12TH GAVI BOARD MEETING

THE GLOBAL ALLIANCE FOR VACCINES & IMMUNIZATION

Partnering with The Vaccine Fund

Geneva, Switzerland

9-10 December 2003

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Summary Report

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1 Report from the field: Cambodia

- The Board welcomed the presentation by the Minister of Health of Cambodia and requested that GAVI Board meetings continue to feature presentations by representatives of countries that are facing different types of challenges.
- It would be good to experiment with an interactive panel, instead of having single presentations, at a future Board meeting.

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2 Recommendations of the Independent Review Committee

- The presentation contained a great deal of information that covered a range of issues that GAVI is attempting to address. In the future the information should be presented in a more straightforward manner in order to facilitate the appropriate decisions and actions.
- It will be important to keep an eye on equity when reviewing countries that are approved for new vaccines but may have low basic immunization coverage in certain areas. The Secretariat committed to look further into this issue in regard to Sudan, which will phase in monovalent hepatitis B and Hib vaccines.
- The discrepancies in data and information submitted from countries through the WHO/UNICEF Joint Reporting Form and the GAVI Progress report is worrying. WHO is committed to increase its efforts to provide the technical support countries need to ensure stronger and more accurate reporting. Efforts to rationalize and harmonize the two parallel reports may also be needed.
- One of the most successful new features developed by the GAVI alliance is the Independent Review Committee (IRC), as evidenced again by the thoroughness of the presentations to the Board. It will be important to maintain the integrity of this mechanism by keeping it independent and ensuring that information flow between the teams is strengthened. To ensure this, the FSP team will meet prior to the monitoring team so that its findings can feed into the monitoring deliberations.

DECISIONS

The Board:

2.1 Approved the financial implications of the recommendations concerning new proposals and continued support. Total commitment: $110 million – $4.8 million for new proposals and $105.2 million for continued support. The Secretariat will forward the request to the Vaccine Fund Executive Committee [which will have teleconference 16 December] on behalf of the GAVI Board.

2.2 Approved the proposal for enhancing the Independent Review Committee (IRC) with an additional team to review financial sustainability plans. However, it placed a caveat that there must be strong collaboration between the new IRC FSP review team and the existing IRC monitoring team.

2.3 Endorsed proposed members of the IRC financial sustainability plan team, and the currently co-opted members of the IRC new proposal and monitoring teams. In addition, Mark Kane, who will be rotating off the Working Group at end 2003, will join the IRC monitoring team.

2.4 Approved the revised terms of reference for the IRC monitoring team but cautioned against further expanding the IRC's role, especially in areas not relating to the monitoring of country-related activities.

2.5 Approved the new vaccine funding policies (concerning phased new vaccine introduction, "switching", the formula for forecasting supply using DTP1, and wastage rates) first presented to the Board in October 2003, and the estimated financial implications. Total commitment could range from $44 to $88 million.

2.6 Agreed to consider all of the policy recommendations of the IRC monitoring team as outlined in the presentation. The Board reiterated its commitment to protect the independence of the IRC.

2.7 Welcomed the commitment of UNICEF and WHO to enhance efforts to help countries improve quality of reporting and information received from countries. This should be done in consultation with the IRC monitoring team to ensure that satisfactory solutions are found to the problems raised by the IRC. The EC is requested to consider a proposal by early February for approval on behalf of the Board.

2.8 Agreed to put on the agenda of the next meeting a longer time for discussion of monitoring, including capacity building in this field.

3 The GAVI 2004-05 Work Plan and Budget

- The work plan truly represents a joint effort of the Alliance. The Board appreciated the intense amount of work of partners and the Secretariat to prepare the work plan and respond to the questions and feedback of the GAVI Executive Committee.

DECISIONS

The Board:

3.1 Approved the proposed GAVI 2004-05 work plan and budget of $34,418,000 with the following caveats:

3.1.1. To delay disbursement of approximately $1.5 million in funding for Vaccine Provision Project (VPP) until the Board has made a decision on the future of the VPP in early 2004.

3.1.2. To delay disbursement of the $600,000 that had been proposed for possible meetings of the IRC monitoring team with countries until the Board has made a decision about how best to improve the quality of reporting and information from countries (see Decision 2.6 above).

3.2 Decided to continue relying upon existing mechanisms (i.e., the GAVI Executive Committee) for monitoring of the work plan.

3.3 Requested further prioritization of the work plan activities, should it not be possible to raise the full cost of the budget, to ensure that the most critical activities are completed.

3.4 Agreed that it would be valuable to track funding related to GAVI added value activities by partners (such as USAID) which are not recorded in the 2004-05 work plan and budget.

4 Development of long term strategy and plan for GAVI

- Since its launch, The Vaccine Fund has made specific contributions to the broader immunization goals of the GAVI alliance. One significant contribution has been intense, short-term investments aimed at reducing costs over time. Examples of short-term investments with expected return include vaccine purchased by Vaccine Fund, the data quality audit and financial sustainability planning.
- Recognizing that one of the most important added value of the alliance has been in areas linked to the use of Vaccine Fund resources, the Board considers that the scope of GAVI and The Vaccine Fund should overlap to the greatest extent possible.
- It may be valuable for The Vaccine Fund to adopt a broader role to respond to more country needs. However, The Vaccine Fund cannot fund all immunization activities. Instead, its use should be framed by the strategic priorities of GAVI and by a clearer understanding of the value add of investments from GAVI/The Vaccine Fund within the broader funding flows of governments and international agencies. For example, the value-add of GAVI/The Vaccine Fund investment may be defined as a catalytic fund to enable innovation and the introduction of new programs and technologies. This definition should occur in the process defined in decision 4.1 below.

DECISIONS

The Board:

4.1 Agreed that the development of the investment case framework should proceed as outlined in the presentation, keeping in mind that the timeline presented for this work may have been over-optimistic. This process should include broad consultation with countries through ICCs, and involve the Vaccine Fund Executive Committee, the GAVI Executive Committee, the full GAVI Board, and other partners.

4.2 Agreed that the work should include a wide and comprehensive consultation process and address the following issues, among others:

- country perspective
- introduction of new vaccines and technologies versus accelerated scale-up of existing immunization programs.
- efficiency and effectiveness
- effects on immunization outcomes

5 GAVI Secretariat and The Vaccine Fund management: launching a path toward convergence

- As the long-term vision for GAVI/The Vaccine Fund are further fleshed out and aligned, it will be important to consider the future of the relevant management structures – GAVI Secretariat and The Vaccine Fund management. Actions to determine the strategic objectives of GAVI/The Vaccine Fund and to evaluate the corresponding management structure(s) of the two entities should be closely linked...
- It will be important to take lessons learned from other institutions and initiatives, and think about which lessons can be learned by the GAVI experience. What are the costs and benefits of the current management structures? What works and what does not work?

DECISIONS

The Board:

5.1 Agreed that the functions of GAVI – as the Alliance – and The Vaccine Fund – as the financial mechanism – should be aligned to the greatest extent possible, and that it is time to look at the GAVI and Vaccine Fund architectures with an eye toward increasing efficiency and performance.

5.2 Requested the GAVI Secretariat and The Vaccine Fund management to explore the practical issues of a convergence. The timeline for this work should be as aggressive as possible, considering that Tore Godal will retire end December 2004 and recruitment for his replacement needs to start in the first quarter of 2004.

5.3 Agreed that a high-level consultant should be retained for this work, as outlined by The Vaccine Fund, and a proposal should be presented to the Executive Committee by 31 January 2004.

6 The Grand Campaign for Child Immunization

- The Vaccine Fund has been reorganized to strengthen its capacity to raise money and awareness. Following consultation with the GAVI Secretariat, the Vaccine Fund Executive Committee and Board and more recently, GAVI partners, The Vaccine Fund has developed a resource mobilization strategy that is based on increased partnership with GAVI partners and outreach to civil society toward re-invigoration of a child survival constituency, particularly in donor countries currently not contributing to GAVI.
- The effort will be particularly mindful of the importance of ensuring that new resources for GAVI are not coming at the expense of support to our partners, upon whom GAVI relies for its success.
- The Grand Campaign for Child Immunization, to be launched in London in late February, will be a three year effort with a goal to build partnerships with civil society organizations (such as child related NGOs, public health organizations, academia, labor and human rights organizations, etc) in support of child immunization in developing countries generally and support for GAVI specifically.
- Her Majesty Queen Rania of Jordan, a Vaccine Fund board member, has agreed to serve as a global voice and face for the Grand Campaign. Beyond London, the plan is to take the campaign to six or more other priority donor countries over 2004.
- The Vaccine Fund staff will remain in close touch with GAVI partners, including UNICEF, WHO and industry as the campaign unfolds.
- The Board welcomed the initiative and requested further updates and continual involvement, specifically mentioning the launch of the campaign.

7 The Vaccine Provision Project (VPP)

- It will be difficult for UNICEF and WHO – as long-established institutions with their own governance and management structures – to adapt to a project management structure with an external function having direct oversight over the defined roles and responsibilities of the three VPP partners. However, many Board members felt that this approach, with an independent manager, should be further pursued at this time.
- Considering that there is no person in the manager position currently, a very short timeline to draft and agree upon the project's scope, terms of reference for a project manager, and process for recruitment of a manager, would be reasonable.
- The increase in prices of combination vaccines is of grave concern. We must consider new ways to maximize the leverage of the Alliance to ensure rapid market entry by new suppliers of affordable combination vaccines. Other GAVI partners – Vaccine Fund, WHO, GAVI Secretariat and others, as necessary – in addition to UNICEF Supply Division may need to engage in negotiations with industry. Furthermore, options such as long-term contracting should be pursued.
- While the heightened activity of WHO and UNICEF to accelerate the pre-qualification process for producers of the most in-demand vaccines is certainly welcomed, more efforts, and more support to WHO may be required.

DECISIONS

The Board:

7.1 Agreed that the most appropriate management and oversight arrangements for the VPP will need to be worked out as soon as possible taking into account the preference of many Board members for a project manager model. This process for finding the solution will be managed by the Executive Secretary with the VPP partners.

7.2 Requested the Executive Committee to move the above process forward with a goal of decision by end January so that recruitment of a project manager, if found necessary, could be pursued thereafter.

7.3 Agreed that whatever the ultimate solution, the VPP partners (WHO, UNICEF and The Vaccine Fund) need to participate at a senior level.

8 Systems Barriers

- The GAVI access milestone will not be reached unless systemic barriers are addressed in countries. While GAVI cannot address all systemic issues immunization can serve as a valuable entry point.
- It will be important to continue to seek opportunities for GAVI to align itself with the 3x5 Initiative since both are so dependent on stronger health systems.
- UNICEF proposed to give a presentation of the "marginal budgeting for bottlenecks" tool in the context of country-led analysis of system-wide barriers and its application to immunization programs in particular. This presentation could be given at the next Board meeting.

9 Financial sustainability update

- It is clear that the World Bank and other financing partners' commitment to health is having a positive effect on securing finance sustainability for immunization in countries. In his visits to countries over the past few months Executive Secretary Tore Godal has received strong commitments from country officials – including heads of state and high level health and finance ministry staff – to secure funds to sustain their immunization programs.
- The costs of the financial sustainability planning process cannot be significantly reduced, because there is a great need for increased capacity for doing this work in health ministries and among immunization professionals. Of course the more that is learned, the more that this process can be streamlined.
- It would be good in a future meeting to have an update about the extent to which FSPs have been successfully integrated into PRSPs, MTEFs and SWAPs by GAVI eligible countries.

DECISIONS

The Board:

9.1 Approved extending the time of vaccine grants to ten years, if a country finds other financial resources to cover some of the costs. This will not change the dollar amounts of grants.

10 Polio

- The Board welcomed the new Strategic Plan for Polio Eradication for 2004-2008, noting the critical importance of closing the funding gap to facilitate the interruption of wild poliovirus transmission within the next 18 months. The Board also noted the central importance of this high-profile global health goal to the future of international immunization efforts, including the other GAVI objectives.

- Noted that the mainstreaming objectives of the initiative should be considered in the context of GAVI on a country-by-country basis. It makes sense to focus this work in the seven large population countries included in the GAVI 2004-05 priorities.

- Recognizing the global importance to immunization programs, the Board agreed that polio should be on the agenda of the next GAVI Board meeting.

DECISIONS

The Board:

10.1 Committed GAVI to a program of high level advocacy in the remaining endemic countries (India, Nigeria, Pakistan, Egypt, Afghanistan, Niger) to ensure appropriate high level oversight and quality of the polio campaigns during the critical period through mid-2005.

10.2 Endorsed the resource mobilization efforts of the polio eradication partnership and reiterated the importance of closing the funding gap at this critical time.

10.3 Agreed to revise the GAVI polio milestone to reflect the new eradication target. The GAVI polio milestone will now read: "By end-2008, the world will be certified polio-free."

10.4 Requested that the polio initiative come back to the Board at a future time with specific proposals as to the monetary and non-monetary role that GAVI could play in accelerating the development of the necessary products for the OPV cessation phase. It would make sense to consider this in the context of the investment case framework activity discussed under section 4.

11 Measles

- The was overwhelming support for the initiative and conceptual support for considering how best to use Vaccine Fund resources in measles mortality reduction activities.
- The Vaccine Fund should not veer from its catalytic role and it would not be appropriate to make a decision about investing in measles without first completing the investment case framework for GAVI discussed under section 4.

DECISIONS

The Board:

11.1 Agreed to advocate for the positive impact that measles mortality reduction activities are having on strengthening routine immunization systems and promote monitoring of key measles indicators and outcomes. The first activity in this area should be to ensure that measles is included on the agenda of the MDG high level consultation on 8-9 January 2004 in Geneva.

11.2 Requested the GAVI Working Group to work with the measles experts to flesh out a concrete proposal to be ready for the full Board by the end of March, considering the urgency of the need. This proposal, which should be considered a test case for the investment case framework activity discussed in section 4, would contain more specific information, such as allocation timeline and criteria, accurate funding information and projections, and defined added value role of GAVI.

11.3 Agreed to review this proposal electronically and discuss it via teleconference to ensure rapid action.

12 ADIPs

- While there is a high expectation that ultimately, the evidence will make a strong investment case for the introduction of rotavirus and pneumococcal vaccines in developing countries, the ADIPs have been designed to find the evidence and not necessarily to 'push' introduction of the vaccines.
- Concern was expressed that the Memoranda of Understanding (MOUs) between the ADIP hosts (Johns Hopkins and PATH) and the GAVI Board Trustee (The Vaccine Fund Trust Account at UNICEF) have not yet been signed. UNICEF committed to have them signed within one to two weeks of the meeting.

DECISIONS

The Board:

12.1 Endorsed the report of the October 2003 ADIP Management Meeting

12.2 Approved the 2004 allocation for the ADIPs: (Rotavirus ADIP: $11,858.353, Pneummococcal ADIP: $8,109,825. The Secretariat will forward the financing request to the Vaccine Fund Executive Committee.

12.3 Requested to be informed when the Memoranda of Understanding (MOUs) between the ADIP hosts (Johns Hopkins and PATH) and the GAVI Board Trustee (The Vaccine Fund Trust Account at UNICEF) are signed by all parties.

12.4 Agreed that the Vaccine Fund President should join the ADIP Management Committee.

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13 New Technologies

DECISIONS

The Board:

13.1 Decided to continue to rely primarily upon partners to fund and implement R&D efforts and not to engage in specific R&D technology efforts at the present time.

13.2 Agreed that GAVI should build upon the current efforts of WHO to undertake a systematic "scan" of the landscape every other year to identify emerging technologies, conduct cost-effectiveness analysis, make recommendations, and advocate for R&D efforts.

13.3 Considered that pre-filled injection devices might be an important technology for GAVI to look at in the future.

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14 Board Turnover

DECISIONS

The Board:

14.1 Accepted the nomination of Sweden to assume the industrialized country government seat being vacated by the United States at the end of 2003. Sweden, whose term will be from January 2004 to December 2006, will be represented by State Secretary Annika Bjurner Söder.

14.2 Accepted the nomination of Bangladesh to assume the developing country government seat being vacated by India at the end of 2003. Bangladesh, whose term will be from January 2004 to December 2006, will be represented by Minister for Health and Family Welfare Dr. Khandaker Mossarraf Hossain, M.P.

14.3 Accepted the nomination of Chiron to assume the industrialized country vaccine industry seat being vacated by Wyeth at the end of 2003. Chiron, whose term will be from January 2004 to December 2006, will be represented by Vice President and President Chiron Vaccines John Lambert.

14.4 Agreed to delay the decision on the technical institute seat until more information is received from the current candidates.

14.5 Decided that Canada should replace the United States on the GAVI Executive Committee. In order to ensure a smooth transition, the US should remain on the EC through Spring 2004.

14.6 Accepted the proposal to have the vaccine industry represented on the Working Group by Elaine Esber of Merck. The Board also accepted the proposal to co-opt USAID into the Working Group, represented by Susan McKinney.

15 Other Business

DECISIONS

The Board:

15.1 Endorsed the planned activities of the Merck Vaccine Network-Africa to develop training centers in Africa to increase the capacity of immunization programs to effectively deliver vaccines.

15.2 Agreed that Dr JW Lee, as the GAVI Chair, should chair the selection committee for the recruitment of the new GAVI Executive Secretary to replace Tore Godal, who will retire at end 2004. This work should be conducted with an eye on the progress of the convergence discussions under point 5 above. The Chair requested UNICEF, who previously managed the selection and recruitment of the current Executive Secretary, to provide him with a description of the earlier process.

15.3 Decided that the next Board meeting should be scheduled for 6-7 July 2004.

15.4 Accepted the invitation by the American Red Cross to host the July GAVI Board meeting at its headquarters in Washington DC.

15.5 Agreed in principle that Board meetings should alternate being held in industrialized and developing countries.

15.6 Decided that at future Board meetings there should be a summary of the discussions and decisions of the Executive Committee that occur between Board meetings.

15.7 Tentative dates for December meeting: 9-10 December 2004.

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Agenda

Report from the field: Cambodia

Presentation available at:
http://www.vaccinealliance.org/home/Board/Board_Reports/12_board_cambodia.php

Recommendations of the Independent Review Committee

Annex 1 Independent Review Committee (IRC) -- Report and Recommendations – November 2003

Presentations available at:
http://www.vaccinealliance.org/home/Board/Board_Reports/12_board_IRCrecs.php

The GAVI 2004-05 Work Plan and Budget

Current work plan available at:
http://www.vaccinealliance.org/home/General_Information/About_alliance/workplan/0405workplanindex.php

Development of long term strategy and plan for GAVI

Presentation available at:
http://www.vaccinealliance.org/home/Board/Board_Reports/12_board_strategy.php

GAVI Secretariat and The Vaccine Fund management: launching a path toward convergence

Annex 2 GAVI Secretariat and The Vaccine Fund management: launching a path toward convergence

Presentation available at:
http://www.vaccinealliance.org/home/Board/Board_Reports/12_board_convergence.php

The Grand Campaign for Child Immunization

The Vaccine Provision Project (VPP)

Annex 3 Lessons Learned from the Pilot Phase – July 02 – October 03

Presentation available at:
http://www.vaccinealliance.org/home/Board/Board_Reports/12_board_vpp.php

Systems Barriers

Annex 4 Addressing Health Systems Barriers to Immunization – Outcome of Consultation with Countries
DRAFT

Presentation available at:
http://www.vaccinealliance.org/home/Board/Board_Reports/12_board_systemsbarriers.php

Financial sustainability update

Presentation available at:
http://www.vaccinealliance.org/home/Board/Board_Reports/12_board_fisustain.php

Polio

Annex 5 *Summary* - Polio Eradication Strategic Plan 2004-2008
'Finishing the Job and Protecting our Investment'

Complete DRAFT strategic plan and presentation available at:
http://www.vaccinealliance.org/home/Board/Board_Reports/12_board_polio.php

Measles

Annex 6 Options for Promoting Synergy Between GAVI and Sustainable Measles Mortality Reduction

Presentation available at:
http://www.vaccinealliance.org/home/Board/Board_Reports/12_board_measles.php

Accelerated Development and Introduction Plans (ADIPs)

Annex 7 ADIP Management Committee Meeting – Report of Decisions and Action Points

Presentation and other documentation available at:
http://www.vaccinealliance.org/home/Board/Board_Reports/12_board_ADIPs.php

New Technologies

Annex 8 The Case for Investment in R&D for Three Immunization Technologies: Recommendations for GAVI Action

Presentation available at:
http://www.vaccinealliance.org/home/Board/Board_Reports/12_board_newtechs.php

Board Turnover

Annex 9 Report on nominations for GAVI Board developing country government seat (Jan '04-Dec'05)

Other Business

Annex 10 Merck Vaccine Network-Africa
Program Overview

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List of annexes

Independent Review Committee (IRC)
Report and Recommendations
November 2003

PART 1: Proposal for an Expanded Independent Review Committee (IRC)

Introduction

The GAVI Board decided, during its June 2002 meeting in Paris, to separate the review of proposals and progress reports in order to avoid potential conflicts of interest. Consequently, the IRC was split into two teams: the Proposal Review Team and the Monitoring Review Team. The established mandate of the Independent Monitoring Team has been endorsed by the GAVI Board.

Financial Sustainability Plans (FSPs) are a requirement under the support offered by the Global Alliance for Vaccines and Immunizations (GAVI). Countries receiving support from GAVI are required to submit FSPs during the second year of support. In 2002, twelve FSPs were submitted and reviewed by the Independent Monitoring Committee. Twenty two countries are expected to submit FSPs for review in 2004, thirty in 2005 and 4 in 2006.

Experience from the 2002 review has indicated that emphasis should be placed on relevance and feasibility of the strategies identified within the FSP for improving prospects for financial sustainability. As a result, there is interest to form a third team under the IRC to review FSPs. The new team members would have more expertise and experience with financial management systems and national planning and budgetary processes in developing countries.

The IRC will therefore have three teams:

- Proposal Review Team
- Monitoring Team
- FSP Review Team

No changes are proposed for the role of the Proposal Review Team. Each team will be accountable to the GAVI Board.

Revised terms of reference for the IRC Monitoring Team

The Monitoring Team of the IRC has conducted three review sessions to date. Based on the reviews, the Monitoring Team has requested to revise its mandate by incorporating more defined Terms of Reference. The Board has introduced some changes to the GAVI entities, (July 2003 GAVI Board report). For example, the ITF (Implementation Task Force), which was fully involved in GAVI monitoring activities, will be dissolved in December 2003. In addition, policies have changed, such as the cancellation of the mid term review. Taking the above modifications into consideration, the Board is requested to approve the updated mandate and modus operandi of the Monitoring Team found below.

The mandate of the IRC monitoring team is to:

1- Review global analyses conducted independently, or by partners, and inform the Board on progress towards the GAVI strategic objectives and milestones that relate to support provided by the Vaccine fund.
2- Make recommendations regarding continuation of annual requests for new vaccines and safety supplies, according to GAVI Board policies, as spelled out in the proposal guidelines and procurement policy (see Annex I). In particular, the IMC should assess changes in targets, wastage rate, and proportion of GAVI support and baseline data.
3- Make recommendations regarding amount of share allocations to countries (based on DQA findings and achievements) according to GAVI Board policies, as spelled out in the proposal guidelines.
4- Report to the GAVI Board specific issues and problems reported by countries in their progress reports. Based on major issues recognized, suggest specific global analyses, evaluations or actions to be performed by the GAVI entities.
5- Report to the GAVI Board any relevant findings through the review process.
6- Provide technical advice and coordination of monitoring or evaluation activities suggested by GAVI entities and partners.
7- Make recommendations on improvement of the monitoring process and possible changes to introduce in relation to GAVI policies.

The modus operandi of the IRC monitoring team is to:

1- The IRC monitoring team will carry out its mandate primarily through the review of country annual reports (the committee should compare country-approved plans with activities reported in the progress reports; special attention should be given to coverage achievements), DQA reports, and if necessary other relevant documentation such as WHO/UNICEF JRFs

2- The IRC monitoring team will formulate its recommendations, which will then be forwarded to the GAVI Board for its decision.

3- The committee may recommend conducting specific studies in order to assess activities, tools, and impact of GAVI. A calendar for those studies is to be suggested by the committee. For some particular studies, the committee might be requested to contribute defining objectives, methodology, reviewing results and making recommendations to the Board in terms of possible changes to GAVI policies or operations.

4- Upon conclusion of the review, the IRC monitoring team is expected to provide, to the GAVI Secretariat, the following reports: a) IMC comments by country b) recommendations for improving the monitoring process c) a consolidated report on progress reports.

5- The IRC monitoring team may decide to constitute subgroups to follow up on some specific issues such as reviewing results of studies.

Proposal for New FSP Review Team

Required skills of team members

Chair – expertise in health financing with experience working on public health and immunization programs.

Members

1. Two to three individuals with extensive EPI Program experience

2. Three to five individuals with expertise and experience with national planning and budgetary processes & financial management systems in developing countries. Familiarity with immunization preferred.
3. One to three international staff with expertise in health financing, particularly experience with national planning & budgetary processes for health in developing countries (regional institutions)
4. At least two individuals, one from groups 1 and 2 above should also be team members of the Independent Monitoring Committee. This will facilitate monitoring FSPs during review of Annual Progress reports

Terms of Reference

The overall mandate is to assess and review Financial Sustainability Plans to ensure an adequate and reliable diagnosis of program costs and future resource requirements, the current and future financing of the national program, and the magnitude and timing of the financing gap. In addition, a major emphasis of the review will be to ascertain how well the FSP strategies and plans are contextualized within the national health financing and NIP situation, and how realistic and feasible these plans will be to implement.

The Team in addition will review all subsequent major and minor revisions of the FSP. They will also conduct and submit pre-assessment of the FSP section of the Annual Progress Report for the Independent Monitoring Team.

Specifically, the committee will:

1. Determine whether the FSP provides an accurate and reliable picture of current costs and future resource requirements of the NIP (at all levels and for all strategies), the current and future financing of the program, and the magnitude and nature of the financing gap.

2. Indicate whether the FSP identifies the key strategies for improving the prospects for financial sustainability (including those which reduce cost, improve efficiency, mobilize additional resources and improve reliability of funding flows), and the extent to which these strategies are in line with the current financing of the health sector more broadly)

3. Ascertain the extent to which the FSP strategies and actions identified are relevant, feasible and well-contextualized within the country context

4. Ascertain both the involvement of the Ministry of Health, Ministry of Finance and program partners in discussions on implementation of the FSP (i.e. implementation of the strategies or actions to improve prospects for financial sustainability) and the extent to which they are prepared to take on the FSP as part of ongoing health planning and budgeting processes within the country.

Products of the review:

1. IRC comments by country, along the line of the four areas addressed above, (country specific details to be incorporated into response to countries

2. A consolidated report on FSPs which addresses trends and issues pertaining to the above four areas across countries

3. A set of recommendations to the GAVI Board and the GAVI/FTF summarizing:

    a. The main recommendations and findings from the country-level analysis regarding the adequacy and accuracy of the program diagnosis; the reliability and feasibility of strategies

and plans; and the extent to which these plans are likely to be implemented, including the prospects for the results of the FSP to be integrated with national planning and budgeting processes, such as annual budget cycle, PRSP reviews, MTEF/SEF/PER reviews and the like.

b. Suggestions for actions to be taken by:

- Countries (in general)
- GAVI partners at country, regional and international level

Current and co-opted members of IRC Proposal and Monitoring Teams

IRC Proposal Team Members

- ***Mr. Oleg Benes*** (Serving since 2001)

Epidemiologist, National Centre of Preventive Medicine, Moldova

(not participating in decisions on Turkmenistan)

- ***Dr Merceline Dahl-Regis*** (Serving since 2001)

Chief Medical Officer, Ministry of Health, Bahamas

- ***Dr Peter Figueroa*** (Serving since 2002)

Chief Medical Officer, Jamaica

- ***Dr Grace Murindwa*** (Serving since 2003)

Principal Health Planner, Ministry of Health, Uganda

- ***Dr Stanislava Popova-Doytcheva*** (Serving since 2001)

Scientist, WHO STC

Bulgaria

(not participating in decisions on Turkmenistan)

- ***Dr Jane Soepardi*** (Serving since 2002)

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

- ***Dr Mean Chhi Vun*** (Serving since 2003)

Deputy Director General of Health, Ministry of Health, Cambodia

Co-opted Member:

- ***Mr Gordon Larsen*** (Co-opted member for this review)

Independent Consultant for EPI, UK

IRC Monitoring Team Members

- ***Mr Fred Binka*** (Serving since 2003)
Executive Director, Indepth – Network, Ghana

- ***Ms Brenda Candries*** (Serving since 2002)
Health Economist, Belgium

- ***Mr Supamit Chunsuttiwat*** (Serving since 2003)
Department of Disease Control, Ministry of Public Health, Thailand

- ***Mr Chenjerai Victor Maziwisa*** (Serving since 2002)
Freelance Management Consultant, Zimbabwe

- ***Dr Andrew Hall*** (Serving since 2003)
Professor of Epidemiology, London School of Hygiene, UK

- ***Mr Mia Bilenge Constantin Miaka*** (Serving since 2002)
Ministry of Health, Congo DR

- ***Ms Gradeline Minja*** (Serving since 2002)
Ministry of Health, Tanzania

- ***Dr Liudmila Mosina*** (Serving since 2002)
Vaccine Program Specialist, CDC, Uzbekistan

- ***Mr Ciro de Quadros*** (Serving since 2002)
Director of International Programs, Sabin Vaccine Institute, USA

- ***Dr Jose Santos*** (Services not provided)
Director General, Secretaria de Salud, Mexico

- ***Ms Sally Stevenson*** (Serving since 2003)
Health Economist, Australia

- ***Mr Viroj Tangcharoensathien*** (Serving since 2003)
Ministry of Health, Thailand

- ***Dr Jingjin Yu*** (Services not provided)
Ministry of Health, China

Co-opted Members:

- ***Dr Basile Kollo*** (Serving since 2003)
Ministry of Health, Cameroun

- ***Mr Alan Tait*** (Serving since 2003)
Consultant, University of Kent & Cantebury, UK

Proposed members of IRC Financial Sustainability Plan Review team

Health economist / Health financing			
Name	**Nominated by**	Sex / nationality	**Details**
Tiberius Muhebwa	FTF	M / Uganda	• Snr Health Economist • UN Economic Commission consultant on ATM • Consultant, Health system appraisal performance for Uganda
Dr. Ann Levin	FTF	F / USA	• Financing and costing studies expert • Research, Health systems operation research • Consultant, Bangladesh, 5yr immunization plan & GAVI Application
Dr Marty Makinen	FTF	M / USA	• Financing Specialist • Chair, Subgroup developing indicators for FSP • Consultant, FSP Training • TA for FSPs, Ghana, Rwanda, Uganda
Daniel Osei	FTF	M / Ghana	• Head, Planning & Budget, MoH • Member FSP Drafting Committee • Member, Government Financial Management Computerisation Program.
KENAISSI Cheriha Nadia	FTF	F / Tunisia	• University professor • Responsible of course in hospital management
Beena Varghese	FTF	Bangladesh	• Head, Health Economics Unit, ICCDR,B • Research on Economics of child health interventions including new vaccines, Economic studies of poverty and health, especially urban health
Alan Tait	Tore Godal	M / United Kingdom	• Public Finance expert
Public health / Immunization			
Name	**Nominated by**	Sex / nationality	**Details**
Clifford Wurie Kamara	FTF	M / Sierra Leone	• Director, Planning & Information • Established Unit responsible for national HIS • Co-ordinator, Health Sector Reconstruction & Development Project • Manager, WB supported Health & Pop. Project
Maria Nakyanzi-Mugisha	Tore Godal	F / Rwanda	• Director (Epidemiology) • Bilingual (French & English)
Maureen Law (Chair)	FTF & Tore Godal	F / Canada	• World Bank Consultant • Director, Human development, WB, E. Asia & Pacific • Chair, Executive Board, WHO

PART 2: New Funding Policies for Board Approval: Clarification of GAVI policies for New Vaccine Support

[NOTE: This document was distributed by email to the Board by Tore Godal on 31 October, with requests for any disagreements to the recommendations to be sent to the Secretariat. As there were no disagreements received from Board members, the recommendations were adopted by implicit Board approval on BLANK October. The Board is now asked to give official Board approval.]

This document outlines issues related to Vaccine Fund support for new vaccine introduction that required policy clarification, specifically in the case:

1. a country chooses to introduce new vaccines in a phased manner;
2. a country that receives new vaccines is approved for and introduces/switches to another antigen;
3. a country forecasts vaccines requirement.

1. Support for countries that opt for a phased vaccine introduction

GAVI support for new vaccines is calculated based on annual targets of infants to be immunized over a period of five years (60 months), starting from the month of introduction. The support is adjusted each year by the Independent Review Committee after review of country annual reports.

As currently applied, countries that chose a phased introduction (i.e. starting in a sub-set of the country with gradual expansion of activities) receive less vaccine than if they had opted for a nationwide coverage right from the start, since vaccine quantities are allocated according to the number of children to be immunized.

- Ten countries to date approved for NVS have adopted a phased introduction of Hepatitis B vaccine, and two countries for Yellow Fever vaccine. Table 1 shows for each country the amount of vaccine that is "unused" because of the phased-in introduction, assuming a five-year support and coverage targets equaling DTP3 (for Hep B) and Measles (for YF vaccine).

Table 1: Vaccine Fund support "unused" by countries due to a phase-in strategy

Country	Type of vaccine	Support approved (US$m)	Period of phase-in (yrs)	Support "missed" due to phase-in (US$m)*	Increment to current support
Bangladesh	Hep B	18.3	3	10.1	55%
Cambodia	DTP-Hep B	4.8	4	5.1	106%
Cote d'Ivoire	DTP-Hep B	6.5	2	1.3	20%
DR Congo	YF	8.1	1	1.2	15%
Korea DPR	Hep B	2.6	1	0.3	11%
Lao PDR	DTP-Hep B	4.0	1	0.5	12%
Liberia	YF	0.4	3	0.2	50%
Myanmar	Hep B	12.7	4	3.6	28%
Nepal	Hep B	4.5	2	0.5	11%
Pakistan	Hep B	25.8	2	7.4	28%
Sri Lanka	Hep B	2.2	4	1.0	45%
Viet Nam	Hep B	12.7	5	3.2	25%
Total		*102.6*		*34.4*	

** Estimates based on 2003 vaccine prices*
Source of data: GAVI Secretariat

The total Vaccine Fund support not accessed by these countries is estimated to be US$ 34.4m, with half accounted by Bangladesh and Pakistan. This represents an additional 60m doses of monovalent Hep B; 6.2m doses of DTP-HepB; and 2 million doses of YF vaccine.

Issue for consideration:

Should countries that chose to phase-in a new vaccine be allowed to retain NVS they "miss" as a result of the phase-in, and use this vaccine in later years?

- Arguments in favor of such a decision could be that countries should not be penalized for making programmatically valid choices (i.e. opting for a phased introduction in order to "pilot-and-adjust" prior to expansion, or to strengthen the immunization system as part of new vaccine introduction); that accessing full support is an issue of equity among countries; and that countries may have chosen differently if they had been made explicitly aware at the time of application of the implications of a phased introduction.

- Other than the additional costs this would incur to GAVI and the Vaccine Fund (estimated at $34.4m), arguments against making such a decision could be that countries should not be encouraged to delay the delivery of these vaccines; and that experience in several countries indicates that a phased strategy is not required to successfully introduce a new vaccine.

Working Group recommendation:
Countries that chose a phased introduction will be offered the opportunity to access the "unused" portion of vaccine in subsequent years (over a period of up to three years). If all countries that have phased in to-date request for this support, this would increase total country approval by $34.4m (2003 vaccine prices).

2. Support for introduction of additional antigens ("switching")

Vaccine Fund support for new and under-used vaccines is currently provided for a period of five years (with a maximum stretching up to eight years) on an "antigen" and not a "product" basis. As such, a country that has received Hep B vaccine support for three years and has applied and been approved for Hib vaccine will receive five year support for Hib but will have only two years of remaining support for Hep B vaccine

This policy is straightforward with regard to monovalent products. However application of the policy for countries that use combination vaccines carries additional challenges, in particular practical aspects of co-funding and procuring a combination product.

This policy clarification is important to help inform countries in their decision-making and to project Vaccine Fund expenditures.

To maintain the basic principle of equitable access to Vaccine Fund resources and to promote program sustainability, the following procedures are proposed:

- The duration of Vaccine Fund support will continue to be determined on an antigen basis, i.e. support will be provided for five years (60 months) from the time a new antigen is approved. Countries can chose to stretch support over a maximum period of eight years.

- The GAVI Secretariat will track Vaccine Fund support to countries by individual antigen. Countries that receive combination vaccines will be responsible to finance the "unfunded" portion of the product when Vaccine Fund support ends.

Proposal

- To manage co-funding of combination products in a practical way, Vaccine Fund support will be calculated and provided as a proportion of total vaccine quantity (doses) needed by the country for this particular product, relative to the price of the additional antigen towards the total product price. UNICEF SD weighted average prices will be used as the basis for calculation. In the case of pentavalent (DTP-Hep B+Hib) vaccine, the Hib component of the pentavalent vaccine accounts for 67% of the total pentavalent vaccine price, when comparing the prices of DTP-HepB and DTP-Hep B+Hib in 2004.

- A country that receives DTP-HepB/HepB vaccine support and is approved for Hib in pentavalent form, will receive the full quantity of pentavalent vaccine needs until Hep B support ends.

- After that and for the remaining period of Hib support, the pentavalent vaccine will be co-funded with 67% of vaccine needs provided by GAVI/Vaccine Fund and 33% covered through other funding sources mobilized by the country.

Table 3 illustrates as a case example GAVI/Vaccine Fund support for countries that switch from tetravalent (DTP-HepB) or monovalent Hep B vaccine to pentavalent (DTP-Hep B+Hib) vaccine.

Table 3: GAVI/VF and country co-funding of the same product

Period of Hep B support (5yrs)				
Period of Hib support (5 yrs)				
Product provided		DTP-HepB	DTP-Hep B+Hib	
Funding source	GAVI / Vaccine Fund	100%	100%	67%
	Other funding source	0%	0%	33%

Working Group recommendation:

The Working Group supports this proposal.

3. **Guidelines for revised vaccine needs forecasting**

General guidance for vaccine needs forecasting can be obtained from the WHO manual 'Procurement of vaccines for public-sector programmes – A reference manual. (WHO/V&B/02.29).

The basic formula to estimate vaccine needs described in this document is the following:

Target Population x Expected Coverage x Number of Doses per Child x Estimated Wastage Factor

In addition, a buffer stock of 25% of total is usually included for the first full ordering year. After the first year, historical utilization data should guide the calculation, taking into account the carry over of stock and expected changes in coverage.

A number of clarifications to this formula appear necessary for its applicability by national programme managers (usually annual forecast), in particular regarding:

a) target population with or without infant mortality;
b) for vaccines with a scheduled number of doses >1;
c) situations where the local wastage rate is not sufficiently known.

WHO principles

1. Estimates should err on the side of overestimation rather than underestimation of vaccine needs since vaccine shortages or refusing vaccination to save stocks could reduce public confidence in

immunization services. Efforts are needed to improve session planning in a way that maximizes efficient use of vaccines, prevents unnecessary demands and reduces drop-outs.

2. It is not possible to advocate a universally acceptable vaccine wastage level. Acceptable wastage levels depend on each programme, based on experience and analysis of local situations (importance of outreach, coverage level, national policies, vial size …).

3. All WHO recommended strategies should be applied in order to reduce the wastage (e.g. multi-dose vial policy, use of vaccine vial monitor, adjustment of vial size to the average size of the immunization session).

4. Wastage rate should be monitored in order to get realistic figures and allow for corrective actions where it is too high.

WHO recommendations for refinements of the vaccine forecast formula:

1. **target population** is the total birth cohort. Rationale: infants who die before the age of 1 year may receive a number of vaccine doses and should therefore be accounted in the target population.

2. For multi-doses vaccines, the **expected coverage** is the coverage expected with the first dose. Rationale: taking subsequent doses would underestimate the total number of doses needed. It should be noted that with high coverage rates, the difference is minimal.

3. If actual **wastage** rate is not available, the following estimations can be used in the formula:
   for lyophilized vaccines:
   wastage rate for 10-20 dose vials: 50% (wastage factor: 2)
   wastage rate for 1-2 dose vials: 10% (wastage factor: 1.11)
   for liquid vaccines
   wastage rate for 10-20 dose vials: 25% (wastage factor: 1.33)
   wastage rate for 1-2 dose vials: 10% (wastage factor: 1.11)

The above estimates do not constitute recommended targets. Only utilization rates documented from national experience will provide an accurate basis for understanding the constraints and determining what an adequate wastage rate target should be.

4. Subsequent orders should be based on historical data (how many children were actually immunized) and should take into account the remaining vaccine balance in stock. Hence the calculation should be adjusted after completion of one full year of vaccine usage (can be split over one or two calendar years).

Financial implications for GAVI/VF

The revision of the formula for vaccines forecasting will result in the following financial implications

- The total funding for 2004-2009 of GAVI/VF supported countries will increase between 42 and 88 million dollars
- The total funding of 5 year GAVI/VF commitment would therefore increase from 1,027 to 1,069-1,115 million dollars.

As an example, Annex 1 documents the calculation of the requirement of vaccines and funds (applying the revised formula) in 9 countries with VF support for Pentavalent.

- UNICEF-SD has confirmed that the increased volume of vaccines (calculated with the revised formula) fits within the quantity forecasted to be procured for 2004-06.

Operational implications

1. The guidelines for submission of Proposals and of Progress report will be revised to forecast vaccines requirement using revised formula for targets of children and for vaccines wastage rate.
2. Countries will be requested to report annually on progress made on management of vaccines stock and of vaccines wastage.
3. Request of vaccines need for 2004 that will be submitted with Annual Progress Report in October 2003 will be adjusted by the Secretariat according to revised formula:
    a. DTP1 = DTP3 x factor of DTP1-DTP3 drop-out (most recent report by country)
    b. Revised maximum acceptable vaccines wastage rate

Proposed Working Group Recommendations:

- To apply the revised formula to adjust the country request of vaccines for 2004
- To revise GAVI guidelines to use the revised formula for country forecast and request of vaccines
- For countries to use revised formula to forecast vaccines requirement for 2005.

Annex A: Application of the revised formula to forecast Pentavalent vaccines

Timeline of 5-year VF commitment to:	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010
Guyana (Pentavalent 1-dose vial)	----------									
Ghana, Kenya, Malawi, Rwanda, Uganda	----------									
Burundi, Zambia	----------									
Yemen	----------									

Currently approved forecast (September 2003)

(in million)	2004	2005	2006	2007	2008	2009	2004 -09
Total births	4.7	6.5	6.7	1.8	1.8	0.9	22.5
Children to be vaccinated with Pentavalent	3.8	5.4	5.6	1.5	1.5	0.7	18.4
Number of Pentavalent doses	12.0	18.0	16.3	4.6	4.8	2.3	58.0
Total fund in US$	45.9	71.4	64.4	18.5	19.2	9.4	228.8

Example scenario:

a) Target of DTP1 in 2004; targets of DTP3 the following years
b) A fixed Vaccines Wastage rate of 10% all years.
c) The financial implication: a 12% increase of the currently approved GAVI commitment for 2004-09

Forecast as per scenario 2

(in million)	2004	2005	2006	2007	2008	2009	2004 -09
Number of Pentavalent doses	14.7	19.9	18.5	4.9	5.0	2.4	65.5
Increased number of doses	2.8	1.9	2.3	0.3	0.3	0.1	7.6
Total fund in US$	56.4	78.8	73.2	19.5	20.3	10.0	258.2
Increased fund in US$	10.5	7.5	8.8	1.0	1.1	0.5	29.4

PART 3: Financial Implications of recommendations from IRC Proposal and Monitoring Team

During September and October, the Secretariat received 11 proposals for support from GAVI/VF and 48 Progress Reports to be reviewed by the Independent Review Committee.

The Independent Review Committee (IRC) was organized into two teams which worked independently: the Proposal Team that met from October 28 to November 1, 2003 to review proposals, and the Monitoring Team that met from October 27 to November 7, 2003 to review progress reports.

Financial implications for 2004-05

Proposal Review:

- The financial implications that result from the recommendations on country proposals are estimated to be US$ 4.8 million for 2004-2005

Monitoring Review:

- The financial implications that result from the recommendations on country reports requesting support for 2004 are estimated to be US $105,228,500 – US$ 9.1 million for Injection Safety Support (INS), US$ 68.8 million for New and Under-Used Vaccines Support (NVS) and US$ 27.3 million for Immunization Services Support (ISS).

Total:

- The total financial demand from these two reviews is of US$ 110 million.

Five- year financial commitment

- Last June, the estimated five-year financial commitment for all country approvals amounted to US$ 1,027 million.
- With the recommended approvals of these two reviews the total financial commitment for 5 years will move to US$ 1.1 billion.
- Countries have started contributing funds for procurement of vaccines, consequently transferring the equivalent GAVI/VF support to later years. One country contributed US$ 1.2 million for 2003 and 5 countries have committed a total of US$ 2.6 million for 2004.
- For a detailed calculation of estimated five-year commitments by country see Table 1.

Table 1: Five year Financial Commitment (December 2003)

#	Country	Type of support	Prior 5-year commitment as of June 2003	Updated 5-year financial commitment
1	**Afghanistan**	ISS	7,255,000	7,255,500
		NVS		
		INS	1,452,500	1,619,000
2	**Albania**	ISS		
		NVS	507,500	452,000
		INS	92,500	102,000
3	**Angola**	ISS	6,565,000	6,565,000
		NVS		
		INS	1,377,000	1,525,000
4	**Armenia**	ISS	60,000	60,000
		NVS	459,000	436,000
		INS	55,000	56,000
5	**Azerbaijan**	ISS	266,000	487,500
		NVS	761,500	775,500
		INS	132,500	145,000
6	**Bangladesh**	ISS	26,935,000	26,935,500
		NVS	17,553,500	16,536,500
		INS	7,397,500	8,204,500
7	**Benin**	ISS		
		NVS	2,771,500	2,692,500
		INS		
8	**Bhutan**	ISS		
		NVS	519,000	**539,500**
		INS	205,000	29,000
9	**Bolivia**	ISS		
		NVS		
		INS		**660,000**
10	**Bosnia & Herz**	ISS		
		NVS	497,500	342,500
		INS		
11	**Burkina Faso**	ISS	4,410,000	4,410,500
		NVS		
		INS	622,000	**806,500**
12	**Burundi**	ISS	2,662,000	2,662,500
		NVS	17,908,500	17,196,500
		INS	419,000	428,000
13	**Cambodia**	ISS	3,012,000	3,012,500
		NVS	6,126,000	**6,161,000**
		INS	668,000	667,500
14	**Cameroon**	ISS	5,556,000	5,557,000
		NVS	4,019,000	**8,483,000**
		INS	1,091,000	1,108,500
15	**Central Afr Rep**	ISS	1,837,000	1,837,000
		NVS	679,000	730,000
		INS	146,000	156,000
16	**Chad**	ISS	2,715,000	2,715,000
		NVS	1,219,000	1,251,500
		INS	374,000	421,500
17	**China**	ISS		
		NVS	22,753,500	22,753,500
		INS	15,926,000	15,926,000
18	**Comoros**	ISS	165,000	173,500
		NVS	255,000	256,500
		INS	37,500	39,500
19	**Congo DRC**	ISS	31,299,000	31,298,500
		NVS	11,407,500	11,694,000
		INS	3,052,500	3,238,000
20	**Congo Rep**	ISS	1,534,500	1,534,500
		NVS	872,500	896,500
		INS	237,500	266,500

#	Country	Type of support	Prior 5-year commitment as of June 2003	Updated 5-year financial commitment
21	**Côte d'Ivoire**	ISS	3,859,000	3,859,500
		NVS	7,615,000	8,057,500
		INS		
22	**Cuba**	ISS		
		NVS		
		INS		
23	**Djibouti**	ISS	271,000	271,000
		NVS		
		INS	31,500	32,000
24	**East Timor**	ISS		
		NVS		
		INS		
25	**Eritrea**	ISS	930,000	930,500
		NVS	2,217,000	2,188,500
		INS	129,500	147,000
26	**Ethiopia**	ISS	19,130,000	19,130,000
		NVS		
		INS	3,017,500	3,074,500
27	**Gambia**	ISS	489,000	489,500
		NVS	3,452,500	**3,280,500**
		INS	107,500	109,000
28	**Georgia**	ISS	341,000	341,500
		NVS	646,500	700,500
		INS	57,000	60,000
29	**Ghana**	ISS	3,359,000	2,888,000
		NVS	47,194,500	44,252,000
		INS	741,000	824,500
30	**Guinea**	ISS	2,585,000	2,585,500
		NVS	1,102,500	1,114,500
		INS		645,500
31	**Guinea-Bissau**	ISS	423,000	423,000
		NVS		
		INS		
32	**Guyana**	ISS		
		NVS	1,204,000	1,329,000
		INS		
33	**Haiti**	ISS	2,171,000	**2,171,000**
		NVS		
		INS		**617,500**
34	**Honduras**	ISS		
		NVS		
		INS	371,500	471,500
35	**India*** **	ISS		
		NVS	4,224,000	4,224,000
		INS		
36	**Indonesia**	ISS	14,808,500	15,659,500
		NVS	16,332,500	14,965,000
		INS	8,859,000	9,475,500
37	**Kenya**	ISS	11,113,000	11,113,500
		NVS	74,209,000	73,497,500
		INS	1,059,500	1,143,500
38	**Korea, DPR**	ISS	3,315,000	3,315,500
		NVS	2,651,000	2,695,000
		INS	741,500	754,500
39	**Kyrgyz Rep**	ISS		
		NVS	1,228,500	1,197,000
		INS	158,500	178,000
40	**Lao PDR**	ISS	2,251,000	2,251,500
		NVS	4,128,500	3,494,500
		INS	281,000	279,000

#	Country	Type of support	Prior 5-year commitment	Updated 5-year financial commitment
41	**Lesotho**	ISS	517,000	517,500
		NVS	507,000	482,500
		INS	109,500	110,500
42	**Liberia**	ISS	2,804,000	2,405,000
		NVS	638,000	645,500
		INS		
43	**Madagascar**	ISS	4,277,000	4,277,500
		NVS	13,495,000	13,917,000
		INS		
44	**Malawi**	ISS		
		NVS	31,412,500	**32,586,000**
		INS		
45	**Mali**	ISS	4,100,000	4,426,000
		NVS	3,161,000	**3,277,500**
		INS	736,000	780,500
46	**Mauritania**	ISS	1,062,000	1,062,000
		NVS		
		INS	182,500	193,000
47	**Moldova**	ISS		
		NVS	481,000	451,500
		INS		
48	**Mongolia**	ISS		
		NVS		
		INS		
49	**Mozambique**	ISS	3,291,000	3,291,000
		NVS	15,056,000	15,975,500
		INS	960,500	986,000
50	**Myanmar**	ISS	7,902,000	7,902,500
		NVS	13,184,500	15,025,500
		INS	1,358,500	1,343,000
51	**Nepal**	ISS	4,494,000	4,494,000
		NVS	4,516,000	**4,232,500**
		INS	1,279,000	**1,317,500**
52	**Nicaragua**	ISS		
		NVS		
		INS		
53	**Niger**	ISS	5,027,000	5,027,000
		NVS		
		INS		**1,128,000**
54	**Nigeria**	ISS	53,020,000	53,020,000
		NVS	27,100,000	28,257,000
		INS		
55	**Pakistan**	ISS	33,900,000	32,508,000
		NVS	25,729,500	26,300,000
		INS	9,044,500	9,521,500
56	**Papua N G**	ISS		
		NVS		
		INS		
57	**Rwanda**	ISS	4,108,000	3,728,000
		NVS	22,360,000	21,256,000
		INS	382,000	406,000
58	**São Tomé**	ISS	67,000	65,500
		NVS	169,500	266,500
		INS	11,500	11,500
59	**Senegal**	ISS	3,983,000	3,983,500
		NVS	18,436,000	19,624,000
		INS	846,500	749,500
60	**Sierra Leone**	ISS	2,353,000	2,423,500
		NVS	1,435,500	1,466,500
		INS	306,000	312,500

#	Country	Type of support	Prior 5-year commitment as of June 2003	Updated 5-year financial commitment
61	**Solomon Isl**	ISS		
		NVS		
		INS		
62	**Somalia**	ISS	3,399,000	3,399,500
		NVS		
		INS	326,500	349,000
63	**Sri Lanka**	ISS		
		NVS	2,481,500	2,456,000
		INS	524,500	589,000
64	**Sudan**	ISS	8,969,000	8,968,500
		NVS		52,915,000
		INS	1,897,000	1,828,000
65	**Tajikistan**	ISS	1,138,000	**1,510,500**
		NVS	999,500	**959,000**
		INS		255,500
66	**Tanzania**	ISS	6,499,000	8,665,500
		NVS	28,053,500	29,822,000
		INS	1,406,000	1,510,000
67	**Togo**	ISS	1,945,000	1,945,500
		NVS	1,011,000	1,035,500
		INS	354,500	374,500
68	**Turkmenistan**	ISS		
		NVS	890,000	828,500
		INS		**161,000**
69	**Ukraine**	ISS		
		NVS	2,878,500	2,768,500
		INS	683,500	747,500
70	**Uganda**	ISS	9,343,000	11,794,500
		NVS	55,752,500	62,878,500
		INS	1,315,500	1,338,000
71	**Uzbekistan**	ISS		
		NVS	3,934,500	3,926,000
		INS	779,000	808,500
72	**Viet Nam**	ISS		
		NVS	12,461,000	11,650,000
		INS	3,140,500	3,296,500
73	**Yemen**	ISS	4,342,000	4,342,000
		NVS	44,004,500	44,019,500
		INS	1,021,500	1,238,000
74	**Zambia**	ISS	2,959,000	2,959,500
		NVS	33,288,500	30,265,000
		INS	743,500	762,500
75	**Zimbabwe**	ISS	3,220,000	3,220,000
		NVS		
		INS	1,198,000	1,319,000
	TOTAL	ISS	332,036,000	335,870,500
		NVS	617,951,500	679,479,500
		INS	77,447,000	84,647,000
			1,027,434,500	**1,099,997,000**

Figures in bold = subject to clarifications

PART 4: Proposal Team Report, November 2003

I. Procedure of the review

The proposal team of the Independent Review Committee (IRC) met in Geneva from 28th October to 1st November 2003 for the review of country proposals for GAVI/VF support.

As usual, each proposal was reviewed by three reviewers. The first reviewer takes a leading role. The Proposal Review Team plenary discusses and makes a final judgment on recommendations for each component of request. All proposals were decided on a consensus basis, no vote was used.

A strict observation of any conflict of interest among Team members for individual proposals was effected with members excusing themselves from the discussion of that proposal.

Eight Proposal Review Team members participated (See Annex A). During this round, the team welcomed Merceline as new Chairperson and Gordon as a new member.

II. Outcome of the review

Eleven countries submitted proposals for this review, with a total of 13 requests for different types of support broken down as follows:

- Injection safety 7 requests
- New and under-used vaccines 6 requests
  - ✓ Introduction of Hep B vaccines 4 requests
  - ✓ Introduction of Hib vaccines 2 requests

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

Table 1: Recommendations on reviewed proposals

	Country	Requests				
		ISS	INS	YF	Hep B	Hib
1	Bolivia		Clarification			
2	Burkina Faso				Conditional	Conditional
3	Cameroon				Clarification	
4	Guinea		Approval			
5	Haiti		Clarification			
6	Madagascar		Re-submission			
7	Mauritania				Conditional	
8	Niger		Clarification			
9	Sudan				Approval	Approval
10	Tajikistan		Approval			
11	Turkmenistan		Clarification			

The financial implications for 2004-2005 that result from these recommendations on country proposals are estimated to be US$ 4,842,500 (Tables 2 and 3) and the financial commitment for a five-year period is estimated to be US$ 60,735,000 (Table 4).

Table 2: Planned disbursements 2004 and 2005 for proposals recommended for approval (in US$)

Country	Immunization Services		New and Under-used Vaccines (estimate)		Injection Safety (estimate)		Other support
	1st investment	2nd investment	2004	2005	2004	2005	2004
Guinea					229,000	198,000	
Sudan			415,000	1,079,500			100,000
Tajikistan					93,500	79,000	
Sub-total			415,000	1,079,500	322,500	277,000	100,000
Total 2,194,000							

Table 3: Planned disbursements 2004 and 2005 for proposals recommended for approval with clarifications (in US$) (*figures subject to change pending receipt of clarifications)*

Country	Immunization Services		New and Under-used Vaccines (estimate)		Injection Safety (estimate)		Other Support
	1st investment	2nd investment	2004	2005	2004	2005	2004
Bolivia					236,000	204,500	
Cameroun			-	979,500			
Haiti					222,500	191,000	
Niger					359,500	346,000	
Turkmenistan					59,500	50,000	
Sub-total				979,500	877,500	791,500	
Total 2,648,500							

Table 4: Commitment of VF support for 3 years of INS and 5 years of NVS (in US$)

	Country	5 years New and Under-Used Vaccines Support	3 years Injection Safety Support	Other Support	TOTAL
1	Bolivia		660,000		660,000
2	Cameroun	4,352,500			4,352,500
3	Guinea		645,500		645,500
4	Haiti		617,500		617,500
5	Niger		1,128,000		1,128,000
6	Sudan	52,815,000		100,000	52,915,000
7	Tajikistan		255,500		255,500
8	Turkmenistan		161,000		161,000
	TOTAL	57,167,500	3,467,500	100,000	60,735,000

III. Analysis of the review outcome

The total approval rate is 66% (only approvals and approvals with clarifications, excluding conditional approvals)

Approval rate by request of supports:

- INS86%
- Hep B 50%
- Hib 50%

By the 10th review, the status of countries applying to GAVI/The VF has remained unchanged: overall 71 countries have applied to GAVI, out of which 69 countries have been approved for at least some components (Figure 1). There are four countries that have never approached GAVI for support: Papua New Guinea, Solomon Islands, Nicaragua and East Timor. We estimate the remaining requests for support in future applications:

ISS	5
INS	17
YF	13
Hep B	16
Hib	37

IV. Notes from the review

A. INDIA's request

In January 2002, the Board has approved India's proposal to support the introduction of hepatitis B vaccination for one and an half year, with the agreement to receive a second proposal in 2003 for an additional three and an half year of GAVI/VF support.

In a letter of September 30, 2003, the Government of India requested to receive Hep B vaccines in 2004 according to the expansion of the immunization plan that was still under elaboration and that will be submitted in the next review round for GAVI/VF support. The quantity requested was indicated in the Progress Report submitted for review on 30 September 2003.

The Proposal Review Team has noted in the Progress Report that the implementation of India's immunization program for hepatitis B is one year behind schedule. They have recorded a balance of vaccine in stock at the beginning of 2004 of 5.71 million doses.

The Proposal Review Team recommends that for 2004 India applies the 2003 immunization plan using vaccines already supplied by GAVI for the same number of targeted children proposed in the approved plan. The Proposal Review Team recommends that the GAVI Board encourage India to submit its application for the May 2004 review.

B. Other notes

1. How efficient is the use of multi-year and vaccine-introduction plans to monitor the progress. Would it be reasonable to measure the status of their implementation? *(For Monitoring Team's decision)*

2. How to assess the functioning of the ICC? *Verify with the Monitoring Team how to stimulate the ICC to become more involved in monitoring the EPI and building technical capacity in the country.*

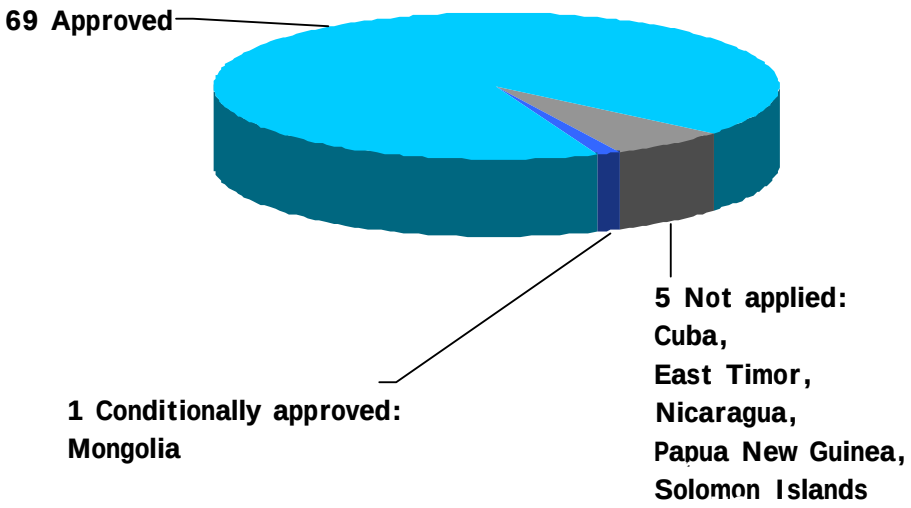
3. Technical Assistance to the countries should be organized assuring participation of local staff in order to build local capacity for development of GAVI/VF proposals. (*For WG to address)*

4. If a country has recently completed a vaccines coverage survey, its report should be submitted to the IRC together with documents for EPI assessment (*Secretariat for guidelines*).

5. Proposed dates for Spring Review are May 25 to June 3, 2004.

Figure 1: Status of requests from eligible countries* after November 2003 review

***75 eligible countries with GNI < US$1,000 / cap**



Annex A: Participating IRC Proposal Team members

- ***Mr. Oleg Benes*** (Serving since 2001)

Epidemiologist, National Centre of Preventive Medicine, Moldova

(not participating in decisions on Turkmenistan)

- ***Dr Merceline Dahl-Regis*** (Serving since 2001)

Chief Medical Officer, Ministry of Health, Bahamas

- ***Dr Peter Figueroa*** (Serving since 2002)

Chief Medical Officer, Jamaica

- ***Mr Gordon Larsen*** (Co-opted member for this review)

Independent Consultant for EPI, UK

- ***Dr Grace Murindwa*** (Serving since 2003)

Principal Health Planner, Ministry of Health, Uganda

- ***Dr Stanislava Popova-Doytcheva*** (Serving since 2001)

Scientist, WHO STC

Bulgaria

(not participating in decisions on Turkmenistan)

- ***Dr Jane Soepardi*** (Serving since 2002)

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

- ***Dr Mean Chhi Vun*** (Serving since 2003)

Deputy Director General of Health, Ministry of Health, Cambodia

Annex B: Proposals recommended for approval

GUINEA

- Injection Safety

SUDAN

- New and under-used vaccines (Hep B and Hib), limited to phases 1 and 2.

TAJIKISTAN

- Injection Safety

Annex C: Proposals recommended for approval with clarifications

BOLIVIA

Injection safety - supplies

- Targets need to be reviewed and the quantities of injection safety supplies in Tables 6.1 and 6.5 recalculated.
- The ICC should provide written assurance that GAVI funds will not replace existing national or donor support for the EPI program.

CAMEROON

New and under-used vaccines (Hep B)

- Targets and indicators of activities of the vaccine introduction plan to be implemented.

HAITI

Injection safety – equivalent amount of funds

- Provide more realistic targets in table 4 and tables 6-1 to 6.4.

NIGER

Injection safety – supplies

- Baseline figures for 2002, the number of surviving infants, and targets for each antigen should be consistent with those of the Progress Report.

TURKMENISTAN

Injection safety – supplies

- Baseline targets, numbers of surviving infants and target children for each antigen and for each year, 2003-2008 (Table 4)
- Details of budget required for each of the activities described in the National Plan of Action for Injection Safety.

Annex D: Proposals recommended for conditional approval

BURKINA FASO

Introduction of new and under-used vaccine (Hep B and Hib):

- Provide:
  - an updated inventory on the cold chain capacity and functioning at the central, intermediate and peripheral levels, with a detailed rehabilitation plan

- A revised and detailed introduction plan for pentavalent vaccine that addresses: timelines, targets, quantifiable indicators for the phased introduction of pentavalent vaccine and revised coverage targets that are realistic

- The ICC should endorse a revised introduction plan that incorporates the recommendations of the 2003 EPI review and provide evidence of cold chain readiness for the introduction of new vaccine.

MAURITANIA

Introduction of monovalent 10-dose hepatitis B vaccine:
The previously imposed conditions were not fully met. Outstanding conditions are:

- In reference to the report of the April 2003 cold chain review provide a strategy to rehabilitate the cold chain at district and sub-district levels, including budgetary requirements, and give evidence of cold chain readiness to introduce the vaccine.

- Revise the timetable for vaccine introduction to include specific activities, tasks, timelines, indicators and targets.

- Revise table 4 of the proposal form considering the stated Infant Mortality Rate (IMR) and the estimated numbers of surviving infants. Revise also the figures for infants vaccinated in 2002 with BCG, OPV3 and DPT3 in consistency with those of the Joint Reporting Form.

- The number of Hep B doses requested for the first year of support (2004) in table 8 contradicts the number stated in table 7.1. Re-constitution syringes are requested although these are not needed for Hep B vaccine.

- Clarify whether the vaccine will be procured through UNICEF or by Government (as mentioned in connection with the previous submission).

Annex E: Proposals recommended for Resubmission

MADAGASCAR

- **Injection Safety**

PART 5: Monitoring Team Report, November 2003

Introduction

The Monitoring team of the Independent Review Committee (IRC) met in Geneva from 27 October to 7 November 2003, to review progress reports. Seven members of the Monitoring Team participated in the review (see annex B).

Forty-eight out of sixty-four countries submitted their 2002 progress report (5 inception reports, 23 first annual reports and 20 second annual reports).

This is the first time the Monitoring Team has made recommendations on rewards, which are based on countries' 2002 performance. Eight countries out of fifteen had both, good achievement in 2002 and a successful DQA. Therefore, these countries were eligible to receive rewards in 2002. Among those eight countries, 770,430 additional children have been vaccinated with DTP3 in comparison to the targets for 2001. As a result of this achievement, the countries will receive the total amount of US$ 14,873,000 (Tajikistan is still pending clarifications).

The Monitoring Team's recommendations for the progress reports are summarized in Annex C. The Board is requested to review those recommendations. For more details regarding the Monitoring Team's country specific comments, please refer to Annex I.

The Monitoring Team's executive summary, which contains both comments as well as policy issues raised during the review, is located in Annex A. The Board is requested to review the major policy issues identified by the Team. These are summarized in Annex D along with the comments from the Working Group teleconference of 20 November 2003.

The Board is also requested to consider the financial implications of the monitoring review of progress reports in October 2003, as outlined in Annex E. The total financial request to be approved by the board is: US$ 105,228,500.

- US$ 27,307,400 for the **Immunization Services Support** (see Annex F). The breakdown of financial implications is as follows:
    - Rewards: the total requested is US$ 14,873,000. The original commitment for those countries to receive rewards was:
      US$ 11,578,500, therefore increasing the request by an additional US$ 3,292,800.
    - Third Investment of Investment: the total requested is
      US$ 12,434,400 (no previously approved amounts)

- US$ 9,122,300 for the **Injection Safety Support** (see Annex G).

- US$ 68,798,800 for the **New Vaccines Support** (see Annex H). This figure was calculated by taking the needs for 2004 (US$ 92,798,500) and subtracting the previously approved amount (US$ 26,249,514).

Annex A: Participating IRC Monitoring Team members

- ***Dr MOSINA Liudmila***
- ***Dr TANGCHAROENSATHIEN Viroj***
- ***BINKA Fred***
- ***STEVENSON Sally***
- ***QUADROS Ciro de***
- ***HALL Andrew J***

- ***Dr KOLLO Basile***

ANNEX B: IRC Monitoring Team Summary Recommendations

No	Country	Report	Support	Decision
1	**Afghanistan**	**AR**	ISS,INS	**Satisfactory**
2	**Albania**	**AR**	NVS,INS	**Satisfactory**
3	**Azerbaijan**	**AR**	ISS,NVS,INS	**Satisfactory subject to clarifications ***
4	**Bangladesh**	**AR**	ISS,NVS,INS	**Satisfactory**
5	**Benin**	**AR**	NVS	**Satisfactory**
6	**Bhutan**	**IR**	NVS,INS	**Satisfactory subject to clarifications**
7	**Bosnia & Herz**	**IR**	NVS	**Satisfactory**
8	**Burkina Faso**	**AR**	ISS,INS	**Satisfactory subject to clarifications**
9	**Burundi**	**AR**	ISS,NVS,INS	**Satisfactory**
10	**Cambodia**	**AR**	ISS,NVS,INS	**Satisfactory subject to clarifications**
11	**Cameroon**	**AR**	ISS.NVS,INS	**Satisfactory**
12	**CAR**	**IR**	ISS,NVS,INS	**Satisfactory**
13	**Congo DR**	**IR**	ISS,NVS,INS	**Satisfactory**
14	**Cote d'Ivoire**	**AR**	ISS,NVS	**Satisfactory**
15	**Eritrea**	**AR**	ISS,NVS,INS	**Satisfactory**
16	**Gambia**	**AR**	ISS,NVS,INS	**Satisfactory subject to clarifications**
17	**Georgia**	**AR**	ISS,NVS,INS	**Satisfactory**
18	**Ghana**	**AR**	ISS,NVS,INS	**Insufficient information ***
19	**Guyana**	**AR**	NVS	**Satisfactory**
20	**Haiti**	**AR**	ISS	**Satisfactory subject to clarifications**
21	**India**	**AR**	NVS	**Satisfactory**
22	**Indonesia**	**AR**	ISS,NVS,INS	**Satisfactory**
23	**Kyrgyz rep**	**AR**	NVS,INS	**Satisfactory**
24	**Lao PDR**	**AR**	ISS,NVS,INS	**Satisfactory**
25	**Lesotho**	**AR**	ISS,NVS,INS	**Satisfactory**
26	**Madagascar**	**AR**	ISS,NVS	**Satisfactory**
27	**Malawi**	**AR**	NVS	**Satisfactory subject to clarifications**
28	**Mali**	**AR**	ISS,NVS,INS	**Satisfactory subject to clarifications**
29	**Moldova**	**AR**	NVS	**Satisfactory**
30	**Mozambique**	**AR**	ISS,NVS,INS	**Satisfactory**
31	**Myanmar**	**AR**	ISS,NVS,INS	**Satisfactory**
32	**Nepal**	**AR**	ISS,NVS,INS	**Satisfactory subject to clarifications**
33	**Niger**	**AR**	ISS	**Satisfactory**
34	**Pakistan**	**AR**	ISS,NVS,INS	**Satisfactory**
35	**Rwanda**	**AR**	ISS,NVS,INS	**Satisfactory subject to clarifications**
36	**Sao Tome**	**AR**	ISS,NVS,INS	**Insufficient information**
37	**Senegal**	**AR**	ISS, NVS,INS	**Satisfactory**
38	**Sri Lanka**	**AR**	INS,NVS	**Satisfactory**
39	**Sudan**	**AR**	ISS,INS	**Satisfactory**

40	**Tajikistan**	**AR**	ISS,NVS	**Satisfactory subject to clarifications**
41	**Tanzania**	**AR**	ISS,NVS,INS	**Satisfactory**
42	**Togo**	**IR**	ISS,NVS,INS	**Satisfactory**
43	**Turkmenistan**	**AR**	NVS	**Satisfactory**
44	**Uganda**	**AR**	ISS,NVS,INS	**Satisfactory**
45	**Vietnam**	**AR**	NVS,INS	**Insufficient information**
46	**Yemen**	**AR**	ISS,NVS,INS	**Insufficient information**
47	**Zambia**	**AR**	ISS;NVS,INS	**Satisfactory**
48	**Zimbabwe**	**AR**	ISS,INS	**Insufficient information ***

*** Note from the Secretariat: clarifications have been provided and were found satisfactory**

ANNEX C: Major policy recommendations of the IRC Monitoring Team

With responses from the GAVI Working Group

1. **GAVI should consider postponing the expansion of the introduction of new vaccines in the India immunization program until a new proposal has been approved.**
   WG response: *India should be encouraged to integrate the introduction of new vaccines into its immunization plan and submit an application for expansion of introduction to other states.*

2. **When disbursements are delayed, GAVI should consider as baseline figures, those of the year prior to the first disbursement and rewards should be calculated accordingly.**
   WG response: *Further analysis is needed before any changes are instituted in determination of the baseline year.*

3. **GAVI should consider applying new criteria for countries in situations of conflict or disasters.**
   WG response: *Existing policy on countries in situations of conflict or natural disasters should be revisited by the Working Group. Additional policies need to be considered to address the issue of continuing GAVI/VF support to previously approved countries.*

4. **GAVI should establish rules regarding countries that did not provide clarifications and requested information from previous progress reviews.**
   WG response: *Guidelines will be submitted for Board consideration on how to manage this situation.*

5. **GAVI should consider changing the labeling of final monitoring review conclusions (satisfactory, satisfactory subject to clarifications, insufficient information).**
   WG response: *The Working Group accepts the proposal to replace the terms currently used by the Monitoring Team for final review conclusions.*

6. **GAVI should consider conducting coverage surveys in all countries at the end period of support to ascertain the validity of data.**

   WG response: *Coverage surveys will be conducted in selected countries based on agreed work plans. Efforts should be made to link up with the plans for other national survey activities such as UNICEF's Macs, DHS, etc.*

7. **GAVI should strengthen the monitoring review process with workshops to be attended by the IRC and EPI managers.**
   WG response: *The Working Group agreed that the quality of the progress reports submitted by countries should be improved and welcomed the initiative of the IRC Monitoring Team to propose a new mechanism. A multipronged approach should be explored. Components could include: Interaction between RWGs and the IRC, strengthening of partner agencies at country and regional levels and use of existing immunization meetings to*

improve reporting on GAVI issues could be explored. The independent role of the IRC must be maintained at all times.

8. **GAVI Partners should support countries to strengthen epidemiological surveillance and establish mechanisms for better monitoring of vaccine stocks.**
   WG response: *The Working Group agreed that technical partners should support countries to strengthen surveillance and improve vaccine stock management.*

9. **GAVI should reinforce the role and effectiveness of ICC members at the country level in preparing and revising the progress reports.**
   WG response: *The current GAVI work plan addresses the issue of strengthening ICCs.*

10. **GAVI partners should work closely with countries to provide reliable estimates of population figures.**
    WG response: *The Working Group agreed that GAVI partners need to work further with countries on provision of reliable population data.*

ANNEX D: TOTAL Financial Requests (in US$)

Country	Immunization Services	Injection Safety	New Vaccines
Afghanistan	1,039,000	30,500	
Albania		2,000	31,500
Azerbaijan	260,500	10,500	123,500
Bangladesh	3,568,000	161,300	2,317,500
Benin			409,500
Bhutan		700	**16,500**
Burkina Faso		**174,500**	
Burundi	325,000	103,000	297,000
Cambodia	668,600	**194,000**	875,000
Cameroon		47,200	
CAR		7,600	59,600
Congo DR		999,500	2,507,500
Cote d'Ivoire			1,850,500
Eritrea	78,600	3,700	319,500
Gambia	64,600	28,500	**507,500**
Georgia	34,000	2,000	117,000
Ghana	70,500	51,500	7,243,500
Guyana			124,500
Indonesia		3,491,000	2,124,000
Kyrgyz rep		4,100	167,000
Lao PDR	715,600	55,500	
Lesotho	74,800	30,500	59,500
Madagascar			2,664,000
Malawi			**8,104,500**
Mali	883,500	37,200	**229,800**
Moldova			23,500

Mozambique		11,400	4,280,500
Myanmar	974,800	893,000	3,022,500
Nepal	705,000	**486,000**	
Niger	870,000		
Pakistan	5,548,000	404,500	4,610,500
Rwanda	151,500	6,000	**3,626,000**
Sao Tome			1,900
Senegal	247,200	165,500	676,500
Sri Lanka		27,000	92,500
Sudan	1,537,200	545,500	
Tajikistan	**542,000**		
Tanzania	3,056,000	43,100	1,254,000
Turkmenistan			65,500
Uganda	4,361,000	413,000	19,393,000
Vietnam		**50,500**	1,173,500
Yemen	567,000	450,500	
Zambia	328,000	170,500	430,000
Zimbabwe	637,000	21,000	
Total request	**27,307,400**	**9,122,300**	**68,798,800**
		Grand Total	105,228,500

NB: amounts in bold are pending clarifications

ANNEX E: Financial Requests Summary -- Immunization Services Support

Country	Type of disbursement	Amount (US$)	Comments
Azerbaijan	First reward	260,500	Original commitment: $ 38,940
Ghana	First reward	70,500	Original commitment: $ 542,400
Mali	First reward	883,500	Original commitment: $ 557,120
Pakistan	First reward	5,548,000	Original commitment: $ 6,940,000
Rwanda	First reward	151,500	Original commitment: $ 531,780
Tanzania	First reward	3,056,000	Original commitment: $ 889,640
Uganda	First reward	4,361,000	Original commitment: $1,909,260
*Tajikistan**	First reward	*542,000*	Original commitment: $169,360
Subtotal		**14,873,000**	
Afghanistan	third investment	1,039,000	
Bangladesh	third investment	3,568,000	
Burundi	third investment	325,000	
Cambodia	third investment	668,600	
Eritrea	third investment	78,600	
Gambia	third investment	64,600	
Georgia	third investment	34,000	
Lao PDR	third investment	715,600	
Lesotho	third investment	74,800	
Myanmar	third investment	974,800	
Nepal	third investment	705,000	
Niger	third investment	870,000	
Senegal	third investment	247,200	

Sudan	third investment	1,537,200	
Yemen	third investment	567,000	
Zambia	third investment	328,000	
Zimbabwe	third investment	637,000	
Subtotal		**12,434,400**	
Burkina Faso	no rewards	0	Original commitment: $ 646,120
Cameroon	no rewards	0	Original commitment: $ 873,340
Cote d'Ivoire	no rewards	0	Original commitment: $ 447,220
Haiti	no rewards	0	Original commitment: $ 84,000
Madagascar	no rewards	0	Original commitment: $ 944,380
Mozambique	no rewards	0	Original commitment: $ 549,320
Sao Tome	no rewards	0	Original commitment: $ 2,200
CAR	second investment	0	
Congo DR	second investment	0	
Indonesia	second investment	0	
Togo	second investment	0	
Total		**27,307,400**	

* pending clarifications

ANNEX F: Financial Request Summary -- Injection Safety Support

Country	Needs for 2004	Requested Amount
Afghanistan	516,000	30,500
Albania	37,500	2,000
Azerbaijan	47,000	10,500
Bangladesh	2,910,000	161,300
Bhutan	9,000	700
Burkina Faso*	298,500	*174,500*
Cameroon	327,000	47,200
CAR	48,500	7,600
Eritrea	51,500	3,700
Georgia	21,500	2,000
Ghana	280,000	51,500
Kyrgyz rep	63,000	4,100
Mali	243,000	37,200
Mozambique	276,000	11,400
Pakistan	2,916,500	404,500
Rwanda	124,500	6,000
Sri Lanka	180,500	27,000
Tanzania	475,500	43,100
Zimbabwe	461,500	21,000
Vietnam*	1,023,000	*50,500*
Sao Tome*	3,000	*0*
Togo	118,000	0
Yemen	450,500	450,500

Gambia	28,500	28,500
Myanmar	893,000	893,000
Nepal*	486,000	*486,000*
Lao PDR	55,500	55,500
Lesotho	30,500	30,500
Burundi	103,000	103,000
Congo DR	999,500	999,500
Indonesia	3,491,000	3,491,000
Sudan	545,500	545,500
Senegal	165,500	165,500
Cambodia*	194,000	*194,000*
Uganda	413,000	413,000
Zambia	170,500	170,500
Total	**18,457,000**	**9,122,300**

** pending clarifications*

ANNEX G: Financial Request Summary -- New Vaccines Support (in US$)

Country	Previously approved	Needs for 2004	Requested Amount
Albania	15,500	47,000	31,500
Azerbaijan	23,500	147,000	123,500
*Bhutan**	67,192	83,500	*16,500*
Burundi	3,109,000	3,406,000	297,000
CAR	76,900	136,500	59,600
Congo DR	111,000	2,618,500	2,507,500
Cote d'Ivoire	45,500	1,896,000	1,850,500
Eritrea	30,500	350,000	319,500
Georgia	11,500	128,500	117,000
Ghana	153,500	7,397,000	7,243,500
Kyrgyz rep	72,996	239,500	167,000
Madagascar	78,000	2,742,000	2,664,000
*Malawi**	125,948	8,230,000	*8,104,500*
*Mali**	553,200	783,000	*229,800*
Moldova	13,000	36,500	23,500
Myanmar	207,000	3,229,500	3,022,500
Pakistan	1,549,500	6,160,000	4,610,500
*Rwanda**	134,500	3,760,500	*3,626,000*
*Sao Tome**	11,600	13,500	*1,900*
Senegal	4,164,000	4,840,500	676,500
Sri Lanka	379,000	471,500	92,500
Tanzania	5,044,000	6,298,000	1,254,000
Turkmenistan	27,000	92,500	65,500
Vietnam	755,500	1,929,000	1,173,500
Zambia	5,056,164	5,486,000	430,000

Togo	161,000	161,000	0
Cameroon	886,500	886,500	0
Bosnia & Herz	90,700	31,000	
Lao PDR	632,514	266,500	
*Nepal**	2,406,300	683,500	
*Tajikistan**	257,000	157,000	
Bangladesh		2,317,500	2,317,500
Benin		409,500	409,500
Cambodia		875,000	875,000
*Gambia**		507,500	*507,500*
Guyana		124,500	124,500
Indonesia		2,124,000	2,124,000
Lesotho		59,500	59,500
Mozambique		4,280,500	4,280,500
Uganda		19,393,000	19,393,000
Total	**26,249,514**	**92,798,500**	**68,798,800**

** pending clarifications*

ANNEX H: IRC Monitoring Team Executive Report

Conclusions and Recommendations

A. Introduction

The Monitoring Team of the Independent Review Committee (IRC) met in Geneva from 27 October to 7 November to review Inception and Annual Reports. The IRC reviewed 48 countries out of the 64 countries that were due to report at this time. Two signed reports were received too late to be reviewed, four submitted their reports without the appropriate signatures, and eleven countries did not submit a report.

The composition of the team included 7 members (their names and affiliations are attached).

B. Summary of Conclusion and Recommendations

1. The IRC commends the Secretariat for following up on the recommendations made to improve the process. Of particular importance was the preparation of country work sheets with all the background information related to the each country. These include the dates that different kinds of support were approved, the dates of transfer of funds and of shipment of supplies, information from previous reviews on denominators and targets as well as DQA dates and results. The IRC also commends UNICEF for the pre-assessment of issues pertaining to supply of vaccines and injection safety materials.

2. The outcome of the review was as follows:

Satisfactory Reports: 32 (66%)
Satisfactory subject to Clarifications: 11 (23%)
Insufficient Information: 5 (11%)

Consequences of the Outcomes:

Satisfactory: country will receive the support requested

Satisfactory subject to Clarifications: Countries will continue to receive support as previously approved. Secretariat follows up to obtain information requested.

Insufficient Information: The Committee could not reach a conclusion or decision for lack of information.

With this review the committee has completed the review of the first year of activities of all countries that have received support from GAVI/VF.

3. This was the first time that the Committee considered the approval of rewards for those countries that surpassed their targets and had satisfactory DQAs. Sixteen of the 48 countries reviewed were eligible to receive rewards. Of these, seven surpassed their target and had satisfactory DQAs (Ghana, Mali, Pakistan, Rwanda, Sierra Leone, Tanzania and Uganda) for rewards totaling US$14,606,380.00. Two countries, Azerbaijan and Tajikistan, surpassed targets and-or had satisfactory DQAs. However, delivery of the rewards will be delayed until clarification is given on the actual number of children under one year of age that have been vaccinated. It appears that the reported figure in the annual report includes children above this age group. These two countries will receive US $802,220.00 once clarifications are received. Countries reviewed that were eligible to receive rewards, but were not approved by the IRC, include those with poor achievement and/or unsuccessful DQA, such as Burkina Faso, Mozambique, Cote d'Ivoire, Cameroon, Sao Tome, Haiti and Madagascar.
It is to be noted that Mozambique, Burkina Faso and Côte d'Ivoire had good performance evidenced by increased number of children being vaccinated compared to the 2001 target but failed to receive the reward due to an unsuccessful DQA.

The IRC Monitoring Committee notes that currently approved targets for many countries were those made in the original proposal. Therefore, it may be advisable for countries to review these in the light of current achievements.

It is important to note that in many instances considerable time elapses from approval to disbursement of ISS funds. The IRC recommends that the disbursement of funds be made when the country has had one year for utilization of the previous disbursement and that the baseline year for the rewards be related to the date of the first disbursement of ISS in the following manner: if first disbursement was made in the first half of a given year the baseline will be the previous year; if first disbursement was made in the second half of a given year the baseline will be the year of this disbursement.

Additionally, as indicated in the last report, the GAVI Board should define a policy that will not penalize those countries eligible to rewards that are in situations of conflict or natural disasters. The principle of such a policy should be that funds be directed to strengthen the national program and at the same time use caution to avoid a situation in which funds can not be properly used.

4. Total US $17,334 million USD of ISS funds were received by countries in 2002 (excluding balance brought forwards from 2001). A total of 28 countries provided complete expenditure data for analysis.

A total of 5,449 million USD was spent by 28 countries (spending rate of 31.43% (max 110.4% Nigeria, Min Bangladesh 0.1%). This may be due to arrival of funds at country level. Six countries had a spending rate below average (Bangladesh, Lao,

Niger, Cameroon, Sudan and Uganda) and seven countries had 100% spending rate (Mozambique, Burundi, Lesotho, Burkina Faso, Azerbaijan, Mali and Nigeria).
Of the total 5,449 million USD spent, training was the highest priority at 20%, IE&C and social mobilization at 13%, use for purchase/maintenance of cold chain equipment at 10%, transport at 9%, and purchase of vehicles at 7%. Epidemiological surveillance (1%), M&E and outreach got the least shares.

Slightly more than half of the funds were spent at district level, 27% at central and 21% by provincial level. However, this breakdown is rather arbitrary in a number of the countries analyzed. Interpretation should be made cautiously, as the purchase of a vehicle at the central level can be used for district outreach clinics. A great variation in this proportion was observed among 27 countries analyzed (Attachment 1).

5. Table 1 shows the total number of doses of new vaccines supplied to the countries during 2001 and 2002.

Table 1: Doses of New Vaccines supplied to the 48 reviewed countries, 2001-2002.

Vaccine	Doses supplied
Hepatitis B*	40,361,369
Hib*	8,597,939
YF	2,027,608

* Alone or in combination

Table 2 presents the number of children reported in JRF that have received new vaccines supplied by GAVI/VF.

Table 2: Number of children vaccinated with new vaccines, JRF 2002

DPT/HepB/Hib	Hep B*		YF	
2002	2001	2002	2001	2002
1,803,297 (6 countries)	1,147,706 (14 countries)	3,971,520 (19 countries)	1,323,617 (9 countries)	2,013,688 (11 countries)
	3,799,471 (15 countries including Indonesia)	9,472,764 (20 countries including Indonesia and Pakistan)		

- Include DTP-HepB
- 54,146 doses of DTP-Hib are not included in the Table.

Thirty nine out of the 48 countries reviewed presented requests for new vaccines for 2004.
Of these, 22 were approved for new vaccines as previously approved either in last year's report or by the proposal committee. Ten countries requested a decrease in targets, resulting in 2,105,221 less children to be vaccinated. Indonesia alone accounts for 1,362,833 of the children. Seven countries requested an increase in the targets resulting in 376,273 additional children to be vaccinated.

6. DPT3 coverage for 48 countries whose 2002 reports were reviewed during this review was analyzed as follows: there are two sources of information on 2002 coverage – one in the JRF and one in the Annual Report – these are not the same for several countries. The data is also dominated by 4 countries with very large populations (India, Indonesia, Pakistan & Bangladesh). Coverage is therefore reported in the Table 3 below, shows figures with and without these large populations, and uses either JRF or AR figures.

Table 3: Number of children vaccinated with DPT3, 2001-2002

Source of information	2001	2002	Change between 2001&2002 (%)	Agreed target	Difference from Target (%)
JRF, all countries	48,278,673	43,634,952	-4,643,721 (9.6% decline)	43,146,583	488369 (1.1% above target)
AR, all countries	38,852,021	39,752,816	+900795 (2.3% increase)	43,146,583	-3,393,767 (7.9% below target)
JRF, without large poplns	13,581,080	14,148,744	+567,664 (4.2% increase)	14,939,288	-790544 (5.3% below target)
AR, without large poplns	13,539,032	14,091,179	+552,147 (4.1% increase	14,939,288	-848,109 (5.7% below target)

- Includes data from all 48 countries reviewed

Using the JRF data 23/48 countries (48%) show a decline in numbers of children vaccinated with DPT3 from 2001 to 2002 (range –98 to –5,682,040). The other 25 countries increased the numbers (range +17 to +579,406).

7. The problem most often mentioned by countries was related to funding issues, from delay of disbursement from the Vaccine Fund to the country as well as bottlenecks for distribution of funds within the country. Other frequently mentioned problems include the delay in the introduction of vaccines, cold chain deficiencies and storage capacity as well as lack of incinerators, insufficient human resources and conflict situations. Country specific problems can be found in attachment 2.

C. Major Issues

The goal of monitoring is to ascertain if programs are functioning and performing well to reach their objectives and targets.

For this specific program, in which countries are pursuing objectives and targets supported by GAVI and the Vaccine fund, where resources and vaccines are being provided, and rewards will be given against outcomes, the monitoring process has to rely on two main aspects: evaluation of the processes (related to measurement of coverage) and the impact of the program in terms of disease outcome (epidemiological surveillance).

At present, the measurement of coverage is hampered by several problems, including identification of population denominators, and poor performing information systems with unreliable reporting.

Epidemiological surveillance has not yet been addressed at a level that may be strengthened to give the Alliance a true measure of impact for disease reduction.

At this juncture, the IRC Monitoring Committee is faced with several issues that will have to be addressed if it is to fulfill its mandate:

1. One major problem that the IRC faces continues to be the discrepancies between the targets presented in the annual and inception reports and those previously approved. Nearly all countries presented different denominators and targets in these reports. The discrepancies between data reported in the Annual Report and that reported in the JRF still persists. This has an impact on both the reward system and in the supply of vaccines. As stressed in the last IRC Report, the committee emphasizes the need for the GAVI partners in country (particularly WHO and UNICEF) to check the figures in the annual report before they sign it as members of the ICC. The Committee notices that 10 countries did not present the minutes of ICC meetings.

Unfortunately, the letter from the Heads of WHO and UNICEF stressing this fact to their country representatives was sent only in September, 2003, 7 months after the Committee's recommendation.

The IRC should not be responsible to decide on the denominators presented by the countries. This function should be a responsibility of agencies such as WHO and/or UNICEF or other UN Agency in discussions with the national authorities.

2. GAVI and the VF do provide funding to support immunization services in more than 64 countries around the world, without any conditionality linked to it. The only basic requirement for the disbursement of funds is the existence of a "functioning ICC". Prior to receiving money from the VF, different types of ICC or coordinating bodies were put in place by the various recipient countries, with different Terms of Reference in different settings.

How to monitor the performance of these ICCs is a great challenge that the donor community and the partners will have to face in the near future, with problems such as vaccine supply shortage to difficulties in reaching marginalized groups and the need to improve deficient information systems. These obstacles should trigger action and support from the ICCs, in order for countries to be in a position to alleviate these constraints.

The only tool available at present to assess the functioning of the ICCs is the minutes of their meetings attached to the progress reports. The attached minutes of ICC meetings presented in these annual reports can be summarized as follows:

The main topics discussed by the ICCs were: approval of plan of action for 2003 and approval of the annual report for 2002. Only three countries out of 40 (6.6%) provided minutes that indicated discussion of the allocation of ISS funds received from the VF as requested in the annual report form.

Table 4 shows the status of countries as they comply with the reporting on the minutes of their ICC meetings for the year 2002:

COUNTRIES	**Minutes provided**	**ICC+ But No minutes**	**Nothing mentioned**
N=40*	**27(67.5%)**	**10(25%)**	**3(7.5%)**

48 countries reviewed
*Countries with ISS and/or DQA

3. In the January, 2003 Report, this Committee emphasized that the final impact of the GAVI/VF will be in the reduction of vaccine preventable diseases targeted by the national immunization programs. It was then suggested that epidemiological surveillance for these diseases be considered a major component of the initiative.

The priority given to this item in the 48 country reports does not give an indication that this issue has had priority in the period under review -1% of the ISS funds were reported to be used for this function.

4. The recommendation that the Working Group consider a policy with regard to the reward system when countries undergo conflict or natural disasters apparently has not been acted upon.

5. Many countries failed to provide clarifications or information that have been requested in previous reports. The IRC recommends that in such cases, in the future, the Secretariat continues the supply of vaccines or INS if country request is less than previously approved. If the quantities exceed previously approved, supply will be provided as previously approved unless full justification is provided with the request.

6. The IRC proposes to no longer use the previous decisions of Satisfactory, Satisfactory subject to clarifications or insufficient information – it will provide the Secretariat with recommendations for action.

7. For those countries that present a very high immunization coverage, depending on the situation in the country and other variables that may come to the attention of the IRC, the Committee may recommend that special surveys and additional surveillance data be presented to validate the numbers, even in the presence of an above threshold DQA. The GAVI Board may wish to consider, at the end of period of support, coverage surveys in all countries to ascertain the validity of the data.

Furthermore, it is the impression of the IRC that that the present process of conducting DQA does not build capacity in the country, with no legacy left behind. However, the principle of independent assessment should be maintained and it is suggested that in country agencies such as, universities and research institutions should be involved with the DQA and DQS processes.

8. A major issue observed related to the information on stock that may be available at the country level at the end of each year. This stock has an important bearing on the request of vaccine for the subsequent year. Therefore, the IRC recommends that special attention be paid at the country level - WHO or UNICEF country advisors should give support - to the identify current stock before the request is presented.

9. The IRC Monitoring Committee understands that there will be another team of the IRC to deal with the Financial Sustainability Plans (FSPs). The mandate for the FSP review team is to review the FSPs. However, countries are required to report on financial sustainability within the AR. It has been assumed that financial sustainability issues are to be analyzed by the FSP review team. FS information found in the progress report is not clearly part of the FSP team mandate.

IRC reports for this session need to include comments by the IRC on the financial sustainability section. This is particularly important for countries who submitted information following the review of their FSP (e.g. Mali). The IRC recommends that the Secretariat indicate to the countries that information on their FS activities sent with the current report will be sent after the FS Team meeting.

The impression is that there has been a positive response to demands for financial sustainability action and information. Development of Action Plans is encouraging but the limited analysis of the funding gap is a concern (see attachment 3).

It will be important that meetings of this new group be synchronized with the meetings of the Monitoring Group, ideally just before the meeting of the latter.

D. The functioning of the IRC Monitoring and Evaluation Team:

Recommendations emanating from this Review

The IRC Monitoring Team remains disconcerted with the current monitoring process. Based in Geneva, and with no contact with the field, there is a gulf between its recommendations which can have a serious impact on the national immunization programs, and the Monitoring Team understanding of the realities in the country. As a consequence, the current format of IRC work is too remote from the field and the Committee is not able to perform a thorough evaluation of country programs. The implications of this include both the quality of the Team's decision-making and the credibility of its decisions.

As a result, after three meetings, the IRC Monitoring Team feels its contribution to the monitoring process of GAVI, and feedback to the countries has serious limitations and the potential for the its full potential to improve the GAVI process is not being realized. To overcome this, the IRC Monitoring Team believes it is imperative to close the gap between itself and the countries.

Although there is improvement in the annual reports of some countries, the majority of countries continue to fail to provide a report with adequate information for a true assessment of progress towards the objectives of the program. This may be a result of continuous lack of engagement of ICC and country advisors from WHO and UNICEF and lack of understanding of program managers in filling the format of the report.

Furthermore, the format now available does not give the opportunity for a true identification of problems and does not provide a work plan for the next period, with identification of activities aimed at solving problems and improving the program, with the identification of costs and responsibilities.

It is therefore suggested that the process for the monitoring and evaluation provides an opportunity to the IRC to dialogue with country managers for a more appropriate feeling of the real situation in each country and a better assessment of the program.

A methodology to address this issue could be the organization of sub-regional meetings with the national program managers, RWG members, selected ICC members, IRC members, the Secretariat and other key players.

Such a meeting would be a workshop in which program managers would be divided in small groups and their annual report on past activities and next year work plan would be analyzed and criticized by the participants in each group. This will require a proactive involvement by IRC members and active participations by WHO, UNICEF and members of the RWG.

This meeting is not to be a regular EPI Mangers Meeting as actually happening, but a workshop for review of reports and preparation of annual work plans.

Such meeting would also have the advantage of cross fertilization and capacity building, with managers learning from each other.

Country Annual Reports would be sent as usual to GAVI Secretariat, following the established guidelines. and after the preparation of background documentation, pre-assessment and other Secretariat functions, such as the background preparation for the IRC Monitoring Committee members (background information for all sections -now scattered in various places - should be provided by the secretariat in a template for the IRC country report (see attachment 4).

Three meetings would be organized at sub-regional level for analysis and discussions between IRC Monitoring Committee members, Program Managers, RWG, ICC members and others.

The 68 countries would be divided in three groups for participation in these meetings which would take place in three different locations in the same week, with three-day duration. Three members of the IRC Monitoring Committee (considering a Committee with 9 members) would participate in each of these meetings to dialogue and discuss the reports and plans with the program managers, RWG and ICC members and others.

At the end of these meetings the country managers would review their reports and plans to be forwarded to GAVI Secretariat within four weeks of the ending of the meeting and the IRC Monitoring Committee members would meet in Geneva -3 to 4 days -for a final decision on the reports and plans.

E. The IRC Monitoring Committee is very pleased with the decision of the Board to have the next round of reviews July 2004, and hopes that the methodology suggested above is accepted.

The IRC Monitoring Committee believes that such approach will greatly enhance the quality of the monitoring and in turn will also have a very positive impact in capacity building and active participation of the various actors involved in the technical cooperation aspects of this initiative.

* *Attachments mentioned in this summary are available upon request through the GAVI Secretariat*

ANNEX I: Country Specific Recommendations

1	**AFGHANISTAN**	**General Recommendation:** Satisfactory report **Specific recommendations:** **INS**: to receive INS support as originally approved in June 2003 **ISS:** to receive the third investment of investment
2	**ALBANIA**	**General Recommendation:** Satisfactory report **Specific recommendations:** **INS**: to receive INS support as per originally approved in June 2003 **NVS**: to receive Hep B vaccine as per request
3	**AZERBAIJAN**	**General Recommendation** Satisfactory report subject to clarification **Specific recommendations** **INS:** to receive INS support as per request **ISS:** the country to submit an estimate of the number of children aged less than one year who were vaccinated with DTP3 in 2002. The rewards for 2002 will be calculated accordingly **NVS**: to provide the ratio of 10 and 20 doses vial, meanwhile Hep B vaccine will be provided as per request for 2004 with the same ratio as in 2003 **From the secretariat: Clarifications have been provided and were found satisfactory**
4	**BANGLADESH**	**General Recommendation:** Satisfactory report **Specific recommendations:** **INS:** to receive INS support as per previously approved **ISS:** to receive the third investment of investment **NVS:** to receive Hep B vaccine as per request
5	**BENIN**	**General Recommendation:** Satisfactory report **Specific recommendations:** **NVS**: to receive Hep B and YF vaccines as per request

6	**BHUTAN**	**General Recommendation:** Satisfactory subject to clarification **Specific recommendations:** **INS:** to receive INS support as originally approved **NVS:** vaccine delivery will be postponed unless satisfactory clarifications are provided: - Justification for the change in population figures and targets - Situation of the current stock of DTP-HepB by the end of 2003 considering the - delayed introduction and previous shipments
7	**BOSNIA HERZEGOVINA**	**General Recommendation:** Satisfactory report **Specific recommendations:** **NVS:** to receive Hep B vaccine as per request
8	**BURKINA FASO**	**General Recommendation:** Satisfactory subject to clarification **Specific recommendations:** **INS:** to receive AD syringes and safety boxes for measles and DTP as per request and for BCG and TT as per previously approved unless satisfactory clarifications are provided on the number of surviving infants and realistic targets (BCG and TT) for 2004 onwards **ISS:** not to get rewards for 2002 because of unsuccessful DQA
9	**BURUNDI**	**General Recommendation** Satisfactory report **Specific recommendations** INS**: to receive INS support as per request** **ISS:** to receive the third investment of investment **NVS:** to receive DTP-Hib and Hep B as per request
10	**CAMBODIA**	**General Recommendation:** Satisfactory report subject to clarification **Specific recommendations:** **INS**: to receive INS support as per request except TT as per previously approved unless the country provide - satisfactory clarifications on the increased TT target for 2004 - commitment from the new donor to provide AD syringes for TT and measles, and safety boxes for all antigens. ISS**: to receive the third investment of investment split in two payments as requested** **NVS**: to receive DTP-HepB as per request (less than previously approved)
11	**CAMEROON**	**General Recommendation:** Satisfactory report **Specific recommendations:** **INS**: to receive INS support as per request for 2004 ISS: **will not receive rewards due to unsuccessful DQA in 2002** **NVS:** to receive YF vaccine as per originally approved in June 2003
12	**CAR**	**General Recommendation:** Satisfactory report **Specific recommendations:** **INS:** to receive INS support as per request **ISS**: to receive the second investment of investment **NVS**: to receive YF vaccine as per request
13	**CONGO DR**	**General Recommendation** Satisfactory report **Specific recommendations** INS: **to receive INS support as per request** **ISS:** to receive the second investment of investment **NVS:** to receive YF vaccine as per request

14	**COTE D'IVOIRE**	**General Recommendation:** Satisfactory report **Specific recommendations:** ISS**: no rewards for 2002 because of unsuccessful DQA** **NVS:** to receive DTP-HepB as per originally approved
15	**ERITREA**	**General Recommendation:** Satisfactory report **Specific recommendations:** **INS:** to receive INS support as per request ISS**: to receive the third investment of investment** NVS**: to receive DTP-HepB as per request for 2004**
16	**GAMBIA**	**General Recommendation:** Satisfactory report subject to clarification **Specific recommendations:** **INS:** to receive INS support as per request ISS**: to receive the third investment of investment** NVS: **to receive DTP-Hib as per request. This support will adjusted if the country wishes to revise its targets for DTP-Hib and Hep B to be the same**
17	**GEORGIA**	**General Recommendation:** satisfactory report **Specific recommendations:** **INS**: to receive INS support as per request for 2004 **ISS:** to receive the third investment of investment **NVS:** to receive Hep B vaccine as per request
18	**GHANA**	**General Recommendation:** Insufficient information **Specific recommendations:** **INS:** the first shipment of injection safety materials will be provided based on previously approved targets. Subsequent shipments will NOT be sent unless clarifications are provided : - a request must be provided, based on clarified targets. **ISS:** to receive rewards for achievement in 2002 **NVS**: to receive the first shipment of DTP-Hep B+Hib vaccine based on previously approved 2004 targets, subsequent shipments will not be sent unless clarifications are provided on - Targets for 2003 – 2006, these should take into account previous achievements. - A revised request for NVS must be submitted based on those targets. **From the secretariat: Clarifications have been provided and were found satisfactory**
19	**GUYANA**	**General Recommendation:** Satisfactory report **Specific recommendations:** **NVS**: to receive DTP-HepB + Hib as per request for
20	**HAITI**	**General Recommendation:** Satisfactory subject to clarifications **Specific recommendations:** **ISS:** the country will not get rewards for 2002 because of unsuccessful DQA and low performance. The country is requested to provide the following clarification: - provide realistic targets for DTP3 for 2003 and onwards taking into account actual achievements

21	**INDIA**	**General Recommendation:** Satisfactory report **Specific recommendations:** **NVS:** to submit an application for further support in 2004
22	**INDONESIA**	**General Recommendation:** Satisfactory report **Specific recommendations:** **INS:** to receive INS support as requested **ISS**: to receive the second investment of investment **NVS:** to receive Hep B Uniject
23	**KYRGYZSTAN**	**General Recommendation** Satisfactory report **Specific recommendations** **INS:** to receive INS support as per request **NVS**: to receive Hep B vaccine as per request
24	**LAO PDR**	**General Recommendation:** Satisfactory report **Specific recommendations:** **INS**: to receive INS support as per request for 2004 **ISS:** to receive the third investment of investment **NVS:** to receive DTP-HepB as per request for 2004
25	**LESOTHO**	**General Recommendation:** Satisfactory report **Specific recommendations:** **INS**: to receive INS support as per request **ISS:** to receive the third investment of investment **NVS**: to receive Hep B vaccine as per request
26	**MADAGASCAR**	**General Recommendation:** Satisfactory report **Specific recommendations:** **ISS**: not to receive rewards because of unsuccessful DQA and low performance in 2002 **NVS**: to receive DTP-HepB as per request
27	**MALAWI**	**General Recommendation:** Satisfactory report subject to clarification **Specific recommendations:** **NVS:** to receive the first shipment of DTP-Hep B+Hib vaccine as per previously approved, further supply will be delayed until satisfactory clarifications are provided on - targets for children to be immunized and wastage targets for 2005 onwards - stock of vaccine at the end of 2003 considering previous achievements
28	**MALI**	**General Recommendation:** Satisfactory subject to clarification **Specific recommendations:** INS**: to receive INS support as per request** **ISS:** to receive rewards for 2002 achievements **NVS:** - to receive Hep B vaccine as previously approved unless satisfactory clarifications are provided for increased request for 2004 - to receive YF vaccine as per request

29	**MOLDOVA**	**General Recommendation** Satisfactory report **Specific recommendations** **NVS:** to receive Hep B vaccine as per request
30	**MOZAMBIQUE**	**General Recommendation:** Satisfactory report **Specific recommendations:** **INS:** to receive INS support as requested **ISS**: not eligible for rewards because of unsuccessful DQA in 2002 **NVS:** to receive DTP-HepB as per request for 2004
31	**MYANMAR**	**General Recommendation:** Satisfactory report **Specific recommendations:** **INS:** to receive INS support as per request **ISS:** to receive the third investment of investment **NVS**: to receive Hep B vaccine as per request
32	**NEPAL**	**General Recommendation:** Satisfactory report subject to clarification **Specific recommendations:** **INS:** to receive as per previously approved unless satisfactory justification are provided on increased targets for 2004 and onwards **ISS:** to receive the third investment of investment **NVS**: : to receive Hep B vaccine as per previously approved unless satisfactory clarifications are provided on increased targets
33	**NIGER**	**General Recommendation:** Satisfactory report **Specific recommendations:** **ISS:** to receive the third investment of investment.
34	**PAKISTAN**	**General Recommendation:** Satisfactory report **Specific recommendations:** **INS:** to receive INS support as per request **ISS**: to receive rewards for 2002 achievement **NVS**: to receive Hep B vaccine as per request
35	**RWANDA**	**General Recommendation:** Satisfactory report subject to clarification **Specific recommendations:** **INS:** to receive INS support as per request **ISS:** to receive rewards for achievements in 2002 **NVS:** to receive the first shipment of DTP-Hep B+Hib vaccines for 2004 as per Request. Subsequent shipments will NOT be sent unless realistic targets are provided for 2004 onwards

36	**SAO TOME**	**General Recommendation** Insufficient information **Specific recommendations** **INS**: to receive a first shipment of INS support using the revised targets provided in table2 of the progress report, no further shipments will be sent unless a satisfactory request is provided **ISS**: no rewards due to low performance in 2002 **NVS**: to receive Hep B vaccine as per request ,shipment of YF will be made according to measles target for 2004 unless satisfactory clarifications are provided on the revised request and the change in vial size
37	**SENEGAL**	**General Recommendation**: Satisfactory report **Specific recommendations:** **INS**: as per request **ISS**: to receive the third investment of investment **NVS**: to receive DTP-Hib and Hep B as per request
38	**SRI LANKA**	**General Recommendation:** Satisfactory report **Specific recommendations:** **INS:** to receive INS support as per request **NVS**: to receive Hep B vaccine as per request
39	**SUDAN**	**General Recommendation:** Satisfactory report **Specific recommendations:** **INS**: to receive INS support as request **ISS:** to receive the third investment of investment
40	**TAJIKISTAN .**	**General Recommendation:** Satisfactory report subject to clarification **Specific recommendations:** **ISS:** the country to submit an estimate of the number of children aged less than one year who were vaccinated with DTP3 in 2002. The rewards for 2002 will be calculated accordingly **NVS**: to receive Hep B vaccine as previously approved unless satisfactory clarifications are provided on changes in targets for 2004 onwards
41	**TANZANIA**	**General Recommendation:** Satisfactory report **Specific recommendations:** **INS:** to receive INS support as per request **ISS**: to receive rewards for achievements in 2002 **NVS:** to receive DTP-Hib as per request for 2004
42	**TOGO**	**General Recommendation** Satisfactory report **Specific recommendations** **INS:** to receive INS support as per request **ISS:** to receive the second investment of investment **NVS:** to receive YF vaccine as per previous approval
43	**TURKMENISTAN**	**General Recommendation:** Satisfactory report * **NVS:** to receive Hep B vaccine as per request however the country is urgently requested to inform of the number of 1 and 10 dose vials remaining in stock to permit the calculation of next shipments

44	**UGANDA**	**General Recommendation:** Satisfactory report **Specific recommendations:** **INS:** to receive INS support as per request **ISS**: to receive rewards for achievements in 2002 **NVS:** to receive DTP- Hep B-Hib as per request
45	**VIETNAM**	**General Recommendation:** Insufficient information **Specific recommendations:** **INS**: the INS support (equivalent amount of cash) will be postponed until a satisfactory request using standard GAVI format is provided. **NVS**: to receive INS support as per request
46	**YEMEN**	**General Recommendation:** Insufficient information **Specific recommendations:** **INS**: to receive the third investment of investment **ISS:** the country should provide new and realistic targets of infants to be vaccinated with DTP-Hep B+Hib **NVS**: to receive INS support as requested
47	**ZAMBIA**	**General Recommendation:** Satisfactory report **Specific recommendations:** INS: **to receive INS support as per request for 2004** **ISS:** to receive the third investment of investment **NVS:** to receive DTP-Hib as per request
48	**ZIMBABWE**	**General Recommendation:** Insufficient information **Specific recommendations:** **INS:** to receive as per request **ISS:** third investment to be available when satisfactory clarifications are provided on number of births, surviving infants and target infants for DTP3 vaccination **From the secretariat: Clarifications have been provided and were found satisfactory**

The GAVI Secretariat and The Vaccine Fund Management: Launching a path toward convergence

Background

At the GAVI Executive Committee meeting on 29 October 2003, two interconnected strategic issues were discussed:

1. The long-term vision for GAVI that would best leverage the full potential of the Alliance - Should GAVI expand its focus outside of those projects which directly relate to The Vaccine Fund? Or, should the use of Vaccine Fund resources be expanded?
2. A closer working relationship between the GAVI Secretariat and The Vaccine Fund Management.

An EC member will initiate discussion on the first issue at the December GAVI Board meeting. The second issue is the topic of this paper.

Rationale

From the very beginning there has been a strong overlap between the objectives of GAVI and The Vaccine Fund, and therefore the focus of the work of the relevant staff. However, it was felt that a separately run GAVI Secretariat and Vaccine Fund management would provide an efficient 'check and balance' on resources raised and disbursed.

With the benefit of experience, it has now become apparent that the separation of responsibilities has not allowed an optimization in the efficiency of operations. Therefore an emerging view is that a revision of the model may be appropriate. In addition, the Executive Secretary of GAVI will be retiring at the end of 2004; it makes sense to use this opportunity to review the current circumstances and potential changes.

In the presentation to the EC by the Executive Secretary of GAVI and the President of The Vaccine Fund, three stages of convergence were considered:

1. Common strategy – agreement on main areas of work, two work plans
2. Unified management – one leader, one work plan
3. Complete merger – one leader, one work plan, and one governing board.

1. Common strategy

We believe that we have gone far towards developing a common strategy. The GAVI Strategic Framework includes long-term financing and recapitalization of the Vaccine Fund. GAVI Secretariat and Vaccine Fund staff communicate regularly on strategic issues. Essentially we feel that this level of co-ordination is the current status quo with the possibility of some limited improvements.

2. Unified management

The key tasks of the GAVI Secretariat and the Vaccine Fund Management have been set out in the Strategic Framework. It is very clear that in its primary mission The Vaccine Fund depends on the GAVI Secretariat in relation to fund-raising as well as accountability for the use of its resources. Similarly The

Vaccine Fund has a key role to play in relation to advocacy, procurement and securing long-term supply of appropriate vaccines (see Annex 1)

Co-location of the GAVI Secretariat and Vaccine Fund Management on the same premises could greatly facilitate the necessary communication and coordination and therefore increase efficiency and effectiveness. Putting the two bodies under one leader would ensure such gains. On the contrary, if the two bodies were kept separate under different leadership it could threaten the excellent collaboration between the two current leaders. This would imply relocation of one of the two teams.

There are strong advantages of having the GAVI Secretariat located within a UN Agency such as UNICEF as it facilitates communication, financial transfers with countries as well as the advantages accrued from having full diplomatic privileges. While Lyon has a WHO Branch and The Vaccine Fund's new premises, Geneva has the added value of close proximity to WHO Headquarters with its full range of expertise; and diplomatic missions often with a Health Attaché. If arrangements could be made whereby The Vaccine Fund would also be located in a close managerial relation with a UN agency then such benefits would also extend to Vaccine Fund management. However, it would be unreasonable to believe that this could be done without financial compensation and therefore a managerial agreement would need to be developed between The Vaccine Fund, as an independent legal entity, and the host UN agency.

Further, a unified management would allow opportunities for efficiency gains in several areas:
1. Program management and planning
2. Operations
3. Communications
4. Resource mobilization

If unified management, including co-location, would be pursued it would be important to ensure the independence of The Vaccine Fund as well as the role of the GAVI Secretariat in ensuring the added value of the Alliance as outlined in the Strategic Framework.

3. Complete merger

A complete merger would entail combining the governance structures. The Vaccine Fund is required to have an independent Board in order to keep its tax-free status in the United States, which has a substantial financial benefit. Therefore we recommend at this stage to keep governance separate with a Vaccine Fund Board primarily focusing on fund-raising and a GAVI Board focusing on policy issues and continued functioning of Alliance participation and leadership.

However one could explore back-to-back meetings of the two Boards and the two Executive Committees.

A complete merger could be considered at a later stage.

The Time Frame

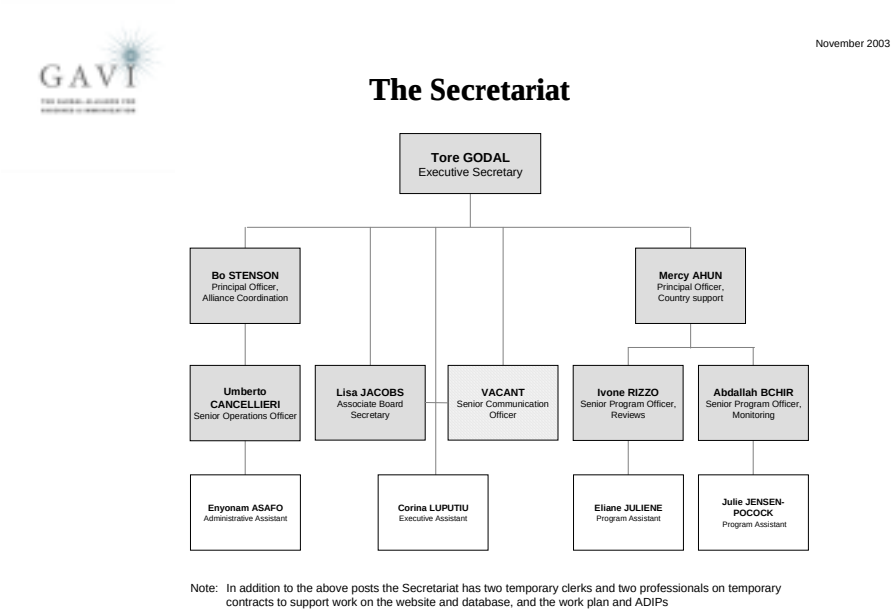
The Executive Secretary of GAVI will retire at the end of 2004, and an open search process is envisioned to find his replacement. Thus if the GAVI and Vaccine Fund Boards agree to move toward unified management, the decision would need to be made before the end of this year, considering the time required to conduct a successful search.

Alignment of GAVI and Vaccine Fund priorities

GAVI priorities for 2004-05	Importance of Vaccine Fund staff involvement
Health information and monitoring systems for action	+++
Contributing to alleviation of system-wide barriers	++
Enhanced efforts in large population countries	++
Procurement / Supply of existing products	+++
Development and introduction of new, near-term products	+++
Managing the process for country support from The Vaccine Fund	+++
Financial sustainability	+++
Recapitalization of The Vaccine Fund	+++
Setting priorities	+++
Monitoring progress	+++

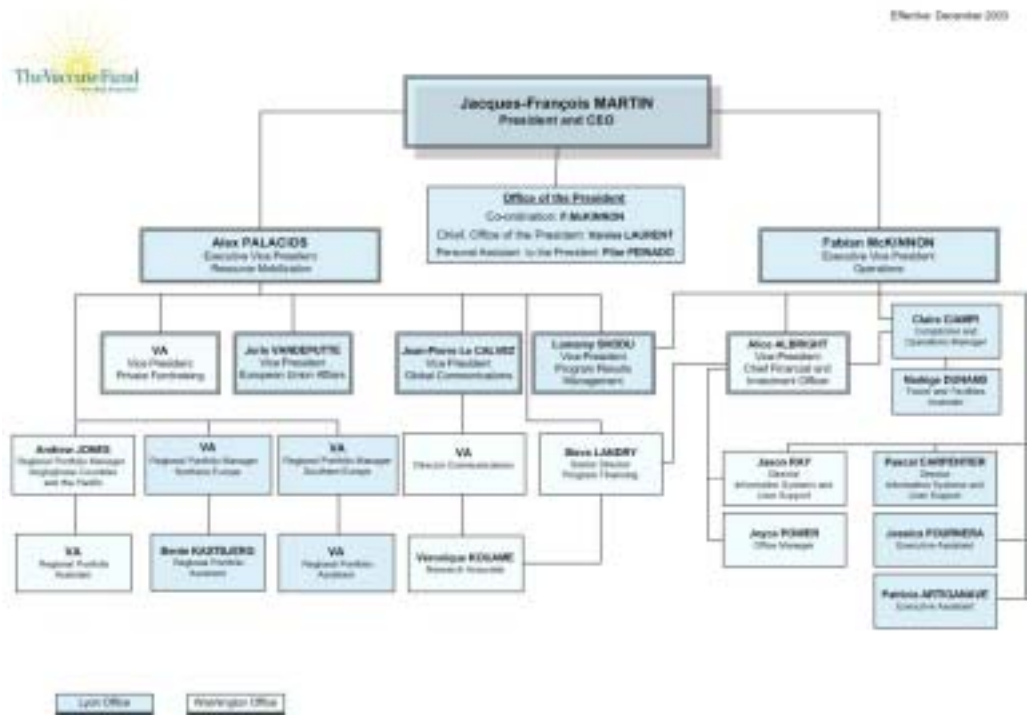
Vaccine Fund strategic objectives for 2002-2006	Importance of GAVI Secretariat staff involvement
Mobilize resources to achieve immunization sufficiency and sustainability	+++
Achieve visibility of The Vaccine Fund so as to secure support for its mission	+++
Manage the Vaccine Fund for efficiency and accountability for results	+++
Ensure with GAVI partners a secure supply of all relevant vaccines that are accessible to all target countries	+++

GAVI Secretariat Organogram



Note: In addition to the above posts the Secretariat has two temporary clerks and two professionals on temporary contracts to support work on the website and database, and the work plan and ADIPs

Vaccine Fund Organogram



The Vaccine Provision Project (VPP)
Lessons learned from the Pilot Phase July 02 – October 03

Draft 29 Nov 03
Under Institutional Review

Executive Summary

This paper summarizes the outcomes and the lessons learned in the second round of vaccine forecasting and procurement organized by the Global Alliance for Vaccines and Immunization (GAVI) for countries eligible for support from The Vaccine Fund.

It has been prepared by Paul Richard Fife[1] in consultation with the institutions tasked by the GAVI Board to pilot the coordinated planning and execution of forecasting and procurement of Vaccine Fund supported vaccines for 2004-06 through the Vaccine Provision Project (VPP), i.e. UNICEF, WHO and The Vaccine Fund, with support from the GAVI Secretariat.

Project background and justification

The GAVI Board established the Vaccine Provision Project in June 2002 based on an in-depth analysis of the global vaccine market and a review of the lessons learned in the first round of GAVI procurement in 2000[2]. Key recommendations endorsed by the Board were as follows:

- Given GAVI's strategic objectives of accessing new products early and obtaining affordable pricing, the GAVI alliance should seek to maintain/enhance large multinational supplier engagement and expand the number of economically viable and high quality emerging suppliers by providing for appropriate returns, creating credible and predictable demand (in part through firm contracting) and working in a collaborative and open fashion with suppliers.

- In light of the shortcomings and inefficiencies observed during the first round of procurement, the alliance should adopt a multi-disciplinary project management approach to forecasting and procurement across program, supply and finance and pilot this with the GAVI forecasting and procurement for 2004-06, with WHO responsible for program issues, UNICEF Supply Division for supply issues, The Vaccine Fund for finance issues, and responsibility for overall coordination and accountability vested in a project manager located in UNICEF Program Division (to retain a strong program focus WHO and UNICEF PD were provided as options).

[1] Sr. Health Advisor and VPP Project Manager in UNICEF PD/Health Section until July 2003
[2] Lessons Learned: New Procurement Strategies for Vaccines, Mercer Management Consulting, 28 June 2002

Main outcomes

Offers

43 products were offered from emerging suppliers and from US and Europe based multinationals. This confirms that GAVI has been successful in stimulating the projected entry of new manufacturers in the production of hep B, Hib and Yellow Fever vaccines for low-income countries, in particular DTP-hep B. Provided efforts are maintained, this will stimulate competition and lead to price pressure as more suppliers enter the market and products mature.

GAVI/Vaccine Fund procurement 2004-06: Summary of Offers

Product	***Number of offers***	***Number of WHO pre-qualified products***	***Number of non WHO pre-qualified products***
hep B	*13*	*6*	*7*
hep B uniject	*4*	*0*	*4*
Hib	*4*	*2*	*2*
DTP-hep B	*11*	*1*	*10*
DTP-hep B+Hib	*4*	*1*	*3*
DTP+Hib	*1*	*1*	*0*
Yellow Fever	*4*	*2*	*2*
Total	*41*	*13*	*28*

Source: UNICEF SD

Awards 2004-06

While awards were originally scheduled to be finalized in June 2003, awards for the full period 2004-06 have as of mid-November 2003 not been issued and made public.

- To date The Vaccine Fund Executive Committee has given its financial approval for the procurement of combination vaccines for the period 2004-06 for already approved countries. These quantities are firmly contracted and represent an estimated total value of US$281.3 million.

- Subject to parameters of the Five Year Supply Approval policies approved by GAVI and The Vaccine Fund in June 2003, financial approval has been given for all monovalent products for 2004-06 representing an estimated total value of US$145.4 million.

- Procurement arrangements for combination vaccine for countries that plan to switch products or that are not yet approved are still outstanding and not secured following the request from the Vaccine Fund Executive Committee to not lock into this option and to explore alternatives.

Procurement arrangements for 2004 have been completed in order to secure timely vaccine delivery. Concerned suppliers have being kept abreast of the situation.

Vaccine prices

The price of monovalent hep B continued to decrease in this procurement cycle, with weighted average price per dose decreasing from $0.32 in 2003 to $0.28 in 2004, and to $0.26 in 2006. This represents a decrease of 19% between 2003 and 2006.

Prices for DTP-based combination vaccines increased in this procurement round, with a price jump between 2003 and 2004 of 10% for DTP-hep B+Hib and of 27% for DTP-hep B. Compared with 2001, dose prices in 2006 will increase from $3.50 to $3.60 (i.e. 3%) for DTP-hep B+Hib, and from $1.10 to 1.29 (i.e. 15%) for DTP-hep B.

Overview of volume quantity and price of vaccines 2004-06

		2004	2005	2006
DTP-hep B	Quantity	11,834,800	15,615,550	44,500,000
	Price	$1,21	$1,25	$1.29
DTP-hep B+Hib	Quantity	15,942,956	33,384,448	37,950,000
	Price	$3.65	$3.60	$3.60
hep B	Quantity	42,400,000	35,500,000	16,000,000
	Price	$0,28	$0,26	$0,26

Quantity: Quantities delivered in 2001-2003 and forecasted 2004-2006
Price: US$ per dose, weighted average price for hep B
Source: UNICEF Supply Division

The price increase is a significant setback and constitutes at least in the near-term a significant challenge for countries and their global partners.

Apparent causes for this increase are the accelerated recouping of investments costs (principally investment into new production facilities but also of original costs), the significant strengthening of the euro against the US dollar since 2001 when initial prices were set, and supplier pricing strategy (multinational manufacturers typically offer low volumes at relatively high price and chose to exit the market as emerging suppliers enter with larger volumes and lower priced products).

Regarding Hib-containing products, analysis of all offered products indicates that the price of Hib is high compared with the basic pediatrics, but not unreasonably high at this point in time, considering estimated production and regulatory costs, price differences between multinational and emerging suppliers for other basic vaccines, and historical experience. Hib prices are comparable across products and across manufacturers, and the price obtained is also comparable with the one recently obtained by the Pan-American Health Organization (PAHO).

The prices obtained for combination vaccines in this procurement highlight the dependency of pricing on product lifecycle and maturity. Despite considerable supplier movement, the combination products preferred by countries became commercially available specifically for GAVI and are still early in their lifecycle.

Significant and sustained price reductions are not likely to be seen until competition has been established. This will occur earlier for DTP-hep B than for DTP-hep B+Hib, which is a more complex vaccine to produce. Two additional producers of DTP-hep B could be expected to enter the market with pre-qualified products nearing 2006 and product maturity is expected to be seen in 2007-09.

Application of recommended procurement strategies

The procurement strategies recommended in the Mercer report were to a large extent applied in this round of procurement:

- Awards have been designed to seek to enhance the supply base with multiple manufacturers for each product type, engaging both multinational and emerging suppliers. Nine product presentations (4 hep B in different dose sizes, 1 DTP-hep B, 1 DTP+Hib, 1 DTP-hep B+Hib, 2 Yellow Fever in different dose sizes) will be contracted from 8 manufacturers (3 multi-nationals and 5 emerging), based in Belgium, Brazil, Cuba, France, India, South Korea and the United States of America.

- Though permanent demand is not yet in place, considerable progress has been made towards establishing credible and predictable demand. A product-specific forecast for Vaccine Fund support vaccines was established despite severe time constraints and used in the tender, and systems for maintaining the forecast and communicating changes with suppliers have been established. The accuracy of the forecast will be tracked during implementation in 2004-06.

- Firm contracting, seen as proof of the commitment to share risks, helped in this round to leverage some price concessions for DTP-hep B and DTP-hep B+Hib vaccine. So far, around 40% of the total vaccine value in the round is scheduled for firm contracting. The prevailing monopoly situation for combination vaccines with several buyers vying for limited supply may have limited in this round the value of firm contract on price and volume concessions, and was seen as most useful in assuring supply availability.

- Manufacturer movement and interest may be seen as indication that appropriate returns have been provided for suppliers.

- Though there is still discussion among the partners on how best to engage manufacturers, collaboration and communication with manufacturers improved compared with the first round with access to the forecast and clearer lines of communication.

Project execution

It is important to recognize that the VPP was a pilot effort and something that had never been done before at least in this fashion, and that it was challenged by real time constraints, a maturing alliance that was learning as it worked and unforeseen external factors such as the pentavalent supply crisis. This was compounded by difficulties caused by staff transition, the US based location of the project manager, and the absence of senior staff from the executing agencies on the Oversight Committee.

The VPP pilot confirmed the usefulness and benefits of working in a coordinated manner across the areas of program, supply and finance. With the addition of the GAVI Secretariat, team composition was found to be appropriate with relevant disciplines and partners represented on the team.

The project management approach allowed for better communication among partners, helped to make headway in defining institutional accountabilities, and was instrumental in improving collaboration across institutions and across disciplines. It was especially beneficial at the start of the project and it is doubtful that a product-specific forecast would have been available for use in the tender without the use of a project management approach.

However, shortcomings and inefficiencies were experienced related to project management and control, in particular in the final stages of the project leading to "slippage" in finalizing the procurement. This needs to be considered seriously as the alliance takes stock of the situation and decides on the way forward.

The main causes for these inefficiencies may be attributed to:

- Inherent institutional resistance to a project management model, with institutional lines of authority and communication not supporting or not compatible with project management requirements. This includes accountability of team members to the project manager, project manager authority to direct the work of others, and partner access to information and participation in decision-making processes. Though the team members to the most extent worked well together and the project management model allowed for some flexibility, representation by individuals may not have replaced the strength that can be provided by more formal institutional representation and may also have reduced institutional ownership.

- Failure to appropriately identify in advance potential obstacles, set and sequence milestones in particular for new steps and work processes, and allow for enough time to address unanticipated challenges. Again it should here be emphasized that it was the first time many of these processes were undertaken, and that future activities will gain from the experiences gained in the pilot.

- Residual ambiguity around partner roles and responsibilities, and failure to effectively address partner differences. This ambiguity led to inefficiencies that could have been minimized by addressing partner expectations and concerns at an earliest possible stage of the project.

Looking ahead, issues of strategic importance

Seek to decrease the price of combination vaccines as early as possible through increased competition

Significant price reduction for combination vaccines is not likely to be seen until competition is established. GAVI partners should ensure that conditions remain favorable and stimulate competition in the period leading up to the next round of procurement. Current prices for combination vaccines should serve as solid incentives for suppliers.

The GAVI Board should encourage WHO to establish the necessary capacity to enable timely processing of requests for prequalification of new products, so that suppliers can complete vaccine development and pre-qualification processes and be considered for awards.

Firm up demand for Hib-containing vaccine

While demand for hep B and DTP-hep B vaccines is on track to become as established as for the traditional EPI vaccines, demand for Hib-containing vaccine is at critical risk due its relatively high price and the financing gap in the post-Vaccine Fund period. Successful Hib vaccine introduction is critical not only for the credibility of GAVI but also for the credibility of future vaccine introduction initiatives.

WHO and other GAVI partners should continue their efforts to support countries in assessing the appropriateness and the program readiness for introducing Hib-containing vaccines, taking into account the supply situation, financial sustainability and other program priorities.

It is encouraging to see that several countries are taking steps towards phasing in locally-mobilized resources as Vaccine Fund support nears its end. GAVI partners should continue to support country efforts including the implementation and realization of national financial sustainability plans.

GAVI and The Vaccine Fund should as part of their strategic planning for 2005-2015 explore ways of addressing the financing gap for currently supported vaccines. Extending support to products still early in their lifecycle may be an option to consider in order to firm up demand until competition is established and more affordable pricing has been achieved.

In view of the DTP-hep B+Hib supply constraints, countries wanting to introduce Hib vaccine may wish to consider alternative Hib-containing products (monovalent Hib, DTP+Hib). Though this in itself would not contribute to increase competition for DTP-hep B+Hib vaccine, it would help accelerate the use of Hib vaccine, protect more children from Hib disease and reduce dependency on one single product. It should be emphasized however that such decisions need to be made by countries themselves.

Recommendations

Scope of activities 2004-05

1. As already reflected in the draft GAVI work plan for 2004-05, efforts of the Alliance should be structured around two main areas of work:

   (a) A primary focus on risk management at global level of hep B, Hib and Yellow Fever vaccine introduction.

With the majority of Vaccine Fund eligible countries well underway with the introduction of newer vaccines, and with a US$570 million procurement plan for 2004-06 soon in place to support this effort, the need to effectively manage vaccine provision at global level is critical. In particular, the alliance needs to have the capacity to detect and act when problems or changes related to program implementation, supply or funding arise, such as new approvals, changes in supply availability, or funding shortfalls.

At global level, a risk management approach grounded on close monitoring of vaccine provision performance across the areas of program, supply and finance would provide significant “added value” to the efforts of any single agency, and would increase the likelihood that changes in any area are known to and appropriately addressed in the other areas.

Such a risk management approach would benefit from building on the experiences and the tools and processes established through the VPP and would be characterized by the establishment of key monitoring parameters, individual partner accountabilities, effective modes of communication and collaboration between partners, and metrics to measure progress and performance.

   (b) Medium-term planning, in particular extending the period of the current forecast and preparing for the next round of GAVI procurement.

In order to track evolution of demand and contribute to the longer-term provision of currently Vaccine Fund supported vaccines, the current 2004-06 forecast would benefit from being extended so that it reflects new approvals and changes in country uptake and in supply availability. This forecast will also form the basis for issuing the next tender and maintaining it will increase its quality and prevent the time rush experienced in this round of procurement. It is recommended that WHO, together with UNICEF and The Vaccine Fund, establish

specifications for a medium-term forecast including timeframe (possibly a rolling forecast looking 5-7 years ahead), partner accountabilities, periodicity of maintenance and ways of sharing it with suppliers and other interested parties.

By starting to plan early for the next round of procurement, GAVI has an opportunity to avoid the time pressure experienced in the first two rounds of procurement and to address the constraints experienced in this last round. Given the complexity of the exercise and the importance of reaching partner consensus on strategies, work processes and respective accountabilities *before* implementation starts, it is recommended that the plan for the next round of procurement be prepared for GAVI Board consideration in early 2005. Building on the experiences from this procurement and considering the market situation, elements to be considered include recommended time span for the next tender; timelines, milestones and indicators; and detailed partner assignments and accountabilities. Accountable focal persons in each institution should be identified as well as institutional oversight mechanisms.

Organizational set-up and implementation

2. Provided that the above recommended areas of work are endorsed, it is recommended that the alliance retain a multi-disciplinary approach to planning and implementation across program, supply and finance, and assign global execution responsibilities in 2004-05 to the same team of partners, i.e. UNICEF, WHO, The Vaccine Fund, with support from the GAVI Secretariat, with the following areas of responsibility:

Responsibility areas for work plan implementation 2004-05

Scope areas	WHO	UNICEF SD	The Vaccine Fund	The GAVI Secretariat
Risk management for hep B, Hib and YF vaccine introduction	Country forecast	Supply delivery	VF funding	Country funding
Medium-term planning (extension of the forecast, preparation for next round of procurement)	Country forecast	Vaccine availability, pipeline products	VF funding	Country funding

3. Review the membership, terms of reference and consider changing the set-up of the Oversight Committee

It is critical that senior staff from implementing agencies be included to assure a high level of institutional accountability and ownership. There may also be scope to include 1-2 subject matter experts relevant to the task at hand in a supportive advisory role to the Board members serving on the committee. In addition to monitor the performance of implementation, the oversight committee should focus on assuring that agencies work effectively and efficiently together and that partner concerns and differences are addressed in a timely fashion.

Two options for Oversight Committee structure are presented for consideration by the GAVI Board:

<u>Option 1: Transfer Oversight Committee functions to the Executive Committee:</u>

The membership and terms of reference for the newly established GAVI Executive Committee are compatible with membership and functional requirements for the oversight committee. Transferring the Oversight Committee functions to the Executive Committee would allow to engage agency representatives at highest level in these critical issues, simplify the GAVI architecture, and minimize transaction costs.

<u>Option 2: Retain the Oversight Committee as a distinct structure:</u>

Keeping a distinct Oversight Committee focusing on forecasting, procurement and vaccine introduction issues would likely allow more time for in-depth discussions and assessment of issues brought to GAVI Board level. Transaction costs however may be higher and institutional representation not as high as at Executive Committee level.

4. At implementation level, further explore optimal option for partner coordination and management

To address the shortcomings experienced in the pilot phase of the VPP, in particular institutional resistance to a project management model and the residual ambiguity around partner roles and responsibilities, it is recommended that the concerned partners closely work with the Oversight Committee (or the Executive Committee) and reach agreement on optimal management structure for the period 2004-05, and that this is reported back to the GAVI Board as early as possible in 2004.

Two different approaches are presented below as options for further consideration by the partners and the GAVI Board. Regardless of the type of arrangement selected, broad cross-institutional agreement and support at highest-level is a precondition for attaining the level of institutional ownership and commitment required for effective and successful implementation.

Option 1: Institutional model with heightened level of accountability

This approach seeks to address the constraints met by the VPP in implementing a project management model across institutions with different cultures and established rules and regulations. The main principle is to replace accountability at individual level (of the project manager and of individual team members) with accountability at institutional level, and ensure effective implementation by increasing the level of institutional accountability.

To achieve this, the following steps are proposed:

- Based on the responsibility areas outlined above for 2004-05 activities, request WHO, UNICEF, The Vaccine Fund and the GAVI Secretariat to develop detailed institutional accountabilities and areas of collaboration.

- Formalize these agreements through a Memorandum of Understanding (or other appropriate mechanism as agreed by the partners) and incorporate activities into regular institutional work plans.

- Secure institutional accountability by requesting executing partners to appoint senior staff at oversight committee level and be externally accountable for the performance of their institutions.

- Establish a convening function to ensure periodic interaction of all parties, monitoring of work plan implementation, and resolution of problems. UNICEF could be asked to assume the convening function, with the understanding that this will rotate among the parties as agreed with the GAVI Board or its Oversight Committee.

- Following determination of the convening function, formalization of institutional accountabilities and streamlining of VPP activities into partners' on-going operations, phase-out the project manager position.

Option 2: Continue with a project management model

The main benefit of retaining a project management model is to keep a fully dedicated project manager as an accountable point of coordination and management across the partners. Constraints met during the pilot phase would however still need to be addressed.

INTRODUCTION

This paper summarizes the outcomes and the lessons learned in the second round of vaccine forecasting and procurement organized by the Global Alliance for Vaccines and Immunization (GAVI) for countries eligible for support from The Vaccine Fund[3].

It has been prepared by Paul Richard Fife[4] in consultation with the institutions tasked by the GAVI Board to pilot the coordinated planning and execution of forecasting and procurement of Vaccine Fund supported vaccines for 2004-06 through the Vaccine Provision Project (VPP), i.e. UNICEF, WHO and The Vaccine Fund, with support from the GAVI Secretariat.

Its main purposes are to systematize the strategic and implementation lessons learned during the pilot phase (July 2002 – October 2003), and bring issues of strategic and operational importance to the attention of the GAVI Board.

PROJECT JUSTIFICATION: THE 2002 MERCER REPORT

In June 2002, the GAVI Board endorsed the recommendations of the Lessons Learned report commissioned from Mercer Management Consulting[5]. The Mercer report provided an in-depth analysis of the implications of the global vaccine market and vaccine manufacturing economics for GAVI's procurement strategies; reviewed the lessons learned in the first round of GAVI procurement in 2000; and laid out strategic and implementation recommendations.

Procurement strategies

In order to increase competition for basic pediatrics and accelerate access to products as they mature, the Mercer report recommended that GAVI should seek to maintain/enhance large multinational supplier engagement to ensure access to new/newer products, while expanding the number of economically viable and high quality emerging suppliers, which can provide affordable pricing on mature products.

It was further recommended that procurement strategies be designed and managed to increase multinational supplier engagement – thereby also creating incentives for emerging suppliers – by providing for appropriate returns; creating credible and predictable demand in part through firm contracting; and working in a collaborative and open fashion with suppliers

The report also recommended that GAVI on new products focus to maximize leverage and minimize costs and that production and use of multi-dose presentations should continue

[3] Information on GAVI and the Vaccine Fund can be found at www.vaccinealliance.org
[4] Sr. Health Advisor and VPP Project Manager in UNICEF PD/Health Section until July 2003.
5 Lessons Learned: New Procurement Strategies for Vaccines (Mercer Management Consulting, 28 June 2002) http://www.vaccinealliance.org/reference/eighth_board/word/FinalMercerRept.doc

since presentation is a key factor in affordability and access regardless of the type of supplier.

Organizational structure and implementation

The Mercer study noted that opportunities were missed in the first round of GAVI procurement to demonstrate credible and predictable demand and to work with suppliers in a collaborative and open fashion. Shortcomings were attributed to extreme pressure of time, an excessive focus on financing as the key constraint (with inadequate attention to program and supply issues); the ineffectiveness of a loose alliance in implementing policy with unclear and overlapping roles and a lack of accountability; and significant discomfort with suppliers as partners in the effort.

To address these shortcomings, the report recommended that GAVI implement a multi-disciplinary approach to plan and manage the introduction of vaccines with contributions from program, supply and financing, and that the alliance ensures that a strong coordinating mechanism between these disciplines is in place.

The GAVI board endorsed the following specific recommendations:

- Increase coordination, decision-making and implementation effectiveness by adopting a project management model.

- Pilot this approach with the upcoming 2004-06 procurement round, with a key objective being to produce an accurate, product-specific forecast that enhances the credibility of demand and commands sufficient confidence amongst partners to allow the majority of GAVI's vaccine to be procured on a firm contract basis.

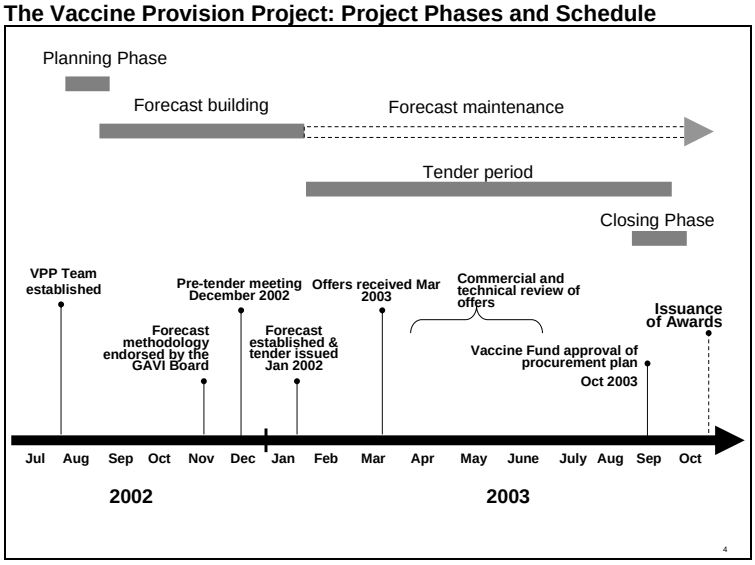
- Assign the Project Manager function to UNICEF Program Division (WHO or UNICEF PD were in the Mercer report recommended as options in order to retain a strong program focus); lead responsibility for program issues within the project team to WHO; lead responsibility for supply to UNICEF Supply Division; and lead responsibility for finance to The Vaccine Fund.

- Ensure that information on demand, product preference and future needs is shared with industry, unless there is a well-defined reason not to do so; and further ensure that bilateral meetings are held with industry when key decisions need to be made or there is a major development.

VPP ACTIVITIES JULY 2002- OCTOBER 2003

The chart below shows the different phases and key milestones of the Vaccine Provision Project, from the GAVI Board meeting in June 2002 until October 2003. Activity areas are described more in detail in annex III.

The Vaccine Provision Project: Project Phases and Schedule



PROGRAM OUTCOME

The Mercer report emphasized the establishment of an accurate product-specific forecast as a central strategy to implement for the GAVI alliance, both to accommodate the long lead-times for vaccine production and as a basis for issuing contracts that would assure suppliers that procurement awards would translate into actual purchases.

Forecast methodology

The methodology for establishing the country forecast was presented to the GAVI Board in November 2003[6]. Central elements were the concepts of "pure demand" and "supply-adjusted" forecasts and of country segmentation.

- "Pure demand" represents countries' preferred product choices and is important for longer-term planning. The "supply-adjusted" forecast takes into account the anticipated market situation and matches country demand with what is available on the market. The supply-adjusted forecast is a "living" forecast that is maintained and reflects changes in country uptake and in available supply.

- Countries were grouped according to their application status and to whether they would be receiving their preferred product or not. This segmentation was useful for assessing the level of uncertainty and risk of change (in choice of product, volume needs or timing) and for considering the use of firm contracting arrangements.

Forecast accuracy and credibility

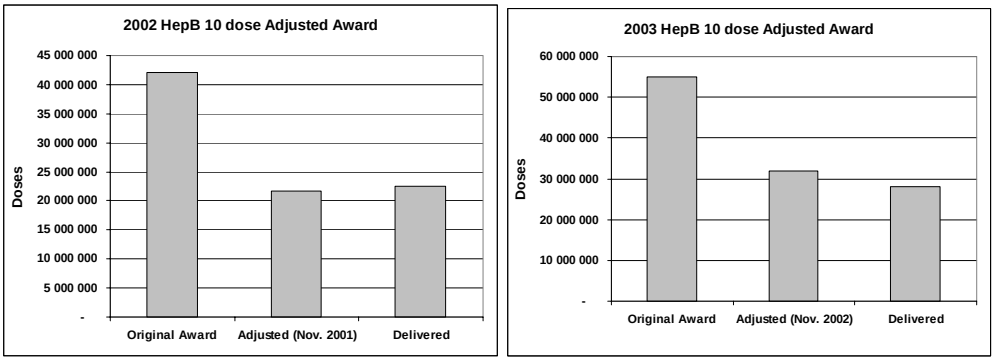
The accuracy of the forecast will only become apparent as implementation proceeds in 2004-06. There are indications that the strength and credibility of the GAVI forecast is on the increase:

[6] http://www.vaccinealliance.org/site_repository/resources/vpp_forcasting_191102.doc

- As implementation proceeds, the number of countries approved for Vaccine Fund support is increasing and this contributes to reduce uncertainty around product choice and time of introduction.

- For approved countries, with the exception of DTP-hep B+Hib vaccine (for which the original formula for calculating vaccine requirements needed to be adjusted with a 10% increase in volume needs), overall variance between forecasted quantities adjusted each November based on country annual reports and actual quantities delivered to countries in 2001-03 was around 5%. This is shown in the charts below and is a major improvement compared with the discrepancy noted in the Mercer report between awarded and actually bought quantities of monovalent Hepatitis B in 2001 and 2002.

Monovalent hep B (10d): original awards (2001), adjusted forecasts and actual deliveries in 2002 and 2003



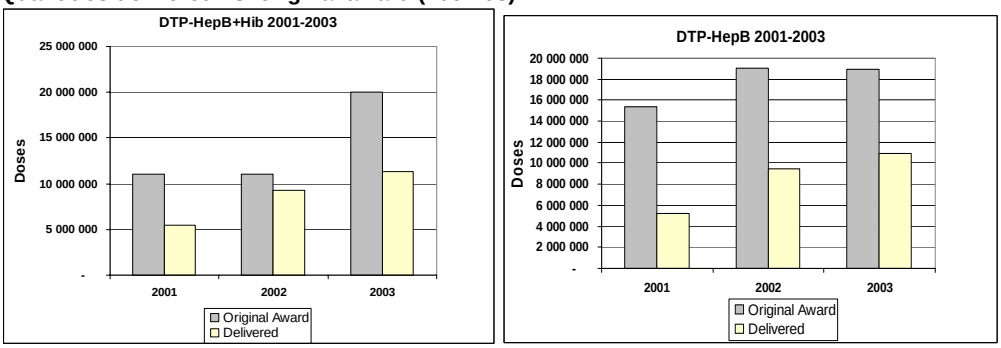
Source: UNICEF SD

- Aggregation and management of country forecasts at global level by UNICEF helps to level off individual country variance and decrease overall risk. Forecast accuracy for traditional EPI vaccines in the market managed through UNICEF procurement is now around 80%.

There was a 25% increase in the DTP-hep B+Hib forecast between December 2002 when the “pure demand” forecast first was established to support the issuance of the tender and May 2003 when WHO updated the forecast to support issuance of awards. This indicates that countries are still making decisions on their final product preferences. Forecast for new demand (i.e. countries not yet approved for Vaccine Fund support) is as such dynamic and needs continuous monitoring and communication. To allow for adjustments as early as possible, UNICEF and awarded suppliers will in the future exchange monthly updates on projected delivery and production plans.

Greater manufacturer accuracy in production planning is required. The charts below show the difference between awarded and delivered quantities of DTP-hep B and DTP-hep B+Hib in 2001-03. While the difference in 2001 is mainly due to delays as countries were preparing for introduction, the variance in 2003 is caused by the reduced availability of these vaccines (overall a 40% loss in 2002 and 2003), forcing several countries to delay introduction of these vaccines. This underscores that in the early stages of implementing the introduction of new vaccines, the availability of products on the market will determine the scope and speed of program implementation.

Quantities delivered vs. original award (2001-03)



Source: UNICEF SD

Program considerations

The supply constraints and the relatively high price of combination vaccines raise questions about the evolution of country demand and the overall pace of introduction of Hib-containing vaccine.

The magnitude of the financing gap for vaccines has been documented by the Financing Task Force[7] for some of the early introducer countries and is of great concern. Some countries have indicated that they may drop Hib and fall back onto DTP-hep B when Vaccine Fund support ends after five years. The price increase seen in this round of procurement is likely to exacerbate in-country discussions, as policy-makers are faced with constrained resources and competing priorities, not least related to the fight against AIDS.

PROCUREMENT OUTCOME

The Mercer report recommended a procurement approach that would engage large multinational suppliers (to ensure access to new/newer products) as well as emerging suppliers (key to affordable pricing as products mature).

Product offers

38 manufacturers from the WHO and UNICEF lists of manufacturers currently or potentially producing vaccines were invited to provide offers. Manufacturers with plans for vaccine products to be WHO pre-qualified were invited to submit as part of their offers timelines for the development of new products, completion of clinical trials, licensing with their National Regulatory Authority (NRA) and submission of prequalification files to WHO. Given that vaccines are complex commodities and various factors need to be considered, including linkages with other products, UNICEF designed the tender as a Request for Proposal (RFP). Offers received are summarized in the table below.

[7] http://www.vaccinealliance.org/home/Board/Board_Reports/11_board_financialsus.php

GAVI/Vaccine Fund procurement 2004-06: Summary of offers

Product	*Number of offers*	*Number of WHO pre-qualified products*	*Number of non WHO pre-qualified products*
hep B	*13*	*6*	*7*
hep B uniject	*4*	*0*	*4*
Hib	*4*	*2*	*2*
DTP-hep B	*11*	*1*	*10*
DTP-hep B+Hib	*4*	*1*	*3*
DTP+Hib	*1*	*1*	*0*
Yellow Fever	*4*	*2*	*2*
Total	**41**	**13**	**28**

Source: UNICEF SD

Two additional products were offered but not considered as programmatically suitable by WHO for this round: (1) hep B+Hib due to operational issues (two doses of hep B+Hib and one additional dose of hep B are required to fully vaccinate a child, complicating the scheduling) and (2) DTP-hep B+Hib-MenA/C due to the need to further assess its epidemiological and programmatic suitability.

Awards 2004-06

Awards are issued by UNICEF on behalf of GAVI and The Vaccine Fund in the form of Long Term Agreements (LTA) for three years (2004-06), with total quantities awarded for each product equal to forecasted quantity needs.

Evaluation of offers included the review of mandatory requirements (e.g. WHO pre-qualification and compliance with UNICEF general terms and conditions); a quantitative review of proposals (products offered, quantities, price, delivery schedule and lead-times, ability to maintain buffer stock, shelf-life, VVM); and a qualitative review of proposals (proven experience and past performance, ability to perform account management / good communication, on-time delivery performance).

Awards have not been given to manufacturers for products that are not WHO pre-qualified. However, proposals of commercial interest will be considered when the products become WHO pre-qualified. Manufacturers have been informed that quantities may be awarded or re-allocated if there is a monopoly or near-monopoly situation, a lack of performance from current manufacturer(s), or insufficient production capacity of current manufacturers (i.e. demand exceeds available supply).

While awards were originally scheduled to be finalized in June 2003, awards for the full period 2004-06 have as of mid-November 2003 not been issued and made public.

- To date the Vaccine Fund Executive Committee has given its financial approval for the procurement of combination vaccines for the period 2004-06 for already approved countries. These quantities are firmly contracted and represent an estimated total value of US$281.3 million.

- Financial approval has also been given for all monovalent products for 2004-06 representing an estimated total value of US$145.4 million, subject to parameters of the Five Year Supply Approval policies approved by GAVI and The Vaccine Fund in June 2003[8].

- Procurement arrangements for combination vaccine for countries that plan to switch products or that are not yet approved are still outstanding and vaccines not secured,

[8] http://www.vaccinealliance.org/home/Board/Board_Reports/telcon_060603.php

following the request from the Vaccine Fund Executive Committee to not lock into this option and to explore alternatives.

At its Dakar meeting in November 2002, the GAVI Board recommended that all vaccines purchased by The Vaccine Fund should include vaccine vial monitors (VVM) after 2003, in line with the WHO/UNICEF global policy on the use of VVM. Except for GSK who will phase in VVMs on GAVI/Vaccine Fund shipments during 2004 and Aventis who is developing its implementation plan, all manufacturers with awards have confirmed that their vaccine will be supplied with VVMs in 2004-06.

No award was given for Hepatitis B in single dose pre-filled device (i.e. Uniject™) since no manufacturer had obtained WHO pre-qualification for this product. In view of the relatively high price on offer and limited confirmed country demand, the cost-effectiveness and viability of this product need to be further considered and criteria for what constitutes an acceptable price established. In view of the limited confirmed demand, country recommendations for the use of these products may also benefit from being more explicitly defined.

Working with manufacturers in an open and collaborative fashion

The purpose of open and collaborative relationships with suppliers is to facilitate production planning, avoid conflicting messages and minimize costs to serve GAVI. It is critical to ensure fair and equal access to information and to maintain confidentiality when appropriate.

As discussed with the VPP Oversight Committee, partners still have different perspectives on how manufacturers should be engaged. Approaches employed by the VPP in this round of forecasting and procurement were presented at a Board teleconference in September 2002 and are reported below.

Pre-tender period

The VPP provided information on the forecast methodology and on the “pure demand” forecast in written communication to all manufacturers in October 2002 and in the tender document in January 2003. The methodology was publicly available through GAVI Board proceedings in December 2002 and on the GAVI website, and was presented together with the “pure demand” forecast at the pre-tender meeting in December 2002. Feedback was overall positive though limited. It was suggested for the future to further quantify and model risk (i.e. issues that could affect forecast accuracy) into “optimistic” and “pessimistic” scenarios.

Tender period

During the tender period, to maintain confidentiality and ensure consistent messages to suppliers, communication with manufacturers was handled bilaterally between UNICEF Supply Division and each individual manufacturer. Meetings were held with all manufacturers that submitted an offer to present and discuss the offer with extensive consultations with suppliers offering the most interesting products.

Post-tender period

Manufacturers have been invited for a debriefing meeting at UNICEF to have a chance to review the outcome of the procurement and discuss issues related to their specific proposal. Manufacturers with awards will during 2004-06 receive monthly updates forecasted needs and monthly meetings will also be organized.

FINANCING OUTCOME

For strategic and financial planning purposes, it is important for the alliance to assess the likely causes of the price increase seen for the combination vaccines in this round, assess whether obtained prices can be considered "fair and reasonable" at this point in time, and get an indication as to how prices are likely to evolve in the future.

Product pricing

The table below provides an overview of the evolution of pricing and volume quantity for hep B, DTP-hep B and DTP-hep B+Hib obtained by UNICEF SD on behalf of GAVI and The Vaccine Fund from 2001-2006.

Quantities and price of vaccines 2001-06

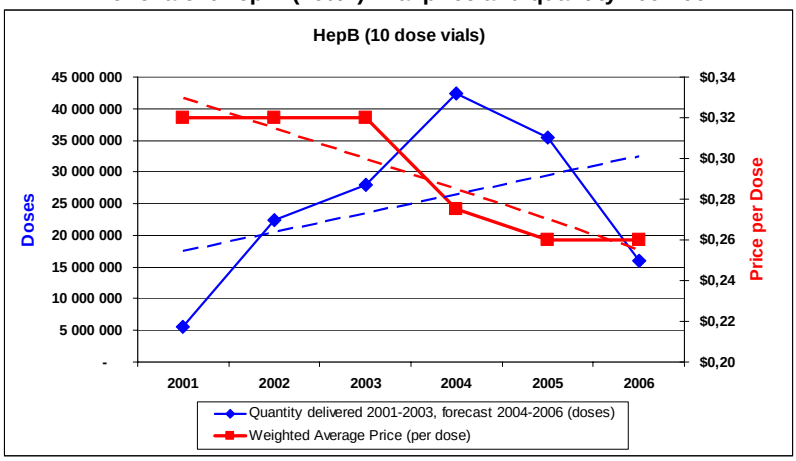
		2001	*2002*	*2003*	*2004*	*2005*	*2006*
DTP-hep B	*Quantity*	*5,264,500*	*9,440,500*	*10,895,500*	*11,834,800*	*15,615,550*	*44,500,000*
	Price	*$1,10*	*$1,05*	*$0,95*	*$1,21*	*$1,25*	*$1.29*
DTP-hep B+Hib	*Quantity*	*2,718,200*	*11,301,400*	*11,293,940*	*15,942,956*	*33,384,448*	*37,950,000*
	Price	*$3.50*	*$3.50*	*$3.27*	*$3.65*	*$3.60*	*$3.60*
hep B	*Quantity*	*5,613,000*	*22,472,400*	*28,009,310*	*42,400,000*	*35,500,000*	*16,000,000*
	Price	*$0,32*	*$0,32*	*$0,32*	*$0,28*	*$0,26*	*$0,26*

Quantity: Quantities delivered in 2001-2003 and forecasted 2004-2006
Price: US$ per dose (weighted average price for hep B)
Source: UNICEF Supply Division

As noted in the Mercer Study, product lifecycle and maturity are critical for product pricing. Typically, a mature product for low-income country markets will be characterized by solid demand and multiple suppliers, including emerging suppliers, with competition acting as the key driver for lower prices.

Monovalent Hepatitis B is the "text-book" case of a maturing product and weighted average price continued to decrease in this procurement cycle from $0.32 in 2003 to $0.28 in 2004, and to $0.26 in 2006. This is a reduction of 19% between 2003 and 2006.

Monovalent hep B (10d/v): vial price and quantity 2001-06

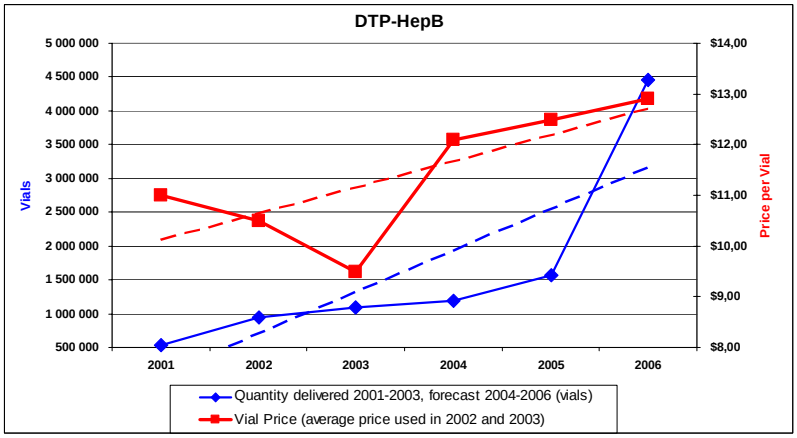


Despite considerable supplier movement, the combination products preferred by countries (DTP-hep B and DTP-hep B+Hib) became commercially available specifically for GAVI and are still early in their product lifecycle.

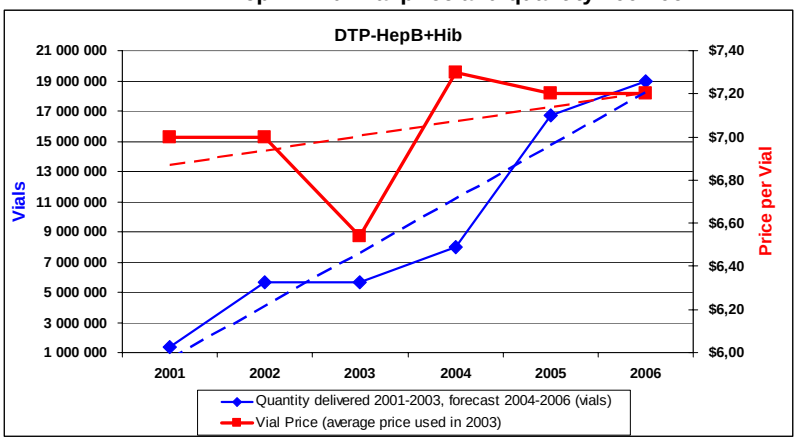
The charts below show price evolution relative to quantities delivered in 2001-03 and forecasted for 2004-06, showing a price jump between 2003 and 2004 of 10% for DTP-hep B+Hib and of 27% for DTP-hep B.

Compared with 2001, dose prices in 2006 will increase from $3.50 to $3.60 (i.e. 3%) for DTP-hep B+Hib (2-dose/vial), and from $1.10 to 1.29 (i.e. 15%) for DTP-hep B (10-dose/vial).

DTP-hep B: vial price and quantity 2001-06



DTP-hep B+Hib: vial price and quantity 2001-06



Discussions with manufacturers and analysis of market conditions indicate that the price increase seen for combination products in 2004-06 compared with 2003 may be attributed to:

- Accelerated supplier recouping of investment costs, principally investments in new DTP production facilities but also of original investments
- pricing strategy: multinational manufacturers typically offer low volumes at relatively high price and chose to exit the market as emerging suppliers enter with larger volumes and lower priced products
- the significant strengthening (of around 20%) of the euro against the US dollar since 2001, when initial prices were set.

Price analysis of all Hib-containing products offered in the tender (Hib, DTP-hep B+Hib, DTP+Hib, hep B-Hib) indicates that the price of Hib is high compared with the basic pediatrics, but not unreasonably high at this point in time:

- Prices of Hib-containing combination vaccines offered in the tender (including products not yet pre-qualified) are comparable across products offered and across manufacturers.
- The price seems to reflect actual production and regulatory costs and is consistent with price differences between multinational and emerging suppliers for other basic vaccines.
- The price is comparable with the price for DTP-hep B+Hib (in single-dose vial without VVM) obtained by the Pan-American Health Organization (PAHO) through its pooled procurement system ($3.76 for 2004, i.e. 3% higher than UNICEF price and an increase from $3.00 in 2003)
- From historical experience, significant and sustained price reductions are not likely to be seen until competition has been established

Price outlook

Global demand for DTP-hep B is now well-established. Two additional manufacturers could be expected to enter the market with pre-qualified products nearing 2006 and this will lead to competition and decreasing prices. Product maturity is expected to be seen in 2007-2009.

DTP-hep B+Hib is technically more complex to produce than DTP-hep B. Considering development and licensure requirements, it is conservatively estimated that additional

quantities are not likely to become available from additional manufacturers until 2006, with maturity and price pressure expected when competition is established.

Country demand for DTP-Hib combinations (in liquid or lyophilized form) has overall been very limited compared with DTP-hep B. This has influenced production planning with only one manufacturer currently offering a pre-qualified product. The future demand for this product is still unknown.

Yellow Fever vaccine

Due to the change of vial size from 20 dose to 10 dose the price per dose of this vaccine has increased from $0.34 in 2002 to $0.80 in 2004, and to $0.97 in 2006 (the price of 10d vials was $0.63 in 2002). It is expected that the increased costs to the program will partly be offset by the reduced vaccine wastage at point of use (less so during campaigns when wastage typically is low).

Firm contracting – a means to an end not an end in itself

The Mercer Study identified the use of contractual commitments (e.g. firm contracting) as a critical tool for GAVI and "proof" of the commitment to share risks associated with the forecast.

In theory, the main benefits for the buyer of entering into a firm contract arrangement are to secure supply quantity and to obtain price concessions. The risk of financial loss (in case countries do not use forecasted volumes) and opportunity costs (i.e. lost investment opportunities) represent significant down-sides. For suppliers, the major benefit lies in the assurance of future purchase and this is expected to influence company decisions on investments and production scale-up.

The use of firm contracting was assessed on a case-to-case basis for all awards considering the level of uncertainty and risk associated with the forecast (using the country segmentation approach) and whether prevailing market conditions for the product in question indicated a strategic need to enter into a firm contracting arrangement.

As of mid November 2003, firm contracting arrangements have been established for products in short supply to secure their availability but only for quantities of already approved countries. The value of firmly contracted supply represents so far around 40% of the total value of this procurement, less than what the Mercer report recommended.

Firm contracting was not entered into for readily available products. While this would have reduced risk for the supplier, it was considered not to be justified in view of its limited utility in securing product availability (since the product is in abundant supply) and in reducing price further than what was achieved. Moving forward it will be important that these non-firm awards translate into actual purchases, and that unforeseen changes be communicated well in advance with suppliers to allow for adjustments.

While firm contracting did allow for some moderate price concessions for DTP-hep B and DTP-hep B+Hib, its overall leverage on price and volumes in this round of procurement proved somewhat limited due to the established monopoly situation and several buyers vying for scarce supply. Under such conditions, firm contracting may first of all be useful in locking supply and securing vaccines rather than leveraging significant price and volume concessions.

Establishment of financial frameworks to support procurement operations

A significant achievement during the period was the design and establishment of the Five Year Supply Approval Framework approved by the GAVI Board and the Vaccine Fund Executive Committee in June 2003[9]. This Framework reconciles the use of multi-year contracting while retaining a performance-based approach to country support.

The delay in closing the procurement and issuing awards is a shortfall and is due to difficulties met in updating the forecast, assessing proposed procurement plans and establishing the legal and fiduciary frameworks necessary to support the implementation of firm contracts.

While this was the subject of discussions between The Vaccine Fund and appropriate units at UNICEF throughout the project cycle with financial estimates shared several times between February and September 2003, fiduciary arrangements between the two institutions were as of mid-November 2003 not yet finalized. Though funding for 2004 procurement has been transferred and vaccines for 2004 have been secured, financial backing needed for the full 2004-06 contracting was not yet available.

Looking back, the project significantly underestimated the time required and potential difficulties related to these processes, many taking place for the first time. While most of these will be resolved in order to complete this procurement, future efforts should realistically set and sequence milestones and allow for unanticipated challenges.

Constraints have also been experienced in relation to release of funds to support on-going operations and vaccine deliveries with delays in funds transfer despite accurate timing and quantity forecasts. This indicates the need to further work on making financing more responsive to program and supply needs, while making sufficient provision for institutional requirements related to fiduciary responsibilities and due diligence processes.

PROJECT EXECUTION

The performance, benefits and shortfalls of the VPP may be assessed at four different levels:

- Did the VPP meet the original targets of schedule and quality (meeting targets)?
- Was it managed in an efficient manner (project efficiency)?
- To what extent did it contribute to fulfill the overall mission of vaccine provision to GAV/Vaccine Fund supported countries (project utility)?
- And what can the organizations and the alliance learn from the pilot project and how can this knowledge be used to improve operations (organizational improvement)?

[9] http://www.vaccinealliance.org/home/Board/Board_Reports/telcon_060603.php

Did the VPP meet the original targets of schedule and quality (meeting targets)?

With regard to schedule, the project was successful in getting quickly off the ground and meeting deadlines for establishing the forecast and issuing the tender.

The procurement, which was originally scheduled to be completed in June 2003, was as of mid November not fully completed for reasons described in previous sections. Procurement arrangements for 2004 however have been made and delivery of supply to countries assured, and concerned manufacturers have also been kept appraised of the situation.

In terms of quality, several of the project metrics measuring progress and performance across the three disciplines (such as forecast accuracy, delivery reliability, uptake of firm offtake and supplier information-sharing) pertain to the implementation period in 2004-06 and will be tracked and reported as implementation proceeds.

With regard to pricing, while price pressure on monovalent hep B was achieved and weighted average price is expected to decrease by 22% between 2003 and 2006, the price increase of combination vaccines is a significant disappointment and constitutes at least in the medium term a major challenge for countries and their global partners.

Was the VPP managed in an efficient manner (project efficiency)?

While several aspects of project management were taken into consideration in the development and implementation of the project, several important aspects did not receive sufficient attention. While headway has been made and experiences in this round will be very valuable in informing the design and implementation of future activities, one should recognize looking back that unclarities remained in setting the goals and the strategies of the project, terms of reference (for the VPP as a whole, the project manager, staff detailed to the project from implementing institutions, and the Oversight Committee), formulating and addressing expectations of each of the partners, and identifying project metrics for each of the partners.

While project planning and control was overall adequate in the first half of the project, inefficiencies became apparent and delays occurred in the final phase in relation to updating the forecast, establishing policy and fiduciary frameworks needed for multi-year contracting and reviewing and approving proposed procurement plans.

Staff transition affected the efficiency of operations and this may also have reduced institutional ownership in the project. The WHO team member responsible for developing the forecast and oversee programmatic issues transferred to another location in December 2002 and the programmatic “leg” of the VPP was sub-optimal until the new WHO team got in place in July 2003. In July 2003, the project manager left the project for family reasons and project coordination was taken on by the GAVI Secretariat.

The success of individual team representatives in drawing on the resources in their institution varied considerably and sub-optimal communication within organizations was also experienced, possibly pointing to the downside of a project team approach based on individuals against a more formal institutional representation.

Despite extensive travel, the project manager remained throughout his assignment based at UNICEF NYHQ in New York and several partners raised this as a drawback compared with a Europe-based location in close proximity to key partners. It was considered though that the institutional backing of UNICEF in its New York Headquarters was important for ensuring supervision and support to the project manager. Overall the project manager did act as a

focal point for the project, following up on project activities in the various agencies, and reporting to the Board and its Oversight Committee.

Differing perspectives between partners hampered operations and could have been minimized if expectations or concerns had been addressed earlier in the project or if the project support group had been convened. It should be emphasized that the absence on the Oversight Committee of senior staff from the implementing agencies (as decided by the GAVI Board in June 2002 contrary to the original recommendation in the Mercer report) may have been a mistake, since such presence would have been beneficial as a way to reinforce institutional accountability and ownership, bring problematic issues to a higher level within institutions and ensure that project activities internally receive the required attention and support.

Project costs were assumed by executing agencies as part of their operations, with extraordinary costs borne by UNICEF (for the project manager position) and the GAVI Secretariat (for convening the Oversight Committee).

Finally, while partner investments in the VPP may seem commensurate to the task at hand, the intensity and frequency of VPP interactions was considered by some as too high, noting that work could have been more efficient if VPP tasks had been better planned and streamlined into institutional plans of work. In particular, the numerous requests for inputs and action, often with tight deadlines, have been raised as a source of frustration.

To what extent did the VPP contribute to fulfill the overall mission of vaccine provision to GAVI/Vaccine Fund supported countries (project utility)?

In the short-term, the VPP met its primary objective of establishing a product-specific forecast and systems are being put in place to monitor country performance, maintain the forecast, and communicate changes with manufacturers. Vaccines needed in 2004 have been secured and a GAVI procurement plan for the full period 2004-06 is expected to soon be in place.

With regard to product affordability, the report attributes the price increase of combination vaccines in 2004-06 to the strengthening of the euro against the US dollar, the accelerated recouping of investments and supplier pricing strategy. It also points to the fundamental issue of product lifecycle and the effects of product maturity on pricing.

DTP-based combination vaccines preferred by countries are still early in their lifecycle. The broadening engagement of multinational and emerging suppliers seen in this procurement should be taken as a strong indication that market competition is on its way with current prices serving as solid incentives for suppliers. Provided efforts are maintained, it is expected that a healthier market with multiple suppliers and more affordable prices will be established, for DTP-hep B in 2007-09. This will in due course contribute to reduce the disparity between high and low-income counties in introducing new vaccines, probably from twenty years as the case was with monovalent hep B to ten years or less for DTP-hep B.

The VPP was instrumental in coordination partner response and managing the pentavalent vaccine crisis in the first half of 2003 when Burundi, Yemen, Zambia were forced to delay the introduction of new vaccine for 18 months and Uganda experienced a country-wide stock-out due to inability at global level to accommodate its increased vaccine needs. The VPP was also useful as a repository for addressing supply-related GAVI policy issues in a cross-disciplinary way, such as the Five Year Supply Approval framework, forecast calculation methodologies and modalities of GAVI/VF supply support.

With regard to Yellow Fever vaccine, the VPP mechanism facilitated the design and establishment of the stockpile approved by the GAVI Board in December 2003. While it is too early to see results yet, this is an example of the facilitative and innovative character of the alliance.

What can the organizations and the alliance learn from the pilot project and how can this knowledge be used to improve operations (organizational improvement)?

It is important to recognize that the VPP was a pilot effort and something that had never been done before at least in this fashion, and that it was challenged by real time constraints, a maturing alliance that was learning as it worked and unforeseen external factors such as the pentavalent supply crisis.

First of all, the VPP pilot confirmed the usefulness and benefits of working in a coordinated manner across the areas of program, supply and finance. With the addition of the GAVI Secretariat, team composition was found to be appropriate with relevant disciplines and partners represented on the team.

The project management approach allowed for better communication among partners, helped to make headway in defining institutional accountabilities, and was instrumental in improving collaboration across institutions and across disciplines. This was especially beneficial at the start of project and it is doubtful that a product-specific forecast would have been available for use in the tender without the use of a project management approach.

However, as noted in previous sections, shortcomings and inefficiencies were experienced and need to be considered as the alliance takes stock of the situation and decides on the way forward. The main causes for these inefficiencies may be attributed to:

- Inherent institutional resistance to a project management model, with institutional lines of authority and communication not supporting or not compatible with project management requirements. This includes accountability of team members to the project manager, project manager authority to direct the work of others, and partner access to information and participation in decision-making processes. Though the team members to the most extent worked well together and the project management model gave some needed flexibility, representation by individuals may not have replaced the strength that can be provided by more formal institutional representation and may also have reduced institutional ownership in the project.

- Failure to appropriately identify in advance potential obstacles, set and sequence milestones in particular for new steps and work processes, and allow for enough time to address unanticipated challenges. Again it should here be emphasized that it was the first time many of these processes were undertaken, and that future activities will gain from the experiences gained in the pilot.

- Residual ambiguity around partner roles and responsibilities, and failure to effectively address partner differences. This ambiguity led to inefficiencies that could have been minimized by addressing partner expectations and concerns at an earliest possible stage of the project.

LOOKING AHEAD, ISSUES OF STRATEGIC IMPORTANCE

Seek to decrease the price of combination vaccines as early as possible through increased competition

Significant price reduction for combination vaccines is not likely to be seen until competition is established. GAVI partners should ensure that conditions remain favorable and stimulate competition in the period leading up to the next round of procurement. In particular, the GAVI Board should encourage WHO to establish the necessary capacity to enable timely processing of requests for prequalification of new products, so that suppliers can complete vaccine development and pre-qualification processes and be considered for awards.

Firm up demand for Hib-containing vaccine

While demand for hep B and DTP-hep B vaccines is on track to become as established as for the traditional EPI vaccines (as demonstrated by the broad country uptake and the healthy market response), demand for Hib-containing vaccine is at critical risk due its relatively high price and the financing gap in the post-Vaccine Fund period. Successful Hib vaccine introduction is critical not only for the credibility of GAVI (with countries as well as with suppliers) but also for the credibility of future vaccine introduction initiatives.

WHO and other GAVI partners should continue their efforts to support countries in assessing the appropriateness and the program readiness for introducing Hib-containing vaccines, taking into account the supply situation, financial sustainability and other program priorities.

It is encouraging to see that several countries are taking steps towards phasing in locally-mobilized resources as Vaccine Fund support nears its end. GAVI partners should continue to support country efforts including the implementation and realization of national financial sustainability plans.

GAVI and The Vaccine Fund should as part of their strategic planning for 2005-2015 explore ways of addressing the financing gap for currently supported vaccines. Extending support to products still early in their lifecycle may be an option to consider in order to firm up demand until competition is established and more affordable pricing has been achieved.

In view of the DTP-hep B+Hib supply constraints, countries wanting to introduce Hib vaccine may wish to consider alternative Hib-containing products (monovalent Hib, DTP+Hib). Though this in itself would not contribute to increase competition for DTP-hep B+Hib vaccine, it would help accelerate the use of Hib vaccine, protect more children from Hib disease and reduce dependency on one single product. It should be emphasized however that such decisions need to be made by countries themselves.

RECOMMENDATIONS

Given the tasks at hand and the experiences and outcomes of the pilot, the following recommendations are put forward for consideration and discussion in relation to vaccine provision strategies in general; and on the scope of GAVI-related vaccine provision activities in 2004-05 and options for organizational set-up and implementation in particular.

Scope of activities 2004-05

1. **Focus on risk management at global level - across program, financing and supply - to support new vaccine introduction**

With the majority of Vaccine Fund eligible countries well underway with the introduction of newer vaccines, and with a US$570 million procurement plan for 2004-06 soon in place to support this effort, the need to effectively manage vaccine provision at global level is critical. In particular, the alliance needs to have the capacity to detect and act when problems or changes related to program implementation, supply or funding arise, such as new approvals, changes in supply availability, or funding shortfalls.

It should be stressed that national Governments are responsible for implementation of immunization programs, and that partner agencies, in particular established multilateral agencies, play a critical role in monitoring country progress and providing technical assistance.

At global level, a risk management approach grounded on close monitoring of vaccine provision performance across the areas of program, supply and finance would provide significant “added value” to the efforts of any single agency, and would increase the likelihood that changes in any area are known to and appropriately addressed in the other areas.

Such a risk management approach would benefit from building on the experiences and the tools and processes established through the VPP and would be characterized by the establishment of key monitoring parameters, individual partner accountabilities, effective modes of communication and collaboration between partners, and metrics to measure progress and performance.

For 2004-05, it is therefore recommended to primarily focus on the management at global level of risks associated with the introduction of Vaccine Fund supported vaccines (hep B, Hib, YF) across the areas of program, supply and finance.

2. **Extend the forecast of hep B, Hib and YF vaccine to support medium-term planning**

The forecast prepared for this procurement round covers primarily the period 2004-06. In order to track evolution of demand and contribute to the longer-term provision of currently supported Vaccine Fund vaccines, the current forecast would benefit from being extended so that it reflects new approvals and changes in country uptake and in supply availability.

This forecast will also form the basis for issuing the next tender and maintaining it will increase its quality and prevent the time rush experienced in this round of procurement. The forecast needs to be accompanied by a funding forecast to demonstrate the longer-term reliability of vaccine procurement.

It is recommended that WHO, together with UNICEF and The Vaccine Fund, establish specifications for a medium-term forecast including timeframe (possibly a rolling forecast looking 5-7 years ahead), partner accountabilities, periodicity of maintenance and ways of sharing it with suppliers and other interested parties.

3. Prepare early for the next round of procurement

By starting to plan early for the next round of procurement, GAVI has an opportunity to avoid the time pressure experienced in the first two rounds of procurement and to address the constraints experienced in this last round. Given the complexity of the exercise and the importance of reaching partner consensus on strategies, work processes and respective accountabilities *before* implementation starts, it is recommended that the plan for the next round of procurement be prepared for GAVI Board consideration in early 2005.

Building on the experiences from this procurement and considering the market situation, elements to be considered include recommended time-span for the next tender; timelines, milestones and indicators; and detailed partner assignments and accountabilities. Accountable focal persons in each institution should be identified as well as institutional oversight mechanisms.

It should be emphasized that the establishment of a long-term forecast and realistic guarantees of future funding are pre-conditions to an effective procurement.

Organizational set-up and implementation

4. Retain a multi-disciplinary approach involving the same partners as in the pilot phase

Provided that the above recommended areas of work are endorsed, it is recommended that the alliance retain a multi-disciplinary approach to planning and implementation across program, supply and finance, and assign global execution responsibilities in 2004-05 to the same team of partners, i.e. UNICEF, WHO, The Vaccine Fund, with support from the GAVI Secretariat, with the following areas of responsibility:

Responsibility areas for work plan implementation 2004-05

Scope areas	*WHO*	*UNICEF SD*	*The Vaccine Fund*	*The GAVI Secretariat*
Risk management for hep B, Hib and YF vaccine introduction	*Country forecast*	*Supply delivery*	*VF funding*	*Country funding*
Medium-term planning (extension of the forecast, preparation for next round of procurement)	*Country forecast*	*Vaccine availability, pipeline products*	*VF funding*	*Country funding*

5. Review the membership and terms of reference, and consider changing the set-up of the Oversight Committee

In view of the experiences in the pilot phase, and regardless of partner coordination and management structures chosen at implementation level, it is recommended to review the composition and terms of reference of the Oversight Committee. Specifically, it is critical that senior staff from implementing agencies be included to assure a high level of institutional accountability and ownership. There may also be scope to include 1-2 subject matter experts relevant to the task at hand in a supportive advisory role to the Board members serving on the committee. In addition to monitor the performance of implementation, the oversight committee should focus on assuring that agencies work effectively and efficiently together and that partner concerns and differences are addressed in a timely fashion.

Two options for Oversight Committee structure are presented for consideration by the GAVI Board:

Option 1: Transfer Oversight Committee functions to the Executive Committee:

The membership and terms of reference for the newly established GAVI Executive Committee are compatible with membership and functional requirements for the oversight committee. Transferring the Oversight Committee functions to the Executive Committee would allow to engage agency representatives at highest level in these critical issues, simplify the GAVI architecture and minimize transaction costs.

Option 2: Retain the Oversight Committee as a distinct structure:

Keeping a distinct Oversight Committee focusing on forecasting, procurement and vaccine introduction issues would likely allow more time for in-depth discussions and assessment of issues brought to GAVI Board level. Transaction costs however may be higher and institutional representation not as high as at Executive Committee level.

6. At implementation level, further explore optimal option for partner coordination

To address the shortcomings experienced in the pilot phase of the VPP, in particular institutional resistance to a project management model and the residual ambiguity around partner roles and responsibilities, it is recommended that the concerned partners closely work with the Oversight Committee (or the Executive Committee) and reach agreement on optimal management structure for the period 2004-05, and that this is reported back to the GAVI Board as early as possible in 2004.

Two different approaches are presented below as options for further consideration by the partners and the GAVI Board. Regardless of the type of arrangement selected, broad cross-institutional agreement and support at highest-level is a precondition for attaining the level of institutional ownership and commitment required for effective and successful implementation.

Option 1: Institutional model with heightened level of accountability

This approach seeks to address the constraints met by the VPP in implementing a project management model across institutions with different cultures and established rules and regulations. The main principle is to replace accountability at individual level (of the project manager and of individual team members) with accountability at institutional level, and ensure effective implementation by increasing the level of institutional accountability.

To achieve this, the following steps are proposed:

- Based on the responsibility areas outlined above for 2004-05 activities, request WHO, UNICEF, The Vaccine Fund and the GAVI Secretariat to develop detailed institutional accountabilities and areas of collaboration.

- Formalize these agreements through a Memorandum of Understanding (or other appropriate mechanism as agreed by the partners) and incorporate activities into regular institutional work plans.

- Secure institutional accountability by requesting executing partners to appoint senior staff at oversight committee level and be externally accountable for the performance of their institutions.

- Establish a convening function to ensure periodic interaction of all parties, monitoring of work plan implementation, and resolution of problems. UNICEF could be asked to assume the convening function, with the understanding that this will rotate among the parties as agreed with the GAVI Board or its Oversight Committee.

- Following determination of the convening function, formalization of institutional accountabilities and streamlining of VPP activities into partners' on-going operations, phase-out the project manager position.

Option 2: Continue with a project management model

The main benefit of retaining a project management model is to keep a fully dedicated project manager as an accountable point of coordination and management across the partners. Constraints met during the pilot phase would however still need to be addressed.

ANNEX 1 : AWARDS 2004-06

Number of doses awarded and weighted average (WA) price per dose of GAVI/Vaccine Fund supported vaccine 2004-2006

hep B 1	2004	2005	2006
Total doses awarded	2 650 000	1 050 000	1 182 000
WA price per dose	0,41	0,41	0,41

hep B 2	2004	2005	2006
Total doses awarded	3 400 000	3 110 000	3 160 000
WA price per dose	0,37	0,36	0,35

hep B 6	2004	2005	2006
Total doses awarded	3 889 980	3 979 980	4 060 020

WA price per dose	0,61	0,61	0,61

hep B 10	2004	2005	2006
Total doses awarded	42 400 000	35 500 000	16 000 000
WA price per dose	0,27	0,27	0,26

DTP-Hib 10	2004	2005	2006
Total doses awarded	3 478 730	201 450	209 910
WA price per dose	2,58	2,80	3,12

YF 5	2004	2005	2006
Total doses awarded	5 000 000	4 000 000	4 000 000
WA price per dose	0,58	0,58	0,60

YF 10	2004	2005	2006
Total doses awarded	13 200 000	11 900 000	11 800 000
WA price per dose	0,80	0,88	0,97

As of 01.12.03

unicef

ANNEX 2: VPP ACTIVITIES JULY 02 – OCTOBER 03

Preparatory and planning phase (lead responsibility: project manager)

- *Project definition developed by UNICEF, WHO and The Vaccine Fund, based on Mercer Study analysis and GAVI Board directions*
- Project outline endorsed by the GAVI Board in August 2002 including project deliverables, project team composition, terms of reference for the project manager; and composition and terms of reference for the Project Oversight Committee and the Project Support Team
- GAVI Board updated in September 2002 on supplier engagement in the forecast process and on timelines for developing the forecast and issue the tender

Establishment of the forecast (lead responsibility: WHO)

- Pre-meeting of WHO, UNICEF, PATH/CVP and the GAVI Secretariat in July 2002 to review available fact base and identify data gaps
- Methodology for establishing an accurate, product specific forecast developed and endorsed by the GAVI Board in November 2002

- "Pure demand" forecast established and major risks assessed. Feedback solicited at an open pre-tender meeting with 26 suppliers in December 2002.
- Tender with "pure demand" forecast issued in January 2003
- Forecast updated into reflect new country approvals, updated country information and changes in actual vaccine uptake (for example the delay in introducing DTP-hep B+Hib in Burundi, Yemen and Zambia). A final update incorporating these significant changes was made in May 2003.
- "Supply-adjusted" forecast established through the matching of "pure demand" forecast with offers received from suppliers.

Procurement activities (lead responsibility: UNICEF SD)

- Manufacturers (38) on WHO and UNICEF lists of manufacturers currently producing and potentially producing invited to participate in the tender.
- Pre-tender meeting with participation of 26 manufacturers, WHO, The Vaccine Fund and the GAVI Secretariat organized 8 December 2002 to present the procurement process, requirements and timelines, and obtain feedback on the forecast
- Tender issued 20 January 2003, 30 proposals received by 14 March 2003.
- Technical review by WHO in March-May of 30 proposals (18 products), including compliance with mandatory requirements, compliance with preferred requirements, and assessment of timelines for pre-qualification for products not WHO-prequalified at time of offer
- Clarification/negotiation meetings with all manufacturers in the period April-June
- Recommendations for awards allocations and contracts forwarded to the Vaccine Fund Executive Committee end June returned with a request to further negotiate combination vaccines
- GAVI Board updated on the procurement process in July 2003
- Review of procurement and negotiations with new recommendations presented to the Vaccine Fund Executive Committee in September 2003
- Official issuance of awards (pending)

Financing issues (lead responsibility: The Vaccine Fund)

- Inputs provided into principles for firm contracting arrangements
- Establishment of financial/fiduciary agreements with UNICEF to support procurement operations and firm contracting arrangements
- Assessment of financial implications of awards and approval of procurement plans

Policy development (responsibility: project manager, WHO, UNICEF SD, Vaccine Fund)

- Establishment of the Five Year Supply Approval Framework, approved by the GAVI Board and The Vaccine Fund in May 2003.

- Identification of outstanding issues and preparation of supply-related policies for consideration by the GAVI Board, including revised policy for allocation of products in limited supply, inputs into country guidelines and annual report forms, and wastage guidelines for Vaccine Fund supported vaccines

Country support and "trouble-shooting" activities (responsibility: project manager, WHO, UNICEF SD)

- (Country support is provided by partner agencies as part of their regular operations, in particular WHO through its Accelerated Vaccine Introduction project and the network of regional advisors)
- Coordination of response to the reduced availability of combination vaccines, including WHO/UNICEF country missions to Zambia, Burundi and Yemen and identification of interim measures.
- Assessment of pentavalent vaccine stock-out in Uganda, including country visit, updates to the GAVI Board and identification and implementation of stop-gap actions

Establishment of a yellow fever vaccine stockpile (responsibility: WHO, project manager)

- Strategies for establishment of a 6m dose YF vaccine stockpile developed and approved by the GAVI Board in November 2002
- Operational guidelines including definition of respective roles and responsibilities developed in January-March 2003 by WHO, UNICEF and The Vaccine Fund
- Contract arrangements established and vaccine stockpile operational in July 2003.

Closing Phase (responsibility: project manager, GAVI Secretariat)

- Preparation of VPP Lessons Learned
- Preparation of draft work plan 2004-05 as part of the overall GAVI work planning process.

ANNEX 3: PROJECT CONTEXT: TRENDS IN THE TRADITIONAL EPI VACCINE MARKET

The global availability of basic pediatric vaccines used in low-income countries (BCG, DTP, OPV, Measles vaccine, TT) worsened dramatically in the late 1990s. From a situation with ample surplus of vaccine, increased product divergence between low- and high-income country markets and manufacturer exit/consolidation have resulted in a massive reduction of vaccine quantities offered on the market to countries and procurement agencies. In 2002 and 2003, the shortage of DTP vaccine led to a reduced production of pentavalent vaccine (DTP-hep B+Hib) and considerable delays in vaccine delivery to countries approved for support by GAVI and The Vaccine Fund.

Since many of the basic pediatrics vaccines are linked (DTP and DTP-based combination vaccines, TT and conjugate vaccine production) or compete for lyophilization and filling capacity, UNICEF Supply Division in agreement with suppliers organized the procurement of

basic pediatric vaccines for 2004-06 together with the tender for GAVI/Vaccine Fund supported products.

The main outcomes of the procurement of basic pediatrics are as follows:

- Availability of BCG, DTP, TT and Measles vaccine is on the increase. Supply is expected to meet demand, including DTP needed for the production of DTP-based combination vaccines. However, careful planning and monitoring of vaccine requirements for routine and supplemental activities must continue in particular for measles vaccine.

- The limited number of manufacturers for each product remains a concern in particular for measles. Broadening the supplier base is necessary to reduce the risks related to depending on some few manufacturers.

- Significant price increases for all the basic pediatrics have occurred and prices can be expected to remain at this level in the medium-term. Weighted average price for DTP will increase from $0.08 per dose in 2003 to $0.12 in 2004 and to $0.14 in 2006. This reflects the market response to the imbalanced supply/demand situation and may be considered a necessary trade-off to prevent further manufacturer exit and secure longer-term supply of basic vaccines to low-income countries. Governments and international donors will need to increase their vaccine budgets to meet the price increase of these vaccines.

Addressing Health Systems Barriers to Immunization
Outcome of Consultation with Countries

Geneva, 27 October 2003
DRAFT

Global Alliance for Vaccines and Immunization (GAVI)

B A C K G R O U N D

Immunization is one of the most cost-effective means to increase life expectancy and is alongside girls' education and access to clean water and sanitation a key intervention for raising productivity and reducing poverty. Immunization has been shown to be correlated with increased height and weight among 12 year olds and improved test scores and language abilities.

The GAVI Board has identified efforts to address system-wide barriers to immunization as a work plan priority for the GAVI alliance in 2004-05. The principal approaches are to seek alignment at global level of key health sector development partners, promote alignment across global initiatives that face similar barriers, and work with selected countries to find the best options where the GAVI alliance can add value over and beyond the work of individual partners. Such efforts will facilitate sustainable scaling-up of immunization and other essential services and contribute towards the achievement of the Millennium Development Goals.

As lead responsible for the development of this work plan area, NORAD with the GAVI Secretariat organized on 27 October in conjunction with the Second Consultation on Macroeconomics and Health (CMH) a one-day Consultation with the following objectives:

- Obtain input from Countries and Global Partners on the most critical and common system-wide barriers to immunization;
- Identify areas where alignment and synergies with other global efforts should be sought;
- Help define areas of most potential and "added value" on which the GAVI alliance should focus in 2004-05.

The meeting was organized as a series of panel discussions, each addressing one of the groups of system barriers identified in the McKinsey Study[10]. A Consultation paper containing statements aiming to describe barriers typically encountered at national level served as background material.

This report summarizes the key issues and the main outcomes of the discussions - as captured from the panel presentations, the plenary discussions and participants' feedback forms. It will inform GAVI work plan activities in 2004-05.

[10] Achieving our immunization goal", prepared by McKinsey & Co. for the GAVI Board in April 2003

PERSPECTIVES AND ISSUES

The Millennium Development Goals will not be reached unless system-wide barriers hampering the delivery of health and other social services are effectively addressed. The work of the Commission on Macroeconomics and Health underscores the lack of political will to sufficiently increase spending on health at sub-national, national and international level as perhaps the most critical barrier to improved health in low-income countries. Removing financial constraints will however not be sufficient and progress also hinges on the ability of countries to increase the capacity of their health sector. In particular, the human resource crisis brought about by AIDS (especially in Southern Africa), the migration of health workers, and the effects of structural reforms on intrinsically frail civil service systems constitute a second fundamental barrier that needs to be addressed in a short, medium and longer-term perspective.

The Consultation paper was found to provide accurate statements on critical system barriers to immunization at country level and useful as an entry point for discussion. It was emphasized that all these system barriers are inter-connected and that advocacy and communications in particular cut across all barriers. Missing elements related to the importance of underlying contextual factors (such as the effects of political stability on political and financial commitment, and of public trust and government credibility on the overall utilization of public health services) and the need to place sustainability at the centre when designing, implementing and evaluating efforts. The need to collaborate with other sectors and to seize the opportunities of potential spin-offs of non-health efforts such as establishment of birth registration systems was also noted.

Country contributions confirmed that the situation at national level is extremely dynamic**. Despite their challenges, countries are driving the process of addressing system-wide barriers, adapting to new situations and technologies, and finding workable ways of handling the fragmentation of development efforts.** Country experiences are under-valued and under-utilized, and the Consultation confirmed the existence of a rich base of potential best practices.

- Uganda has immunization as one of 12 priority components in its Uganda Minimum Health Care Package (UMCHP). The program receives support from presidential level and immunization data is routinely provided to political leaders alongside data on AIDS. Immunization costing data and scenario options have been prepared by the health ministry through the GAVI/FSP process and have catalyzed discussions with the finance ministry. Funding from the Poverty Action Fund (PAF) is increasingly being used for priority programs at sub-national level including immunization. The SWAp mechanism has increased transparency and trust among stakeholders.

- Though not yet optimally implemented, Mali is delivering a complete intervention programme to populations with limited access to health centers. Such a multi-purpose approach to delivery engaging several programs and sectors has helped define support needs and drive logistics and training efforts. The re-establishment of community committees has contributed to increase service coverage.

- Ghana has through its reform efforts started to address human resources issues head-on, by reforming organizational structures and posts, organizing management training and focusing on individual and institutional development. Identification of a package of interventions has been crucial for guiding the process. Broader efforts are underway to address the serious brain drain between professions, from the public to the private sector, and internationally).

- Haiti's national communication plan for immunization for 2003-07 aims to improve quality of services and change behavior of parents and personnel. Indicators to monitor progress have been established, and innovative approaches such as media management and crisis management efforts

initiated. Task forces from central level have helped to launch campaigns and establish local partners committees in the districts.

- Though still short of the target of 15% set by African Heads of State in Abuja (April 2001), Tanzania allocates 12% of its national budget to health with funds targeted towards regions most in need. In Tanzania (as the case is in Uganda) a completed immunization certificate has become a requirement for school enrolment. The Tanzania presentation stressed the need for countries to assess the benefits and risks presented by global opportunities before moving ahead with new initiatives. National ownership and strong management capacity at central level is key to handle technical and donor requirements.

A multitude of efforts involving bilateral agencies, UN agencies, the World Bank system, foundations, NGOs and global initiatives are underway to address system-wide barriers. While there is some room and scope for working in parallel, the Consultation confirmed the need for building on and seeking synergies with existing efforts rather than initiating new immunization-specific efforts at global level:

- WHO is strengthening its normative function and collaborative role with Member States in addressing system-wide barriers. Acceleration of priority efforts (such as the "three by five") will be designed based on Country Health System reviews and seeks to build on and strengthen national health systems. The newly established Health Metrics Network (HMN) is a response to the explosion in tools and data with only limited system strengthening benefits.

- The World Bank includes immunization into its policy dialogue with countries and its support to health sector projects and budget support initiatives (PRSC). DTP3 coverage is used as a trigger for measuring progress in the social sector in many PRSPs and as a proxy for quality of basic health services and health system performance. Efforts have been initiated to benchmark immunization performance in selected countries in order to promote learning between high- and low-performing countries and optimize Bank investment in immunization. Comprehensive efforts related to health manpower issues are also underway.

- Through its country programs of cooperation, UNICEF is supporting the planning and implementation of services using locally appropriate modes of service delivery including family and community based care, population oriented services and campaigns. Intensified efforts have recently turned towards analyzing and addressing local bottlenecks using data available at peripheral level. As part of the GAVI work plan 2004-05, UNICEF is coordinating efforts to work with governments in seven large-population countries to increase coverage through intensified district level planning and expansion of services.

- Roll-Back Malaria (RBM) is looking at rapid scale-up of malaria control tools i.e. insecticide-treated bed nets, intermittent preventive treatment, prompt and effective case management and malaria surveillance, initially in countries that are ready to demonstrate and document success. There is a potential to improve interactions between immunization and malaria efforts in several areas in particular linking malaria prevention to antenatal and EPI services.

- BRAC in Bangladesh is an example of the critical importance NGOs can play as advocates and mobilizers for improved health and development at local level and as service providers in particular to marginalized populations. New approaches are needed so that Governments better support and make more use of local NGOs.

- The private sector is a critical partner in the delivery of health services in many countries. More work is needed on private/public interaction and how to effectively maximize service delivery in both sectors.

There are clear parallels between current global initiatives and previous global efforts such as Health For All and Universal Childhood Immunization (UCI). Lessons learned should be applied so that current efforts can be sustained over the longer-term, at least until 2015. Putting a moratorium on new global initiatives and working through existing frameworks was suggested as a way to reduce the burden on countries and individuals and reduce fragmentation of efforts.

GAVI as an alliance of partners working together to increase the use of vaccines in low-income countries cannot take on all system barriers but can be useful in bringing partners together in a joint effort to address some few specific issues and promote harmonization of partner approaches at country level. Its ability as an innovator and a convener has been demonstrated through the work on financial sustainability, data quality, and performance-based financial support.

The Consultation emphasized the need to **support national priority setting and decision-making processes and embed partner actions within national strategic and policy frameworks.** Realistic goals for the immunization program should be set within the short, medium and long-term of a SWAp and/or PRSP, making sure that national immunization plans are fully integrated with these. This will promote consistency and sustainability of approaches, synergies and accountability across stakeholders and levels, and reduce the burden on systems and individuals.

While broad-based efforts to reach all segments of the population with vaccines need to continue, **there is scope for an increased emphasis on pro-poor approaches and actions.** Marginalized groups typically use public services less frequently, suffer worse health and carry a disproportionate disease burden load. Immunization carries a pathfinder potential in making more use of the power of its data (from health information systems, household surveys and disease surveillance), disaggregated by gender, age, geography and income groups to be made available to stakeholders and help guide efforts to reach marginalized and underserved groups. NGOs can play a critical role in this area.

Several participants noted that GAVI should consider formulating short-term and longer-term goals for addressing system-wide barriers, considering realistic timeframes for action and impact, partners' ability to influence processes, available resources and the work of other initiatives. In the short-term, the work plan 2004-05 will serve as a platform for GAVI action. Formulation of longer-term efforts could be done as part of the strategic plan development for 2005-2015.

POTENTIAL AREAS OF FOCUS 2004-05

Recognizing that the specific types and magnitude of barriers vary *between* and *within* countries and that flexibility in analysis and identification of solutions at local level is required, the Consultation allowed to focus in on potential areas at national level outlined below where the alliance can provide an added value (defined as coordination and consensus-making; funding; innovation; advocacy and communications) and where there could be potential to see progress/results in the short-term. This is summarized in annex 1.

At global level, these are times of tremendous opportunity for focus on investment and driving alignment. The agenda should build on country abilities to cope with the complex agenda of system strengthening. GAVI can make strategic contributions across global initiatives and mainstream development efforts, focusing on MDG and Poverty Reduction goals, as well as among partners within the GAVI framework, using the comparative advantage of the different partners to link the immunization effort with system and

service strengthening efforts. It is also time for becoming more concrete on human resource barriers, mapping what needs to be done and engaging in joint efforts within a common framework.

Political and Financial Commitment

GAVI efforts are carried out by partners in the alliance and not by GAVI as a distinct entity. National coordination mechanisms (the immunization-specific interagency coordination committee (ICC) or other similar Government-led coordination mechanism set within higher-level strategic frameworks) are country level reflections of the global partnership. In the short-term, there is scope to **strengthen national coordination mechanisms and use them as entry points for addressing system-wide barriers to immunization**.

Taking into account the country-specific context, potential actions would include clarifying relationships and harmonizing and establishing effective links to broader frameworks and processes such as a SWAp.

The following areas may benefit the most from special GAVI focus and contribute to reinforce the essential functions of a national coordination mechanism:

- Following-up on availability and predictability of funding (domestic and external)
- Monitoring of performance at sub-national level including coverage and financial allocation/disbursements/use, and
- Establishing pathfinder actions to identify and reach poor and marginalized groups.

Another potential area for GAVI focus is to **make available immunization pathfinder experiences for other programmes and the broader health sector**. As already seen in some countries, the work on financial sustainability (which is a requirement for GAVI/Vaccine Fund support) has been expanded to the costing and financing of other high priority interventions or to a defined minimum package of interventions. This could contribute to better-informed policy choice in dealing with competing priorities and to leverage financial support from finance ministries.

Physical Infrastructure and Equipment

The strength and reach of the health infrastructure vary greatly between and within countries. Local analysis and cost-effectiveness considerations are required when deciding on optimal service delivery strategies. While the most sustainable and cost-effective way to provide vaccines and other commodities is through an integrated delivery of services at fixed sites (e.g. health centers), close-to-client services provided through outreach activities constitute in many settings a critical element to improve access.

Partner efforts are underway to strengthen district micro planning for immunization and revitalize outreach activities, i.e. the WHO and UNICEF "RED" strategy of Reaching Each District. Population-oriented outreach services are also the focus of attention for a range of other initiatives and programs that seek to deliver interventions or services. .

GAVI can provide an added value by **encouraging and documenting cross-program collaboration and focusing on areas critical to the quality and sustainability of outreach approaches,** including:

- links to broader district planning, budgeting and monitoring processes
- costing of outreach services and assessment of their cost-effectiveness
- definition of interventions including the curative/preventive care mix
- exploring how to engage the private sector, in particular NGOs
- targeting marginalized and poor groups including urban and peri-urban poor and ethnic minorities.

Monitoring and Information Systems

Immunization programs have traditionally been at the forefront of producing and using data to inform program decisions. The data quality audit (DQA) introduced by GAVI to support the implementation of a performance-based reward system has helped uncover system weaknesses in national information systems, especially at peripheral level. GAVI will in 2004-05 continue to invest in data quality through DQA activities and by transforming the DQA into a self-assessment tool for self-administration at country level.

There was general agreement that there is scope for **working on immunization sub-systems as a way to support broader efforts to establish user-friendly quality monitoring and evaluation systems for the health sector and the PRSPs and MDGs**. Experiences with using immunization data (e.g. DTP3 coverage) as part of a small sub-set of indicators for measuring district performance and providing feedback to politicians and decision-makers could be looked into.

Another area to further explore is the use of **benchmark approaches to immunization coverage at sub-national level as a way to identify and address system bottlenecks for priority interventions and programs.** In addition to shifting the focus to sub-national level, this could provide opportunities to link up with performance-based schemes beyond immunization and help Governments and donors in prioritizing and allocating resources.

Management of Delivery / Human Resources

At global level, GAVI can help **push the comprehensive human resource agenda forward by contributing to the efforts underway at WHO, the World Bank and the Rockefeller Foundation (i.e. the Joint Learning Initiative).**

At national level, while an immunization entry point offers limited opportunity to influence macro-policies, there is room for positive change in areas traditionally under the influence of the EPI program and its external partners. GAVI could add value by **establishing a body of evidence and of best practices, share pathfinder experiences, and seek to harmonize partner efforts in the areas of training/capacity development and of incentives.**

Many countries experience an overload of in-service training resulting in significant costs and dubious benefits. This is brought about by a fragmented approach to capacity development in health, a lack of coordination between programs, the unfortunate practice of using training activities as a way to provide staff incentives, often worsened by donor pressure and earmarking of funds.

Staff motivation is critical for effective delivery of services. In resource-poor settings with low and insecure salaries, the use of incentives in vertical programs such as immunization has tended to skew priorities and made programs vulnerable to drops in external sources of funding.

The work will focus on establishing a body of evidence through operational research on **best practices in Human Resources** including on:

- Training/capacity development and
- Use of staff incentives

Social Mobilization and Demand Creation

Advocacy and demand creation are critical for maintaining the focus on immunization and protect its place in the basic package of cost-effective life-saving interventions. This becomes the more important in view of the current environment with competing priorities and tension between curative and preventive services.

Advocacy, social mobilization and communication are cross-cutting issues that need to accompany and support partner efforts in all areas, both on the supply side to increase quality, continuity and trust in the delivery of services and on the demand side to increase awareness of the benefits of immunization and to encourage the use of services. Promoting the use of a "coverage language" based on immunization data could in this respect both advance the rights agenda and help in transforming program information into tools for advocacy.

GAVI's added value may lie in **promoting synergies between various initiatives, including immunization initiatives,** both in advocacy efforts targeting decision-makers and in communication and mobilization efforts towards communities and families. Expanding the collaboration between local governments and NGOs may be important.

ANNEX 1: POTENTIAL AREAS OF FOCUS 2004-05

Focus at global level (Target 1 in the work plan)	System wide barriers	Focus areas at national level (Targets 2&3 in the work plan)
Contribute with GAVI pathfinder experiences to macro-level development and advocacy efforts in particular in the areas of human resources, monitoring, and increased investment in health Collate and disseminate best practices documented through country-level activities Seek to harmonize efforts to address system barriers by global alignment of major health development stakeholders, both within GAVI and with other global initiatives	**Political and Financial Commitment**	Strengthen ICC or other mechanisms with similar **national coordination function** and harmonize with broader processes (SWAps, PRSP), and use as a partnership entry point for addressing system barriers, in particular: • Pro-poor actions • Availability and predictability of financial resources • Monitoring of financial and program performance at sub-national level Use immunization specific work on **financial sustainability as a pathfinder** that can be applied to costing and financing other high priority services, with a focus on predictability and on informed policy choices in dealing with competing priorities Note: importance to set this within national strategic frameworks to drive synergies and coordination in a context of multiple initiatives and stakeholders
	Physical Infrastructure and Equipment	Focus on cross-program collaboration and sustainability of **close-to-client services** (e.g. outreach services), as critical element to improve access • Links to district level planning and budgeting processes • Cost-effectiveness of strategies • Engagement of private sector including NGOs Note: link to social mobilization/demand, balance between preventive/curative, supply availability

	Monitoring and Information Systems	Use **district level data** to identify and address system bottlenecks to priority interventions and programs Note: potential of focusing on immunization sub-systems and support efforts on comprehensive health sector systems and link with PRSP and MDG processes
	Management of Delivery / Human Resources	Establish through operational research body of evidence on **best practices in Human Resources** including on (a) training/capacity development and (b) use of staff incentives
	Social Mobilization and Demand Creation	Promote **synergies across immunization and non-immunization initiatives** Note: not a stand-alone topic, links to all other areas.

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A. Countries

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ATTACHMENT

Selection of countries for system wide barriers work

Introduction

One of the key objectives of the GAVI 2004/5 work plan on system barriers is to seek harmonization of efforts to address system wide barriers of major health stake holders within GAVI and other initiatives. Within GAVI, other agencies have also identified system wide barriers as a major issue and there are efforts to work within countries to address these issues. Efforts should be explored on how to bring the work of the different partners, both within and outside GAVI together on this issue.

UNICEF is using the marginal Budgeting for Bottlenecks, MBB, in selected countries to identify country/province specific "implementation constraints" of health system and estimate the "marginal costs" to overcome them. MBB uses existing information available for selected tracer interventions to identify the "bottlenecks," (weakest links in the chain of conditions), and debate various options to address them. Work has started in eight countries and there are plans to include more countries in this initiative.

In reaching its target of reaching 3,000,000 people infected with HIV by the end of 2005, **WHO** intends to use work with health systems to address the issues in a sustainable fashion. The target countries for this initiative will be indicated in early December, 2003.

The **World Bank** will soon initiate a plan to target selected countries to support improvement in immunization coverage in Africa using system wide approaches. The selection of countries is based on immunization performance over the past five years. A matrix was used to select a range of countries from high to low performance.

Please see the list below for selected countries

Selected Countries, UNICEF & WB

WB	UNICEF
1. Mauritania	**Mauritania**
2. Ethiopia	**Ethiopia**
3. Mali	**Mali**
4. Senegal	**Madagascar**
5. Burkina Faso	**Benin**
6. Rwanda	**Sierra Leone**
7. Cameroon	**Ghana**
8. Kenya	**India (Madhya Pradesh)**
9. Cameroon	

Proposed countries for system wide barriers selection - GAVI

High performers		Low Performers	
Coverage	Country		
70 – 89% Countries have achieved a consistent increase of coverage (0 -3% points) between 97 - 2002	Tanzania Rwanda Burundi Ghana Bhutan	**70 – 89%** High performers, but negative annual rate of change in past five years	Vietnam Malawi
50 – 69% More than 3% point increase annually from 97 - 2002	Togo Uganda	**50 – 69%** Mixed performance, some with stagnating coverage, failed DQAs, or very wide confidence interval	Lao Kenya Madagascar *Yemen
< 50% Traditionally low performing countries, but with consistent increase in coverage from 97 - 02	Mali §Burkina Faso Sierra Leone	**< 50%** Traditional low performers	Haiti Niger Chad CAR

§Burkina Faso failed DQA
*Yemen did not fail the DQA

Polio Eradication Strategic Plan 2004-2008
'Finishing the Job and Protecting our Investment'

Background:

Since 1988, the polio eradication partnership has been guided by multi-year strategic plans. The Polio Eradication Strategic Plan 2004-2008 replaces the year 2000 plan[11]. The new plan reflects the major tactical revisions introduced in 2003 to interrupt polio transmission, the revised timeframe for certification of eradication, and the decision to stop immunization with oral polio vaccine (OPV) as soon as possible after global certification.

The Polio Strategic Plan is being presented to the Board due to the major implications for GAVI contained therein.

Timeline:

The new plan outlines the key polio eradication activities for the next two phases of the initiative and prepares for the third:

- *Interruption of Poliovirus Transmission Phase* (2004-2005)
- *Global Certification and 'Mainstreaming' Phase* (2006-2008),
- *OPV Cessation Phase* (from 2009).

Major Issues and Implications:

1) New Target Dates: end-2004 is the target for interrupting wild poliovirus transmission (the last case could occur in mid-2005 without major implications). The target date for global certification is revised to 2008.

2) Sub-National Focus: the plan targets the 5 areas linked to 75% of cases worldwide (Kano, Nigeria; Uttar Pradesh and Bihar, India; Northwest Frontier Province and Sindh, Pakistan). Intensified activities will be tailored to each area, with strong political oversight to access civil administration resources and enhance accountability.

3) Routine Immunization & Importation Preparedness: the curtailing of polio campaigns in non-endemic areas has increased the risk of importations and cVDPVs[12], resulting in a much greater emphasis on routine immunization, particularly in very high risk areas (e.g. countries surrounding Nigeria). This provides an excellent opportunity for enhanced collaboration with GAVI on immunization strengthening.

4) Products for OPV Cessation: stopping OPV soon after certification requires markedly accelerated development of monovalent OPV (mOPV), IPV produced from Sabin strains (S-IPV), and IPV-containing combination vaccines. Mechanisms must also be in place to ensure countries that desire or need these products have access to them by 2009.

[11] Global Polio Eradication Strategic Plan 2001-2005. WHO Document No. WHO/Polio/00.05.
[12] circulating vaccine-derived poliovirus (cVDPV).

5) Global Certification and 'Mainstreaming': to avoid a cessation of activities after the interruption of transmission, the Plan outlines the work needed to achieve certification and mainstream the polio infrastructure, including the human resources, into other disease control, surveillance and response programmes.

Recommendations to the Board:

The Board is requested to:

1. Revise the GAVI milestones to reflect the new target date of 2008 for global certification of polio eradication that will be announced at the January 2004 launch of Polio Eradication Global Strategic Plan.

2. Advocate for the rapid interruption of polio transmission in Nigeria, India, Pakistan, Niger, Afghanistan and Egypt (by end-2004) and for close collaboration with the polio initiative to ensure higher routine immunization coverage in all countries to protect against importations in this critical phase.

3. Explore mechanisms for promoting the development of the products needed to stop OPV and strategies for ensuring that all countries can access the appropriate products, should they desire.

Attachment: Draft Polio Strategic Plan, 2004-08 [in PDF format]

Options for Promoting Synergy Between GAVI and Sustainable Measles Mortality Reduction

1. Introduction

The purpose of this document is to propose potential areas for synergy between GAVI and reduction of measles mortality activities.

Despite the availability of a safe, highly effective and inexpensive measles vaccine, in 2002 there were between 30 to 40 million measles cases resulting in approximately 643,000 deaths[13]. Measles is the leading cause of vaccine preventable deaths in children and is an important cause of under-5 mortality. Failure to deliver at least one dose of measles vaccine to all children remains the primary reason for continuing high measles morbidity and mortality.

Some important considerations about measles disease burden:

- 50% of measles deaths occur in Africa
- 75% of measles deaths occur in children < 5 years of age
- 98% of measles deaths occur in countries eligible to receive support from GAVI and the Vaccine Fund

In recognition of this unacceptable situation, at its 2002 meeting in Dakar, Senegal, the GAVI Board issued a statement on measles. (Annex 1)

The statement:

- Highlights the unacceptable burden of measles deaths
- Supports the WHO/UNICEF comprehensive strategy for sustainable measles mortality reduction
- Endorses the WHO/UNICEF "Framework for Collaboration" to ensure a sustainable reduction in measles deaths and health system strengthening
- Calls upon GAVI partners to financially support national immunization plans, including the full implementation of sustainable measles mortality reduction strategies

Several global goals have been established for measles mortality reduction:

- The 2000 Millennium Development Goal to reduce under-5 mortality by 2/3 by 2015 compared to 1990 levels. The main immunization indicator for progress toward this goal is the percentage of 1 year old children vaccinated against measles.

- The 2002 UN General Assembly Special Session "World Fit for Children" established the goal to reduce measles deaths by 50% by 2005 (compared to 1999 levels of 870,000 deaths).

- The 2003 World Health Assembly resolution on Measles Mortality Reduction requests countries to fully implement the WHO/UNICEF comprehensive measles mortality reduction strategy in order to achieve the above goals.

[13] Annual estimates of measles mortality are updated by WHO/IVB. The most recent updated estimates for measles deaths from 1999-2002 are: 870,000, 764,000, 704,000, and 643,000.

Accordingly, over 200 senior delegates from over 50 countries and international institutions assembled at a landmark meeting held in Cape Town, South Africa in October 2003. In this meeting, participants examined technical, operational and financial aspects of work already accomplished and discussed plans for the future. The meeting culminated with acclamation of the Cape Town Declaration which translated the commitment of all concerned to further the goal of measles mortality reduction with the utmost sense of urgency. (Annex 2)

2. WHO/UNICEF Comprehensive Strategy for Sustainable Measles Mortality Reduction

The achievement of measles mortality reduction requires improvement in both the coverage and quality of immunization services. Sustainable measles mortality reduction is possible by implementing the following comprehensive strategy.

- **Strengthen routine immunization services**

Countries should aim to achieve at least 90 per cent routine vaccination coverage in each district and nationally with at least one dose of measles vaccine administered to children who are nine months of age or shortly thereafter. Over time, achieving and maintaining high routine immunization coverage of successive birth cohorts can be expected to result in a marked and sustained decline in measles morbidity and mortality.

In addition to achieving high measles coverage, efforts are needed to assure that all immunizations are administered in a safe manner. Injection safety for all immunizations services must be strengthened through effective training and supervision, use of proper injection equipment, including safety boxes and the safe disposal and management of immunization waste.

To strengthen immunization services, WHO and UNICEF are working with countries to plan and implement the Reaching Every District (RED) Strategy. Components of this strategy include:

- Re-establishment of outreach services
- Supportive supervision
- Community links with service delivery
- Monitoring and use of data for action
- Planning and management of resources

- **Provide all children with a second opportunity for measles immunization**

A single-dose of measles vaccine administered at 9 months of age with coverage of 90% will only protect about 75% of each birth cohort. Approximately one quarter of each birth cohort will remain susceptible to measles because they either missed their measles vaccination, or were vaccinated but failed to develop immunity. Without additional immunization efforts, the number of susceptible children will accumulate over time, increasing the probability of a large measles outbreak.

Following a one-time-only "catch-up" campaign (generally targeting children 9 months through 14 years of age), the second opportunity for measles immunization can be delivered through routine or supplemental immunization activities, as appropriate. As coverage with routine services improves the need for periodic “follow-up” supplementary activities decreases. Campaigns are no longer needed when countries can maintain a routine two-dose vaccination schedule capable of coverage of 90% through routine services, and have a functioning system to identify and follow-up defaulters.

- **Enhance measles surveillance**

Countries should establish effective surveillance for measles and accurate monitoring of vaccination coverage by district as defined in WHO surveillance standards. This is critical for developing appropriate immunization strategies, determining the impact of immunization activities and the ongoing refinement of policies and strategies. Where appropriate, rubella/congenital rubella syndrome (CRS) surveillance activities should be integrated with those of measles.

Worldwide today, building on the infrastructure developed in the polio eradication initiative, over 600 national and sub-national laboratories have joined in a coordinated measles surveillance and diagnosis network that includes routine performance monitoring and quality control procedures. The same infrastructure is being used to enhance capacity for rubella and yellow fever surveillance.

- **Assure appropriate measles case management**

Most measles deaths follow complications such as pneumonia, croup and diarrhea, and are also frequently associated with malnutrition. In addition, measles may result in long-term health problems including blindness, deafness, chronic lung disease, poor growth and recurrent infections. Although measles vaccine is the best public health tool for the prevention of the disease, prompt and correct treatment of measles is vital for saving the lives and preventing disability in those who have not been protected. Treatment with vitamin A supplementation is highly effective (reduces measles case-fatality by 50%), along with management of diarrhea, and use of antibiotics for complications.

- **Link sustainable measles mortality reduction activities with other priority public health interventions**

Measles immunization (both through routine services and supplemental immunization activities) should be used as an opportunity to administer vitamin A prophylaxis in areas where vitamin A deficiency is prevalent. This should contribute to a reduction of overall mortality among children less than five years of age. Moreover, measles mortality reduction activities provide an excellent opportunity to link other interventions such as maternal and neonatal tetanus elimination, rubella/CRS control, provision of anti-helminthics and the delivery of insecticide treated bed-nets.

To assure that measles mortality reduction activities are appropriately implemented, WHO and UNICEF have adopted a ***Framework for Collaboration*** (Annex 3) to guide their cooperation with countries. Components of this framework include:

- Existence of a comprehensive multi-year immunization plan of action with full integration of measles mortality reduction activities. Measles cannot be an ad hoc activity.

- Clearly defined goals and strategies for measles mortality reduction with articulation of plans for assuring financial sustainability and developing human resources.

- Existence of a surveillance system for monitoring measles epidemiology, supported by an efficient laboratory network, preferably integrated with surveillance for other diseases of public health importance.

- A special focus is needed for countries with very large populations or those experiencing or recovering from complex emergencies.

3. Partnership Approach

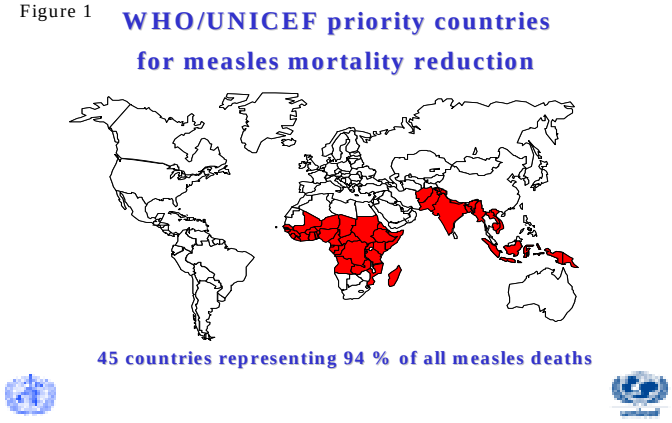
The key to rapid and high quality implementation in Africa has been the Measles Partnership. Beginning in 2001, The Measles Partnership, with core membership of American Red Cross, United Nations' Foundation, CDC, WHO and UNICEF, committed itself to implementing the WHO/UNICEF Comprehensive Strategy for Sustainable Measles Mortality Reduction. Their goal was to vaccinated 200 million children by 2005.

As of December, 2003, over $60 million has been allocated to countries in Africa for catch-up campaigns, and over 100 million children have been vaccinated. The average coverage for second opportunity vaccination is over 90%. The Measles Partnership is ahead of schedule and exceeding targets. The Partnership now includes additional significant support from CIDA, the LDS Church, Vodafone and Gates Foundation as well as in-country donors. Following the Cape Town Measles Meeting, there is substantial interest from other WHO Regions to adopt a similar model for implementing their Regional plans with initial Partnership efforts already under way in EURO, EMRO and WPRO.

4. Progress in sustainably reducing measles deaths during the period 2001-2003

In their joint strategic plan, WHO and UNICEF have identified 45 priority countries to target for enhanced measles mortality reduction activities from 2001-2005 (Figure 1). These countries account for over 94% of global measles deaths.
Of these, 15 countries had routine measles coverage of less than 50% in 2001. Annex 4 summarizes WHO/UNICEF best estimates of routine measles coverage in these countries for the period 1998 through 2002.

Figure 1



By end 2003, 29 (64%) of these countries have provided a second opportunity through national "catch up" campaigns:

Afghanistan, Angola, Benin, Burkina Faso, Burundi, Cambodia, Cameroon, Cote d'Ivoire[1], Democratic Republic of Congo[1], Eritrea, Ethiopia[14], Ghana, Guinea, Indonesia[1], Kenya, Lao PDR, Liberia[1], Mali, Myanmar[1], Papua New Guinea, Rwanda, Senegal, Sierra Leone, Sudan[1], Tanzania, Togo, Uganda, Vietnam, Zambia.

In these countries, a second opportunity for measles immunization was provided to children in the targeted age groups, generally 9 months through 14 years of age. The Measles Partnership (American Red Cross, CDC, United Nations Foundation, UNICEF and WHO) has provided significant support for measles mortality reduction activities in Africa.
Cumulatively, over 120 million children between 9 months and 14 years of age were vaccinated in these supplementary activities. In each of these countries over 90% of the children targeted were reached resulting

[14] These countries will complete their campaign activities in 2004.

in a marked reduction in measles deaths. It is estimated that over 220,000 deaths from measles have been averted in these countries due to the supplementary activities. In the next three years the remaining 16 measles priority countries will be targeted for intervention.

5. Financial resources for measles mortality reduction activities

On the basis of national plans of action, an attempt has been made to estimate overall costs for implementation of sustainable measles mortality reduction activities in the 45 WHO/UNICEF priority countries (Annex 5). Efforts are being made to refine these cost estimates and to extend them through the year 2010. Preliminary estimates indicate that about US $300 million is required to implement the measles activities needed to achieve the 2005 goal for measles mortality reduction.

Country ownership and financial sustainability are critical components of the strategy for sustainable measles mortality reduction. In this regard, it is expected that the primary responsibility for financing measles mortality reduction activities will be national governments and their local partners.

Coordination of activity and financial planning will occur within national Interagency Coordinating Committees (ICCs). Indeed, it is expected that at least 25% (and up to 100% in some countries) of costs for measles mortality reduction activities will be mobilized locally through national budgets and with support of local partners. Assistance from external partners will be sought to fill funding gaps. All countries are expected to include measles mortality reduction activities within their multi-year Immunization and Financial Sustainability Plans.

Global polio eradication remains the overriding priority and measles mortality activities will need to be planned accordingly.

6. Proposed Steps to Achieving Synergy between GAVI and Measles Mortality Reduction Activities

It is imperative that GAVI and Measles Mortality Reduction activities strive to assure synergy, both to build strong immunization systems and achieve rapid reduction in measles deaths. The following sections of this paper put forward a number of options for consideration.

In reviewing the proposed options for greater synergy with measles mortality reduction activities, the Board is faced with a number of challenges:

- GAVI's funding has not been targeted towards the leading cause of vaccine-preventable deaths, and this presents a "moral issue";
- Fundraising for the Vaccine Fund might be enhanced if GAVI presented a mechanism for direct support for measles mortality reduction activities;
- A closer relationship between GAVI and measles activities could help partners (who participate in both) provide more integrated (and less contradictory) guidance to countries.

6a). How measles mortality reduction activities can help achieve GAVI goals

(i) Advocacy support: Utilize advocacy opportunities to further GAVI cause:

- Use measles activities to stress GAVI's critical support to achieve high routine measles coverage as part of immunization system strengthening
- Use measles safe injection capacity to strengthen routine immunization injection safety

- Use media opportunities (print, web, etc) to promote completion of the routine immunization series for each child.

(ii) Comprehensive approach: Use the WHO/UNICEF comprehensive strategy for sustainable measles mortality reduction to also strengthen routine immunization systems, including:

- Provision of financial support: minimum of 10% of total supplementary immunization budget should be utilized to strengthening routine immunization services, including implementation of the RED strategy with district level assessment and micro-planning;

- Expand measles monitoring (including data management) and surveillance systems to include routine immunization at the district level;

- Use of measles SIAs as a stimulus to provide 'refresher training' for routine immunization, conduct immunization safety reviews (safe injection practices, waste disposal capacity, AEFI surveillance) and support the development and implementation of EPI plans of action;

- Use supplementary immunization activity micro-plans to identify and include "un-reached" children in routine services;

- Use measles as an entry point in areas where measles mortality and demand for measles vaccination is high, to sensitize communities and decision makers to create demand for other available vaccines.

(iii) Strengthen Linkages: Utilize supplementary measles activities to strengthen the routine immunization delivery system, such as:

- Improve the cold chain, including the provision of cold chain equipment

- Build capacity of country EPI staff (e.g. injection safety, epidemiology of vaccine-preventable diseases, management, surveillance, monitoring and evaluation)

- Improve partner coordination at the national level: promoting linkages between routine immunization and measles mortality reduction activities through Interagency Coordinating Committees (ICCs).

6b). Options for GAVI to help achieve and sustain the goal of measles mortality reduction

(i) Advocacy support: Advocate for the positive impact that measles mortality reduction activities are having on strengthening routine immunization systems

(ii) Support monitoring of global targets: Promote monitoring of key measles indicators (measles vaccination coverage for both first and second opportunities) and outcomes (progress toward 50% reduction in measles deaths)

(iii) Vaccine and injection equipment support: Contribute US $10 million/per year over the next 2-5 years for purchase of bundled measles vaccine and operational costs for measles mortality control activities in the 45 priority countries.

- This would provide priority countries with upwards of 170 million doses of measles vaccine and demonstrate urgent action by GAVI to measles (and the 2005 and MDG mortality reduction goals) due to underutilization of measles vaccine.

(iv) Build capacity for the second routine dose of measles vaccine:

- The second opportunity for measles vaccine is commonly offered through campaigns. As routine systems improve, the second opportunity for measles immunization may be more appropriately delivered through a 2-dose routine schedule. GAVI and measles partners should work together, to support demonstration projects and operations research, to identify appropriate mechanisms for transitioning from campaigns to 2-dose routine delivery.[15]

- Expand the number of interventions (GAVI Objective #2) offered at the second routine measles contact to catch-up all missed vaccinations, provide second dose of vitamin A, bed net re-treatment, and de-worming.

- Ensure that the cost of a second dose routine measles vaccination and any "follow-up" campaigns are included in the Financial Sustainability Planning process supported by GAVI.

ANNEX 1: PRESS RELEASE
COMPREHENSIVE IMMUNIZATION STRATEGY CAN GREATLY REDUCE CHILD DEATHS FROM MEASLES

GAVI Board Endorses Plan and Calls for More Funds

NEW YORK/GENEVA, 7 January 2003 - A comprehensive measles immunization strategy could prevent an estimated 2.3 million child deaths in Africa this decade, markedly reducing the death toll from measles on the continent. WHO and UNICEF made this encouraging announcement at a recent board meeting of the Global Alliance for Vaccines and Immunization (GAVI).

Of all the vaccine-preventable diseases, measles is still the leading cause of child deaths. Every year, measles affects over 30 million children and claims the lives of nearly 800,000 – more than half of them in Africa. The new immunization strategy has been extremely effective in a block of seven southern African countries. Through this strategy Botswana, Lesotho, Malawi, Namibia, South Africa, Swaziland and Zimbabwe have reduced measles deaths to near zero since the year 2000.

"We have the opportunity to save well over 2 million young lives using a proven strategy," said Carol Bellamy, Executive Director of UNICEF and Chair of the GAVI board. "Measles immunizations have saved the lives of over 130,000 children in Africa this year. We must now build on this success and ensure that every child is adequately vaccinated and protected against measles."

The GAVI board endorsed the WHO/UNICEF comprehensive measles immunization strategy to achieve a sustainable reduction in measles deaths. This strategy provides children with two opportunities for measles immunization. The first opportunity is given at 9 months of age through the country's routine immunization delivery system, and a second through supplementary immunization campaigns conducted every 3-4 years to ensure that every child is reached.

"The child death toll from measles – a completely preventable disease – is unacceptable. GAVI's mandate is to increase children's access to vaccines, and measles vaccine is a proven life saver," said Dr Gro Harlem Brundtland, Director-General of the WHO and a GAVI board member. "But a comprehensive measles

[15] Potentially some countries could achieve high 2-dose routine measles coverage in some areas, hence over time the "measles follow-up" supplementary immunization would not need to be national in scale, but rather focus only on those areas with low 2-dose coverage.

immunization strategy requires sustained funding. I encourage the GAVI partners to do their utmost to fund the full implementation of this important strategy."

WHO and UNICEF currently estimate that an additional US$ 200 million will be required to implement the comprehensive measles strategy. The funds would pay for the vaccines, safe injection materials, refrigeration equipment, transportation and personnel both to strengthen routine immunization activities and to conduct the supplementary measles immunization activities in the African region from 2003-2010.

"Reducing measles deaths on a long-term basis is an important part of the UN Millennium Development Goals and measles mortality reduction strategies form an integral part of countries' immunization plans which the Alliance promotes", said Dr Tore Godal, GAVI's Executive Secretary.

GAVI fully supports the UN goals related to measles prevention. These include the UN Special Session on Children resolution to reduce measles deaths by 50% by the year 2005, as well as the UN Millennium Development Goals, which include the target to reduce the under-five mortality rate by two thirds. The proportion of children immunized against measles by one year of age is a key indicator for measuring the achievement of these goals.

Reducing measles deaths in a sustainable manner is the objective of the ***Measles Initiative***, a broad-based partnership co-coordinated by the American Red Cross and including the Centers for Disease Control and Prevention (CDC), the UN Foundation, UNICEF, WHO, the Canadian International Development Agency (CIDA), governments, civil society and the private sector. In 2001 and 2002, the Measles Initiative has delivered measles vaccine to over 70 million children in 16 African countries.

The Global Alliance for Vaccines and Immunization (GAVI) is a public-private partnership focused on increasing access to vaccines among children in poor countries. Partners include national governments, UNICEF, WHO, The World Bank, the Bill & Melinda Gates Foundation, the vaccine industry, public health institutions and NGOs. The Vaccine Fund is a new financing resource created to support the GAVI immunization goals, providing financial support directly to low-income countries to strengthen their immunization services and to purchase new and under-used vaccines.

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ANNEX 2: CAPE TOWN MEASLES DECLARATION 17 October 2003

ALARMED that in 1999 alone an estimated 875,000 infants and children died from measles, and that measles continues to cause hundreds of thousands of child deaths each year, especially in developing countries;

STRESSING the importance of achieving the goals adopted by the United Nations General Assembly Special Session on Children in 2002 and the World Health Assembly in 2003 to reduce measles deaths by 50% compared with 1999 levels by the end of 2005, and the United Nations Millennium Declaration target to reduce the under-five child mortality rate by two-thirds by the year 2015 compared with 1990 levels;

RECOGNIZING that measles deaths are primarily due to lack of immunization with existing safe, effective and inexpensive measles vaccines and incomplete implementation of proven strategies;

NOTING the critical importance of continuing to strengthen routine immunization services, including the provision of a second opportunity for measles immunization, as the foundation of a comprehensive strategy to reduce measles deaths sustainably and the essential role of surveillance in monitoring and guiding measles control efforts;

HIGHLIGHTING the importance of developing multi-year immunization plans, the full integration of measles mortality reduction activities with other national health goals and mobilizing necessary human and financial resources for sustainable measles mortality reduction;

WELCOMING the remarkable progress that has been made by the Region of the Americas in interrupting measles virus circulation and the ongoing efforts in Africa, with strong support from the Measles Initiative to reduce measles deaths;

Those present at the Global Meeting for Sustainable Measles Mortality Reduction and Immunization Systems Strengthening declare our intent to:

SUPPORT the WHO/UNICEF Global Strategic Plan for Measles Mortality Reduction and Regional Elimination, 2001-2005 with special attention to increasing routine measles immunization coverage to at least 90 per cent coverage in all countries, combined with providing all children with a 'second opportunity' for measles immunization either through the routine immunization schedule or periodic supplemental immunization activities;

WORK TOGETHER to identify the human and financial resources to strengthen immunization and health systems and to reduce measles deaths throughout the world;

ADVOCATE to strengthen immunization systems and reduce further measles mortality according to the strengths of each partner.

Annex 3: 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 in 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 outline 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 fulfill 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 4: WHO/UNICEF "best" estimate of routine measles vaccination coverage in the 45 priority countries for sustainable measles mortality reduction activities, 1998-2002

Country	1998	1999	2000	2001	2002
Afghanistan	40	40	35	46	44
Angola	65	46	41	72	74
Bangladesh	72	76	76	76	77
Benin	66	75	68	65	78
Burkina Faso	46	46	46	46	46
Burundi	76	75	75	75	75
Cambodia	52	55	65	59	52
Cameroon	57	62	62	62	62
Central Afr Rep	39	37	36	35	35
Chad	30	30	42	36	55
Congo	21	23	34	35	37
Côte d'Ivoire	66	62	73	61	56
DR Congo	20	15	46	37	45
Djibouti	21	23	50	49	62
Equatorial Guinea	82	51	51	51	51
Eritrea	81	88	86	84	84
Ethiopia	46	27	52	52	52
Gabon	56	55	55	55	55
Ghana	73	73	84	81	81
Guinea	52	52	52	52	54
Guinea-Bissau	61	70	59	48	47
India	51	50	56	56	67
Indonesia	71	71	73	76	76
Kenya	78	76	77	78	78
Lao	71	71	42	50	55
Liberia	NA	NA	52	78	57
Madagascar	46	55	55	55	61
Mali	54	52	49	37	33
Mozambique	58	58	58	58	58
Myanmar	85	85	84	73	75
Nepal	72	72	71	71	71
Niger	35	36	34	51	48
Nigeria	40	40	40	40	40
Pakistan	55	56	56	57	57
Pap New Guinea	59	57	68	58	71
Rwanda	78	78	74	69	69
Senegal	62	60	48	48	54
Sierra Leone	NA	62	37	53	60
Somalia	47	38	38	36	45
Sudan	49	53	47	67	49
Togo	50	57	58	58	58
Uganda	53	57	56	61	77
Tanzania	78	72	78	83	89
Viet Nam	96	93	97	97	96
Zambia	85	85	85	85	85

ANNEX 5: Estimated Costs of Measles Mortality Reduction Activities, 2004-5

Costs have been estimated by combining the costs of bundled vaccine, syringes and safety boxes with the estimated operational costs of providing the second opportunity for measles immunization as part of the comprehensive strategy. The operational costs include: transport, training, per diems, injection safety, social mobilization, cold chain strengthening and surveillance. These estimates need to be considered as general estimates only. Actual costs vary both between and within countries. The five larger targeted countries with a population over 100 million (India, Indonesia, Pakistan, Bangladesh and Nigeria) will conduct multi-year phased supplementary immunization activities to implement the second opportunity most of them starting in 2005.

The following assumptions have been made in estimating costs:

- Vaccine/syringe cost = $0.29/dose
- Operational costs = $0.60/child vaccinated
- Wastage rate for vaccines/syringes = 10%

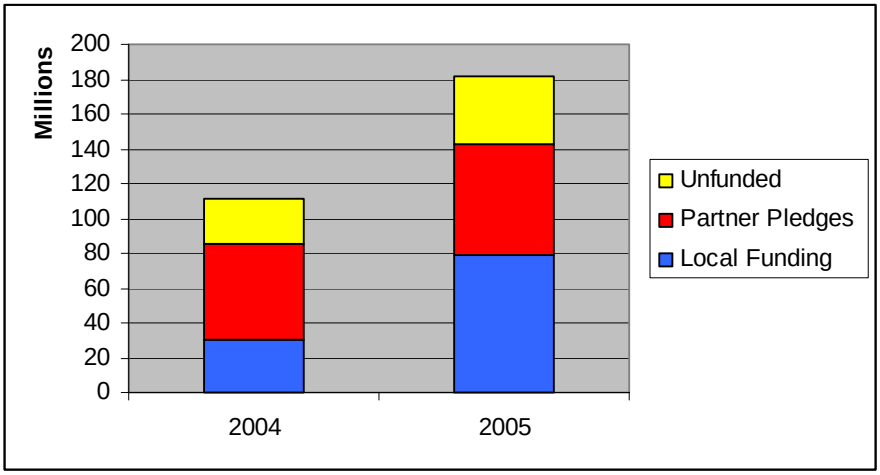
Table 1. Financial resource requirements to provide a second opportunity for measles immunization in the 45 WHO/UNICEF priority countries by donor supported activity and by country size, 2004-2005

Year	Children Targeted	Vaccine Cost	Ops Cost	Total	Local Funding	Partner Pledges	Funding gap
2004							
Group 1	94,414,000	$27,380,060	$56,648,400	$84,028,460	$17,702,600	$41,542,160	$24,783,700
Group 2	32,127,000	$9,316,830	$19,276,200	$28,593,030	$12,047,792	$14,135,880	$2,409,358
TOTAL	126,541,000	$36,696,890	$75,924,600	$112,621,490	$29,750,392	$55,678,040	$27,193,058
2005							
Group 1	32,815,000	$9,516,350	$19,689,000	$29,205,350	$6,152,815	$10,336,725	$12,715,810
Group 2	173,533,000	$50,324,570	$104,119,800	$154,444,370	$73,076,100	$54,662,895	$26,705,375
TOTAL	206,348,000	$59,840,920	$123,808,800	$183,649,720	$79,228,915	$64,999,620	$39,421,185

Group 1 Countries: Priority countries with population less then 100 million.

Group 2 Large Countries: India, Indonesia, Pakistan, Bangladesh and Nigeria

Figure 1. Financial resource requirements to provide a second opportunity for measles immunization in the 45 WHO/UNICEF priority countries, 2004-2005



ADIP Management Committee Meeting
Report of Decisions and Action Points

15-16 October 2003
Seattle, Washington
Bill & Melinda Gates Foundation

1. ADIP Management Committee Membership and TORs

The Committee:

1.1. Accepted the terms of reference as included in the meeting folders.

1.2. Committed to act as the main communication vehicle between the ADIP teams and the GAVI Board in order to ensure consistency between ADIPs and overall GAVI strategic directions.

1.3. Agreed that its main management responsibilities are to:
1.3.1. advise the Rotavirus and Pneumococcal ADIPs on priorities and operations; and
1.3.2. make recommendations to the GAVI Board concerning ADIP management and funding.

1.4. Agreed that the GAVI Secretariat should facilitate the operations of the Committee

2. Definition of success

The Committee:

2.1. Decided that the main goal for the ADIPs should be to provide the GAVI Board and GAVI partners – including developing country governments, technical partners and the Vaccine Fund– the evidence base they need to evaluate the potential value of introducing pneumococcal and/or rotavirus vaccines.

2.2. Agreed that, from the perspective of the GAVI/VF Boards, the evidence base could point in one of three directions:
- Evidence in favor of using VF funding to procure vaccine and accelerate introduction of vaccine in VF eligible countries
- Evidence not in favor of using VF funding to procure vaccine and accelerate introduction of vaccine in VF eligible countries
- Evidence in favor of introduction of vaccine in VF eligible countries, however, evidence indicate that GAVI and The Vaccine Fund resources do not have an added value role in accelerating this introduction.

2.3. Requested each ADIP to update the criteria for success, based on this discussion.

3. Framework for the investment case

The Committee:

3.1. Endorsed the following framework upon which to build an investment case for each ADIP:
- Pricing, including a prediction of vaccine price reductions over time
- Uptake strategy
- Revenue and financing strategy over the course of a few years
- Outcome measure (disease and deaths averted) relying on surrogate measures of disease burden and vaccine efficacy

3.2. Agreed that developing the investment case is the most important aspect of the ADIPs. The Committee will review and assess each of the ADIP investment cases at each meeting, and ADIP team leaders will be asked to revise their casework as necessary, based on these discussions.

3.3. Welcomed the proposal of the Vaccine Fund to suggest a system for consistent communication between the ADIPs and VF staff in order to synchronize fundraising activities with data emerging from the ADIPs.

3.4. Requested each ADIP team to provide a one-pager on their activities and goals, for use by the Vaccine Fund and the Secretariat in fundraising discussions and meetings.

4. Definition of 'late-stage' vaccine candidate

The Committee:

4.1. Defined the criteria for a 'late-stage' vaccine candidate as follows:
- Vaccine candidate has positive safety and efficacy data from phase I and II trials; and
- Vaccine candidate is produced by a producer[16] that has put candidate on a credible trajectory toward immediate phase III and introducing it in a market

4.2. Agreed that even if the above criteria are met with a certain vaccine candidate, the ADIP teams will need to evaluate and prioritize the opportunities and decided whether they have the human and other resources to pursue that vaccine candidate.

5. Segmentation of countries

The Committee:

[16] A 'producer' might be an emerging supplier that has licensed a candidate and would therefore need to re-conduct phase I and II clinical trials. However, funding for these early clinical trials would not be provided by the ADIPs.

5.1. Agreed that the ADIPs could choose to support a defined set of countries in their preparation toward early introduction of rotavirus and/or pneumococcal vaccines.
5.2. Decided that ADIP resources could be used for research (e.g., surveillance) and support activities in middle income countries, if those efforts are demonstrated to contribute to accelerating the introduction of new vaccines in all developing countries.
5.3. Requested that each GAVI/Vaccine Fund eligible country be sent an invitation to submit an 'Expression of Interest' in working with the ADIPs toward early introduction of rotavirus and/or pneumococcal vaccines. The GAVI Secretariat will help facilitate this. The invitation should also be distributed more widely through internet and other means.

5.4. Agreed that disease burden and cost effectiveness studies should be conducted in an appropriate mix of geographic settings. Furthermore, data resulting from these studies must be verified by independent experts.

6. Budgets for 2004

The Committee:

6.1. Reiterated the need for any potential agreement with an industry partner to be presented to, and approved by, the Committee before it is signed.

6.2. Endorsed the proposed 2004 budgets for the pneumococcal ADIP. However, in order to ensure that resources are available when needed, the team leader will re-examine his program budget to identify encumbrances that extend beyond 2004, so that these may be included in the 2004 budget. Once the revised 2004 pneumococcal ADIP budget is received, pending endorsement by the Chair, it will be forwarded to the full GAVI Board with a recommendation to approve.

6.3. Endorsed the proposed 2004 budgets for the rotavirus. However, in order to ensure that resources are available when needed, the team leader will re-examine his program budget to identify encumbrances that extend beyond 2004, so that these may be included in the 2004 budget. Once the revised 2004 rotavirus ADIP budget is received, pending endorsement by the Chair, it will be forwarded to the full GAVI Board with a recommendation to approve.

6.4. Agreed that it should receive the normal audited reports that are provided to the respective ADIP hosts. If the Committee feels these are not sufficient for adequate oversight, the ADIP teams will work with the Committee chair to develop appropriate reports.

7. GAVI-ADIP agreements

The Committee:

7.1. Expressed its concern about the slow progress in completing the memoranda of understanding between the ADIP teams and the UNICEF Vaccine Fund Trust Account, which is acting as trustee on behalf of the GAVI and Vaccine Fund Boards,

and urged all partners to intensify activity to finalize the MOUs.

7.2. Decided that if the MOUs are not completed by the time of the next GAVI Board meeting on 9-10 December, the Committee would recommend to the Board that it may need to consider whether the Vaccine Fund, rather than UNICEF, should enter into agreement.

8. Other issues

The Committee:

8.1. Scheduled its next meeting for 9-10 June 2004. The location will be determined at a later date; Johns Hopkins School of Public Health has offered to host the meeting in Baltimore.

8.2. Decided that the two ADIP team leaders should work with the Committee Chair to develop the presentation to the GAVI Board at its meeting in December. The presentations should include:

- Summary plans and progress reports
- Definitions of success

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The Case for Investment in R&D for Three Immunization Technologies: Recommendations for GAVI Action

This report was prepared by the GAVI Working Group to summarize and build upon the findings of the New Technology Working Group (NTWG) and provide recommendations to the GAVI Board for research and development (R&D) for immunization technologies. Recommendations are provided both for development of each specific set of technologies (nested in the three sections of the report) and for GAVI's broader role in R&D for vaccines and immunization.

Background

During its meeting in Stockholm in March 2002, the GAVI Board reviewed a proposal by the R&D Task Force regarding priority technologies for improving the quality and reach of immunization services. Three priorities for technology development were identified:

- Reduced costs and improved efficacy through elimination of the cold chain;
- Performance monitoring through detection of biomarkers of effective immunization; and,
- Improved safety through improved management of infectious waste and/or elimination of the use of sharps.

In each of the three areas, the R&D Task Force chose one specific technology as a promising example for further study by the New Technology Working Group (NTWG) of the R&D TF. These included:

1. Sugar glass stabilization for elimination of the cold chain
2. Non-invasive tetanus antitoxin tests for performance monitoring; and,
3. Defanging devices for improved safety.

The NTWG prepared a detailed scientific report on these selected technologies that was discussed by the GAVI Working Group in June 2003. Before the presentation of these findings to the Board, the Working Group recommended the preparation of a succinct summary and the inclusion of additional analysis, including:

- The "landscape" of current R&D efforts for related technologies;
- The summary of data establishing the "public health case" and "business case" for investment in these technologies; and,
- Specific recommendations to the GAVI Board for action in the development of these and other new technologies for immunization.

Section 1: Sugar Glass Stabilization

Magnitude of the Problem

All current vaccines are thermolabile, requiring continuous storage and transport in a cold chain to ensure their potency and safety. This thermolability of vaccines, along with the cost and fragility of the cold chain in resource-poor settings, defines a substantial set of constraints to cost-effective immunization:

- Annualized direct costs of establishing and maintaining the logistics-intensive cold chain in the developing world, which are estimated at US $200 million [17];
- Frequent detection of breaks in the cold chain (including damage due to both heat and freezing) and resulting spoilage of vaccine, estimated to result in costs in excess of US $100 million per year [18];
- Further undetected failures of the cold chain (especially due to freezing, as the vaccine vial monitors - VVMs – that are currently in use detect only heat exposure), resulting in an unknown reduction in efficacy of vaccines, excess morbidity and mortality due to vaccine preventable disease, and damage to the public confidence in immunization[19];
- Additional logistical burden, costs, and compromise of safety due to the need to reconstitute those vaccines that are lyophilized to enhance stability.

Technical Landscape

Other Candidate Technologies

Several technologies are currently employed routinely to solve the problem of thermolability, by continuously maintaining a "cold chain" from the moment of release of vaccine from the manufacturer, through international transport and supply depots, to where vaccines are administered. These include technologies for refrigeration, insulation (such as cold boxes), and temperature monitoring (including vaccine vial monitors to detect heat-compromise). No acceptable technology is in use to detect freeze damage. Other current and potential candidate technologies to solve the problem of thermolability include:

Vaccine Vial Monitors (VVMs): VVMs enable the end-user of a vaccine to identify whether any heat exposure has endangered the efficacy of the vaccine. This permits minor breaks in the cold chain to be accommodated without undue vaccine wastage and ensures that heat-compromised vaccine is "flagged" to be discarded. While VVMs are not yet in universal use for all GAVI-procured vaccines, efforts are underway to clear the last remaining barriers.

Improved Refrigeration Systems: Several improvements in refrigeration systems are slowly being implemented as equipment ages and requires replacement. Central stores of vaccine stock can be protected with computer-based monitoring to reduce both detected and undetected temperature damage. Ice-lined

[17] Jodar LP, Aguado TM, Lloyd J, Lambert PM. Revolutionizing Immunizations. Gen Eng News 1998; 18:6.

[18] Martin to provide references

[19] In Australia, exposure to sub-zero temperatures occurred to nearly 50% of hep B vaccines [6], and freezing was identified as the greatest threat to vaccine potency [7]. A study in Indonesia (CM Nelson, et al. Hepatitis B vaccine freezing in the Indonesian cold chain: evidence and solutions. Bull WHO, 2003) showed up to 75% of liquid vaccine was exposed to sub-zero temperatures. In areas where climatic conditions are frequently sub-zero vaccine-freezing is a very significant problem and some studies have detected up to 40% of vials exposed to freezing temperatures [9], suggesting that winter-freezing of vaccines being a likely cause of the diphtheria epidemic (1998) in the Soviet Union (Ask Martin to provide references).

refrigeration equipment with better temperature control is being introduced gradually in intermediate stores to protect against accidental freezing of vaccines. At the periphery, replacement of kerosene refrigerators with hybrid solar equipment will result in better temperature control. These improvements will further drive up the annual costs of refrigeration for vaccines in developing countries, already conservatively estimated at US $200 million per year[20].

Lyophilization: Lyophilization of vaccines (e.g. Measles, Hib, Rotavirus, meningococcal polysaccharide) involves immobilizing in a cake of semi-crystalline sugar (lactose or sorbitol supplemented with mannitol, amino acids and, in older vaccines, proteins such as gelatin or bovine serum). This confers reasonable stability (typically several weeks at ambient temperature) and resistance to freezing but storage in the cold chain is still required. Unfortunately as soon as vaccines are reconstituted they begin to lose activity and must be kept cool. Vaccine not used within several hours is wasted. As mentioned above the increased logistical and safety problems associated with vaccines that require reconstitution make this approach problematic. Hence, although this approach could theoretically be applied to alum-containing vaccines to render them freeze-resistant, the gain is offset by the increased logistics.

Sugar Glass Stabilization

Instead of entrapping vaccine in crystalline sugar (lyophilization), it may be entrapped in an amorphous sugar (sugar glass) with a high transition temperature. Molecular mobility is thereby significantly reduced, resulting in stabilization. Despite the evidence of this effect from extensive pre-clinical studies, the vaccine industry has not pursued the final development of the technology. The cold chain is considered an inconsequential barrier in the primary market of the industrialized world, so that the expected benefits would not justify the costs of reformulation and re-licensure of existing vaccines. As long as the "traditional" vaccines require a cold chain, there is little incentive to apply the technology in the formulation of new vaccine products.

Most sugar glass technologies yield a dry product, such as a foamed glass or powder. At present, dry vaccines must be reconstituted for administration, bringing new logistical hurdles and safety risks with the requirement for field use of a sterile diluent and the needles and syringes required to introduce the diluent into the vial. Thermostability is lost after reconstitution, so that ice must then be available to keep the newly reconstituted vaccine cool prior to administration. Several vaccines (BCG, measles, yellow fever, and freeze-dried Hib) currently require reconstitution; however the conversion of currently liquid vaccines to dry formulations would not likely be an acceptable trade-off for thermostability.

Sugar glass technology, therefore, would be most compelling in an injectable dry format or a thermostable liquid, so that no reconstitution is required. Ballistic delivery systems for dry vaccines have been developed, including for intradermal delivery of a powder formulation (such as Powderject© technology) and for subcutaneous delivery of vaccine that is micro-encapsulated in a projectile (such as the Injectile© technology). A sugar-glass stabilized vaccine could be delivered dry by either of these methods. Although this approach could offer the additional advantage of the elimination of sharps, there remain several technical hurdles to both formulation and delivery. Since these technologies are in earlier stages of development, this report focuses solely on the liquid form for which delivery systems already exist.

Sugar-glassified vaccine may be suspended in non-aqueous, liquid perfluorocarbons (PFCs) without sacrificing thermostability. PFCs have the advantage of having already been tested and approved for use as a blood substitute and as an injectable contrasting agent. In addition to being thermostable (to both sub-freezing and elevated temperatures), vaccines formulated in this manner do not require bacteriostatic agents such as thimerosol (since the liquid does not support bacterial growth), and require no reconstitution prior to injection.

Cambridge Biostability Limited (CBL) has developed a technique to suspend glassified vaccine microspheres in PFCs. To obtain a stable liquid, the density of the composite vaccine microspheres must

[20] Jodar LP, Aguado TM, Lloyd J, Lambert PM. Revolutionizing Immunizations. Gen Eng News 1998; 18:6.

be precisely matched with the high density of the PFC liquids. The resulting suspension does not require shaking before injection and is physically stable for years. After injection, the composite glass microspheres dissolve in body water and the PFCs are eliminated by evaporation through the lungs or skin.

Several vaccines, including hepatitis B, Hib, and tetanus toxoid, have been prepared as composite-glass microspheres and suspended in PFCs using the density matching process developed by CBL. Animal trials with the tetanus toxoid vaccine suggest that immune responses are greater and more sustained than with conventional vaccines. Studies of thermostability with the hepatitis B vaccine indicate stability improvement up to 60°C and the absence of heat damage after one week at -20°C, reflecting the conversion of a freeze-sensitive vaccine to a freeze-safe vaccine. Final, longer-term stability results will be available before the end of 2003.

Operational Feasibility

Thermostable vaccines, if they can be successfully developed and proved affordable, would represent a solution to the daunting operational challenges presented by the thermolability of current vaccines. Preclinical data suggest that it is technically feasible to produce sugar-glass stabilized vaccines. Several late-stage R&D obstacles remain to be addressed, however, before this technology can be rolled out.

The Bill & Melinda Gates Foundation is preparing to fund a project, with implementation coordinated by PATH, to demonstrate the technical and operational feasibility of stabilizing GAVI vaccines using the CBL technology. The project will identify and address the current and potential hurdles to final development and application of this technology, including by:

- Comprehensively identifying and evaluating the optimal liquid suspension medium(s) based on required specifications, supply, cost, and environmental impact;
- Conducting formulation and stability studies with multiple vaccine producers;
- Identifying producers to whom the technology will be transferred;
- Clarifying regulatory issues and facilitating progress through these pathways;
- Enabling preclinical testing and clinical trials
- Addressing barriers to scaling up production;
- Assuring the intellectual property “freedom to practice” and back up rights for sustainable access to the products for public use;
- Demonstrating the value of thermostable vaccines for key stakeholders, including through strengthened cost-benefit evaluation; and,
- Identifying and exploring other potential applications of this technology, such as for new combination vaccines (which may reduce the number of injections needed) and for slow release of antigen (which may eliminate the need for booster doses).

The possible environmental impact of PFCs must also be considered since, although they are not highly volatile, they may contribute to the “greenhouse effect” and to global warming. Most countries have signed agreements to significantly reduce the use of PFCs. If applied to only 3 childhood vaccines, and used worldwide at a dose of 0.5 ml per dose per child, this corresponds to 500,000 liters of PFC, which would be excreted unchanged into the environment. Although regulations specify that PFCs may be used in cases where they are the only alternative available (on the basis of either performance or safety), expert opinion from environmental experts should be sought prior to initiating the development program.

Expected Cost-Effectiveness

The benefits of introduction of thermostable vaccines would accrue from:

- Reduction or elimination of the costs of the cold chain (savings would be substantial only if all routine childhood vaccines can be made thermostable);
- Increased safety, if the need for sterile reconstitution can eliminated (such as for measles vaccine, which is lyophilized to enhance heat stability);
- Increased efficacy due to elimination of freezing and heat damage; and,
- Reduced wastage and discard of vaccine due to detected heat damage and freezing, expiry, and discard of the unused portions of multidose vials.

The costs of introduction of thermostable vaccines would accrue from:

- The cost of the remaining R&D to proof of concept;
- The cost of reformulating, re-licensing, and modifying production of existing vaccines, ensuring sustainable access to products, and introducing the technology; and,
- The marginal cost of materials for application to new vaccines.

It should be acknowledged at the outset that there is little basis for estimation of the true extent of the health benefits due to increased efficacy of vaccines and improved safety if the need for reconstitution of lyophilized vaccines and/or the use of needles (through ballistic delivery) can be eliminated. For the following analysis, the benefits are limited solely to the economic benefits due to elimination of the costs of the cold chain and the reduced wastage and discard of detected heat damage and freezing:

One-time costs for late-stage R&D (US$40-60 million) and for change in production facilities (US$50-100 million) can be amortized over 10 years to yield an annual cost of US$15-30 million. With the expected production capacity of 100 million doses per year, this yields a per-dose cost of US$0.15 to US$0.30. The cost of the PFC (ranging from the US$60/L for non-GMP material to the current proposed price of US$1000/L for GMP product) will add $0.03 to US$0.50 per dose, assuming 0.5 ml will be used for each dose of vaccine. Other marginal recurrent costs are assumed to be negligible. Using the 100 million-dose annual production estimate, the material costs add US$3-50 million per year, yielding a total incremental cost per annum of $US18-80 million. Since this figure is most sensitive to the cost of the PFC, it is clear that substantial cost savings would be realized in the likely event that the cost of GMP PFCs is forced down over time.

Expected cost savings due to reduced wastage of vaccine will be most sensitive to the costs of the highest priced vaccines. For the pentavalent (DTP-hep B-Hib) vaccine alone (@ US$3.20/dose), cost savings of US$80 million (at a conservative wastage rate of 25%) to US$160 million (at the more likely wastage rate of 50%) due to heat damage, freeze-damage, and discard of unused portions of multi-dose vials. If all routing vaccines could be made thermostable, additional annual savings of US$200 million due to the elimination of the annual direct costs of the management of the cold chain[21] suggest a potential cost savings of US$280-360 million. Even without consideration of the substantial health benefits due to improved vaccine safety and efficacy, the net economic benefit of the development of this technology would be in the range of US$200-342 million annually.

If ballistic delivery of a dry powder formulation is undertaken instead, the recurrent cost savings (due to the lack of need for the PFC solute) could be substantial. However, in view of the larger technical hurdles and likely longer timeline for R&D, it is difficult to estimate costs and benefits for this alternative.

Conclusions: Sugar Glass Stabilization

Thermostable vaccines would enable elimination of the cold chain, profoundly simplifying logistics and enhancing vaccination efficacy and efficiency. Technologies to achieve thermostability would provide disproportionate benefits to the developing would, so should receive targeted attention by GAVI and its partners. Sugar glass stabilized vaccines, delivered in a liquid format, show promise of reducing costs due

[21] Jodar LP, Aguado TM, Lloyd J, Lambert PM. Revolutionizing Immunizations. Gen Eng News 1998; 18:6.

to vaccine wastage and maintenance of the cold chain and of reducing threats to vaccine safety and efficacy. The full health and economic benefits of the rollout of this technology cannot be reaped until sugar glass stabilization of all routine vaccines can enable elimination of the cold chain altogether.

The findings of the NTWG and the analysis by the Working Group regarding these technologies enable the following conclusions specific to sugar glass stabilization technologies:

- GAVI should continue to assess priorities for R&D in this important area and make specific recommendations for technology development to mitigate the tremendous cost of vaccine thermolability.

- High priority is already assigned to R&D for both liquid and solid sugar glass stabilized vaccines. It is appropriate that initial attention by GAVI partners should be focused on liquid formulations, since ballistic delivery systems for solid formulations still need to be developed. Although delivery of solid formulations would enable further improvements in safety through elimination of sharps, this R&D is likely to be an area of investment for industrialized world markets (in view of the special needs for delivery of several DNA vaccines currently under development). Urgent attention should be focused on further R&D for this technology to address questions of the feasibility of industrial scaling and validation of the products and processes for production.

- Mitigation of the pressing problem of freeze damage through development of freeze-detectors or addition of cryoprotectants should be a further priority for R&D, especially if sugar glass stabilization should prove less than feasible.

- GAVI should promote further studies to identify the health and economic costs of cold-chain efficacy. Special attention should be given to the measurement of excess morbidity and mortality due to safety breaches, reduced vaccine efficacy, and the effects of undetected breaks in the cold chain.

Section 2: Non-Invasive Tetanus Antitoxin Test

Magnitude of the Problem

GAVI's performance-based release of funding has relied upon country-level information systems and GAVI-conducted Data Quality Audits (DQAs). But service statistics are often a poor reflection of actual coverage[22]. Furthermore, vaccination rates may not correlate fully with actual immunization, such as when breaches in the cold chain result in delivery of ineffective vaccines. The ultimate measure of the impact of immunization, the incidence of vaccine-preventable disease, is also subject to factors unrelated to immunization, including social patterns, climate change, and natural variation of the pathogen. Disease incidence measures are particularly unsatisfactory as an indicator of immunization systems performance when coverage levels are low.

Technical Landscape

Tests for biomarkers of immunization systems performance have therefore been proposed in an effort to measure both coverage and quality. Most currently available tests of antibody induced by vaccination require blood to be drawn, with attendant economic costs and safety risks. Processing of samples generally requires separation of serum and testing that requires laboratory support.

Other Candidate Technologies

[22] Murray, et al, 2003.

Routine Health Information Systems: The most viable alternatives to serological tests are measures of vaccination coverage provided by health information systems. Since reliable denominator data are rarely available, routine service statistics frequently provide substantial overestimates of coverage. Data quality audits (DQAs) have been introduced by GAVI to provide some measure of the credibility of the information system, but DQAs cannot correct for the absence of reliable denominator data. Population-based surveys provide a more credible measure of true coverage[19]; however these figures do not reflect other aspects of system performance, including variations in functional immunity (such as due to effectiveness of the cold chain).

Serological Tests: The gold standard for detecting TT antibody level is an animal-based toxin neutralizing assay: this assay is complicated, expensive and time consuming. The best-known ELISA-based laboratory test is Baxter's double-antigen ELISA test, which detects and quantifies antibodies to tetanus or diphtheria toxoid[23]. The assay results correlate well with the toxin-neutralizing assay and is specific for IgG antibodies. It uses a biotin-streptavidin system for amplification of the signal followed by ELISA detection. These tests have showed a remarkably sensitive detection limit of 0.00002 IU/ml for both antibodies, high validity, and are suitable for quantifying antibodies in blood samples collected on filter paper as well as from serum.

Non-Invasive Tetanus Antitoxin Tests

The development of a non-invasive test for tetanus antibody has been proposed in order to enable rapid, population-based assessment of the efficiency of immunization delivery systems. Detection of antibody to tetanus toxoid (TT) has the advantage that antibody derived from immunization differs from that induced by natural infection (although, in view of the high mortality rates associated with tetanus, survivors with naturally occurring antibody are rare). An oral fluid-based test was proposed to address the costs, logistical hurdles, and safety risks associated with serum sampling. Oral fluid-based assays have been successfully developed to detect infection with HIV, measles, rubella, and hepatitis B[24].

The NTWG report proposed specific technologies for development of a rapid test for anti-TT antibody in oral fluid. Design and cost assumptions were based on an expected number of tests per year of 40,000. It was proposed that a commercially available and relatively expensive oral fluid collection device be used, along with an immunoassay capable of detecting 0.01 IU/ml standard protective level of antibody. Since the level of antibody in oral fluid is 400 to 1000-fold lower than that found in serum, sensitivity must be very high to detect protective levels of antibody. Studies suggest that rates of fall-off in antibody levels after immunization are so variable that tests may be useful only within a relatively short period (less than one year) after immunization[25].

The available information regarding the proposed test is presented in the table below along with data for a serum-based rapid test kit under development by PATH and Baxter's commercially available ELISA test. Although some estimates can be offered, the data regarding actual costs and performance characteristics for the PATH test and the oral fluid-based test proposed by the NTWG are inadequate to permit valid comparisons.

	Oral fluid-based TT Ab test kit	Serum-based TT Ab test kit	ELISA
Sensitivity	unknown	unknown	0,00002 IU/ml
Specificity/validity	unknown	unknown	high
Ease of use	easy	easy	difficult
Safety	high	medium	medium
Operational feasibility	high	medium	medium
Unit cost (per test)	unknown	Less than 2 $	?
Start-up costs	low	low	very high

[23] Kristiansen et al., 1997. Improved ELISA for determination of anti-diphtheria and/or anti-tetanus antitoxin antibodies in sera. APMIS 105:843-853

[24] NTWG report, http://www.vaccinealliance.org/site_repository/resources/NTWG_global.pdf. 2003.

[25] WHO Publication: WHO/EPI/GEN/93.13 (edited by A. Galazka).

(Infrastructures etc.)			

*Compliance for oral fluid collection of the samples reported roughly 15% higher than for blood sample collection[26]

The market for tetanus toxin antibody detection is limited to those few cases in which there may be relative contraindications to tetanus vaccination or presumptive post-exposure prophylaxis with tetanus antitoxin. Although Baxter has successfully developed the serum-based double-antigen ELISA test (which detects immunity to both diphtheria and tetanus), the added value of an oral fluid-based test is unlikely to offer adequate comparative advantage in order to justify commercialization. A public sector market of only 40,000 tests per year would be inadequate to compel commercial development.

Operational Feasibility

The sole potential application for such a test is population-based surveys. Although the desired performance criteria might be different for research applications (e.g., cost control would be a lower priority), the NTWG assumed a primary purpose of routine monitoring of program effectiveness. The following target product profile can be defined for a TT antibody detection test, in order to specify the optimal and acceptable ranges of product performance characteristics:

- Easily performed on infants (in addition to older children and adults),
- High specificity (detecting antibody levels that correlate with full protection),
- Requires little or no training for reliable use and interpretation,
- Rapid (results available in minutes to enable immunization of those whose antibody levels do not correlate with protection),
- Available in a multiple test format for population-based surveys with a shelf life of years, and,
- Reliably detect antibody among those who are "fully immunized" according to recommendations for tetanus immunization.

Expected Cost-Effectiveness

Since the proposed test is a management tool, rather than an individual health care intervention, it is impossible to calculate classical cost-effectiveness values based on years of life saved. In view of the proposed target product profile, it is unlikely that the price of the test would be within an acceptable range for routine use for performance monitoring. The NTWG report estimates a cost per test between US$5 and US$15. It is possible, however, especially using a cheaper method for oral fluid collection, that the cost per test could be substantially reduced. It was pointed out in the report, for example, that the oral fluid collection tools for HIV tests had a more affordable unit price of $0.50 to US$1.50. Nonetheless, even with this reduced cost of the oral fluid collection device, the cost per test would unlikely be less than US$3.00-$5.00. Within the current technological and cost parameters, the proposed test does not compare favorably with the other available methods for immunization program performance monitoring.

Conclusions: Non-Invasive Tetanus Antitoxin Test

Improved tools for assessment of immunization service performance remain a highly desirable R&D goal. The NTWG developed a "roadmap" for development of an oral fluid-based tetanus antitoxin assay, suggesting a contract with an academic institution with an industrial partner. The research required to develop such a tool is, however, more "upstream" than for the other two technologies that were the

[26] Tamshiro et al. Serological diagnosis of HIV injection using oral fluid samples. WHO Bulletin, v.72, 1994.

focus of the NTWG report. GAVI should continue to monitor the development of this technology along with the landscape of other emerging technologies for opportunities to develop tools that would achieve the desired goal.

Section 3: Defanging Devices

Magnitude of the Problem

Millions of unsafe injections are given each day. WHO estimates that unsafe injections each year cause 32 million cases of hepatitis B, 7 million infections with hepatitis C, and 98,000 new infections with HIV[27]. It is further estimated that unsafe injections cause 1.3 million premature deaths annually – resulting in the loss of 26 million years of life and an annual economic burden of US$535 million in direct medical costs[28]. While injections for immunization are, by far, safer than most other injections given in the developing world, the delivery of vaccines by injection incurs an ethical obligation to take all reasonable steps to ensure injection safety, including safe disposal.

National and district health authorities in many developing countries demonstrate little interest and commitment for the safe disposal of needles and syringes, as illustrated by experience in Cambodia[29], the Eastern Mediterranean[30], India [31] and Africa[32].

Technical Landscape

Proper containment and disposal of sharps medical waste, in conjunction with auto-destruct (AD), or other safety syringes containing re-use prevention features, can reduce needlestick injuries, prevent improper reuse of needle-syringes, and reduce volume of medical waste and its risk to the community and environment[33]. While this report focuses primarily on defanging devices, a brief review of the technology "landscape" is provided.

Existing Sharps Management Technologies

Sharps boxes: Burnable sharps disposal boxes are a temporary storage device for used needle and syringes, and only one step of the disposal process. They are often not supplied or are available in insufficient numbers, are frequently found dangerously overfilled because they are not removed promptly, and are occasionally pilfered to improperly "recycle" non-A-D needle-syringes. If the boxes are to be burned in an incinerator, further operational problems are introduced by the requirement for transport to the incinerator site and storage before incineration.

Incineration: Incinerators that reach at least 800º C can nearly completely eliminate sharps waste, except for a small residue of sterile ash and metal. Their limitations include their cost, occasional community resistance to potential pollution, and lack of transport and fuel to deliver waste to centrally located units. Open burning at lower temperatures of certain plastics can release toxic pollutants[34]. To minimize

[27] Safe Injection Global Network (SIGN), Annual meeting report, 2002. Kane, A.J. et al. Unsafe injections in the developing world and transmission of blood-borne pathogens: review of the literature and regional estimates. Technet Consultation, WHO (1998).
[28] State of the World's Vaccines and Immunization, WHO, Geneva (2002).
[29] Laurent, 1998.
[30] Zghondi, 2002.
[31] Rajasekara et al. Injection practices in Southern part of India. Public Health 117 (2003) 208-231.
[32] Dicko et al. Safety of immunization injections in Africa. Bulletin of the World Health Organization 2000 78(2).
[33] Prüss, 1999.
[34] MRC, 1999.

pollution from improper burning, some Indian states forbid waste generators to operate their own incinerators; rather, they must bring waste to centralized approved ones[35].

Disposal pits: Digging pits in the ground is an option for local disposal of the residue of sharps waste from either burned disposal boxes, from the incomplete combustion of incinerators, or the direct deposits of unprocessed needle-syringes. Such disposal pits have the potential disadvantages of susceptibility to exposure through erosion or excavation, introduction of the risk of contamination of ground water used for drinking, and requiring a large amount of space if they contain bulky syringes.

Defanging Devices

Defanging devices limit exposure of the sharp hazard at the point of use by removing the needle and containing it until it is destroyed.

Electric Needle Destroyers: Most destroyers operate on mains (wall) electric current and apply a direct current electrical voltage across the needle in order to destroy it. Others use mains current to recharge 5-to-10 ampere-hour sealed lead acid batteries, which make them quite heavy. Prices of basic models range from approximately $100 to 200. More complex models may cost $800. Drawbacks to existing electric needle-destroyer technology include: (1) downtime due to frequent power shortages, (2) high price, (3) immobility of heavy tabletop models, (4) need for frequent replacement of worn electrodes, (5) inconsistent or incomplete destruction of the needles, leaving sharp stubs, (6) splattering or misting of blood, (7) generation of obnoxious fumes, noise, and sparks, and (8) the resulting prohibition of their use in explosive atmospheres where oxygen and anesthesia are in use[36].

Manual Needle Removers: Several non-electric needle cutters are marketed throughout the world, many of them produced in developing countries. Drawbacks of some of the devices are their short blade life, which requires frequent cutting blade replacement, and the lack of portability for use in outreach settings. Other technical drawbacks can include fluid splashing and contamination[37], and ease of access to the infectious needle shafts. Improved designs of manual needle removers are now available that disable the syringe as well as the needle. These have been shown to have a longer blade life and be free from splatter. Technical challenges remain to minimize handling of the contaminated needles by health care workers and waste disposal personnel, and to improve portability for outreach.

Two manual needle removers have been developed and are on the market (Balcan, NoMoreSharps). In addition, a number of other manufacturers have prototype devices under development (Chitsein, NoMoreSharps, BD).

Current R&D landscape

Since 1998, PATH has assessed sharps disposal needs and available technologies, with funding from the U.S. Agency for International Development's HealthTech program, the Bill & Melinda Gates Foundation Appropriate Technologies in Health Program, and the Children's Vaccine Program. PATH evaluated electric and chemical needle destroyers[38], provided technical background of a luer-slip needle removal device to five manufacturers and to WHO, conducted bench evaluations of six different manual needle removers in various stages of development and marketing from four external manufacturers and developers, commissioned a study to examine splatter and surface contamination from needle remover use[39], commissioned a market study of

[35] Dalal, 2001.
[36] Muller, 2001a; PATH, 2000; PATH, 2003.
[37] Hersh et al. Ensuring Injection Safety during Measles Immunization Campaigns. Journal of Infectious Diseases 2003; 187 (Suppl 1): S299-306.
[38] PATH, 2000.
[39] NAMSA, 2002.

needle removers in India[40], introduced needle removers to immunization programs in India, Mozambique, Senegal, Cote d'Ivoire and Indonesia, and designed two needle removal devices.

In May 2003, PATH began a formal evaluation of three needle removers (Balcan and two PATH designs) in India in 9 project sites to assess safety and acceptability of the devices to health care workers and waste disposal personnel; the disposition of both the contained needles and the defanged syringes; and the reliability, maintenance, and durability of the devices in the evaluation. This evaluation will last six months, and is expected to record the experience of 30,000 injections. The project will observe and track the total number of injections as well as numbers of needlestick injuries to the health worker and waste handler in all project sites. According to US experts on needlestick among health workers, it is difficult to obtain reliable injury data for rate calculations because of the high degree of underreporting and variability of reporting over time[41]. There is no consensus, even in the US, regarding the best denominator to calculate injury rates for comparisons. And, most significantly, the sample size required detecting reductions in needlestick rates ranges from 94,000 to 4.6 million injections. Because of the lack of reliable needlestick baseline data, and the large number of injections and needle stick incidents required to show a statistically significant difference, this project will not be able to make comparisons on needlestick rates. PATH has adapted the evaluation protocol from India to a generic format for application in other countries.

One PATH needle remover design, focused on the particular needs of outreach immunization, is being released to interested commercialization partners, with the ultimate goal of placing the design in the public domain. This will allow for local adaptations to be made from the core technology.

WHO has drafted an equipment performance specification for needle removers, cutters or destroyers. In addition, WHO developed a checklist of issues to monitor in demonstration projects making use of needle removers in developing country setting (the PATH protocol addresses these issues). WHO/EA is planning an evaluation in Eritrea of sharps disposal systems, including needle removers, to begin in November 2003. A pre-pilot was carried out during a measles campaign in Eritrea at the end of September. Other WHO evaluations are under discussion in Ukraine, Kenya and Uganda.

WHO specifications and guidelines for use are important market incentives to potential manufacturers. Given the local variations that are likely to arise from the simplicity of this technology, application of WHO specifications and guidelines for needle remover use would enable local manufacturers to provide products, much as locally made safety boxes are being used.

Operational Feasibility

"Defanging" must occur immediately after the injection has been completed, before the needle-syringe leaves the hand of the person who performed the injection. Therefore, the needle remover must be located within one step of all loci where vaccinations are administered.

All waste handling technologies must fit into an overall framework of administration and management, involving policy guidelines, supply chain logistics, training for behavioral change, and supporting legislation. Ideally, final destruction or disposal of waste should occur as near as possible to the point where the waste is generated. No solution will fit all circumstances—it is likely that a number of solutions will be needed to meet the specific conditions of different sites. Options for processing of infectious sharps waste differ according to the site. It is useful to consider these options in terms of rural outreach, rural clinic, and urban clinic settings with low-to-medium infrastructure. (It is assumed that

[40] Dalal, 2001.
[41] Pugliese, 2001.

urban clinics in high infrastructure environments would have transitioned to specialized collection and disposal systems for hazardous waste.) Portability is the critical constraint for outreach. Use of a portable needle remover would enable the contained needles and the used syringes to be safely transported back to the rural clinic for disposal.

The two waste streams that are created from effective needle removal—contained needles and 'defanged' and disabled syringes—need to be disposed of properly. It is recommended that the contained needles be emptied into a protected needle pit. These pits can be located at primary health care facilities, and therefore, transport of the hazardous sharps is avoided. The defanged syringes can be collected in various ways—in a safety box, or handled along with other "infectious waste" in less expensive yellow plastic bags until disposal. Depending on location, ultimate disposal of the syringes may be incineration, burning, plastic reprocessing, or via regular municipal waste. There is some uncertainty about the need for disinfection of the syringes as a reprocessing step or before the syringes could be disposed in regular municipal waste.

Expected Cost-Effectiveness

Use of needle removers, even in conjunction with safety boxes for syringe body disposal, is no more expensive than using safety boxes alone. For example, assuming 20,000 injections, a $30 needle remover, and considering that a $0.66 5-liter safety box holds 150 syringes with needles or 235 syringes without needles, associated costs are:

Needle remover + Safety boxes		Safety boxes alone	
Needle remover	$30	No needle remover	
Safety boxes needed: 86	$57	Safety boxes needed: 134	$88
Total cost	$87	Total cost	$88

This calculation will vary depending on the size of the syringes, how the safety box is filled, the cost of the needle remover, and the cost and need for replacement needle containers. If syringe bodies were disposed of in yellow plastic bags instead of safety boxes, then the total cost would be much less.

WHO staff modeled the number of needle removers that might be needed. Details of their approaches and data are provided in the New Technologies Task Force report (Section 7.2.2). They conclude that approximately 1.0 to 1.25 million devices could be needed for immunization programs in all developing countries. For all injections (10% immunization, 90% curative), they estimate that 10 to 12.5 million devices could be needed.

Operational effectiveness remains to be fully measured—in terms of effects on safety and waste disposal systems. Country-level data are needed on the extent of improper disposal and rate of needle-stick injury to both health workers and community members. With such data, the risk of disease transmission can be fully determined. Impact on the waste disposal systems can be measured by cost per volume or weight of the disposed waste.

If needle removal devices are designed and used appropriately, their impact may:

- Reduce the overall volume of sharps waste by 90 percent; and,
- Prevent millions of iatrogenic infections from the improper reuse of unsterile disposable needle-syringes.

Conclusions: Defanging Devices

GAVI partners are already working to evaluate the role of needle removers and to encourage the supply of appropriate and low cost devices. This analysis suggests the following conclusions specific to defanging devices:

- Ongoing work by partners to documents the effectiveness and safety of needle removers should continue, with complementary work to develop training materials, job aids, and evaluation tools as indicated.

- WHO's work on equipment specifications should be given priority and guidelines for sharps disposal should be adapted as needed, based on emerging findings, to include needle removers.

Summary of Priority for Immunization Technology Development

	Sugar Glass Stabilization	Defanging Devices for Sharps Removal	Non-invasive Assay for TT Antibody
Magnitude of the Problem Addressed	+++	++	+
Technical Feasibility	++	+++	+
Field Operational Feasibility	+++	++	++
Expected Effectiveness	++	++	+
Cost/Savings	+++	++	+
Overall Priority	+++	++	+/-

Recommendations for R&D for Immunization Technologies:

Based on the work of the NTWG and the subsequent analysis by the GAVI Working Group, the following recommendations are made:

- With their uniquely comprehensive view of global and country immunization activities, GAVI and its partners are well positioned to identify emerging needs and opportunities to develop and introduce new immunization technologies. GAVI should develop a systematic mechanism to undertake biannual "scans" of the landscape of emerging technologies, to conduct cost-effectiveness analysis, to make recommendations, and to advocate for R&D efforts.

- GAVI should continue to rely primarily upon partners to fund and implement R&D efforts. GAVI should strengthen links with donor and technical partners who can:

    - Convene the periodic reviews of emerging needs and opportunities for immunization technology development; and,
    - Design and fund programs of R&D to address these needs and opportunities.

- GAVI should work particularly closely with WHO to ensure that global guidelines and policies are developed and put in place to ensure the smooth introduction of needed immunization technologies. Once promising technologies are ready for broad introduction, GAVI should accelerate the process by endorsing WHO recommendations, providing incentives in support of introduction and diffusion of these innovations, and (where appropriate) using Vaccine Fund resources to initiate progress toward sustainable funding for these technologies.

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- ***Mark Kane / Janet Vail*** , CVP/PATH
- ***Martin Friede / Teresa Aguado***, WHO
- ***Steve Landry***, VF
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Report on nominations for GAVI Board developing country government seat (Jan '04-Dec'05)

1. On 2 October 2003 a letter signed by the Executive Secretary of GAVI (Dr. Tore Godal) was sent to all relevant countries. This letter highlighted the GAVI Board functions, core responsibilities of Board members, criteria for selection of Board members and called for nominations for the Board seat no later than 10 November 2003. Each nomination should include details of eligibility against the selection criteria and include:

1) a brief curriculum vitae of the individual;
2) details of the constituency's commitment to GAVI activities

2. In response to this letter 15 nominations were received (1 withdrawn) by the GAVI Secretariat within the deadline. The remaining 14 candidates were:

- **Armenia,** Republic of
- **Bangladesh**, People's Republic of
- **Burkina Faso**
- **Central African Republic**
- **China**, People's Republic of
- **Côte d'Ivoire**, Republic of
- **Guinea**, Republic of
- **Guinea-Bissau**, Republic of
- **Madagascar**, Republic of
- **Mali**, Republic of
- **Moldova**, Republic of
- **Nigeria**, Federal Republic of
- **Senegal**, Republic of
- **Tanzania**, United Republic of

Based on the CVs of the applicants, their current position, professional background and relevant experience, commitment to serve the constituency of developing countries and importance to GAVI mission, including achieving a regional balance of developing country Board membership, 5 candidates were short-listed by the GAVI Secretariat and circulated to developing country Board members.

The Board members were invited to rank these five applicants and as a result, the Minister of Health from Bangladesh (see attached application), has been proposed to succeed India on the GAVI Board.

Merck Vaccine Network-Africa
Program Overview

Program Objective

In support of the Global Alliance for Vaccines and Immunization (GAVI), grants will be awarded to develop sustainable training Centers in Africa to increase the capacity of immunization programs to effectively deliver vaccines. The Merck Vaccine Network-Africa (MVN-A) Program will contribute to the training of national and regional mid- to high-level program managers in vaccine management and immunization services.

Program Design

The multi-year program will provide grants to United States (U.S.), European, or other academic institutions that have partnerships with academic institutions in Africa to establish the training Centers.

Key elements of the MVN-A program include:

- Each Center will receive $200,000 per grant year for up to four years. Funding will be provided by The Merck Company Foundation, the philanthropic arm of Merck & Co., Inc.;
- Centers will build upon existing academic collaborations;
- Each site will form a Technical Advisory Group, composed of national and regional officials, including World Health Organization (WHO) and WHO African regional officials (AFRO), to provide ongoing guidance to the Center;
- Training activities will focus on the needs of national and regional mid- to high-level program managers;
- The training curricula will be adapted from source materials developed by WHO and other GAVI partners;
- Efforts will be made to ensure Center activities are coordinated with other GAVI partner training initiatives (e.g. Global Training Network); and
- Efforts will be made to ensure Center activities are consistent, sustainable, and integrated with other GAVI, GAVI partner, and local/regional immunization initiatives.

Current MVN-A Training Centers

In November 2003 following a competitive grants process, grants were awarded to the following collaborations to develop Centers in Mali and Kenya.

Mali - University of Maryland School of Medicine, Center for Vaccine Development and Centre National d' Appui à la Lutte contre la Maladie in Bamako; and

Kenya - Indiana University School of Medicine and Moi University Faculty of Health Sciences in Eldoret.

12th GAVI BOARD MEETING
9-10 December 2003, Geneva
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56. Dr. Carole Presern, First Secretary (Health and Development), Permanent Mission of the UK to the UN at Geneva

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57. **Dr. E. Anne Peterson, Assistant Administrator for the Bureau for Global Health, U.S. Agency for International Development (USAID)
58. Ms. Susan McKinney, Advisor for Immunisation; Maternal and Child Health, USAID

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59. **Dr. Muctaru A. S. Jalloh, National President, Sierra Leone Red Cross Society
60. Dr. Mark Grabowsky, Senior Technical Advisor, American Red Cross

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