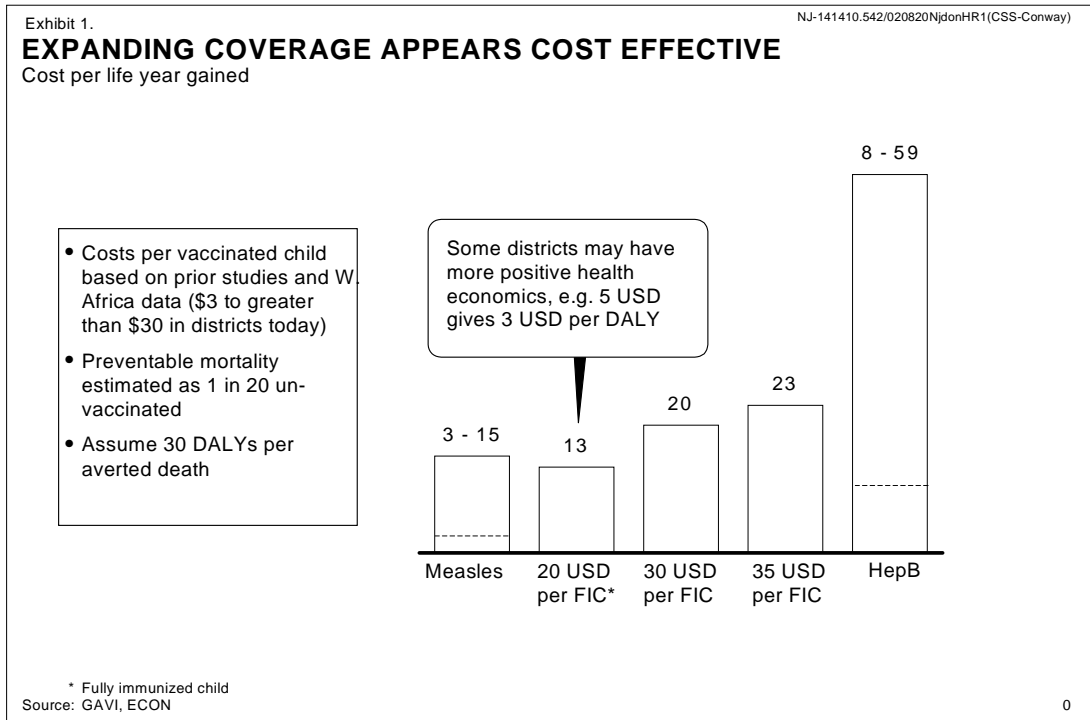
Resources required

This will be a substantial effort given the breadth and complexity of the issues to be addressed. Notwithstanding the challenge, given the importance of this effort, we are committed to making this project fit into your budget. Therefore, we will assume well over 50% of the normal fees, a level that slightly exceeds "at cost". The total cost (fees and expenses) for the 4-month project would be approximately \$500,000 to \$600,000.

* * *

Annex 3.2b

Exhibits



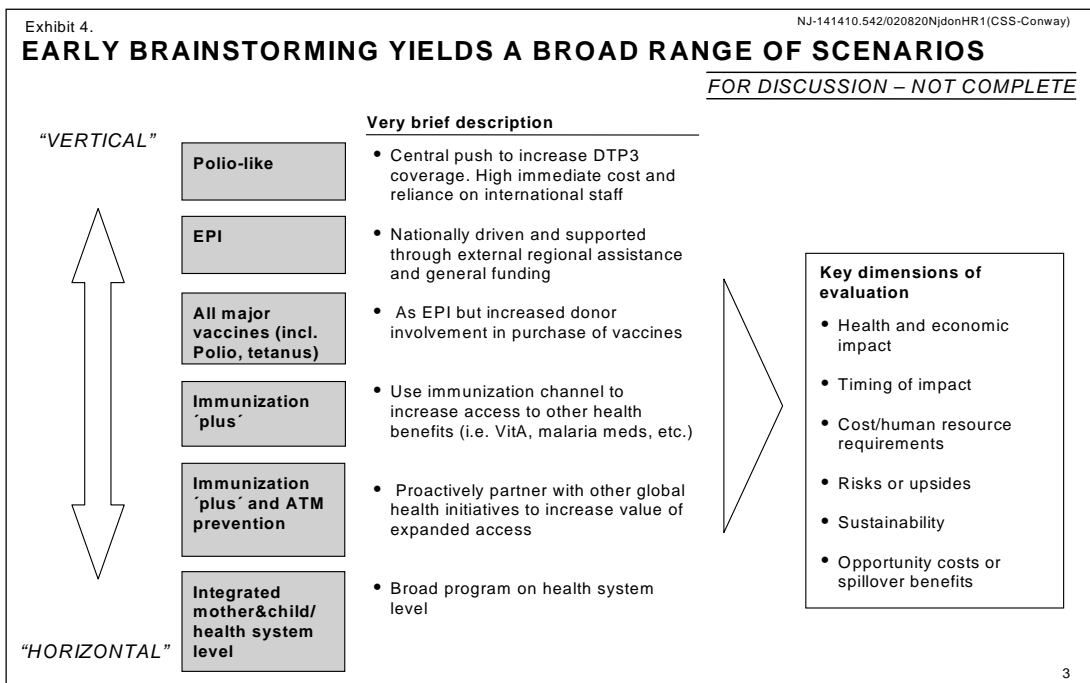
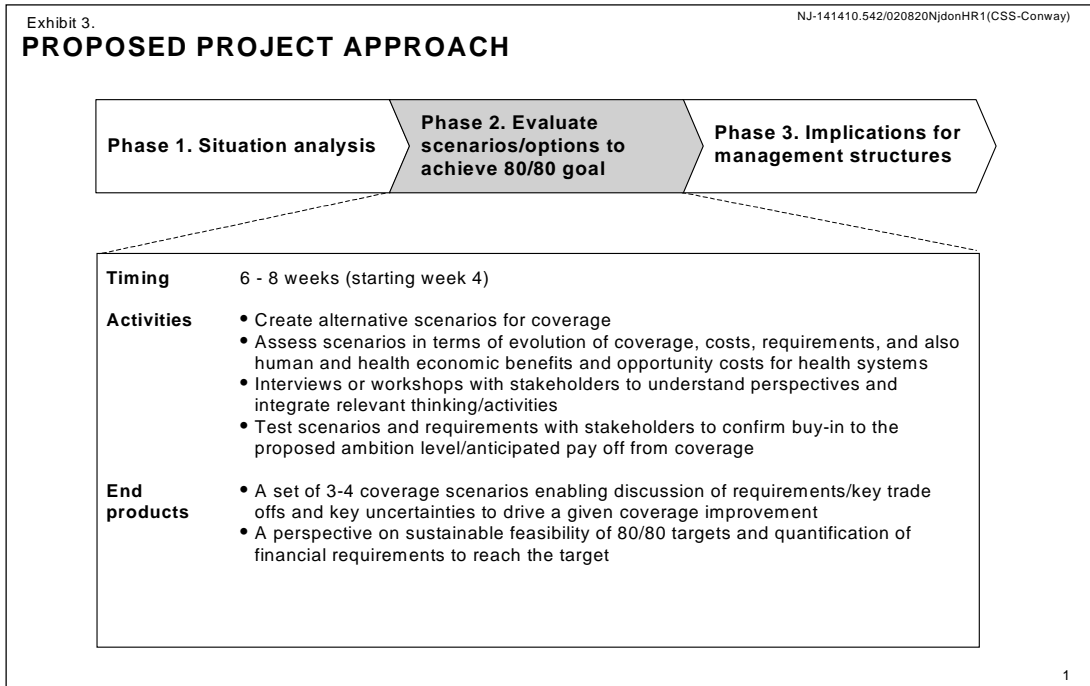
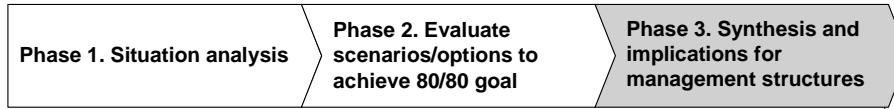


Exhibit 5.

NJ-141410.542/020820NjdonHR1(CSS-Conway)

PROPOSED PROJECT APPROACH



Timing	2 - 3 weeks (starting week 10)
Activities	<ul style="list-style-type: none"> • Draft document capturing conclusions from prior phases • Test conclusions with stakeholders to confirm buy in to proposed ambition level, benefits, and requirements • Suggest ways for GAVI to strengthen existing management structures and models for collaboration among partners and stakeholders • Recommend management systems and reporting procedures to facilitate the approach.
End products	<ul style="list-style-type: none"> • Recommendation on strengthening management structures • Outline of potential management systems and reporting structures • Description of coverage approach for stakeholders, covering for example <ul style="list-style-type: none"> – Health and economic impact – Spill over effects/trade offs – Management structures and roles – Timelines – Resources required

Annex 4

Human Resources for Immunization

1. Context

The Global Alliance for Vaccines and Immunization (GAVI) has six strategic objectives, four of which require substantial work at the country level:

- To improve access to sustainable immunization services (80/80 goal)¹.
- To support the national and international accelerated disease control targets for vaccine-preventable diseases.
- To expand the use of all existing safe and cost-effective vaccines, and promote delivery of other appropriate interventions at immunization contacts.
- To accelerate the introduction of new vaccines.

WHO and UNICEF estimate that global childhood immunization coverage was 73% in 2001. This global percentage hides great regional variation with less than 50% coverage in Africa. Countries with weak health systems are lagging behind and have the furthest distance to go. Currently, only 44 (out of 165) developing countries (27%) achieve 80% coverage in all districts².

To accelerate progress towards GAVI's objectives, there is increasing consensus among partners that reaching the more than 10 million unimmunized³ children requires an intensive effort to build national immunization systems and support district capacity to:

- Re-establish immunization outreach services,
- Provide supportive supervision,
- Build community links with service delivery,
- Monitor and use data for action,
- Plan and manage resources.

¹ It is a GAVI goal that by 2005, 80% of developing countries will have 80% immunization coverage in all districts. This is commonly referred to as the "80/80 goal".

² In addition to the 44 countries reporting achievement of the 80/80 goal, a further 18 countries are estimated to have national DTP coverage of 90% or more, and could be considered to have achieved the 80/80 goal. This analysis would mean that 62/165 (37.5%) developing countries achieved 80/80 in 2001.

³ Estimated 10 million unvaccinated children need to be reached to achieve 80% coverage in all districts; 30 million children need to be vaccinated to achieve 100% coverage.

2. Investing in human resources to achieve GAVI objectives

Lessons learned from two decades of implementing immunization programs indicate that the current immunization strategies for improving coverage and addressing disease control are effective. However, strategies alone will not achieve GAVI's goals; success depends on adaptation and implementation at the country level. The sustainability of the results requires that countries develop and implement their immunization strategies in the context of the national health system. This requires sufficient number and appropriate distribution of human resources with the necessary skills-base at national and sub-national levels.

Since substantial new financial resources have been secured, the greatest risk to GAVI and other international health objectives is the crisis in the availability, quality and management of human resources in the health sector of most developing countries. The reasons for the crisis are complex and are related to inadequate planning and training, chronic staff shortages, stagnating or declining salaries, little recognition or opportunity for advancement, depletion due to brain drain, HIV/AIDS scourge, etc.

Against a backdrop of a proliferation of large global health initiatives, of which GAVI is but one, national capacity to rapidly scale-up in the short term does not exist. To achieve its immunization goals and strengthen health systems, GAVI must begin to consider investments in human resources equally as important as its funding of new vaccines, immunization safety or services strengthening.

3. Human resource skills needed for GAVI's objectives

The delivery of immunization services today is a complex technological and managerial endeavor. High-performing programs ensure that all core functions of the immunization system are safely and effectively implemented -- from vaccine supply and distribution, to service delivery within the community, to surveillance and monitoring/reporting. The skills required to fulfil these core functions and plan, coordinate, and supervise the many 100,000's of vaccinators who actually provide vaccination itself, can be categorized into three areas:

- Planning (including microplanning, information management, social mobilization, logistics, vaccine forecasting/supply, injection safety, etc).
- Surveillance strengthening (monitoring, reporting and disease surveillance).
- Management capacity (technical, management/supervision, and financial skills development).

In all countries with low routine immunization coverage, there is a need to have capacities for the management of integrated immunization activities in all districts. Based on a conservative estimate of one immunization management "focal point" per district and province/state in the 103 countries currently not achieving the 80/80 goal, an estimated 25,000 individuals⁴ with the necessary skills set are needed to achieve and sustain GAVI's objectives.

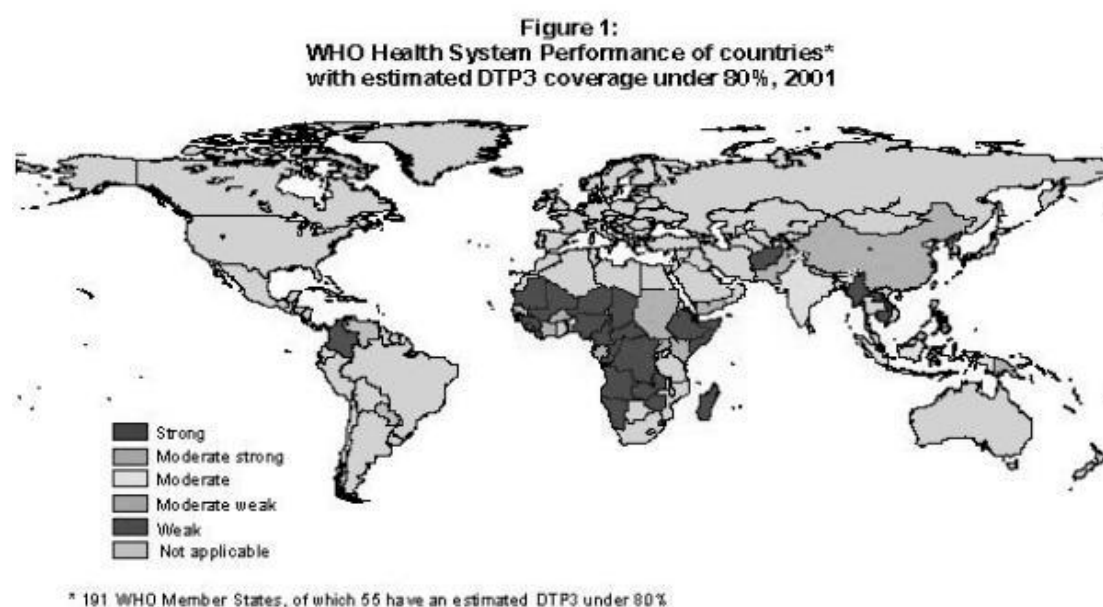
The availability of human resources with the needed immunization skills varies from country to country depending primarily on the strength of the health system (Figure 1).

⁴ Based on information currently available to WHO, there are 22,965 districts and 1,830 provinces in the 103 countries not currently achieving 80/80.

Those countries with strong health systems usually have an adequately trained and retained workforce. In countries with weak health systems, often the level of skill required is not available in country, or the quantity of skilled personnel is insufficient in number (as may also be the case in countries with large populations).

In order to improve countries capacities to reach sustainable GAVI goals, GAVI must advocate for national investments in human resources, for example, through Inter-agency Coordinating Committees (ICCs) and discussions on health sector reform.

Recognizing that substantial time will be required for countries to establish, deploy, and administer the immunization management staff required, in the short-term GAVI must invest in externally financed human resources while national capacities are being developed. These externally financed human resources might constitute less than 10% of the estimated 25,000 staff required and would be deployed with the intent that this be for a limited period of time. The primary objective of these externally financed staff would be to develop capacities at national and local levels.



4. Role of Externally Financed Human Resources

The role and type of externally financed human resources varies depending on the strength of the health system (Table 1). Since 2000, The Vaccine Fund has been providing initial health systems financing to the weakest countries through its "Immunization Services Strengthening" window. These financial inputs have been complemented by substantial technical assistance from a variety of GAVI Partners, particularly the World Health Organization and UNICEF.

The rationale for external technical assistance or human resources support, particularly in countries with the weakest health systems and/or complex emergencies, is multifold. External funding of human resources is necessary to:

- i). Fill capacity gaps when the needed skill set is not sufficiently present in country;

- ii). Retain qualified national staff who would otherwise emigrate;
- iii). Overcome the organizational and bureaucratic inertia that prevents many national programs from making progress and build technical and management capacities;
- iv). Facilitate global information exchange and coordination of efforts.

Experience of support to public health programs in developing countries demonstrates that these challenges can be overcome with the deployment of competent externally financed human resources.

The primary focus of externally funded staff is to develop national capacities in the management and provision of immunization services in the context of national health systems. Agencies and governments would together determine the external technical assistance needs, if any, and plans for the deployment of such assistance. These needs would be reviewed and shared with the broader partnership through the ICC mechanism.

Table 1: Role of externally financed HR by health system performance

Health System Performance	Role of Externally Financed Human Resources				
	Policy Advice	Knowledge sharing and advocacy	R&D, monitoring	Catalyzing, design & development of technical strategies	Implementation
Strong	X	X			
Moderate Strong	X	X			
Moderate	X	X	X	X	
Moderate Weak	X	X	X	X	X
Weak	X	X	X	X	X

5. WHO, UNICEF and externally financed human resources

As the lead UN agencies in immunization, WHO and UNICEF are committed to achieving not only the GAVI objectives, but also the child survival goals expressed in the Millennium Development Goals and the World Fit For Children Goals, confirmed during the United Nations General Assembly Special Session on Children in May 2002. This means ensuring the necessary staffing to cover the wide-range of roles and responsibilities outlined in Annex 4.1 while building national capacity to increasingly assume the majority of these responsibilities.

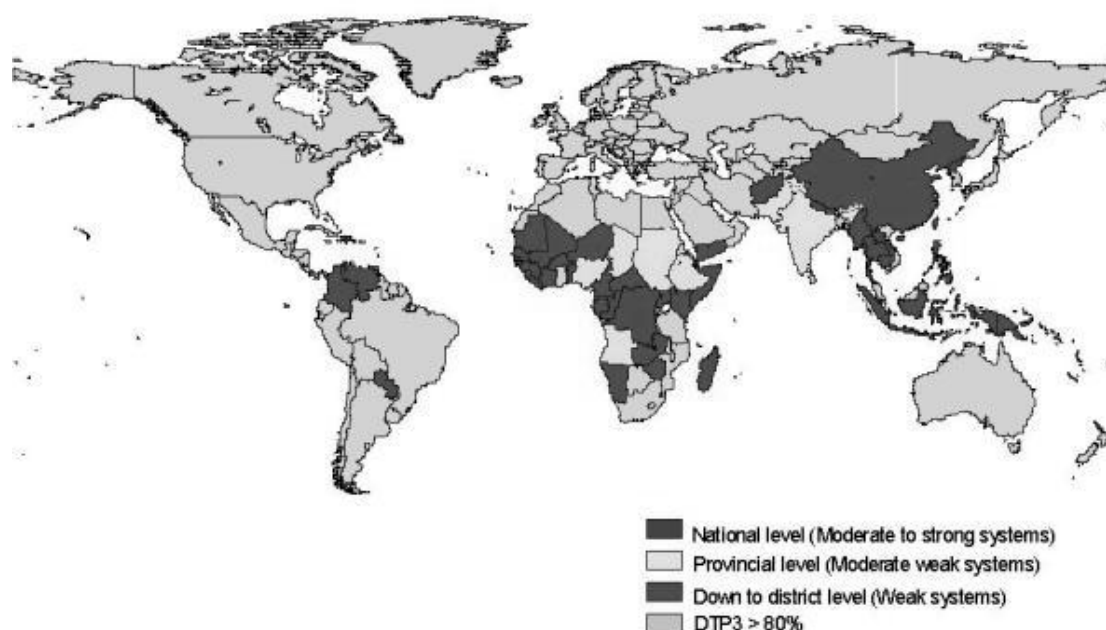
At the request of the GAVI Board, an analysis of the geographic distribution and estimated total numbers of externally financed human resources needed by the two lead agencies to support the achievement of GAVI goals and national capacity building in

those countries with the weakest health systems and/or complex emergencies is currently being undertaken by WHO and UNICEF.

To determine the number and distribution at national and sub-national levels, WHO/UNICEF considered the deployment pattern of their existing human resources, national administrative structures, immunization coverage, unimmunized population, and health system strength (per World Health Report, 2000). Only in a very few cases where there is an absence of any health system is there a need to deploy human resources below the province or state level. For countries with stronger performing health systems deployment at the national level should be sufficient. Countries with very large populations and complex emergencies require special consideration even if the health system performance is somewhat stronger (See Figure 2).

The roles and responsibilities of WHO and UNICEF Regional and Sub-Regional Offices are fundamentally oriented to support the strengthening of national capacities, coordinating with Partners (particularly through the GAVI Regional Working Groups and the GAVI Implementation Task Force), and adapting strategies to regional context. Therefore adequate and appropriate staffing of regional and sub-regional offices is a critical component of the externally funded human resources needed to achieve GAVI objectives at country level.

Figure 2: countries with DTP < 80% distribution of staff in and by health system



Based on this methodology and analysis, preliminary calculations suggest that to achieve GAVI objectives -- that is to build national capacities to sustain and increase current immunization coverage and thereby access the more that 10 million children who are currently unimmunized -- a preliminary estimate of approximately 1,000 externally-funded human resources will be required (Table 2).

These figures have been determined in consultation with WHO/UNICEF Regional Offices on a country-by-country basis (detailed spreadsheets are available). However, it is understood that all final decisions regarding in-country staffing requirements will need ICC discussion, input from the GAVI Regional Working Groups, and most importantly negotiation with national governments.

Table 2: Summary of distribution and number of externally funded HR required to achieve GAVI objectives

Level	Strength of health system	Estimated unimmunized children, 2001	International externally funded staff needed	National externally funded staff needed	Annual cost (US\$ millions)
National & sub-national	Strong	967,816	0	0	-
	Moderate - Strong	1,564,577	11	8	\$1,416,000
	Moderate	4,152,176	21	202	\$4,944,000
	Moderate - Weak	6,827,187	34	294	\$7,608,000
	Weak	10,303,267	57	338	\$10,896,000
Sub-total		23,971,639	123	842	\$24,864,000
Regional & sub-regional	NA	NA	65	60	\$7,800,000
TOTAL			188	902	\$32,664,000

6. WHO/UNICEF existing human resources opportunities and gaps

WHO

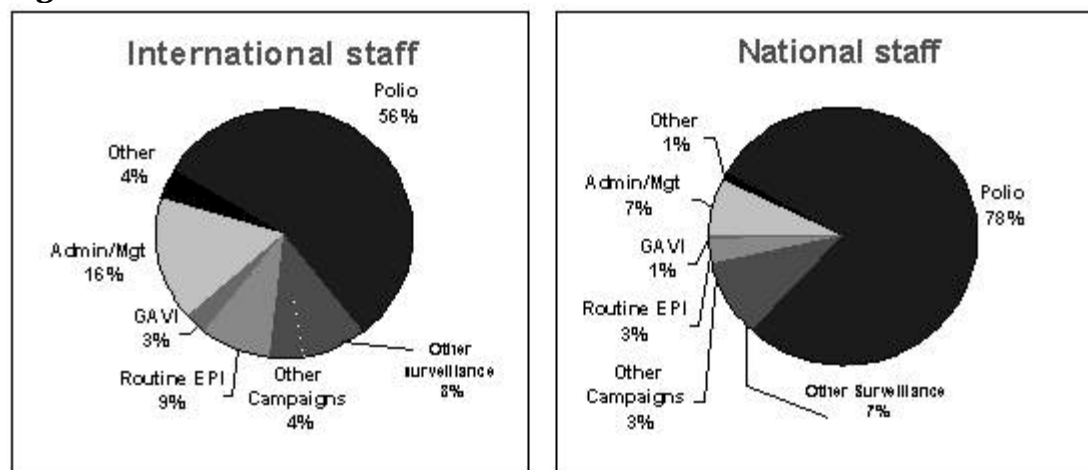
Since the mid-1990's there has been a substantial scaling-up of externally funded technical assistance through WHO and UNICEF in those countries with the weakest health systems (see Annex 4.2). Consequently, these agencies now provide the full range of assistance outlined in Table 1, including in some cases, the actual implementation of immunization and surveillance services (e.g. south Sudan, Somalia, Afghanistan). It is important to note that more than 95% of the existing country-based externally funded human resources are working in countries with either weak or moderately weak health systems which contain the largest number of unimmunized children.

Although this growth was largely driven by accelerated disease control targets, particularly polio eradication, these externally funded staff are now central to the ongoing work to improve access to other vaccines in these areas. In Ethiopia, for example, polio-funded Surveillance Officers are using a checklist during their visits in order to strengthen routine immunization systems (Annex 4.3). Opportunities like this will increase as the number of polio endemic countries is further reduced. However, there

will be a need to retain levels of staffing for supplementary immunization activities and AFP surveillance through 2005 and global certification of polio eradication.

Recognizing that the skills of existing and future externally funded immunization staff might need to be substantially different than those required to date at country level, in 2001 WHO undertook an extensive survey of 1,010 of the national and international field staff that were externally funded through the polio eradication initiative. As outlined in Figure 3 below, 91% of these internationals and 100% of these nationals are already working on non-polio activities with such work constituting 46% and 22% of their time, respectively. Of the non-polio activities, the majority of their time was spent on activities related to the strengthening of routine immunization services and surveillance for other diseases of public health importance. Furthermore, their skill-base in information management, microplanning, mapping, social mobilization, monitoring and disease surveillance could substantially contribute to national capacity building to improve immunization access, monitoring capacity and disease surveillance quality.

Figure 3: Polio staff activities – Use of staff time, 2001



UNICEF

UNICEF has identified Immunization Plus as one of five organizational priorities in its medium term strategic plan 2002-2005. Staffing needs of UNICEF Country Offices are identified at country level through the Country Program planning exercise. A survey in June 2000 indicated that hundreds of UNICEF staff at all levels (Representative, Program Coordinator, operations and supply staff; M&E and program staff) allocate a proportion of their time to support immunization activities in the majority of the 164 UNICEF field offices. This staff represents the backbone of UNICEF field presence and is usually funded by UNICEF core resources supplemented by other resources.

In coordination with WHO (and other partners), UNICEF is working with governments for the development of national capacity and achievement of substantial progress in the four core Immunization Plus target areas (planning, monitoring and resource mobilization for Immunization Plus; ensuring vaccine security; building communication support for Immunization Plus; and reaching the unreached).

7. Next Steps

In consultation with national governments and using the existing WHO & UNICEF country planning processes (i.e. WHO CCS; UNICEF Country Program Exercise), the next steps in the planning and deployment of externally financed human resources for immunization include:

- Further analysis of the gaps between the existing/planned externally financed technical assistance and the strength of the health system, the number of unimmunized children and surveillance, monitoring and reporting capacity in each country.
- Development of a training plan and materials to augment the capacity of these human resources to facilitate national capacity building efforts to improve access to immunization, monitoring of service delivery and surveillance.
- Establish a comprehensive financing plan for this externally financed technical assistance that encompasses funding available through accelerated disease control initiatives as well as other channels.

8. Questions to the GAVI Board

Summary Conclusion #1: In the medium and long-term, national governments must be supported to incorporate a human resource element into their plans for immunization strengthening (also as part of their broader health sector human resource planning). This work on human resource planning should compliment and be on par with the national financial sustainability planning for immunization. The externally funded human resources deployed through WHO and UNICEF must contribute to both these processes.

Question #1a: Recognizing that human resources planning and investment is essential for long term sustainability of immunization programs, should The Vaccine Fund/GAVI request countries prepare a 5-year Human Resources Plan for Immunization as a requirement to receive VF/GAVI funding?

Question #1b: Should a GAVI Task Force (or sub-group of an existing task force) be established to facilitate national work on long-term planning of human resources for immunization?

Summary Conclusion #2: To strengthen immunization systems, national capacity for immunization could be "back stopped" and rapidly improved with externally financed human resources deployed through WHO and UNICEF, particularly in countries with weak performing health systems and/or complex emergencies.

Question #2: While making efforts to strengthen national capacities, how should GAVI support UNICEF/WHO to bridge human resources skills gaps in priority countries with weak health systems and/or complex emergencies, and coverage less than 80%?

Annex 4.1

Major Function	Elements	Level			Mechanisms & Tools
		Global	Regional/Sub-Region	Country	
Policy, Norms & Standards	Recommendations on quality/safety Positions, Imm Policy doc, etc. Int'l Standard & Reference Materials	WHO	WHO		SAGE/TCG ECBS
Strategy Dev'l & Strat Planning	incl. other interventions (e.g. Vit A)	WHO/Unicef	WHO/Unicef	WHO/Unicef	SAGE/TCG
Supply of Quality Vaccines & Injection Equipment	Pre-qualification (incl. NRA) Procurement Demand/Supply Forecasting Production	WHO Unicef/WHO Unicef/WHO WHO	WHO Unicef/WHO WHO/Unicef	WHO Unicef/WHO Unicef	NRA Assess. VP Project Annual Forecast/ICG DCVMN
Research & Product Develop.	New vaccines Equipment development Operational research	WHO WHO WHO/Unicef	WHO WHO WHO		IVR PIS, SIGN, IVR IVR
External Relations	Advocacy (political commitment) Resource Mobilization Public Information	WHO/Unicef WHO/Unicef Unicef/WHO	WHO/Unicef WHO Unicef/WHO	Unicef/WHO Unicef Unicef	ICCs ICCs
Monitoring & Evaluation	Coverage Surveillance Data Laboratory Special Surveys System Indicators	WHO/Unicef WHO WHO Unicef/WHO WHO/Unicef	WHO/Unicef WHO WHO WHO/Unicef WHO/Unicef	Unicef/WHO WHO WHO Unicef/WHO WHO/Unicef	Joint Report Form WHO Procedures WHO Procedures 30-cluster/MICS/WHS Joint Report Form
Country Operations & Programme Evaluation	Technical Guidelines HR Dev't (incl. training/supervision) Multiyear & work plans (incl. microplans) Microplan implementation Assessments/Reviews SocMob/Behaviour Change Logistics (incl. cold chain) Financial Sustainability	WHO WHO/Unicef WHO/Unicef Unicef WHO Unicef/WHO	WHO WHO/Unicef WHO/Unicef WHO/Unicef Unicef WHO WHO/Unicef	WHO/Unicef WHO/Unicef WHO/Unicef Unicef/WHO WHO/Unicef Unicef/WHO Unicef/WHO Unicef	SAGE/TCGs/ECBS RWGs/GTN, etc ICCs RWGs/ICCs SIGN (other?) Vaccine Mgmt training FSAT

Annex 4.2

Current WHO and UNICEF immunization human resources

Table 3. Summary of current number and cost of externally funded WHO* & UNICEF staff by health system performance and estimated number of unimmunized children

Level	Strength of Health System	Estimated unimmunized children, 2001	International externally funded staff, 2002	National externally funded staff, 2002	Annual Cost (US\$ millions)
HQ					
- Global support	NA	NA	62	0	\$7,440,000
- RO/ Country Support	NA	NA	126	0	\$15,120,000
Region & sub-regional	NA	NA	91	66	\$12,108,000
National & sub-national	Strong	967,816	1	0	\$120,000
	Moderate-Strong	1,564,577	16	35	\$2,550,000
	Moderate	4,152,176	27	857	\$15,580,800
	Moderate-Weak	6,827,187	86	630	\$17,880,000
	Weak	10,303,267	113	946	\$22,641,600
TOTAL		23,971,639	522	2,534	\$93,440,400

- Includes WHO admin/support staff, including drivers.

Annex 4.3

POLIO ERADICATION CHECK LIST FOR CENTRES /POSTS /STATIONS

CONSULTANT: _____ DATE _____

REGION _____ ZONE _____ WOREDA _____ HEALTH FACILITY _____

EQUIPMENT AVAILABLE

RADIO _____ TELE-PHONE _____ MOTOR BIKE/S _____ BICYCLE /S _____

STAFF

HEALTH WORKERS _____ HEALTH WORKERS SENSITISED _____

FOCAL PERSON _____ TRAINED ? _____ WHERE ? _____ DATE _____

AFP DEFINITION :

ACUTE ? _____ FLACCID ? _____ PARALYSIS ? _____

CHECK FOR :

INJECTION PARALYSIS _____ RESIDUAL PARALYSIS _____

RECORDS:

REGISTERS ADEQUATE ? _____
 UNDER 5 CLINIC _____ OUTPATIENT _____ EMERGENCY _____ IMCI _____

INPATIENT PAEDIATRIC _____ NEUROLOGY _____ PHYSIOTHERAPY _____ # OF RECORDS EXAMINED _____

FOR BELOW DETAILED INFORMATION MUST BE RECORDED

AFP ? _____ REPORTED ? _____ NEONATAL TETANUS ? _____ REPORTED ? _____

MEASLES /COMPLICATED _____ REPORTED ? _____ ONCHOCERCIASIS ? _____ KEBELE /S (list) _____

GUINEA-WORM ? _____ KEBELE/S (list) _____

Please inform Zonal/Regional and National Eradication Programs

IDS REPORTS

WEEKLY _____ MONTHLY _____ QUARTERLY _____ ZERO REPORTING _____

POPULATION

TOTAL (in catchment area of facility) _____ SOURCE _____ UNDER 5 _____ SOURCE (eg % ;NIDs; Guinea-Worm Census) _____ WHEN STOPPED _____

UNDER 1 _____

EPI ACTIVITY

YES _____ NO _____ If NO, WHY ? _____ WHEN STOPPED _____

A. STATIC SITES _____ SESSIONS PER WEEK _____ LAST WEEK SESSIONS _____

B. OUTREACH SITES _____ #FUNCTIONAL _____ per MONTH _____

SITES Visited LAST MONTH _____

EPI REGISTER

IN USE ? _____

CHILD
TRACEABLE ? _____

EPI COVERAGE FOR EACH OF THE LAST 3 MONTHS

DTP1 _____ DTP3 _____ OPV1 _____ OPV3 _____

COLD CHAIN

#FRIDGES

FRIDGE 1 FRIDGE 2 FRIDGE 3 FRIDGE 4

TYPE ?(eg solar) _____

MODEL ? _____

FUNCTIONAL ? _____

if no, why ? _____

TEMP CHARTS? _____

If no, why ? _____

CORRECTLY _____

FILLED IN _____

AM/PM ? _____

ADEQUATE _____

TEMPS ? _____

OPV SUPPLY NUMBER OF VIALS :

10 dose (total) GOOD _____ EXPIRED _____ VVM 3&4 _____ NO LABELS

20 dose (total) GOOD _____ EXPIRED _____ VVM 3&4 _____ NO LABELS

Vaccine Storage :

OPV Fridge Freezer Tetanus Toxoid : Fridge Freezer

SAFE INJECTION PRACTICES:

REUSING DISPOSABLE NEEDLES?:

Annex 5

Establishment of a strategic stockpile for yellow fever vaccine to accelerate control and contribute to vaccine security

Executive Summary

GAVI country guidelines for support from The Vaccine Fund include the provision of yellow fever vaccine for use in routine infant immunization programs. To date, 8 countries have been approved for yellow fever vaccine support.

Yellow fever has re-emerged as a disease of considerable public health importance in west and central Africa. A major constraining factor for the control of this disease has been the very limited global availability of vaccine. This has been compounded by the lack of funding resulting in uncertain demand and, ultimately, supply shortage, and also in a shortage of suitable lyophilisation capacity. In recent years, this vaccine shortage has led to a reduced level of immunization activities in a number of countries and has resulted in great difficulties in mobilizing vaccines for outbreak responses. A contributor to this situation is the erratic purchasing patterns of countries in Africa, and with it the diversion of supply intended for routine infant immunization into outbreak control.

Furthermore, routine infant immunization alone will not prevent yellow fever outbreaks for at least three decades, during which population immunity levels will gradually be increased. It has been demonstrated and it is accepted that, to achieve sustained control of yellow fever, a combination of routine immunization and preventive campaigns in high-risk districts is needed.

This document was prepared by WHO, UNICEF and The Vaccine Fund (facilitated through their work on the Vaccine Provision Project (VPP) established by the GAVI Board), in consultation with partners involved in the yellow fever International Coordinating Group (ICG). It outlines a comprehensive approach to yellow fever control efforts through (i) helping avoid disruption in vaccine supply for routine immunization programs; (ii) securing the availability, on time, of vaccines for outbreak response; and (iii) organizing preventive campaigns in high-risk areas.

The centerpiece of the strategy is the establishment and strategic management of a vaccine stockpile to be used for preventive campaigns and emergency response activities, which will, through the establishment of a stable and predictable vaccine supply, eliminate the threat to the supply for routine immunization. It is proposed that The Vaccine Fund cover the costs of creating and replenishing this strategic stockpile – at an estimated cost of US\$ 3 million per year – for an initial period of three years (total cost US\$ 9 million). This multi-year commitment is a key element in making the strategy work. After three years, continuation of the scheme will depend on extension of Vaccine Fund support or on mobilization of other funding sources.

Implementation of this strategy will:

- Prevent disruption of routine infant vaccination programs;
- Accelerate the reduction of yellow fever disease burden in Africa;
- Help increase and sustain overall yellow fever vaccine production capacity;
- Ensure a stable and manageable stockpile for outbreak control;
- Leverage additional partner resources;
- Enhance the trust in GAVI's ability to address complex vaccine supply issues.

The GAVI Board is requested to consider:

- (1) Expanding the scope of GAVI/Vaccine Fund support for yellow fever control as outlined in this paper;
- (2) Whether the support for catch-up campaign activities that target age groups other than infants could be seen as setting a precedence for other antigens (e.g. meningitis, measles);
- (3) Providing GAVI/Vaccine Fund support for a trial period of three years – with performance and impact to be assessed prior to extension.

With GAVI Board endorsement of the principles described in the paper, WHO, UNICEF, The Vaccine Fund and Partners at global, regional and country level, each according to their defined accountabilities, will take the necessary steps to establish the global supply capacity and stockpile; set in place transparent and effective management mechanisms; assist countries in strengthening their yellow fever control activities within the framework of their multi-year plans; and mobilize resources needed to implement preventive campaigns in a timely manner.

Background

Yellow fever is a viral haemorrhagic fever which strikes an estimated 200,000 persons worldwide each year and causes an estimated 30,000 deaths. Most of these cases and deaths occur in Africa, where weak surveillance and control systems make the estimation of the true burden of the disease difficult. Thirty-three countries in Africa are considered to be at risk for yellow fever.

The disease was successfully controlled in Africa between 1940 and 1960, when mass immunization campaigns were carried out in francophone west and central Africa. At that time, west and central African countries did not have yellow fever vaccination as part of their routine childhood immunization, thus leaving all those born after the last campaigns in 1960 unimmunized. Currently, yellow fever is part of the routine immunization programs in seventeen countries in Africa, though vaccination coverage has remained low in most of these countries. Eleven countries in South America are yellow fever endemic but have in place effective routine and outbreak control systems supported by PAHO.

The resurgence of yellow fever starting in the 1980s is related to the build-up of unprotected populations after the last campaigns in the 1960s and the change in the density and distribution of the vector population due to deforestation and urbanization.

Since 2000, GAVI has provided countries the opportunity to apply for yellow fever vaccine support from The Vaccine Fund. Annex 5.1 shows risk status and vaccine introduction and approval status for yellow fever endemic countries in Africa as of October 2002. The WHO AFRO's plan of action stipulates that all high and medium risk countries (Groups 1 and 2) by the end of 2004 will have introduced yellow fever as part of routine infant immunization programs.

Strategies for yellow fever control

WHO recommends strategies for both yellow fever outbreak prevention and outbreak control as outlined below.

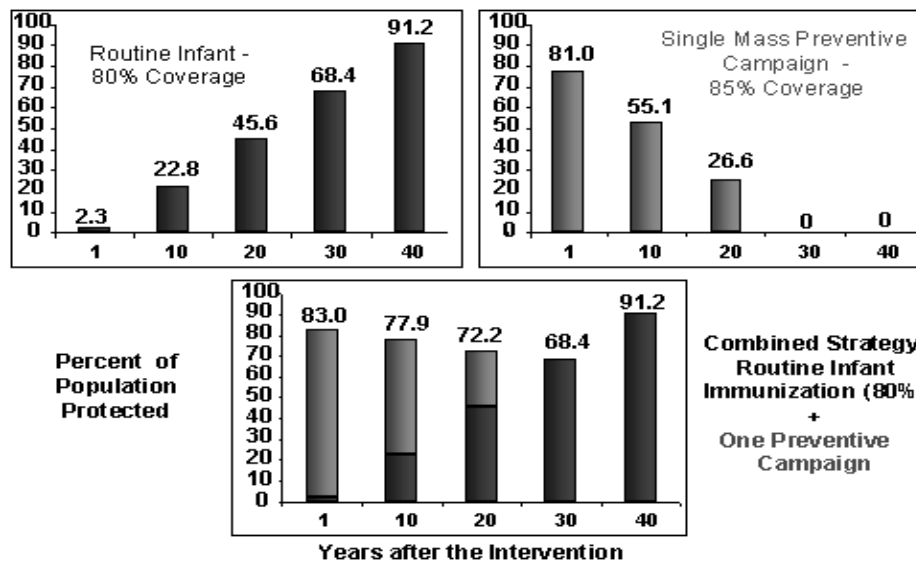
Outbreak prevention

A two-component strategy for outbreak prevention is recommended:

- The introduction of yellow fever vaccination into routine infant immunization systems;
- Preventive mass immunization campaigns in high-risk districts.

Routine infant immunization alone will not create sufficiently high population immunity to prevent yellow fever outbreaks for at least three decades. It is therefore critical for the achievement of sustained yellow fever control that support be provided to countries to organize preventive campaigns in their high-risk districts. Countries that have organized such preventive campaigns will subsequently consolidate yellow fever control through sustained routine infant immunization achieving high coverage levels.

Figure 1 shows a simple model to estimate the impact of yellow fever prevention strategies either alone or in combination. It shows that the combined use of routine infant immunization along with a **single** preventive campaign is the most effective approach to reducing the number of susceptible population and prevention of yellow fever. Routine infant immunization, even at 80% coverage, without preventive campaigns will not prevent outbreaks for at least three decades. This combined approach has also been proven effective in both the Gambia and Trinidad where yellow fever outbreaks have been and continue to be prevented. Furthermore, this combined strategy is expected to be effective in preventing outbreaks, albeit for a shorter time period, even in the absence of high routine infant immunization coverage.

Figure 1. Estimated Impact of YF Prevention Strategies

(Source of data: WHO, V&B, VAM)

Outbreak response

There is still no specific therapy for yellow fever, from which 50% of severely affected patients will die. The only way of halting outbreaks is through emergency mass campaigns. For this reason, WHO recommends two strategies for yellow fever outbreak control:

- Strengthening of outbreak response and improved epidemic preparedness;
- Strengthening of case-based surveillance including laboratory capacity to confirm suspected yellow fever cases.

Effective outbreak response is often hindered by both lack of funds and shortage of vaccine. For example, an emergency campaign in response to an urban outbreak in Abidjan, Côte d'Ivoire in 2001 immunized nearly 3 million people in eight days, averting an estimated 30,000 deaths. The following year when an urban outbreak threatened the city of Conakry in Guinea, no funds could be rapidly identified to purchase adequate supplies of vaccine for an emergency campaign to protect 2 million people at risk for yellow fever.

In addition, experience so far has shown that when funds are not immediately available to purchase yellow fever vaccine for outbreak response, supplies are diverted from the routine infant immunization program. This not only causes disruption to this crucial component of the yellow fever prevention strategy, it actually makes it worse by reducing the numbers of infants immunized and therefore increasing the adult unprotected pool. This diversion of routine vaccine supplies to outbreak response has been witnessed during the current yellow fever outbreak in Touba, Senegal.

Yellow fever vaccine supply and security

Current vaccine supply is inadequate to meet the demands for outbreak prevention and outbreak control, mainly because there is uncertain level of demand, which in itself is partially fed by uncertain supply. This situation is made more complex by the limited

number of WHO pre-qualified suppliers (currently three: Aventis Pasteur, Institut Pasteur Dakar, Biomanguinhos), the long production lead times and the imperative to give priority to controlling sporadic and unpredictable outbreaks. Limited lyophilisation capacity is also a contributor; this should be somewhat alleviated by using the larger dose vials that are preferred for campaign use in the recipient countries. An objective of this strategy will be to establish more than one appropriate and reliable producer of vaccine.

In order to overcome this current deficiency it is necessary to establish a supply structure that is predictable, sufficient, properly underwritten with long-term commitments, and appropriate to meet the different demands of infant immunization, preventive campaigns and outbreak response. This is made more achievable with the mandate given to the Vaccine Provision Project by the GAVI Board specifically to meet such needs. It will involve both a short term and a longer-term stabilization of supply based on the confidence that there will be predictable and commercially viable demand in order to support the capital and working capital commitments manufacturers need to make. That The Vaccine Fund can make long-term commitments to the purchase of such vaccines is an important aspect, and this strength can be used favorably.

In 2001, confronted with a worldwide shortage of vaccine, WHO and its partners created a mechanism to establish and manage a strategic stockpile of yellow fever vaccine available for emergency use by countries experiencing epidemics. Due to lack of funding this stockpile was not capitalized and remained “virtual” – meaning that a stock was not created and kept at any manufacturer. A special sub-group for yellow fever was formed within the International Coordinating Group (ICG) mechanism, which already managed an emergency stockpile of meningitis vaccine.

The stockpile was initially set at 2 million doses, from which vaccine was released only to countries satisfying specific epidemiological and operational criteria. Since the stockpile was not pre-funded, countries or their partners had to cover the costs of the requested vaccine prior to its release and shipment. This led to considerable delays in response to the outbreak threatening the escalation of the outbreaks. Experiences indicated that it was difficult for manufacturers to maintain a stockpile when the total demand was low and vaccine shelf-life was relatively short; that emergency requirements were underestimated (for example, the urban outbreak in Abidjan required nearly 3 million doses); and that routine infant vaccination often got disrupted as vaccines were re-routed toward outbreak control activities.

Proposed strategy: expanding the strategic stockpile

It is proposed that a yellow fever vaccine stockpile of 6 million doses to be used for both preventive campaigns and outbreak response be established. The preventive campaigns are made possible by the ability to secure the replenishment of the stockpile using The Vaccine Fund’s financial strength, the need to accommodate the relatively short shelf life of the vaccine, its long production lead time, and the fact that the released vaccine can be made available to the recipient countries at no cost if necessary.

The dual-purpose of the stockpile would be to:

- Provide an emergency stock of yellow fever vaccine for use in outbreak response;
- Make available yellow fever vaccine for planned preventive campaigns in high-risk districts in west and central African countries – within the framework of national multi-year plans.

Additional benefits would be to:

- Secure a guaranteed higher demand for yellow fever vaccine thereby providing manufacturers with an incentive to increase production capacity and to use it to produce sufficient vaccine doses for the GAVI supported programs;
- Eliminate the risk that vaccine for routine immunization gets diverted to outbreak control activities.

The size of the stockpile (6 million doses) has been set based on the amount of vaccine expected to be used each year for preventive campaigns. This would also be large enough to ensure adequate outbreak response and coverage in a moderate-large city or in several concurrent outbreaks. The current cost of a stockpile of 6 million doses (bundled with safe injection supplies) is US\$ 3 million.

Principles for stockpile allocation

In good time before expiry date, unused yellow fever vaccine in the stockpile will be released for preventive campaigns in districts at high risk for yellow fever. Annex 5.2 provides a summary of activities foreseen in the period 2003-2006, with support provided to 2-3 countries per year.

Countries have been selected according to their epidemiological, entomological and program readiness status. All countries are high-risk countries that have experienced at least one yellow fever outbreak since 1980. They should already have included yellow fever vaccination as part of their routine infant immunization and should provide a detailed plan for the preventive campaign.

WHO and partners will work with countries to support the planning and effective implementation of preventive campaigns using six million doses of vaccine each year.

WHO and UNICEF will also assist countries to raise the necessary funds to cover the operational costs of the campaign and will provide technical support for planning and implementation of the campaigns. Countries will not be requested to pay for the vaccine, since GAVI and The Vaccine Fund under the proposed arrangement will replenish the vaccine stockpile of 6 million doses.

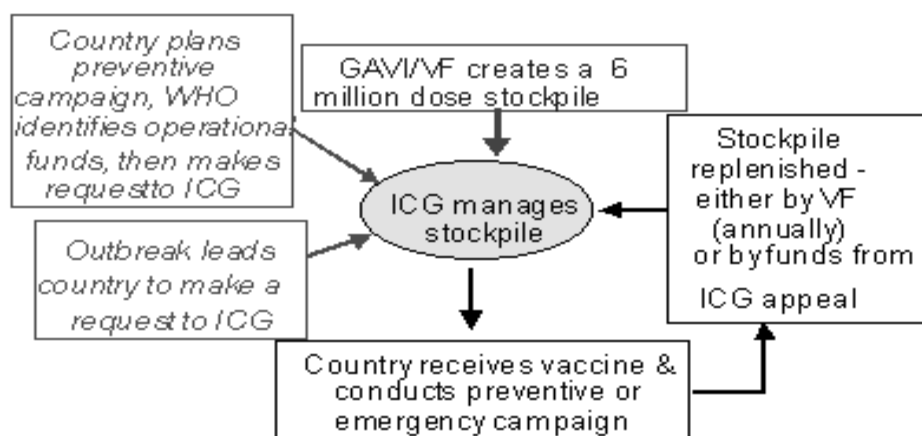
In the event of an outbreak, eligible countries will be able to access the stockpile for immediate use if no other vaccine is readily available. However, they will be expected to provide funds, once available, to purchase vaccine to replenish the stockpile. Vaccine would be replaced at the price current at the time of replenishment, and in the same quantity as had been utilized. This provides an incentive for countries to implement the outbreak prevention strategies rather than continue with the “fire-fighting” approach, since payments for the vaccine would have to be made by the countries for outbreak response but not for preventive campaigns.

Management of the stockpile – roles and responsibilities

The yellow fever vaccine stockpile would be held by manufacturer(s) in coordination with UNICEF Supply Division. Vaccine allocation from the stockpile would be managed by WHO and the International Coordinating Group (ICG). UNICEF Supply Division

will be responsible for procurement, shipping and delivery of the vaccine. This is illustrated in Figure 2.

**Figure 2. Stockpile of Yellow Fever Vaccine
Preventive Campaigns and Outbreak Emergency
Response to Accelerate Yellow Fever Control**



Expected impact and benefits of the proposed strategy

The proposed strategy will:

- Establish a stable and secure global supply of vaccine that will ensure that there will be sufficient vaccine to meet the needs for the GAVI/Vaccine Fund supported routine infant immunization;
- Provide a stockpile that can be strategically managed and is sufficient to meet the probable needs for outbreak control;
- Allow the stockpile to be replenished on a planned basis well before the expiry of the vaccine, and therefore be instrumental in allowing countries to implement sound preventive strategies for the control of yellow fever and, over time, reduce the size and frequency of yellow fever outbreaks - thereby reducing the morbidity and mortality caused by yellow fever in the African region;
- Contribute to guaranteeing demand at a level that should provide manufacturers with an incentive to increase and sustain production capacity; and
- Contribute to leverage resources from partners and donors.

It should be recognized that this strategy is made possible by the mechanisms that GAVI has put into place, and as such will reinforce the benefits that the Alliance can bring into the immunization arena.

Proposed GAVI and Vaccine Fund investment

The cost of 6 million doses of yellow fever vaccine bundled with safe injection equipment is estimated at US\$ 3 million– i.e. this is the annual cost of implementing the vaccine provision part of this program. The significant programmatic aspects and costs of implementing the planned campaigns will be met by GAVI Partners, primarily UNICEF and WHO.

A key aspect of the strategy is to use the strength that GAVI and The Vaccine Fund bring, particularly in this case the ability make a multi-year commitment to the purchase of vaccine for the stockpile, as well as for the routine immunizations that are part of the approved applications to GAVI for Vaccine Fund support. It is proposed that in the first instance GAVI and The Vaccine Fund would support the establishment and replenishment of the stockpile for a trial period of three years. This would provide sufficient time to establish a stable production and supply situation, and the procedures to implement the strategy – with an assessment to be done at the beginning of the third year. The total cost is estimated at US\$ 9 million (US\$ 3 million per year for three years).
Risk analysis

Major risks for failing to implement the proposed strategy are as follows:

- Poor planning and country support for implementation of preventive campaigns could lead to preventive campaigns not being organized on time, with under-use and even expiry of stockpiled vaccine;
- Likewise, failure to secure operational costs will delay preventive campaigns with similar consequences;
- Major yellow fever outbreaks and global yellow fever vaccine shortage could lead to depletion of the yellow fever vaccine stockpile;
- Routine immunization coverage will need to be substantially increased and maintained at high levels in order to increase the time period of effectiveness of the combined strategy.

The proposed approach may be perceived as setting a precedent whereby GAVI/The Vaccine Fund support the purchase of vaccines for supplementary immunization activities (i.e. campaigns), departing from the primary GAVI and Vaccine Fund focus on supporting strengthening of routine immunization systems. This could become an issue in particular with regards to meningitis vaccine, when a conjugate vaccine becomes available, since supplementary immunization activities will also be required.

While it is not proposed that GAVI depart from its strong focus on routine immunization strengthening, the decision to expand support to yellow fever control as proposed in this paper could be made on the following basis:

1. The strategy directly contributes to routine immunization by addressing the issue of global vaccine shortage and by helping avoid the currently experienced disruptions of routine activities caused by the diversion of stocks for outbreak response activities.
2. Yellow fever vaccine is one of the original three GAVI priority antigens and GAVI support will have little impact on the disease burden unless a combined strategy of routine immunization and preventive campaigns is implemented.
3. Unlike other disease prevention strategies requiring repeated campaigns (e.g. measles), yellow fever prevention can be achieved with only one campaign plus routine infant immunization, provided that high coverage is achieved in both.
4. The proposed investment is relatively limited (\$3 million per year) and the strategy includes (i) the condition that increased partner commitment be leveraged to finance

the operational costs of the preventive campaigns and (ii) a reimbursement of the vaccines used for outbreak response activities through coordinated appeals.

5. It is proposed that the success of the mechanism be assessed after 2 years.

Necessary follow-up actions

- Identification of suitable manufacturer(s) for establishment of stockpile (UNICEF SD).
- Development of the contractual arrangements to make the necessary multi-year commitments to manufacturers, and of The Vaccine Fund's resources. Vaccine Fund to advise of the information needed by the VF to decide whether to support financing of the mechanism.
- Strengthening country support and monitoring systems – in particular to make sure that all high-risk countries introduce yellow fever vaccine in their routine program; strengthen surveillance; and plan and implement their preventive campaigns in a safe and effective manner (primary responsibility: WHO).
- Mobilizing resources to secure operational costs in planned preventive campaigns (WHO, UNICEF).
- Specific roles and responsibilities to be defined among the Partners.

References

- Yellow fever Technical Consensus Meeting , Geneva 2-3 March, 1998 (WHO/EPI/GEN/98.08)
- Yellow Fever. J. Vainio and F. Cutts. 1998 (WHO/EPI/GEN/98.11)
- Control of Yellow Fever in the African Region, Four Year plan of action 2002-2005, WHO, 2002
- Monath, T.P. and Nasidi, A., Should yellow fever vaccine be included in the expanded program of immunization in Africa? A cost-effectiveness analysis for Nigeria, Am. J. of Tropical Medicine and Hygiene 48(2):274-299, 1993.

Annex 5.1

Country status in the African region (from draft Africa Plan of Action 2002-2005)

Group	Categories**	Countries	Priority interventions
1A	High-risk Large epidemics in recent years, and/or high number of reported cases, and/or having common borders with countries with large recent epidemics. And/or one or more of the following: High vector density; highly populated; "countries in greatest need" for assistance; generally poor EPI and weak infrastructure; poor surveillance systems.	<u>Nigeria</u> , <u>Cameroon</u> , <u>Kenya*</u> , <u>Liberia*</u> , <u>Burkina Faso</u> , <u>Guinea*</u> , <u>Senegal</u> , <u>Mali*</u> , <u>Benin*</u> , <u>Ghana*</u> , <u>Côte d'Ivoire</u> , <u>Sierra Leone*</u> , <u>Togo*</u> , <u>Gabon</u> , <u>CAR</u> , <u>Angola</u>	<ol style="list-style-type: none"> 1. Establish case-based and entomological surveillance for yellow fever. 2. Establish national level capacity for yellow fever IgM testing. 3. Introduce yellow fever into routine EPI/or increase yellow fever antigen coverage to protective levels (>80%). 4. Conduct preventive campaigns in high-risk districts.
1B	High-risk Same as 1A but have not reported an outbreak since 1980.	<u>Equatorial Guinea</u> , <u>Guinea Bissau</u> , <u>Congo</u> , <u>DR Congo*</u>	<ol style="list-style-type: none"> 1. as above 2. Establish national level capacity for yellow fever IgM testing, or have access to another lab with the capacity for proficient yellow fever IgM testing. 3. As above
2	Medium risk No reported epidemics/cases for at least 30 years. And/or countries that have already incorporated yellow fever immunization into the routine EPI but recording low coverage; countries with relatively weak EPI program; countries with very few districts bordering known epidemic zones.	<u>Mauritania</u> , <u>Chad</u> , <u>Niger</u> , <u>Uganda</u> , <u>Ethiopia</u>	As group 1B above
3	Low risk No reported epidemics in the past 50 years, or yellow fever incorporated into EPI with good coverage levels (more than 80%)	<u>Rwanda</u> , <u>Burundi</u> , <u>Gambia</u> , <u>Tanzania</u> , <u>Cape Verde</u> , <u>Sao Tome & Principe*</u>	<ol style="list-style-type: none"> 1 and 2 as above and 3. Sustain EPI program (if yellow fever is included in EPI).

Underlined countries: do not yet have yellow fever as part of EPI

*Countries marked with * have started the process of introduction of yellow fever vaccine in EPI or have been approved for yellow fever vaccine by GAVI.*

*** Categorization of countries is reviewed and adjusted as new information, epidemiological and entomological data become available*

Annex 5.2

Proposed Countries For Preventive Campaigns And Numbers Of Doses Used Per Country

Year	Number of doses										Total
	Benin	Burkina Faso	Cote d'Ivoire	Guinea	Kenya	Liberia	Mali	Sierra Leone	Senegal	Togo	
2003					900,000		1,500,000			2,500,000	4,900,000
2004									5,000,000		5,000,000
2005				3,800,000				1,500,000			5,300,000
2006			3,400,000					1,500,000			4,900,000
2007	2,250,000	2,600,000				900,000					5,750,000
Total Per Country	2,250,000	2,600,000	3,400,000	3,800,000	900,000	900,000	1,500,000	3,000,000	5,000,000	2,500,000	25,850,000

The table shows proposed countries for intervention by year. This proposal does not exclude support for countries not already included, and may change with changing circumstances such as the risk status, or changes in countries' priorities and capacity for implementation.

To determine the recipient countries and the numbers of doses needed, meetings were held with teams (EPI and surveillance officers both at the National and WHO country level) from 15 countries during the EPI Managers meeting in Lome, 2002. Further discussions were also held during country visits and with the WHO ICP for West Africa. Specific information was compiled about the number and populations of the districts that are considered to be at high risk for yellow fever. In addition, information concerning the countries' plans for preventive campaigns was also obtained. Eight out of the 10 countries in the above table have plans for preventive campaigns in their high-risk districts. None of the 8 countries had funding to support such plans, but were in the process of trying to find sufficient funds. Of those, 4 countries (Guinea, Kenya, Mali, and Sierra Leone) have submitted forecasts to UNICEF SD for 2002 of a total of 5.6 million doses. Guinea was able to obtain donor support for a preventive campaign that took place in July/August 2002. Kenya and Sierra Leone were forced to withdraw their requests for vaccine for 2002 because of lack of available funding. The number of doses was calculated using the total population (of persons aged 9 months) and taking into account a wastage rate of 15%.

Annex 6

GAVI statement on an immunization system strengthening approach to measles mortality reduction

Of the vaccine-preventable diseases, measles is the leading killer of children accounting for nearly 800,000 deaths each year. Over half of global measles deaths occur in African infants and children. Indeed, the overwhelming majority (> 98%) of global measles deaths occur in the 74 countries eligible to receive support from The Vaccine Fund.

GAVI fully supports the 2002 United Nations General Assembly Special Session on Children resolution to reduce measles deaths by 50% by the year 2005 from the 1999 baseline of 875,000 deaths. Moreover, GAVI endorses the United Nations Millennium Development Goals, which include the target to reduce the under-five mortality rate by two thirds. An indicator for both of these targets is the proportion of 1-year-old children immunized against measles.

Given the availability of safe, effective and relatively inexpensive measles vaccine and proven vaccination strategies, the current global burden of measles deaths is unacceptable. Infants and children living in developing countries have the human right not to die from measles.

To achieve a sustainable reduction in measles deaths, a comprehensive vaccination strategy is needed. While the ongoing strengthening of routine immunization services is the foundation of the WHO/UNICEF recommended strategy for sustainable measles mortality reduction, periodic supplementary immunization activities are required to achieve and maintain high measles population immunity and to sustainably reduce the level of measles virus circulation. Such supplementary immunization activities may be needed until routine immunization services are able to achieve and maintain high (\geq 90%) coverage for both the first and second opportunities for measles immunization.

To reduce measles deaths on a long-term basis, 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, GAVI supports the WHO-UNICEF *Framework for Collaboration*, which outlines criteria that must be satisfied in national plans of action to help ensure sustainability of impact.

GAVI welcomes information about the remarkable progress that has been made in reducing measles deaths in Africa by strengthening routine immunization systems and conducting measles supplementary immunization activities through support of the ***Measles Initiative***.

To sustainably reduce measles deaths, GAVI calls upon its partners to financially support national immunization plans, including the full implementation of measles mortality reduction strategies.

Annex 6.1

WHO/UNICEF framework for collaboration to ensure sustainable measles mortality reduction

To achieve sustainable reduction of measles it is important to set out a framework for good practice. Based on experience gained in a number of countries, at a Measles Informal Consultation held in Geneva in January 2002, WHO and its partners identified and agreed upon criteria that should be used to assess national plans of actions, so that the sustainability objective is achieved. These criteria are outlined below.

The following criteria should be satisfied before embarking on accelerated measles control efforts or there should at least be a commitment by the country and its partners to fulfil them in timely manner.

1. There must be a multi-year immunization plan including measles activities, with a detailed 1-year work-plan, both endorsed by the national inter-agency coordinating committee (ICC) and with a clearly defined role for all key stakeholders.
2. The plan should include a defined strategy, financing plan and adequate human resources (technical support) to sustain the impact for at least 5 years. This involves identifying and addressing the reasons for low coverage to ensure that at least 90% of children receive a first opportunity for measles immunization, and providing a second opportunity for measles immunization through either routine immunization or measles supplementary immunization activities, as appropriate.
3. If measles supplementary immunization activities are implemented, they should be in accordance with broader country and regional immunization and health goals, and include funding for a comprehensive evaluation plan. When conducting measles supplementary immunization activities, the priority is to protect children at highest risk from dying from measles (in general children <5 years), as well as those in older age groups as they are often important sources of measles virus infection for young children.
4. Measles surveillance activities should be in place, or in the process of being established, to obtain and analyze basic data for monitoring and evaluating impact. These activities should be built on existing infrastructure (e.g. AFP surveillance) and facilitate development of integrated surveillance systems.
5. Countries with large populations or those experiencing complex emergencies represent an opportunity for partners to work in close collaboration in reducing measles deaths. Sufficient planning time is essential to ensure high-quality and sustainable impact of measles mortality reduction activities. Careful assessment of feasibility and operational issues (e.g. considering progressive implementation by geographic area and/or age group) is needed, particularly in polio-endemic countries, to ensure that measles mortality reduction and polio eradication activities are synergistic.

Annex 7

Report of the 1st meeting of the GAVI Board Oversight Committee – Vaccine Provision Project – 1 November, 2003

With reference to the recommendations of the Mercer study, the GAVI Board set up a small VPP Oversight Committee consisting of Dr. Fatoumata Nafo-Traoré and Dr. Sigrun Mogedal, expanded to include the Executive Secretary of GAVI. The first meeting of the committee was held on 1 November 2002 in Geneva. Dr. Tore Godal, Executive Secretary of GAVI and Dr. Paul Fife, VPP project manager, attended the meeting in addition to the two board members mentioned above.

Two telephone conference calls were arranged to enable the committee to hold discussions with: i) Mr. Piers Whitehead, ii) the members of the VPP team: Ms. Shanelle Hall (UNICEF Supply Division), Ms. Alice Albright and Mr. John Marshall (Vaccine Fund) and Dr. Pem Namgyal (WHO).

Objectives of the meeting

1. To review work progress of the VPP;
2. To provide preliminary feedback on policy issues relating to the forecast;
3. To identify and review issues to be reported to the GAVI Board.

Forecasting methodology

The methodological approach used to forecast GAVI/Vaccine Fund (2004-2006) vaccine requirements was considered satisfactory. The general principles chosen were appropriate. For the forecasting of hep B and Hib vaccines, the analysis addressed the risks and uncertainties associated with the behavior of countries in terms of changes in the presentation of vaccines, and large countries whose applications had not yet been approved. It also included a categorization of countries (groups 1 to 5) by vaccination coverage in countries, wastage, country needs, the quality of information provided, and the diversity of the parties involved. For yellow fever, it was proposed that a buffer stock be created for vaccination campaigns in districts at risk. However, the decision to be taken by the Board at its Dakar meeting would affect the way in which yellow fever vaccine forecasts were made. The main issues raised related to:

- The quality of the information provided by countries and vaccine manufacturers and its effect on the quality of forecasts;
- Security in terms of the availability of funding;
- Ways and means of consulting manufacturers/industries;
- Proper coordination of programming, acquisition and funding activities;
- Results and follow-up action.

It emerged from the discussions that particular attention should be given to strengthening forecasting in countries. This would guarantee: i) that forecasting activities would be sustained; ii) that countries would adopt the process and would be given

responsibility. It would also be desirable to add a pragmatic methodological dimension. For example, examining DTP plans and supplies for the last 5 years.

Teamwork

Great efforts to collaborate and work as a team have been made and must be maintained by the various agencies. The VPP team is a very good one; members are motivated and aware of what is at stake. It has established for itself a program of work for the short-term relating to speeding up the introduction of vaccines against yellow fever, hep B and Hib. It has thus far kept to the timeline for this program of work.

It is very clear that the exercise has strengthened collaboration and information sharing between the various partners and has been highly beneficial. Everyone felt that the VPP should serve as an example for other areas of activity. Involved institutions and individuals have been able to integrate VPP activities into their regular operations. This is positive and needs to continue. The main constraint is time management because of the size of the workload. The oversight committee confirms that the project manager is a full-time position and recommends that the project manager be relieved of responsibilities not related to VPP focus areas. Dr Namgyal will take up another assignment from mid-December and therefore WHO as a matter of urgency should identify his replacement.

Contact with vaccine manufacturers/industries

The committee was convinced that issues concerning relations with vaccine manufacturers would not be easy: how would manufacturers be involved? via what channels? with what kinds of message? Further consideration to a well-defined expanded strategy to relate and involve manufacturers/industries is needed.

Recommendations to the Board

1. Endorse the forecast methodology chosen while stressing the need for strong involvement of countries in the forecasting process;
2. Endorse the use, for forecasting purposes, of 10% wastage for the 2 doses of pentavalent vaccine;
3. Request the provision of guidance on how to approach manufacturers in the next update (30 January 2003).

Next steps

1. The VPP manager should submit a three-monthly report during January 2003;
2. End April 2003, the VPP would include in its work plan a critical-path analysis and would propose, based on a clear supply picture, an updated policy of products in limited supply. It would also take stock of the lessons learnt during the first phase of the procurement process;
3. The oversight committee would seek, through the work of the committee, to obtain the advice of suitable experts.

Annex 7.1

The Vaccine Provision Project: Progress update

Update on VPP activities

VPP activities September – November 2002, since the GAVI Board update on 12 September 2002:

- VPP team meetings or conference calls held 2-3 times per month;
- Forecast methodology working paper developed and disseminated (including to vaccine manufacturers);
- Preliminary forecast scenarios 2004-2006 developed, based on analysis of country plans and consultations with country and regional representatives;
- Input provided into the proposal for expansion of GAVI and Vaccine Fund support to yellow fever control (e.g. establishment of vaccine stockpile);
- Management of pentavalent vaccine shortage and support to countries ;
- Review meeting held with the GAVI Board Oversight Committee (1 November 2002).

Activities planned November 2002 – March 2003:

- Consult with stakeholders at the GAVI Partners' meeting 20-22 November;
- Finalize the provisional forecast by 25 November;
- Organize pre-tender meeting with all interested vaccine manufacturers on 10 December (UNICEF Supply Division);
- Issue tender in January 2003, with public notification of awards in May 2003 (UNICEF Supply Division);
- Review VPP early experiences, identify priorities, and develop project plan 2003-2004 by 31 April 2003.

Development of an accurate product-specific forecast 2004-2006

The methodology used to develop the forecast for yellow fever and for hep B and Hib containing vaccines is described in the enclosed working paper *Forecasting methodology for GAVI/Vaccine Fund supported products 2004-2006*. The VPP is preparing forecast scenarios based on this methodology.

The GAVI Board is requested to take note of the major assumptions and risks identified in the Forecast Methodology and provide feedback on the principles outlined in the paper.

Annex 7.2

Forecasting methodology for GAVI/Vaccine Fund supported products 2004-2006

Introduction

This document provides a summary of the approach used by the GAVI Vaccine Provision Project team for the development of a product-specific accurate forecast for Vaccine Fund supported vaccines (hep B and Hib containing vaccines; yellow fever vaccine) for the period 2004-2006. UNICEF will use the forecast in its 2003 tender for Vaccine Fund supported vaccines.

Schedule

- End November: 2004-2006 forecast available
- December 2002: pre-tender meeting with vaccine manufacturers with presentation and discussion of the forecast
- January 2003: issuance of tender for 2004-2006
- January – May 2003: tender period
- May 2003: public notification of awards 2004-2006

Forecast specifications

Globally and for each country:

- Vaccine formulation (type of vaccine)
- Vaccine presentation (vial size)
- Annual quantities 2004-2006
- Basis for the forecast (how values were calculated, what assumptions were used, assessment of program readiness)

Several scenarios may need to be developed due to scarce vaccine supply.

General principles

- The forecast will be country-driven and will reflect product preference and vaccine introduction and expansion plans set by national health authorities in countries eligible for Vaccine Fund support and agreed upon within inter-agency coordinating committees (ICCs) or equivalent country coordination mechanisms. Primary sources of data are country applications (including national multi-year plans) approved by GAVI for Vaccine Fund support; annual progress reports; financial sustainability plans; and country consultations.
- To mitigate the problem of historically inaccurate country forecasts and to increase the likelihood of developing an accurate and credible forecast, factors that can significantly affect forecast will be identified, analyzed and managed. Reducing risk and uncertainty will be done by:

- Validating projected estimates against historical data and documented country performance;
 - Consulting with subject matter experts (e.g. WHO technical units, GAVI regional working groups);
 - Opting for scenarios on the more conservative and realistic side;
 - Sharing and seeking feedback from vaccine manufacturers on the methodology applied in this forecast and on the data itself. This will occur in an open and transparent manner with fair access to information through 1) an advisory to all manufacturers with WHO pre-qualified products, 2) posting on the GAVI website, and 3) the pre-tender meeting in December 2002.
-
- In order to develop allocation policies due to a scarce supply, country demand will be assessed against estimated global availability of supply and allocation. The estimated global availability will not be made public due to confidentiality of the information that is used to develop the estimates
 - The final forecast will represent a “best-estimate” of country demand at one particular point of time. It will be maintained so that it takes into account decisions made by countries, new approvals of country applications and changes in the global availability of supply.
 - The forecast will take into account lessons learned in the 2000 GAVI forecasting and in countries’ experiences with new vaccine introduction.
 - The Vaccine Provision Project will seek policy guidance from the GAVI Board whenever required, such as for the allocation of vaccines that are in limited supply.
 - The forecast will be based on sound programmatic principles and follow WHO recommended disease control strategies. Due to differing epidemiology and disease control strategies, different approaches will be applied for the forecasting of yellow fever vaccine and of hep B and Hib containing vaccines (see sections below).
 - Actual country demand is highly dependent upon the availability of combination vaccines that are of limited supply. The upcoming tendering process will provide the first round of information from manufacturers regarding availability through 2006. However, since some manufacturers’ actual availabilities compared to forecasts have been off in the first GAVI tender by factors exceeding 100%, actual country demand can be expected to vary until manufacturers demonstrate their ability to provide the quantities that are forecasted to be provided.

Methodology for forecasting of hep B and Hib containing vaccines

The following steps summarize the process used by the VPP to forecast hep B and Hib containing vaccine needs. Some steps may overlap or take place over a longer period of time.

Step 1: Categorize VF-eligible countries according to application status, product preference and current use.

Group 1: Countries approved for and using combination vaccine (DTP-hep B and DTP-hep B + Hib).

Group 2: Countries approved for combination vaccine but currently using monovalent hep B due to limited supply; and countries currently using monovalent hep B that have indicated in their applications they plan to switch to combination vaccine during the period 2004-2006.

Group 3: Countries approved for and using monovalent hep B.

Group 4: Countries not yet approved for hep B or Hib support.

Group 5: Countries procuring through PAHO (no action needed other than coordinating with PAHO).

Step 2a: Validate major variables for countries with plans already approved for hep B and/or Hib vaccine (Groups 1, 2 and 3).

- Immunization coverage targets 2004-2006
- Projected wastage rates for VF supported vaccines
- Funding status of VF supported vaccines

Step 2b: Project program performance and timing of application for countries that have not yet been approved for hep B or Hib vaccine support – with a focus on countries with largest vaccine needs (e.g. those with largest number of children to be reached).

- Immunization coverage and program readiness
- Timing of application eligibility (i.e. when DTP3>50%)
- Timing of application
- Timing of approval
- Timing of actual vaccine introduction

Step 2c: Assess whether eligible countries plan to switch products or submit application for more products 2004-2006.

- Countries in group 1 currently using DTP-hep B that may switch to DTP-hep B + Hib

Step 3: Assess country demand against estimated global availability of supply and allocation, in order to develop allocation policies due to scarce supply.

Step 4: Identify policy issues and prepare issues and options paper for consideration by the GAVI Board on 18-19 November 2002.

- GAVI strategic intent 2003-2006 and implications on supply
- Allocation of products in limited quantity (i.e. update the GAVI Board policy of 2000 on vaccines in limited supply)
- Issues related to Hib
- Technical issues

Step 5: Consult with pivotal countries.

- Largest countries (i.e. with largest number of children to be immunized) with outstanding issues
- Potential “switchers” (i.e. countries that may switch from one product to another)

Step 6: Final review and resolution of outstanding issues – forecast available.

Step 7: Pre-tender meeting with manufacturers that have WHO pre-qualified vaccines.

- Presentation of forecast
- Incorporation of feedback from manufacturers

Step 8: Issuance of tender and negotiation with manufacturers.

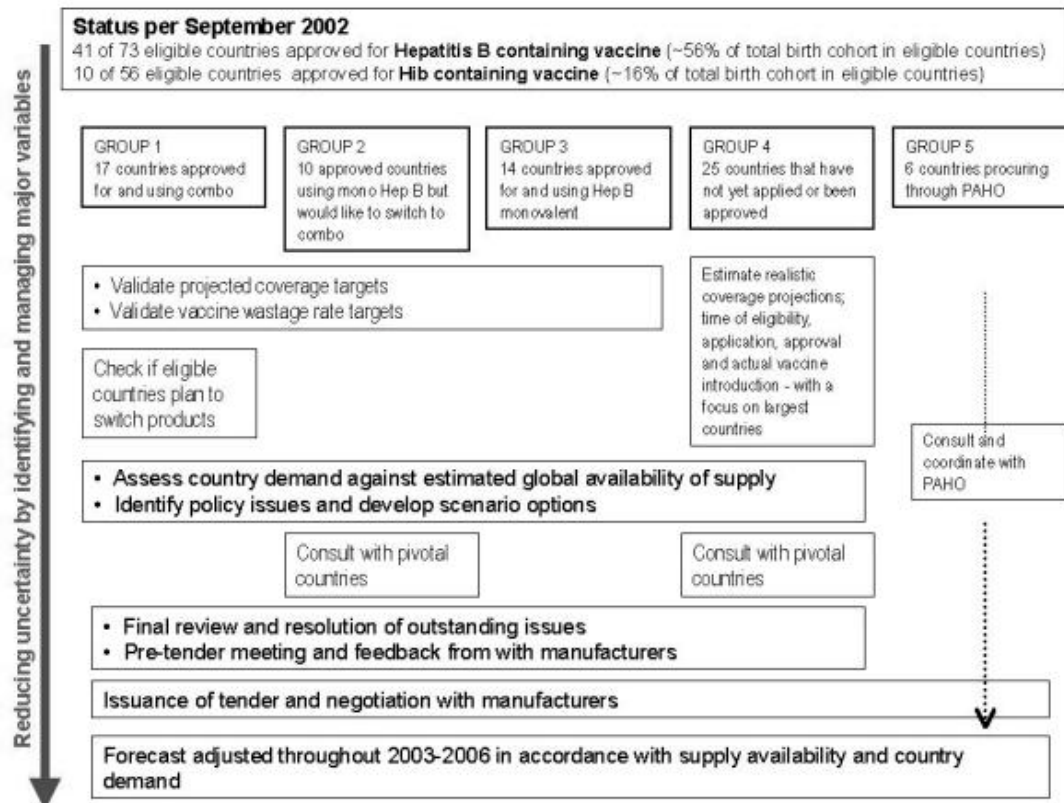
Step 9: Availability will be compared to country demand and forecasts will be adjusted accordingly. This step will be repeated as availability changes throughout the 2004-2006 time frame.

Main assumptions used in the 2004-2006 forecast

- No significant supply disruption (e.g. market exit of manufacturer; regulatory constraints);
- No country program disruption of significance for total vaccine uptake (e.g. large-scale conflict, natural disaster, or public perception backlash);
- Replacement funding will become available for countries whose Vaccine Fund support for hep B and Hib containing vaccines ends in 2006 (this currently represents around 20% of the value of total demand in 2006).

Major areas of risk/uncertainty in the 2004-2006 forecast

- Projected pace of introduction and vaccine uptake in large countries not yet approved for Vaccine Fund support (group 4 countries).
- Actual country uptake and sustained use of Hib vaccine (including “switching” to Hib-containing products), in particular the uncertainty related to the need to secure funding for unfunded vaccine in 2006 (when VF support ends for Round 1 countries).
- Choice of countries when confronted with limited vaccine supply (i.e. will they wait for their preferred product, or will they introduce a temporary replacement product).



Slide 1: Summary of forecasting methodology for hep B and Hib containing vaccine

Methodology for forecasting of yellow fever vaccine

GAVI and The Vaccine Fund currently support yellow fever vaccine for use in routine infant vaccination programs. GAVI partners are exploring options for expanding the strategic scope of Vaccine Fund support to accelerate YF control and alleviate YF vaccine supply constraints. Specifically, it is proposed to establish a strategic vaccine stockpile to serve as a reserve in case of YF outbreaks, with unused vaccine to be used each year in pre-planned preventive campaigns in high-risk districts in West and Central Africa.

The GAVI Board will consider this strategy at its Dakar meeting on 18-19 November 2002, which is being prepared by WHO, UNICEF and other partners in the Inter-Agency Coordinating Group on yellow fever (ICG)⁵. Endorsement by the GAVI Board with a decision to support the establishment of the strategic stockpile will affect the scope and methodology of the VPP forecast for yellow fever vaccine.

The steps below outline the methodology used to forecast the Vaccine Fund supported YF vaccine needs.

Step 1a: For routine vaccination needs, validate variables in plans of countries already approved for YF vaccine.

⁵ “Establishment of a strategic stockpile for yellow fever vaccine to accelerate YF control and contribute to YF vaccine security”, a paper for the GAVI Board meeting on 18-19 November 2002

- Immunization coverage targets
- Projected wastage rates

Step 1b: For routine vaccine needs, estimate program performance and timing of application for countries that have not yet been approved for YF vaccine support.

- Timing of application
- Timing of approval
- Timing of actual vaccine introduction
- Immunization coverage and program readiness

Step 1c: Assess modalities for expanding Vaccine Fund support for yellow fever control, including strategic approach, stockpile management issues, funding arrangements, and roles and responsibilities of partners involved. Estimate vaccine needs for the stockpile. Submit proposal for Vaccine Fund support to the GAVI Board 18-19 November 2002 (WHO, UNICEF, ICG partners).

Step 2: Preparation of final forecast to be used in the GAVI tender (i.e. the sum of vaccine needs estimated in steps 1a, 1b and 1c). Vaccine needs for the stockpile (step 1c) is contingent on GAVI Board and Vaccine Fund endorsement.

Main assumptions used in the 2004-2006 forecast

- Global supply availability of yellow fever vaccine will meet stockpiling and routine vaccination needs.
- Preventive campaigns will take place as planned in west and central Africa so that unused vaccine in the stockpile is utilized (contingent on GAVI Board and Vaccine Fund endorsement in November 2002).
- The ICG mechanism continues to be managed in a coordinated and effective manner.

Major areas of risk/uncertainty in the 2004-2006 forecast

- Preventive campaigns in high-risk districts in west and central Africa may not be organized on time, leading to under-utilization and expiration of stockpiled vaccine - due to poor planning and support for timely implementation of quality preventive campaigns; or lack of funding to cover operational costs.
- Major YF outbreaks that deplete YF vaccine stock.

Annex 7.2a

List of Vaccine Fund eligible countries by category (per October 2002)

Country	Surviving Infants ⁽¹⁾	DTP3 coverage 2001 ⁽²⁾	Vaccine presentation ⁽³⁾
GROUP 1: Countries approved for hep B and/or Hib and using combination vaccine			
Bhutan	16,707	88%	DTP-hep B 2003
Burundi	272,363	74%	DTP-hep B+Hib 2003
Cambodia	465,382	60%	DTP-hep B
Côte d'Ivoire	499,692	57%	DTP-hep B
Eritrea	100,872	93%	DTP-hep B
Gambia	54,018	96%	hep B & DTP-Hib
Ghana	709,618	80%	DTP-hep B+Hib
Kenya	1,363,575	76%	DTP-hep B+Hib
Lao PDR	211,273	40%	DTP-hep B
Madagascar	651,308	55%	DTP-hep B
Malawi	527,021	90%	DTP-hep B+Hib
Mozambique	725,314	80%	DTP-hep B
Rwanda	347,468	86%	DTP-hep B+Hib
Tanzania	1,395,173	85%	DTP-hep B
Uganda	1,028,354	60%	DTP-hep B+Hib 2002
Yemen	612,924	76%	DTP-hep B+Hib
Zambia	431,249	78%	DTP-hep B+Hib
GROUP 2: Approved for combination but currently using monovalent vaccine			
Bangladesh	3,721,155	83%	hep B
Benin	248,102	76%	hep B
Cameroon	626,328	43%	Conditional
Comoros	21,953	70%	hep B
Korea DPR	445,065	37%	hep B
Lesotho	65,666	85%	hep B
Mali	409,040	51%	DTP-hep B (Conditional)
Nepal	744,286	72%	<i>DTP-hep B</i>
Pakistan	5,126,000	56%	hep B
Sri Lanka	322,366	99%	hep B 2003
Zimbabwe	427,273	75%	Conditional

Source of data: (1) and (3) GAVI Secretariat; (2) WHO/UNICEF best estimates 2001

Country	Surviving Infants ⁽¹⁾	DTP3 coverage 2001 ⁽²⁾	Vaccine presentation ⁽³⁾
<i>GROUP 3: Approved for hep B or Hib and using monovalent vaccine</i>			
Albania	60,000	97%	hep B, Hib (Conditional)
Armenia	35,800	94%	hep B
Azerbaijan	108,386	98%	hep B
Bosnia & Herzegovina	36,859	91%	hep B
Georgia	50,776	86%	hep B
Kyrgyz Rep	100,000	99%	hep B
Moldova	41,900	90%	hep B
Myanmar	1,277,000	72%	hep B
Tajikistan	157,804	83%	hep B
Turkmenistan	100,000	95%	hep B
Ukraine	395,176	99%	hep B
Uzbekistan	514,000	97%	hep B
Viet Nam	1,622,676	98%	hep B
<i>GROUP 4: Countries not yet approved for hep B or Hib</i>			
Afghanistan	922,960	44%	
Angola	631,000	41%	
Burkina Faso	478,518	41%	
Central Africa Republic	131,612	23%	
Chad	359,000	53%	
Congo DRC	2,425,327	40%	
Djibouti	24,762	49%	
Ethiopia	2,607,000	56%	
Guinea	296,785	43%	
Guinea-Bissau	43,500	47%	
Liberia	158,661	62%	
Mauritania	106,768	61%	
Mongolia	55,000	95%	
Niger	522,991	31%	
Nigeria	4,752,028	26%	
Papua New Guinea	151,000	56%	
São Tome	5,900	82%	
Senegal	429,380	52%	
Sierra Leone	209,006	44%	
Solomon Islands	17,000	78%	
Somalia	270,769	33%	
Sudan	1,056,729	46%	
Togo	196,240	64%	
<i>GROUP 5: Countries procuring through PAHO</i>			
Bolivia	254,000	81%	
Cuba	135,000	99%	
Guyana	20,500	85%	DTP-hep B+Hib
Haiti	273,105	43%	
Honduras	198,000	95%	
Nicaragua	167,000	92%	

Source of data: (1) and (3) Country applications (GAVI Secretariat); (2) WHO/UNICEF best estimates 2001

Annex 8

Update on the adoption of vaccine vial monitors (VVMs) for all EPI vaccines

Introduction

Since 1996, all oral polio vaccine available from UNICEF has been labeled with VVMs. Initial reviews point to the programmatic advantages and cost/benefits of VVMs⁽¹⁻⁷⁾.

While acknowledging that the addition of VVMs to each vial of vaccine will have implications for vaccine production and vaccine price, the programmatic value was such that WHO and UNICEF issued a joint policy in 1999 supporting the use of VVMs for all EPI vaccines⁽⁸⁾. WHO, PATH and other partners have since developed guidelines for health workers and assisted in the implementation of VVMs. UNICEF has taken specific action on this policy by including the provision of VVMs as part of the minimum requirements in its purchase of vaccines.

Currently, eleven manufacturers have taken the necessary steps to include VVMs on some or all of their vaccines supplied to UNICEF, both EPI vaccines and newer vaccines supported by The Vaccine Fund.

It has been recognized that in instances where vaccines are in short supply, VVM implementation should not be required if this reduces the quantity or slows down the delivery of needed vaccines to children.

Technical Review

On 27 March, 2002, WHO held a technical review of VVM implementation with 50 participants from vaccine manufacturers, time-temperature indicator technology companies and GAVI Partners to discuss issues that needed to be addressed in order to ensure that all vaccines used in developing countries could be labeled with VVMs. While the invaluable role of VVMs in improving the quality of immunization efforts throughout the world was recognized, a number of concerns were identified including regulatory requirements, liability, validity issues and logistical constraints.

With regard to regulatory concerns, it was agreed that it is the responsibility of vaccine manufacturers to contact national regulatory authorities, with the assistance from WHO and the VVM manufacturer. In addition, it was agreed that individual manufacturers might want to seek legal counsel with regard to their liability for vaccines with VVM and act accordingly.

It was further agreed that validation and conformity studies should follow WHO standard test procedures, and where manufacturers need additional testing to meet internal or national regulatory authority requirements, the VVM manufacturer would provide assistance. With regard to logistical issues, the VVM manufacturer also agreed to continue working closely with vaccine manufacturers to identify the best solutions for VVM application.

Action required

Countries are not able to realize the programmatic quality improvements and potential financial benefits that VVMs present until all vaccines supplied to them include VVMs. Likewise, the GAVI partners are not able to allocate necessary financial and technical resources needed to support countries with VVM implementation until this happens.

The majority of developing countries have multiple sources for the supply of vaccines including procurement by UNICEF, WHO, PAHO, bilateral donors and the countries themselves. An important next step is for all procuring agencies to assess the value of emulating the experience of UNICEF in putting VVMs among their procurement requirements.

At the same time, it is important that all vaccine manufacturers that are not currently providing their vaccines labeled with VVMs identify all the issues relevant to the provision of VVMs and a schedule for resolving them.

Recommendations

The GAVI Board, in recognizing the progress made:

1. Recommends further immediate intensive action by appropriate GAVI Partners to accelerate the implementation of VVMs, consistent with ensuring vaccine security.
2. Sets as an objective that all vaccines supported by The Vaccine Fund will include VVMs after 2003.
3. Urges all national and international agencies procuring vaccines to include VVMs as a requirement latest as of 2004, so the full programmatic benefits of VVMs can be realized.
4. Urges vaccine manufacturers to complete the preparation needed to provide all vaccines with VVMs within a stated time schedule, but no later than end-2003.
5. Requests industry members of the GAVI Board to provide an update on action taken at the first meeting of the Board in 2003.
6. Understands that where vaccines are in short supply, VVM implementation should not be required if this reduces the quantity of vaccines available or slows down their delivery.

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Annex 9

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