

Evaluation of the GAVI Phase 1 Performance (2000-2005)

Prepared for The GAVI Alliance

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ACRONYMS

ADIP Accelerated Development and Introduction Plan

AMC Advanced Market Commitment

APR Annual Progress Report
ATF Advocacy Task Force

CGD Center for Global Development

CEPA Cambridge Economic and Policy Associates

CMYP Comprehensive Multi-year PlanCVI Children's Vaccine Initiative

DQA Data Quality Audit

DTP Diphtheria, Tetanus, Pertussis vaccineEPI Expanded Program on Immunization

FSP Financial Sustainability Plan

FTF Financing Task Force

GAVI Alliance (formerly Global Alliance for Vaccines and Immunization)

GDP Gross Domestic Product

GFATM/GF Global Fund to fight AIDS, Tuberculosis and Malaria

GHP Global Health Partnership

HepB Hepatitis BHI Hib Initiative

Hib Haemophilus influenza type BHIPC Highly Indebted Poor Countries

HLSP HLSP Limited

HSS Health System Strengthening support

IBRD International Bank for Reconstruction and Development

ICC Inter-agency Coordinating Committee

IFFIm International Financing Facility for Immunization

INS Injection Safety Support

IRC Independent Review Committee
ISS Immunization Services Support

JRF WHO-UNICEF Joint Reporting Form

Abt Associates Inc. Acronyms

LICUS Low Income Country Under Stress

MC Management Committee (for the ADIPs)

MCV Measles-containing VaccineMDG Millennium Development GoalMNT Maternal and Neonatal Tetanus

MOH Ministry of Health

cMYP Comprehensive Multi-Year PlanNGO Non-governmental organizationNIP National Immunization Program

NVS New Vaccine Support
RFP Request for Proposal

RWG Regional Working Group

SIA Supplementary Immunization Activity

SC Steering Committee

TFCC Task Force on Country Coordination

TOR Terms of Reference
TT Tetanus Toxoid

UNICEF United Nations Children's Fund

WG Working Group

WHO World Health Organization

YF Yellow Fever

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- Kenneth Carlson (Abt) conducted the statistical analyses presented;
- Wilma Gormley (TRG) participated in interviewing GAVI Board and Working Group members, and drafted sections of this report;
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EXECUTIVE SUMMARY

Introduction

The GAVI Alliance is comprised of partners from the private and public sectors, dedicated to improving health and saving the lives of children through the support of widespread vaccine use. It was created in 1999 as a partnership between multilateral organizations such as WHO, UNICEF, the World Bank and the Bill and Melinda Gates Foundation, bilateral aid organizations, developing country governments, research institutes, civil society and vaccine manufacturers. Under the first phase of GAVI (2000-2005), GAVI adopted a mission of "saving children's lives and protecting people's health through the widespread use of safe vaccines, with a particular focus on the needs of developing countries." During Phase 1, GAVI supported country governments with monetary support through its immunization services support (ISS) program, and in-kind provisions of new and underused vaccines (NVS) and related injection safety equipment (INS). GAVI also undertook initiatives at the global level to support development and introduction of new vaccines, as well as to advocate for increased attention and funding to immunization.

This evaluation was commissioned by the GAVI Board, to examine specific research questions that were developed through a consultative process, thus representing ones where there was broad interest from a variety of stakeholders. Some issues that were later identified as areas of interest, such as the value-formoney of partner-led activities funded by GAVI, were not addressed. Abt began work its work November 2007. An independent Steering Committee provided guidance throughout the implementation of the evaluation. The objectives of this evaluation as specified in the RFP were:

- To identify and learn from the successes and weaknesses of GAVI in Phase 1, including how well it has evolved and learned from experience over the period 2000-2005;
- To contribute to the refinement or adjustment of GAVI policies in the next strategic phase of work; and
- To document the impact and to evaluate the efficiency and effectiveness of the GAVI Alliance's use of resources during Phase 1.

We organized the research questions posed in the RFP along a framework encompassing program results, organizational structure, management approaches, and lastly cross cutting principles that underpin GAVI's mission and impact.

Approach and Methods

We used quantitative and qualitative data analysis to address the questions in the RFP. We relied primarily on quantitative data to examine the results of GAVI activities, including country approvals, funding disbursements, immunization coverage data, and vaccine prices. This data is from a variety of sources including WHO, UNICEF, Joint Reporting Forms, World Bank, and the GAVI Secretariat.

To evaluate GAVI's organizational structures, management approaches, and cross-cutting principles, we conducted interviews of key informants representing GAVI Alliance and GAVI Fund Boards, Working

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Group and task team members, GAVI Secretariat staff and independent experts and researchers. Additionally, we held discussions at Regional Working Group (RWG) and EPI Managers' meetings, and conducted country visits to six countries selected to represent outliers, such as higher or weaker performers, stronger management or suspected mismanagement. Related to ADIP management and vaccine pricing and supply, we selected another group of informants comprised of ADIP staff, ADIP Management Committee Members and Permanent Observers, vaccine manufacturers and other partners. Informant interviews were conducted using semi-structured interview guides that were targeted for different types of informants.

We also reviewed internal GAVI documentation, relevant GAVI-commissioned studies and evaluations, as well as external evaluations of GAVI's performance and impact. To the extent that the evaluation questions given to us had been addressed by previous studies and evaluations, we relied on those findings.

An earlier draft of this report was provided to informants for review – all comments were compiled and are included as an annex to this report. Any factual errors brought to our attention through this review process have been corrected. Comments that represent a difference of interpretation or opinion may or may not have been incorporated, however, all comments are presented in the annex.

As specified in the RFP, this evaluation is limited to Phase 1. We considered information on more current developments as provided in GAVI documentation and other evaluations, and incorporated this information if necessary to develop recommendations that reflect the current reality, or to adequately address some of the questions posed. For example, RFP questions related to the ADIPs could not be adequately addressed if we were to ignore developments and information after 2005, including the findings of the GAVI-commissioned ADIP evaluation. However, our data collection was not intended to represent findings related to Phase 2, nor do we evaluate Phase 2 performance.

Overview of Findings

Programs and Activities

During Phase 1, GAVI significantly increased access to immunization, and expanded use of new vaccines through its support to immunization programs in recipient countries. Nearly all eligible countries applied for ISS and INS funding, while 79% of eligible countries applied for HepB vaccine. Uptake of Hib vaccine and YF vaccine was lower, with 25% and 50%, respectively, of eligible countries applying for support. In aggregate, coverage rates increased in GAVI countries during the course of Phase 1 – the DTP3 coverage rate increased from 64% to 71%, HepB3 coverage rate increased from 16% to 46%, and Hib3 coverage rate increased from 1% to 7%. Nonetheless, there is room for improvement of ISS funding to improve the design of the reward incentive, and to provide support to underperforming countries. (text Sections 4.1.1, 4.1.2, and 4.1.3)

Overall, ISS and NVS support, adjusted for number of infants, favored LICUS, lower coverage, and lower income countries. In contrast, INS support was distributed nearly proportional to the distribution of infants across country groups, with modestly higher allocations in higher coverage, non-LICUS, and higher income countries. Disparities in immunization coverage based on urban/rural residence and gender were reduced during Phase 1, and changes can be correlated to GAVI funding. However, there was no reduction in disparities based on mother's education or birth order. There is evidence that wealth-based disparities in immunization coverage also decreased during GAVI Phase 1, but this is based on data from five countries only, and is not statistically significant. Despite the overall achievements, there is great variability on a country by country level, and GAVI has not developed effective approaches for facilitating support to underperforming countries. (text Section 4.1.4)

The cost per additional child immunized with DTP3 was \$8.31, while the cost per pertussis death averted was \$933. The cost per child reached with HepB/Hib/YF vaccine was \$5.31 – data limitations prevent us from calculating cost per death averted by new vaccine. The lack of cost data disaggregated by vaccine is a very important finding, as it prevents GAVI from accurately evaluating the cost effectiveness of the programs and vaccines that it supports. During Phase 1, GAVI contributed to 15.8 million additional children immunized with DTP3, 90.5 million additional children immunized against HepB, 14.1 million against Hib, and 13 million against yellow fever. The additional children immunized resulted in preventing 1.48 million future deaths from HepB, 141,000 future deaths from pertussis, and 112,000 premature deaths from Hib among the cohort of children born in 2001-2005. Using statistical analysis to calculate the portion of children immunized that can be attributed to GAVI interventions, 2.4 million children were immunized with DTP3, and 40.2 million children immunized with HepB3 during Phase 1. (text Sections 4.1.5 and 4.3.1)

GAVI's results in influencing vaccine pricing and supply are more mixed. GAVI's improvements in forecasting and procurement mechanisms, and its long-term funding did attract additional vaccine suppliers, although they were not pre-qualified until after Phase 1. The prices for the two vaccines that represented the bulk of the NVS program did not decline during Phase 1. Given GAVI's preference for vaccine presentations for which there were only single suppliers, its assumption that market forces would bring down vaccine prices was unrealistic. The ADIPs were successful in compiling the disease burden data to support introduction of the vaccines, and advocating for their use. However, little work has been done to tackle important in-country introduction issues (such as cold chain, storage or logistics), which are critical for vaccine introduction. (text Sections 4.2 and 4.3.3)

GAVI and its partners were successful in positioning immunization as a centerpiece in international development. Immunization is more prominent within the health literature, and is recognized as a core health service. Significant achievements include aligning immunization with achievement of MDG4, securing the IFFIm, and ensuring funding for Pneumococcal vaccine through the AMC. Given how quickly decisions were made, its loose strategic framework, and the technical challenges of some activities, GAVI's Phase 1 results are impressive. (*text Section 4.3.4*)

Organizational Structures

The GAVI Alliance was designed as an unincorporated partnership governed by a Board consisting of representatives from stakeholders, relying on partner organizations to implement activities. The GAVI Fund was created as a companion organization, with the legal status required to accept, manage, and disburse funding for GAVI Alliance activities, as well as to provide oversight on the GAVI Alliance. The two Boards had very different cultures – with the GAVI Alliance Board being consensus-driven and cognizant of political positions of Board members, while the Fund Board embodied a culture that focused primarily on the final results. Both the GAVI Alliance and the GAVI Fund had minimal management staff. The GAVI Alliance relied on a Working Group, various task teams, and Independent Review Committees for technical analysis, policy development, and program oversight. The WG and task forces were important fora for critical input and debate, and partnership and trust-building. (text Section 5.1)

During the course of Phase 1, GAVI undertook incremental governance changes aimed at managing the growing size and complexity of its programs without diminishing the original partnership principles. Two key weaknesses of its governance structure that were never resolved were poorly defined roles and responsibilities of stakeholders and management entities, and poor accountability given the dual GAVI Alliance and GAVI Fund roles. Although GAVI did not always adhere to principles of good governance, its partners were committed and engaged, and its structures were sufficient to allow quick decision making, innovation and flexibility, and open debate and self-assessment. (text Section 5.2)

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GAVI was successful in gaining and maintaining the commitment of its partners, and continuously sought ways to ensure stakeholder input. A true partnership emerged not only among the most senior leaders in setting broad principles, but among the technical staff of partner organizations who worked together in policy setting, and at regional and country level to support implementation. The effectiveness of the partnership rested on the partners' common purpose, trust and commitment, and strong leadership, which made up for shortfalls in areas such as clarity of partner roles and responsibilities, clear governance structures, and accountability mechanisms. The challenge will be to find ways to formalize relationships and responsibilities without losing the initial enthusiasm and commitment that made the partnership succeed. (text Section 5.3)

Management Approaches

Until the introduction of the investment case approach in 2005, GAVI had no formal framework to guide decision making – its early decision making was driven by the need for quick decisions and quick results. The investment case approach instilled rigor to analysis of new activities, but its value was limited by the absence of a strategic framework for resource allocation. Although GAVI has made efforts to consider country priorities and promotes country planning and ownership in some ways, its policies strongly encourage countries to apply for new vaccines. GAVI did not always have strong data and analyses, or universal support, for all its policies. During Phase 1, 18% of GAVI funding was allocated to increasing access to immunization services, 73% to expanding use of new vaccines, 4% to accelerated disease control, and 4% to accelerating development and introduction of new vaccines. It does not appear that these allocations were based on consideration of strategic priorities, activity costs, potential impact, and cost effectiveness. Although GAVI's approach of country-led programming prevented it from making firm programming allocations, its implementation policies (country qualification criteria for NVS and ISS, amount of ISS reward funding, etc.) certainly influenced programming allocations. (text Section 6.1)

The incremental organizational changes that took place during Phase 1, particularly the diminution of the WG and task forces, and expansion of the Secretariat, may affect partner ownership of decision-making, reducing the level of commitment at technical and implementation levels of partner organization. The process of group discussions within task forces and the WG had its flaws, but the majority of informants, as well as other studies, found they were important for technical debate, producing the challenging, self-questioning and innovative characteristics that were recognized to be positive attributes under Phase 1. (text Section 6.1.5)

Effective communication was difficult in the early years because of the large amount of information for dissemination, and the under-developed communications mechanisms. The WG, RWGs, and ICCs played important roles in facilitating communications among partners at all levels. There is room for improvement in communications between Board members and their constituents, and on the GAVI website. (*text Section 6.2*)

Management of support to recipient countries improved significantly over Phase 1, and is generally considered strong. Nonetheless, there was room for improvement related to follow-up of country specific issues identified through evaluations, indicated on APRs, or reported by the IRCs. In-country mechanisms for monitoring use of funds were not effective in some countries. GAVI's largest investment, NVS, has never been subject to evaluation that incorporates review of program design, implementation, and cost effectiveness. Although GAVI does not appear to score well on the OECD Aid Effectiveness indicators, it does act in ways that reflect the principles of the Paris declaration. (*text Section 6.3*)

GAVI lacked a clear strategy, specific activities, or defined roles and responsibilities related to advocacy. Despite its success in fund raising, many respondents believe that GAVI has not fully carried out its responsibility as the global advocate for immunization. Management of the ADIPs relied on a

Management Committee that many perceive as inappropriately staffed and operating under a poorly-defined scope of work, with limited engagement with the GAVI Board or GAVI Secretariat. GAVI lacked an evaluation policy and framework, and an evaluation plan during Phase 1. The organizational and management challenges that GAVI faced during Phase 1 are very similar to ones identified during the evaluation of the first five years of the GFATM, such as lack of clarity in vision, strategy, and management processes. (text Sections 6.4 and 6.5)

Sustainability Approach

GAVI's approach to sustainability was based on a three-pronged strategy encompassing: 1) supporting financial sustainability at country level; 2) influencing vaccine supply and demand to reduce prices; and, 3) developing innovative financing sources. GAVI-introduced Financial Sustainability Plans (FSP) represented the first time NIPs became aware of the full cost of the immunization program. The process for development also broadened the group of stakeholders with responsibility for immunization to include Ministries of Finance. Total funding for immunization increased during Phase 1, mostly as a result of GAVI funding, and mostly for new vaccines. For countries that introduced pentavalent vaccine, immunization program costs totaled 9.2% of government health expenditures. Despite adopting country level sustainability as a core element of its strategy, and much effort to support countries toward sustainability, limited progress was made. Funding flows for immunization have changed such that many bilateral donors, who had previously funded immunization through assistance programs in individual countries, now direct all assistance through GAVI, making it more difficult for countries to generate increased funding from in-country donors. (text Section 7.1)

At the global level, GAVI had limited success in influencing vaccine pricing, and had no strategy for influencing vaccine markets in order to obtain more favorable pricing while maintaining vaccine security. In the area of innovative financing, GAVI has had important accomplishments. The IFFIm secured \$1.23 billion of new funding for GAVI. The AMC provides \$1.5 billion for pneumococcal vaccines, as well as an innovative approach for managing supply and pricing. The reality is that funding at these levels eclipses even the most optimistic expectations of recipient country contributions. (*text Sections 4.2.2 and 4.3.4*)

GAVI's commitment to the principle of sustainability is closely linked to its long term vision and strategy. GAVI's funding commitments to date indicate that introducing new vaccines are its highest priority. Its current co-financing policy also encourages countries to apply for more expensive pentavalent vaccine because the minimum co-financing requirement is less than the cost of existing vaccines that they would have to finance themselves. Such policies to promote new vaccine uptake may meet GAVI's short term objectives, but there are no long range agreements on the appropriate level of financial responsibility to be assigned to countries, or projections of GAVI's own ability to continue financing these and other newer vaccines. (text Sections 6.1.6 and 8.4)

GAVI's Value-added

GAVI remained true to its principle of added-value, improving, but not replacing, the efforts of its partners. GAVI facilitated great leaps in coordination and consensus building – it is credited with creating a spirit of collaboration and a cohesive immunization agenda. GAVI also made full use of its unique flexibility in accessing funds to raise global immunization funding to unprecedented levels. GAVI pursued innovative approaches to address challenging problems, including ISS funding and ADIPs. GAVI partners realize that for all the strengths and skills of the partner institutions, none of them could have accomplished these results. (*text Section 7.2*)

Because GAVI relied on some degree of ambiguity to build consensus, differences remain among partners around strategic priorities. While it is unlikely that everyone will ever fully agree on the

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priorities, GAVI can play an important role in advancing this discussion by providing the data and analysis needed to support decision making, and facilitating open discussions around strategic decisions and resource allocations such that the final policies represent compromises that all partners support. GAVI must decide with its partners the areas where its own Secretariat adds value in management and coordination, versus areas where its partners are better suited to carry out activities. Partner involvement in policy setting and decision making is still critical for creating the atmosphere that characterized Phase 1, that produced the collaboration and innovation which made GAVI successful. GAVI's voice as a global advocate for immunization, representing all the relevant stakeholders to promote the use of vaccines, is a core part of its added value – however, it has primarily used its voice for global level fundraising, and has underutilized its position to build country level ownership and commitment, closely linked with its sustainability strategy. (text Sections 6.1, 6.4.1 and 7.2)

Conclusions and Recommendations

Based on the findings from Phase 1, we propose the following recommendations going forward. These recommendations seek ways to build on strengths and to address weaknesses. The recommendations are grouped into seven broad areas that represent important elements for GAVI's future success, and are prioritized within each of the seven broad areas.

Improving Support to Countries

- 1. GAVI ISS support has improved DTP3 coverage rates across the set of recipient countries, but there is significant variability at country level, and GAVI has not been effective at supporting underperforming countries. GAVI should focus more attention on improving performance in underperforming countries, working with in-country partners to provide additional support. Focusing on a few priority countries, the GAVI Secretariat should initiate discussions with partners at country and regional level to identify critical problems, develop individualized solutions, and identify sources of additional inputs. The GAVI Board should institute a mechanism to regularly review progress in underperforming countries.
- 2. Overall, GAVI's management of its support to countries is effective, but there is room for improvement in areas such as translation of documents, notification of funding transfers, and better communication of the rationale for IRC recommendations. The GAVI Secretariat should propose a process for ensuring resolution of problems identified within recipient countries that includes briefings for the Country Support Team of problems identified through one-time evaluations, improving Country Support Team and Finance and Administration coordination regarding funding transfers, and most importantly establishing a process for regular internal review of the problems identified and resolution status.
- 3. The ADIPs were effective in compiling data to support new vaccine introduction, and advocating for their use. However, the key weakness of the ADIP model was that it did not adequately prepare countries for vaccine introduction. The GAVI Secretariat should ensure that the Accelerated Vaccine Introduction project incorporates all the elements of support required at country level (in logistics, cold chain, and other areas) for introduction of Pneumococcal and Rotavirus vaccines, convening independent reviewers.
- 4. Although financial monitoring was adequate in the majority of recipient countries, there were countries where ISS funds were used inappropriately. At the same time, the flexibility of GAVI funding, and the minimal reporting burden at country level, were important advantages of GAVI support that should be maintained. GAVI's Transparency and Accountability Policy represents a clear direction forward. The GAVI Secretariat should ensure appropriate implementation procedures, including specifying response procedures for reported improprieties or other noncompliance.

Improving Strategic Decision Making

- 5. GAVI allowed countries to set their own priorities for use of ISS funding, but its overall policies governing support to countries strongly promoted adoption of new vaccines. GAVI did not always have strong scientific evidence, or universal support for all of its strategic policies – such as Hib introduction. As a result, there was a perception that GAVI pushes new vaccines inappropriately. GAVI must ensure that its positions and policies have strong scientific foundations and widespread support throughout its partner organizations, and must seek additional ways to allow countries to set priorities for themselves regarding how to improve its immunization programs, particularly as it embarks on new activities. The GAVI Board should commission an independent review of how the package of country support feeds into GAVI's global strategic priorities and whether those priorities correspond to country level priorities, incorporating input from a broad group of recipient countries, feeding into a review of the design of the package of GAVI support to countries. Policy changes to consider include more differentiation among countries eligible to apply for new vaccines – for example, whereas countries with DTP3 coverage rates above 50% were able to apply for HepB, Hib and YF vaccine, that coverage rate might be increased for countries applying for more expensive Pneumococcal vaccine – thus encouraging lower coverage countries to continue to strengthen their existing program before adding more vaccines.
- 6. GAVI's decision making in the early years of Phase 1 focused on speed and results, without an overall strategic framework. To some extent, the lack of clarity may have reflected lingering differences in priorities among partners. Strategic planning has improved significantly with the Phase 2 Strategic Plan and Roadmap, and current workplans include budgets for activities to be undertaken in support of different strategic objectives. Nonetheless, there appears to be limited discussion to prioritize GAVI's strategic objectives, and to assess the costs required to meet the objectives that takes into consideration their expected impact. *The GAVI Secretariat should provide to the GAVI Board additional information on projected program and workplan costs for achieving various objectives, ensuring that the relative allocations among activities are in line overall strategic priorities, and supported by all partners*.
- 7. GAVI was not able to provide vaccine cost data disaggregated by vaccine, which limited ability to conduct cost effectiveness analysis of NVS funding this data is necessary not only for internal programming decisions but also effective advocacy. GAVI realized the importance of this issue and has undertaken steps in Phase 2 to address it. The GAVI Secretariat should ensure that the current information provided by UNICEF is sufficient to allow accurate cost effectiveness evaluation of its programs.

Strengthening Evaluation Mechanisms

- 8. Although GAVI's NVS represented its largest investment under Phase 1, it has not been independently evaluated, examining components such as program design, implementation, and cost effectiveness. The GAVI Board should commission an evaluation of NVS including program design, implementation, and cost effectiveness, as well as assesses how it fits into GAVI's overall strategic framework.
- 9. Under Phase 1, GAVI lacked a clear evaluation policy, evaluation framework, and indicators for evaluation as a result, this evaluation is being completed approximately three years after the end of Phase 1. The GAVI Board should commission a team to ensure there is partner consensus on the evaluation framework, indicators, and process for Phase 2, so that evaluation of Phase 2 can be conducted in a timely fashion to inform the next phase of GAVI's work.
- 10. One of the core strengths of the partnership under Phase 1 was the high level of commitment and goodwill. At the same time, however, its partner roles and responsibilities and organizational structures were not always clear and were under constant change. To address this weakness,

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GAVI has appropriately turned more attention to formalizing the partnership agreements and organizational structures in recent years, but focus should now return to ensuring and revitalizing partner goodwill and commitment. To maintain appropriate focus on these issues, the GAVI Board should ensure that the Phase 2 evaluation framework includes indicators to evaluate partner satisfaction and commitment, and ensure there is broad partner consensus on appropriate evaluation indicators.

Ensuring an Effective Partnership

- 11. Partners believed that GAVI was successful at consensus building because it provided avenues for technical debate and input from partners at the technical and implementation level, necessary both for innovation and consensus building, resulting in programming innovations such as ISS funding and the ADIPs. In the midst of the current reorganization, GAVI should ensure that such mechanisms for partner inputs are integrated into the governance and management structure. The GAVI Board should examine the structures for technical debate among the partners within the new governance arrangements, consulting with technical and implementation level representatives of partner institutions to solicit their feedback to the currently proposed structures. The GAVI Board should also ensure that the Phase 2 evaluation framework includes evaluation of the effectiveness of structures for coordinating partner technical inputs.
- 12. GAVI was generally successful in building trust between partners, which was critical to its success in Phase 1. Nonetheless some issues reflecting lack of trust and understanding, as well as lack of transparency were identified. More open communications would help to alleviate these issues. The GAVI Secretariat should present a proposal to partners outlining additional ways to ensure that all substantive discussions among partners and with Secretariat staff, including those that occur outside of Board meetings, are shared as openly as possible either with notes posted for public access on the GAVI website, or on a protected website that all partners can access.
- 13. Under Phase 1, it was difficult for developing country Board members to represent their constituents. This weakness is identified across GHPs, and GAVI has tried to address the situation by providing additional support to these Board members. Other ways to solicit country inputs should be explored, not only limited to Board level representation, and taking advantage of partner-coordinated regional events. The GAVI Secretariat should coordinate with partners to take advantage of opportunities presented by regional meetings to engage in substantive dialogue with countries, and propose a plan for how those discussions would feed into global level decision-making.
- 14. During much of Phase 1, the Secretariat was not adequately staffed to manage all of GAVI's activities effectively. In response, the Board has expanded the Secretariat staff to take on additional responsibilities, which may also create discomfort with partners if it appears that the Secretariat is taking over partner efforts. A study was commissioned in 2006 to examine the structure and functions of the Secretariat, and a follow-on study is planned. There should be an ongoing regular mechanism for ensuring that the structure of the Secretariat (size, staffing, role and authority) serves the partnership effectively. The GAVI Board should ensure the development of a framework and regular process for assessing the Secretariat's structure and performance, ensuring adequate input from GAVI partners.

Maximizing Added Value

15. In Phase 1, GAVI built credibility as an honest broker and neutral technical expert – overall, its policies were the result of technical debate and consensus involving a variety of partners. There had long been broad support and recommendations for most of GAVI's activities – strengthening immunization programs, introducing Hepatitis B, and improving injection safety – the debate focused on technical strategy. There were still strategic areas, however, where differences of

- opinion remained throughout Phase 1. GAVI should do more to advance consensus by providing strong data and analysis to support strategic decision making, and allowing sufficient debate and deliberation so that all partners buy into the final policy decision. The GAVI Board should ensure there is open access to deliberations and discussions regarding new vaccine policies, mechanisms for ensuring inputs from a broad variety of perspectives, and appropriate analysis to support its policies. The GAVI Board should also request that the Phase 2 evaluation framework incorporate inputs from a variety of perspectives regarding GAVI's effectiveness as an honest broker and technical expert.
- 16. While GAVI has been very successful in fund raising during Phase 1, less attention has been paid to building ownership and increasing funding commitments at country level, and strengthening broad commitment to the overall immunization agenda. GAVI must transition from advocacy focused on fund raising and introducing vaccines, to a clear strategy at country level and within the international community that focuses on the additional efforts required from partners and other agencies to improve immunization program performance. There has also been criticism that GAVI has not increased total funding for immunization, merely redirected it to GAVI. The GAVI Secretariat should work with partners to develop a clear advocacy strategy with targeted messages, particularly at country level. Additionally, the GAVI Board should commission a study that analyzes the historical funding flows for immunization, incorporating data at global, regional and country level, to assess whether total funding for immunization has increased since the inception of GAVI, as well as develops a methodology for reporting on future funding changes.

Understanding Vaccine Market Dynamics

- 17. Under Phase 1, GAVI was not very successful at influencing vaccine supply and pricing. Phase 1 demonstrated that it takes a long time to increase vaccine supply it was eight years between the inception of GAVI and the availability of a second pentavalent vaccine supplier. The ultimate impact on prices is yet to be seen. GAVI must increase its efforts to understand the vaccine market, in order to develop realistic long term pricing projections and goals this work should be integrated into GAVI's ongoing workplan, with appropriate outputs used to inform strategic planning. The GAVI Board should commission an in-depth analysis of the vaccine markets that includes analysis of the production costs, technical complexities of various vaccines, transferability of technology, other barriers to entry and demand forecasts, in order to inform procurement strategy, strategic planning, and sustainability policy.
- 18. GAVI's vaccine strategy in Phase 1, based on the assumption that creating and demonstrating a market for vaccines in developing countries would attract new suppliers, create competition, and lower prices, did not come to fruition. GAVI must recognize that it is participating in markets with few buyers and sellers and high entry barriers, and develop alternative approaches for procurement of new vaccines that provide sufficient incentives to manufacturers and ensures vaccine security. While GAVI has taken various studies of the vaccine market and the procurement agent function, more should be done to investigate new approaches, since this is a critical component of GAVI's long term mission. *The GAVI Board should commission a study of innovative ways to structure procurement of new vaccines (other than short term fixed price contracts) that may be more advantageous over the long term.*

Reassessing Strategies for Sustainability

19. Lack of long range planning and conflicting objectives (promoting new vaccines vs. improving sustainability) have limited the progress toward financial sustainability at country level. GAVI should reassess its sustainability definition and approach to ensure there is broad partner agreement on the importance of sustainability relative to adding new vaccines, and to develop a long term financing plan for all vaccines. *The GAVI Board should appoint a team to coordinate*

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work in this area, starting with a partners meeting to solicit input and build consensus on appropriate principles and policies, leading to development of a sustainability strategy that may incorporate a revised definition of sustainability, revision of the co-financing policy, and new vaccine procurement strategy.

1. BACKGROUND TO THE STUDY

The GAVI Alliance is an alliance involving multiple partners from the private and public sectors, dedicated to improving health and saving the lives of children through the support of widespread vaccine use. It was created in 1999 as a partnership between multilateral organizations such as WHO, UNICEF, the World Bank and the Bill and Melinda Gates Foundation, bilateral aid organizations, developing country governments, research institutes, civil society and vaccine manufacturers. Under the first phase of GAVI (2000-2005), GAVI adopted a mission of "saving children's lives and protecting people's health through the widespread use of safe vaccines, with a particular focus on the needs of developing countries," which was operationalized through its six strategic objectives:¹

- Improve access to sustainable immunization services;
- Expand the use of all existing safe and cost-effective vaccines, and promote delivery of other appropriate interventions at immunization contacts;
- Support the national and international accelerated disease control targets for vaccinepreventable diseases;
- Accelerate the development and introduction of new vaccines and technologies;
- Accelerate research and development efforts for vaccines needed primarily in developing countries; and
- Make immunization coverage a centerpiece in international development efforts.

GAVI supported country governments with monetary support through its immunization services support (ISS) program, and in-kind provisions of new and underused vaccines (NVS) and related injection safety equipment (INS). GAVI also undertook initiatives at the global level to support development and introduction of new vaccines, as well as to advocate for increased attention and funding to immunization.

This evaluation was commissioned in June 2006 by the GAVI Board to evaluate GAVI's performance under Phase 1, and to identify lessons learned for the future. GAVI contracted with an independent organization to develop a conceptual model for evaluation, together with specific evaluation questions, through a consultative process incorporating stakeholder input.² Based on this work, an independent Steering Committee (SC)³ developed the evaluation questions in the Request for Proposal (RFP), and GAVI solicited proposals. Abt Associates was selected to conduct this evaluation and began its work in November 2007. Annex A provides the scope of work as specified in the RFP, including a list of 20 evaluation questions. The scope of the evaluation was quite comprehensive, encompassing review of organizational structures, management processes, program design and results, as well as basic principles that form the foundation of GAVI. In consultation with the SC, which provided guidance throughout the course of this evaluation, the evaluation approach for some questions were revised, and other questions were eliminated due to postponement of other assessments – these changes are noted also in Annex A.

¹ GAVI Strategic Objectives 2000-2005

² Evaluation Framework: GAVI Alliance and GAVI Fund Phase 1 (2000-2005)

³ SC members are: Tale Kvalvaag and Ruth Levine (co-chairs), Abdallah Bchir, Shawn Gilchrist, Steven Landry, Bjorn Melgaard, and Jean-Louis Sarbib.

The GAVI Alliance has commissioned a number of evaluations and studies, findings of which have led to program refinements and development of new strategies. One overarching principle of this evaluation is that it not replicate previous or concurrent studies, but instead incorporate their findings. To the extent that there may be gaps in information and analysis pertinent to future GAVI strategy and programs that fall outside the scope of this evaluation, it was agreed that we would provide recommendations that identify evaluation gaps and propose solutions.

The authors and the SC realize the timing of this evaluation is not ideal. GAVI has embarked on a new phase of work, including adopting new strategic objectives in 2007.⁴ Nonetheless, this evaluation should serve as a record of the activities and results of Phase 1, as well as a compilation of the lessons learned, in order to refine the policies and activities currently adopted by GAVI to achieve its strategic objectives.

⁴ The GAVI strategic objectives for 2007-10 are:

[•] Contribute to strengthening the capacity of the health system to deliver immunisation and other health services in a sustainable manner;

Accelerate the uptake and use of underused and new vaccines and associated technologies and improve vaccine supply security;

[•] Increase the predictability and sustainability of long-term financing for national immunisation programmes;

Increase and assess the added value of GAVI as a public-private global health partnership through improved efficiency, increased advocacy and continued innovation.

2. HISTORY OF GAVI

This evaluation covers GAVI's performance in its first five years, a time when much energy was focused on formation of the Alliance, development of appropriate strategies and programs, and establishing governance and operating procedures. This period was one of significant change and introspection, and it is important to understand the path of GAVI's growth in examining how it performed.

2.1 The First Years

In the late 1990's, the Expanded Programs of Immunization (EPI), which had successfully increased immunization in developing countries during the 1980's, were faltering. Coverage in many countries had dropped significantly. Further, Hepatitis B vaccine, which was relatively inexpensive, could save many lives, and had been on the market for years, was not being taken up by developing country governments as part of their immunization programs. It was estimated that some 30 million children were not getting their basic immunizations, which could have prevented millions of deaths. The immunization community was aware of these issues. An earlier attempt to pull together a public-private partnership to bring more international focus to immunization, the Children's Vaccine Initiative (CVI), had failed to make major inroads because of lack of funding and unresolved issues among the partner organizations.

This was the situation into which the Global Alliance for Vaccines and Immunizations (GAVI) was born. Several factors enabled its formation. First and most importantly, the Bill and Melinda Gates Foundation⁵, convinced that immunizations must be made available to the world's children, was willing to provide \$750 million to this effort, if the right organizational framework could be achieved. Secondly, the partners who had been part of the CVI, including WHO, the World Bank, UNICEF, the Rockefeller Foundation and the vaccine industry, remained committed to saving lives by expanding reach and effectiveness of immunization programs in developing countries. They now had the lessons – both successes and failures – from the CVI to build on. Further, there was already in place a group of midlevel, highly committed people from these institutions who were given the mandate to do the groundwork, in conjunction with the Gates-supported Children's Vaccine Program of PATH, to structure a new partnership – this group of individuals would later become the GAVI Working Group (WG).

Within a matter of a few months, from the time the CVI was abandoned in March 1999⁶ until the Protoboard meeting for the new GAVI in July, the outlines for the new partnership were in place, building on the experience of the CVI and engaging bilateral donors and technical and research institutes as well as the CVI partners. Partners defined GAVI's mission as "saving children's lives and protecting people's health through the widespread use of safe vaccines, with a particular focus on the needs of developing countries."

The GAVI Alliance was intentionally designed as an unincorporated alliance of partners, with the shared goals of increasing immunization coverage of the world's children and delivering new and underused

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⁵ Referred to as the Gates Foundation throughout this report.

⁶ At a meeting of representatives of UN agencies, bilateral donors, private foundations, and industry representatives, held at Rockefeller Foundation's Villa Serbellone in Bellagio, Italy on March 15 – 17, 1999, WHO announced that it would terminate the CVI at the end of 1999. Donors agreed to work together to form a new alliance.

vaccines that had strong potential for reducing child mortality. As an informal alliance, GAVI had no legal status. Though not all partners favored this approach, it was adopted as an effective way of coordinating efforts and achieving consensus and coherence among partners. It was envisioned that while the alliance would expand funding for immunization, it would rely on the partner organizations to provide technical expertise to recipient countries to support achievement of GAVI's goals. The partners viewed GAVI as a way of jump-starting expansion of immunization programs. Initially, Gates Foundation funding was assured for five years, with the expectation that over that time, the increased global demand for key vaccines would bring prices down such that GAVI funding would no longer be necessary.

Key features of the alliance were:

- Reliance on the partners to design, implement and monitor programs not just at the Board level but in the recipient countries as well. The Alliance was supported by a small Secretariat hosted by UNICEF. This structure was intended to avoid some of the turf tensions that had plagued the CVI,⁹ as well as enable GAVI to be nimble in decision-making.
- Representation from vaccine manufacturers on the Board, in recognition that industry had a vital role to play in ensuring that vaccines were available and priced to be affordable in the developing world.
- Adoption of the strategic objectives and milestones developed for the CVI, revising them over time.
- Representation from the recipient countries on the Board.

At the same time, the Global Fund for Children's Vaccines (later called the Vaccine Fund and then the GAVI Fund) was set up as a US 501C3 (non-profit) organization, as the entity that could accept funding from donors and disburse them to recipient countries. The Fund, with a Board consisting of individuals with financial expertise as well as well-known celebrities, had responsibility for oversight and management of the funds contributed to the alliance, as well as responsibility for fund raising and advocacy. The Fund Board had a management staff to run day to day operations. A trust account was also set up at UNICEF to mobilize funds from other donors. From the start, the GAVI Alliance was responsible for programmatic decision-making, while the Vaccine Fund held fiduciary responsibility.¹⁰

The perception of partners at the time was that a global public-private partnership would assure the commitment of all stakeholders, and would result in faster action than would be possible by individual donors. The core principles of GAVI, recognized by its partners from the onset, were made explicit in its 2004-2005 Strategic Framework, which stated: "The basic spirit of the alliance is to focus on those areas in which no one partner can work effectively alone and to add value to what partners are already doing." The Strategic Framework defined GAVI's "added value" in four areas: 1) coordination and consensus-

⁷ "Discussion Paper: The Story of GAVI's Evolution" presented by CEPA at GAVI Alliance and Fund Joint Board meeting May 11 – 12, 2007. Some partners, e.g. the World Bank and industry representatives, preferred a more robust organization to support the alliance, but UNICEF and WHO preferred a small, non-technical secretariat with little authority.

⁸ "Discussion Paper: The Story of GAVI's Evolution" presented by CEPA at GAVI Alliance and Fund Joint Board meeting, May 11-12, 2007.

⁹ Muraskin, William. 2005. *Crusade to Immunize the World's Children*, Global BioBusiness Books. See Chapter 5.

¹⁰ The report from the first GAVI Board meeting of October 1999 describes the legal status and functions of the GAVI Fund, including fund raising, management and investment of the Fund's resources, and release of funds for program activities on the recommendation of the GAVI Board. Also see <u>Collaborative mechanisms between the GAVI Board and the Vaccine Fund Board regarding disbursements of support to countries</u>, adopted by GAVI Board Oct 4, 2000, which sets out the GAVI Alliance Board's role as the highest body of the alliance, and describes Vaccine Fund's responsibility in determining support for particular activities upon recommendation of the GAVI Alliance Board.

building; 2) funding support from the Vaccine Fund – which both adds significant new resources and employs new and innovative funding strategies; 3) innovation – introducing new programmatic tools and approaches, and 4) advocacy and communications.

2.2 GAVI's Growth

Given the small size of the Secretariat, GAVI Alliance could not have ramped up as quickly as it did without calling on the WG that had been formed in the CVI days to support the Secretariat. The WG consisted of mid-level technical people who represented most of the partners on the Board, and were given the time and mandate by their Board members to develop the policies and programs that would guide GAVI's work. With this group's help, GAVI was able to develop the New Vaccine Support (NVS) and Immunization Services Support (ISS) funding windows, call for proposals, and approve country funding in 2000. The third funding window, Injection Safety (INS), was introduced in mid-2001. These were the three types of support available to GAVI-eligible countries under Phase 1. By mid-2001, half of all GAVI-eligible countries had been approved for at least one type of support. Specially selected Independent Review Committees (IRCs) were established to ensure impartial, technically-sound review of proposals. Since UNICEF already had the UN mandate for procuring vaccines, UNICEF carried out procurement of vaccines and related materials for GAVI.¹¹ By the end of Phase 1, 73 countries had been approved for support.

While the Gates Foundation provided the groundbreaking funding, bilateral donors began contributing to GAVI very quickly. The UK was the first, in 2000, followed the next year by Denmark, the Netherlands, Norway¹², Sweden and the U.S. By 2003, GAVI already had received well over a billion dollars in contributions from partners; donor contributions by the end of Phase 1 totaled \$1.67 billion. Table 1shows the contributions by donor under Phase 1.

Table 1: Donor Contributions During Phase 1 (2000-2005)

	1999- 2000	2001	2002	2003	2004	2005
Canada	0	0	1,880,356	4,755,421	6,032,835	130,868,641
Denmark	0	1,147,407	0	0	3,338,879	3,416,107
European Commission (EC)	0	0	0	1,260,000	0	0
France	0	0	0	0	6,029,114	0
Ireland	0	0	510,750	623,750	650,000	831,460
Luxembourg	0	0	0	0	0	645,150
Netherlands	0	24,060,335	13,375,172	16,492,642	17,329,866	15,859,414
Norway	0	17,894,690	21,325,656	21,791,087	40,924,593	39,534,594
Sweden	0	1,892,133	1,114,800	2,385,182	4,931,430	12,663,401
United Kingdom	4,463,400	0	15,048,250	5,605,950	18,491,535	6,625,149
United States	0	48,092,000	53,000,000	58,000,000	59,640,000	64,480,000

¹¹ Although GAVI provides all countries the option to procure vaccines and supplies independently, the vast majority rely on GAVI procurements through UNICEF.

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¹² Norway was an important donor, as it was the largest (and first) multi-year commitment other than the Gates Foundation.

Table 1: Donor Contributions During Phase 1 (2000-2005)

	1999- 2000	2001	2002	2003	2004	2005
Government Donors + EC	4,463,400	93,086,564	106,254,984	110,914,032	157,368,252	274,923,916
Gates Foundation	325,000,000	425,000,000	0	3,500,000	5,000,000	154,338,000
Other Private	20,000	0	1,630,361	2,580,847	1,805,051	473,480
Private and institutions	325,020,000	425,000,000	1,630,361	6,080,847	6,805,051	154,811,480
Total Contributions	329,483,400	518,086,564	107,885,345	116,994,879	164,173,303	429,735,396
Total Cumulative	329,483,400	847,569,964	955,455,309	1,072,450,188	1,236,623,491	1,666,358,887

Source: GAVI Website

As GAVI grew, it initiated new activities and new types of funding that contributed to its overall mission. The ADIPs (Accelerated Development and Introduction Plans) were created in 2003 specifically to accelerate the introduction of pneumococcal and rotavirus vaccines in developing countries. The Hib Initiative was created in 2005 to support partners and countries in the collection and analysis of Hib disease data, to inform country decision-makers of the value of Hib immunization and to accelerate Hib vaccine introduction into developing countries. By the end of Phase 1 GAVI was preparing to open a new financing window for health systems support and had the promise of a very large expansion of long-term financing through the IFFIm mechanism. Table 2 summarizes important Phase 1 events.

Table 2: Timeline of Key Events in GAVI Phase 1

Year	Governance	Financing	Programs	Other Key Decisions
1999	Protoboard creates GAVI, GAVI Board meets, Vaccine Fund is created, GAVI Alliance Secretariat formed	Bill & Melinda Gates Foundation make preliminary grant		
2000	GAVI Alliance and Vaccine Fund are officially "launched" Vaccine Fund creates Executive Committee	Gates Foundation, UK and other private foundations contribute	First rounds of proposals received and programs approved for New Vaccine Support (NVS) and Immunization Services Support (ISS)	Board recognizes need for capacity building to accompany vaccine supply.
2001	Vaccine Fund hires management staff	Denmark, the Netherlands, Norway, Sweden, the US make initial contributions	Injection Safety (INS) window is introduced. Funding cap (\$40 million over five years) is approved for China, India and Indonesia By June, 36 countries have approved GAVI funding.	Shortages of combination vaccines identified and strategies to deal with the problem discussed.
2002	GAVI Alliance Board delegates more responsibilities to Secretariat and Working Group to enable Board to focus on policy issues.	Canada and Ireland make initial contributions.	GAVI Board endorses creation of ADIPs Board agrees that DQAs will be used to determine whether data quality is adequate to justify reward payments under ISS.	

Year	Governance	Financing	Programs	Other Key Decisions
2003	GAVI Alliance Board Executive Committee (EC) and some standing committees are created to substitute for the large number of sub-groups. The EC is responsible for strategic planning, coordination, and supervision of the Secretariat, for approval by the board.	The EC makes its first contribution.	Pneumococcal and Rotavirus vaccine ADIPs approved and initiated. Work began on developing investment case framework	Definition of GAVI's value added.
2004	Decision made to merge GAVI Alliance Secretariat and Vaccine Fund management. New GAVI Executive Secretary appointed, effective 2005	France makes its initial contribution	Investment case framework initiated GAVI realizes that with high cost of combination vaccines, five year framework to achieve sustainability is too short, and asks for investment case for bridge financing. IFFIm mechanism is introduced.	2004-2005 strategic framework clarifies "value added". And defines it operationally as (1) coordination and consensus-building; (2) funding support from the Vaccine Fund; (3) innovation; and (4) advocacy and communications
2005	EC agrees on conditions for approving convergence of Fund management and Secretariat. GAVI Alliance and Fund Board Executive Committees begin holding joint meetings. First joint meeting of Alliance and Fund Boards.	Luxembourg becomes the 10 th bilateral donor to GAVI Fund.	Investment cases done for use of IFFIm for measles, maternal and neo-natal tetanus, and polio stockpile. Investment case approach evaluated, recommended for continued use. Health System Strengthening approved for \$500 million over five years. AMC concept introduced.	Board decided a two-year stategy/workplan was inadequate and agreed to a five year strategic plan ¹³

Source: GAVI Board reports and associated documents

2.3 Changes in the Global Health Context

During GAVI Phase 1, the environment for global health and global health funding underwent significant changes. The use of the global health partnership as a model for targeting funding to priority diseases or health interventions grew significantly. It was also a time when interest was growing from private foundations in improving international health. At the inception of GAVI, the international community was also coming to the realization that the challenge of HIV/AIDS was not diminishing, and many years of control and prevention efforts were insufficient for managing the disease.

Abt Associates Inc. 2. History of GAVI 29

¹³ GAVI. 2005. Joint GAVI and Fund executive committee meeting.

GAVI was one of the earlier global public-private health partnerships (GHPs) – at its inception, it represented a new approach for collaboration among a variety of public and private sector partners. Organizations and individuals who had worked in immunization for many years were re-energized by the new concept and the available funding. These organizations, as well as others who were new to global health or immunization, all welcomed the opportunity to be part of this new effort.

GAVI was seen as a trailblazer, but others quickly followed. Over time, GAVI became one of a proliferation of GHPs – 23 by one account¹⁴ and over 90¹⁵ by another. Board members of the GAVI Alliance are frequently on the boards of other GHPs as well. The novel approach that GAVI developed became business as usual – immunization is one of a host of urgent health priorities that all partners commit to making special efforts to address.

The proliferation of GHPs has led to criticisms (that they skew country health priorities, deprive stakeholders of a voice in decision-making, fail to consider private sector approaches, and waste resources through poor harmonization), but has also led to identification of lessons about what makes for effective partnerships. The Global Fund to fight AIDS, Tuberculosis and Malaria (GFATM) is probably the best known of these GHPs, and one with which GAVI is often compared. Lessons about GHPs have informed GAVI's organizational structure, particularly its growing emphasis on country consultation and adequate representation from recipient countries on the Board.

The period of GAVI Phase 1 also marked a time when funding for international health from private foundations increased significantly. As an example, the Bill and Melinda Gates Foundation has disbursed \$9.5 billion for international health programs since its inception. Their interest in developing innovative approaches for tackling international health problems contributed to the number of GHPs. One of the new approaches adopted from private sector that became widely used was performance-based incentives – GAVI being one of the pioneers in this regard with the design of the reward structure of ISS funding. The significant funding from private foundations also changed the mindset about what was feasible in international health (as GAVI has demonstrated in the area of immunization), and influenced the health agenda.

At the inception of GAVI, HIV/AIDS programs focused only on prevention and control, with only limited success. The costs of providing treatment in developing countries seemed an unsurmountable obstacle. The creation of the GFATM in 2001 began a very substantial increase in funding for HIV/AIDS.¹⁶ The US President's Emergency Plan for AIDS Relief (PEPFAR) was launched in 2003 with a commitment of \$15 billion, further increasing resources for HIV/AIDS.¹⁷ The issue of the sustainability of these types of efforts became unimportant in comparison with the prospect of managing such a terrible disease, and also changed the discussion regarding the shared responsibility of the international community. In many developing countries, GFATM is the largest health program, represents a substantial share of the overall health sector, and also attracts a significant share of scarce human resources due to its rich funding levels – one study of HIV/AIDS expenditures in four African countries found total GF and PEPFAR resources were equivalent to total public and private expenditures on health.¹⁸ The resources for other health interventions pale by comparison, rendering HIV/AIDS the highest health priority by default.

Evaluation of the GAVI Alliance Phase 1 (2000-2005)

¹⁴ Buse, Kent and Andrew Harmer. 2007. *Global Health: Making Partnerships Work; a briefing paper*; Overseas Development Institute.

¹⁵ McKinsey & Co. 2005. Global Health Partnerships – Synthesized Output.

¹⁶ Pledges to-date total \$11.0 billion. Accessed 9/12/08 http://www.theglobalfund.org/en/files/pledges&contributions.xls.

¹⁷ PEFPAR. 2005. US Five Year Global HIV/AIDS Strategy.

¹⁸ Dmytraczenko, Tania, et al. 2004. "HIV/AIDS Expenditures in sub-Saharan African: Observations from Kenya, Rwanda, and Zambia." World AIDS Conference. Presented at UNAIDS coordinated pre-conference meeting. Data quoted is from Malawi, Mozambique, Ethiopia, and Zambia.

3. APPROACH AND METHODS

The objectives of this evaluation as specified in the RFP were:

- To identify and learn from the successes and weaknesses of GAVI in Phase 1, including how well it has evolved and learned from experience over the period 2000-2005;
- To contribute to the refinement or adjustment of GAVI policies in the next strategic phase of work; and
- To document the impact and to evaluate the efficiency and effectiveness of the GAVI Alliance's use of resources during Phase 1.

Moreover, this evaluation was to address specific questions that were detailed in the RFP. The questions detailed in the RFP were loosely framed as encompassing structures and roles, activities, strategic objectives, and performance and impact. We have chosen to re-organize these questions along a framework that allows us to more clearly distinguish between program results, organizational structure, management approaches, and lastly cross cutting principles that underpin GAVI's mission and impact. Given the timeframe under evaluation, which represented a period of significant change and development, organizational structure and management represent significant components of this evaluation. Table 3 presents the RFP questions summarized and reorganized as presented in this report.

Table 3: Summary of RFP Questions

	RFP Questions (summarized)
Program Results	How successful have GAVI Alliance's key Phase 1 programmes (ISS, Injection Safety, uptake of new and underused vaccines) been in terms of country uptake and results?
	To what extent did GAVI Fund & the GAVI Alliance achieve value for money in terms of activities undertaken?
	Who has benefited from GAVI Alliance Initiatives – including the extent to which fragile states, the poorest countries, and the poorest of poor within countries are reached?
	What have the ADIPs achieved and how useful a model is this for the future?
	To what extent has the GAVI Fund & GAVI Alliance been successful influencing vaccine pricing and supply? What can be learnt from the Phase 1 experience to strengthen and improve the future strategic response in this area?
	What progress has been made against each of the strategic objectives?
Organizational Structure	How well has the GAVI Fund governance structure worked? Is there clarity of role/responsibilities between various entities?
	To what extent, and to what effect, has the GAVI Fund fulfilled its role as a 'watch dog' of the GAVI Alliance? Is it best structured to do this?
	Was the Governance composition and structure maximally 'fit for purpose?'
	How well has the partnership worked to ensure efficient working by all partners? How appropriately has GAVI evolved its structures and

	working practices over time?	
Management Approaches	How effective have strategic decision making approaches used by the GAVI Alliance been?	
	How effective has the GAVI Alliance & GAVI Fund communication and advocacy systems been at all levels and how well are they coordinated with other partners?	
	How harmonised and aligned is GAVI Alliance funding and programmatic support (including monitoring & evaluation) with other funding and activities at country level, including in federal systems?	
	To what extent has GAVI enabled an effective, efficient and acceptable approach to technical assistance provision at country level?	
	How adequate and appropriate has the GAVI Alliance approach to monitoring and evaluation at country level been?	
	How successful and efficient has the GAVI Fund been in resource mobilization?	
Cross Cutting Principles	What added value have the GAVI Alliance and GAVI Fund brought to international efforts in immunization, beyond programmes funded?	
	Are countries likely to be able to sustain the improvements in immunization achieved with support from GAVI?	

These questions were identified using a stakeholder consultation process, so represent ones where there was broad interest from a variety of stakeholders. There are undoubtedly many other issues that could also be addressed, but we limited ourselves to the questions from the RFP. As such, some issues that were later identified as areas of interest, such as the value-for-money of partner-led activities funded by GAVI, were not addressed.

We used quantitative and qualitative analysis methods to address the questions posed. An overall description of the approaches used is provided below, with details of the specific approaches for each evaluation question shown in Annex B.

As specified in the RFP, this evaluation is limited to Phase 1. We considered information on more current developments as provided in GAVI documentation and other evaluations, in order to update ourselves on organizational, program and policy changes that affect the applicability of our conclusions and recommendations, and to reflect what has already occurred. For example, we were asked to examine the ADIP's achievements and whether that is a useful model for vaccine development – that cannot be adequately addressed if we were to ignore developments and information after 2005, such as the GAVI-commissioned ADIP evaluation. Similarly, we incorporated information from governance studies that occurred after 2005 and the current reorganization in order to capture the current reality. However, our data collection was not intended to represent findings related to Phase 2, we do not have comprehensive information on Phase 2 progress, nor do we evaluate Phase 2 performance.

3.1 Qualitative Analysis

Evaluation of organizational structure, management approaches, and the impact of GAVI's broader principles was based on qualitative analysis methods. Data for these areas was collected through key informant interviews, discussions at Regional Working Group (RWG) and EPI Managers' meetings, and country visits. In addition, we reviewed internal GAVI documentation, relevant GAVI-commissioned studies and evaluations, as well as external evaluations of GAVI's performance and impact. To the extent that some of the evaluation questions given to us had been addressed by previous studies and evaluations,

we relied on those findings. Where we identified gaps in analysis or significant variation in results, we incorporated ways to expand on or clarify issues in our data collection and analysis. The qualitative findings reported represent data that has been validated from several sources; we use detailed data from country visits to illustrate broader findings confirmed from various sources.

3.1.1 Key Informant Interviews at Global Level

Key informant interviews were used to gather information for many components of this evaluation. We interviewed two groups of informants at global level. The first group of 37 informants consisted of GAVI Alliance and GAVI Fund Board members (14), Working Group and task force members (7), GAVI Secretariat staff (7), and other knowledgeable informants, generally researchers and opinion-leaders (9). The primary topics discussed in these interviews were:

- Communications and advocacy
- Strategic decision making and investment case approach
- Structure of the partnership and relationships between partners
- GAVI's added value

These interviews were semi-structured using targeted interview guides for each type of informant, as shown in Annex C. For external researchers and opinion-leaders, the discussion sometimes focused only on one or two key topics that were the focus of their research.

Both the SC and the GAVI Secretariat provided input into the selection of informants. We initially prepared a list of key informants who were representative across the GAVI partners, participated in GAVI as members of various organizational structures, and were involved during various points in Phase 1. Based on SC feedback we made several additions. The interview list was further revised with inputs from staff at the GAVI Secretariat. Approximately one-third of the key informants continued their involvement with GAVI into Phase 2.

We interviewed a second group of 20 key informants consisting of ADIP staff, ADIP Management Committee members and Permanent Observers, vaccine manufacturers, and GAVI partners more actively involved with the ADIPs (i.e. WHO, UNICEF, USAID) for information on:

- ADIPs, their management, and impact on country uptake of new vaccines
- GAVI impact on vaccine pricing and supply

The interview guides for these topics are provided in Annex D, while a complete list of interviewees is shown in Annex E.

3.1.2 Discussions at Regional Working Group and EPI Managers' Meetings

In order to obtain feedback from country and partner staff at country and regional level, we attended three RWG meetings (Southeast Asia, Central Africa, and West Africa) and three EPI managers meetings (Central Africa, West Africa and East Africa). During these meetings, our researchers met with EPI managers and their staff, WHO and UNICEF EPI officers, as well as representatives of other organizations working in immunization at country level. Some discussions occurred within the full RWG, while other discussions took place within country teams. Our researchers used semi-structured interview guides to lead these discussions. The interview guide is included in Annex F.

These discussions focused on seven topics:

- Communications
- Strategic decision making
- Roles and responsibilities of the RWG
- Working relationships between partners at regional and country level
- Advocacy
- GAVI's added value
- Sustainability

These discussions were very helpful in supplementing and confirming information found at global and country level. It also provided access to perspectives from many more countries than was available from direct visits to countries. Annex G provides a summary of the feedback from these meetings.

3.1.3 Country Visits

Study countries were selected based on researchers' prior knowledge of the in-country environment and specific characteristics that render experiences of selected countries more interesting for study. Based on this information, we reviewed all GAVI recipient countries and prepared a short list of ones deemed more interesting for study of our research questions. These countries tended to be the outliers – countries that have had significant donor investments or have been isolated, have experienced significant performance improvements or declines, or with a history of strong management or mismanagement. We were more inclined toward middle and lower coverage countries, since the higher performing countries have limited numbers of unreached populations, require less TA, and are likely more pro-active in seeking information from GAVI as needed. With consideration of regional distribution (since the RWG effectiveness may affect country perception of GAVI, effective communications, coordination of TA, etc), we sought to identify six countries with the following criteria:

- At least 2 SWAP countries
- At least 2 LICUS countries
- Range of performance under GAVI
- Countries identified as having issues in internal monitoring
- Countries with more stable NIP staff better-positioned to address evolution of GAVI communication, M&E, technical assistance, etc

Table 4 provides profiles of the type of countries for in-depth study, our shortlisted countries, and the six selected study countries highlighted.

Table 4: Proposed Country Profiles and Countries for In-depth Study

Profile	Country	Other Considerations
Significant improvement,	Mali	SWAp country, early application
representative of better NIP in Africa, still under 90% coverage	Niger	
7 tilled, Still drider 30 % coverage	Senegal	
Previously mid-coverage	<mark>Malawi</mark>	SWAp country
surpassing 90% coverage	Tanzania	SWAp country
Concerns regarding transparency of ISS management	Democratic Republic of Congo	LICUS country, post conflict, CSO pilot country
	Uganda	SWAp country
Former Soviet republic, little	Tajikistan	High coverage
improvement	Uzbekistan	High coverage
Large, decentralized state with significant sub-national authority	Indonesia	Former stellar performer with declining coverage, CSO pilot
	Nigeria	Transparency, governance, information reliability issues
Isolated and neglected	Lao People's Democratic Republic	LICUS country
Former conflict country	Democratic Republic of Congo	LICUS
	Afghanistan	LICUS
	Vietnam	Long history with GAVI, should be objective and thoughtful

Although the study team had originally proposed Tajikistan, it was agreed to substitute Uzbekistan based on input from the GAVI Secretariat. It was felt that Tajikistan posed a particularly challenging environment and thus is not representative of its region.

The in-depth study visits consisted of 8-12 day visits in country by one researcher.¹⁹ Visits were conducted between March and May. Researchers met with officials from the National Immunization Program, Ministry of Health, Ministry of Finance, Inter-agency Coordinating Committee, and other donor representatives. The researchers used an interview guide that focused discussions in eight areas:

- Communications and advocacy
- Monitoring and evaluation
- Coordination of technical assistance
- Sustainability of improvements
- In country beneficiaries of GAVI
- Impact of ADIPs on uptake of new vaccines
- Harmonization with other programs
- Value added of GAVI

The guide provided to researchers, which provides more detail on the types of people contacted, as well as the interview questions is provided in Annex H. A report of key findings from each of the study

¹⁹ The research in Laos was conducted in five days.

countries is presented in Annex I. In some cases the findings from in-depth study countries provide tangible evidence that confirms and expands upon other sources of information, allowing us to make generalizations across GAVI countries. In other cases they provide more anecdotal information that may not be prevalent across all countries, but are nonetheless worth noting. These findings are referenced throughout this report in the relevant sections.

3.1.4 Document review

We consulted relevant literature prior to our data collection to familiarize ourselves with key issues, and to inform development of data collection instruments. In this initial process we relied heavily on the literature cited in *Evaluation Framework: GAVI Alliance & GAVI Fund Phase 1 (2000-2005)*. We also reviewed GAVI internal documentation, such as Board meeting minutes, briefing documents, internal strategy documents, task force discussions. In the course of our research, we learned of additional studies and evaluations, and reviewed those if available. As we analyzed our findings, we repeatedly returned to previous studies and evaluations, as well as GAVI internal documentation to validate findings.

We also reviewed documents describing current activities within GAVI in order to update ourselves on current developments that may affect our recommendations.

A full list of references is presented in Annex M.

3.2 Quantitative Analysis

We used quantitative methods to analyze the impact of GAVI's Phase 1 country programs, including the uptake and results of programs, cost effectiveness, and contribution to GAVI's strategic objectives.

3.2.1 Data Sources

We used many different sources of information for indicators of immunization coverage, immunization expenditure and GAVI funding, immunization program strategies, and political, economic, and health sector conditions. Table 5 summarizes the key indicators and sources of data.

Table 5: Summary of Key Indicators and Data Sources

Indicators	Data Sources	Years Available			
Immunization coverage					
DTP3, HepB, and Hib Coverage Rate	WHO-UNICEF Estimates	1995-2005			
Target population (surviving infants)	JRF official country estimates	2000-2005			
Number of additional children reached with DTP3, HepB, Hib and YF vaccines with GAVI support	Estimates provided by WHO department of Immunization, Vaccines and Biologicals	2000-2005			
Immunization expenditure and GAVI funding					
ISS expenditures per year	Annual Progress Reports from 53 countries ²⁰	2001-2005			
	Data from IRC member Dr. Viroj Tangcharoensathien				
Countries approved for GAVI support	GAVI Secretariat	2000-2005			

²⁰ In earlier years, the number of APRs is less than 53, because countries begin submitting APRs only after they receive GAVI funding. Countries applied for support at different phases – only recipient countries would have completed APRs in earlier years.

Indicators	Data Sources	Years Available		
(by type of support)				
GAVI financial data	GAVI/VF Official Financial Statements	2000-2005		
Shipments of GAVI-supported vaccines to recipient countries	UNICEF shipments data	2001-2005		
Political, economic, and health sector conditions				
Per capita GDP in international dollars ⁸	World Health Statistics 2006, WHO	1998-2003		
List of LICUS (Low Income Countries Under Stress) countries	Improving GAVI's Engagement and Effectiveness in Fragile States, GAVI October 2006	2006		
IBRD Political Stability Index	World Bank	1996-2005		

3.2.2 Analysis Methods

We used data on country approvals and country coverage rates to evaluate the uptake and results of GAVI country programs, analyzing percentage of GAVI eligible countries that introduced GAVI programs and changes in coverage rates across GAVI countries. We conducted cost effectiveness analysis using an indicator of cost per death averted, however, the analysis was limited due to data constraints. We examined the distribution of GAVI funding by different country groups, as well as funding per child across different country groups. We also analyzed GAVI's impact on in-country disparities in immunization rates using regression analysis. Based on a statistical model used in two previous evaluations of ISS funding, we analyze the extent to which changes in DTP3 and HepB3 coverage rates can be attributed to GAVI programs. More detailed explanations of the data used and analyses conducted are presented in their relevant sections.

3.3 Limitations of the Analyses

We sought to make the best use of available data and the most feasible approaches to additional data collection and analysis given our time constraints. However, our analyses is compromised by several limitations – most importantly, the timing of the evaluation, data limitations, sampling of informants, and data reliability. Our findings are biased by the fact that this evaluation of the 2000-2005 period was conducted in 2008. In some ways we know much more regarding eventual outcomes than at the end of Phase 1, but we are also biased by current perceptions. We limit our findings to those related to the Phase 1 period, and clearly delineate additional information on developments that fall outside of that period – such information is used where applicable to show GAVI results which were not demonstrable based on data only through 2005, or to answer RFP questions that required more up-to-date information. Where key informants report on activities or developments after Phase 1, we do not include those findings in this report, however, it should be recognized that their comments on Phase 1 may be biased by more recent experiences.

Our ability to attribute changes in immunization performance to GAVI is limited. We do not have an appropriate set of countries, whose immunization performance can be used as a counterfactual. All countries with annual per capital income under US \$1,000 were eligible for GAVI support – using non-GAVI eligible countries as a comparison group would not be appropriate as they would necessarily be higher income countries. Further, the number of GAVI-eligible countries that did not receive support is very few, so they also cannot be used as a control group. Nonetheless, we present data from GAVI countries and non-GAVI middle income countries to examine observable differences, realizing they are

not an ideal comparison group. In the absence of a counter-factual, we used regression analysis to determine what changes seen over the period of Phase 1 can be attributed to GAVI activities. Many of GAVI's activities and results cannot be quantified in this way, or data required for analysis is unavailable, so the extent to which changes can be attributed to GAVI is limited. In the section on GAVI's results, we have clearly denoted those findings that are only descriptive, as opposed to ones based on statistical analysis.

Lastly, our selection of informants at country, regional and global level affects our findings. While our key informants represented a variety of stakeholders involved with GAVI in various capacities, our selection of external researchers to some extent reflects a bias toward more critical voices. Our country level findings are drawn from visits to six countries, selected to represent experiences and perceptions among the diverse group of 75 GAVI-eligible countries. We also use findings from regional meetings to supplement and confirm country level findings, however, our approach does not allow us to draw strong inferences by type of country or by region. Nonetheless, there are important findings and messages from country and regional level, many of which reiterate findings from other studies and evaluations.

Data related to immunization coverage for quantitative analyses are based on data sources that GAVI, UNICEF, and WHO rely upon. To the extent the WHO-UNICEF coverage estimates and country estimates reported in WHO-UNICEF Joint Reporting Forms may be inaccurate, the reliability of our conclusions are compromised. Despite their weaknesses, these sources represent the most reliable and comprehensive cross-country data available.

3.4 Review Process

As mentioned, the SC provided guidance throughout the implementation of this evaluation, including reviewing earlier drafts of this report. A draft of this report was also provided to informants for review – all comments were compiled and are presented in Annex J. Any factual errors brought to our attention through this review process have been corrected. Comments that represent differences of interpretation or opinion may or may not have been incorporated, however, all comments are included in the annex.

3.5 Definitions

GAVI's complex organizational structure, and the name changes that have occurred for various entities can be a source of confusion. The terminology used in this report is defined below.

- **GAVI** (used alone) or the **Alliance** refers to the **GAVI Alliance**, previously the Global Alliance for Vaccines and Immunization.
- **Fund** refers to the **GAVI Fund**, previously the Children's Vaccine Fund.
- **Board** or **GAVI Board** refers to the GAVI Alliance Board. The **GAVI Fund Board** is always referred to in full or as the **Fund Board**.
- **Partners** or **stakeholders** are used interchangeably to refer to the independent organizations that participate in the Alliance. Partners may or may not have a seat on the GAVI Board.
- **Constituent** or **constituency group** refers to a GAVI partner or partners (with no Board seat) whom another Board member is responsible for representing.
- Permanent members or permanent partners refers to the four partners with permanent Board seats Bill and Melinda Gates Foundation, WHO, UNICEF, and the World Bank

- Task teams and task forces are used interchangeably to denote subsidiary structures with partner representation that were created to conduct specific tasks.
- Interviewees, informants, and respondents are used interchangeably to refer to individuals at global, regional and country level that provided information for this evaluation.

4. RESULTS OF PHASE I ACTIVITIES

Under Phase 1, GAVI provided direct support to countries and initiated other programs in support of its strategic objectives. The bulk of GAVI funding (\$713 million, representing 90% of funds disbursed through end-2005) was directed to its three country programs – Immunization Services Support (ISS), New Vaccine Support (NVS) and Injection Safety (INS). These programs made valuable contributions to advancing immunization on a global scale and are widely recognized as important GAVI achievements. Another \$62 million was disbursed to fund the ADIPs and Hib Initiative, yellow fever stockpile, and Africa Measles Campaign. We also include in this section a discussion of GAVI's impact on vaccine supply and pricing. Even though this was not a discretely funded activity, it is an important element that underlies GAVI's ability to fulfill its overall mission.

4.1 Uptake and Results from Country Programs

GAVI provided direct support to countries through its ISS, NVS and INS programs. GAVI ISS funding was provided to national governments to strengthen immunization services. Initial ISS "investment" funding was paid in installments over three years. Thereafter, additional ISS "reward" funding was paid for immunizing additional children, calculated at \$20 per additional child receiving DTP3 above the number of children in the baseline year, as reported in their applications. Reward funding was only provided to countries that immunized additional children, and successfully completed their Data Quality Audit (DQA) verifying their data quality. Countries also received Hepatitis B (HepB), Haemophilus influenza type B (Hib), and Yellow Fever (YF) vaccines through GAVI's NVS program. Lastly, countries could receive INS support, which provided auto-disable (AD) syringes and safety boxes sufficient for use with all injectable vaccines. GAVI-eligible countries applied for funding or commodities under each of these programs as they deemed appropriate.

GAVI impact is analyzed based on the level of country uptake, results as measured by immunization coverage, and also the beneficiaries of GAVI support.

4.1.1 Country Uptake of GAVI Support

By December 2005, 73 of the 75 countries eligible for GAVI support had been approved for at least one type of support, and 70 have actually received support.²¹ Figure 1 shows the uptake of each type of GAVI support during Phase 1, as measured by the cumulative number of approved country applications each year. Uptake of ISS and INS support was very rapid, particularly in the first half of Phase 1. Uptake of new vaccines was more variable, with rapid uptake of HepB vaccines, but relatively slower uptake of YF and Hib vaccine support.

²¹ GAVI. 2005. Annual Progress Report.

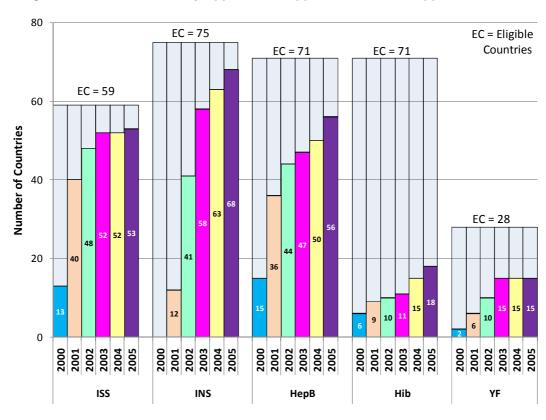


Figure 1: Number of Country Applications Approved for GAVI Support, 2000-2005

Note: Number of eligible countries shown in brackets; a country was considered eligible for a particular type of GAVI support if it became eligible for that type of support in at least one year in 2000-2004.

Source: GAVI Secretariat Memo, 22 November 2007 (see annex for number of proposals approved by year), from GAVI Alliance & Board meeting 28-29 Nov 2007, YF approval status from GAVI Secretariat

Table 6 summarizes total country uptake by the end of 2005. Uptake of ISS has been particularly dramatic, with 90% of eligible countries approved and receiving this type of support by the end of 2005. Uptake of INS support was equally high; this type of support became available only in 2001, but in the following four years the number of countries approved for INS support reached 91% of those eligible.

Table 6: Percent of Eligible Countries Approved for GAVI Support during Phase 1

Type of GAVI Support (number of eligible countries)	Cumulative Number of Approved Applications	Percent of Eligible Countries Approved for Support
ISS (n=59)	53	90%
INS (n=75)	68	91%
HepB (n=71)	56	79%
Hib (n=71)	18	25%
YF (n=28)	15	54%

Note: Number of eligible countries shown in parentheses; a country was considered eligible for a particular type of GAVI support if it became eligible for that type of support in at least one year in 2000-2004.

Source: GAVI Secretariat data

Uptake of NVS varied by type of vaccine. While 79% of eligible countries were approved for HepB support by end-2005, only 25% of eligible countries were approved for Hib support. Some of the countries that were eligible but did not receive HepB support are Latin American countries that received HepB vaccine from PAHO, and most of the remaining countries that were eligible but not approved for HepB support were LICUS countries. Two factors contributed to the low uptake of Hib vaccine. First, there was an earlier GAVI recommendation that countries conduct a burden of disease study of Hib before applying for support – this recommendation has since been revised. Secondly, there was a global shortage of pentavalent vaccine, so some countries were discouraged from applying. While GAVI provided YF vaccines to only 14 of the 28 GAVI countries where YF vaccine is recommended by WHO for use in national immunization programs, other GAVI-eligible countries used YF vaccine for routine immunization without GAVI support.²² Half of the countries approved for YF support were LICUS countries, whereas a third of the remaining eligible countries were LICUS countries.

Comparing the number of surviving infants in GAVI-eligible countries that have introduced new and underused vaccines at the beginning and at the end of Phase 1 shows that more than three times as many infants had access²³ to HepB vaccine by the end of Phase 1. As shown in Figure 2, the number of infants in countries using HepB vaccine grew from 18.9 million in 2000 to 64.2 million, representing an additional 45.3 million infants, and 86% of infants in all eligible countries. The number of infants in countries using Hib vaccine grew nearly 16 times in this time period, from 555,000 to 8.8 million infants with access to Hib vaccine. Nonetheless, this still only represents 12% of all infants in GAVI-eligible countries. The number of infants in countries using yellow fever vaccine increased from 5.4 million to 16.0 million, representing almost a threefold increase, covering 76% of all infants in GAVI-eligible countries.

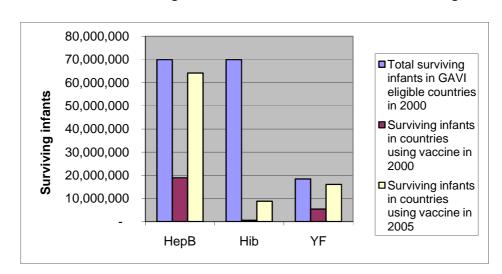


Figure 2: Increase in Infants Using New and Underutilized Vaccines in GAVI-eligible Countries

Note: Countries using vaccine with or without GAVI support. Source: WHO-GAVI Progress Report 2000-2006 (Table 1)

²² GAVI. 2004. Annual Progress Report.

²³ Actual in-country access issues are not considered here – "access" here refers only to the total target population in GAVI-eligible countries that have introduced HepB.

Nearly all eligible countries applied for ISS and INS funding, while 79% of eligible countries applied for HepB vaccine. Uptake of Hib vaccine and YF vaccine was lower, with 25% and 50%, respectively, of eligible countries applying for support. The number of infants in countries that had introduced HepB, Hib, and YF, respectively, represented 86%, 12%, and 76% of all infants in eligible countries.

4.1.2 **Results of GAVI Support**

In addition to examining the number of countries approved for support, we also examined the number of countries that actually received support. From 2000-2005, 52 countries received ISS funding (88% of eligible countries), 51 received INS support (68%), 50 received HepB (70%), 15 received Hib (21%), and 14 received YF vaccines (50%).²⁴ The proportion of eligible countries that were approved and that also received ISS in Phase 1 is nearly the same, indicating that by the end of Phase 1, approved countries were receiving ISS funding promptly. A similar pattern is observed for HepB, YF and Hib vaccines provided under NVS. However, one in four countries approved for INS in Phase 1 had not received injection supplies by end-2005.

Once GAVI support is received at the country level, the ability of the country to utilize the support in a timely manner would influence country results. The 2007 ISS evaluation found that the average country spending of ISS funds received during Phase 1 was 85%.

Country results are measured by the increase in coverage or number of children immunized with GAVI support (compared to a baseline, pre-GAVI year).²⁵ Routine immunization coverage, measured by DTP3 coverage rate, in the 75 GAVI-eligible countries increased from 64% in 2000 to 71% in 2005, as shown in Figure 3. Coverage with HepB3 increased nearly three times during Phase 1, from 16% to 46%; while coverage with Hib3 increased from 1% to 7%.

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²⁴ Measured by the number of countries that received shipments from UNICEF (Source: UNICEF shipments data for GAVI)

account) 25 Based on data from WHO, which under a mandate from the GAVI working group for M&E, measures and reports these indicators on an annual basis.

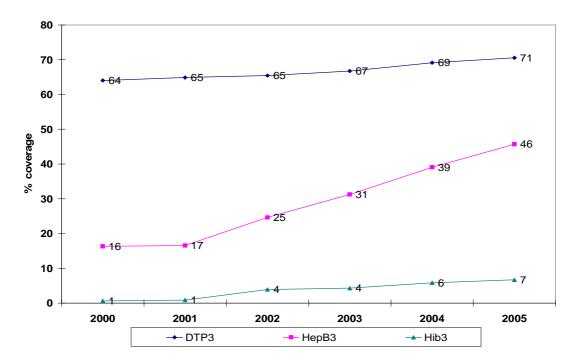


Figure 3: Immunization Coverage Rates in 75 GAVI Countries (children <12 months)

Source: WHO/UNICEF estimates

WHO's 2007 official publication on global vaccine coverage states for Yellow Fever immunization that "the number of countries providing meaningful data has varied over time and has been generally substandard." Accordingly, we do not present YF coverage rates.

By the end of Phase 1, nearly all countries had received ISS and INS support, and many more countries were using HepB, Hib and YF vaccine than in 2000. The results can be seen in measurable increases in coverage rates for GAVI countries. Nonetheless, uptake for Hib and YF was more limited than for HepB, and there is significant country level variation in results.

4.1.3 Lessons Learned from ISS Funding

ISS is a performance-based funding mechanism that provides funding to immunization programs conditional upon improved performance. This strategy allows countries and governments to spend ISS funds in any manner they deem appropriate, but funding in later years is based on increases in the number of immunized children. While ISS was certainly not the first time performance-based funding had been used to improve health, it represented innovative design given its large scale (with 59 eligible countries), combined with its emphasis on country-led programming and a single result indicator.

Under GAVI Phase 1, initial ISS "investment" funding was paid in installments over three years, based on each country's self-projected number of children to be immunized with DTP3 in the first year after application. Thereafter, additional ISS "reward" funding of \$20 was paid for each additional child immunized above the projected first year targets. The system for reporting the number of children immunized with DTP3 was validated through a one-time Data Quality Audit (DQA) conducted by GAVI-retained external auditors. Reward funding was contingent upon both increasing the number of children immunized with DTP3 and achieving a verification factor of 80 percent or higher on the DQA.

The evaluation of ISS funding conducted in 2007 found that ISS had a statistically significant positive effect on DTP3 coverage in recipient countries. The flexibility of GAVI funding was a unique characteristic allowing National Immunization Programs (NIP) unprecedented ability to pursue country-specific priorities, although the ability of each country to use this funding effectively to improve immunization performance depended very much on the available technical capacity. GAVI did not have mechanisms to support underperforming countries. There was also room for improvements that focus on refining the reward mechanism to broaden the program objectives and to increase their applicability for higher coverage countries.²⁶

The evaluation examined the factors that were correlated with higher performance, including macroeconomic and political factors, health funding and other health priorities, immunization program activities, ISS management and planning, and ISS expenditures by category. The variables that proved statistically significant in influencing the ISS effect included GDP (negative effect), political stability (positive effect) and the presence of a current conflict (negative effect). The importance of political stability highlights the challenges of working in many of the ISS recipient countries. Other variables, such as national health expenditures, are correlated with higher coverage rates, but did not change the estimated effect of ISS funding.

No statistical correlation was found between immunization performance and variables representing specific immunization program activities, ISS planning and management, or ISS expenditures by category, partly due to limited data and the difficulties in quantifying these variables. Based on case study research, the study found that more emphasis on social mobilization, higher technical capacity within the NIP and more technical inputs from its partners, and increased expenditures on immunization from sources other than GAVI were factors common across higher performing countries.

GAVI's focus on number of children immunized was found to reward countries with higher population growth – the population growth rate alone predicts whether a country receives rewards in 76% of countries. At the end of Phase 1, 51 countries were eligible for rewards – of those, 36 were approved for rewards, of which 26 had received reward funding. Qualifying for reward funding not only depended on the number of children immunized, but also on the number of children initially projected to be immunized in the first year, allowing countries to manipulate their projections to ensure funding is received upfront as investment shares. Approximately two-thirds of the 15 countries that did not qualify for rewards did not pass their DQA, while the remainder did not immunize additional children. Receiving rewards had no effect on the next years' performance, partly because funding is not immediately used once it is received, and also because the analysis was based on a limited number of countries available for analysis.

The evaluation also found that the cost of immunizing an additional child increased at higher coverage rates. Statistical modeling estimated that the cost of immunizing an additional child to be \$23 at 50% DTP3 coverage rate, increasing to \$53 at 80% coverage rate. This finding lead to recommendations related to restructuring the reward incentive.

Overall, the findings were inconclusive regarding whether the reward incentive is responsible for ISS' positive results. Evidence from case study countries found that the flexibility of funding may have been a more important factor affecting its impact. As importantly, higher performing countries had active partners providing strong technical inputs and increasing resource commitments that complemented ISS funding.

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²⁶ Information presented in this section is taken from: Chee, Grace, Natasha Hsi, Kenneth Carlson, Slavea Chankova, Patricia Taylor. September 2007. *Evaluation of the First Five Years of GAVI Immunization Services Support Funding*. Bethesda, MD: Abt Associates Inc.

In aggregate, coverage rates increased in GAVI countries during the course of Phase 1 - the DTP3 coverage rate increased from 64% to 71%, HepB3 coverage rate increased from 16% to 46%, and Hib3 coverage rate increased from 1% to 7%. Nonetheless, there is room for improvement of ISS funding to improve the design of the reward incentive, and to provide support to underperforming countries.

4.1.4 **Beneficiaries of GAVI Country Support**

We investigated whether different groups of countries, or different population groups within countries, were more likely to benefit from GAVI support.

4.1.4.1 Allocation of Funding by Country Groups

We investigated differences in the likelihood and amount of GAVI support received based on three country characteristics: 1) Low-Income Country Under Stress (LICUS) status; 2) country income; and, 3) immunization coverage rates. For our analysis, a country was categorized as LICUS if it was designated as a 'core' or 'severe' LICUS country by the World Bank in 2005.²⁷ Data on GDP per capita in international dollars for 2000 was obtained from WHO's online database (WHOHIS) as the indicator for country income. The measure for immunization coverage was the DTP3 coverage rate in the first year of GAVI application.²⁸ We measure the amount of GAVI support by the total amount of commitments that a country had received as of December 2005 by type of support. We use the number of surviving infants reported by a country in the country's first GAVI application in all analyses. All data used for these analyses is shown in Annex K.

These analyses are intended to capture how the package of GAVI policies (eligibility criteria, application requirements, etc.) impact how support is allocated by beneficiary groups. For this reason, we include all GAVI countries in our analysis, even though some were not eligible for ISS funding because of high coverage rates, while others were not eligible for NVS due to low coverage rates.

In Phase 1, all non-LICUS countries received some type of GAVI support, while two LICUS countries (Timor-Leste and Solomon Islands) did not receive any support from GAVI. LICUS countries were more likely to receive ISS than non-LICUS countries, but less likely to receive INS or NVS, shown in Figure 4.

4. Results of Phase 1 Activities

²⁷ World Bank's FY2006 starts in mid-2005. The list of LICUS countries can be found at: http://www.worldbank.org/ieg/licus/docs/appendix_b.pdf

²⁸ Source: GAVI Secretariat. For the two countries that did not apply for GAVI support in Phase 1, we used: first year of coverage data available (2002) for Timor-Leste and 2000 for Solomon Islands.

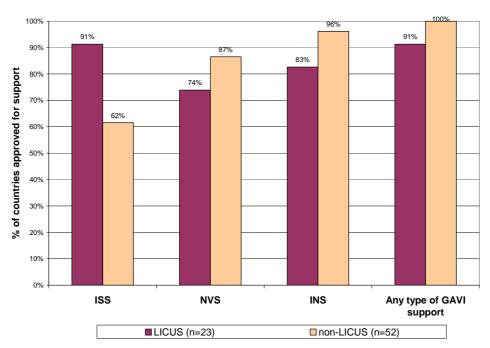


Figure 4: Country Approvals for GAVI Support by LICUS Status

Source: GAVI Secretariat and World Bank data.

While 16% of surviving infants in GAVI-eligible countries lived in LICUS countries, 45% of approved ISS funding and 20% of approved NVS was for LICUS countries. Figure 5 shows that of the total GAVI support approved in Phase 1, 25% was for LICUS countries.

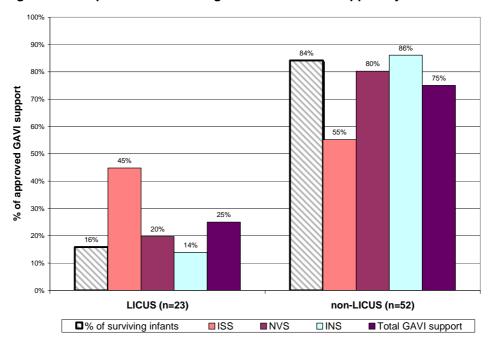


Figure 5: Comparison of Surviving Infants and GAVI Support by LICUS Status

Source: GAVI Secretariat and World Bank data.

We examined whether GAVI support was concentrated in higher or lower coverage countries. Figure 6 shows that countries with baseline DTP3 coverage of under 65% were more likely to receive ISS than countries with coverage of 65% or more, which reflects the Phase 1 policy that limited ISS support to countries with DTP3 coverage rates under 80%.²⁹ There are no notable differences in the likelihood of receiving INS or NVS support between high and low coverage countries.

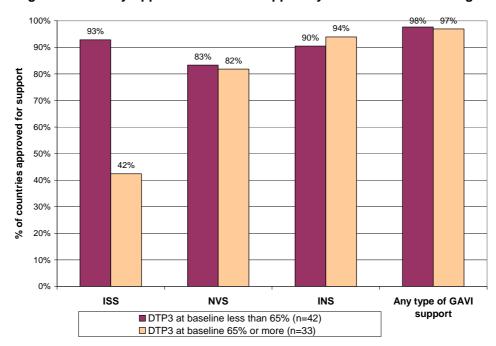


Figure 6: Country Approvals for GAVI Support by DTP3 Baseline Coverage

Source: GAVI Secretariat data

²⁹ If we consider only ISS-eligible countries, there is no difference in the proportion of countries in each coverage groups that received ISS (all 14 countries with coverage between 65% and 80% received ISS).

As shown in Figure 7, countries in the lower baseline coverage group accounted for 58% of surviving infants in GAVI countries, but received 75% of ISS funding and 67% of NVS. Two factors explain the higher share of NVS received by lower coverage countries relative to their share of infants: 1) the lower coverage group included more countries approved for the more expensive pentavalent vaccine than the higher-coverage group³⁰; and, 2) nearly all countries that received YF support were from the lowercoverage group. The share of INS funding by coverage group is similar to the share of infants in each group.

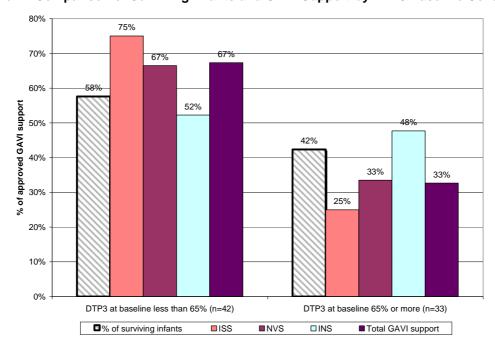


Figure 7: Comparison of Surviving Infants and GAVI Support by DTP3 Baseline Coverage

Source: GAVI Secretariat data

³⁰ Of the 18 countries approved for pentavalent vaccine by end-2005, 11 countries had coverage below 65% at first application.

To examine whether GAVI supported higher or lower income countries, we divided the 75 GAVI eligible countries into five equally-sized groups (quintiles) ranked by GDP per capita, and compared approved GAVI funding across these country groups. As shown in Figure 8, countries in the two richest quintiles (the 30 countries with highest GDP per capita) were less likely to receive ISS than the poorer countries – 36% and 47% of countries in the fourth and fifth quintile respectively received ISS, compared to 87-100% of countries in the poorer three quintiles. This result is due to the fact that richer countries are also those with higher DTP3 coverage (so fewer of them are eligible for ISS funding).³¹ There are no substantial differences across the five quintiles in the likelihood of receiving NVS or INS.

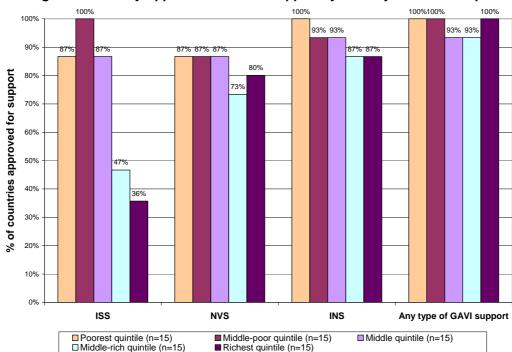


Figure 8: Country Approvals for GAVI Support by Country Income Group

Source: GAVI Secretariat data; WHO data on GDP per capita in international dollars for 2000 (for determining quintiles).

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³¹ Many of the richer countries were not eligible for ISS, whereas there was only one country (Malawi) in the three poorer quintiles that was not eligible. Once an adjustment is made for country eligibility (so we compare the proportions of eligible countries in each quintile that received ISS), there is no notable difference among quintiles in the likelihood of receiving ISS.

As shown in Figure 9, countries in the poorest two quintiles received a significantly higher share of total ISS and NVS funding, compared to their share of surviving infants, whereas the opposite pattern is found for countries in the two richest quintiles. The high proportion of surviving infants in the middle country quintile is driven by India. Excluding India and China from the analysis shows similar results for all quintiles except for the middle quintile where the proportion of infants becomes similar to the proportion of ISS received.

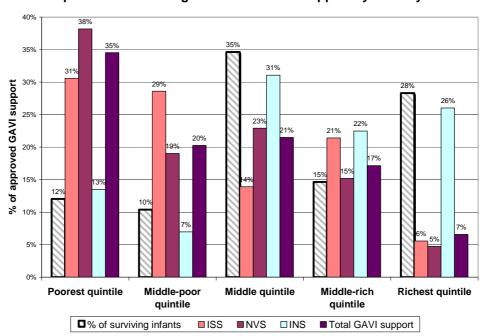


Figure 9: Comparison of Surviving Infants and GAVI Support by Country Income Group

Table 7 summarizes the amount of GAVI support per surviving infant for different country groups. Countries with baseline DTP3 coverage below 65% received more than twice the amount of ISS funding per infant than countries with higher coverage. The amount of ISS support per surviving infant in LICUS countries was more than four times the amount in non-LICUS countries. Total NVS support per surviving infant to countries in the two lowest income quintiles was nearly six times more than support to the two highest quintiles.

Table 7: Approved GAVI Support per Surviving Infant by Country Group, 2000-2005 (USD)

Country Group (number of countries)	ISS	NVS	INS	Total GAVI Support
Average of all countries	3.75	11.44	1.28	16.48
DTP3 less than 65% (n=42)	4.88	13.21	1.16	19.25
DTP3 65% or more (n=33)	2.21	9.04	1.10	19.25
211 3 33 % 31 mars (n=33)		0.01		12.70
LICUS (n=23)	10.59	14.25	1.13	25.97
non-LICUS (n=52)	2.46	10.91	1.31	14.69
Poorest two quintiles (n=30)	9.89	29.20	1.17	40.26
Richest two quintiles (n=30)	2.35	5.30	1.45	9.11

Overall, ISS and NVS support, adjusted for number of infants, favored LICUS, lower coverage, and lower income countries. In contrast, INS support was distributed nearly proportional to the distribution of infants across country groups, with modestly higher allocations in higher coverage, non-LICUS, and higher income countries.

4.1.4.2 Impact on Disparities in Immunization Coverage

The in-depth country study visits yielded some information on beneficiaries at country level. All countries visited introduced new vaccines on a national scale, so all children benefitted equally from NVS assistance. For in-depth study countries which received ISS funds (Malawi and Uzbekistan were not eligible because DTP3 coverage exceeded 80%), ISS funding was targeted toward different populations. In Mali, ISS funds were primarily targeted toward poor performing districts. In both DRC and Laos, ISS funds were distributed to those districts that lacked other donor funding. These findings confirm the findings of the 2007 ISS evaluation, but provide little information on characteristics of beneficiaries.

We conducted quantitative analysis of changes in immunization coverage for underserved or vulnerable populations at country level based on data from 23 countries where Demographic and Health Surveys (DHS) were conducted before and after a country started receiving support under Phase 1. We analyzed DHS reported immunization rates for children aged 13-24 months disaggregated by four classifications:

- Urban or Rural residence
- Gender
- Mother's education
- Birth order

Each of these characteristics is a predictor of immunization rates in at least some countries – that is, disparities in immunization rates exist based on these characteristics. Place of residence and mother's education are also indicators of wealth and income. Recent editions of the DHS have included questions about household wealth, but too few pre-ISS surveys included this information to support analysis. To supplement DHS information, we used UNICEF's Multiple Indicator Cluster Surveys to provide information about five countries where a survey was conducted both before and after a country started receiving GAVI support, and the survey included data on household wealth.

Rural or Urban Residence

In most GAVI-eligible countries, children in rural areas are less likely to be immunized than their urban peers. Before ISS funding became available, half the countries reported urban coverage of 73% or higher for urban children, compared with 48% or higher for rural children. The odds of coverage were more than twice as high in cities as in rural areas.³²

During ISS funding, the disparity was significantly reduced. The arrows in Figure 10 show the change in coverage from the first DHS to the second. The red dashed lines mark the points where urban and rural coverage are equal. In 6 of the 23 countries, overall coverage was lower in the second survey than in the first. In these countries, there is little change in disparity. In the 17 countries where coverage increased, most of the arrows point toward the diagonal line, representing a decrease in the disparity between urban and rural children. Across all 23 countries, the decrease in disparity is statistically significant.³³

³² Based on DHS data from 23 countries.

 $^{^{33}}$ A t-test of the change in log odds yields t = 2.34 with 22 degrees of freedom. p = 0.014. Non-parametric tests give similar results.

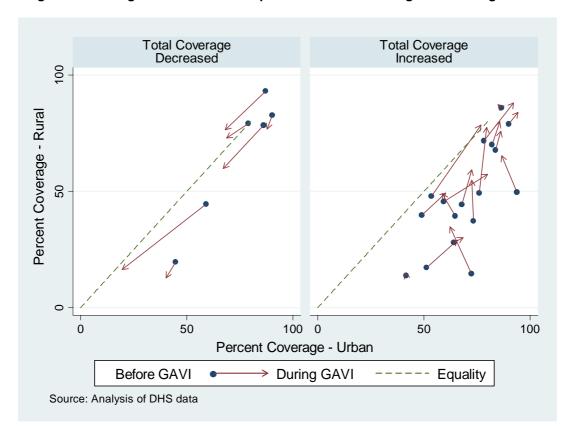
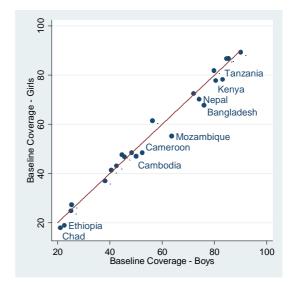


Figure 10: Change in Urban/Rural Disparities in DTP3 Coverage Rate during Phase 1

Gender

In nine of the 23 countries (identified in the figure to the right) boys had at least a 10% advantage in the odds of immunization before GAVI, with six countries where the difference is 20% or higher. (There are no countries where girls have a 20% advantage.)

In six of these nine countries, coverage moved closer to equality. Figure 11 shows the pre-GAVI and during-GAVI coverage for boys and girls in each of the nine countries. Arrows that point toward the diagonal line show movement toward equality. Arrows parallel to the diagonal show increased coverage for both boys and girls, with little change in the gap between genders.



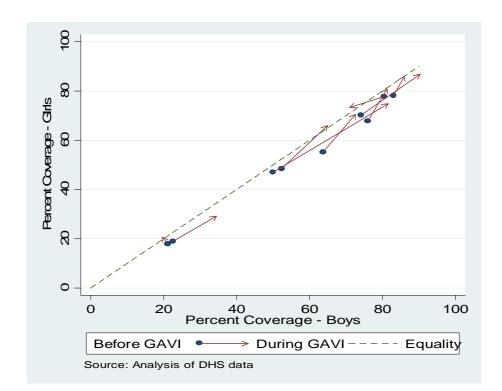


Figure 11: Change in Gender Disparities in DTP3 Coverage Rate during Phase 1

The standard errors associated with typical DHS coverage estimates are about two percentage points for the total population. For subsets of the population (boys or girls) the standard errors would be about three percentage points. Thus we would expect some differences from year to year simply because of sampling variation. In particular, if immunization rates were completely unrelated to gender, we would expect countries with large differences in one sample to have (on average) no differences in another sample, simply because both measures were a combination of zero real difference plus a random error. To test whether the shifts we observed were consistent with such random sampling variation, we compared the average difference between boys and girls in the pre-GAVI survey to the average difference in the survey conducted during GAVI support.³⁴ Before GAVI, the mean difference between boys and girls was .056 (s.e.= .036); during GAVI the mean difference was -.030 (s.e.= .047). The change is statistically significant at level .05.³⁵

Mother's Education

Mothers' education is strongly related to the probability that children will be immunized. We found no evidence that gaps related to mothers' education are diminished during the period of ISS funding. While some countries moved toward equal coverage, approximately equal numbers moved in the opposite direction. Overall, we found no significant differences in odds ratios comparing children whose mothers had only primary education with either those with no education or those with more.

³⁴ We used the log of the odds ratio so that differences would have an approximately normal distribution independent of the total coverage rate.

³⁵ The non-ISS countries did not show significant gender inequality at any time during this period, and did not change significantly.

Birth Order

Immunization data are collected on children in their second year of age. The birth order of the index child is highly correlated with family size, and we cannot make any causal inference about whether we should think of the data as describing the effect of one attribute instead of the other. Generally, first-born children are about 15 to 20 percent more likely to be immunized than siblings born second or third, and 30 to 40 percent more likely to be immunized than those born fourth or fifth. There is no evidence that these disparities changed systematically during GAVI Phase 1 – some countries moved toward greater equality, but nearly equal numbers moved in the opposite direction.

Household Wealth

We found five GAVI countries where UNICEF's Multiple Indicator Cluster Surveys (MICS) provided immunization data for children of different income levels. A typical survey in this series includes about 1,500 children between the ages of 12 and 23 months. Estimates of DTP3 coverage for the children in each wealth quintile have a margin of error of approximately five percentage points.

As shown in Figure 12, overall coverage improved in all five countries. In three of the five countries (Niger, Togo, and Gambia) changes (shown by the arrows in the figure at the right) moved in the direction of equality of coverage (shown by the dashed line). Guinea Bissau and Côte d'Ivoire experienced large coverage improvements for every segment of the wealth distribution, including those in the lowest quintile, but in both countries children of wealthy families retained a significant advantage.

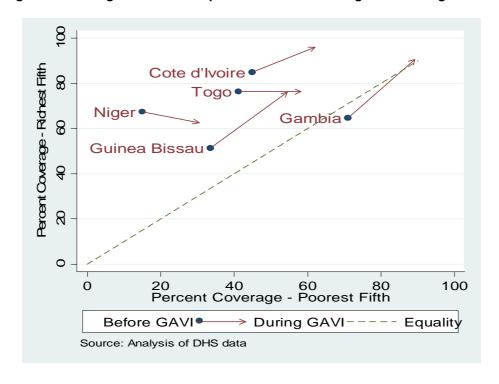


Figure 12: Change in Income Disparities in DTP3 Coverage Rate during Phase 1

Because only five countries provide suitable data, these changes are not statistically conclusive. They are, however, consistent with the interpretation that the benefits of GAVI were widely shared, and played a part in reducing economic disparities in coverage.

Our ability to look at change in the distribution of immunization coverage within countries is limited by the available data. Nevertheless, there is evidence that disparities were reduced. The gaps between urban and rural coverage rates were significantly narrowed during GAVI Phase 1. Moreover, most of the countries with large gaps in coverage between boys and girls moved toward equality. Both of these improvements are too large to have occurred by chance alone, although we cannot rule out the possibility that they resulted from actions independent from GAVI that we did not consider. We did not find changes in disparities based on mother's education or birth order, although our failure to find an effect does not mean that there was none. It is also possible that these disparities are more resistant to change because they require changing behaviors, unlike urban/rural differences, which can be reduced by improving access. One of the findings of the 2007 ISS evaluation was that higher performing countries tended to focus more on social mobilization and community linkages, which are critical to changing behavioral norms.

Disparities in immunization coverage based on urban/rural residence and gender were reduced during Phase 1, and changes can be correlated to GAVI funding. However, there is no reduction in disparities based on mother's education or birth order. There is evidence that wealth-based disparities in immunization coverage also decreased during GAVI Phase 1, but this is based on data from five countries only, and is not statistically significant.

4.1.5 Cost and Effectiveness of GAVI Support to Countries

We analyzed the cost and effectiveness of GAVI investments in ISS by estimating the cost per additional child immunized, and cost per death averted. Due to data limitations detailed below, we are unable to calculate the cost per death averted for NVS, but can only present the cost per additional child immunized across all three vaccines supported by GAVI.

The most important limitation to our analysis is that there is no data on GAVI expenditures by type of vaccine. GAVI does not track its expenditures by type of vaccine. Deriving expenditures by type of vaccine using data from UNICEF vaccine shipments to GAVI countries was not feasible due to the many combinations of vaccine presentations received by countries and lack of information on the unit costs related to each specific vaccine shipment. Lack of this data prevents us from calculating cost and effectiveness by new vaccine. This limitation also reduces the accuracy of our calculations for ISS because we are unable to attribute a portion of the cost of combination vaccines containing DTP to increases in DTP3 coverage. Thus, our calculations underestimate the expenditures per child immunized with HepB/Hib/YF.

A second limitation arises from GAVI accounting procedures – some portion of its program and management and general administrative (M&GA) expenses (e.g. those that relate to activities undertaken by UNICEF) are not reported on GAVI's financial statements. Because we allocate a portion of the total M&GA expenses to each of GAVI's country support windows, and the reported M&GA expenses do not capture some of the costs incurred by partners, our total calculated expenditures for each program is underestimated. We cannot gauge the magnitude of the gap, however, it likely represents a fraction of the total costs of the ISS and NVS programs, and is too small to materially change our conclusions.

Our estimate of the cost of GAVI's ISS and NVS programs includes the funds disbursed to countries during Phase 1, together with GAVI's M&GA and fundraising expenditures (which we allocated to each program in proportion to the amount disbursed to countries under the program). We use the GAVI audited financial statements for 2000-2005 for the data on expenditures. We use data from WHO's Department of Immunization, Vaccines and Biologicals on the estimated number of additional children reached with DTP3, HepB, Hib, and YF vaccines with full or partial support from GAVI during Phase 1.36

In Phase 1, the estimated GAVI expenditures related to ISS were \$131.6 million, as shown in Table 8. WHO estimates that GAVI support helped immunize 15.8 million additional children with DPT3, and avert 141,000 future pertussis deaths. Accordingly, GAVI expenditures per additional child reached with DTP3 in GAVI countries is \$8.31, and each pertussis death averted with GAVI support corresponds to \$933.35 of ISS program expenditures.

Table 8: Expenditures and Effectiveness of Immunization Services Support (ISS) in Phase 1

GAVI Expenditures related to ISS	
ISS disbursements to countries	124,500,000
M&GA and fundraising expenditure allocation for ISS	7,101,759
Total ISS Expenditures	131,601,759
Additional children immunized with DTP3 with GAVI support	15,845,000
Expenditures per child reached with DTP3	\$ 8.31
Future pertussis deaths averted with GAVI support	141,000
Expenditures per pertussis death averted	\$ 933.35

While an additional 15.8 million children were immunized with DTP3 in GAVI countries, not all of those additional children immunized can be attributed to GAVI support. Some portion of the additional children immunized would have been immunized in the absence of GAVI. The 2007 ISS evaluation used statistical modeling to estimate the increase in immunization coverage that can be attributed to GAVI. Based on that model, it is estimated that 2.4 million additional children were immunized with DPT3 as a result of ISS funding. This figure translates into GAVI expenditures of \$55 per additional child immunized with DPT3.

The estimated GAVI expenditures related to NVS and Hib Initiative (HI) totaled \$527.8 million, as shown in Table 9. We included the costs associated with the HI, as its objective was to increase country uptake, and ultimately Hib coverage. According to WHO estimates, GAVI support helped immunize 99.5 million additional children with HepB, Hib, or YF vaccine.³⁷ Accordingly, each additional child reached with HepB, Hib, or YF vaccine in countries supported by GAVI for these antigens cost \$5.31 of GAVI expenditures.

³⁶ These are all additional children immunized in GAVI/VF countries during Phase 1, over the number of children immunized in the year before GAVI support in each country (baseline year).

³⁷ Total number of children reached with any one of the antigen supported under NVS by GAVI (HepB, Hib, or YF), so children reached with more than one antigen are not double-counted in this figure.

Table 9: Expenditures and Effectiveness of New Vaccine Support (NVS) in Phase 1

GAVI Expenditures related to NVS and Hib Initiative (HI)	
NVS disbursements to countries	496,900,000
Hib Initiative	2,400,000
M&GA and fundraising expenditure allocation for NVS and HI	28,481,192
Total NVS and HI Expenditures	527,781,192
Additional children immunized with HepB/Hib/YF with GAVI support	99,462,000
Expenditures per child reached with HepB/Hib/YF vaccine	5.31

WHO estimates 1.6 million averted future deaths caused by Hib or Hepatitis B, however, they did not estimate averted YF deaths as "there is as yet no satisfactory model for [estimating deaths averted for] yellow fever." Because we are unable to disaggregate the costs for HepB and Hib vaccine, we cannot provide estimates of the cost per death averted for these antigens.

The expenditures per additional child immunized with DTP3 was \$8.31, while the expenditures per pertussis death averted was \$933. The expenditures per child reached with HepB/Hib/YF vaccine was \$5.31 – data limitations prevent us from calculating expenditures per death averted by new vaccine. The lack of cost data disaggregated by vaccine is a very important finding, as it prevents GAVI from accurately evaluating the cost and effectiveness of the programs and vaccines that it supports.

4.2 Results of GAVI Activities in Vaccine Supply and Introduction

Two of the evaluation questions in the RFP address new vaccines and vaccine supply:

- the extent to which GAVI has successfully influenced vaccine pricing and supply; and,
- the achievements of the Accelerated Development and Introduction Plans (ADIP), and its usefulness as a future model for accelerating vaccine introduction.

These two activities represent important components toward fulfilling GAVI's overall mission. Embedded in the original design of NVS was the premise that increased demand would lower the price of these underused vaccines, so that countries GAVI support could eventually be phased out. Progress in this area is important to underpin GAVI's emphasis on sustainability, and to ensure that future donor support can be targeted toward new vaccines. It has been well documented that developing countries lagged as much as 15 to 20 years behind developed nations in the introduction of life-saving vaccines. The ADIPs were undertaken to shorten the lag time for developing country introduction of Pneumococcal and Rotavirus vaccines, both of which were available in developed countries.

³⁸ WHO, 2007. Department of Immunizations, Vaccines, and Biologicals. WHO Report on GAVI Progress 2000-2006 & Projected Achievements 2007-2010.

4.2.1 Accelerating Development and Introduction Plans (ADIPs)

While we relied heavily on findings from the 2007 GAVI-commissioned evaluation of the ADIPs³⁹, we also interviewed key informants at WHO, UNICEF, the World Bank, ADIP management, and vaccine manufacturers. See Annex E for full list of persons interviewed regarding the ADIPs. The interviews focused on: 1) whether the ADIP model would be a useful model for the future as both ADIPs come to an end in 2008, and 2) the extent to which the ADIPs have made it more likely that there will be more rapid country uptake of new vaccines when they are ready for introduction. These were specific questions posed in the RFP for this evaluation.

The Pneumococcal and Rotavirus ADIPs were funded in 2003 for a period of five years, with an additional one-year funded extension for 2008. The ADIPs followed the structure presented by McKinsey & Co. 40 in response to the GAVI-commissioned project to develop a strategy to achieve early and affordable supply of these two vaccines. The PneumoADIP was led by the Johns Hopkins University Bloomberg School of Public Health, and the Rota ADIP was led by PATH – each group was funded with an initial \$30 million over a five year period, 2003-2007, to carry out their activities. The extensions for the 2008 activities for both programs were funded with an additional \$20 million to continue strategic vaccine introduction activities and ensure a smooth transition to their key partners, UNICEF and WHO. GAVI also committed an additional \$31.6 million for clinical trials for rotavirus and post-introduction evaluations for pneumococcal vaccine in Africa and Asia through 2009-2010. Overall, GAVI has invested \$112 million over seven years to accelerate the development and introduction of Pneumococcal and Rotavirus vaccines in developing countries.

In 2007, GAVI commissioned an evaluation of the ADIPs and the Hib Initiative. ⁴¹ This report concluded that the PneumoADIP delivered sound disease burden data to support introduction of the vaccine, encouraged the multinational manufacturer, Wyeth, to go through the WHO prequalification process with their 7-valent vaccine, and provided serotype data on pneumococcal disease from developing countries to support the development of a vaccine with improved characteristics. In addition the PneumoADIP presented a solid business case for multinational manufacturers to supply available and future products at tiered prices. The Rota ADIP was successful in showing the cost-effectiveness of the rotavirus vaccine, as well as its impact on known disease burden. Supporting both multinational and emerging suppliers, the Rota ADIP increased competition which should facilitate adequate supply of the vaccine at affordable prices. Similarly to the PneumoADIP, the Rota ADIP also worked with manufacturers to offer the vaccines at tiered prices.

As proposed by McKinsey at the June 2002 GAVI Board meeting, each ADIP was organized around three areas of focus:

- 1. Establish value: disease burden assessment and impact of vaccine on disease burden
- 2. Communicate value: development of a communications strategy
- 3. Deliver value: vaccine pricing and supply

Interviewees agreed that the structure of the ADIPs was appropriate, and that more importantly the focus of a group of people dedicated to the introduction of a single vaccine accelerated the introduction process. Most people interviewed believed that the ADIPs were able to move much faster than if the same work had been done by traditional immunization partners. This focus on a single vaccine was seen as

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³⁹ Milstien, Julie, Cohen, Jillian Clare and Olsen, Ingvar Theo. 2007. An evaluation of GAVI Alliance efforts to introduce new vaccines via the Accelerated Development and Introduction Plans (ADIPs) and the Hib Initiative (HI). HLSP.
⁴⁰ See Accelerated Development and Introduction of Priority New Vaccines: the case of pneumococcal and rotavirus vaccines, 8th GAVI Board Meeting, 19-20 June 2002, Paris.

⁴¹ Milstien, Julie, Cohen, Jillian Clare and Olsen, Ingvar Theo. 2007. An evaluation of GAVI Alliance efforts to introduce new vaccines via the Accelerated Development and Introduction Plans (ADIPs) and the Hib Initiative (HI). HLSP.

problematic by some, since each ADIP would promote its vaccine without comparing the relative costs and benefits of other vaccines, and advocacy information from different ADIPs that may be difficult for decision makers to decipher. Others recognized this weakness but felt the benefits outweighed the disadvantages. The strength of the ADIP model was its focused attention on a single vaccine in a way that individual GAVI partners were unable to provide.

For the most part, the ADIPs focused on upstream issues, establishing disease burden and communicating the value of and advocating for the vaccine at global and regional level. The multinational manufacturers interviewed appreciated the ADIP's accomplishments in establishing disease burden in various parts of the world, communicating the importance of the vaccine to countries and partners – the ADIPs were essentially creating demand for their products. While this benefited multinational manufacturers, emerging market suppliers, felt left out of the process.⁴² This was reflected in the interviews with both groups of manufacturers.

Interviewees for this evaluation generally agreed that the ADIPs were successful in establishing and communicating value of their respective vaccines, however there was disagreement regarding each ADIP's ability to deliver value. Some suggested that the timeframe within which the ADIPs were to introduce vaccines into the countries was not appropriate. Delivery systems were considered critical for the introduction of the new vaccines and were part of the "deliver value" set of activities described in the McKinsey report:

To successfully introduce the vaccines, long-term vaccine supply must be assured, and national immunization systems must be able to deliver the vaccine to the end users. A strong national delivery system is a critical factor in each government's decision to introduce a new vaccine.... The costs associated with introducing the new vaccines will be significant... Understanding the impact of Pneumococcal and Rotavirus on cold chain, storage, transportation systems, personnel training, etc, is critical for country level decision makers to implement these vaccines. Raising the national and international funds needed to strengthen delivery will require a compelling and broad communication effort. ⁴³

Despite the original emphasis on downstream introduction issues within the ADIP model, the ADIPs' strategic objectives adopted by the GAVI Board in December 2003 do not explicitly mention delivery systems for vaccine introduction. The strategic objectives endorsed by the ADIP Management Committee (MC)⁴⁴ and the GAVI Board were to:

- Provide information that enables decision-makers, the GAVI Alliance Board and its partners to make an evidence-based decision regarding vaccine use.
- Increase the access to affordable, sustainable vaccine supply for the world's poorest countries.⁴⁵

Countries are just now beginning to apply and prepare for the introduction of vaccines. The downstream issues related to country vaccine introduction were mentioned repeatedly as the ADIP's unfinished agenda, yet it is unclear as to whether it was ever in the ADIP's mandate. The lack of planning for the critical transition of the ADIP's upstream work to on-the-ground country introduction was seen by most people interviewed as a critical flaw in the ADIP model. For this reason, some multilateral and bilateral GAVI partners would not recommend the use of the ADIP model for other vaccines.

4. Results of Phase 1 Activities

⁴² Emerging market manufacturers were not included because they did not have any candidate vaccines.

⁴³ McKinsey & Co. Accelerated Development and Introduction of Priority New Vaccines: The case of pneumococcal and rotavirus vaccines. 8th GAVI Board Meeting – 19-20 June 2002, Paris.

⁴⁴ The MC was an independent structure created by GAVI to manage the ADIPs. The MC also served as the liaison between the ADIP and the GAVI Board.

⁴⁵ GAVI Alliance. 2006. Accelerated Introduction of New Vaccines. Board document #4.

Many interviewees brought up the model of the Hib Initiative as an alternative, although it should be noted that the Hib Initiative was working under a different mandate – to work specifically on increasing country introduction of an already available Hib vaccine. Neither the Rota ADIP nor the PneumoADIP were working with a WHO prequalified vaccine in 2003, whereas the Hib Initiative was advocating the use of a vaccine that was not only WHO prequalified but also endorsed by the Strategy Advisory Group of Experts (SAGE) for use in all countries. The comparisons between the different models for implementation may not be appropriate, although interviewees emphasized the need for some kind of coordinated transition plan at this critical juncture when countries will have the option of introducing Hib, pneumococcal and rotavirus vaccine into their immunization schedules.

The ADIPs were successful in compiling the disease burden data to support introduction of the vaccines, and advocating for their use. However, little work has been done to tackle important in-country introduction issues (such as cold chain, storage or logistics), which are critical for vaccine introduction.

4.2.2 Influencing Vaccine Supply and Pricing

To accelerate the delivery of new and under-utilized vaccines to the developing world was one of GAVI's core objectives. Although WHO had recommended the use of HepB vaccine for all countries, the major barrier to introduction for GAVI countries was the high price. The price of monovalent HepB vaccine in 2000 was \$0.50-\$0.75/dose, much higher than other vaccines in the EPI schedule in developing countries, which were in the range of \$0.06-\$0.10/dose for measles, oral polio and DTP. For Hib vaccines, the barriers included both its high price, as well as the lack of country level information on the impact of the disease. Hib vaccine prices in 2000 in monovalent or combination presentation ranged from \$2.60 - \$3.50/dose. Progress in ensuring reliable supply and affordable prices is an important element of GAVI's ability to achieve its core objectives over the long term.

We reviewed the pricing and competitive environment for HepB and Hib vaccine before, during, and after Phase 1 to examine GAVI's impact in influencing vaccine supply and pricing. Ideally we would have preferred data not only on the number of suppliers but the total production capacity for each vaccine, but such information was not available from manufacturers. It should also be noted that not only are the manufacturers proprietary with data on capacity and pricing, but detailed data on pricing for products procured through UNICEF is also limited.

4.2.2.1 Hepatitis B Vaccine Supply and Pricing

The HepB vaccine was first introduced in 1981. In 2000, there were 13 licensed monovalent HepB vaccines, and two DTP-HepB combination vaccines. Most of the industrialized manufacturers had moved from the monovalent vaccine presentation to the HepB combination vaccines, leaving the monovalent market to emerging suppliers who were supplying HepB at marginal prices. Although monovalent HepB vaccine became widely available, GAVI's stated vaccine preference for DTP combination vaccines influenced countries decisions for adoption. Over the next five years several of the emerging suppliers would also begin the transition to include HepB into combination vaccines to respond to the market demands and retain profitability. Seventy-nine percent of the supply for HepB monovalent products were produced by emerging suppliers by 2000 and steadily increased over the next 5 years.⁴⁷

⁴⁶ MMR weekly September 12, 2003/52(36);868-870

⁴⁷ David Wood. 2007. WHO pre-qualification presentation.

Prices for HepB had begun a decline by the early 1990's due to the efforts of several experts who in the mid-1980s began the push to have HepB included in developing country immunization schedules and to facilitate the technology transfer to emerging manufacturers. The technology for the HepB vaccine allowed simple and efficient production, and was easily transferrable. The increase in global demand for the vaccine and the number of manufacturers able to enter the market, including new Korean and Indian manufacturers, created the perfect environment for a significant decline in prices for monovalent HepB by 1996-1997. As shown in Figure 13, the price drastically declined from \$2.25 to \$0.75. As competition increased, prices continued to decline causing some manufacturers to exit the market, unable to remain profitable. At the same time, demand for combination products increased thereby reducing the demand for monovalent HepB. This market transition to combination products rendered the monovalent product less desirable forcing prices to under \$0.50 per dose by 2005 as manufacturers tried to capture market share. During this same period, the price of HepB vaccine combined with DTP (the presentation preferred by GAVI) followed a different trend. Figure 13 shows that prices for DTP-HepB increased from \$1.00/dose in 2000 to \$1.25/dose in 2005.

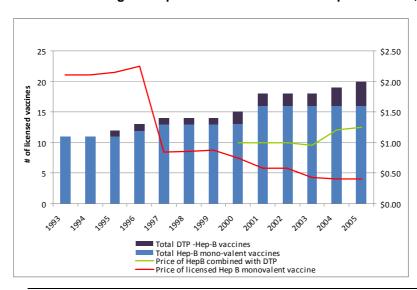


Figure 13: UNICEF Pricing for HepB monovalent and DTP-HepB Vaccines, 1993-2005

4.2.2.2 Hib Vaccine Supply and Pricing

The first Hib conjugate vaccine was introduced in 1987, six years after the introduction of HepB vaccines. The Hib vaccine was produced using a novel technology, a conjugation process, which was more complex to manufacturer than for the HepB vaccine. Limited access to the technology and knowledge of the conjugation process in the early years of Hib introduction slowed the pace of new manufacturers entering the market, specifically for the emerging manufacturers. There were eight monovalent and five Hib combination vaccines available in 2000, however, there was only one manufacturer of the pentavalent DTP-HepB+Hib combination, which was ultimately the GAVI-preferred product. The pentavalent vaccine allowed for immediate inclusion into existing delivery systems, minimizing the cost of introduction and delivery. Between 2000 and 2005, three additional Hib vaccines were licensed, including two new pentavalent products, however only one pentavalent product would be pre-qualified during Phase 1, a requirement for purchase by GAVI under the UNICEF procurement system.

⁴⁸ Immunization Financing in Developing Countries and the International Vaccine Market. 2001. Asian Development Bank, p.43

⁴⁹ UNICEF WAP pricing 2000-2005

⁵⁰ Clinical Microbiology Reviews, October 2001, p.872-908, Vol. 14, No. 4

As shown in Figure 14, the price of Hib vaccines had taken a sharp drop just prior to the beginning of GAVI, from \$5.00/dose to approximately \$2.50/dose. Due to GAVI's preference for the use of combination vaccines, there was a sharp rise in the demand for pentavalent vaccine, resulting in a supply shortage. Except for a one-year dip in 2003, the price for pentavalent vaccine ranged from \$3.50 to \$3.60/dose during all of GAVI Phase 1. Interestingly, the price for the tetravalent DTP-HepB also decreased moderately in 2003, only to increase again the following year.

GAVI's vaccine prices were also impacted by the weakening US dollar during Phase 1, which depreciated significantly vis-a-vis the Euro. Although GAVI operated in US dollars and procurement contracts were denominated in US dollars, the manufacturer of the pentavalent vaccine was a European company with Europe-based production. From the manufacturer's perspective, the price of the vaccine was decreasing, although GAVI did not realize any resulting benefit.

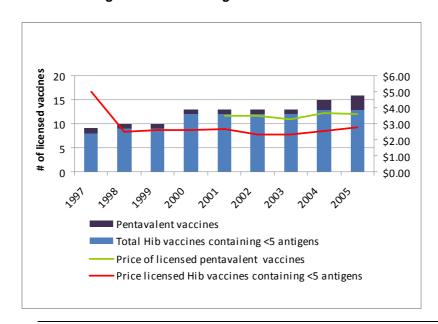


Figure 14: UNICEF Pricing for Hib Containing Vaccines and Pentavalent Vaccine, 1997-2005

4.2.2.3 GAVI Impact on Price and Supply

In addition to reviewing the data on pricing and suppliers, we conducted interviews with key informants affiliated with the ADIPs, WHO, UNICEF, World Bank, and industrialized and emerging manufacturers. Overall, GAVI had very little influence on vaccine prices during Phase 1. However when asked about GAVI's most valuable contribution, interviewees agreed that GAVI's funding stream provided an important signal to industry that there was a significant, long-term, reliable market for these products, thus encouraging market entrants. In many ways, GAVI created the market for Hib combination vaccines in developing countries, and at least accelerated the growth of the combination HepB vaccine market. Nonetheless, respondents pointed to missed opportunities and mixed messages early on that limited GAVI's effectiveness in this area.

GAVI's assumption that a significant increase in demand would drive down vaccine prices did not come to fruition during Phase 1. The major downward price trend for monovalent HepB vaccine began prior to GAVI due to a highly competitive market environment and the 1992 WHO recommendation of HepB into EPI programs. The slight decline in monovalent HepB price during Phase 1 can be attributed to its mature product status with over 20 years on the market and an increase in demand for combination

vaccines. This decline was not particularly relevant to GAVI or its recipient countries, as GAVI supported most countries to introduce the DTP-Hep B combination vaccine, which increased in price in 2003.

Prices for Hib containing vaccines did not decline during GAVI Phase 1. GAVI and its partners encouraged (some say pushed) countries to apply for a pentavalent vaccine which was only being supplied by one manufacturer, with the assumption that increased demand would lead to increased supply. At the same time, manufacturers were frustrated because a tetravalent (DTP+Hib) vaccine was readily available, but there was limited demand from developing countries. The production of DTP-HepB+Hib was already at full capacity to meet the demands of the industrialized market, and GAVI underestimated the time required to expand production capacity. Both industrialized manufacturers and other GAVI partners agree that there were missed opportunities for dialogue in the early years of GAVI that contributed in the ultimate shortage of pentavalent vaccine. Countries' demand for combination vaccines and reluctance to accept readily available monovalent presentations (a position supported by GAVI) affected both the supply and pricing of combination products.

GAVI's actions did positively influence vaccine supply – the number of manufacturers producing prequalified products suitable for the GAVI market increased from 10 in 2000 to 24 by 2005. Factors that influenced supply were the establishment of the procurement reference group that was seen very favorably by WHO and vaccine manufacturers, and the long term (3 year) agreements that UNICEF has negotiated with manufacturers. Over the period of Phase 1, forecasting has improved and vaccine manufacturers have greater confidence in the forecasts. Nonetheless, the new suppliers did not offer the two products most demanded by GAVI, combination DTP-HepB and DTP-HepB+Hib.

Figure 15 shows the number of WHO pre-qualified HepB and Hib vaccines at three points since the formation of GAVI. From 2000-2005, there was only one pre-qualified product for each of the two vaccine combinations GAVI countries most demanded, DTP-HepB and DTP-HepB+Hib. Under this scenario, it is not surprising that prices did not decline. Some informants believe the future may be more promising however, as there are today five pre-qualified DTP-HepB vaccines (although two vaccines are targeting single-country sales), and four pre-qualified pentavalent vaccines, with an additional one in the pre-qualification process and four in the pipeline for future consideration. GAVI has stimulated manufacturer interest in the developing country market, as demonstrated by the number of products pre-qualified or in the pre-qualification process. Nonetheless, the current optimism on future price declines seems based only on the increasing number of suppliers – we have not found more thorough assessments of projected demand or production costs, two other critical factors that affect price.

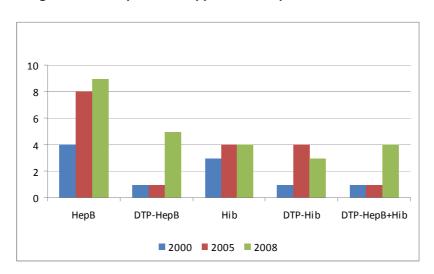


Figure 15: Pre-qualified Suppliers for HepB and Hib Vaccines

Nonetheless, many respondents felt that GAVI could have done more. Other actions that respondents suggest may have led to better results sooner include engaging emerging suppliers earlier, earlier emphasis on producing rigorous forecasts that manufacturers could rely upon, encouraging use of alternative vaccine presentations, encouraging UNICEF toward multi-year contracts earlier, and investing additional resources in working with WHO to improve its pre-qualification process.

GAVI's most important impact was less a result of its strategy or actions, but of its long term funding. GAVI represented an assurance of a long-term stable market to manufacturers, however, it did not actively encourage new manufacturers to enter the market. For all of Phase 1, GAVI relied on one monopoly supplier for each of its two key vaccines. Some respondents referred to the suppliers as "benevolent monopolists" but also admit that one would not expect a monopolist to lower its price. Many respondents believed that GAVI's original assumptions were overly optimistic and unrealistic. One of the critical flaws in GAVI's assumptions was underestimating the barriers to market entry – eight years lapsed from the beginning of GAVI until the entry of a second supplier for pentavalent vaccine.

We were unable to find documentation that articulated GAVI's strategy for influencing vaccine supply and pricing. Given its position as the largest and an extremely well-funded buyer of vaccines for developing countries and its preference for vaccine presentations for which there were only single suppliers, its assumption that market forces would bring down vaccine prices was inappropriate. More analysis of the economics of vaccine production and vaccine markets, and development of strategies to create competitive and sustainable vaccine markets is needed.

4.2.2.4 PAHO Prices for Pentavalent Vaccine

The market for vaccines in developing countries is very thin, with only a few buyers and sellers, so it is difficult to examine "market" prices. We compared GAVI prices for Hib vaccines during Phase 1 with prices paid by the Pan American Health Organization (PAHO) to see whether prices paid by GAVI were in line with those paid by similar purchasers. Figure 16 shows PAHO and UNICEF prices during Phase 1. As shown, while prices were identical in the early years, PAHO prices were then higher than UNICEF prices, by as much as \$0.50/dose.

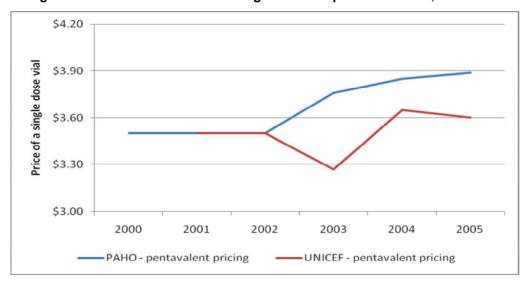


Figure 16: PAHO and UNICEF Pricing for DTP-HepB+Hib Vaccine, 2000-2005

This data confirms that UNICEF prices for the poorest countries were slightly lower than prices for higher income countries. It also illustrates potential upcoming issues regarding tiered pricing as new vaccines become available, given expectations that pricing for GAVI countries will be lower than for other markets that can afford higher prices.

GAVI's improvements in forecasting and procurement mechanisms, and its long-term funding did attract additional vaccine suppliers, although they were not pre-qualified until after Phase 1. The prices for the two vaccines that represented the bulk of the NVS program did not decline during Phase 1. Given GAVI's preference for vaccine presentations for which there were only single suppliers, its assumption that market forces would bring down vaccine prices was unrealistic.

4.3 Progress toward Strategic Objectives

During the development of GAVI, its partners committed themselves to six strategic objectives. Table 10 lists each of these objectives, alongside GAVI's programs and activities that focused on each objective.

Table 10: GAVI Strategic Objectives, Programs and Activities

Strategic Objective	Programs and Activities
Improve access to sustainable immunization services	• ISS
Services	• INS
2) Expand the use of all existing safe and cost-	NVS
effective vaccines, and promote delivery of other appropriate interventions at immunization contacts	• INS
	Hib Initiative
Support the national and international accelerated disease control targets for vaccine-preventable diseases	In Nov 2005, approved funding of \$191 million, \$147 million and \$62 million for polio, measles, and maternal and neonatal tetanus
	Funded YF stockpile
Accelerate the development and introduction of new vaccines and technologies	• ADIPs
5) Accelerate research and development efforts for vaccines needed primarily in developing countries	• ADIPs
6) Make immunization coverage a centerpiece in	Work of Advocacy Task Force
international development efforts	Activities undertaken by
	Secretariat staff and by Executive Secretary

GAVI's early focus was on the first two objectives, designing and implementing country level programs very quickly. Due to low uptake of Hib vaccine, GAVI funded the Hib Initiative. Accelerating development of new vaccines was contracted out to external organizations for implementation through the ADIPs. After much debate, GAVI funded vaccine stockpiles and contributed to global disease elimination initiatives for the purpose of accelerated disease control, but these decisions did not occur until near the end of Phase 1. In contrast, responsibility for activities to make immunization a centerpiece of development was mostly kept in-house, within a relatively lean Secretariat.

4.3.1 Increasing Access to Immunization and Expanding Use of New Vaccines

We evaluate the extent to which GAVI's programs and activities contributed to increasing access to immunization, and expanding use of HepB, Hib, and YF. We use data on immunization coverage and new vaccine uptake from middle income countries over the course of Phase 1 to examine observable trends. We also present historical data on new vaccine introduction that shows long term trends in new vaccine introduction and GAVI's influence. Further, we examine GAVI contributions to increasing immunization in two ways: 1) using WHO generated estimates of the number of children immunized by antigen during GAVI Phase 1, and the resulting deaths averted; and, 2) using statistical modeling to estimate the number of children immunized with DTP3 and HepB3 that are attributable to GAVI support. The latter method is based on modeling used in two previous evaluations of ISS funding.⁵¹ However, due to data limitations, it can only be used to estimate DTP3 and HepB3 coverage attributable to GAVI support, because there is almost no historical data of Hib and YF coverage rates that can be used to examine trends prior to GAVI.

4.3.1.1 Comparison with Historical and Concurrent Trends

We compare data on immunization coverage and new vaccine uptake between GAVI and middle income countries over Phase 1 to examine observable differences. We also present historical data on new vaccine introduction that shows long term trends in new vaccine introduction and GAVI's influence.

We used WHO-UNICEF estimates of immunization coverage for middle income countries, defined as countries with per capita income of \$906 – \$11,115. Since all countries with per capita income under \$1,000 qualify for GAVI support, there is overlap between these two groups. We removed all GAVI-eligible countries from the middle income group, and compare DTP3, HepB3, and Hib3 coverage rates during GAVI Phase 1. Use of the term 'middle income countries' in this section refers to only middle income countries that are not GAVI-eligible.

As shown in Figure 17, DTP3 coverage rates in middle income countries were unchanged over the course of Phase 1 (88% in 2000 and 89% in 2005), while DTP3 coverage rates in GAVI countries increased from 64% to 71%. Trends in HepB3 coverage rates were also moderately better in GAVI countries, increasing 30 percentage points (from 16% to 46%) from 2000 to 2005, while the coverage rate in middle income countries increased 26 percentage points (from 54% to 80%) over the same period. Examining Hib3 coverage rates, however, middle income countries perform much better than GAVI countries. The Hib3 coverage rate in GAVI countries increased from 1% to 7% during Phase 1, while the Hib3 coverage rate in middle income countries increased from 22% to 52%.

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⁵¹ Chee, Grace, Natasha Hsi, Kenneth Carlson, Slavea Chankova, Patricia Taylor. September 2007. Evaluation of the First Five Years of GAVI Immunization Services Support Funding. Bethesda, MD: Abt Associates Inc.
Lu, Chunling, Catherine Michaud, Emmanuela Gakidou, Kashif Khan, and Christopher Muray. 2006. "Effects of the Global Alliance for Vaccines And Immunization on diphtheria, tetanus, and pertussis vaccine coverage: an independent assessment." Lancet 368: 1088-95.

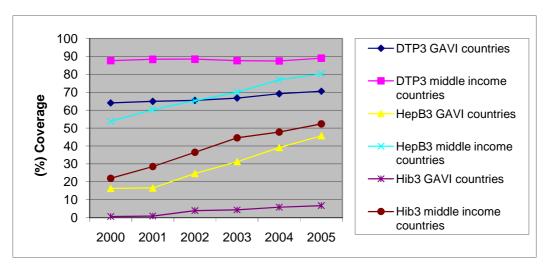


Figure 17: Coverage Rates for GAVI-Eligible and Middle Income Countries

Note: GAVI-eligible middle income countries are not included in calculations for middle income countries; they are included in GAVI country calculations.

Source: WHO UNICEF Estimates.

We also examined data on uptake of HepB and Hib for these two groups of countries. Increased uptake of HepB vaccine is not very meaningful for middle income countries because all but one had introduced HepB vaccine by 2000. Table 11 shows the number of GAVI countries and middle income countries using HepB and Hib in 2000 and 2005. As the data shows, during Phase 1, 37 GAVI countries introduced HepB vaccine, representing nearly a three-fold increase. Fifteen GAVI countries introduced Hib vaccine during Phase 1, almost a five-fold increase. During the same period, 20 additional middle income countries introduced Hib vaccine, an increase of 43%. No middle income countries introduced HepB vaccine, as all but one was already using HepB vaccine at the inception of GAVI.

Table 11: Number of Countries Using HepB and Hib Vaccine

	Vaccine	2000	2005	Number Increased
GAVI Countries	HepB	20	57	37
	Hib	4	19	15
Non GAVI-eligible middle income countries	HepB	72	72	
	Hib	47	67	20

Source: WHO UNICEF information on vaccine usage. Non GAVI-eligible middle income countries include middle income countries in 2000 as defined by the World Bank (GNI \$906-\$11,115), with all GAVI eligible middle income countries removed.

In addition to examining trends in immunization coverage and uptake in middle income countries during Phase 1, we also review the historical data on vaccine introduction in low income countries. As shown in Figure 18, the uptake of new vaccines in low income countries has increased dramatically since the inception of GAVI. Whereas 30% of infants in low income countries had access to HepB vaccine in 2000, nearly 100% had access by 2008. The increase in Hib is also dramatic, increasing from 5% of infants in 2000 to 65% of infants by 2008.

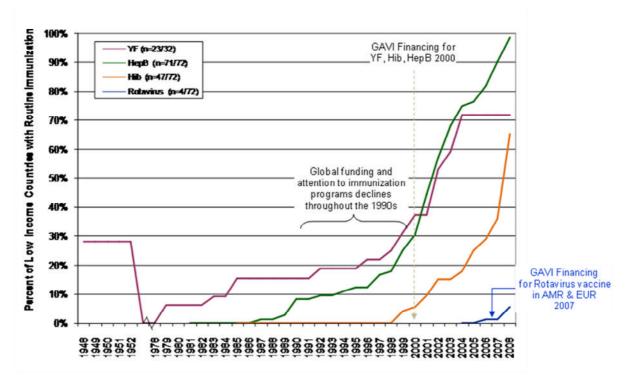


Figure 18: Historical Data on Vaccine Uptake in Low Income Countries

Note: Data shown is by percent of total infants.

Source: "New Vaccine Introduction." Presentation to the Bill and Melinda Gates Foundation, August 5, 2008, by Applied Strategies Inc.

Examining historical data and trends in middle income countries provide a point of reference for examining GAVI's achievements and contributions. Since the inception of GAVI, low income countries have made significant progress in introducing new vaccines and increasing coverage rates, compared with historical trends and with middle income countries over the same period. While coverage rates in low income countries still lag middle income countries, their rate of improvement in DTP3 and HepB3 coverage rates were higher than in middle income countries. The increase in Hib3 coverage rate in low income countries, however, lagged middle income countries. We should not draw strong conclusions from this data as the differences between middle income countries and GAVI countries render them an imperfect comparator, and the differences shown represent observed trends that may or may not be attributable to GAVI.

4.3.1.2 WHO Estimates of Children Immunized by Antigen

The WHO Department of Immunization, Vaccines and Biologicals prepares annual estimates of GAVI progress. WHO reports on several indicators, including the estimated number of children immunized with different antigens, supported by GAVI. The WHO estimates include all additional children immunized in recipient countries, compared to the number of children immunized in the year before GAVI support. WHO also estimates the number of pertussis, Hib, and HepB future deaths averted among the additional children immunized with GAVI support. We rely on the WHO estimates for the number of additional children immunized and future deaths averted in GAVI countries.

As shown in Figure 19, based on WHO estimates, 15.8 million additional children were immunized with DTP3 by the end of 2005 in the countries where GAVI provided ISS funding, compared to the baseline

year (pre-ISS year for each country).⁵² Similarly, in the countries receiving NVS, 90.5 million additional children were immunized against HepB, 14.1 million against Hib, and 13 million against yellow fever, compared to the number of children immunized in 2000. As previously discussed, uptake of HepB vaccine was higher than for Hib and YF, resulting in many more additional children immunized.

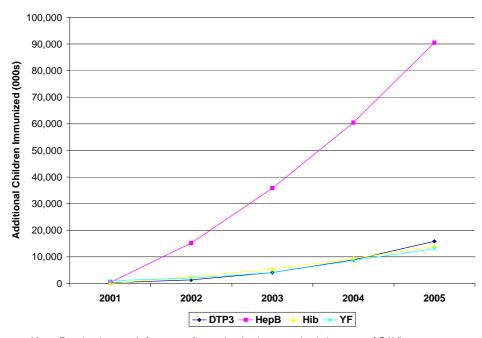


Figure 19: Additional Children Immunized in GAVI Countries*

Note: Results shown only for group of countries that have received given type of GAVI support. Source: WHO/UNICEF Estimates

⁵² DTP3 coverage is a widely-accepted indicator or routine coverage, which is the focus of ISS funding. GAVI does not provide DTP vaccines, except in combination with Hepatitis B or Hib vaccine.

As shown in Figure 20, among GAVI's country programs, Hep B vaccine was responsible for the bulk of future deaths averted. The additional children immunized resulted in preventing 1.48 million future deaths from HepB⁵³, 141,000 future deaths from pertussis, and 112,000 premature deaths from Hib among the cohort of children born in 2001-2005. We are unable to estimate the deaths prevented by YF vaccine.

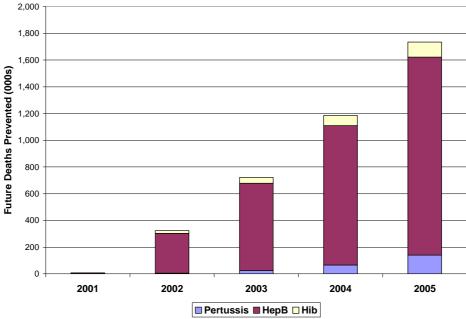


Figure 20: Future Deaths Prevented by Antigen in GAVI Countries

Note: Results shown only for group of countries that have received given type of GAVI support. Source: WHO/UNICEF Estimates

For HepB and Hib, the total number of averted deaths refers to the vaccinated cohorts in Phase 1 years, reached with full or partial support from GAVI. For pertussis, the number refers to the additional number of deaths averted due to the coverage increase.

4.3.1.3 Estimates of Children Immunized Attributable to GAVI Support

The WHO estimates include all children immunized with GAVI-supported vaccines, but in reality there are many factors besides GAVI, that drive immunization coverage. We have no appropriate counterfactual evidence of the changes in immunization rates without GAVI inputs. GAVI ISS funding provided cash contributions, but during the same period, other inputs to the immunization program were also changing. To estimate the "GAVI-specific effect", analyses need to control for external factors, which include political stability, government spending and other policies, other donor support, etc. These other factors may have brought about changes in the number of children immunized, with or without GAVI support. Two studies were completed in 2006 and 2007 to analyze the effect of ISS funding on DTP3 rates – these studies relied on statistical modeling to estimate the increase in DTP3 coverage that could be attributed to ISS funding. A model was created using regression analysis to correlate ISS funding with DTP3 coverage rates, accounting for the effects of per capita GDP and political stability.⁵⁴ Using this model, we can estimate the number of children immunized with DTP3 specifically attributable to GAVI. As shown in Table 12, GAVI ISS funding contributed to an additional 2.39 million children immunized with DTP3.

⁵³ WHO estimate based on deaths from Hepatitis B that would otherwise have occurred in adulthood.

⁵⁴ Chee, Grace, Natasha Hsi, Kenneth Carlson, Slavea Chankova, Patricia Taylor. September 2007. *Evaluation of the First Five Years of GAVI Immunization Services Support Funding*. Bethesda, MD: Abt Associates Inc.

Table 12: Estimated Number of Children Immunized with DTP3 Attributable to GAVI ISS Funding

	DTP3 Coverage as of 1998-2000			
	Less than 50%	50% to 75%	Greater than 75%	Total
2001	18,881	65,167	49,864	133,912
2002	80,495	50,313	30,204	161,013
2003	147,538	84,353	42,629	274,520
2004	440,380	197,284	109,176	746,840
2005	589,078	282,518	203,660	1,075,256
Total	1,276,372	679,635	435,534	2,391,541

Although GAVI supplied vaccines to countries, we cannot attribute ALL children immunized with these vaccines in GAVI countries to GAVI support. In some countries, HepB had been used prior to GAVI, while others may have introduced HepB even without GAVI support. Again, without an appropriate counterfactual, we rely on statistical analysis to estimate the number of children immunized with HepB that can be attributed to GAVI support. Based on the model used to estimate the effects of ISS funding, we estimated the effects of GAVI HepB support. We used GAVI shipment of HepB vaccine as the independent variable to predict HepB3 coverage rate. Data limitations reduce the precision of these estimates, but the data is nonetheless sufficient to allow us to draw statistically rigorous conclusions. Details of two alternative model specifications and results are shown in Annex L. Based on one of the model specifications, we estimate that GAVI has contributed to an additional 40.2 million children immunized with HepB3, as show in Table 13.

Table 13: Estimated Number of Children Immunized with HepB3 Attributable to GAVI

	Millions of Children
2001	1.7
2002	7.8
2003	9.9
2004	10.1
2005	10.7
Total HepB3	40.2

During Phase 1, GAVI contributed to 15.8 million additional children immunized with DTP3, 90.5 million additional children immunized against HepB, 14.1 million against Hib, and 13 million against yellow fever. The additional children immunized resulted in preventing 1.48 million future deaths from HepB, 141,000 future deaths from pertussis, and 112,000 premature deaths from Hib among the cohort of children born in 2001-2005. Using statistical analysis to calculate the portion of children immunized that can be attributed to GAVI interventions, 2.4 million children were immunized with DTP3, and 40.2 million children immunized with HepB3 during Phase 1.

4.3.2 Supporting Accelerated Disease Control

In support of accelerated disease control initiatives, GAVI funded vaccine stockpiles and contributed to global disease elimination initiatives. The majority of these commitments were made at the end of 2005 – as of year-end 2005, \$15.8 million had been disbursed for the YF stockpile, and \$12.5 million had been disbursed for the Africa Measles Campaign.⁵⁵ Although supporting disease control was always on the agenda for GAVI, and was one of six strategic objectives, the amount of time and level of deliberation required before funding commitment would suggest that this was a lower priority. We do not systematically evaluate GAVI's contribution in this area, however, given that only limited funding had been disbursed at the end of Phase 1, it is unlikely GAVI had significant impact during Phase 1.

4.3.3 Accelerating Introduction of Vaccines in Developing Countries

While the ADIPs have been able to establish and communicate the need for Pneumococcal and Rotavirus vaccines, they have been less successful in the final steps required for country uptake – ensuring long term supply of an appropriate vaccine, at an affordable price, with introduction plans that consider the delivery systems at country level.

The ADIPs invested resources to ensure the availability of an appropriate vaccine for developing countries. In the case of pneumococcal vaccine, the PneumoADIP made the decision to work with Wyeth to introduce its 7-valent vaccine that had been approved and used in industrialized markets. While this product was not ideal for developing countries, the PneumoADIP successfully advocated for the introduction of the 7-valent vaccine in pre-filled syringes based upon the number of lives saved. The PneumoADIP also supported both Wyeth and GSK on the addition of serotypes to produce 10- and 13-valent vaccines, and on improvement of the product presentation, to develop a product more appropriate for developing countries. Although GAVI is accepting country applications for the 7-valent vaccine, it is still in the WHO pre-qualification process, and pricing negotiations with Wyeth are ongoing.

The Rota ADIP chose to pursue a vaccine which had not yet been pre-qualified, but was licensed and registered in a middle income country. With funding from the Rota ADIP, GSK conducted clinical trials in Asia and Africa to establish the efficacy of their product in these regions. Although many interviewees believe that the multinational suppliers would have eventually brought these products to market on their own, most agree that GAVI funding provided the critical incentive for them to make the investments in developing country markets.

The multinational suppliers interviewed for this evaluation emphasized the lack of understanding of the vaccine production timeline and the resulting inappropriate assumptions that were made by both the GAVI Board and WG. The rotavirus and pneumococcal vaccine presentation and packaging differ significantly from the traditional EPI antigens or even the newer Hib presentations; neither vaccine was developed specifically for developing country markets, and so their suitability in these settings was not previously considered. Nevertheless, some GAVI partners and countries blame manufacturers for trying to introduce inappropriate vaccines into developing countries. Other informants, however, noted that it takes a minimum of five years to build and validate a vaccine manufacturing facility, vaccines have complex development and production timelines, short shelf lives, and manufacturers are not willing to commit to these significant investments without reliable strategic and supply chain demand forecasts.

Another factor in country uptake is the availability of financing. The ADIPs provided the evidence to the GAVI Board for investing in pneumococcal and rotavirus vaccine. The GAVI Board commitment of \$200 million for early introduction of pneumococcal and rotavirus vaccines was the direct result of the

⁵⁵ The GAVI Alliance Accounts, Combined Financial Statements for the year-ended December 31, 2005.

work of the ADIPs. New and innovative financing mechanisms such as the IFFIm and the Advance Market Commitment for pneumococcal vaccine will provide reliable financing streams for these vaccines. The PneumoADIP successfully advocated for Pneumococcal vaccine to be the target of the first AMC. ⁵⁶ Although it is unclear to what extent these results should be credited to the ADIPs, or to GAVI or its partners, these financing mechanisms represent great progress in ensuring future funding for new vaccines.

Neither the PneumoADIP nor the Rota ADIP devoted resources toward preparing countries to introduce the vaccine. Some interviewees mentioned that the GAVI partners and tasks teams were working on those delivery system issues, but that there was poor coordination of these efforts with the ADIPs. As the ADIPs end this year, and countries begin to introduce the pneumococcal and rotavirus vaccines, there is a growing concern from GAVI partners interviewed that the systems are not in place to deliver the vaccines to children and that much work still needs to be done to ensure that the vaccines introduced are appropriate both in their serotypes, and in their packaging and presentation.

Our findings from in-depth study countries further support the finding that while countries have the evidence base to support introduction, little has been done to ensure an adequate delivery system. In Malawi, the Wellcome Trust was already funding disease burden data for pediatric meningitis, which supports introduction of pneumococcal vaccine. Indonesia has disease burden data that supports introduction of Hib vaccine, and is studying pneumococcal serotypes in a six-province study, funded by the Pneumo ADIP. In Uzbekistan, the Rota ADIP funded surveillance in anticipation of the introduction of rotavirus vaccine.

The ADIPs successfully advocated for the use of Pneumococcal and Rotavirus vaccines, as well as funding for Pneumococcal vaccine. Additional work is required, however, to ensure that the vaccines ultimately introduced are suitable for GAVI countries, and that countries have the necessary infrastructure (cold chain, storage, logistics) to ensure smooth introduction and efficient usage.

4.3.4 Positioning Immunization as a Centerpiece in International Development

GAVI and its partners were committed to increasing the visibility of immunization and communicating the important role of immunization within health and development. These efforts were part of GAVI's strategy to further institutionalize immunization with all stakeholders, in order to ensure long-term commitment. Our assessment in this area is based on data from key informant interviews, discussions at regional and country level, and literature review to assess changes in focus and interest.

4.3.4.1 Increased Interest and Change in Agenda

To document the level of interest in immunization, and trends in discussion topics, we conducted a targeted review of literature in *The Lancet*, a leading independent general medical journal, and *PubMed*, the U.S. National Institutes of Health archive of biomedical and life sciences journal literature. Our searches were of the 1996-2006 timeframe. The searches conducted used the following key words:

- "Immunization" and "Injection Safety"
- "Immunization" and "Millennium Development Goals"

⁵⁶ Milstien, Julie, Cohen, Jillian Clare and Olsen, Ingvar Theo. 2007. *An evaluation of GAVI Alliance efforts to introduce new vaccines via the Accelerated Development and Introduction Plans (ADIPs) and the Hib Initiative (HI)*. HLSP.

- "Immunization" and "Health Systems"
- "Immunization" and "Funding"
- "Immunization" and "Polio vaccine"
- "Immunization" and "Hepatitis B"
- "Immunization" and "Hib vaccine"
- "Immunization" and "measles"

There were limited discernable trends based on the last four searches by vaccine. Results for the first four key word searches from *The Lancet* are shown in Figure 21. During GAVI Phase 1, there was increasing interest in immunization, particularly funding for immunization, and the linkage between immunization and health systems. Further, injection safety, and immunization linked to the MDGs, which at the beginning of this period was not part of the picture, became part of the agenda. The increased interest also appears to coincide with the beginning of GAVI in 2000.

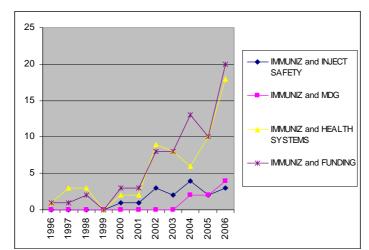


Figure 21: Results of Lancet Keyword Searches, 1996-2006

Results of keyword searches from *PubMed* found similar results, as shown in Figure 22.

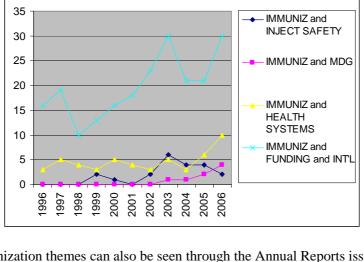


Figure 22: Results of PubMed Keyword Searches, 1996-2006

The change in immunization themes can also be seen through the Annual Reports issued by WHO and UNICEF, two core GAVI partners. Table 14 summarizes the key themes from WHO and UNICEF Annual Reports from 1996-2005. Prior to 2000, the immunization discussion focused on the traditional six vaccines that comprised the Expanded Program on Immunization, and polio eradication. Starting in 2000, there is more discussion of new vaccines, and in integrating immunization with other health services. Further, WHO and UNICEF jointly adopt a global strategy for immunization. These developments all represent progress in coordination of immunization actors, and institutionalization of immunization as a core health service.

Table 14: Key Themes in Immunization from WHO and UNICEF Annual Reports

Key Themes	WHO Annual Report	UNICEF Annual Report
1996-1999	As a result of EPI, by 1995, over 80% of the world's children had been immunized against the six major childhood diseases - diphtheria, tetanus, whooping cough, poliomyelitis, measles and tuberculosis, compared to less than 5% in 1974 Decrease in the incidence of paralytic polio in the developing world, only after the routine immunization of infants with OPV in the late 1970s Reduction in the incidence of measles and NNT in developing nations	Progress in immunization against the six major childhood killer diseases Setting immunization targets for 2000 and ensuring increased access to immunization Near eradication of polio through routine immunization and National Immunization Days
2000-2005	Limitations of the vertical approach to immunization – focus on an integrated health systems approach – IMCI GAVI and its contribution to uplifting the profile of immunization Increase in vaccine coverage in developing nations against polio, NNT and measles	Bundling immunization with other services, like Vitamin A supplementation and distribution of mosquito nets – 'Immunization Plus' Supporting the Global Polio Eradication Initiative to quell the resurgence of polio in West Africa. Official acceptance of the Global Immunization Vision and Strategy (GIVS),

Key Themes	WHO Annual Report	UNICEF Annual Report
		designed by the World Health Organization and UNICEF
		Access to new vaccines - Hepatitis B and Hib
		Getting results through GAVI – UNICEF's role in procuring and supplying vaccines for GAVI

4.3.4.2 Major Achievements

In addition to increased interest and visibility, GAVI and its partners also took advantage of changes in the landscape of international development to advance the importance of immunization, and shaped in the development of important new financing vehicles for immunization. GAVI's efforts resulted in several major achievements:

- Aligning immunization as a critical intervention for achievement of MDG 4 to reduce child mortality by two-thirds between 1990 and 2015
- Securing the International Financing Facility for Immunization (IFFIm)
- Ensuring funding for Pneumococcal vaccine through the Advanced Market Commitment (AMC)⁵⁷

More effective than press releases or events, these achievements help to ensure that there is ongoing funding and commitment for immunization. Although it is not possible to quantify the extent of GAVI's influence, they were important contributors to all these developments.

GAVI has been successful at advocating to the international community, and to a lesser extent to developing countries, that immunization is a cost-effective means of contributing to achievement of MDG 4 – reduction of child mortality. Given the international focus on the MDGs, GAVI's efforts to build its advocacy messages around one of the MDG goals was very effective at ensuring continuing attention to immunization. During country visits, respondents referred to the MDGs as one of the reasons for increasing government commitment to immunization. Some key informants also mentioned that as we approach 2015, funding for immunization may increase if it becomes apparent that progress toward that goal may be behind schedule, although one informant also mentioned that it may cause some countries or donors to support unsustainable approaches that provide one-shot results.

The International Financing Facility (IFF) was first conceived in 2003 by the UK Treasury and DFID as a mechanism to frontload aid to fund the MDGs. In 2005, the UK committed £1 billion over 15 years to the first IFF for Immunization (IFFIm), and additional commitments from six countries followed. The World Bank is the Treasury Manager for the IFFIm and GAVI is the implementing agency. The IFFIm relies on legally binding commitments from sovereign governments for its AAA bond rating, allowing it to raise funds in international capital markets at interest rates comparable to other sovereign debt. To date, IFFIm has raised \$1.23 billion through two bond issues, with nearly all of the proceeds to be used to support GAVI programs. Positioning immunization as the focus of the first IFF is an important achievement for GAVI. This facility allows countries to make commitments over a long term, but provides GAVI with immediate cash injection. While it is unclear whether the IFFIm will continue to be used as a mechanism for funding immunization over the long term, it is an important mechanism that significantly increases the pool of predictable funding for immunization over the medium term.

⁵⁷ The AMC was only in the very early stages of development at the end of Phase 1.

The development of the AMC also marked an important achievement for GAVI. The concept of the AMC was first presented at a G8 Summit in 2005 – that event in itself is an indicator of the increased importance and visibility of immunization within the international community. The AMC for Pneumococcal vaccine was launched in 2007 with commitments of \$1.5 billion from five countries and the Gates Foundation. The AMC not only provides assured funding for Pneumococcal vaccine over the medium term, but is an innovative mechanism for influencing vaccine pricing, supply, and development that may have important implications for development of new vaccines for developing countries.

It is important to note that none of these achievements began with ideas originating within GAVI. The MDGs were developed before GAVI, and both the IFFIm and the AMC were ideas first developed within external organizations loosely affiliated with GAVI, although GAVI staff became involved from the early development stages of the IFFIm and AMC. These achievements not only demonstrate GAVI's ability to work with partners to achieve common goals, but also its ability to build on emerging trends and ideas to benefit immunization objectives.

GAVI and its partners were successful in positioning immunization as a centerpiece in international development. Immunization is more prominent within the health literature, and is recognized as a core health service. Significant achievements include aligning immunization with achievement of MDG4, securing the IFFIm, and ensuring funding for Pneumococcal vaccine through the AMC.

5. ORGANIZATIONAL STRUCTURES

GAVI's organizational structures evolved a great deal during Phase 1. Being a trailblazer among global health partnerships meant it had no model to copy from – it relied on internal examinations for lessons on organizational improvement. We review GAVI's governance and management structures and their evolution, as well as the structure of the partnership, and how they affected GAVI's ability to achieve its mission.

5.1 Governance and Management Structures

GAVI was designed as an alliance of key stakeholders who shared a common vision: to save lives by greatly expanding reach and effectiveness of immunization programs in developing countries. This arrangement was intended to ensure that GAVI did not become an implementing entity on its own, but would rely on its partner organizations to undertake all activities except for internal management. Activities undertaken jointly by the partners included determining GAVI's strategic directions and investments made, supporting countries in developing their project proposals, approving and monitoring country activity, and providing technical expertise and financial resources to recipient countries to support achievement of GAVI's goals.

The GAVI alliance established a set of "philosophical principles." 58

- 1. GAVI is an alliance [in which] partners work together to achieve greater effectiveness and synergies through enhanced coordination, consensus building and coherence.
- 2. The goals of the GAVI alliance are by definition consistent with the goals of respective partner institutions. Partners are jointly responsible for ensuring agreed outcomes through the implementation of necessary activities, resourcing, and accountability.
- 3. Partners are committed to increase the impact of their efforts at country level towards the GAVI milestones and strategic objectives.
- 4. The availability of additional resources for immunization including the Vaccine Fund and the promotion of sustainable financing solutions for countries.

GAVI's organizational structure relied primarily on partner representatives, organized through various governance and management mechanisms, to carry out its operations:

- the GAVI Alliance Board;
- the GAVI Fund (formerly called the Vaccine Fund) Board;
- Executive Committees for both Boards;
- Secretariat or management unit to serve the boards;
- Task teams or committees to work on specific topics;
- a partner-staffed Working Group (WG); and,

⁵⁸ GAVI Alliance Board sub-group meeting, 14 December 2002. Clear Definition of GAVI Added Value.

■ Independent Review Committees (IRC).

These different entities were established at different times, and their roles and responsibilities changed over the course of Phase 1. Each of these structures is discussed below.

5.1.1 The GAVI Alliance Board

The Alliance Board operated on a "stakeholder" model, in which Board members represented all of the major stakeholders concerned about immunization in developing countries, each bringing a different perspective and different skills. Board decisions were made by consensus. Its members were high-level individuals representing WHO, UNICEF, the World Bank, the Gates Foundation, bilateral donors, the pharmaceutical industry (both multinationals and developing country industry), developing country governments, research and development institutes, technical health institutes, and civil society (foundations). The chair rotated between WHO and UNICEF, as the two international organizations with a global mandate for implementing immunization programs. WHO, UNICEF, the World Bank and Gates Foundation were permanent board members, while others rotated among various members of their constituency groups. The Board structure adopted in 2000 included 16 Board members, as shown in Table 15.

Table 15: GAVI Board Structure, 2000

Renewable (permanent)	Board Chair (rotates between UNICEF and WHO)
Seats (5)	Bill and Melinda Gates Fdtn
	UNICEF
	World Bank
	WHO
Rotational Seats (11)	OECD country governments (3)
	Developing country governments (2)
	OECD country industry
	Foundations
	Research and Development Institutes
	Nongovernmental Organizations
	Technical Health Institute
	Developing country industry

Over time, as Board members realized that there were gaps in stakeholder representation on the Board, adjustments were made to Board composition – for example, to add GAVI Fund representation, and to increase representation from developing countries and from bilateral donors. As the GAVI Alliance's program grew and the issues facing the Board became more complex, the Board appointed an Executive Committee in 2003 for strategic planning, coordination, and supervision of the Secretariat. Changes to the GAVI Alliance Board are summarized in Table 16.

Table 16: GAVI Board Changes to Improve Constituency Representation

2002	•	Added seat for President of the Vaccine Fund to improve coordination
	•	Added third developing country seat
	•	Dropped Foundation seat (with the Gates Fdtn to represent all private foundations)
	•	Total 17 Board seats
2003	•	Increased rotating Board member terms from 2 to 3 years to provide better continuity
2005	•	Added one seat for IFFIm donors
	•	Added fourth developing country seat
	•	Combined R&D institute and Technical Health institute seats
	•	Stipulated Vaccine Fund seat could be represented by any VF Board member
	•	Total 18 Board seats

5.1.2 The GAVI Fund Board

The GAVI Fund, formerly known as the Vaccine Fund, was created in 1999 as a companion organization to the GAVI Alliance, as a legal vehicle (a U.S. 501C3 non-profit organization) to carry out fund raising, accept donor contributions, manage and invest these contributions, and disburse funds for immunization program activity. Since its mandate was financial rather than programmatic, its board consisted of individuals with strong business and financial skills, as well as individuals whose personal prestige and interest would enable them to lead the fund-raising effort successfully. All Board members served as individuals – not as representatives of another entity. In addition, it was decided early on that there should be some duplication in membership between the Alliance and the Fund Boards. The GAVI Fund President and CEO represented the Fund on the GAVI Alliance Board to foster communications between the two boards.

All Board members held permanent seats, and the number of Board members could be decreased or increased as needed. Initial Board membership was two persons, increasing rapidly in the first two years, then increasing further over Phase 1, adding financial sector experts, but also dropping a couple of inactive Board members, for a total 14 Board members by 2005.

The Fund created an Executive Committee to conduct urgent business between regular board meetings. It relied on a management unit to support its work, until 2005 when Fund management was merged into the Alliance's Secretariat, in order to improve coordination between GAVI and the Fund. Like the Secretariat, the Fund management increased staffing every year as the Fund's operations grew.

5.1.3 GAVI Alliance and GAVI Fund Board Interaction

Under this dual board arrangement, the GAVI Alliance Board made the technical decisions – strategic directions for funding, specific programs to be offered, country eligibility criteria, and the application and approval process. As the legal entity overseeing funding, the GAVI Fund Board confirmed the decisions made by the Alliance Board and approved the transfer of funds. The relationship between GAVI and the Fund was spelled out in an agreement of October 2000. The Fund Board reviewed programs endorsed by the GAVI Alliance Board, based on availability of funds and other factors, before approving funding. The GAVI Alliance and the Fund were expected to collaborate closely in making these decisions. After the Fund Board approved funding requests, funds were transferred to UNICEF's Vaccine Trust Fund Account, from which the GAVI Alliance could enact disbursements. If the Fund Board did not agree with the GAVI Alliance Board's recommendations, and the two Boards could not reach agreement, the GAVI Alliance Board could use funds already transferred to UNICEF's Vaccine Trust Fund Account to

initiate the programs. Overlapping membership between the two Boards and Fund Board representation in the GAVI working group were expected to minimize potential disagreements between them.

The concept of the GAVI Fund was to play a "watchdog" function, to ensure that resources were used efficiently, fairly and transparently.⁵⁹ This oversight role was particularly important to assure the Gates Foundation that its \$750 million contribution to an unproven, fledgling entity would have sufficient controls until it was clear that the GAVI partners would act in a responsible manner. Further, in the early years, some key contributors were concerned that Alliance partners might cede to political pressures to use GAVI funds for something other than immunization. The Fund Board, consisting of individuals without institutional affiliations, would be able to resist such pressures. The Fund was to be independent of the Alliance, however, it was also important to exercise control cautiously because of the need to foster collegiality among the GAVI partners.

For the most part, the arrangement worked, though from time to time the Boards noted the need to improve interaction between the Alliance and the Fund. For example, a governance study in 2002 pointed out differences between the GAVI Alliance and Fund in their approaches to financial sustainability, the extent to GAVI should support vaccine research, and strategic timeframes – the Fund was developing a 10 year strategy while the GAVI Alliance had not yet determined its future beyond 2005. The close working relationship between the Fund's President, Jacques Francois Martin, and the Executive Secretary of the Alliance's secretariat, Tore Godal, helped to resolve issues that arose between the two Boards.⁶⁰

As time went on and the GAVI Alliance proved that the partners could act responsibly and within GAVI's mandate, as shown by successful support introduction, concerns about the need for a strong oversight role for the Fund dissipated. Relationships between the Alliance and the Fund (such as representation by the Fund on the Alliance Board) were worked out such that potential conflicts could be handled collaboratively. In addition, the Alliance developed its own internal checks on its funding decisions, most importantly, a process for funding decisions to be reviewed by an Independent Review Committee (IRC). During Phase I, informants considered the IRC to be conscientious and objective, although the IRC process is one of the few components of GAVI's operations that has never been evaluated, nor was its effectiveness part of the scope of this evaluation.⁶¹

5.1.4 **GAVI Alliance and GAVI Fund Management Entities**

The Secretariat, the management entity for the GAVI Alliance, was intended to be "lean and mean", as described by some informants, both to foster the spirit of partner reliance and to allow for quick decision making. It consisted of the Executive Secretary, who came from WHO and had a strong background in immunization, and several administrative staff with no technical skills in immunization. The management unit of the GAVI Fund supported the Fund Board and carried out the day-to-day responsibilities associated with managing the Fund's large and growing asset portfolio. The Fund's CEO came from the pharmaceutical industry and had been an important advocate of industry as a partner during the CVI days.62

⁵⁹ Information for this section of the report is taken almost entirely from William Muraskin. 2005. *Crusade to Immunize the* World's Children. USC Marshall.

⁶⁰ Caines, Karen, and Hatib Njie, 2002, Report of External Review of Functions and Interactions of the Working Group, Secretariat and Board.

⁶¹ An exception is the evaluation of the first set of Investment Cases, where the role of the IRC was examined to some extent. It concluded that while the IRC's views and recommendations were considered by the Board, the Board also considered other factors, including political factors. Thus, even use of the IRC mechanism did not completely insulate the Board from political pressures – though this was not necessarily inappropriate either.

62 Jacques Francois Martin had been CEO of Institut Mérieux, Biocine and Chiron Vaccines.

Both the Alliance Secretariat and the Fund management unit had to grow as the size and complexity of GAVI's assets and programs grew. As shown in Table 17, the GAVI Alliance and Fund Boards authorized staff increases every year. Over time, it became apparent that there were areas of duplication (especially in fund-raising and advocacy areas) and areas of disconnect ("messaging" of GAVI's strategy), and that there were efficiencies to be gained in converging the two management entities into one, including potential staff efficiencies and simplified communications with partners.⁶³ The merging of the Fund management unit with the GAVI Secretariat took place in 2005, with the Secretariat's Executive Secretary leading the expanded Secretariat and reporting to both Boards.

Table 17: Growth of the Alliance Secretariat and Fund Management Staffing

Year	Alliance Secretariat	Fund Management	Total
2000	6	0	6
2001	8	10	18
2002	9	15	24
2003	14	18	32
2004	15	24	39
2005	Converged		55

Source: Figures for 2000 through 2004 were provided by the GAVI Secretariat. Figures for 2005 are from "GAVI Secretariat Headcount in 2007", presented at the 7 Feb. 2007 Joint Executive Committee meeting of GAVI Alliance and GAVI Fund.

5.1.5 Task Forces and the Working Group (WG)

During Phase 1, the GAVI Alliance Board and Secretariat relied heavily on a WG consisting of mid-level individuals with expertise in and commitment to immunization, generally representing organizations with Board seats, to inform Board decisions and to ensure effective implementation. This is the same working group that had convened in the last years of the CVI and helped create the framework for GAVI. The original membership in the WG was agreed upon at the Proto-Board meeting, and was later amended to include developing country representatives. Its scope was rather vague and there seemed to be continual reassessment of its role. The initial "Guiding Principles" agreed to at the 3rd Board meeting of 2001 named the WG as one of four key structures of the Alliance (in addition to the Board, the Partners Meeting, and the Secretariat) and made it independent of the Secretariat. But by June 2002 the Executive Secretary was made chair of the WG and given authority for rotation/replacement of WG members (in consultation with the partner they represent). By the end of 2005, the WG was no longer even considered "part of the overall governance structure". Nonetheless, informants believed it played a critical role in strategy development and program design under Phase 1, and represented the critical technical thinking behind issues and recommendations presented to the Board.

The GAVI Board also created four subject-specific task forces: Advocacy, Financing, Country Coordination, and Research & Development, each comprised of partner representatives. As GAVI achieved early success in attracting and disbursing funds and began to grow, the GAVI Board established other task teams to share the increasing burden of technical analysis, policy development, and program oversight (e.g. a research and development task team). The additional task teams increased opportunities for partners to participate more deeply in development of GAVI policies, but also complicated the governance structure.⁶⁴

⁶³ GAVI Alliance Executive Committee board retreat report, June 2-3, 2004.

⁶⁴ We cannot identify complete records of all the task teams during Phase 1, but there were approximately 8-12 time-limited and standing task teams near the end of Phase 1.

By the end of Phase 1, with changes in organizational structure, tendency of GAVI Board members to become more involved in detailed decision-making, inception of the Executive Committee, and growth of the Secretariat, the GAVI Board's reliance on partner-staffed task forces and the WG declined substantially. The WG was no longer a central vehicle for partners to discuss, debate and frame consensus recommendations on the key issues for the Board. As the CEPA governance study pointed out, "In essence, there has been a shift in the nature of GAVI from the informal Alliance partnership embodied in the WG, towards a 'partnership institution' in its own right."

5.1.6 Independent Review Committee (IRC)

GAVI created several Independent Review Committees (IRCs) to ensure that proposals and programs received impartial, technically competent and transparent review. Separate IRCs were established to review new applications from eligible countries, to monitor country progress and make recommendations for future funding, and to review investment cases. IRC membership is made up of technical experts who can assess programs from all aspects, generally coming from academia and technical institutes, **not** partner organizations, and including individuals from developing countries. IRC assessments and recommendations are presented to the Board to aid in their decision-making. The widely-perceived quality and unbiased nature of IRC assessments is considered an important means of assuring accountability.

A summary of the GAVI governance and management structures, and key elements of their evolution are summarized below in Table 18.65

Table 18: Summary of GAVI Governance and Management Structures

Structure	Composition	Responsibilities/ Mandate	Evolution
GAVI Alliance Board	Membership representing the major GAVI stakeholders: countries, multilateral agencies, pharmaceutical industry, research and	Overall policy and strategic direction for GAVI	15 members in 2000, increasing to 18 in 2005, with increases for bilaterals and developing countries.
	technical institutions, private foundations		Executive Committee formed in 2003
GAVI Fund Board	Independent members with financial or fund-raising skills, and members representing the major contributors	Fundraising, management and investment of contributions, oversight of use of funds	Initially 2 members in 2000, increasing to 14 in 2005
GAVI Alliance and Fund Board Executive Committees	Selected Board members	Responsible for recommendations on specific topics such as investments, audit	No major growth in committee structure during Phase I.
GAVI Alliance Secretariat	Salaried employees of GAVI, hosted by UNICEF, led by Executive Secretary with strong technical knowledge	Support the Board by preparing for Board meetings, communicating with partners, implementing actions approved by the Board	6 staff in 2000, growing to 15 in 2004 prior to convergence with Fund management staff in 2005.
GAVI Fund management	Salaried employees of the GAVI Fund under direction of a CEO	Management support for the Fund Board	10 staff in 2001, growing to 24 in 2004 to assure adequate financial management
GAVI Alliance	Staff of GAVI Alliance partner	Support for the Board and Secretariat in developing	Initially very important, became less central to the

 $^{^{65}}$ This information is summarized from Board meeting documents, governance documents and interviews.

Structure	Composition	Responsibilities/ Mandate	Evolution
Working Group	organizations	workplans and programs, determining implementation arrangements, and monitoring progress	Alliance's decision-making as governance structures became more complex and the Board clarified roles and responsibilities
GAVI Alliance Task Forces	Staff of GAVI Alliance partners organizations, GAVI Secretariat staff and other experts	Research, analysis and recommendations on specific topics of interest to the Board	Review of task forces' activities, concluding that there were other mechanisms to carry out some of their functions, led GAVI Board to eliminate some task forces in latter years of Phase I. ⁶⁶

The GAVI Alliance was designed as an unincorporated partnership governed by a Board consisting of representatives from stakeholders, relying on partner organizations to implement activities. The GAVI Fund was created as a companion organization, with the legal status required to accept, manage, and disburse funding for GAVI Alliance activities, as well as to provide oversight on the GAVI Alliance. Both the GAVI Alliance and the GAVI Fund had minimal management staff. The GAVI Alliance relied on a Working Group, various task teams, and Independent Review Committees for technical analysis, policy development, and program oversight.

5.2 Effectiveness of Governance and Management Structures

We assess GAVI's effectiveness in this area based on information from previous studies, GAVI internal documents, and interviews with key informants. We assess the suitability of the organizational structures at various points, as well as whether they evolved appropriately to address changes in GAVI's operations and operating environment.

Since its inception, GAVI has been concerned about the effectiveness of its governance and management structures. Assessments were continually undertaken during Phase 1 to review and improve various aspects of its governance. The result was a series of incremental changes that were aimed at helping GAVI deal effectively with ever-increasing programs and issues without diminishing the advantages that members felt stemmed from the original concept of the alliance. Table 19 presents the changes resulting from the assessments undertaken during Phase 1.

 $^{^{66}}$ 11^{th} GAVI Board meeting, Sub-group Review of Task Forces.

Table 19: GAVI Governance Studies and Resultant Changes

Year	Assessment/Study	Changes Adopted
2000	Collaborative Mechanisms between GAVI Board and Fund Board Regarding Disbursements of Support to Countries	Clarified relationship between Vaccine Fund and UNICEF as trustee of Vaccine Trust Fund, specified how disputes between GAVI and Vaccine Fund Boards would be resolved and called for duplication in membership between the two Boards for better coordination and communications.
2001	GAVI and the Vaccine Fund: Roles and Responsibilities	Spelled out roles and responsibilities of the Working Group, task forces, IRC, RWGs, ICC, individual partners, and the Secretariat.
		Enhanced the Secretariat to support the Working Group, whose tasks had become "overwhelming".
2002	Report of External Review of Functions and Interactions of the GAVI Working Group, Secretariat and Board	Expanded day-to-day responsibilities of Secretariat and Working Group to enable Board members to focus on strategic issues.
2003	Proposal for Improved GAVI Board Operations	Created the GAVI Board Executive Committee to take on most of the strategic planning, coordination, and supervision of the Secretariat, for approval by the full Board.
2003 to 2004	Optimal Structures and Processes for GAVI and the Vaccine Fund Moving Forward - Recommendations from the EC Retreat and Supplementary Report to the GAVI Board on Convergence	Led to decision to converge GAVI Secretariat with Vaccine Fund management team in order to avoid duplication and to effect cost savings.
2004	Strengthening GAVI's Governance Processes and	Defined and limited role of Executive Committee to ensure full board did not become "rubber stamp".
	Structure in the Context of Convergence	Called for strategic plan that specifies roles and responsibilities of different partners and exact scope of the GAVI workplan.
		Made process changes including clear rules for decision-making, institution of performance monitoring for Board, Secretariat and Working Group
2005	GAVI Management and Staffing Review	As approved by the Board, expanded Secretariat staff to assure financial controls, agreed to larger management study of the Secretariat.

Most of the governance changes that the GAVI Alliance adopted during Phase I were intended to achieve the same end – managing the growing size and complexity of GAVI programs such that the Board could focus on the major strategic and policy objectives, while maintaining some involvement in lower-level policy decisions and analysis. Routine decision making and implementation was shifted to subsidiary governance entities and, increasingly, to the Secretariat. Consequently, the GAVI Alliance changed substantially during Phase I, including substantial growth in the management structure. While these incremental changes surely helped, GAVI governance and management was continuously in the mode of "catching up" with GAVI's operational growth.

Despite the numerous assessments and changes throughout Phase 1, Board members continued to raise issues regarding respective roles of partners, and the decision-making process, leading to further assessments and changes. Table 20 presents a sampling of concerns raised in Phase 1 Board meetings. These concerns speak to the constant "catch-up" mode and lack of clarity on the roles of various governance structures.

Table 20: Sampling of Partner Concerns Documented in Board Meeting Minutes

Board Meeting	Discussion/Comments in Board Minutes
2 nd board meeting (2000)	Several members wished to be more involved and have closer links with Working Group
6 th Board meeting (2001)	The Board noted that even though GAVI is thought to have a light structure, the organogram is actually quite complex, with task forces, regional working groups, etc. The Working Group is acting as a virtual secretariat, with distinction that members remain in partner agencies. There needs to be clear accountability for priority tasks assigned by the board.
8 th Board meeting (2002)	GAVI Alliance faces a transition from its initial emphasis on development of policies and procedures at the global level to a focus on implementation at the country level. While a looser alliance approach initially was instrumental to achieve the broad thinking and consensus building, the implementation stage requires more active management.
10 th Board meeting (2003):	The experience of development of the 2003 workplan raised concerns over whether GAVI and its supporting entities were taking over activities which should be carried out as part of the remit of individual partners. This reflected lack of adequate guidance by the board for workplan preparation.
17 th joint Alliance-Fund Board meeting (2005):	The Boards re-establish responsibilities of Alliance and Fund Board and Executive Committee for Phase 2. They state that informal Alliance working groups are not considered part of the overall governance structure. Review of their roles within the organization should be considered under a separate process.

There was confusion regarding the responsibilities of the GAVI Fund versus the Alliance. The WG was at times seen as too all-powerful and non-transparent, and at times seen as an essential element of the partnership. Task forces tended to take on lives of their own, developing their own workplans and budgets, with limited oversight from an overburdened Board. Under the converged management arrangement, despite the official agreement that the Executive Secretary would report to both Boards, it was unclear to representatives of some Board members to whom the Executive Secretary really reported. Further, the GAVI Alliance and GAVI Fund Boards had very different cultures – with one that was consensus-driven and cognizant of political positions of Board members, and the other focused primarily on the final results. A certain amount of ambiguity was at times useful to maintain commitment by all the partners – it enabled partners to interpret GAVI's mandate and their own roles and responsibilities in ways acceptable to the institutions they represented. With respect to governance and management, as well as strategic decision-making (discussed in a later section), ambiguity was sometimes used to facilitate agreement among partners.

In 2007, the increased size and scope of GAVI operations, new financing mechanisms (IFFIm), and legal issues in the US (related to GAVI Fund accountability requirements) and in Switzerland (related to UNICEF hosting of the GAVI Secretariat) made it necessary for GAVI to undertake a more sweeping change in governance. Based on recommendations from a governance study conducted by CEPA, GAVI is in the process of restructuring itself from an informal alliance to a legal entity, merged with the GAVI Fund, registered as a Swiss Foundation.

5.2.1 GAVI Fund Structure and its Role as "Watchdog" of the GAVI Alliance

It does not appear from available documentation that the GAVI Fund experienced "growing pains" to the same extent as did the GAVI Alliance. As a corporate type of board, it did not have to achieve compromise among competing stakeholder interests. The Fund Board's issues appeared more to do with

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its relationship with the Alliance regarding decision-making authority, and its fund-raising and advocacy role (where there was some confusion as to relative responsibilities between the Alliance and the Fund).

There was lack of clarity about the Fund's "watchdog" role. On the one hand, it existed primarily to manage the funds over which the GAVI Alliance had programmatic decision-making authority. On the other hand, it was expected to provide a check on GAVI Alliance decision-making, to ensure that funds were used properly. In the interest of maintaining collegiality and generating trust, everyone accepted a situation of "constructive ambiguity" as to the Fund's role as "watchdog". As the CEPA study pointed out, this ambiguity posed a high level of risk to Board members as the scope of GAVI's operations grows, particularly the Fund Board members, who formally have the fiduciary responsibility.

Partly because of the "constructive ambiguity" about the Fund's watchdog role, and partly because of partner satisfaction with GAVI's performance, the Fund does not appear to have pursued its watchdog role very aggressively. While it was possible for the Fund to question or withhold funding for GAVI programs, such occasions were rare. Despite the mandate to provide oversight, the composition of the GAVI Fund Board did not provide the technical expertise to question GAVI Alliance decisions on technical grounds. Problems with the dual-board system, cited in the CEPA assessment, worked against the Fund's ability to perform proper oversight. The CEPA governance assessment team concluded that the dual-board system led to significant management and accountability problems:⁶⁸

- There was great potential for confusion about which entity was responsible for doing what, to whom the parties were accountable, and who made decisions when consensus cannot be achieved.
- Neither the Alliance nor Fund Boards had complete knowledge over all of GAVI's activities, because of the separation of programmatic (oversight of the expenditures) and funding aspects.
- It was not clear as to whom the senior management team was accountable, and who was responsible for performance managing the CEO, leading to insufficient scrutiny of management team performance.
- There were significant inefficiencies in servicing two separate boards and supporting governance entities, so that a disproportionate amount of time of senior management was diverted from pursuing the Board's priority activities.
- There were risks for members of both Boards, for the Alliance Board members to the extent that they did not have legal control over the deployment of resources by the Fund and for Fund Board members to the extent that they were not perceived to be fulfilling their fiduciary responsibilities.

As the CEPA assessment noted, GAVI's accountability problems have not been exposed because its programs have generally performed well. However, given GAVI's current position as a multi-billion dollar entity with a tendency toward undertaking high value but high risk initiatives, it is necessary to resolve the problems noted above. GAVI has taken steps to do this through merging the Fund with the Alliance, converting the alliance to a separate legal entity, and enabling the new entity to maintain its Secretariat internally rather than housing it in UNICEF.

⁶⁷ Muraskin, William. 2005. *Crusade to Immunize the World's Children*, Global BioBusiness Books, Marshall School of Business, University of Southern California.

⁶⁸ The following points are taken from "The case for integrating GAVI's governance structures", CEPA, GovDoc #11d, presented at the GAVI joint Board meeting of February 26, 2008.

Since there is no longer a separate entity (the Fund) to serve as "watchdog", the new structure calls for the partners themselves to take responsibility, through initiation of a standing Audit committee, to oversee both internal and external audit, and through a standing committee for program and policy which, among other things, reviews the overall performance of GAVI through internal and external evaluations and the IRC process.

5.2.2 GAVI Alliance Governance: "Fit for purpose"?

To assess whether GAVI Alliance governance structure and composition were "fit for purpose," we rely heavily on work conducted by CEPA. GAVI's governance structure is evaluated based on: 1) adherence to principles of good governance; and, 2) ability to act.

CEPA identified key elements of good governance against which to assess GAVI's governance structure and composition, summarized as follows: ⁶⁹

- 1. Written constitution documents which clearly articulate and codify the mission and purpose of the entity and its approach to governance.
- 2. Clear distinction between various levels of governance, parties involved, and their roles, responsibilities and powers.
- 3. Board of directors of an appropriate size, composition, and clearly defined mechanisms for appointment.
- 4. Clearly defined, explicit mechanisms for decision-making, including voting rights and processes for resolving differences of view at each level of the organization.
- 5. Clear procedures for dealing with conflicts of interest.
- 6. Proper incentives for various parties to pursue objectives that are in the interests of the organization, as well as facilitate effective performance monitoring and performance improvement mechanisms.
- 7. Timely and accurate disclosure on all material matters regarding the organization, including its financial situation, performance, ownership, and governance.

Against these criteria, CEPA identified some important weaknesses in GAVI's governance structure as it grew during Phase I. Addressing these weaknesses was the basis for the subsequent major governance changes that GAVI is undergoing during Phase II. The core weaknesses were:

- A complex governance structure that does not adequately define roles and responsibilities at various levels of the organization. Consequently, lack of clarity about the 'vertical relationships' within GAVI Alliance and Fund both between the Boards and the Executive Committees, and also between the Boards/Executive Committees/Sub-committees (including task teams and the WG) and the Secretariat.
- Inadequate articulation of the definition, roles and powers of stakeholders.
- Separation of programmatic and fiduciary responsibilities between the GAVI Alliance and the Fund, creating the potential for differences of view as neither group has the full knowledge and information of GAVI's operations; absence of clear rules and processes to resolve disagreements.
- Lack of guidelines to explicitly address potential conflicts of interest arising from the multiple roles of the GAVI Alliance partners as Board members and technical implementation partners, and additionally in the case of UNICEF, as the host for the GAVI Secretariat possibly exacerbated through the workplan process of allocating resources and

 $^{^{69}}$ Discussion paper prepared for the GAVI Alliance and Fund Board meeting 11-12 May 2007, prepared by CEPA and CA Legal

responsibility.

For all of its growing pains, GAVI has held on to some key characteristics that enabled it to attain and maintain its leadership position in the global immunization community. Previous studies – as well as our review of Board reports and actions – point to these key factors in GAVI's success:

- The ability to make decisions and act quickly when necessary
- The ability to innovate and to adapt to changing situations
- The willingness to self-assess, listen to criticisms of others, and adjust accordingly

Some have concluded that GAVI has succeeded despite its governance, rather than because of it. As the Branding Study⁷⁰ put it, "It is interesting – and somewhat anomalous – that the organization is seen as efficient and business-like in its operations but ponderous in governance." One could certainly argue that GAVI did not always adhere to principles of good governance. However, this same study also proposes that GAVI's position in the international community and its success depends on the confidence of its partners, a value that GAVI seemed to hold highly.

GAVI's tendency for introspection, the desire of all partners to meet each others' concerns and keep all engaged, and their desire to continue to bring added value to achieve immunization goals, have led GAVI to a process of continuous though incremental efforts towards self-improvement. While perhaps not rapid or radical enough to keep pace with its growth, these efforts enabled it to continue operating effectively throughout Phase 1. Most informants agreed that keeping a small Secretariat, and relying on the WG and task forces, enabled partners to interact not just in the Board, but at technical staff levels where good science took precedence over political and turf issues. But GAVI also recognized that routine management became increasingly complex, and slowly expanded the Secretariat to keep pace. Task forces and the WG were used effectively to allow critical input and debate, and to encourage partners' ownership of decisions, which arguably was more important in the earlier years of Phase 1. One of the challenges in the transition to a more efficient model for governance, favoring greater responsibility by management (as opposed to subsidiary partnership groups such as the WG), to carry out the analysis and make recommendations for key decisions, will be to ensure that there are mechanisms for arriving at consensus in ways that will keep all the stakeholders committed and engaged.

During the course of Phase 1, GAVI undertook incremental governance changes aimed at managing the growing size and complexity of its programs without diminishing the original partnership principles. Two key weaknesses of its governance structure that were never resolved were poorly defined roles and responsibilities of stakeholders and management entities, and poor accountability given the dual GAVI Alliance and GAVI Fund roles. Although GAVI did not always adhere to principles of good governance, its partners were committed and engaged, and its structures were sufficient to allow quick decision making, innovation and flexibility, and open debate and self-assessment.

5.3 GAVI's Partnership Structure

The GAVI partners and their commitment to the Alliance were critical to GAVI's success in rapidly expanding immunization coverage, and perhaps enabled the Alliance to overcome inefficiencies in

⁷⁰ Saatchi and Saatchi Simko. 2005. Report and Recommendations on development and implementation of a Brand Strategy and Corporate Identity for GAVI and the Vaccine Fund.

governance and management. Nonetheless, there were, and are, underlying tensions in the partnership, some of which may be constructive, but others which if left unresolved constrain GAVI's ability to achieve its overall mission.

5.3.1 Initial Partnership Framework

The GAVI Alliance was designed to rely on the partner organizations to implement a common set of activities. Among the founding partners, each would be responsible for activities where it had distinct comparative advantage. UNICEF brought expertise in vaccine requirements, procurement and supply chain management, expertise in global and country-level advocacy, along with its vast experience in program implementation at country level. WHO brought high quality scientific and technical expertise in disease-focused responses and in vaccine and drug quality assurance. WHO also had strong trusting relationships with developing country governments and could provide technical assistance to support governments in developing and implementing immunization policy and programs. The World Bank brought experience with mechanisms for financing immunization. The Gates Foundation brought substantial monetary resources and a strong commitment and belief that millions of lives could be saved by providing vaccines for the world's poor children. In addition to the founding partners, other key partner stakeholder groups critical to the GAVI Alliance were developing country governments, bilateral development agencies, both multinational and emerging suppliers from the vaccine industry, civil society (including foundations and technical service providers), technical and research institutes, and other multilateral agencies working in health and general development.

The governance mechanisms and operating policies and procedures were established to take full advantage of the expertise of partners and to actively engage them in carrying out the work at global, regional, and country level. Partner coordination mechanisms included the WG at global level, the Regional Working Groups (RWG), and Inter-agency Coordination Committees (ICCs) at country level.

Most people felt that the WG, composed of representatives of key partners, was particularly effective. These early leaders had vast experience and expertise in immunization and were passionately committed to immunization. They formed strong relationships among themselves and were critical to GAVI's success. Interviewees found that in these early groups (the WG and certain task teams), members were enthusiastic, open with one another, able to debate and disagree while arriving at innovative solutions to perplexing problems. At the same time, it was unclear to some how members were selected to be on the WG or on the task teams. Some felt that the inner workings of these groups could have been more transparent.

The RWGs were created by partners at regional level, in particular, WHO and UNICEF regional staff, but also included technical partners active in the region (such as representatives from the USAID-supported Immunizations Basics Project), to act as an interface between GAVI and recipient countries. Although they were not formally a part of the GAVI management structure, they played an important role in digesting GAVI rules and requirements for countries, and providing a cohesive voice for country concerns. Since GAVI had no presence at the country or regional level except through its partners, "RWGs are ... relied upon by the Secretariat, WG and task forces to coordinate support, consultation, financial sustainability, planning and monitoring in their respective areas. ... RWGs provide an important forum for networking, coordination, consensus building, and advocacy at the regional and sub-regional level, and bridge for information flow between country and global levels". The control of the regional staff, but also included the region also included the regio

⁷² Report on Task Forces, 11th GAVI Board Meeting, 15-16 July, 2003

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⁷¹ HLSP. 2006. Immunization: mapping the bigger picture. Final Report to GAVI Roles and Responsibilities Task Force.

GAVI required evidence of a functioning Interagency Coordinating Committee (ICC) as a condition for country proposals. ICCs consisted of immunization partners in the country, including representatives from recipient country government, WHO, UNICEF, the World Bank, bilateral donors, technical institutes, and (to a much lesser extent during Phase 1) civil society. Although most countries had standing ICCs prior to GAVI (established as part of polio eradication efforts), the GAVI requirements revived their role and broadened their scope and membership. The ICCs were responsible for preparing country applications, overseeing implementation, monitoring progress at country level. In all in-depth study countries, GAVI was credited with fostering greater coordination and consultation among immunization program partners – often this was cited as the greatest achievement of GAVI.

GAVI relied on its partners for strategy development and program design, implementation of core activities at global level (such as advocacy), communications with countries, and implementation and monitoring at country level. Maintaining partner commitment and creating effective channels for input was critical to the success of GAVI.

5.3.2 Elements of the Partnership

Since there have been a number of public-private partnerships formed in recent years, there are studies and papers that define the elements of an effective partnership. The most commonly cited elements of an effective partnership are the following:

- 1. an agreed-upon compelling purpose;
- 2. strong participatory leadership;
- 3. governance structures that are clear, transparent, and balance the need to respond quickly with opportunities for wide participation;
- 4. attention to process, with clear delineation of roles and responsibilities of the partners, agreements on communications practices, and how decisions will be made;
- 5. power equity among the key partners;
- 6. trust that partners are being transparent and will do what they say they will; and
- 7. mechanisms for holding partners accountable. 73 74 75

Based on this framework, we used information from prior studies, as well as data from key informants to assess how GAVI measures against each of these elements. While the GAVI partnership was strong in some elements and functioned effectively for much of Phase 1, various issues emerged.

5.3.2.1 Agreed-upon Compelling Purpose

GAVI had a clear mission statement to which all partners were and remain committed: "To save children's lives and protect people's health through the widespread use of safe vaccines, with a particular focus on the needs of developing countries." There has been less agreement among partners, however, about specific strategies to be employed. Interviews indicate unresolved tensions regarding GAVI strategy along three key themes:

- The importance of introducing new higher cost vaccines in developing country versus strengthening country immunization systems to expand coverage of existing vaccines.
- The need to achieve rapid uptake of new vaccines versus the need to ensure sustainability of

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⁷³ Assessing the Impact of Global Health Partnerships. DFID Health Resource Centre.

⁷⁴ World Bank. 2007. Sourcebook for Evaluating Global and Regional Partnership Programs, Indicative Principles and Standards. IEG-World Bank. 2007.

⁷⁵ USAID Capacity Project, 2006. Using Collaborative Approaches for Reaching Human Resource For Health Goals.

⁷⁶ GAVI. 2000. Guiding Principles of the Global Alliance for Vaccines and Immunization.

GAVI investments.

Pursuit of a global agenda for immunization (e.g. selecting certain key vaccines to focus on, in the interest of increasing production and lowering costs) versus accommodating country desires for vaccine priorities (e.g. measles, yellow fever).

Over the course of Phase 1, GAVI altered its priorities among these areas based upon early experience and on shifting power among partners (e.g., increased board membership by bilateral donors has resulted in greater attention to health systems), but as stated earlier, GAVI has also relied on a degree of "constructive ambiguity" in its decisions to gloss over potential differences between partners.

5.3.2.2 Strong Participatory Leadership

Strong, participatory leadership is a critical factor in the success of any partnership. From the very start, leaders need to demonstrate their eagerness to develop collaborative relationships and to build shared ownership of the challenges and outcomes. Leaders must see the potential of the partnership and communicate this vision in inspiring ways.⁷⁷

The effectiveness of the GAVI Board in decision-making varied over the course of Phase 1, depending on the Board Chair and the member dynamics. Given this scenario, the role of the Executive Secretary of the Secretariat was critical. Respondents felt that the Executive Secretary possessed attributes that were particularly relevant during this early period – diplomacy, low-profile stature, openness to others' opinions – enabling him to create consensus and maneuver through contentious issues without damaging relationships. As leader of the WG, he presented WG recommendations to the Board as he saw fit, and because of the ambiguity in Board decisions, he had a great deal of freedom in interpretation, but according to informants, he did so in ways that were satisfactory to most of the partners.

5.3.2.3 Clear and Transparent Governance Structures

The Alliance in Phase 1 placed a high priority on wide participation, although there was not always complete transparency in decision making. For example, the WG, which included broad partner representation, and where much of GAVI's early strategies and programming decisions originated, was referred to by some as a "black box" because of perceived lack of transparency on how decisions were made; but at the same time, it was hailed by others as "the crucible in which the spirit of the alliance was born."⁷⁸

GAVI was able to make decisions quickly, despite the participatory nature of its governance, partly because of its lean management structure. Its other advantages were the availability of sufficient funding to avoid making difficult investment choices, along with a key contributor (the Gates Foundation) that was more willing to take risks than government donors would have been. Over time, as the international community gained confidence in GAVI, the pressure for quick action and quick results was somewhat reduced. The Alliance Board became more concerned about careful review of proposals, increased stakeholder participation (especially from developing countries), and appropriate management of the growing programs. Interviewees indicated that the pace of decision-making slowed over the course of Phase 1, compared with the earlier years when decision making was extremely rapid.

Despite governance structures that were not always clear or transparent and subject to frequent adjustment during Phase 1, GAVI was able to engage its partners to take action. For the most part, GAVI's internal

⁷⁷ Training Resources Group. 2001. Selecting Partners: Practical Considerations for Forming Partnerships. Tips and Tools Series: Collaborative Alliances.

⁷⁸ Quote from a key informant interview.

management structure increased, while subsidiary partnership groups like the WG and task teams have decreased. As a result, some partners felt that by the end of Phase 1 GAVI began to function more like a separate organization and less like an alliance. Some partners feel there were increasingly fewer opportunities to participate in GAVI, diminishing partner enthusiasm and commitment.⁷⁹

5.3.2.4 Processes: Roles and Responsibilities, Communications

There has been no clear definition of what each partner is expected to bring to the Alliance, beyond those of the founding partners described above. We were unable to identify documentation that clearly spelled out the responsibilities of each of the partners, except for MOUs between GAVI and UNICEF regarding housing of the Secretariat and for activities described in the annual work plans. Each of the Board members interviewed had a clear sense of the value that his or her organization brought to GAVI, but these views were not necessarily shared by other partners; consequently, there were misunderstandings between partners regarding their respective roles and responsibilities.

Two examples of sub-optimal results due to this lack of clarity relates to the role of the vaccine manufacturers, and the role of UNICEF in advocacy. While virtually all partners recognized the importance of engagement with vaccine manufacturers, there remains a degree of misunderstanding and distrust among the public-sector partners about the vaccine industry's objectives and potential contribution. Issues related to lingering concerns about conflict of interest, unclear expectations of the manufacturers, and limited understanding of their potential inputs were never resolved. Similarly, several respondents noted that UNICEF was responsible for coordinating advocacy efforts. Although we found limited information as to their expected role and activities by which to judge their outputs, the general perception of respondents is that UNICEF underperformed in this respect.

While communications procedures continued to improve over the course of Phase 1 (as will be discussed later), broad partner participation was reliant more on informal mechanisms than formal communications channels. Informal communications occurred between the Secretariat and Board members, within the WG and task teams, as well as within RWGs and country ICCs. Formal communications between the partners primarily occurred during Board meetings, and in advance of Board meetings, with the Secretariat sending Board members large amounts of documentation to support their recommended actions. Board members who were not represented in the WG or other task teams, and who did not have staff to digest these materials, could not realistically participate fully in decision-making. Given the number of actions to be approved at the Board meeting, that forum could not be used for substantive discussion or debate.

5.3.2.5 Power Equity among Key Partners

Full and equitable partner participation was an important theme that characterized GAVI Alliance throughout Phase 1, and several of the enacted governance changes (in Board representation and in establishing membership and rotation rules for WG and task teams) were intended to achieve that. While much authority and control remained in the hands of the permanent partners on the Board, other partners

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⁷⁹ As the 2002 McKinsey study, "Developing Successful Global Health Alliances", points out, this problem is not unique to GAVI. "Global health alliances, with their desire for consensus, are prone to having too many people involved in decisions, too little individual accountability for decisions, and therefore slow decision-making. To overcome this problem without putting too much power in the hands of a few, it can be quite useful to develop a roadmap for how the alliance will make its 10 to 15 most important decisions. (GAVI website.)

80 This view was reflected both in interviews carried out by the evaluation team, and in the HLSP "Evaluation Framework:

This view was reflected both in interviews carried out by the evaluation team, and in the HLSP "Evaluation Framework: GAVI Alliance and GAVI Fund Phase 1", November 2006, which identified lack of clarity about the roles of different GAVI partners and questions about the involvement of manufacturers in the GAVI Alliance as areas of concern. (pages 19-21).

and stakeholders were included and their opinions were heard and heeded. Most partners felt that Gates Foundation, even though it brought substantial resources, was careful not to dominate decision-making. In general, there was good partner representation on the GAVI Board, the WG and task teams, however, some of the bilateral partners that did not have Board or WG representation did not feel sufficiently included.

Interviewees also pointed to two groups that have been underrepresented on the board, and have not been able to fully represent their constituencies – recipient countries and civil society. Key informants reported that developing country participation on the Board has been inconsistent – occasionally there were very active Board members from developing countries, but more often than not they were rather inactive. Most times, Board members from developing countries did not have the resources they needed to be informed and play a strong role on the Board. Further, there is no regular mechanism for developing country representatives to inform or obtain feedback from the recipient countries who they are supposed to represent. Given the vast differences among the recipient countries, it is unrealistic to expect that three or four developing country Board members can effectively represent all recipient countries, without a regularized, formal process to keep them in regular contact with their constituency group.⁸¹

It was also difficult to engage developing country representatives in the WG, as it represents a significant time commitment, in addition to their in-country responsibilities, and these WG members did not view themselves as representatives for all recipient countries.

Some respondents also noted potential benefits from reaching out to the large countries for which GAVI funds are capped. These countries could play a larger role in GAVI's policy discussions and development, because improving immunization coverage in these countries is essential for achieving MDG 4. It was also suggested that GAVI engage countries not eligible for GAVI funding by virtue of income status, as they may have a great deal to offer in terms of their experience in immunization programs – specifically, the Latin American countries were suggested.

Civil society has been underrepresented in GAVI, but has a great deal to offer. Civil society organizations play a significant role in expanding the health infrastructure and providing services at country level, and can play an important advocacy role within GAVI. The new CSO funding window that was created after Phase 1 provides a good opportunity to engage them, and most country representatives interviewed talked about plans within their ICCs to increase the role of CSOs. International CSOs also have a very important role to play in global advocacy for immunization. Though GAVI has one international CSO seat on its Board, this may not be adequate to take advantage of the vast implementation experience and strong lobbying skills that CSOs can bring to bear.

All respondents felt that active, committed partners were essential to success, and wanted to make sure the practices in Phase 1 that proved so valuable in solidifying the partnership are continued. Principal among these are continuing the quest for feedback and for identifying problems and making improvements, staying open and transparent, looking for ways to keep partners involved and committed, and communicating in ways that strengthen trust and understanding.

5.3.2.6 Trust between Partners

GAVI's great success was that it has effectively brought together different stakeholders to find common ground to make progress on the goal they are all committed to achieve. As partners have learned how to

⁸¹ At the 20th Board meeting in May 2007, The Board agreed upon a set of measures to strengthen developing country participation, including GAVI contracts for support people to help prepare Board members for meetings, IT support when needed, and occasional retreats for Ministers of Health. These changes may help to resolve some of the problems identified.

work together, within GAVI and within other public-private health partnerships that have emerged, trust among partners has increased. This is the conclusion of the vast majority of people interviewed for this assessment, who consider its success in bringing partners together one of GAVI's greatest added values. However, lack of a clear and widely-understood delineation of the roles and responsibilities of the individual GAVI partners has contributed to some level of lingering distrust among some members.

The role of two core partners – WHO and UNICEF – as both decision-making Board members and implementing agents for GAVI activities leads to some concern by other partners, who are uneasy about the potential conflict of interest involved in having GAVI partners making decisions to provide funds for their own agencies. UNICEF receives GAVI funding to absorb costs of housing the Secretariat (although this will no longer be the case under the new administrative structure), and for the costs of carrying out vaccine procurement; WHO obtains GAVI funds to carry out some of the technical support it undertakes on behalf of GAVI. Some partners point out that WHO centrally has reduced its own funding for immunization and increasingly relies on GAVI funding to carry out core activities. The overall changes in funding flows that concentrate donor funds for immunization within GAVI also contribute to this situation. Suggested responses to this conflict include convening a separate IRC review of the workplan to affirm that funding going to WHO and other GAVI partners is appropriate.

Key informants had differing views on the role of vaccine manufacturers and their contribution to the Alliance. Some partners felt that industry has not contributed as expected, stating that while industry members have played active roles in task teams, their role on the Board has been less to contribute than to protect their own interests. On the other hand, industry representatives believe they have demonstrated commitment by providing GAVI the lowest global vaccine prices and engaging in contracts where the manufacturer bears significant risk. In return, industry has been sidelined over time, and with the decreasing importance of the WG and task teams, their opportunities to participate have been further reduced. This issue was also pointed out in the mapping study in 2006.⁸² There are also different views regarding the extent to which GAVI should work with multinational manufacturers on new and emerging vaccines, versus with developing country manufacturers to increase supply and lower the price of existing vaccines.⁸³

Lack of understanding on both sides has limited the effectiveness of vaccine manufacturers as partners. Inappropriate expectations may also account for part of the problem – expectations that manufacturers' participation would mean lower vaccine prices were misguided. At the beginning of GAVI, manufacturers committed to contributions in the areas of supply, education and social mobilization, and development of new vaccines and related technologies. It is unfair for the vaccine industry to be held accountable for results it has not agreed to, and are not necessarily in their own interests. Whether the contributions made by manufacturers are sufficient to warrant a partnership role can be subject to debate, however, as it is not clear whether GAVI derives additional value by engaging them as partners, over and above the benefits of collaborative supplier relationships. At the same time, increased input from vaccine manufacturers may be useful in areas such as designing incentives to promote development of new vaccines for developing countries, reducing barriers to market entry, or facilitating technical partnerships that could reduce the cost of vaccine production. More dialogue and explicit delineation of the specific areas where the vaccine manufacturers can add value is necessary.

Organizational change is always threatening, whether small incremental changes that characterized Phase 1, or the major change GAVI is now undergoing. Constant changes in the governance and management

⁸² Druce, Nel, Martine Donoghue, Cheri Grace and Veronica Walford. 2006. Immunization – Mapping the Bigger Picture, Final report to GAVI roles and responsibilities task team. HLSP.

^{83 &}quot;HLSP, 2006. Evaluation Framework: GAVI Alliance and GAVI Fund, Phase I.

⁸⁴ Druce, Nel, Martine Donoghue, Cheri Grace and Veronica Walford. 2006. Immunization – Mapping the Bigger Picture, Final report to GAVI roles and responsibilities task team. HLSP.

structures exacerbate any underlying trust issues – no sooner does a partner become accustomed to a newfound position on a task team than that task team dissolved. As the Secretariat grew, it became less clear to some partners whether the Secretariat served the Alliance or was yet another partner, which raised additional concerns regarding trust between the Secretariat and GAVI partners. Respondents from the Secretariat are very clear that their mandate is to consult with partners, support participation, and increase transparency in the organization. Nonetheless, comments from some partners about perceived lack of transparency make it clear that the Secretariat needs to make special efforts to ensure that its work is viewed as fair and impartial, in support of all the Board members and the common objectives of the Alliance.

5.3.2.7 Mechanisms for Holding Partners Accountable

To ensure a successful alliance partners must fulfill their responsibilities and commitments in a timely and high-quality manner. Accountability can be undermined when partners fail to carry out planned activities or do so poorly. GAVI, like many alliances, has not been able to hold partners entirely accountable for carrying out their commitments. Respondents noted that partnerships like GAVI do not work so well without a formal system of accountability for partners – work plans, deadlines, deliverables, and sanctions for non-performance.

Reflecting on Phase 1, some interviewees felt that GAVI probably accomplished more in the end by relying on the Secretariat than if the Board had dedicated more effort to making sure that partners followed through (e.g. giving the Secretariat greater responsibility for advocacy activities as partners were unable to do so effectively). Others noted when GAVI did try to hold partners a bit more accountable for performance and put the spotlight on certain performance gaps, although it made some feel uncomfortable, performance did improve. Respondents noted that if GAVI is to be an alliance and not an operational entity itself, it must respect the operational roles of the partners and find mutually acceptable ways to ensure accountability but not supersede those responsibilities.

5.3.3 Effectiveness of the Partnership

GAVI deserves great credit in gaining and maintaining the commitment of partners, and for continuously seeking ways to ensure that key stakeholders had a voice. Among the partners interviewed for this evaluation, their pride in GAVI's achievements and their own role in it was almost universal. Among outside observers interviewed, there was agreement that GAVI has minimized the criticisms often lodged at global health partnerships, such as excessive skewing of country priorities, depriving developing country partners of a voice in decision making, and poor harmonization. GAVI's success in this respect reflects the fact that major stakeholders, including developing countries and the vaccine industry, were included in decision making.

While creating the partnership was a great achievement, it has not come without costs. Ensuring commitment from all partners required some degree of "constructive ambiguity" regarding roles and responsibilities and strategic objectives, which made it difficult to hold partners accountable; maintaining a minimalist Secretariat in order to encourage partnership participation made it difficult to manage the growing programs. During Phase 1, the effectiveness of the partnership rested on the compelling common purpose, trust and commitment from partners, and strong leadership, which made up for shortfalls in areas such as clarity of partner roles and responsibilities, clear governance structures, and accountability mechanisms.

Everyone seems to want GAVI to succeed. While it may never be possible to eliminate all of the "constructive ambiguity" that helped bring partners together in Phase 1, its negative consequences may now exceed its benefits. However, the challenge will be to find ways to formalize relationships and

responsibilities without losing "some of [the] magic and the initial enthusiasm that made the partnership possible." There is a need for GAVI partners to define their respective roles and responsibilities to the partnership more clearly, to institute some mechanism to ensure that they can undertake those responsibilities and be held accountable for them, and to ensure that there are sufficient opportunities for partners to participate in GAVI's decision-making. As GAVI undergoes its current restructuring, the Secretariat has a major role to play in reaching out to all its stakeholders, and ensuring the trust of members in the partnership by making sure that the process of reshaping GAVI is transparent to all.

GAVI was successful in gaining and maintaining the commitment of its partners, and continuously sought ways to ensure stakeholder input. The effectiveness of the partnership rested on the partners' common purpose, trust and commitment, and strong leadership, which made up for shortfalls in areas such as clarity of partner roles and responsibilities, clear governance structures, and accountability mechanisms. The challenge will be to find ways to formalize relationships and responsibilities without losing the initial enthusiasm and commitment that made the partnership succeed.

⁸⁵ Buse, Kent and Andrew Harmer. 2007. "Seven Habits of Highly Effective Global Public-Private Partnerships: Practice and Potential." *Social Science and Medicine* (64) 259 – 271.

6. MANAGEMENT APPROACHES

In this section, we analyze the effectiveness of GAVI's management approaches. In addition to examining GAVI's decision making and communications processes, we also examine how GAVI managed its support to countries and other global activities.

6.1 Strategic Decision Making Approaches

To examine GAVI's strategic decision making in Phase 1, we reviewed GAVI internal documentation that described the process, and changes to the process, as well as documentation and accounts of how specific decisions were made. In addition, we interviewed key informants to get insights on actual practices, as well as their perceptions of the roles of various Board members and organization structures. Lastly, we assess how organizational changes might affect future decision making.

6.1.1 Earlier Decision Making Approaches

GAVI's original mission, strategic objectives and milestones had been developed for the Proto-board meeting in 1999, and were adopted by the GAVI Board. Over the course of Phase 1, changes were made to better link its objectives and milestones with MDGs and other globally-accepted targets.

During GAVI's first years, there was little focus on setting strategic directions, or using strategic objectives to drive decision making. Board members were mainly focused on figuring out the role of the Alliance vis a vis the partners, how the partners would work together, how to achieve consensus, and how to conduct themselves around the board table. Nor was there a great need for strategic decision-making on investments. The resource envelope was large thanks to the Gates Foundation grant and the growing donor contributions. There was a perceived need to show results quickly, and the strategic objectives that seemed most straightforward were to expand existing immunization coverage and to introduce underused vaccines. Among new vaccines to promote, there were really only Hep B, Hib, and YF. Injection safety and logistics issues led to the decision to focus on combination vaccines and the addition of injection safety support. In essence, these were the core strategic decisions made at the beginning of GAVI.

A key GAVI principle, reflected in virtually all of its documentation, was full participation of all partners to the alliance. Though not reflected in formal documentation, there were two other implicit principles, understood by the partners that guided GAVI's decision-making in the early years:

- Quick decision-making, since one of the reasons for forming GAVI was that funneling these new resources through existing partner institutions would be a slow, bureaucratic process;
- Quick results, in order to demonstrate the value of GAVI to existing and potential donors, and because of the urgency of meeting immunization needs of children in developing countries.

GAVI Alliance Initial Goals and Milestones (preliminary from the Protoboard meeting, and amended as noted)

Mission: To save children's lives and protect people's health through the widespread use of safe vaccines, with a particular focus on the needs of developing countries.

Strategic objectives (summarized):

- To improve access to sustainable immunization services;
- To expand use of all existing cost-effective vaccines and (added 2001) promote delivery of other appropriate interventions at immunization contacts;
- To support national and international disease control targets for vaccine-preventable diseases; (added 2001)
- To accelerate the development and introduction of new vaccines;
- To accelerate research and development for vaccines and related projects needed by developing countries:
- To make immunization coverage an integral part of the design and assessment of health systems and international development efforts.

Milestones:

- 80% of countries with routine immunization coverage in 80% of districts by 2005 (*Revised 2003 as follows*) By 2010 or sooner all countries will have routine immunization coverage at 90% nationally with at least 80% coverage in every district.
- Hep B introduction in 80% of all countries with adequate delivery systems by 2002; in all countries by 2007
- Hib introduction in 50% of the poorest countries with adequate delivery systems by 2005
- The world to be certified polio-free by 2005 (this milestone was added 2001, and amended 2003 as follows) The world to be certified polio-free by 2008.
- Clinical trials for rotavirus and pneumococcus completed and a means to ensure their availability by 2005.
- During 2000 the Global Alliance should present an analysis of potential benefit, current market and
 policy failure in the level of research, development and commercialization of candidate vaccines for
 HIV/AIDS, malaria and tuberculosis, and should make recommendations for financial and
 institutional mechanisms to overcome these problems. (*Milestone was dropped in 2001*)

The early Board relied on the Secretariat, which in turn relied on the WG (whose members had already been working together for some time and for the most part knew each other well) to analyze program options and provide recommendations. Still, most informants concluded that the Board was by no means a rubber stamp – WG members had institutional links with Board members, and briefed their Board members in advance of meetings. However, those Board members that had no representation on the WG, such as some bilaterals and developing country members, considered the decision-making process less than transparent. Behind the scenes, some respondents felt that the four permanent members (the Gates Foundation, UNICEF, WHO and the World Bank), and particularly the Gates Foundation by virtue of its generous grant, had the greatest influence on GAVI's strategic directions.

One of the strengths which most informants to this evaluation found in a decision-making process that relied so heavily on the WG and other task teams is that it provided a "space" outside of their home institutions where partners could debate, challenge each other, try out new ideas, and eventually achieve consensus on a GAVI approach. While Board members could never really take off their institutional hats, members of the WG and task teams had more flexibility to do so; some felt there was less pressure to represent their institutional interests within these groups. The result, many believe, was a pioneering,

can-do outlook by team members that contributed to some of GAVI's important decisions and innovations:

- The initial decision to offer funding to all GAVI eligible countries, rather than starting with a few pre-selected countries in a pilot mode.
- Performance-based funding for ISS, which allowed countries flexibility to use funds as they deemed appropriate, but based future funding on performance, with verification by a Data Quality Audit (DQA) to ensure reliable data.
- A strong emphasis on injection safety.
- Introduction of Financial Sustainability Plans (FSP), which country representatives consider very important in putting a focus on the financial implications of vaccine introduction.
- Transition to three-year procurement contracts by UNICEF, to provide assurances to industry that increased production of vaccines was warranted.

While not all of these ideas necessarily originated with the WG or task teams, those groups nurtured the ideas, and adapted and endorsed them for GAVI's use.

There were downsides to reliance on the WG and task teams as well. Not all task forces operated effectively. For example, the Advocacy Task Force's proposed strategy was never approved by the Board, and it was criticized for failure to define its vision for a global advocacy role related to GAVI's goals, too much focus on one-off events, and insufficient attention to supporting and learning from country level action.⁸⁶ The WG's deliberations were not always considered transparent by Board members.

As GAVI's resources and programs grew, decision-making became more complex and the Board demanded heavier involvement in the details and analyses of decisions it would take. New issues for Board consideration emerged as well:

- With the pressure to show immediate results reduced, there was renewed interest in health systems.
- New vaccines were entering the market that may be appropriate for GAVI countries.
- There was greater recognition that for GAVI to influence vaccine markets positively (attract new entrants and increase competition, resulting in lower prices) it would need to provide assurance of global funding for longer than five years.
- It became clear that WHO could not take on all the country-level responsibilities for technical leadership in GAVI programs without support from GAVI.

Governance changes were made in 2003 that altered the decision-making structure. The institution of an Executive Committee (which again included the four permanent members of the Alliance, as well as one member from developing countries and one from an OECD country) responsible for strategic decision-making helped to flag and resolve many issues outside of regular board meetings. Many of the task teams were replaced by a smaller number of standing committees. The WG's role was redefined to reduce its responsibilities.

⁸⁶ Feek, Warren. 2002. Review of the GAVI ATF. The Communications Initiative.

6.1.2 Introduction of Investment Case Approach

As GAVI attracted more resources from more donors, and as new ideas germinated for use of these funds, GAVI realized that it needed a more systematic approach to investment decisions. The World Bank took on the responsibility for developing the investment case format, based its internal approach to project proposal decisions. Investment cases were to be used for large resource allocation decisions, rather than country proposals, and were generally to be applied to commitments of \$300 million or more.

Investment cases were first used in 2004, and their first four applications were evaluated in 2005. The findings from that evaluation are consistent with findings from informants in this study.⁸⁷ Investment cases had been intended to be the second part of a two-phased process, in which the first phase was to determine funding levels for an overall investment "window" (e.g. new vaccines, immunization services support).⁸⁸ Investment proposals for each window could then be assessed and compared, so that the soundest, most cost-effective proposals could be selected.

In fact, however, the investment windows were not pre-determined, and proposals came in and received consideration one at a time. Therefore there was no opportunity to compare one potential investment to another. Investment cases were prepared by proponents, so they sometimes read like advocacy documents rather than impartial analyses. The IRC did not have enough time to research and confirm the assumptions behind the investment case analyses, even when they found some of them to be questionable.

Nonetheless, investment cases have enabled the Board to engage in a much more informed and critical discussion of potential investments. The process of developing and reviewing investment cases involved outside experts as well as a great deal of partner dialogue, so individual decisions were better because of the use of the investment cases, but the broader framework for investment decisions was lacking. Most informants believe that investment cases or similar analyses should continue to used, but within a strategic framework for investment decisions, timed so that alternative uses of funds may be compared, applied consistently to all appropriate investments, and given sufficient time and resources for the IRC to conduct a thorough review. There is no consensus as to whether investment cases should be used for all types of investments or just for vaccine-related investments for which cost-effectiveness can be more easily calculated, however, some form of analytical review is needed for all investments.

6.1.3 Absence of a Strategic Framework for Resource Allocation

Until GAVI developed a five-year Strategic Plan at the end of Phase 1, there was no well-defined framework to guide long-term investment decisions. The broad objectives and milestones that GAVI accepted and adapted at its inception were global objectives that had been originally developed for the CVI, based upon goals and objectives from the World Health Assembly and the World Summit for Children. While these were a good starting place, some respondents to this evaluation felt that there was not a good analysis of what GAVI's contribution to those objectives might be, nor were there time-limited goals and quantitative milestones set for GAVI-supported programs. 90

GAVI did not state clearly the expected results of its investment strategy, nor did it identify priority areas for investment. Based on financing to date, however, promoting new vaccines took priority over the other objectives. The absence of clear objectives and milestones, with appropriate resources apportioned to each, may reflect the lack of agreement among partners on priorities. While the partners all shared

⁸⁷ Donahue, Martine, and Mark Watson. 2005. Lessons Learned from Investment Case Approach. HLSP.

 $^{^{88}}$ Based on discussions in Board reports and key informant interviews.

⁸⁹ Protoboard meeting minutes and comments from interviewees.

 $^{^{90}}$ This has changed in Phase II. The 2007–2010 GAVI Roadmap includes detailed targets to measure GAVI's contributions.

commitment to GAVI's overall mission of saving children's lives through immunization, there were, and continue to be, two schools of thought as to how to proceed. Some partners favored placing greatest emphasis on acceleration of new vaccine introduction, while others believed that focus on strengthening the system within which immunizations are delivered was the top priority to maximize delivery of existing vaccines. Here again, the partners allowed for a certain amount of "constructive ambiguity" in the interest of reaching consensus, since there were ample resources to address both new vaccines and immunization delivery system issues.

Until the introduction of the investment case approach in 2005, GAVI had no formal framework to guide decision making. The investment case approach instilled rigor to analysis of new activities, but its value was limited by the absence of a strategic framework for resource allocation.

6.1.4 Balancing a Global Agenda with Country Priorities

As a global health initiative with a defined mission, GAVI's global agenda takes precedence over individual countries' expressed needs. In fact, all disease- or intervention-specific global health initiatives by definition pursue their own agenda, and in doing so tend to skew country resource allocations.

GAVI has made special efforts, however, to consider country priorities and needs in the way in which it delivers support. GAVI makes funds available for both vaccines and service delivery, but countries are under no obligation to apply. ISS has been designed in such a way as to allow countries flexibility to implement the program as appropriate to their situation. GAVI conducted country consultations and partner meetings to get country feedback, and has increased Board representation by developing countries, and provided these Board members staff and communications resources so that they can serve effectively.

During discussions in RWG meetings and in-depth country visits, respondents agreed that while GAVI's investment priorities were established centrally, they were generally appropriate for GAVI countries. For the most part, GAVI promoted vaccines that were in the country's plans but for which funding was not yet available. GAVI did influence country decisions, but this was generally to improve them, for instance focusing attention on injection safety. In-country respondents generally felt that GAVI has been responsive to country inputs in revising its policies, although they also noted that change did not come quickly. Some examples: GAVI's redefinition of sustainability to include mobilization of donor funds and not just government allocations; GAVI's willingness to extend Phase 1 funding when countries proved unable to take over vaccine financing within five years; GAVI's willingness to make adjustments to ensure data collection requirements are consistent with the country's own data system, and to provide support to countries to make needed improvements in data quality. Growth of the country support staff within the Secretariat has allowed for more one-on-one contact between GAVI and recipient countries, and this has been helpful in many ways.

Nonetheless, there is a perception that GAVI sometimes pushes new vaccines inappropriately – often this comment is directed at Hib vaccine. Originally, GAVI had required that countries applying for Hib vaccine have disease burden data available to justify its use, but this requirement was later removed. Hib vaccine is relatively expensive (approximately \$10 for a three-dose regimen), and its cost effectiveness

relative to the cost effectiveness of investing additional funds for improving DTP3 or HepB3 coverage rates is unclear.⁹¹

GAVI uses its funding policies to encourage countries to adopt new vaccines, by providing hard to resist financial advantages – many countries may apply for pentavalent vaccine simply to receive DTP-HepB for a minimal price. Lao PDR is applying for pentavalent vaccine even though it is unable to finance its existing service delivery costs and has limited strategies for generating additional funds, resulting in a DTP3 coverage rate of 51% in 2007. Country level informants mention that there are staff within GAVI partner agencies that do not fully support these efforts. Whether GAVI's policy incentives are considered inappropriate depends on whether there is universal support for the policies pushed – for example, GAVI pushed countries to improve injection safety, but no informant mentioned this as an area where GAVI was overly pushy. Instead, many informants cited improvements in injection safety as one of GAVI's most important achievements. It would be extremely damaging if recently published articles that mention GAVI specifically as inappropriately aligned with manufacturers to push expensive vaccines on developing countries gain broader acceptance. GAVI's positions and policies were not always widely supported by all staff in partner organizations, nor was there always strong data and analyses to support its policies.

While GAVI was not always accommodating to country needs in Phase 1, most informants believe GAVI did better on this score than many of the GHPs. Even so, informants believe that GAVI did not have an effective way of ensuring that recipient countries had a sufficient voice in GAVI decision-making. Most importantly, GAVI uses its funding policies to promote its agenda, even though there was not always strong evidence that its agenda was technically sound, nor was there universal agreement around that agenda.

Although GAVI has made efforts to consider country priorities and promotes country planning and ownership in some ways, its policies strongly encourage countries to apply for new vaccines. GAVI did not always have strong data and analyses, or universal support, for all its policies.

6.1.5 Changes in Organizational Structure and their Effect on Decision Making

As discussed, GAVI underwent a series of incremental changes to its governance and management structure during Phase 1, and a major change to organizational structure is currently underway. This section examines how changes during Phase 1 impacted the nature of decision-making.

6.1.5.1 Expanded Role of the Board

Over the course of Phase 1, the Board took on an expanded role in detailed review of key issues, rather than relying on recommendations from the WG or task teams. This trend required that Board members invest more time to conduct sufficient due diligence. Because of the increasing number and complexity of issues going to the Board, three Board meetings were required nearly every year, which were also supplemented by numerous teleconferences or electronic board meetings. Further, the number of agenda items for board meetings, and related background papers to be digested before these meetings, has grown. For example, the 13th Board meeting held mid-2004 included an agenda of 16 substantive and technical

⁹¹ We were unable to provide this information due to lack of data on vaccine costs.

⁹² Puliyel, Jacob M. and Yennapu Madhavi. 2008. "Vaccines: Policy for public good or private profit?" *Indian Journal of Medical Research* (127): 1-3.

⁹³ Ramachandran, R. 2008. "Global Push." Frontline: 16-19.

agenda items including review of important investment cases, considering bridge financing of certain vaccines, review of the ISS evaluation, apprving budget items, and considering governance changes. Concerns were raised as to whether Board members were able to give thoughtful consideration to all the issues. Some Board members can rely on their staff and advisors, but others, such as the developing country representatives and civil society representative, do not have these resources behind them.

Creation of the Executive Committee, who dedicate more time to their role on the Board and have taken some of the day-to-day decision-making burden off the other Board members, has helped improve quality of decision-making. This has led to a perspective by some partners, however, that the Executive Committee held too much influence on Board decision-making. Those who have spent more time on an issue and understand it well had an advantage over other Board members who have not.

6.1.5.2 Diminution of the Role of the Working Group and Task Teams

In the early years of Phase 1, GAVI relied heavily on the WG and various task teams to develop its core programs and policies. Division of analytical tasks among a large number of teams meant there was little central management of the activities or understanding of the issues. Some of the task teams had outlived their usefulness yet continued on, creating new tasks for themselves, adding to the confusion and inefficiency. These management difficulties led to reduction of the number, and the scope of responsibilities, of these task teams.

Many partners viewed the WG and task teams as important means for them to participate fully in the partnership. The CEPA study recognized that these entities were "the primary 'fora' in which the partners/stakeholders have coordinated their activities, provided technical advice/inputs, developed strategies, and suggested new approaches to policy and programme delivery." The reduction of these groups may have diminished the role of partners in decision-making – engaging in the partnership through Board meetings does not provide staff at technical levels of partner institutions the in-depth substantive participation that they want. Without substantial partner participation that builds commitment at the technical and implementation level, GAVI may lose the advantages it had in the beginning – the pioneering, challenging spirit that promoted rigorous debate and innovative thinking.

6.1.5.3 Expansion of the Secretariat

Growth of the Secretariat was essential to keep pace with the demands of a larger, more complex GAVI. The original Secretariat was too small – "anemic" and "anorexic" were words used by two informants. The assumption was made at the start that partners should assume as much responsibility as possible, leaving only an administrative and Board-servicing role for the Secretariat. In reality, even with a highly committed group of people in the WG and task teams, partners were not able to take on all the added tasks associated with GAVI. Managing a portfolio of three different funding windows for 75 eligible countries alone is an enormous task, let alone other tasks that were initially left to partners, such as advocacy and technical support to recipient countries. Throughout Phase 1, the Board increasingly authorized additional Secretariat staff in order to manage growing responsibilities.

Respondents perceived that over the course of Phase 1, the Secretariat increasingly took over more responsibilities that were previously shared with the WG and task teams, such as presentation of issues to the Board, and interpretation and implementation of Board decisions. Another perception from respondents is that the Secretariat increasingly relied on internal and non-partner technical expertise, rather than engaging partners.

⁹⁴ CEPA. 2007. GAVI Governance – Development of a preferred option.

There were two potential issues with the Secretariat internalizing and/or outsourcing the analytical work and framing the policy issues. One critical question is not whether decision-making was better, but whether partners felt the same level of ownership of, and commitment to, decisions arrived at in this way. Along with the loss of ownership comes a potential loss of trust, questioning of the analytical basis for recommendations made to the Board, and fears that the decision-making process and the analysis behind it are no longer transparent. The second question is whether GAVI can maintain its positive attributes of being innovative and self-challenging with less partner engagement in technical inputs and policy setting. Internalizing and formalizing an organization's management is a normal function of growth, however, concerns about potential loss of partner coordination mechanisms as the GAVI Secretariat grew were voiced so frequently that they are a cause for concern, given the importance of ownership and trust in a stakeholder-based alliance.

The incremental organizational changes that took place during Phase 1, particularly the diminution of the WG and task forces, and expansion of the Secretariat, may affect partner ownership of decision-making, reducing the level of commitment at technical and implementation levels of partner organization.

6.1.6 Did Decision Making Approaches Result in a Balanced Portfolio?

As discussed in an earlier section, GAVI's policies and requirements for country support resulted in relatively more funding per infant allocated toward LICUS countries, countries with lower DTP3 coverage rates at baseline, and lower income countries. While some of this allocation bias was intentional (during Phase 1 countries with DTP3 coverage over 80% were not eligible for ISS funding), other allocations biases may not have been intended.

While GAVI partners in principle may support providing relatively more funding to these types of countries that represent greater need, there is some evidence that they may not have the capacity to make optimal use of GAVI funding. An evaluation of ISS funding in 2007 found that ISS funding was less effective at improving DTP3 coverage in LICUS countries than in non-LICUS countries. That evaluation also found that costs for immunizing additional children increases at higher coverage rates, thus ISS funding had a larger effect in lower coverage countries. One of the evaluation recommendations was for GAVI to revise the ISS reward mechanism, emphasizing the importance of considering equity objectives, cost effectiveness, resource limitations, as well as GAVI's overall resource allocation policy in this decision.

We examined GAVI's funding disbursements by type of activity, as shown in Figure 23. During Phase 1, NVS represented 64% of the GAVI portfolio under Phase 1. GAVI's two other country support windows are much smaller by comparison, with ISS accounting for 16% of funds disbursed, and INS accounting for 12% of funding disbursed. Overall, 92% of total GAVI program funding went directly to recipient countries.

⁹⁵ Chee, Grace, Natasha Hsi, Kenneth Carlson, Slavea Chankova, Patricia Taylor. September 2007. *Evaluation of the First Five Years of GAVI Immunization Services Support Funding*. Bethesda, MD: Abt Associates Inc.

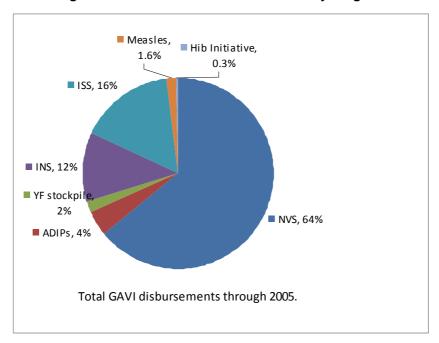


Figure 23: GAVI Phase 1 Disbursements by Program

The picture is similar if we examine funding commitments rather than disbursements. Total funding commitments to recipient countries represent 90% of funding commitments, of which 62% is committed to NVS, 21% to ISS, and 7% to INS.

GAVI's funding allocations were primarily targeted at new vaccines, even though advancing use of underused vaccines is only one of six objectives. Table 21 shows GAVI's strategic objectives, with a corresponding calculation of the proportional funding allocation.

Table 21: GAVI Strategic Objectives and Funding Allocations

Strategic Objective(s)	Portion of Program Funding Allocated*	
1) Improve access to sustainable immunization services	18%	
2) Expand the use of all existing safe and cost-effective vaccines, and promote delivery of other appropriate interventions at immunization contacts	73%	
Support the national and international accelerated disease control targets for vaccine-preventable diseases	4%	
Accelerate the development and introduction of new vaccines and technologies	4%	
5) Accelerate research and development efforts for vaccines needed primarily in developing countries		
6) Make immunization coverage a centerpiece in international development efforts	No specific program to support this objective**	

 $^{^{\}star}$ Funding for INS is allocated across Objectives 1 and 2, proportional to their funding levels.

^{**} Activities that support this objective are recognized as part of GAVI's fundraising expenses. Total fundraising expenses for yearending December 2005 was \$6.35 million, representing 4% of program expenses in that year. Source: GAVI Alliance Combined Financial Statements for the year-ended December 31, 2005.

Based on this analysis, GAVI's funding allocations clearly focused on supporting underused vaccines, and improving access to sustainable immunizations. Given that GAVI's decision making processes under Phase 1 were not always guided by formal structures or strategies, it is not clear whether this is intentional, considering strategic priorities, differences in activity costs, potential impact, and cost-effectiveness, or whether this is by chance, and does not necessarily reflect partner priorities or other considerations.

Under Phase 2 to date, these proportions would change somewhat, given \$800 million has been committed to Health System Support (HSS). But at the same time, GAVI has committed \$1.3 billion to co-finance the Pneumo AMC. Even though the percentage allocations will change, overall funding emphasis will remain on new vaccines.

During Phase 1, 18% of GAVI funding was allocated to increasing access to immunization services, 73% to expanding use of new vaccines, 4% to accelerated disease control, and 4% to accelerating development and introduction of new vaccines. It does not appear that these allocations were based on consideration of strategic priorities, activity costs, potential impact, and cost effectiveness.

6.2 Communications Processes

In order to operate effectively under a governance and management structure as complex as that of GAVI, good communications are critical. Given the reliance on partners for implementation, good communications were required not only between partners at the Board level, but also between partners at regional and country level. Establishing GAVI's strategies and policies not only required agreement within the Board and WG, but also communication to all operational levels of partner organizations. Further, as a stakeholder alliance, some Board members represented not one organization, but many – 75 eligible countries, dozens of bilateral aid agencies, and a myriad of civil society organizations. Mechanisms to ensure appropriate information flows in all directions were required. GAVI partners generally found communications to have improved significantly, but also mention various problems under Phase 1. Data for this section is based on key informant interviews, discussions during RWG meetings with EPI Managers and regional representatives of partner organizations, as well as discussions during visits to in-depth study countries.

Additionally, GAVI was building its communications procedures with recipient countries, as well as managing external communications given the international attention on this new partnership – all within a thinly-staffed Secretariat. The effectiveness of communications in these areas is discussed later sections.

6.2.1 Among GAVI Partners at Global, Regional and Country levels

Communication among partners occurs in the Board, in the WG and task teams, within RWGs, and at the country level in the ICCs. Each of these forums plays an important role in policy-setting and implementation.

Within the GAVI Alliance Board, background information regarding upcoming Board discussions, along with recommended decisions, were distributed by the Secretariat in advance of each Board meeting. The Board members were expected to read and digest a large amount of information (some say at a level of detail inappropriate for a Board) within a short period of time. Many Board members also had organizational representation on the WG or various task teams, so their colleagues/staff participated in preparation of the recommended decisions. Other Board members (mostly bilateral donor organizations) relied on staff support to digest materials and put issues into context. For a third group of Board

members, however, it was difficult to complete all the homework needed to participate fully in decision making. Some Board members suggested that more frequent communications would have been helpful.

The issue for Board members was not primarily whether they were provided a sufficient amount of information, but whether they had the time or support needed to digest the information, understand the decision implications, and provide input. Those Board members whose organizations were also represented on the WG and on key task teams had a definite advantage over those who had no such representation. They had advance knowledge of the issues that these groups were addressing, the views of different partners, where consensus could be reached, and the opportunity to influence the recommendation. Board members with WG representation (with access to in-depth staff support) pointed out that the discussion within the Board meeting often did not represent the complexity of each issue. Thus, it is understandable that Board members whose organizations did not participate in preparing the recommendations felt excluded from what appeared to be a non-transparent decision making process.

Members of the WG all were satisfied with the level of communication within the group, particularly among the most active members who developed close personal relationships. The WG also worked closely with the Secretariat, as the Executive Secretary was part of the WG. What appeared to be lacking was documentation and dissemination of the deliberations within the WG to the broader set of GAVI partners. We did not specifically seek out input from members of various task teams regarding communications within the team.

The RWGs played an important role in partner coordination at regional level and in communicating GAVI policies and requirements to countries. Within the RWGs, partners discussed upcoming country applications, implementation problems, GAVI decisions, and partner support needed to address country issues.

At the country level, most respondents credit GAVI for reviving the ICCs, and using that forum to strengthen partner communication and collaboration. Respondents generally consider relationships and communications between partners at country level to have improved over Phase 1, which was not true in all countries at the beginning of GAVI.

6.2.2 With Operational Levels within Partner Organizations

The process of informing partners at regional and country level of GAVI's newly established programs and policies was quite challenging. In the first few years, decisions were made and policies enacted very quickly. Going back to the 2000-2002 time period, GAVI was in a continuing mode of disseminating information regarding its new programs and procedures (which changed practically on a weekly basis), a sampling of which is listed below:

- NVS support eligibility requirements, vaccines available, length of commitment
- ISS funding eligibility requirements, investment amount, reward mechanism
- Country application process application requirements, submission deadlines
- INS support length of commitment
- One-time support for new vaccine introduction
- Independent Review Committee (IRC) process
- Financial Sustainability Plans (FSPs)
- Annual Progress Reports (APRs)

Data Quality Audits (DQAs)

GAVI programs were to be introduced in 75 countries, relying solely on partners for implementation. Effective mechanisms for communication with regional and country representatives of partner organizations were critical, and yet were not always in place.

During the very initial period, some GAVI partners conducted country visits to present GAVI to country governments and in-country partners. Soon after, there began a series of regional trainings to disseminate information about GAVI policies and procedures to WHO and UNICEF EPI staff, and national EPI Managers. While these meetings were helpful, they did not represent a mechanism for routine communication.

GAVI's partners also were responsible for communicating information about GAVI throughout their own organizations, but this was often rather adhoc. A WG member may communicate with several colleagues in regional offices regarding new GAVI policies; this communication may get forwarded to country level staff, who may mention it with his or her counterparts in-country; these counterparts may go back to their regional and home offices for clarification and guidance. It took some time for GAVI to be placed on the agenda of regular meetings within its partner organizations to ensure relevant new policies and issues were discussed with all staff. Some respondents also felt that UNICEF's and WHO's role as GAVI's representatives in-country was not appropriate because they were limited by the need to maintain good political relationships in-country, and the need to represent the interests of their own organizations.

In Phase 2, with the growth of the Country Support team within the Secretariat, GAVI communicates directly with recipient countries and partner staff in those countries, although there are lingering issues as described in a later section. Also, GAVI's pace has slowed so people have more time to absorb new procedures and policies. Lastly, the GAVI website was cited as a useful information source by country informants, reflecting GAVI financing for internet connections in some cases, and improved internet access overall.

6.2.3 Between Board Members and their Constituency Groups

Some Board members who represent broad constituency groups, in particular developing countries, have no effective means to solicit inputs from their colleagues who are not represented on the Board. Country consultations prior to major decisions by the Board and occasional partners meetings have been valuable, but these do not provide sufficient opportunity for collaboration from recipient countries. In addition, Ministers of Health, who represent recipient countries on the Board, are too busy to spend much time thinking about GAVI's programmatic issues. OECD countries had their own mechanisms for comparing notes, but even among this group, it was unclear whether Board members represented their bilateral institution, or a group of countries.

In recent years, GAVI has tried to address this weakness by providing funding to developing country Board members for staff to assist the Board member, and for regional consultation meetings. Nonetheless, nearly all interviewees agree that the mechanisms in place during Phase 1 were insufficient.

6.2.4 Within the Public Forum

GAVI's website is an important resource for partners at all levels and for the global health community in general. It could be used not only as a tool for advocacy but also for transparent information

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⁹⁶ These meetings were generally supported by the Children's Vaccine Program at PATH in collaboration with GAVI and its partners.

dissemination. Over the course of Phase 1, country level respondents increasingly used this resource for information and clarification of GAVI policies.

At the global level, there was mixed feedback regarding the quality of the website. Some respondents thought it was underutilized as a mechanism for open communication. Results of important decisions, or GAVI-commissioned studies, were not always posted for all partners and the general public, or were posted only after a long time lag. Data on disbursements to countries were not easily accessible. Respondents recommended changes to the website that would make it more valuable to users, and would increase GAVI's transparency, including:

- Placing key documents under more appropriate headings (e.g. Annual Progress Reports fit better under "Performance – Global Results" rather than under "Media and Publications").
- Organizing country data in an easier-to-access format similar to that used by the Global Fund, to make specific country information easier to find.
- Getting results of key studies and board decisions up onto the website sooner.

Effective communication was difficult in the early years because of the large amount of information for dissemination, and the under-developed communications mechanisms. The WG, RWGs, and ICCs played important roles in facilitating communications among partners at all levels. There is room for improvement in communications between Board members and their constituents, and on the GAVI website.

6.3 Management of GAVI Support to Countries

Based on our findings (as detailed in an earlier section), GAVI's support to countries in Phase 1 was quite successful – they were readily accepted by countries, achieved measurable results, and contributed to GAVI's strategic objectives. This section examines GAVI's management approach to see whether there are lessons that can contribute to even better outcomes in this area. The focus, however, is limited to the questions posed in the RFP.

GAVI initially had no structure or staff within the Secretariat to manage its country support mechanisms. It relied on the Task Force on Country Coordination (TFCC)⁹⁷, working together with the WG, to develop its application and review procedures, and support countries to undertake expanded immunization programs. An IRC reviewed country applications under the oversight of the WG. RWGs and GAVI partners' representatives on country ICCs also supported country application and implementation. It was not until 2003 that it created a small Country Support team within the Secretariat. This team was responsible for processing country proposals and monitoring progress, including communicating directly with recipient countries, answering their questions, and helping to ensure that they received the technical support they needed. The Country Support team has grown since 2003, and recipient country representatives interviewed consider this a valuable improvement.

6.3.1 Communication with Countries

Communications from GAVI to recipient countries have improved significantly since the Secretariat's Country Support team has been expanded, but issues remain. GAVI official communications go directly to the Minister of Health, with electronic copies transmitted at the same time to RWG members and ICC

⁹⁷ The TFCC later was known as the Implementation Task Force.

members. Although this is useful in maintaining high level awareness, it has sometimes resulted in delays if people required to take action were not informed on a timely basis. For example, the Secretary General in DRC and the Permanent Secretary in Malawi were critical players but wee not routinely informed of GAVI communications. In DRC, different MOH departments are responsible for different GAVI funding windows, and the right department does not always receive information needed. In Laos, a new WHO EPI Officer who has been in his position for approximately six months has not yet been added to the GAVI mailing list. Absence of communications to countries on funding transfers was a criticism highlighted during country consultations in spring 2005, and remained an issue for country informants to this evaluation. The problem of delayed or inadequate translation of GAVI policies, application guidelines and other important documents was raised both in discussions at EPI Managers meetings and in two in-depth study countries had also been raised during previous GAVI evaluations, yet still has not been addressed adequately.

In the beginning of GAVI Phase 1, the RWG played a key role in disseminating information about GAVI to countries, and acted as a forum for partners to exchange information. In Indonesia, donors found the RWG more useful than the NIP. In Laos, respondents thought the RWG greatly strengthened the collective voices from countries in the early years. More recently, with the expansion of the Secretariat's Country Support Team, there is more opportunity for direct communication with GAVI through email, or with representatives of the Country Support team that routinely attend RWG meetings. Informants in indepth study countries note they tend to get information directly from GAVI these days.

Despite many improvements over Phase 1, information continued to get lost. A concern for country officials is that while they receive the results of IRC deliberations about project proposals, they do not receive a detailed explanation of the rationale for these decisions. Their questions go to the Country Support liaison at the Secretariat, who may not be fully conversant with the IRC's deliberations. At the same time, countries sometimes make requests to GAVI within their proposals to consider changes to program criteria. While the IRC's country-specific findings and recommendations go to the Board, discussion of these larger issues sometimes do not. During country visits, respondents in Uzbekistan and Laos, including some senior officials at partner agencies, felt that communications only went one-way and there was little opportunity to provide feedback to GAVI policies or be involved in their development. On the other hand, respondents in Malawi perceive GAVI to be very responsive to their needs and concerns.¹⁰⁰

6.3.2 Monitoring and Evaluation

GAVI's monitoring and reporting requirements at country level are minimal, compared with other donors. It primarily relies on two tools for monitoring of progress in-country – the Data Quality Audit (DQA), the Annual Progress Reports (APR), and WHO-UNICEF estimates. The one-time DQA reviews the accuracy of reported data – 80% verification of reported data is required for countries to receive ISS reward funds. The APRs provide information of ISS expenditures, children vaccinated, wastage rates, etc. The DQA is meant to verify that what is reported in APRs is reliable. There were some respondents at country level that found the DQA tool, and the way it was implemented, to be insufficient as an instrument for verifying coverage.

Generally, countries perceive GAVI's monitoring and evaluation requirements to be appropriate – of the in-depth study countries, Uzbekistan, Indonesia, and Malawi found GAVI's reporting requirements were

⁹⁸ HLSP. 2005. Lessons from GAVI Phase 1 and Design of Phase 2: Findings of the Country Consultation Process.

⁹⁹ Translation issue was raised during discussions in Mali and Uzbekistan, and during EPI managers meetings in West and Central Africa.

¹⁰⁰ It should be noted that the Minister of Health for Malawi during much of Phase 1 was a GAVI Board member.

reasonable. Much of the information requested by GAVI was already required by WHO/UNICEF through the Joint Reporting Form, and therefore not a burden on countries.

One of GAVI's initial operating principles with ISS funding was that NIPs, together with their donor partners, would program, manage, and monitor the use of funds as appropriate. GAVI set no rules or guidelines regarding how the funding should be used or administered. Most countries used existing financial management systems (primarily through MOH, but sometimes WHO). GAVI had no mechanism for monitoring that funds were used as planned or as reported – it relied solely on its partners working through the ICC. In most countries, this flexibility was very effective for allowing funds to be allocated to the priority needs, as well as creating ownership by all partners, including in-country health officials at all levels – and created no financial management problems.

In some countries, the in-country mechanisms were insufficient for monitoring use of funds effectively. During country visits, respondents in Laos, Mali and DRC raised concerns regarding weak monitoring of ISS funds and lack of accountability. In Mali, the NIP had little control over financing because of their position within the MOH, and the ICC was not functioning well. In DRC, greater problems regarding the misuse of ISS funds led to an external audit of ISS funds and removal of key NIP staff members. Although ICC members were aware of these issues in 2004, they nonetheless signed the APR indicating concurrence with the reported information. Respondents in Laos also suggested more stringent oversight at country level would have been useful. While the country selection purposefully included countries with previously known management issues, these examples highlight a need for GAVI to develop a mechanism to monitor funding use better, without compromising the flexibility that was such a positive attribute of ISS funding.

There were evaluations of GAVI support to countries on a global level. GAVI commissioned two evaluations of ISS funding – one in 2004, and another in 2006/2007. These evaluations examined the results of GAVI's ISS funding on a global scale, and identified country specific factors that may have affected country-level results. While these evaluations provided information from selected study countries, GAVI has not conducted targeted country-level evaluations (of underperforming countries, for example) as part of performance improvement efforts. An evaluation of INS is currently underway, focusing on sustainability after the end of GAVI support. While there is data on the results of GAVI's NVS in terms of additional children immunized, there was no evaluation of components such as program design and implementation, factors affecting uptake, cost effectiveness, country level results or variability in country results. Our current evaluation was to incorporate analysis of cost effectiveness, but lack of required data on vaccine costs prevented such analysis.

6.3.3 Technical Assistance at Country Level

Technical assistance to recipient countries is provided by GAVI partners, partially funded through the GAVI workplan. As with M&E, GAVI relies on its partners with country presence to coordinate technical inputs at country level, and does not directly intervene. The ICC has been an effective mechanism for promoting collaboration among partners, however, it was not the mechanism for coordinating technical assistance in most countries. Technical needs were generally discussed in a less formal forum (such as within the Technical Working Group or adhoc meetings among partners). In Uzbekistan, WHO and UNICEF both had multiyear workplans (including technical support) corresponding to the EPI strategic plan; the ICC was more important in coordinating TA for new and adhoc activities such as GAVI applications and supplementary immunization activities.

¹⁰¹ Chee, Grace, Natasha Hsi, Kenneth Carlson, Slavea Chankova, Patricia Taylor. 2007. *Evaluation of the First Five Years of GAVI Immunization Services Support Funding*. Bethesda, MD: Abt Associates Inc.

The process for identifying technical assistance needs or responding to those needs was quite varied across countries. Overall, it appeared that short-term technical needs to develop specific activity plans were adequately met – for example DRC received external TA for the development of the Financial Sustainability Plan, the Hib introduction Plan, the Data Quality Audit, the comprehensive Multi-Year Plan, the cold chain rehabilitation plan, and the pneumococcal introduction plan. Where there was inadequate technical support was in long-term management and capacity building. Both Laos and DRC expressed a need for more long term [resident] technical support to assist with overall management of the NIP.

One of the findings of the 2007 ISS Evaluation was that countries with strong Technical Working Groups (TWGs), comprised of collaborative partners providing strong technical oversight and input in strategic planning, tended to perform better. Another finding of that evaluation was that there was inadequate follow up by the Secretariat to address problems identified or reported in APRs. While most countries performed well with GAVI support, there is not an established mechanism to provide ongoing technical assistance to, and follow-up with, countries that require additional support.

6.3.4 Harmonization of GAVI Funding and Programs at Country Level

Recipient countries generally consider GAVI funding well-aligned with in-country priorities and administrative systems, and well-harmonized with other donors. In all in-depth study countries, the national immunization program (NIP) budgets the use of GAVI funds based on the NIP workplan with partner input, and administers the funding using existing financial management and oversight procedures. GAVI support is well-aligned in that they allow countries to use existing administrative structures and procedures to manage funding.

GAVI was generally harmonization neutral – it did not create fragmentation nor did it improve harmonization; it fit into health systems that were well-harmonized and less-harmonized. While GAVI required coordination mechanisms (ICCs) have improved coordination of NIP activities in some countries, GAVI has not improved coordination between NIP and the broader health system – in most countries the NIP is not well coordinated with the overall health system. GAVI seems to fit into both fragmented and harmonized health systems easily. In Malawi, where donor funding was well-harmonized, funding for NIP at central level was included in the MOH budget, and funding for costs associated with service delivery were included in district health plans. In DRC, where the MOH is still in development, GAVI and the NIP, like most other health programs, operate outside the MOH.

While staff at GAVI partner organizations were aware of discussions related to harmonization of development assistance, representatives from government agencies often had little knowledge or feedback in this area. Respondents perceived GAVI to be well-harmonized because it allowed countries to set priorities and decide funding allocations, and had less stringent reporting and auditing requirements (compared with the Global Fund for example). Some respondents believed that better harmonization cannot occur at country level given the weak capacity within the MOH. Others thought that increased alignment would be a natural progression in health system improvements, but that one organization could not push this process ahead of other necessary improvements.

We also reviewed the OECD indicators for monitoring implementation of the Paris Declaration agreements to see how GAVI performed. The 2006 baseline survey measured aid effectiveness in 34 countries, based on a set of 12 indicators – the data is available by country and by donor. Table 22 shows GAVI's results from the 2006 baseline survey, compared with the global average for the six indicators for which GAVI data were available.

¹⁰² OECD. 2006. 2006 Survey on Monitoring the Paris Declaration.

Table 22: GAVI Performance on OECD Aid Effectiveness Indicators

Indicator*	GAVI	Global Baseline
Aid flows are aligned on national priorities (3)	0%	88%
Use of country public financial management (PFM) systems (5a)	33%	40%
Use of country procurement systems (5b)	2%	39%
Avoid parallel implementation structures (6)	0	1,832
Aid is more predictable (7)	0%	70%
Use of programme based approaches (9)	17%	43%

^{*} Numbers in parentheses denote OECD indicator number. Both GAVI and global results presented are the weighted average results.

Source: OECD. 2006 Survey on Monitoring the Paris Declaration.

On the surface, GAVI scores poorly, but further explanation is warranted. For example, GAVI scores poorly on use of country procurement systems (Indicator 5b) because the large bulk of GAVI country support is for vaccines and injection supplies, for which UNICEF is GAVI's procurement agent. Countries may choose to procure their own supplies, but vaccines procured through UNICEF are obtained at competitive prices, quality is assured, and supplies are highly predictable. For the most part only a few countries choose to procure supplies independently. On the other hand, GAVI's ISS funding is provided in cash to countries, and managed using the financial management system deemed appropriate by the ICC. On the use of country PFM systems (Indicator 5a), GAVI's score is near the global average.

GAVI also scores poorly on alignment of assistance with national priorities (Indicator 3), and on the predictability of its assistance (Indicator 7). Both of these indicators rely on the amount of aid recorded in the government budget as the numerator. Because the bulk of GAVI assistance is disbursed in the form of commodities, it is generally not recorded on government budgets. But even cash funding for ISS is usually recorded at a subnational level, either only within a NIP account, or within an account of the department under which the NIP falls. Given that countries chose to apply for GAVI assistance, and only apply for the programs they want, and that the assistance provided in cash is programmed how and when the country deems appropriate, GAVI is probably better aligned with country priorities than Indicator 3 represents. Based on analysis in Section 4.1, a high proportion of countries received assistance once approved, so GAVI funding is also likely more predictable than its score on Indicator 7 appears.

GAVI generally did not formally participate in program based approaches (Indicator 9) such as SWAps during Phase 1¹⁰³, however, in countries where there are health sector SWAps, planning and implementation tends to follow existing workplans and procedures. Malawi is an example of a country where most in-country officials perceive GAVI to be supportive of the sector-wide workplan, although it is not formally a SWAp participant. Although GAVI's score on this indicator is below the global average, as a whole, it is aligned with sector-wide approaches in countries that have adopted such an approach.

GAVI's approach of relying on the NIP to implement programs should be praised – it has not contributed to any of the 1,832 parallel implementation units (Indicator 6) that exist in the 34 countries included in this survey. While GAVI does not score well based on the OECD indicators, based on responses from country and regional level, as well as more detailed analysis of the indicators, it does act in ways that reflect the principles of the Paris Declaration. Nonetheless, as GAVI countries begin implementation under HSS funding, further analysis to see how to improve adherence to these principles would be useful.

¹⁰³ Although not the rule, there are a few countries where GAVI has contributed to the SWAp basket.

6.3.5 Effectiveness of Advocacy in Countries

There was mixed reaction on whether GAVI has been an effective advocate for immunization in GAVI eligible countries. Although all agree GAVI has increased awareness of governments of the importance of immunization, awareness has not always translated into funding commitments. Some countries such as Malawi and Indonesia received high level visits from the GAVI Executive Secretary, which was seen very favorably because of the increased visibility for immunization. Countries requested that GAVI continue these visits, not only because it highlights immunization, but because it provides access to people at levels higher than the Ministry of Health, such as the Parliament and the President. Other countries such as Mali and Uzbekistan believed that immunization had always been a national priority and GAVI contributed little in this regard.

The ICC has been used in a positive manner to increase collaboration between partners, between ministries, and even between departments within the MOH who normally would not have any other venue for dialogue. GAVI's requirement to involve the MOF is perceived to be quite useful, as that relationship had never before been established. While the MOF may not necessarily make funding allocation decisions, in most countries it is a more powerful ministry, and a good supporter. GAVI is credited with increased collaboration among traditional partners, and extending relationships with new supporters, which is not only important for advocacy, but for increased integration of health services.

GAVI's impact on increasing government funding allocations has been mixed. In Malawi, Mali, Uzbekistan, and Laos, the government has contributed to co-financing of new vaccines. In DRC and Indonesia, it has been more difficult to obtain reliable funding from the government. DRC was only able to co-finance vaccines in 2004 and 2006. Delays in funding releases in Indonesia led to stock-outs in 2004, 2006 and 2007. In Laos, respondents thought GAVI has improved moral commitment, but this has not been supported by necessary funding allocation to deliver services.

Management of support to recipient countries improved significantly over Phase 1, and is generally considered strong. Nonetheless, there was room for improvement related to follow-up of country specific issues identified through evaluations, indicated on APRs, or reported by the IRCs. In-country mechanisms for monitoring use of funds were not effective in some countries. GAVI's largest investment, NVS, has never been subject to evaluation that incorporates review of program design, implementation, and cost effectiveness. Although GAVI does not appear to score well on the OECD Aid Effectiveness indicators, it does act in ways that reflect the principles of the Paris declaration.

6.4 Management of Other Activities

In addition to GAVI support to countries, other major activities of Phase 1 included advocacy, resource mobilization, and the ADIPs. GAVI's management of these activities is examined here.

6.4.1 Advocacy and Resource Mobilization

We did not find a defined strategy guiding advocacy or resource mobilization in Phase 1. Though draft strategies were developed by the Advocacy Task Force (ATF), they were never approved or implemented by the Board. Nor were responsibilities for advocacy and fund raising clearly delineated. The Fund Board was expected to take responsibility for fund raising, but the GAVI Alliance also undertook advocacy activities at both the global and country level. Broadly, GAVI sought to raise visibility among donor nations and international institutions about the importance of immunization to save children's lives,

and to impress upon countries the cost-effectiveness of immunization as an integral part of child survival programs, but we did not find documentation of specific strategies or fund raising goals. As recently as 2005 there were discussions between the Alliance and Fund Boards as to where responsibility for fund raising lay. A joint meeting of the two Board's executive committees agreed that fundraising is a responsibility of the whole Alliance, including the GAVI and Fund Boards, but that it is a primary responsibility of the GAVI Fund. 104

The start up of GAVI created significant international attention and interest. Fund raising was one of the GAVI Fund's responsibilities, and to accomplish this, the Board included well-known international figures like Nelson Mandela, Queen Rania of Jordan, Mary Robinson, and Mstislav Rostropovich. Appearances by these figures to speak about GAVI at major events helped to increase GAVI's stature. While these personalities were very effective in creating visibility for GAVI, they had no specific fund raising responsibilities. The GAVI Fund also considered it more appropriate for the GAVI Alliance Board members to approach the bilateral donor community, since they had a better grasp of the subject matter and had personal relationships with representatives of these donors. Many informants pointed to the Executive Secretary as the person who carried out much of the donor advocacy personally, particularly among the European donors. It was not clear to what extent GAVI considered alternative sources of funding, such as from individuals, or solicited funds from private foundations.

The ATF was one of four task forces created at the inception of GAVI. With UNICEF as the lead agency, the ATF was responsible for developing a global communications strategy and workplan for advocacy and communications. Its stated mission was to: "mobilise increased attention and commitment; ensure collaboration, coordination and information sharing on communication and advocacy activities; promote increased awareness and capacity for effective communications; and, provide advocacy support to promote research and development." Much of the early work focused on increased awareness of GAVI through high-profile events as the GAVI launch, the World Economic Forum, and the UN General Assembly Special Session on Children.

An assessment of the work of the ATF carried out in May 2002 concluded that GAVI will ultimately be judged by country-level improvements, resource trends and policy work, not global events. Based on recommendations from this assessment, the ATF gave increased attention to regional and country-level communication support, though global advocacy was still important. In mid-2003, the ATF was disbanded and replaced by a Global Advocacy Coordinating Group comprised of UNICEF, WHO, the Secretariat, the Vaccine Fund, the CVP and Gates Foundation. From that point on, it appears that the responsibility for advocacy fell increasingly onto the Secretariat.

A GAVI coordinated event in 2002 attended by Ministers of Health and Ministers of Finance to publicly endorse their country FSPs was often credited as having important impact in broadening the responsibility for immunization. During country visits and discussions with EPI Managers, respondents often mentioned this event as significantly raising the importance of immunization, along with GAVI official

¹⁰⁴ Joint Executive Committee teleconference, January 2005

The Fund considered revising its board structure in 2004 to distinguish between the advocacy board members and the governing board members, and clarify responsibilities of each, but this recommendation was not adopted. Board Restructuring and Implementation Plan, presented to the Fund Board November, 2004

¹⁰⁶ GAVI Financial statements indicate total donations of \$6.5 million were received from private foundations. Under Phase 2, the GAVI embarked on targeted private sector fund raising efforts.

¹⁰⁷ Report of GAVI Proto-Board meeting, July 12 – 13, 1999, Annex 4

Review of the GAVI ATF, Warren Feek, the Communications Initiative, May 1, 2002.

¹⁰⁹ Review of the GAVI ATF, Warren Feek, the Communications Initiative, May 1, 2002.

¹¹⁰ Draft advocacy task force strategy document, 2002.

¹¹¹ GAVI Board Sub-group Review of Task Forces, Annex 2a, Final Recommendations, presented and approved at 11th GAVI Board Meeting, 15-16 July

visits that included meetings with very senior leaders such as the President and Prime Minister. Awareness and commitment has not always translated into funding – in three out of six study countries (Congo DRC, Indonesia and Lao PDR), lack of timely funding remains a continual problem for the NIP. Overall, GAVI's effectiveness at increasing funding at country level is mixed.

Many informants, including the former Executive Secretary, were critical of GAVI's management of advocacy activities, despite increasing funding commitments under Phase 1. Informant comments also reflected the sentiment that the funding raised was not an indicator of effective advocacy – informants found "GAVI was better at fund raising than at advocacy," or "fund raising was almost unnecessary." Some interviewees found the ATF more concerned with preparation of advocacy materials, and pulling together disease incidence information, rather than developing an overall advocacy approach. Interviewees also indicated that with UNICEF as leader of GAVI's advocacy efforts, there was some confusion as to whether the advocacy related to UNICEF's activities or to GAVI's. The various comments point to a lack of clarity on strategy, activities, or roles and responsibilities.

GAVI funded a Branding Study in 2005, aimed at developing a consistent message and image to the international community. The study concluded that gaining the confidence of its partners was the most important step GAVI could take to improve its standing in the international community. "To this end, GAVI needs to make clear that it is an Alliance and not a separate entity, and to link its identity to a concept that Alliance partners can share comfortably." GAVI did not need to develop a strong "brand" in recipient countries, where the target audience is narrow and GAVI's presence is largely manifest through partner agencies. "Success of GAVI ultimately depends on its standing in the public and private sector donor communities. Meeting their expectations is your first task." To that end, GAVI was quite successful during Phase 1, as demonstrated by partner commitments to the Alliance in funding and in spirit.

Most informants agree that GAVI put immunization back on the map and showed how immunization would contribute to the MDGs. Not all agree, however, that GAVI has done enough to make the case globally that a large portion of the major remaining causes of child mortality, such as acute respiratory infections and diarrheal diseases, are vaccine-preventable. Some informants also expressed concern that GAVI sometimes took credit for achievements that belonged to partners. GAVI's best advocacy was its success in implementing programs quickly and in demonstrating measurable results. That the first International Finance Facility (IFF) focused on immunization, and that significant funding has been committed to the AMC for Pneumococcal vaccine, indicate continued support within the international community.

Although funding commitment at the global level was a critical first step, GAVI was less successful at creating sufficient ownership and commitment for immunization at country level. This weakness was evidenced by limited increases in country budgets for immunization, as discussed in a later section. In this area, development of strategies that combine the strengths at global level (data, analysis, communication) with GAVI's extensive partner presence at country level will be useful.

While GAVI was successful in fund raising, there is still recognition that it would have benefited from a clear strategy and management structure for advocacy and fund raising. This finding seems particularly important given the comments heard widely from country participants that it is becoming more difficult for immunization to compete in priority with the growing number of competing global health issues and related GHPs. Lastly, that the positive results from Phase 1 are generally attributed to the strength of partner relationships, and measurable program results also implies that GAVI must be careful to ensure

¹¹³ Satchi and Satchi Simko. 2005. Branding Study.

¹¹² Saatchi and Saatchi Simko. 2005. Report and Recommendations on development and implementation of a Brand Strategy and Corporate Identity for GAVI and the Vaccine Fund.

continued strong performance in these areas, and to closely link future advocacy strategies to these strengths.

6.4.2 Management of the ADIPs

In retrospect, GAVI was not well-structured to manage the ADIPs. When the ADIPs were funded in 2002, the Secretariat employed eight staff. Management of the ADIPs relied on a Management Committee (MC), which was established along the lines of the earlier task teams, comprised of relevant stakeholders and technical experts. This model is similar to the early model GAVI used for managing its country programs – review of country proposals by an Independent Review Committee (IRC), with technical input on program design and policy decisions from the Task Force on Country Coordination (TFCC). However, for its country programs, GAVI soon realized they required additional management through a dedicated team, and thus the Country Support team was slowly established and expanded within the Secretariat. For the ADIPs, however, no similar team was created within the Secretariat during Phase 1.¹¹⁴

Also unlike the country programs, there was no ongoing monitoring mechanism, nor were there clear indicators or milestones developed from the onset. The country programs relied on APRs reviewed by an IRC to assess progress, which developed detailed feedback for each country, as well as a report of broad findings and issues. No such process was developed for regular independent review of the ADIPs.

Almost across the board, respondents (including some MC members) found the MC weak – it did not have a clearly defined role, was inappropriately staffed, acted more as a technical advisory group than a management group, was too removed from the Secretariat, and focused on details rather than the big picture. Some interviewees felt they had to rely on other mechanisms to ensure that their opinions were heard at the Secretariat. Despite emphasis on activities to ensure country-level readiness for vaccine introduction in the original ADIP model, the strategic objectives endorsed by the MC did not make this explicit. Nor was another organization or project tasked with activities such as evaluating cold chain or transportation system readiness for a new vaccine, taking into account the available vaccine presentations.

The relationship between the ADIPs and the Secretariat was not strong, especially in the early years of the ADIP, resulting in a lack of communication and engagement from the GAVI Board and Secretariat. Informants affiliated with the management of the ADIPs in various capacities often reflected the sentiment that the Secretariat showed little interest in their progress. These findings were also documented in the evaluation of the ADIPs and Hib Initiative conducted in 2007.¹¹⁵

It is difficult to assess the extent to which the weak management function may have limited the final achievements of the ADIPs. There were potentially mixed messages on the expectations from the ADIPs. At the same time, some respondents believed that in retrospect, it was unrealistic to expect the ADIP to accomplish all of its originally-assigned tasks with five years. Regardless, it appears that management of the follow-on project for accelerated vaccine introduction would benefit from stronger management and more involvement from the Secretariat.

6.4.3 Monitoring and Evaluation at Global Level

Although not originally part of the RFP questions, the SC asked Abt to examine the strengths and weaknesses of GAVI's monitoring and evaluation (M&E) activities under Phase 1. As noted earlier, the

¹¹⁴ Milstien, Julie, Cohen, Jillian Clare and Olsen, Ingvar Theo. 2007. An evaluation of GAVI Alliance efforts to introduce new vaccines via the Accelerated Development and Introduction Plans (ADIPs) and the Hib Initiative (HI). HLSP.
¹¹⁵ ibid

GAVI Board commissioned this evaluation of Phase 1 in 2006. At that time there was no evaluation framework, and it was only in 2007 that a framework was adopted for evaluation of Phase 1. The lack of preparation for a Phase 1 evaluation limited the usefulness of Phase 1 lessons learned in informing the activities and policies under Phase 2. GAVI commissioned many assessments and evaluations to address specific issues as they arose, particularly related to governance functions and responsibilities as discussed earlier, but we found no overall evaluation policy, evaluation framework, or evaluation plan for Phase 1.

While the evaluations of GAVI's ISS funding found that ISS has had a positive effect on DTP3 coverage rates, they also found that the evidence is still unclear as to whether the reward mechanism is the key driver of improvements. There were respondents in in-depth study countries who noted that the DQA was inadequate in its ability to assess the quality of immunization data. While the DQA was useful for identifying some data reliability issues, and provided an impetus to partners to address those issues, little more has been done in recent years to review data quality. Given that ISS reward calculations are based on country reported data, ensuring reliable coverage data must remain a high priority for GAVI.

As we noted earlier, there has never been an evaluation of NVS funding. There is little documentation of implementation experience at country level, examination of GAVI policies on country decision-making related to new vaccine introduction, or analysis of cost effectiveness of NVS. Even as GAVI prepares to introduce additional new vaccines, we have found no evaluation framework or plan related to NVS.

The topics for this evaluation included assessment of the results of GAVI activities, as well as its governance structures and management approaches. Two very important broader questions that have not been addressed are: 1) whether GAVI's portfolio of activities represents the best approach toward achieving its strategic objectives; and 2) how GAVI's overall mission fits into the global health and development architecture. Examining both these questions would provide useful input to strategic planning, as well as advocacy.

GAVI lacked a clear strategy, specific activities, or defined roles and responsibilities related to advocacy. Despite its success in fund raising, many respondents believe that GAVI has not fully carried out its responsibility as the global advocate for immunization. Management of the ADIPs relied on a Management Committee that many perceive as inappropriately staffed and operating under a poorly-defined scope of work, with limited engagement with the GAVI Board or GAVI Secretariat. GAVI lacked an evaluation policy and framework, and an evaluation plan during Phase 1.

6.5 Comparison with Similar Organizations

The challenges that GAVI faced in rationalizing its organizational structures and managing its portfolio of activities during Phase 1 are not uncommon to a developing and growing organization. The challenges were compounded by the need to incorporate the perspectives and interests of the many different public organizations that formed GAVI. In this section, we compare GAVI's experiences with those of the GF, based on the GF's recent evaluation of its first five years of operations. The GF is appropriate for comparison in many ways – both are large and well-known GHPs, both adhere to the principle that they are not implementing agencies, and both are committed to country ownership and country-led implementation.

All GF evaluation findings reported in this section are based on the Study Area 1 report – The Global Fund to fight
 AIDS, Tuberculosis and Malaria. November 2007. The Global Fund 5 Year Evaluation: Summary Paper on Study Area 1
 Organizational Efficiency and Effectiveness. All GF evaluation findings reported in this section are based on this report.

The GF evaluation was conducted as three distinct studies examining: 1) organizational efficiency and effectiveness of the GF; 2) effectiveness of the GF partner environment; and, 3) impact of the GF on the three diseases. At the time of this evaluation, only the findings from the study of organizational efficiency and effectiveness were available, which examined four topics:

- Strategy, vision, mission and business plan
- Partnership principles and strategy
- Governance
- Organizational structure and processes

We compare the findings across the two organizations along these areas. In the area of organizational structure, we also compare measures of organizational efficiency and bureaucracy between the GAVI, GF, and the Millenium Challenge Corporation (MCC). The MCC is different from GAVI and the GF in that it is a bilateral institution and its focus of activities expands beyond health to "promoting sustainable growth that reduces poverty." Nonetheless, it represents an innovative approach for delivering development assistance that is performance-based, country-led, and aims for minimal bureaucracy.

6.5.1 Strategy, vision, mission and business plan

The GF evaluation found that there are tensions within the founding principles of the GF, and lack of clarity on their specific interpretation that hinder the ability of the principles to provide consistent coherent programmatic guidance. Among some of the issues that have arisen are encouraging country ownership while maximizing impact, defining the boundary of not being an implementation agency when sometimes hands-on involvement is required to coordinate technical assistance or procurement, and enforcing the principle of performance-based funding that requires discontinuation of funding when poor performance is exhibited.

These issues are very similar to ones identified during GAVI Phase 1. One of the issues that the GF seems to be grappling with is the extent to which it needs to step beyond being purely a funding agency, not necessarily to becoming an implementer, but a coordinator and facilitator. A recommendation from the evaluation is that the GF should prioritize its guiding principles, which can be difficult to implement. Principles such as ensuring country ownership and country-led program design conflicts with the principle of being balanced in terms of regions, diseases, and interventions when country-designed applications are not naturally balanced by region and countries prioritize one intervention over others. These issues are very similar to ones that GAVI faced during Phase 1, and on which continued evaluation and clarification is still needed.

6.5.2 Partnership principles and strategy

Since the GF does not engage in implementation, partnerships are a core part of its strategy and essential to its success, however, the evaluation found that there are not clear and transparent partnership arrangements. Another finding was that the Board did not pay sufficient attention to development of partnership strategies. The second evaluation study will examine this question in further detail, however, one of the interim recommendations is to articulate clearly the roles of its main partners through a transparent and participatory process.

Comparatively, GAVI has moved further ahead on this issue. To some extent, it had a head start since two of its permanent partners, WHO and UNICEF, had areas of clear comparative advantage and more defined roles at country and global level related to immunization prior to GAVI. Comparatively, GAVI

¹¹⁷ Easterly, William (ed). 2008. Reinventing Foreign Aid. Cambridge, MA: MIT Press.

has invested more time in engaging its partners, and building consensus and commitment, although there are some areas where more clarification is needed. Just as GAVI required that country ICCs be involved in programming and oversight at country level, the GF required Country Coordinating Mechanisms (CCMs), with similar responsibilities. For both GAVI and GF, the country level coordinating mechanisms have played an important role in building country ownership and partner consensus.

6.5.3 Governance

The evaluation of the GF found that its Board was overburdened with operational issues around grant management, which distracted it from more strategic decisions. The evaluation also found that the Board was overwhelmed by documentation – each Board meeting in 2005 averaged over 300 pages of briefing documents and 70 topics up for discussion. Further, it was difficult for developing country constituencies to have an effective voice at the Board.

The evolution of GAVI governance was quite different, with significant focus on partnership building, effective governance, and strategic decisions. While the GAVI Board also felt overwhelmed, it did not appear to be bogged down in policy and management details, relying on a WG and other task teams to relieve it of some of those responsibilities. Admittedly, the GF operates on a larger scale in terms of the number of recipient countries, some with multiple grantees, and total funding disbursed, adding to the complexity of its operations. Although to varying degrees, both organizations appeared to be in "catchup" mode in its start-up years.

6.5.4 Organizational Structure and Processes

The GF evaluation identified a series of managerial and organizational issues within the organization. Some areas where experiences paralleled GAVI were grant application and management, resource mobilization, monitoring grant expenditures and performance, and procurement. Like the GF, GAVI has been criticized for being burdensome in its application process. The GF has a relatively low application success rate, and its procedures have been criticized for being overly complicated. Ensuring high quality proposals is challenging given the pressure to disburse funds – both organizations' success in fund raising only further exacerbates this pressure to disburse funding. Weaknesses were also identified related to the GF's financial tracking and lack of standardized service indicators. GAVI's reliance on a single indicator simplifies performance monitoring, however, it has also faced problems of weak financial monitoring in selected countries. Lastly, similar to findings of this evaluation, the GF also is realizing that more attention must be paid to effective procurement, and is moving toward policies on pooled procurement, and development of innovative approaches to procurement.

We compare the size of management across the GAVI, GF and the MCC. All three organizations represent new approaches for development that aim to minimize bureaucracy, with no direct involvement in implementation. While staffing is an imperfect indicator of bureaucracy, it is an indication of the level of management and supervision required to enforce its policies. Table 23 compares the size, scope, and management of these organizations.

Table 23: Comparison of GAVI, GF and MCC Staffing, 2006

Characteristic	GAVI	GFATM	MCC
Number of countries	75	132	23
Number of programs	3 types of support at country level	363 programs, as each program is individually designed at country level	16 Millennium Challenge Compacts 22 Millennium Challenge Threshold Programs
Total Funding	\$1.6 billion committed	\$3.4 billion committed	Up to \$2 billion per year
Staffing	55	200	230, including staff in recipient countries

Source of GF and MCC data was Easterly, William (ed). 2008. Reinventing Foreign Aid. Cambridge, MA: MIT Press OECD. GAVI staffing data was obtained from "GAVI Secretariat Headcount in 2007", presented at the 7 Feb. 2007 Joint Executive Committee meeting of GAVI Alliance and GAVI Fund.

It is difficult to use these comparisons to draw conclusions regarding appropriate staffing as the three organizations operate so differently. Compared to the GF and the MCC, GAVI was the most thinly staffed. That said, it also managed a smaller pool of funding, with more limited scope in terms of the types of activities funded. The GF evaluation found that its human resources policies required improvement, the organization may be understaffed, and that fears of the GF becoming a huge bureaucracy were overplayed. Certainly in our evaluation of Phase 1, we found activities that would have benefited from additional management and oversight. Maintaining small administrative structures and minimizing bureaucracy while effectively managing its activities appears to be a common theme for these organizations.

The organizational and management challenges that GAVI faced during Phase 1 are very similar to ones identified during the evaluation of the first five years of the GF. Similar weaknesses were identified related to lack of clarity in vision and strategy, and management processes of GAVI and the GF. GAVI appears to have performed better than the GF in building an effective partnership and effective governance. Like GAVI and the GF, the MCC also faces challenges in managing effectively while minimizing bureaucracy.

7. CROSS CUTTING PRINCIPLES

The RFP also included questions related to cross cutting principles that were adopted by GAVI — emphasis on sustainability, and providing value-added through a multi-sector partnership. These questions examine whether GAVI has adhered to these principles in its program design, organizational structure, and management, as well as how these principles are incorporated into GAVI's longer term vision and affect its potential impact.

7.1 Sustainability of GAVI Programs at Country Level

As mentioned, an underlying premise of NVS was that with the assurance of significant demand from developing countries for underused vaccines, new vaccine manufacturers would enter the market driving down the vaccine price, such that it would be affordable for GAVI countries. Future GAVI support could then be directed to additional new vaccines. The partners recognized financial sustainability as an important principle from the beginning, and imbedded its importance in GAVI's first strategic objective, "to improve access to **sustainable** immunization services." Another widely recognized principle that was less well-documented was that GAVI funding should be additional to, and not replace, existing donor or government funding.

7.1.1 Financing Task Force and Financial Sustainability Plans

To help develop appropriate policies to support GAVI's sustainability objective, the Financing Task Force (FTF) was one of the three task forces initially established by GAVI. The FTF worked in three key areas:

- Financial sustainability at country level
- Vaccine supply and demand, including improved forecasting
- Innovative financing sources

All three factors are critical to the sustainability of GAVI supported programs. As discussed in earlier sections, GAVI has made important achievements in the area of innovative financing (though coming to fruition just after the end of Phase 1). GAVI has also improved forecasting and the number of available vaccines has increased – although that has not yet provided sufficient pressure to reduce vaccine prices, there are expectations that the price of pentavalent vaccine is poised to decline. This section focuses on financial sustainability at the country level.

Despite partner commitment to the principle of sustainability, the early years revealed profound differences in the definition of financial sustainability. It was not until June 2001 that GAVI adopted the following definition of financial sustainability:

Although self-sufficiency is the ultimate goal, in the nearer term sustainable financing is the ability of a country to mobilize and efficiently use domestic and supplementary external resources on a reliable basis to achieve current and future target levels of immunization performance in terms of access, utilization, quality, safety and equity.

Prior to this official definition, countries received mixed messages on what was expected of them, depending on partner representatives at regional and country level. There were some perceptions that GAVI's adoption of such a liberal definition, after all the talk about sustainability, would undermine its future credibility on this issue. In one of the country visits, one informant commented that "countries see right through that, they know GAVI won't stop funding vaccines." Further, while GAVI encouraged countries to co-finance their immunization program costs, it did not require them to do so.

The FTF undertook several activities to support sustainability at country level. One important GAVI innovation at country level was the introduction of Financial Sustainability Plans (FSPs). Every GAVI recipient country was required to prepare an FSP two years after it began receiving support. For many countries, this process represented the first time that NIPs became aware of the full costs of the immunization program. It became apparent that vaccines were the highest cost component of immunization programs, as a result of new vaccines introduced. While most countries found the FSP to be a useful tool, some believed that financial implications of the new vaccines should have been made known from the beginning. The FSPs became recognized as an important tool and its components are now incorporated into Comprehensive Multi-year Plan (CMYP), a planning tool developed by WHO and UNICEF, and endorsed for use in all WHO member countries.

As important as the financial projection analyses that comprise the FSP is the process of FSP development. GAVI required that countries involve a broad range of stakeholders in FSP development, including the Ministry of Finance. Both the Minister of Health and the Minister of Finance were to sign the FSP indicating their approval and commitment. A public inauguration event was held, with Ministers of Health and Ministers of Finance publicly signing the FSP pledging commitment to funding immunization. In discussions regarding advocacy, countries today still mention the importance of this event in broadening the responsibility for financial sustainability beyond the NIP.

The FTF also supported development of the immunization financing database, which represented the first attempt to systematically compile data on immunization financing across a large set of countries. To improve data comparability, the FTF supported development of the FSP Costing Tool, which provided a common methodology for countries to calculate the cost their immunization program inputs.

An assessment of the lessons learned in the area of sustainability provided the following conclusions:¹¹⁸

- The cost implications of introducing Hep B and particularly Hib vaccines were more important than anticipated, and in most countries, vaccines became the largest immunization cost component.
- The FSP was a valuable tool in planning, mobilizing and monitoring resource allocation for immunization; however, it failed to include monitoring indicators and the process did not make adequate provision for follow-up of implementation.
- While national governments continued their efforts to increase financing, this was not followed by additional funding from other partners. As such, the financial transition away from GAVI resources was delayed.
- Compounding the issue of financial sustainability was the fact that the price of combination products did not drop as rapidly as expected within the five year timeframe, although this has now changed as emerging supplier competitors have entered the market.
- Financial sustainability is far from assured and will be exacerbated as more costly new vaccines are introduced.

Evaluation of the GAVI Alliance Phase 1 (2000-2005)

¹¹⁸ GAVI Alliance. 2008. Immunization Financial Sustainability in the Poorest Countries: Lessons from GAVI 2000-2006.

For all of the FTF's efforts in assisting countries to analyze their financial situation, countries found implementation of the FSPs very challenging. GAVI and its partners provided little follow-up to assist countries in implementing activities that would improve their financial sustainability. Disbanding of the FTF may also have been partly to blame for the lack of follow-up. Nor were new approaches introduced, beyond supporting in-country advocacy. Efforts to link debt relief for Highly Indebted Poor Countries (HIPC) to funding for immunization proved unsuccessful.

7.1.2 GAVI Impact on Immunization Financing during Phase 1

Based on data from a review of 50 FSPs submitted, funding for immunization has been experiencing a positive trend, and funding from all sources has been increasing to support routine immunization. Overall, GAVI Phase 1 support has been additional with only limited replacement of existing investment for immunization. Excluding GAVI funding, funding for routine immunization from all sources has increased between the baseline and the year with GAVI, although there are individual country variations. Of the 50 countries included in the analysis, five saw a drop in their overall funding even with additional GAVI resources made available. Excluding GAVI Phase 1 support, 17 of 50 countries saw a drop in immunization funding. However, it is difficult to determine whether this trend is cyclical, or indicative of a real downward movement in funding from government and donors. Further, it is difficult to conclude whether GAVI resources influenced these country trends.¹¹⁹

The 2007 evaluation of ISS funding also examined the question of whether GAVI replaced other funding, with inconclusive results. Based on FSPs from 27 countries with data available for analysis, excluding vaccine costs and GAVI ISS funding, 20 countries recorded lower expenditures on routine immunization during GAVI Phase 1. The 2007 ISS evaluation also analyzed more current data from five of six countries visited as part of that evaluation. Across those five countries, non-vaccine, non-ISS expenditures for routine immunization increased in all countries.

Another analysis based on WHO-UNICEF Joint Reporting Form (JRF) data across 185 member countries found that government funding for vaccines has been steady or rising modestly from 2000 to 2006, while overall government funding for routine immunization has been steady or declining.¹²² Further, government funding for some vaccines, specifically Hib, continues to be a challenge. Financial sustainability has become increasingly challenging particularly for higher cost vaccines, and increasingly focuses on financing of vaccine costs.

Total funding for immunization certainly increased during GAVI Phase 1 in GAVI-recipient countries. However, a significant portion of that increase was attributable to GAVI funding, and a significant portion of the increase was for new vaccines. While neither of these findings represent negative outcomes for countries, it is less clear whether GAVI funding has been additional, as originally intended, or whether there has been increased funding to support effective delivery of these new vaccines.

7. Cross Cutting Principles

¹¹⁹ Information in this paragraph is taken from "Immunization Financial Sustainability in the Poorest Countries: Lessons from GAVI 2000-2006." GAVI Alliance.¹²⁰ Chee, Grace, Natasha Hsi, Kenneth Carlson, Slavea Chankova, Patricia Taylor. September 2007. Evaluation of the

Chee, Grace, Natasha Hsi, Kenneth Carlson, Slavea Chankova, Patricia Taylor. September 2007. Evaluation of the First Five Years of GAVI Immunization Services Support Funding. Bethesda, MD: Abt Associates Inc.
 Four of the five countries had data from 2005, the fifth had data from 2004.

¹²² Lydon, Patrick, Pa Lamin Beyai, Irtaza Chaudhri, Niyazi Cakmak, Alexis Satoulou and Laure Dumolard. 2008.

[&]quot;Government financing for health and specific national budget lines: The case of vaccines and immunization." Vaccines: available online July 14, 2008.

7.1.3 Sustainability of Injection Safety Support (INS)

GAVI provided Injection Safety Support (INS) to countries in the form of auto-disable (AD) syringes and safety boxes sufficient for use with all injectable vaccines. INS support was provided to 69 countries for a three-year period – support ended for 58 of these 69 countries in 2006.

A study commissioned by GAVI is currently underway to analyze the sustainability of INS. The study focuses on the countries for which support has ended. Although the data is still being analyzed, preliminary findings indicate that the vast majority of recipient countries have found alternative funding sources to replace INS the first year that funding ends. Nearly all countries in the study are covering the cost of AD syringes and safety boxes with funding by government and/or donor sources. The data also indicates that the use of AD syringes has broadened from immunization to other health services in some countries. In all countries, the use of disposable technology has heightened the awareness of the need for better healthcare waste management. Overall, nearly all INS recipient countries have sustained the use of AD syringes after transitioning from sterilizable or standard disposable syringes in the immunization programs.¹²³

Informants both at global level and in in-depth study countries cited the importance of GAVI's role in advancement of injection safety, and noted this as one of GAVI's important achievements. GAVI's time-limited support provided the impetus to address the injection safety problem, but there appears to be broad ongoing commitment to providing safe injections through the use of AD syringes.

7.1.4 Outlook on Sustainability

Very few countries that have introduced new vaccines under Phase 1 are able to pay for the full cost of the vaccine. Sustainability was raised as a serious concern in all of the in-depth study countries. In 2007, Uzbekistan took over full funding for Hepatitis B vaccine introduced under GAVI. It has just been approved for pentavalent vaccine, but believes financing the full cost of pentavalent vaccine at current prices would not be feasible. None of the other five countries visited are able to finance more than a fraction of their vaccine costs.

A GAVI internal monitoring report found that at the end of Phase 1, ten countries had contributed financing for new vaccines supported by GAVI.¹²⁴ However, GAVI's formal co-financing policy that was later adopted actually reduced the required contributions for some countries. While we do not have data across all countries, GAVI's co-financing policy reduced government contributions in two of six in-depth study countries. The government of Malawi contributed \$1.0 million in 2005 for vaccines, which was reduced by approximately half after implementation of the co-financing guidelines. In 2007, Uzbekistan took over full financing of all vaccines, including HepB introduced with GAVI support – however it has applied and has been approved for pentavalent vaccine, which reduces its original costs for DTP and HepB by about \$0.12 per dose after meeting the co-financing requirements, and comes with free syringes.

With some exceptions, governments are able to meet the co-financing requirements at their current levels, however, they are concerned with increasing co-financing levels. Respondents in Laos, Mali, and Malawi were very explicit in stating that expecting increasing co-financing levels in such low income countries was unreasonable. At the same time, all believed that some level of co-financing was appropriate, at least as a symbol of government ownership. Some respondents felt that it was unfair for GAVI to impose a new standard and then expect the countries to pay for it. Laos and DRC are both heavily reliant on partners for immunization funding, and there is no sign that the funding situation will change in the near

¹²³ Information in this paragraph was made available to us by the authors of the current study conducted by JSI.

¹²⁴ GAVI. 2005. GAVI Country Support Monitoring and Evaluation: 2005 Annual Report.

future. In Indonesia, which has not relied on GAVI funding for vaccines, problems with funding delays, as well as administrative changes, affected vaccine procurement and caused vaccine stock-outs. There are also questions of whether the increasingly higher standards are cost effective and appropriate.

During GAVI Phase 1, expenditures on routine immunization increased significantly not only due to higher cost from new vaccines, but also increases in other operating expenses. Overall, this trend is positive, since routine immunization was previously underfunded. In some cases, GAVI was a catalyst for increased investments in immunization from other donors, but in other cases, countries became reliant on GAVI to support critical operating costs. In Laos, dependence on ISS funding created a serious gap in unfunded outreach costs once all investment funds were depleted and reward funding was not forthcoming. In approximately 65% of the country, there has not been reliable funding for outreach services from the end of 2006 to the time of the in-country research for this evaluation. In Indonesia, ISS funding supported operating costs at a time when government funding for health services was increasingly unreliable.

Based on country projections from FSPs, immunization program costs are projected to average 3.7% of government health expenditures in the period from 2005-2010. For those countries that introduced DTP-HepB, those costs are higher, at 6.0% of government health expenditures, and for those countries that introduced DTP-HepB+Hib, those costs represent 9.2% of government health expenditures. ¹²⁵ In addition, GAVI NVS will be extended to include Pneumococcal vaccine, which will further increase immunization program costs in those countries that introduce Pneumococcal vaccine. Given these projections, it appears that continued GAVI support will be required.

As part of its approach for funding for NVS and ISS, GAVI did initiate improvements that will have lasting impact in many countries. The most important difference cited in study countries is increased coordination and consultation among NIP partners, as well providing a framework for including non-traditional partners such as MOF. In many higher performing countries, availability of GAVI funding, together with increased donor support, has lead to systemic improvements including better trained staff, more ownership at district level, and increased community involvement, which will have lasting impact beyond GAVI funding. These changes do not sustain themselves indefinitely, however, and continued focus and attention is needed to ensure strong ongoing performance.

GAVI's continued advancement of immunization programs to new standards including state-of-the art vaccines and related technologies, while also requesting that countries take over financing represents an inherent conflict that requires more attention. The limited experience after the end of INS funding shows that other sources of support were forthcoming after GAVI support ended. However, there is no similar evidence on whether GAVI funding for new vaccines would be replaced if GAVI support were to end. Given the much higher cost of new vaccines supported by GAVI, compared with the cost of AD syringes, identifying alternative sources of funding will be more challenging than for AD syringes. GAVI's approach to sustainability requires a broader discussion, with more in-depth analysis of changes in funding flows for immunization and agreement on what is appropriate expenditure on immunization given competing health needs.

¹²⁵ GAVI Alliance. 2008. Immunization Financial Sustainability in the Poorest Countries: Lessons from GAVI 2000-2006.

GAVI-introduced Financial Sustainability Plans (FSP) represented the first time NIPs became aware of the full cost of the immunization program. The process for development also broadened the group of stakeholders with responsibility for immunization to include Ministries of Finance. Total funding for immunization increased during Phase 1, mostly as a result of GAVI funding, and mostly for new vaccines. For countries that introduced pentavalent vaccine, immunization program costs totaled 9.2% of government health expenditures. Preliminary findings show that in the majority of countries where INS support ended, other sources of support were found to replace GAVI funding. However, the outlook for NVS is much more challenging given their much higher cost.

7.2 Value-added of GAVI

From the inception of GAVI, there was some tension as to the mandate of the partnership vis a vis the individual partners. This tension was particularly acute with WHO and UNICEF, two organizations that previously had the global responsibility for childhood immunization. The intention of GAVI was to improve the effectiveness of ongoing efforts, not to take over those efforts. It took GAVI several years to define clearly how the partnership would add value to the work of each of the partners.

7.2.1 Definition of Added Value

In December 2002, GAVI set out for itself philosophical principles to ensure that it focused its activities on added value. ¹²⁶ These underscored that GAVI is an alliance in which partners work together to achieve greater effectiveness through enhanced coordination, consensus building, and coherence to achieve common goals. Operationally, GAVI determined that implementation is entirely the responsibility of partners, who have a responsibility to invest in the alliance, to monitor themselves and each other to assure that appropriate investments are made, and that GAVI added value efforts should be in response to country needs and in support of country activities.

GAVI's 2004-2005 strategic framework clarified GAVI's added value further:

The basic spirit of the alliance is to focus on those areas in which no one partner can work effectively alone and to add value to what partners are already doing. GAVI "added value" has been defined operationally in four clusters:

- **Coordination and consensus-building**...around policies, strategies and priorities, [assigning] responsibility to the [partner] that has the comparative advantage.
- Funding support to countries from the [GAVI] Fund. The Alliance needs to ensure that it is fully capitalizing on the [GAVI] Fund's comparative advantage to employ new and innovative funding strategies.
- Innovation...including the country proposal and review process, performance-based grants for immunization services support, financial sustainability planning, the DQA, the VPP 127, and the ADIPs. GAVI needs to...capture best practices from the field, conduct operational research to assess their applicability to other settings and support their implementation.
- Advocacy and communications. GAVI has great potential to affect decision-making among policy makers and donors on the value of vaccination for reducing poverty and infant

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 ¹²⁶ Clear Definition of GAVI Added Value, from GAVI Board sub-group meeting, Amsterdam, 14 December 2002
 127 The Vaccine Provision Project, implemented in 2002 to correct deficiencies of the first procurement in 2000 through forecasting of demand and procurement across program, supply and financing, in order to provide credible and predictable demand forecasts that would stimulate industry to produce the needed vaccines.

7.2.2 GAVI's Performance on its Clusters of Added Value

The GAVI Alliance did add value in ways that resulted in better outcomes for immunization than its partners could have achieved individually. GAVI held a global mandate as a stakeholder alliance that its individual partners did not have – providing it more credibility than its partners to facilitate consensus building, access funding, and act as the global advocate for immunization. Further, its loose organizational structure allowed it the freedom to implement innovative, unproven programs on a large scale. All these elements contributed to GAVI's ultimate achievements. For the most part, GAVI took full advantage of its unique role and structure to further its mission. Nonetheless, more could have been done in some areas, as detailed in the discussion below.

7.2.2.1 Coordination and Consensus-building

GAVI partners and observers interviewed agreed that GAVI has effectively brought together all of the major stakeholders to work on the goal of reducing mortality from vaccine-preventable diseases, elevating the level of discussion. For many observers and stakeholders, this is its most valuable contribution, and it in turn has led to:

- a much better understanding of the perspectives and special concerns of the partners;
- increased expectations of, and increased pressure on, the partners to perform;
- a culture of listening to the views and needs expressed by partners and of adapting to accommodate those views (frequently described by interviewees as a learning culture); and,
- a can-do, pioneering attitude among partners that has led to innovative approaches.

These results could not have been achieved without the Gates Foundation resources and the donor funds that followed soon after. GAVI Phase 1 represented the first time in years that the level of funding dedicated to immunization was anywhere near commensurate with the need. But interviewees agreed that progress in increasing immunization coverage and introducing new vaccines would have been much slower had that money been distributed to the GAVI partners. It was the broad partnership that enabled success. As one respondent put it, GAVI created a venue and a way of bringing together the best minds of the partners to work on challenges that were not being addressed adequately by others.

While GAVI facilitated great leaps in coordination and consensus building, one group of stakeholders that has not been sufficiently included in discussions and in the decision making process are the vaccine manufacturers. While all partners recognized the importance of including vaccine manufacturers, there has been no consensus on what they should contribute, and there continues to be some lingering misunderstanding on both sides. That the inputs from manufacturers were underutilized, while GAVI's progress in managing vaccine supply and pricing was limited, represents a missed opportunity.

Despite the progress made during Phase 1, there were still areas where differences between GAVI partners remain – most notably concerning the importance of introducing new higher cost vaccines versus strengthening immunization systems to expand coverage of existing vaccines, and achieving rapid uptake of new vaccines versus ensuring sustainability. While full consensus may never be possible, GAVI could advance the discussion by improving the data and analysis to support decision making and advocacy (both with the international development community and within its partner organizations). Facilitating more open discussions around resource allocations decisions would also help to build consensus on these

¹²⁸ GAVI Strategic Framework 2004-2005; GAVI Secretariat, 22 July 2003, Board meeting #11, July 2003

issues. Lastly, GAVI must be able fully prepared to defend its programming and policy decisions to its partners and to the international community.

7.2.2.2 Funding Support from the GAVI Fund

The additional money that the GAVI partnership brought to immunization was an essential enabling factor critical to its achievements. Its importance was not only in the amount of money available, which was substantial, but also the way in which it was provided – GAVI was subjected to none of the bureaucratic procedures of its partner institutions, allowing it to make quick decisions, make longer-term commitments, and invest in innovative and necessarily riskier programs. GAVI was able to make five year commitments to countries, which while in retrospect may not have been long enough, represented a much longer commitment than any of its partners could have provided.

Equally importantly, GAVI was able to access additional funding in ways that individual partners were not, such as through private donations, and innovative financing methods like the IFFIm. By representing the common goals of a broad range of stakeholders, GAVI enjoys the confidence of the international community, which continues to provide funding support, both directly and through contributions to IFFIm and the AMC – its ability to show results quickly was an important factor for success in this area. Mechanisms such as the IFFIm and the AMC assure vaccine manufacturers that there is predictable financing for vaccines, leading developing country manufacturers to enter the market, and multinational manufacturers to invest in adapting existing products for developing countries

GAVI made full use of its flexibility in accessing and programming funds to add value. Some partners argue, however, that while the funding contributed to GAVI in its early years was additional, subsequent contributions merely represent funds that would otherwise have gone directly to partners for immunization. There is also the argument that donor funding for GAVI would have been used for other health initiatives. We did not analyze changes in the international flow of funds for health or immunization, so we are unable to verify to what extent either of these claims is true. However, as recommended by the ISS evaluation, analysis of the flow of funds for immunization incorporating changes at global and country level is important to demonstrate the additionality of GAVI funding. Given GAVI's mandate, however, it is rightfully promoting additional funding for immunization – it is up to each donor organization to make its own decisions regarding the importance of immunization versus other health interventions before contributing.

7.2.2.3 Innovation

GAVI was innovative in many ways, but its design and management of ISS funding may the most notable and most successful. ISS made funds available to all eligible countries that wished to apply, used an IRC to ensure impartial review of proposals, allowed countries full discretion to program funds, and tied future funding to country performance. Along with these basic design principles, ISS also introduced innovative management tools and processes. GAVI required countries use a collaborative approach to managing funds through an ICC, conduct a DQA to ensure reliable data, and develop FSPs to understand the financial future of their NIPs. An evaluation of ISS funding under Phase 1 found that ISS funding has been a direct contributor to increasing immunization coverage in recipient countries.

Initiation of the ADIPs represented an innovative, comprehensive approach to addressing the problem of the long lag time between use of a new vaccine in OECD and developing countries. While the ADIPs did not achieve all of their ultimate objectives (possibly due to a combination of implementation issues and unrealistic expectations), most informants thought it was appropriately structured to address the problem.

Innovation is not only an important added value, it is also a source of great pride to GAVI partners, who value being part of a group that is on the cutting-edge of immunization initiatives. As such, it is a critical part of partners' sense of "ownership." Some partners believe that GAVI's innovativeness was a result of the pioneering and learning culture associated with a new, well-funded partnership, with donors (particularly the Gates Foundation) that encouraged new thinking and accepted a higher level of risk-taking. As GAVI grew in size and complexity, this culture began to decline – such organizational evolution is very typical. But because this culture is so important to producing the value-added results of the partnership – both for partner ownership and innovative thinking – GAVI should take steps to necessary to revive this culture, which characterized the early years of the Alliance.

7.2.2.4 Advocacy

A sentiment expressed by a variety of informants was that GAVI "put immunization back on the map." It demonstrated the importance of improved immunization services and introduction of new vaccines to save millions of children's lives in a cost-effective way. At the same time, some informants expressed dissatisfaction with GAVI's advocacy efforts – comments that point to the difference between fundraising and advocacy reflect perceptions that advocacy was sometimes to promote GAVI, and not necessarily immunization. Nonetheless, by most accounts, GAVI elevated discussions of immunization, as well as the resource envelope, to unprecedented levels.

Regional and country representatives said that one of GAVI's most important contributions was that it helped increase understanding of the importance of immunization within their countries. NIP Managers in in-depth study countries said that GAVI was instrumental in building country ownership for immunization programs. Providing ISS financing without earmarking so that governments could program funding as needed, requiring governments to increase budgets for immunization, and requiring agreement by all the ICC partners all helped build country ownership of the immunization program. GAVI's incountry advocacy that focused on Ministers of Finance as well as Ministers of Health broadened the national support for immunization financing. While respondents noted that GAVI increased the visibility of immunization, they also expressed concern about the impact of GAVI's injection of new vaccines on future budgets for immunizations. Even further increased advocacy efforts would be needed to assure that the additional vaccines could be maintained. Meanwhile, a host of other global health priorities have taken precedence over immunization programs in terms of visibility, global resource availability, and incountry resource needs. Respondents questioned whether immunization could continue to compete for resources with these other priorities, without greatly enhanced advocacy from GAVI.

It is interesting that while most informants at country level felt that GAVI was a good advocate, measurable outcomes in the form of increased budgets have been limited (in contrast, there is significantly more funding at global level, yet a sense that GAVI underachieved). Country representatives universally doubted whether their countries would be able to sustain programs once GAVI funding ended. Country level informants can provide examples of increased commitment, including messages from the highest level leaders, and budget lines for vaccines (even though the actual contribution may be limited). However, increased advocacy at country level is required to maintain commitment, and to translate that commitment to increased funding.

While GAVI has made some valuable inputs in this area, respondents felt it did not fully take advantage of its position and the international attention. GAVI used its record of accomplishments to generate funding, but has been less effective at communicating the unfinished agenda in immunization. GAVI was, and is, the global voice for immunization, representing the major bilateral and multilateral stakeholders, as well as developing countries. As such, respondents felt GAVI could have done more to remind the international community of its agenda, assess how trends in development affect immunization, and strengthen the global focus.

GAVI remained true to its principle of added-value, improving, but not replacing, the efforts of its partners. GAVI facilitated great leaps in coordination and consensus building, while it made full use of its flexibility in accessing and programming funds to add value. GAVI used innovative approaches, with ISS funding and ADIPs representing new approaches to problems. While GAVI "put immunization back on the map," it underutilized its position as the global advocate for immunization.

8. DISCUSSION AND LESSONS LEARNED

GAVI's accomplishments and experiences during Phase 1 provide important lessons learned. We distilled our findings to identity the most important strengths and weaknesses of GAVI performance under each area of evaluation, and analyze how they impact GAVI's future. Since this evaluation was conducted over two years after the end of Phase 1, we also include some information on the current situation within GAVI, as much has changed since the end of Phase 1. Our understanding of current developments is based on information from the GAVI website, documents provided to us by informants and the GAVI Secretariat, and informants' remarks. However, it does not represent a complete assessment of the current situation.

8.1 Programs and Activities

GAVI's support to countries (NVS, ISS, INS) in Phase 1 was generally successful. NVS contributed to introduction of Hepatitis B vaccine on a global scale, and made important contributions to introduction of Hib and YF vaccines. GAVI contributed to higher DTP3 coverage rates globally. GAVI's INS program provided the impetus for a new standard for injection safety, and early evidence shows that its effects are sustainable after the end of GAVI support. Phase 1 policies resulted in allocating relatively more funding to countries in greater need – LICUS countries, lower income countries, and countries with lower DTP3 coverage rates. GAVI also appears to be contributing to decreasing urban/rural and gender disparities in immunization services.

Despite the overall achievements, there is great variability on a country by country level, and GAVI has not developed effective approaches for facilitating support to underperforming countries. One of the factors identified in the 2007 ISS evaluation as differentiating higher performing countries was strong technical capacity at country level – both within the NIP and/or provided through partners.¹²⁹

While targeting funding to countries in greater need is appropriate in some respects (for example – the cost per additional child immunized is lower in countries with lower coverage rates), there is also evidence that some of these countries (LICUS countries, for example) are not as effective at making good use of ISS funding. The 2007 ISS Evaluation found that LICUS countries were less effective in LICUS countries than in other countries, and had essentially no impact in countries with a current conflict. LICUS countries were also less likely to qualify for rewards – 59% of eligible LICUS countries were approved for rewards, compared with 79% of non-LICUS countries. Given this evidence, other types of program design may be more appropriate to support these countries.

GAVI funding contributed to reducing urban/rural and gender based disparities in immunization coverage rates. We did not find changes in disparities based on mother's education or birth order. It is possible that these disparities are more resistant to change, and require more persistent interventions focusing on behavior change.

¹²⁹ Chee, Grace, Natasha Hsi, Kenneth Carlson, Slavea Chankova, Patricia Taylor. September 2007. Evaluation of the First Five Years of GAVI Immunization Services Support Funding. Bethesda, MD: Abt Associates Inc.
¹³⁰ Ibid.

¹³¹ Ibid.

Due to limitations in vaccine cost data, we can only provide limited information on the cost effectiveness of GAVI's support to countries. Based on disbursements and total additional children immunized with DTP3, costs to GAVI were \$8.31 per additional child immunized with DTP3, translating to \$933 per death averted. The lack of data necessary to provide cost effectiveness estimates by vaccine must be addressed. Without such data, GAVI cannot accurately assess how best to program funding – within the immunization arena, GAVI must be able to evaluate whether it is putting its resources to best use. It is important GAVI develop an internal mechanism to compile such data for research and evaluation purposes without infringing on contractual agreements with suppliers.

GAVI's results in influencing vaccine pricing and supply are more mixed. GAVI had no impact on reducing the prices of the two vaccines that represent the bulk of its NVS program, and during all of Phase 1, there was only a single supplier for each of these vaccines. GAVI's improvements in forecasting and procurement, and its long-term funding did attract additional suppliers. Since the end of Phase 1, four additional DTP-HepB suppliers have been pre-qualified and there is one additional pre-qualified DTP-HepB+Hib supplier. Although four more pentavalent suppliers are in the pre-qualification process, there may be over-optimistic expectations of future price reductions. GAVI must recognize that the market for vaccines in developing countries is characterized by few buyers and few sellers, and reassess its strategy or assumption that market forces will create healthy competition and lower vaccine prices. Such a thin market with high entry barriers is easily subject to over- or under-supply – neither of which would benefit GAVI in the long term. While GAVI pursued work in vaccine pricing strategy in its early years, they seemed to become lower priorities.

Its model for accelerating new vaccine introduction, the ADIPs, has been successful in establishing the disease burden, demonstrating the vaccine benefits, and communicating those findings to generate funding support, but has many critics because of its failure to prepare countries for vaccine introduction. Despite significant investments in the ADIPs, activities in this area did not appear to be high priorities. GAVI should be more pro-active in overseeing in-country preparations for introduction of new vaccines.

GAVI's portfolio of activities, with their individual strengths and weaknesses, represent significant advances toward GAVI's strategic objectives as a whole. GAVI significantly increased access to immunization, and expanded use of new vaccines. By building on its early success and momentum, and closely aligning immunization with MDG 4, GAVI has increased the visibility and importance of immunization to generate significant additional funding at the global level. The ADIPs did go most of the distance toward country introduction, even if they did not fully reach their targets by some expectations. GAVI has attracted additional vaccine manufacturers, but has not yet seen benefits in terms of reduced prices. Given how quickly decisions were made, its loose strategic framework, and the technical challenges of some activities, GAVI's Phase 1 results are impressive.

Table 24: Lessons Learned from GAVI Programs and Activities

What Worked Well	Current Situation/Challenges Ahead
ISS funding was successful in increasing DTP3 coverage across the set of recipient countries (although some countries experienced no improvements).	No change.
By the end of Phase 1, 56 of 71 eligible countries were approved for HepB support.	Currently 63 countries have been approved for HepB support.
GAVI changed the global standard for safe injection by promoting use of AD syringes.	Preliminary data shows that use of AD syringes is sustained after the end of GAVI support.

¹³² Milstien, Julie, Cohen, Jillian Clare and Olsen, Ingvar Theo. 2007. *An evaluation of GAVI Alliance efforts to introduce new vaccines via the Accelerated Development and Introduction Plans (ADIPs) and the Hib Initiative (HI).* HLSP.

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What Worked Well	Current Situation/Challenges Ahead
ADIPs have compiled substantial evidence to support introduction of Pneumo and Rota vaccines.	No change.
GAVI aligned immunization with MDG 4, significantly increasing its visibility and ability to attract funds.	No change.
What Required Improvement	Current Situation/Challenges Ahead
GAVI has not been very effective at supporting underperforming countries.	This was a finding of the 2007 ISS study, and the Board has authorized a team to address these issues.
The design of GAVI country support may not be appropriate for LICUS countries, which tend to have lower rates of uptake and achieve lower results.	GAVI has established a Task Team focused on developing alternative models for providing support to LICUS countries.
The ISS reward system tended to reward countries with high population growth rates.	This was a finding of the 2007 ISS study, and the Board has authorized a team to address these issues.
By the end of Phase 1,18 of 71 eligible countries were approved for Hib, and 14 of 28 for YF.	Currently 44 countries have introduced Hib, and 17 have applied for YF. GAVI funded the Hib Initiative to compile data for promoting use of Hib vaccine.
The management structure for the ADIPs was weak.	The current design of the AVI should incorporate the findings from the ADIP evaluation and this evaluation to ensure a clear management structure and process, and appropriate milestones from the onset.
Data on cost of vaccines is not available for accurate assessment of the cost effectiveness of various programs.	GAVI undertook a Procurement Agent Study for Rota and Pneumo in 2007, in which issues on transparency of pricing information are discussed. The Procurement Reference Group may also follow up in this area.
GAVI was not successful at reducing vaccine prices and attracting new vaccine suppliers during Phase 1.	In 2008, a second supplier for pentavalent vaccine was pre-qualified. Some informants expect price declines. Building healthy vaccine markets is included as a defined objective in the 2007-10 strategy.

8.2 Organizational Structures

GAVI's organizational structure during Phase 1 was under constant evaluation and change. The original creation followed few rules – as operations began, structures and responsibilities were questioned and redefined, and incremental adjustments were made to address issues identified. Task forces and the WG were used to allow critical input and debate, and to encourage partners' ownership of decisions. The Secretariat structure was minimal, and at times insufficient to manage all of GAVI's activities. Further, two key weaknesses of the organization structure were never resolved – lack of clarity on roles and responsibilities at all levels of the organization, and lack of accountability given the dual GAVI Alliance and GAVI Fund Boards. These weaknesses were addressed as part of a comprehensive review of governance structures in 2007, and the joint Boards have agreed to establish a new legal entity that merges the GAVI Alliance and GAVI Fund, among other changes.

The commitment of the partners was critical to GAVI's success. Building the partnership – creating a common agenda, encouraging broad participation, and building trust among the partners – was a high priority under Phase 1, even if it meant some inefficiency and ambiguity. A true partnership emerged not only among the most senior leaders in setting broad principles, but among the technical staff of partner organizations who worked together in policy setting, and at regional and country level to support implementation.

One of the ways that GAVI was able to achieve this broad partnership was to rely on what some informants referred to as "constructive ambiguity" on certain difficult issues. While this was perhaps

necessary in the beginning, it created another set of issues for GAVI. For example, partner roles and responsibilities were never clearly articulated, and there were no mechanisms for holding partners accountable. The 2006 study, *Immunization – Mapping the Bigger Picture*, concluded that there is growing clarity on organizational mandates, comparative advantages, and the division of labor among partners at the global level. However, further agreement is required by partners on their comparative advantages in relation to GAVI's specific objectives in the context of broader GIVS goals.¹³³

Developing countries and vaccine manufacturers are two groups of partners that have not been able to participate in decision making and policy setting as fully as other partners. Although it may be inappropriate for vaccine manufacturers to participate in decisions regarding vaccine development strategy or resource allocation, their potential contributions to a more competitive and secure vaccine market are not fully defined nor understood. Like other GHPs, GAVI has not been very successful at engaging developing country representatives as true partners, although GAVI has taken steps after Phase 1 to encourage more communication within the constituency group, and provide resources to support the Board member. Given the strong presence of GAVI partners at regional level, and positive role the RWGs played in providing a voice for countries under Phase 1, it may be useful to explore how these structures could play a useful role in coordinating inputs from recipient countries. GAVI must continue to examine how best to utilize its partners' inputs toward attaining its strategic objectives.

The GAVI WG and task forces played a critical role in program design and policy setting in the early years. As importantly, they were fora for partnership and trust-building. Partners that had no institutional representation in these groups criticized them as being non-transparent and exclusive. For the partners included, and to other outside observers, however, they represented important arenas for technical discussion, debate, and innovation. The value-added of the partnership and the collaborative process is lost if such arenas are lost. This type of forum that allows in-depth technical debate, with representation linked to Board members, could also enable more efficient Board actions and serve a due diligence function.

GAVI's organizational structures under Phase 1 were by no means ideal or efficient, but they were adequate primarily because all partners were committed to making the partnership work, and so accepted a degree of "constructive ambiguity" in many areas. Since the end of Phase 1, much energy has been dedicated to reorganizing the governance and management structures, so as to provide a clearer operating structure. While these efforts are absolutely necessary, a strong partnership relies both on a well-defined framework or agreement, as well as goodwill and commitment. The critical challenge in the transition to a more corporate model for governance will be to ensure that there are mechanisms for arriving at consensus in ways that will keep all the stakeholders committed and engaged.

Table 25: Lessons Learned about GAVI's Organizational Structure

What Worked Well	Current Situation/Challenges Ahead
GAVI partners were extremely committed to the success of the partnership at leadership, policy making, and implementation levels.	This spirit of commitment and partnership seems less evident currently.
GAVI was able to make decisions and act quickly when necessary.	Decision making began to slow as operations became more complex while organizational structure remained loose and somewhat vague. The new structure may speed up decision-making, but risks doing so at the expense of stakeholder involvement.
GAVI was innovative and able to adapt to changing	It will be a challenge to ensure that the new organizational structure includes forums for debate and

 $^{^{133}}$ "Immunization: Mapping the Bigger Picture"; Final report to GAVI of the Roles and Responsibilities task team, Nel Druce et al, HLSP, May 2006

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What Worked Well	Current Situation/Challenges Ahead
situations.	innovation which were so important in Phase 1.
GAVI was open-minded, willing to self-assess, listen to criticisms of its partners and others, and adjust accordingly.	It will be a challenge to ensure that the spirit of introspection and open self-criticism remains a part of the expanded GAVI Secretariat.
WG and task forces were seen as fora for open technical debate and consensus-building around policy-setting and program-design.	These structures have been replaced, but maintaining avenues for partner discussion and debate at a technical level is important in the current environment.
What Required Improvement	Current Situation/Challenges Ahead
Role and responsibilities of various levels of the organization were not clearly defined.	New governance structure corrects this situation.
There was no accountability due to separation of programmatic and fiduciary responsibilities between GAVI Alliance and GAVI Fund.	New governance structure corrects this situation.
There was inadequate articulation of the definition, roles and powers of stakeholders.	A Roles and Responsibilities Task Team was formed to work on this issue
There were no guidelines to explicitly address potential conflicts of interest arising from the multiple roles of the GAVI Alliance partners as Board members and technical implementation partners.	No information on most recent progress.
GAVI often took the path of least resistance, resulting in the dilution of key policies and ongoing ambiguity around key issues – leaving underlying unresolved tensions within the partnership.	CEPA's governance work revived these discussions. No information on most recent progress.
Developing countries and vaccine manufacturers were less included in some decisions and discussions than other partners, and their potential inputs are not clearly defined and may be underutilized.	Issue not adequately addressed.

8.3 Management Approaches

GAVI's decision-making approaches evolved substantially over Phase 1, starting from almost no strategic planning to development of a five year strategic plan for Phase 2. Instead, the overarching priorities were quick decisions and quick results. Based on these guiding principles, GAVI developed its windows of support to countries and their corresponding implementation policies. Introduction of the investment case approach provided necessary structure and rigor, but its value was limited by the lack of a broader strategic framework and funding allocations. To a large extent, GAVI's rich resources mitigated the need to make strategic allocation decisions – for much of Phase 1, the emphasis was on spending money.

Strategic planning may have also suffered from a reliance on "constructive ambiguity" for broad partner agreement. Every partner's priority had to be included and supported, with no clear definition of their relative importance within the partnership. Under this arrangement, 18% of GAVI's Phase 1 funding was directed to increasing access to sustainable immunization services, while 73% of funding was focused on expanding use of new vaccines. By contrast, 4% of its funding was allocated for accelerating disease control (YF, measles), and 4% for accelerating development and introduction of new vaccines (ADIPs and Hib Initiative). It is not clear whether this allocation coincidentally reflects partners' views of the relative importance of these various initiatives. Although GAVI's approach of country-led programming prevented it from making firm programming allocations, its implementation policies (country qualification criteria for NVS and ISS, amount of reward funding, etc.) certainly influenced programming allocations.

Effective communication was difficult in the early years because there was a huge amount of information to disseminate, and communication mechanisms were still under development. Most respondents felt GAVI communications at all levels improved over Phase 1. Structures such as the WG, RWG and ICCs played important roles at facilitating communication among partners at all levels. Expansion of the Country Support Team facilitated better communications with recipient countries. There was feedback reflecting a perception that as the management structure and communications mechanisms became more formalized, communications became less open. Many respondents also felt the GAVI website could be made more user-friendly, and better used as a vehicle for transparent communications.

GAVI's support to immunization programs in 75 eligible countries represents its biggest achievements. Management of support to countries improved significantly over Phase 1, and is generally considered to be strong. Nonetheless, this evaluation found areas for improvements:

- Communications to countries still sometimes did not reach all the appropriate actors or was only in English so was inaccessible
- Lack of timely notification of funding transfers remains a persistent issue, even though this was identified as a problem in previous evaluations
- Country level monitoring was considered by some to be inadequate leading to inappropriate use of funds
- Advocacy at country level was good, but has not been followed by funding commitments
- Mechanisms for providing support to underperforming countries are lacking

One over-arching weakness in management of country support is the lack of a mechanism to monitor follow-up of issues identified through special evaluations or through the IRC process – many issues identified in this evaluation have been raised before. While some are administrative issues that might only affect a few countries, and may have limited negative consequences, a better system for appropriate follow up is required.

While the design of its ISS funding promoted country-driven planning and ownership, GAVI's overall policies around country support strongly promoted adoption of new vaccines. GAVI did not always have strong scientific evidence, or universal support for all of its strategic policies, leading to a perception that GAVI pushes new vaccines inappropriately – this criticism is primarily aimed at Hib vaccine. There is not clear evidence that introducing Hib vaccine should be the highest priority for immunization program in all countries. Given some of the difficulties related to ensuring recipient country input at the policy-making level, GAVI should develop policies that allow countries more flexibility to decide for themselves the priority needs of their own national immunization programs, providing GAVI support as appropriate.

Reflecting some of the start-up nature of Phase 1, GAVI had no evaluation policy, evaluation framework or evaluation plan for Phase 1. Abt began its research on this evaluation nearly two years after the end of Phase 1, thus limiting the usefulness of its findings in informing Phase 2 activities and policies. GAVI's NVS represents GAVI's single largest investment, accounting for 64% of total funds disbursed under Phase 1. Yet there has not been an evaluation of NVS that incorporates review of program design, implementation, and cost effectiveness. Further examination of this program is warranted.

GAVI management in some areas was not always very effective. GAVI's approach to advocacy lacked a clear strategy, specific activities, or defined roles and responsibilities. As a result, many respondents felt GAVI has not fulfilled its role as the global advocate for immunization, despite its success in generating funding commitments. Further, there is also a perception that advocacy was always to promote GAVI, not necessarily immunization. Management of the ADIPs was also weak, with GAVI relying on a Management Committee that was generally perceived to be inappropriately staffed operating with a

poorly-defined scope of work. To some extent, given limited capacity within the Secretariat, it was appropriate that relatively much more attention was paid to the country support efforts, since they represented the large bulk of GAVI investments. Nonetheless, more attention should have been given to other activities that represented critical elements of GAVI's long term strategy and value-added.

The size of the Secretariat was a subject on which there was a wide range of opinions. What is important, however, is not the number of staff or the budget, but that it performs functions which all partners agree are appropriate. The experience in Phase 1 showed that some important activities can get lost if no one who can be held accountable is responsible for coordination and management. Partners have come to the opinion that often this responsibility is most effectively discharged within the Secretariat. However, coordination and management is quite different from policy setting and decision making (or even "decision framing"), and in this latter arena few informants, including Secretariat staff, thought the Secretariat should hold primary responsibility. While the process of group discussions within task forces and the WG under Phase 1 had its flaws, the majority of informants, as well as other studies, found they were important fora for building ownership and trust among all partners.

In addition to building ownership and trust, the WG and task forces were forums for technical debate, where technical staff would bring varied experiences and perspectives to developing programs and policies around the best technical solutions without representing institutional interests. On a country level, previous evaluations have shown that better performers tend to have strong Technical Working Groups (TWGs) that allowed technical debate in strategy development. The importance of open debate at a technical level cannot be devalued. The increasing tendency of the Secretariat toward internalizing the debate, together with a reorganized Board with many members that do not bring immunization expertise, represents a trend toward decreasing technical challenge and diminishing technical inputs from partners.

The key issue related to management approaches is better definition of appropriate roles and responsibilities of partners, and management, respectively in making decisions. The concern ahead is that with the diminution of subsidiary structures, and in light of the huge workload already facing Board members, the framing of strategic decisions and the analysis behind them falls increasingly to the Secretariat. This situation could potentially reduce partner ownership of decisions (and consequently commitment to GAVI), and reduce the challenging, self-questioning and innovative characteristics that were recognized to be positive attributes of GAVI under Phase 1.

Table 26: Lessons Learned about GAVI's Management Approaches

What Worked Well	Current Situation/Challenges Ahead
Decisions were made quickly, driven by strong technical inputs, with limited institutional baggage, with the Board relying on WG recommendations.	The new significantly expanded Board may reduce GAVI's ability for quick decision making.
GAVI's country programs were generally well-managed through the Country Support team, although there were areas for improvement.	There are specific outstanding issues that need to be addressed.
GAVI was innovative in its management approaches for country support – use of FSP and DQA represented important new contributions.	No change.
Management approaches included various forums for technical debate at many levels, including partners, promoting innovation and partner ownership.	The current challenge is to ensure there is space for technical input and debate under the new organizational structure.
What Required Improvement	Current Situation/Challenges Ahead
There was no long term strategic framework, nor resource allocation guidelines. GAVI's funding allocationsdid not consider strategic priorities, activity	GAVI Phase 2 Strategic Plan and Roadmap clarifies framework, and has clear milestones associated with each objective, but does not seem to translate those

What Worked Well	Current Situation/Challenges Ahead
costs, potential impact, or cost effectiveness.	milestones into estimated funding requirements or analysis of cost effectiveness.
While ISS funding allowed countries flexibility in programming funding, GAVI's overall policies strongly promoted adoption of new vaccines, even though that may not have been the highest priority in all countries.	No change. Co-financing policy further reinforces this bias toward new vaccines.
The Secretariat was too minimalist and could not manage all of GAVI's activities adequately – particularly in the area of advocacy and ADIPs.	With the growing Secretariat, the challenge will be to ensure that all partners are comfortable with its expanded responsibilities, and there is clarity on the division between management, and policy setting and decision making.
There was inadequate followup on specific country implementation issues that were identified through evaluations, in APRs, or reported by the IRC.	Issues were also documented in the 2007 ISS Evaluation.
Monitoring at country level was considered by some to be inadequate leading to inappropriate use of funds.	GAVI has just adopted a Transparency Policy.
Mechanisms for providing support to underperforming countries are lacking.	Issue identified in the 2007 ISS Evaluation. No information on most recent progress.
GAVI's single largest investment, in NVS, has never been independently evaluated.	No change.
GAVI had no evaluation policy, evaluation framework, or evaluation plan during Phase 1.	Strategic Plan sets out clear indicators. No information on other plans.
Advocacy focused on fund raising and promoting GAVI, not necessarily immunization; at country level advocacy was considered good, but has not been followed by funding commitments.	This finding also reflects the lack of an overall advocacy strategy that focuses on country objectives. No information on most current progress.

8.4 Sustainability

As embodied in the work of the FTF, GAVI's approach to sustainability was based on a three-pronged strategy encompassing: 1) supporting financial sustainability at country level; 2) influencing vaccine supply and demand to reduce prices; and, 3) developing innovative financing sources. GAVI's success in these areas has been mixed, with structuring financing innovations the main area with obvious achievements.

Despite GAVI adopting sustainability as a core element of its programs, and much effort made to support countries in their efforts toward sustainability, there has been limited progress in this area. GAVI started with a difficult situation – improving financial sustainability of vaccines that, at their current prices, represent significant increases in health spending. For many recipient countries, the cost of three doses of the DTP-HepB+Hib regimen for one child (approximately \$10) represents the annual per capita health expenditure. Self-sufficiency was an unlikely option, nor was it an appropriate goal for most GAVI-eligible countries in the near-term. Under this scenario, it was difficult for GAVI to define sustainability, let alone develop a solution or approach.

GAVI supported countries to calculate the cost of their immunization programs and assess their financing situation through the FSP, which was nearly unprecedented for NIPs, and represented a significant advancement. Through the FSP process, GAVI also broadened the set of stakeholders concerned with financial sustainability to include Ministers of Finance and other government officials. But it has not done enough to support countries in advocacy efforts, offer explicit incentives for countries to address

their financing gaps, or develop innovative financing approaches at country level. As the FSPs revealed the impact of the new vaccines on program cost, much of GAVI's focus on financial sustainability became centered on vaccine cost.

Additionally, GAVI has sent mixed messages regarding its position on sustainability. GAVI's co-financing and other policies aim primarily to encourage country uptake of new vaccines, and in some countries actually reduce the level of funding that governments had committed in earlier years. Countries may apply for pentavalent vaccine in order to receive DTP-HepB vaccine at a minimum price. These policies undermine GAVI's credibility on this issue, and set back advocacy efforts at the country level.

GAVI has had limited success in influencing vaccine supply and pricing. Prices for the most important vaccine presentations DTP-HepB and DTP-HepB+Hib increased moderately under Phase 1, mostly because there remained one supplier for each product throughout Phase 1. Prices for monovalent HepB did decline, but few GAVI countries use this presentation. GAVI has demonstrated there is demand and available funding, and new suppliers have entered the market since the end of Phase 1, with more forthcoming. Some informants anticipate additional suppliers will create downward pressure on prices, but the basis for this optimism is unclear. Nonetheless, GAVI has no strategy for influencing vaccine markets to obtain more favorable pricing while maintaining vaccine security.

In the area of innovative financing, GAVI has had important accomplishments. The IFFIm secured \$1.23 billion of new funding for GAVI. The AMC provides \$1.5 billion for pneumococcal vaccines, as well as an innovative approach for managing supply and pricing. The reality is that funding at these levels eclipses even the most optimistic expectations of recipient country contributions.

Since its inception, GAVI has attracted the support of many bilateral donors – including donors who had always funded immunization programs, as well as new donors. While this trend is positive, it has also affected funding flows such that GAVI's definition of sustainability at the country level may need to be reassessed. Many bilateral donors, who had previously funded immunization through their assistance programs in individual countries, now direct all funding through GAVI (although we do not have data to allow comparison of total funding over time.) Expecting countries to be able to generate increased funding from their in-country donors may be less realistic in this scenario. It also makes it extremely difficult to accurately assess the extent to which GAVI funding is additional at country level.

Lack of long range planning and conflicting objectives (promoting new vaccines vs. enforcing sustainability) have resulted in a situation where countries limit their financial contributions to the minimum required, manufacturers may not make best efforts to moderate prices, and GAVI is left paying nearly the full bill because it is more determined in its commitment to immunizing children than any other group. In addition, GAVI continues to weaken its current position with actions such as soliciting and approving country applications for pneumococcal vaccine before a price was negotiated with the vaccine supplier. Like under Phase 1, countries do not know the cost of the vaccine and the long term financial implications; at the same time, GAVI's negotiating position with the sole vaccine manufacturer is compromised as commitments to countries are already in place.

Given the current situation, GAVI and its partners might be wise to reassess its sustainability definition and approach. To begin with, GAVI partners must agree upon the importance of country level sustainability within their overall mission. An alternative approach would evaluate the sustainability of immunization globally, so that GAVI and its partners hold the responsibility for advocating for funding to ensure continuation of its in-country programs. However, given that recipient country contributions are important not only for financial but also ownership reasons, we do not advocate that countries be released from responsibility. However, other measures of contribution may be considered, such as targets based on percentage of total government budget or government health budget, rather than a dollar contribution

based on the number of vaccines introduced, as stipulated by the current co-financing policy. More differentiation between countries may also be appropriate to ensure that country contributions are better matched to their ability to pay. GAVI might also consider broadening the focus beyond vaccine sustainability to other components of a sustainable immunization program, including sustainability of service delivery costs, or integration within broader government planning and budgeting, although some of these components are more difficult to quantify.

Lastly, GAVI needs to be more realistic about its measures for enforcing country financing requirements, or lack of them. The recently approved default policy sets out the consequences of country failure to cofinance vaccines. It focuses on early warning systems and makes provisions under which countries can appeal and request exceptions due to extenuating circumstances. Nonetheless, in the worst case, it endorses a decision to disrupt a national immunization program due to government failure to meet cofinancing requirements.

GAVI's commitment to the principle of sustainability is closely linked to its long term vision and strategy. GAVI's funding commitments to date indicate introducing new vaccines are its highest priority. Its current co-financing policy also reinforces this by encouraging countries to apply for more expensive pentavalent vaccine because the minimum co-financing requirement is less than the cost of existing vaccines that they would have to finance themselves. Such policies to promote new vaccine uptake may meet GAVI's short term objectives, but there are no long range agreements on the appropriate level of financial responsibility to be assigned to countries, or projections of GAVI's own ability to continue financing these and other newer vaccines.

Table 27: Lessons Learned about GAVI's Sustainability Approach

What Worked Well	Current Situation/Challenges Ahead
The FSP was a useful tool to assess future financing needs, and to increase awareness of immunization costs at country level.	FSP incorporated into the CMYP, a joint WHO UNICEF developed planning process.
GAVI has attracted significantly more money for vaccines and immunization through innovative financing mechanisms and increasing donor support.	No change.
GAVI has attracted more vaccine manufacturers, which may create downward pressure on vaccine prices in the future.	At the same time, total demand is increasing as additional countries introduce pentavalent vaccine. Price of pentavalent vaccine should be closely monitored.
What Required Improvement	Current Situation/Challenges Ahead
GAVI has sent mixed messages about country level sustainability.	GAVI's current co-financing policy allows countries to introduce more expensive vaccines while at the same time contribute less.
GAVI promoted use of new more expensive vaccines despite limited progress in improving financial sustainability of existing vaccines.	No change. Co-financing Policy scheduled for review in 2009.
Although an important component of its vision for long term sustainability, GAVI's expectations of declining vaccine prices were based on weak assumptions.	No information on most recent progress.
GAVI has limited incentives for countries to improve their sustainability, or mechanisms to enforce co-financing requrements that do not conflict with its internal mission.	No change. Co-financing Policy scheduled for review in 2009.

8.5 Value-Added

The intention of GAVI was to improve the global efforts of its partners in immunization, not to take over those efforts. For the most part, GAVI has remained true to this principle under Phase 1. GAVI's most important contributions have been in the area of coordination and consensus building – nowhere is this reflected more strongly than in discussions with partners at country level. GAVI is credited with creating a spirit of collaboration and a cohesive immunization agenda, a big step forward from the situation before GAVI of conflicting priorities and vertical programs within national immunization programs. GAVI has also taken advantage of its unique position to raise global immunization funding to unprecedented levels, as well as to design innovative financing and programming approaches. GAVI partners realize that for all the strengths and skills of the partner institutions, none of them could have accomplished these results.

At the same time, GAVI could not have been successful without its partners' support. Partners chose to participate, to collaborate, to contribute funding, and to debate constructively to create innovative solutions – GAVI added value as the facilitator.

Because GAVI relied on some degree of ambiguity to build consensus, differences remain among partners around strategic priorities. While it is unlikely that everyone will ever fully agree on the priorities, GAVI can play an important role in advancing this discussion by providing the data and analysis needed to support decision making, and facilitating open discussions around strategic decisions and resource allocations such that the final policies represent compromises that all partners support.

GAVI's initial organizational principle of a stakeholder alliance relying entirely on partners for implementation may no longer be appropriate – the experience of Phase 1 shows that with the current scale and complexity of its programs, management is sometimes more effectively carried out when the GAVI Secretariat steps in. GAVI must decide with its partners the areas where its own Secretariat adds value in management and coordination, versus areas where its partners are better suited to carry out activities. Most importantly, GAVI and its partners must define more clearly the difference between management, and policy setting and decision making. Partner involvement in the latter two areas is still critical for creating the atmosphere that characterized Phase 1, that produced the collaboration and innovation which made GAVI successful.

Partners have suggested mechanisms for partner engagement at mid-level in addition to the Board – it is at this level that policies and programs become jointly owned. GAVI's partners are large institutions, within which immunization is one activity – the leaders of these organizations cannot focus only on championing immunization or GAVI, nor can they be fully knowledgeable on all of the technical complexities underlying policy decisions or implementation problems. The Board is not the forum for debate and innovation – if partners do not have representatives involved at the policy setting and implementation level, the spirit of partnership and drive for innovation will be compromised.

GAVI's voice as a global advocate for immunization, representing all the relevant stakeholders to promote the use of vaccines, is a core part of its added value – however, it has primarily used its voice for global level fundraising, and has underutilized its position to build country level ownership and commitment, closely linked with its sustainability strategy. GAVI broadened the stakeholders to include Ministers of Finance and other government officials, but did not follow through to strengthen advocacy activities at country level.

As a public private partnership, GAVI generates extra scrutiny if there are any perceptions that it is inappropriately promoting vaccines. GAVI and its partners are responsible for ensuring that its policies and programming decisions are based on strong scientific evidence, including analysis of cost effectiveness, and that this evidence is communicated effectively. Uptake of Hib vaccine was slow

because many people believed that the data to support its use was insufficient – despite increased country uptake more recently, this perception persists even among staff of GAVI's partner organizations at country level. Immunization has always held a position as one of the most cost effective health interventions – as the global advocate, GAVI must ensure that this position remains irrefutable in order to maintain commitment at global and country level.

Table 28: Lessons Learned about GAVI's Value Added

What Worked Well	Current Situation/Challenges Ahead
GAVI was very effective at facilitating collaboration and building consensus at all levels of the partnership.	The new organizational structure may limit opportunities for partner collaboration and consensus building at technical level.
GAVI took advantage of its unique position to use innovative programming approaches and take risks in ways that were not feasible for its partners.	The new organizational structure may limit opportunities for technical discussions that encourage innovation.
GAVI made full use of its ability and flexibility in accessing funding to expand the resource envelop for immunization, and to make longer term commitments to countries and to vaccine manufacturers	No change.
What Required Improvement	Current Situation/Challenges Ahead
GAVI must strengthen its credibility as the global advocate, by compiling the data and analysis to ensure technically sound policies, and building ownership in recipient countries	No information on most recent progress.
GAVI's extreme position to leave all implementation and management to its partners was not always appropriate; in some areas, the Secretariat may be best positioned to manage, and sometimes conduct activities (eg, advocacy), and adds value by doing so.	The challenge is that as the responsibilities of the GAVI Secretariat increases, it does not lean toward the other extreme, overly internalizing activities. This extreme tends to compromise ownership and innovation.

9. CONCLUSIONS AND RECOMMENDATIONS

9.1 Overall Conclusions

For better or worse, GAVI functions as an independent entity – this was the perception from partners by the end of Phase 1, and this will become the legal reality once the current reorganization is completed. Nonetheless, GAVI exists and succeeds because of a global mandate provided by the stakeholders who created it and continue to govern it. It is this mandate that provides GAVI the credibility to facilitate consensus building, access funding, and act as the global advocate for immunization. Without its partners' support, GAVI has no mandate. Without the credibility and mandate to act as the consensus builder, GAVI loses its core advantage over its partners, and the area where it adds the greatest value.

Reviewing GAVI's Phase 1 activities, its greatest successes were in its support to immunization programs in eligible countries. GAVI advanced immunization programs on a global scale – increasing coverage of the traditional vaccines, introducing vaccines which were previously considered unaffordable, and creating a new standard in injection safety. In the implementation of these programs, GAVI promoted coordination at all levels of the partnership – from the WG which debated program design, to the RWGs which supported countries in their GAVI applications, to the country ICCs which oversaw implementation at country level. It is not by coincidence that its greatest successes were in programs where GAVI built a spirit of trust and partnership at all levels.

Unfortunately, creating that spirit of trust and partnership around other areas, such as to improve vaccine supply and pricing, is more difficult. In these areas, there are important unresolved issues among partners, and the institutional interests of partners are not completely aligned. Two critical partners in these activities, the vaccine manufacturers, and UNICEF as GAVI's procurement agent, have vested interests in the outcomes of these developments. More dialogue is needed to facilitate trust and understanding in this area. In addition, better understanding of the economics of vaccine production, and development of new strategies for favorably influencing vaccine supply and pricing that recognizes the distortions of the vaccine market is needed.

Having been given the mandate as the global advocate for immunization, GAVI must live up to that task. Despite huge success in fund raising, the general consensus is that there was much room for improvement in this regard. In the current environment, GAVI must make even more effort to remain focused on its primary mission, and ensure that its mission, and the strategies employed in pursuit of that mission, is unquestionable. Within the arena of immunization, GAVI must be able to justify its programs with strong data and analysis.

Although sustainability was one of the core principles adopted by GAVI early on, the prospect of country level sustainability is even more remote today than at the beginning of GAVI. With the addition of new vaccines, costs of immunization programs in all GAVI countries have increased significantly. As GAVI is poised to add another more expensive vaccine to the immunization schedule, its approach to sustainability and the long term burden it places on countries must be reevaluated.

In line with GAVI's mandate to enhance its partners' efforts, its partners must also put in place mechanisms that can enhance GAVI's efforts. If GAVI is to maintain the advantages it has as an alliance, its partners cannot relieve themselves of responsibility for immunization merely by funding GAVI. If partners no longer consider immunization an in-house activity, they weaken GAVI's voice. The bilateral and multilateral partners must continue their commitment at all levels – their representatives at country level must remain active partners in ICCs to support GAVI activities. ISS funding was most effective in countries where partners also increased their technical contributions alongside GAVI. Similarly, there must be renewed effort to work with industry partners to develop strategies that will eventually lead to vaccine affordability for the benefit of both industry and countries. The global mission can only be achieved if GAVI and its partners remain focused – to that end, each must remind each other of their responsibilities. GAVI's added-value was not only in aligning the agenda, but then having each of its partners delivering the message of the common agenda at all levels. That was how immunization became a centerpiece of international development.

Under Phase 1, GAVI often blazed ahead based on broad principles and ideas, not necessarily detailed plans, coming back to fix and clarify as needed. This pace has allowed GAVI to accomplish a lot in a short time, while negative consequences have been minimized because GAVI has been introspective and open to criticism, and partners have been forgiving because they jointly owned the broad ideas and the decision to blaze ahead. In the spirit of innovation, there will be failures, but if all partners do not fully own the decisions, the result will be blame instead of introspection.

9.2 Recommendations

Based on the findings from Phase 1, we propose the following recommendations going forward. These recommendations seek ways to build on strengths and to address weaknesses. The recommendations are grouped into seven broad areas that represent important elements for GAVI's future success, and are prioritized within each of the seven broad areas

9.2.1 Improving Support to Countries

- 1. GAVI ISS support has improved DTP3 coverage rates across the set of recipient countries, but there is significant variability at country level, and GAVI has not been effective at supporting underperforming countries. GAVI should focus more attention on improving performance in underperforming countries, working with in-country partners to provide additional support. Focusing on a few priority countries, the GAVI Secretariat should initiate discussions with partners at country and regional level to identify critical problems, develop individualized solutions, and identify sources of additional inputs. The GAVI Board should institute a mechanism to regularly review progress in underperforming countries.
- 2. Overall, GAVI's management of its support to countries is effective, but there is room for improvement in areas such as translation of documents, notification of funding transfers, and better communication of the rationale for IRC recommendations. The GAVI Secretariat should propose a process for ensuring resolution of problems identified within recipient countries that includes briefings for the Country Support Team of problems identified through one-time evaluations, improving Country Support Team and Finance and Administration coordination regarding funding transfers, and most importantly establishing a process for regular internal review of the problems identified and resolution status.
- 3. The ADIPs were effective in compiling data to support new vaccine introduction, and advocating for their use. However, the key weakness of the ADIP model was that it did not adequately prepare countries for vaccine introduction. *The GAVI Secretariat should ensure that the*

- Accelerated Vaccine Introduction project incorporates all the elements of support required at country level (in logistics, cold chain, and other areas) for introduction of Pneumococcal and Rotavirus vaccines, convening independent reviewers.
- 4. Although financial monitoring was adequate in the majority of recipient countries, there were countries where ISS funds were used inappropriately. At the same time, the flexibility of GAVI funding, and the minimal reporting burden at country level, were important advantages of GAVI support that should be maintained. GAVI's Transparency and Accountability Policy represents a clear direction forward. The GAVI Secretariat should ensure appropriate implementation procedures, including specifying response procedures for reported improprieties or other noncompliance.

9.2.2 Improving Strategic Decision Making

- 5. GAVI allowed countries to set their own priorities for use of ISS funding, but its overall policies governing support to countries strongly promoted adoption of new vaccines. GAVI did not always have strong scientific evidence, or universal support for all of its strategic policies – such as Hib introduction. As a result, there was a perception that GAVI pushes new vaccines inappropriately. GAVI must ensure that its positions and policies have strong scientific foundations and widespread support throughout its partner organizations, and must seek additional ways to allow countries to set priorities for themselves regarding how to improve its immunization programs, particularly as it embarks on new activities. The GAVI Board should commission an independent review of how the package of country support feeds into GAVI's global strategic priorities and whether those priorities correspond to country level priorities, incorporating input from a broad group of recipient countries, feeding into a review of the design of the package of GAVI support to countries. Policy changes to consider include more differentiation among countries eligible to apply for new vaccines – for example, whereas countries with DTP3 coverage rates above 50% were able to apply for HepB, Hib and YF vaccine, that coverage rate might be increased for countries applying for more expensive Pneumococcal vaccine – thus encouraging lower coverage countries to continue to strengthen their existing program before adding more vaccines.
- 6. GAVI's decision making in the early years of Phase 1 focused on speed and results, without an overall strategic framework. To some extent, the lack of clarity may have reflected lingering differences in priorities among partners. Strategic planning has improved significantly with the Phase 2 Strategic Plan and Roadmap, and current workplans include budgets for activities to be undertaken in support of different strategic objectives. Nonetheless, there appears to be limited discussion to prioritize GAVI's strategic objectives, and to assess the costs required to meet the objectives that takes into consideration their expected impact. *The GAVI Secretariat should provide to the GAVI Board additional information on projected program and workplan costs for achieving various objectives, ensuring that the relative allocations among activities are in line overall strategic priorities, and supported by all partners*.
- 7. GAVI was not able to provide vaccine cost data disaggregated by vaccine, which limited ability to conduct cost effectiveness analysis of NVS funding this data is necessary not only for internal programming decisions but also effective advocacy. GAVI realized the importance of this issue and has undertaken steps in Phase 2 to address it. *The GAVI Secretariat should ensure that the current information provided by UNICEF is sufficient to allow accurate cost effectiveness evaluation of its programs*.

9.2.3 Strengthening Evaluation Mechanisms

- 8. Although GAVI's NVS represented its largest investment under Phase 1, it has not been independently evaluated, examining components such as program design, implementation, and cost effectiveness. The GAVI Board should commission an evaluation of NVS including program design, implementation, and cost effectiveness, as well as assesses how it fits into GAVI's overall strategic framework.
- 9. Under Phase 1, GAVI lacked a clear evaluation policy, evaluation framework, and indicators for evaluation as a result, this evaluation is being completed approximately three years after the end of Phase 1. The GAVI Board should commission a team to ensure there is partner consensus on the evaluation framework, indicators, and process for Phase 2, so that evaluation of Phase 2 can be conducted in a timely fashion to inform the next phase of GAVI's work.
- 10. One of the core strengths of the partnership under Phase 1 was the high level of commitment and goodwill. At the same time, however, its partner roles and responsibilities and organizational structures were not always clear and were under constant change. To address this weakness, GAVI has appropriately turned more attention to formalizing the partnership agreements and organizational structures in recent years, but focus should now return to ensuring and revitalizing partner goodwill and commitment. To maintain appropriate focus on these issues, the GAVI Board should ensure that the Phase 2 evaluation framework includes indicators to evaluate partner satisfaction and commitment, and ensure there is broad partner consensus on appropriate evaluation indicators.

9.2.4 Ensuring an Effective Partnership

- 11. Partners believed that GAVI was successful at consensus building because it provided avenues for technical debate and input from partners at the technical and implementation level, necessary both for innovation and consensus building, resulting in programming innovations such as ISS funding and the ADIPs. In the midst of the current reorganization, GAVI should ensure that such mechanisms for partner inputs are integrated into the governance and management structure. The GAVI Board should examine the structures for technical debate among the partners within the new governance arrangements, consulting with technical and implementation level representatives of partner institutions to solicit their feedback to the currently proposed structures. The GAVI Board should also ensure that the Phase 2 evaluation framework includes evaluation of the effectiveness of structures for coordinating partner technical inputs.
- 12. GAVI was generally successful in building trust between partners, which was critical to its success in Phase 1. Nonetheless some issues reflecting lack of trust and understanding, as well as lack of transparency were identified. More open communications would help to alleviate these issues. The GAVI Secretariat should present a proposal to partners outlining additional ways to ensure that all substantive discussions among partners and with Secretariat staff, including those that occur outside of Board meetings, are shared as openly as possible either with notes posted for public access on the GAVI website, or on a protected website that all partners can access.
- 13. Under Phase 1, it was difficult for developing country Board members to represent their constituents. This weakness is identified across GHPs, and GAVI has tried to address the situation by providing additional support to these Board members. Other ways to solicit country inputs should be explored, not only limited to Board level representation, and taking advantage of partner-coordinated regional events. The GAVI Secretariat should coordinate with partners to take advantage of opportunities presented by regional meetings to engage in substantive dialogue with countries, and propose a plan for how those discussions would feed into global level decision-making.

14. During much of Phase 1, the Secretariat was not adequately staffed to manage all of GAVI's activities effectively. In response, the Board has expanded the Secretariat staff to take on additional responsibilities, which may also create discomfort with partners if it appears that the Secretariat is taking over partner efforts. A study was commissioned in 2006 to examine the structure and functions of the Secretariat, and a follow-on study is planned. There should be an ongoing regular mechanism for ensuring that the structure of the Secretariat (size, staffing, role and authority) serves the partnership effectively. *The GAVI Board should ensure the development of a framework and regular process for assessing the Secretariat's structure and performance, ensuring adequate input from GAVI partners*.

9.2.5 Maximizing Added Value

- 15. In Phase 1, GAVI built credibility as an honest broker and neutral technical expert overall, its policies were the result of technical debate and consensus involving a variety of partners. There had long been broad support and recommendations for most of GAVI's activities strengthening immunization programs, introducing Hepatitis B, and improving injection safety the debate focused on technical strategy. There were still strategic areas, however, where differences of opinion remained throughout Phase 1. GAVI should do more to advance consensus by providing strong data and analysis to support strategic decision making, and allowing sufficient debate and deliberation so that all partners buy into the final policy decision. *The GAVI Board should ensure there is open access to deliberations and discussions regarding new vaccine policies, mechanisms for ensuring inputs from a broad variety of perspectives, and appropriate analysis to support its policies. The GAVI Board should also request that the Phase 2 evaluation framework incorporate inputs from a variety of perspectives regarding GAVI's effectiveness as an honest broker and technical expert.*
- 16. While GAVI has been very successful in fund raising during Phase 1, less attention has been paid to building ownership and increasing funding commitments at country level, and strengthening broad commitment to the overall immunization agenda. GAVI must transition from advocacy focused on fund raising and introducing vaccines, to a clear strategy at country level and within the international community that focuses on the additional efforts required from partners and other agencies to improve immunization program performance. There has also been criticism that GAVI has not increased total funding for immunization, merely redirected it to GAVI. The GAVI Secretariat should work with partners to develop a clear advocacy strategy with targeted messages, particularly at country level. Additionally, the GAVI Board should commission a study that analyzes the historical funding flows for immunization, incorporating data at global, regional and country level, to assess whether total funding for immunization has increased since the inception of GAVI, as well as develops a methodology for reporting on future funding changes.

9.2.6 Understanding Vaccine Market Dynamics

17. Under Phase 1, GAVI was not very successful at influencing vaccine supply and pricing. Phase 1 demonstrated that it takes a long time to increase vaccine supply – it was eight years between the inception of GAVI and the availability of a second pentavalent vaccine supplier. The ultimate impact on prices is yet to be seen. GAVI must increase its efforts to understand the vaccine market, in order to develop realistic long term pricing projections and goals – this work should be integrated into GAVI's ongoing workplan, with appropriate outputs used to inform strategic planning. The GAVI Board should commission an in-depth analysis of the vaccine markets that includes analysis of the production costs, technical complexities of various vaccines, transferability of technology, other barriers to entry and demand forecasts, in order to inform procurement strategy, strategic planning, and sustainability policy.

18. GAVI's vaccine strategy in Phase 1, based on the assumption that creating and demonstrating a market for vaccines in developing countries would attract new suppliers, create competition, and lower prices, did not come to fruition. GAVI must recognize that it is participating in markets with few buyers and sellers and high entry barriers, and develop alternative approaches for procurement of new vaccines that provide sufficient incentives to manufacturers and ensures vaccine security. While GAVI has taken various studies of the vaccine market and the procurement agent function, more should be done to investigate new approaches, since this is a critical component of GAVI's long term mission. *The GAVI Board should commission a study of innovative ways to structure procurement of new vaccines (other than short term fixed price contracts) that may be more advantageous over the long term.*

9.2.7 Reassessing Strategies for Sustainability

19. Lack of long range planning and conflicting objectives (promoting new vaccines vs. improving sustainability) have limited the progress toward financial sustainability at country level. GAVI should reassess its sustainability definition and approach to ensure there is broad partner agreement on the importance of sustainability relative to adding new vaccines, and to develop a long term financing plan for all vaccines. The GAVI Board should appoint a team to coordinate work in this area, starting with a partners meeting to solicit input and build consensus on appropriate principles and policies, leading to development of a sustainability strategy that may incorporate a revised definition of sustainability, revision of the co-financing policy, and new vaccine procurement strategy.

9.3 Applying Phase 1 Evaluation Findings to Current Developments

It is important to incorporate the developments since 2005 and the current reality to maximize the applicability of Phase 1 findings. In Section 8, we provided observations of how strengths and weaknesses found during Phase 1 are currently being addressed within GAVI. In addition, our recommendations are framed so that they are applicable under the current environment.

In the course of conducting our research on Phase 1, we also have information from documents reviewed and key informant interviews, which combined with our conclusions regarding Phase 1, lead us to some comments regarding GAVI's current activities. Our information and understanding of current developments may be somewhat incomplete – it is not based on comprehensive data collection (as that was not part of our scope of work) but on documents that we found on the GAVI website or were provided to us, and unsolicited informants' remarks. Further, the informants for this evaluation were selected primarily to represent Phase 1 (approximately one-third of the informants continued to be involved in GAVI into Phase 2), and may not adequately represent all of the current stakeholders. Lastly, these comments focus on a few issues and should not be treated as a comprehensive assessment of the current situation, however, they do highlight areas worthy of additional attention and analysis.

Since the end of Phase 1, GAVI has embarked on three major new activities:

- Provision of Health Systems Support (HSS) funding
- Re-organization of the GAVI Alliance and GAVI Fund into a Swiss foundation, including merger of the two Boards
- Introduction of Pneumococcal and Rotavirus vaccine

HSS funding allows GAVI a new opportunity to encourage integration of NIPs into country health plans to further institutionalize immunization as a basic health service. However, HSS can have lots of contradictory goals and agendas – unless carefully managed, HSS could stray far afield from

immunization issues and could dilute GAVI's ability to achieve its immunization vision. Although not directly questioned about HSS, concerns were raised by informants at global, regional and country level regarding the goals, design, and implementation of HSS. Informants also questioned the potential impact that could be achieved from the limited scale of funding provided through GAVI. Lastly, there were informant perceptions that NIPs were not sufficiently included in the planning process. GAVI must find ways to ensure that HSS funding benefits immunization programs, and also provides collateral benefits to the health system.

One of the challenges of HSS is that the GAVI partners that have been most active at country level, UNICEF and WHO, are not sufficiently staffed to provide the necessary technical support at regional and country level. These partners provided critical support to countries in programming and managing ISS, and introducing new vaccines and AD syringes; they are not as well-suited to provide the necessary support for health systems strengthening, nor are other partners clearly positioned for this role. The level of technical and financial support from other partners was a determinant of country performance in ISS funding – its importance should not be underestimated. Informants also noted that the partner coordination mechanisms (ICCs and RWGs) that were effective for ISS, NVS and INS are not always appropriate for because of the skill set of the members of those groups. There are no simple answers to these questions, but GAVI may wish to conduct targeted assessments to identify solutions to these problems even prior to a more comprehensive HSS evaluation.

Under Phase 1, one of the governance weaknesses identified was the lack of clarity in roles and responsibilities and lack of accountability. The Phase 2 decision to merge GAVI Alliance and GAVI Fund into one entity resolves some important governance issues (particularly accountability) found, but also has implications for GAVI's strategic decision-making. The combined board for the new organization is now greatly enlarged (28 members), 12 of who are not stakeholders and do not necessarily have an expertise in immunization or in health systems, but who vote on every strategic and programming decision. One potential result is that stakeholder partners become less influential in decision making, which may diminish partner commitment and buy-in. Further, unless there are strong mechanisms for coordinating partner technical inputs, the non-stakeholder board members would increasingly rely solely on the Secretariat for recommendations.

An added challenge is to effectively merge the consensus-driven partnership decision-making process that has characterized the GAVI Alliance with the more bottom-line driven approach used by the GAVI Fund. The former relies heavily on deep board involvement in detailed analysis of decisions (supported by their own institutional staff), takes into consideration the political implications for member institutions, and is willing to accept somewhat vague decisions in the interest of consensus. The latter does not involve the board in such a level of detail, and is not concerned with the institutional affiliation of individual board members. Unless there are strong communications mechanisms and understanding of the perspectives of various board members, it will be difficult to arrive at decisions acceptable to all partners.

The impact of the merger on partner inputs, together with the growth of the Secretariat, was voiced as an area of concern by many informants. As shown in Table 29, there has been a significant increase in internal technical and policy staff within the Secretariat.

Table 29: GAVI Secretariat Staffing Changes

Office	End 2005	End 2006	2007
Executive (including Governance and Legal)	11	11	12
Technical and Policy	0	7	11
Country Support	9	10	11
Finance	12	13	17
Operations	7	10	12
Program Funding & Communications	16	19	25
Total	55	70	88

Source: Summarized from "GAVI Secretariat Headcount in 2007", presented at the 7 Feb. 2007 Joint Executive Committee meeting of GAVI Alliance and GAVI Fund.

Many informants expressed concern over the ability of partners to influence GAVI's policies in the future. The new Board, which includes fewer health and development professionals, may rely increasingly on the expanded Secretariat for technical recommendations. Some informants point to development of the HSS policies and implementation as an area where there has not been sufficient partner involvement.

The money raised for the AMC for Pneumococcal vaccine is unprecedented, but the evidence must clearly justify the addition of another more expensive vaccine in countries that have shown little ability to pay for vaccines introduced under Phase 1. It is not sufficient that the leaders of partner institutions be convinced of the decision – commitment at the technical and implementation level is also required. Some informants suggested that more differentiation between countries and possibly individual country analysis may be necessary with more expensive vaccines, in order to ensure that newer vaccines continue to represent cost effective interventions. More analysis to understand the country conditions (including disease burden, health costs, overall immunization coverage rates) under which Pneumococcal or Rotavirus vaccine is clearly justified on a cost effectiveness basis may be useful to address questions concerning its appropriateness. Additionally, other informants questioned adding expensive vaccines in light of the future financial burden for countries – in this regard, reassessment of GAVI's sustainability principles and policies is necessary.

GAVI's new initiatives represent great opportunities and great risks. Phase 1 showed that providing the forum for, and investing the time and effort into, consensus building was an important part of GAVI's success. Thorough and transparent deliberation of difficult issues to ensure that the organization preserves and builds on its strengths while addressing its weaknesses, is ever more important to succeed in these activities.

ANNEX A: ANNOTATED RFP QUESTIONS FOR THE GAVI FUND & GAVI ALLIANCE PHASE I EVALUATION (2000-2005)

The *purpose* of the evaluation is to strengthen GAVI's continued development in its second phase (2006-2010) by assessing the performance and the results of GAVI over its first five years. The findings of this evaluation will also serve an important function in terms of accountability to donors and GAVI eligible countries. The 2007-2010 strategy reflects some but possibly not all lessons from Phase I. The evaluation should therefore help identify additional lessons that could further improve GAVI's future performance.

The *objectives* of the evaluation are:

- To identify and learn from the successes and weaknesses of the GAVI in Phase 1, including how well it has evolved and learnt from experience over the period 2000-2005.
- To contribute to refinement or adjustment of GAVI policies in its next strategic phase of work.
- To document impact and to evaluate the efficiency and effectiveness of the GAVI Alliance's use of resources during Phase 1.

The *scope of work* is as follows:

- This evaluation will address areas of structures/roles, activities, strategic objectives, performance and impact of GAVI.
- The team conducting the evaluation should be guided by the evaluation questions (as outlined in section 2.3) and approaches approved as a product of the design phase of this work. There are 20 questions to be addressed by the evaluation team.
- This request for proposals invites applicants to undertake the GAVI Phase 1 Evaluation with the exception of the specialist evaluation of fiduciary and asset management of the GAVI Fund. This work has been commissioned separately to independent financial experts who will deliver their findings in time for use by this evaluation team. The evaluation team is expected to draw upon the findings of the expert financial review and integrate them into the broader analysis evaluation. The Terms of Reference for Independent Financial Expert Review are attached for information (Annex 3).
- The team will also draw upon earlier studies (including recent evaluations of the Accelerated Development & Introduction Plans and Immunization Services Support) in the overall evaluation report.

	Structures /Roles: GAVI Alliance				
	Evaluation Question	Agreements with SC*			
1	Was the Governance composition and structure maximally 'fit for purpose?' This includes the representation of constituencies in decision making structures (e.g. developing country representation, private industry, civil society), and overall leadership quality.	It was agreed that Abt would rely only on previous work (primarily by CEPA) to address this question, and would not conduct any additional primary research.			
2	How effective have strategic decision making approaches used by the GAVI Alliance been? Are there lessons for GAVI Phase 2 e.g. in terms of whether decisions have been driven by country needs and priorities versus a global health agenda; whether the 'investment case' approach results in a balanced portfolio overall; whether decision making has been transparent?				
3	How harmonised and aligned is GAVI Alliance funding and programmatic support (including monitoring & evaluation) with other funding and activities at country level, including in federal systems?				
4	How well has the partnership worked to ensure efficient working by all partners – e.g. cost of involvement, co-ordination of roles and responsibilities, size of Secretariat, use of task forces and forums etc? How appropriately has GAVI evolved its structures and working practices over time?				
5	How adequate and appropriate has the GAVI Alliance approach to monitoring and evaluation at country level been?				
	Structures /Roles: GAVI Fund				
	Evaluation Question	Agreements with SC*			
6	How well has the GAVI Fund governance structure worked? Is there clarity of role/responsibilities between the GAVI Fund Board vs CEO; the GAVI Fund Board vs the GAVI Alliance Board? How well does it suit future needs /demands?	It was agreed that Abt would rely only on previous work (primarily by CEPA) to address this question, and would not conduct any additional primary research.			
7	Has fiduciary responsibility been exercised optimally, is the GAVI Fund well structured to do this – are systems enabling?	Abt had originally proposed to rely on results of a separately conducted study on fiduciary responsibility, which has been indefinitely delayed. As a result, Abt will not report any findings in this area.			
8	To what extent, and to what effect, has the GAVI Fund fulfilled its role as a 'watch dog' of the GAVI Alliance? Is it best structured to do this?	It was agreed that Abt would rely only on previous work (primarily by CEPA) to address this question, and would not conduct any additional primary research.			
	Activities: GAVI Alliance				
	Evaluation Question	Agreements with SC*			
9	What added value have the GAVI Alliance and GAVI Fund brought to international efforts in immunization, beyond programmes funded? Has the GAVI Alliance enabled partners to 'do more' and 'do it better?' What has the Public Private Partnership dimension of GAVI achieved – what is its added value?				
10	How successful have GAVI Alliance's key Phase 1 programmes (ISS, Injection Safety, uptake of new and underused vaccines) been in terms of country uptake and results? What are the lessons from innovations such				

	as performance based funding in ISS? More broadly, how successful have GAVI's efforts been to be innovative?	
11	To what extent did GAVI Fund & the GAVI Alliance achieve value for money in terms of activities undertaken? Are there lessons and/or implications to be considered for the next strategic period of work?	
12	How effective has the GAVI Alliance & GAVI Fund communication and advocacy systems been at all levels (i.e. between governance entities, partners and countries), and how well are they coordinated with other partners?	
13	To what extent has GAVI enabled an effective, efficient and acceptable approach to technical assistance provision at country level?	
14	What have the ADIPs achieved and how useful a model is this for the future?	
	Activities: GAVI Alliance	
	Evaluation Question	Agreements with SC*
15	How successful and efficient has the GAVI Fund been in resource mobilization? Were optimal fund raising strategies employed – e.g. could more have been raised? Has the GAVI Fund been innovative in line with GAVI's aims?	
	Activities: GAVI Fund	
	Evaluation Question	Agreements with SC*
16	Has the GAVI Fund optimally managed resources /assets – have assets been invested and managed to best effect? Were there adequate systems for monitoring performance in this area?	Abt had originally proposed to rely on results of a separately conducted study on fiduciary responsibility, which has been indefinitely delayed. As a result, Abt will not report any findings in this area.
	Strategic Objectives	
	Evaluation Question	Agreements with SC*
17	What progress has been made against each of the strategic objectives?	
	 What contribution has GAVI made to increasing access to immunization, to expanding use of Hib, Hepatitis B and Yellow Fever vaccines, and to accelerated disease control? 	
	• To what extent have the ADIPs made it more likely that there will be a	
	more rapid country uptake of new vaccines when they are ready for introduction?	
	introduction?How has the Alliance contributed to making immunization a centerpiece	
	introduction?How has the Alliance contributed to making immunization a centerpiece of international development efforts?	Agreements with SC*
18	introduction? • How has the Alliance contributed to making immunization a centerpiece of international development efforts? Performance & Impact	Agreements with SC*
18	 introduction? How has the Alliance contributed to making immunization a centerpiece of international development efforts? Performance & Impact Evaluation Question Who has benefited from GAVI Alliance Initiatives – including the extent to which fragile states, the poorest countries, and the poorest of poor within countries are reached? What are the comparative 'inputs' and 'outcomes' 	Agreements with SC*

achieved with support from GAVI?

These comments were later added by Abt Associates, to note agreements made with the SC at the inception of the evaluation.

ANNEX B: METHODOLOGY FOR 20 EVALUATION QUESTIONS

Evaluation Questions	Key Document Review	Quantitative Analysis	Key Informant Interviews	RWG or EPI Managers Meetings	In- Depth Country Visits
1) Was the Governance composition and structure maximally 'fit for purpose?' This includes the representation of constituencies in decision making structures (e.g. developing country representation, private industry, civil society), and overall leadership quality.	 Web-based descriptions of GAVI organization structure and roles Reports of GAVI Alliance Meetings and Telecons, GAVI Executive Committee meetings, and telecons, and joint GAVI Alliance-GAVI Fund Board meetings and Executive Committee meetings. Various dates, 1999 through 2007. GAVI. 2008. GAVI Alliance Handbook. Previous GAVI governance work 				
2) How effective have strategic decision making approaches used by the GAVI Alliance been? Are there lessons for GAVI Phase 2 e.g. in terms of whether decisions have been driven by country needs and priorities versus a global health agenda; whether the 'investment case' approach results in a balanced portfolio overall; whether	 McKinsey & Company. 2003. Achieving our Immunization Goal. Report on External Review of the Functions and Interactions of the GAVI WG, Secretariat, and Board GAVI. 2008. GAVI Alliance Handbook. Previous GAVI governance work Reports of GAVI Alliance Meetings and Telecons, GAVI Executive Committee meetings, and telecons, and joint GAVI Alliance-GAVI Fund Board meetings and Executive Committee meetings. Various dates, 1999 through 2007. Donahue, Martine, and Mark Watson. 2005. Lessons Learned from Investment Case Approach. HLSP. Bloom, David, David Canning and Mark Weston. 2005. "The Value of Vaccination", World Economics, Vol. 6, No. 3. 				

Evaluation Questions	Key Document Review	Quantitative Analysis	Key Informant Interviews	RWG or EPI Managers Meetings	In- Depth Country Visits
decision making has been transparent?					
3) How harmonized and aligned is GAVI Alliance funding and programmatic support (including monitoring & evaluation) with other funding and activities at country level, including in federal systems?	 Lele, Uma and Naveen Sarna, Ramesh Govindaraj, and Yianni Konstantopoulos. 2004. Global Health Programs, Millennium Development goals, and the World Bank's Role: Addressing Challenges of Globalization: An Independent Evaluation of the World Bank's Approach to Global Programs, The World Bank. Lob-Levyt, Julian, and Rebecca Affolder. 2006. "Innovative Financing for Human Development." The Lancet 367: 885-887. Bloom, David, David Canning and Mark Weston. 2005. "The Value of Vaccination", World Economics, Vol. 6, No. 3. GAVI Independent Review Committee Monitoring Team. September 2003. "GAVI Independent Review Committee Monitoring Team: Review of Annual Progress Report." Geneva. Lele, Uma, Ronald Ridker, and Jagadish Upadhyay. 2005. Health System Capacities in Developing Countries and Global Health Initiatives on Communicable Diseases. "Public Sector Vaccine Procurement Approaches." Discussion paper prepared for GAVI Alliance. N.d. Muraskin. William. 2004. "The Global Alliance for Vaccines and Immunization: Is it a New Model for Effective Public-Private Cooperation in International Public Health?" American Journal of Public Health, Vol. 94, No. 11. WHO. 2006. Strengthening the road to renewal. The Lancet. Vol 367. Chee, Grace, Natasha Hsi, Kenneth Carlson, Slavea Chankova and Patricia Taylor. 2007. Evaluation of the First Five Years of GAVI Immunization Services Support Funding. Bethesda, MD: Abt Associates Inc. 				
4) How well has the partnership worked to ensure efficient working by all partners – e.g. cost of involvement, coordination of roles and responsibilities, size of Secretariat, use of task	 All literature associated with Governance and leadership listed above McKinsey & Company. 2003. Achieving our Immunization Goal. Chee, Grace, Rebecca Fields, Natasha Hsi, Whitney Schott. 2004. Evaluation of GAVI Immunization Services Support Funding. Bethesda, MD: Abt Associates Inc. GAVI Independent Review Committee Monitoring Team. September 2003. "GAVI Independent Review Committee 				

Evaluation Questions	Key Document Review	Quantitative Analysis	Key Informant Interviews	RWG or EPI Managers Meetings	In- Depth Country Visits
How appropriately has GAVI evolved its structures and working practices over time?	 HLSP. 2005. Lessons from GAVI Phase 1 and Design of Phase 2: Findings of the Country Consultation Process. "Public Sector Vaccine Procurement Approaches." Discussion paper prepared for GAVI Alliance. N.d. Muraskin, William. 2005. Crusade to Immunize the World's Children, Global BioBusiness Books, Marshall School of Business, University of Southern California. GAVI Alliance. 2008. Immunization Financial Sustainability in the Poorest Countries: Lessons from GAVI 2000-2006. Reports of GAVI Alliance Meetings and Telecons, GAVI Executive Committee meetings, and telecons, and joint GAVI Alliance-GAVI Fund Board meetings and Executive Committee meetings. Various dates, 1999 through 2007. Caines, Karen, and Kent Buse. 2004. Assessing the Impact of Global Health Partnerships. DFID Health Resource Center. 				
5) How adequate and appropriate has the GAVI Alliance approach to monitoring and evaluation at country level been?	 Bchir, Abdallah, Zulfiqar Bhutta, Fred Binka, et al. 2006. "Better health statistics are possible." The Lancet 367: 190-192. Chee, Grace, Rebecca Fields, Natasha Hsi, Whitney Schott. 2004. Evaluation of GAVI Immunization Services Support Funding. Bethesda, MD: Abt Associates Inc. Lele, Uma and Naveen Sarna, Ramesh Govindaraj, and Yianni Konstantopoulos. 2004. Global Health Programs, Millennium Development goals, and the World Bank's Role: Addressing Challenges of Globalization: An Independent Evaluation of the World Bank's Approach to Global Programs, The World Bank. Chee, Grace, Natasha Hsi, Kenneth Carlson, Slavea Chankova and Patricia Taylor. 2007. Evaluation of the First Five Years of GAVI Immunization Services Support Funding. Bethesda, MD: Abt Associates Inc. 				
6) How well has the GAVI Fund governance structure worked? Is there clarity of role/responsibilities between the GAVI Fund Board vs CEO; the GAVI Fund Board vs the	 All literature associated with Governance and leadership listed above. Reports of GAVI Alliance Meetings and Telecons, GAVI Executive Committee meetings, and telecons, and joint GAVI Alliance-GAVI Fund Board meetings and Executive Committee meetings. Various dates, 1999 through 2007. 				

Evaluation Questions	Key Document Review	Quantitative Analysis	Key Informant Interviews	RWG or EPI Managers Meetings	In- Depth Country Visits
GAVI Alliance Board? How well does it suit future needs /demands?					
8) To what extent, and to what effect, has the GAVI Fund fulfilled its role as a 'watch dog' of the GAVI Alliance? Is it best structured to do this?	All literature associated with Governance and leadership listed above.				
9) What added value have the GAVI Alliance and GAVI Fund brought to international efforts in immunization, beyond programmes funded? Has the GAVI Alliance enabled partners to 'do more' and 'do it better?' What has the Public Private Partnership dimension of GAVI achieved – what is its added value?	 All literature associated with Governance and leadership listed above. McKinsey value added study Buse, Kent and Andres Harmer. 2007. "Seven Habits of Highly Effective Global Public-Private Partnerships: Practice and Potential." Social Science and Medicine (64) 259 – 271. Caines, Karen, and Kent Buse. 2004. Assessing the Impact of Global Health Partnerships. DFID Health Resource Center. 				
10) How successful have GAVI Alliance's key Phase 1 programmes (ISS, injection safety, uptake of new and underused vaccines) been in terms of country uptake and results? What are the lessons from innovations such as performance based funding in ISS? More broadly, how successful	 McKinsey & Company. 2003. Achieving our Immunization Goal. Lu, Chunling, Catherine Michaud, Emmanuela Gakidou, Kashif Khan, and Christopher Muray. 2006. "Effects of the Global Alliance for Vaccines And Immunization on diphtheria, tetanus, and pertussis vaccine coverage: an independent assessment." Lancet 368: 1088-95. GAVI Independent Review Committee Monitoring Team. September 2003. "GAVI Independent Review Committee Monitoring Team: Review of Annual Progress Report." Geneva. Lele, Uma and Naveen Sarna, Ramesh Govindaraj, and Yianni Konstantopoulos. 2004. Global Health Programs, Millennium Development goals, and the World Bank's Role: Addressing Challenges of Globalization: An Independent Evaluation of the World Bank's Approach to Global Programs, The World Bank. 				

Evaluation Questions	Key Document Review	Quantitative Analysis	Key Informant Interviews	RWG or EPI Managers Meetings	In- Depth Country Visits
have GAVI's efforts been to be innovative?	 Lele, Uma, Ronald Ridker, and Jagadish Upadhyay. 2005. Health System Capacities in Developing Countries and Global Health Initiatives on Communicable Diseases. HLSP. 2005. Lessons from GAVI Phase 1 and Design of Phase 2: Findings of the Country Consultation Process. Bloom, David, David Canning and Mark Weston. 2005. "The Value of Vaccination", World Economics, Vol. 6, No. 3. Chee, Grace, Natasha Hsi, Kenneth Carlson, Slavea Chankova and Patricia Taylor. 2007. Evaluation of the First Five Years of GAVI Immunization Services Support Funding. Bethesda, MD: Abt Associates Inc. 				
11) To what extent did GAVI Fund & the GAVI Alliance achieve value for money in terms of activities undertaken? Are there lessons and/or implications to be considered for the next strategic period of work?	 HLSP. 2005. Lessons from GAVI Phase 1 and Design of Phase 2: Findings of the Country Consultation Process. Milstien, Julie, Cohen, Jillian Clare and Olsen, Ingvar Theo. 2007. An evaluation of GAVI Alliance efforts to introduce new vaccines via the Accelerated Development and Introduction Plans (ADIPs) and the Hib Initiative (HI). HLSP. Chee, Grace, Natasha Hsi, Kenneth Carlson, Slavea Chankova and Patricia Taylor. 2007. Evaluation of the First Five Years of GAVI Immunization Services Support Funding. Bethesda, MD: Abt Associates Inc. 				
12) How effective has the GAVI Alliance & GAVI Fund communication and advocacy systems been at all levels (i.e. between governance entities, partners and countries), and how well are they coordinated with other partners?	 McKinsey & Company. 2003. Achieving our Immunization Goal. Chee, Grace, Rebecca Fields, Natasha Hsi, Whitney Schott. 2004. Evaluation of GAVI Immunization Services Support Funding. Bethesda, MD: Abt Associates Inc. GAVI Independent Review Committee Monitoring Team. September 2003. "GAVI Independent Review Committee Monitoring Team: Review of Annual Progress Report." Geneva. HLSP. 2005. Lessons from GAVI Phase 1 and Design of Phase 2: Findings of the Country Consultation Process. "Public Sector Vaccine Procurement Approaches." Discussion paper prepared for GAVI Alliance. N.d. Muraskin. William. 2004. "The Global Alliance for Vaccines and Immunization: Is it a New Model for Effective Public-Private Cooperation in International Public Health?" American Journal of 				
13) To what extent has GAVI enabled an	 Public Health, Vol. 94, No. 11. Caines, Karen, and Kent Buse. 2004. Assessing the Impact of Global Health Partnerships. DFID Health Resource Center. 				

Evaluation Questions	Key Document Review	Quantitative Analysis	Key Informant Interviews	RWG or EPI Managers Meetings	In- Depth Country Visits
effective, efficient and acceptable approach to technical assistance provision at country level?	 Lele, Uma, Ronald Ridker, and Jagadish Upadhyay. 2005. Health System Capacities in Developing Countries and Global Health Initiatives on Communicable Diseases. HLSP. 2006. Immunization: mapping the bigger picture. Final Report to GAVI Roles and Responsibilities Task Force. 				
	 Chee, Grace, Natasha Hsi, Kenneth Carlson, Slavea Chankova and Patricia Taylor. 2007. Evaluation of the First Five Years of GAVI Immunization Services Support Funding. Bethesda, MD: Abt Associates Inc. 				
14) What have the ADIPs achieved and how useful a model is this for the future?	Milstien, Julie, Cohen, Jillian Clare and Olsen, Ingvar Theo. 2007. An evaluation of GAVI Alliance efforts to introduce new vaccines via the Accelerated Development and Introduction Plans (ADIPs) and the Hib Initiative (HI). HLSP.				
17) What progress has been made against each of the strategic objectives?	 McKinsey & Company. 2003. Achieving our Immunization Goal. Lu, Chunling, Catherine Michaud, Emmanuela Gakidou, Kashif Khan, and Christopher Muray. 2006. "Effects of the Global Alliance for Vaccines And Immunization on diphtheria, tetanus, and 				
What contribution has GAVI made to increasing access to immunization, to expanding use of Hib, Hepatitis B and Yellow Fever vaccines, and to accelerated disease control?	 pertussis vaccine coverage: an independent assessment." Lancet 368: 1088-95. Lele, Uma and Naveen Sarna, Ramesh Govindaraj, and Yianni Konstantopoulos. 2004. Global Health Programs, Millennium Development goals, and the World Bank's Role: Addressing Challenges of Globalization: An Independent Evaluation of the World Bank's Approach to Global Programs, The World Bank. Lele, Uma, Ronald Ridker, and Jagadish Upadhyay. 2005. Health System Capacities in Developing Countries and Global Health 				
To what extent have the ADIPs made it more likely that there will be a more rapid country uptake of new vaccines when they are ready for introduction?	 Initiatives on Communicable Diseases. HLSP. 2005. Lessons from GAVI Phase 1 and Design of Phase 2: Findings of the Country Consultation Process. Bloom, David, David Canning and Mark Weston. 2005. "The Value of Vaccination", World Economics, Vol. 6, No. 3. Milstien, Julie, Cohen, Jillian Clare and Olsen, Ingvar Theo. 2007. An evaluation of GAVI Alliance efforts to introduce new vaccines via the Accelerated Development and Introduction Plans (ADIPs) 				
How has the Alliance contributed to making immunization a centerpiece of	 and the Hib Initiative (HI). HLSP. Chee, Grace, Natasha Hsi, Kenneth Carlson, Slavea Chankova and Patricia Taylor. 2007. Evaluation of the First Five Years of GAVI Immunization Services Support Funding. Bethesda, MD: Abt 				

Evaluation Questions	Key Document Review	Quantitative Analysis	Key Informant Interviews	RWG or EPI Managers Meetings	In- Depth Country Visits
international development efforts?	Associates Inc.				
18) Who has benefited from GAVI Alliance Initiatives – including the extent to which fragile states, the poorest countries, and the poorest of poor within countries are reached? What are the comparative 'inputs' and 'outcomes' between countries receiving support?	 McKinsey & Company. 2003. Achieving our Immunization Goal. Lu, Chunling, Catherine Michaud, Emmanuela Gakidou, Kashif Khan, and Christopher Muray. 2006. "Effects of the Global Alliance for Vaccines And Immunization on diphtheria, tetanus, and pertussis vaccine coverage: an independent assessment." Lancet 368: 1088-95. Lele, Uma and Naveen Sarna, Ramesh Govindaraj, and Yianni Konstantopoulos. 2004. Global Health Programs, Millennium Development goals, and the World Bank's Role: Addressing Challenges of Globalization: An Independent Evaluation of the World Bank's Approach to Global Programs, The World Bank. Lele, Uma, Ronald Ridker, and Jagadish Upadhyay. 2005. Health System Capacities in Developing Countries and Global Health Initiatives on Communicable Diseases. HLSP. 2005. Lessons from GAVI Phase 1 and Design of Phase 2: Findings of the Country Consultation Process. Bloom, David, David Canning and Mark Weston. 2005. "The Value of Vaccination", World Economics, Vol. 6, No. 3. HLSP, 2006. Evaluation Framework: GAVI Alliance and GAVI Fund, Phase I. Chee, Grace, Natasha Hsi, Kenneth Carlson, Slavea Chankova and Patricia Taylor. 2007. Evaluation of the First Five Years of GAVI Immunization Services Support Funding. Bethesda, MD: Abt 				
19) To what extent has the GAVI Fund & GAVI Alliance been successful influencing vaccine pricing and supply? What can be learnt from the Phase 1 experience to strengthen and improve the future strategic response in this area?	 Associates Inc. McKinsey & Company. 2003. Achieving our Immunization Goal. Lessons learned: new procurement strategies for vaccines, June 2002 by Mercer; Milstien, Julie, Cohen, Jillian Clare and Olsen, Ingvar Theo. 2007. An evaluation of GAVI Alliance efforts to introduce new vaccines via the Accelerated Development and Introduction Plans (ADIPs) and the Hib Initiative (HI). HLSP. Boston Consulting Group. 2005. Global Vaccine Supply: The Changing Role of Suppliers. GAVI supply strategy 16th Board mtg, GAVI/VF Long-Term Vaccine Supply Strategy, Recommendations from the GAVI/VF Secretariat by Donald Strombom; 				

Evaluation Questions	Key Document Review	Quantitative Analysis	Key Informant Interviews	RWG or EPI Managers Meetings	In- Depth Country Visits
	 GAVI. 2007. Hib and Hep B Procurement Reference Group Report to the Board. GAVI 2005. Recommended Supply Strategy for Hib and Hep B Containing Vaccines. 				
20) Are countries likely to be able to sustain the improvements in immunization achieved with support from GAVI?	 Caines, Karen, and Kent Buse. 2004. Assessing the Impact of Global Health Partnerships. DFID Health Resource Center. GAVI Alliance. 2008. Immunization Financial Sustainability in the Poorest Countries: Lessons from GAVI 2000-2006. Brugha, Ruairi, and Mary Starling, and Gill Walt. 2002. "GAVI, the First Steps: Lessons for the Global Fund." The Lancet Vol. 359. Lele, Uma and Naveen Sarna, Ramesh Govindaraj, and Yianni Konstantopoulos. 2004. Global Health Programs, Millennium Development goals, and the World Bank's Role: Addressing Challenges of Globalization: An Independent Evaluation of the World Bank's Approach to Global Programs, The World Bank. HLSP. 2005. Lessons from GAVI Phase 1 and Design of Phase 2: Findings of the Country Consultation Process. "New Products into Old Systems: The GAVI from a country perspective, LSHTM 2002 "Public Sector Vaccine Procurement Approaches." Discussion paper prepared for GAVI Alliance. N.d. 				

ANNEX C: INTERVIEW GUIDES FOR GAVI BOARD, WG, AND SECRETARIAT

GAVI Phase 1 Evaluation Interview Questions for GAVI Board Members (past and present)

(For each interviewee, confirm and note current or past role on Board or ExCom, whether participating (or formerly participated) in any task teams, years on board and/or task teams)

Introductory comments:

- The GAVI Alliance has commissioned Abt Associates to evaluate the performance of GAVI during Phase 1 (2000-2005) to identify lessons that may be useful for strengthening performance and the attainment of long term strategic objectives. GAVI identified 20 evaluation questions to be addressed in broad areas of governance, fiduciary responsibility, vaccine supply and pricing, country responsiveness, value and effectiveness of the partnership, and program impact.
- The evaluation team is aware of the recent decisions regarding changes in GAVI's governance structure. We are not revisiting those issues, but will instead focus on: GAVI's strategic decisionmaking processes, how well the partnership has worked, GAVI's added value, and effectiveness of its communications and advocacy efforts.
- The evaluation reviews Phase I through 2005, so that will be our focus. We are interested in changes during Phase II, however, in order to make sure our findings and recommendations remain relevant today.
- Our evaluation report will not identify who made specific comments, though we may use anonymous quotes to illustrate certain points, so please speak freely.

Strategic Decision-making and Communications:

- 1. How would you assess the Board's ability to exert leadership on GAVI strategic direction and operations?
 - Some critics have said the Board's role is to "rubber stamp" decisions that have already been made. Can you comment on this?
 - Would you say that Board members tend to arrive at their decisions based on independent thinking, or do they follow some leaders? If so, who are/were those leaders?
 - How has the Board's role in decision-making changed over time?
 - Is the balance of authority between the Board and Secretariat appropriate ie, with one setting policy and the other interpreting and implanting policy?
 - At GAVI's inception, was there real consensus among all the partners about GAVI's mandate and objectives? How were the strategic objectives and milestones developed who was involved and what was the approval process?

- 2. How important are the Working Group and time-limited task teams in influencing Board decision-making?
- 3. Have you found the strategic plan and the annual workplan to be useful guides for Board decision-making?
 - Did the Board have a major role in developing and guiding GAVI's strategic objectives and strategic plans? If not, who did? (Note for interviewer: Until 2005, strategic plans covered two years. In 2005 the Board decided that there should be a strategic plan covering the five year Phase II period.)
 - Board meeting notes reveal that at various times the Board has found the workplans that are derived from the strategic plans to be more strategic and outcomes-focused. Has this occurred, and has it been helpful in directing GAVI's resources effectively to the strategic objectives?
- 4. How do you normally get briefed so that you can represent your organization or constituency group at board meetings?
 - What is your most reliable source for information and recommendations for decision-making?
 - Is the information timely and adequate to arrive at decisions?
 - Do you have your own staff (within your organization) who provide research and analysis for you prior to making important decisions, or do you rely on the GAVI structure (secretariat, working group)?
- 5. Can you comment on adequacy of communications channels outside of board meetings both to get inputs for decision-making and to relay decisions to partners outside the board i.e. is the decision-making process inclusive and transparent?
- 6. How does GAVI arrive at decisions when country priorities seem to conflict with GAVI's global objectives? For example, GAVI's objective of accelerating use of underused and new vaccines leads to an emphasis on combination vaccines; but some have argued that shifting priority from expansion of existing immunization programs to new, higher-cost vaccine programs can lead to a financing burden countries cannot afford without GAVI funds and strain the capacities of the local health system.
 - Are you satisfied with the balance GAVI has been able to achieve between country needs and priorities and GAVI's global priorities?

(Note to interviewer: If a former board member, ask the question below for former board members here.)

7. Have you been satisfied with use of investment cases to determine global funding priorities? Have they been used consistently and appropriately? Do they provide you with the information you need for decision-making?

Effectiveness and Value-added of partnership:

- 8. How are Working Group members selected? Does the Working Group reflect the various constituencies in the GAVI partnership?
 - How are the members of other Task Teams selected?

- Is it important that these groups reflect the views of all GAVI partners, or is their importance in their technical skills?
- 9. Do the various stakeholder constituencies on the board contribute equitably? Do you feel they are adequately representing their constituencies?
- 10. What do you consider to be the major value added of the GAVI partnership? That is, what can GAVI do that your organization alone can't do? (E.g. bringing international and country-level attention to the need for immunization; bringing additional resources to the problem; being innovative in approach)
 - How has it changed over time?
 - How can it be enhanced?
 - What is has the public-private aspect achieved?
- 11. What do you view as the major value that your organization brings to the alliance?
 - What are the resources that your organization has to provide in order for you to participate effectively, including resources you use to communicate with the other members of the constituency group you represent?
- 12. How effective have GAVI's advocacy efforts been? Have they been coordinated with other partners?

FOR FORMER BOARD MEMBERS ACTIVE PRIOR TO 2004:

How did the Board decide on the priority programs, ISS, INS, and NVS?

How were the decisions made to invest in ADIPs?

For WHO Board Member Only:

Can you comment on the interaction between WHO, the research institutions and the pharmaceutical industries on the board, especially regarding recommended drug regimes? How do these relationships impact on Board decisions about global immunization priorities?

How has WHO's role as the primary technical resource for the board changed with the growth in the number of partners and the growth in the Secretariat?

For Board Reps of Developing Countries Only:

As a representative of countries receiving support from GAVI, do you consider that GAVI has given balanced attention to strategic directions at the global level and the country level? Are resources available for strengthening ICCs and for technical support in program design and implementation adequate?

How do you communicate with officials of other recipient countries to ensure that their views are represented at Board meetings?

For Board Reps of the Pharmaceutical Industry

Some argue that the partnership has not created the value added expected, that is, increased R&D in new vaccines, improved supply and reduced prices? Do you think that GAVI's original premise - that creating a larger market for new vaccines will bring prices down - can be achieved? How?

How do you make sure you are representing the other pharmaceutical manufacturers whom you represent in the partnership? What means of communication and information sharing do you use?

For everyone:

Are there any other issues on your mind that you would like to address?

Questions for GAVI Working Group and other Task Team Members

<u>Introductory comments:</u>

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- The evaluation team is aware of the recent decisions regarding changes in GAVI's governance structure. We are not revisiting those issues, but will instead focus on: GAVI's strategic decisionmaking processes, how well the partnership has worked, GAVI's added value, and effectiveness of its communications and advocacy efforts.
- The evaluation reviews Phase I through 2005, so that will be our focus. We are interested in changes during Phase II, however, in order to make sure our findings and recommendations remain relevant today.
- Our evaluation report will not identify who made specific comments, though we may use anonymous quotes to illustrate certain points, so please speak freely.

Strategic Decision-making:

- 1. How would you assess the Board's ability to exert leadership on GAVI strategic direction and operations?
 - How important is the strategic plan and annual workplan in Board decision-making?
 - How does the work of the working group (or your task team) feed into the decision-making processes of the Board? What would make it work better?
- 2. What is the role of the Secretariat in supporting decision-making, and how has it changed over the years?
 - Is the division of responsibilities between the Board, the working group, task teams and the secretariat appropriate in terms of supporting strategic decision-making?
 - To what extent does the working group (or your task team) interact with or rely on the secretariat?
 - Does the Secretariat interpret Board decisions? How do members of the working group (or task team) influence that interpretation?
- 3. How does the working group (or task team) arrive at decisions about priorities and determine when a topic is ready to present to the Board for decision?
 - By consensus?
 - Do a few members tend to lead the decisions?
 - In making its recommendations, how does the working group achieve a balance between GAVI's global objectives and individual country priorities (or, alternatively, between GAVI's global and country-oriented objectives). An example would be investment in new and underused

- combination vaccines versus concern with country health system's ability to implement more complex systems and sustain costs.
- 4. What are the primary means of communications for you to get information about GAVI policies and decisions, especially information related to the work of your team, and do you find these to be adequate?
- 5. What are your views on use of investment cases to determine global funding priorities? Have they been used effectively to establish priorities and allocate funds? When should they be used? Would you change the process in any way?

How the Partnership Works

- 6. How well does the partnership work within the Working Group (or task team) and at other levels of the organization?
 - How has that changed given the growing influence of the Secretariat?
 - Is there sufficient representation of the stakeholder constituencies in the working group?
- 7. When working on the team, do you see yourself as representing your own organization, or primarily as a technical expert?
 - Do you have the time, resources and information you need to fulfill your responsibilities on the working group (or task team)? What would help you the most?
 - Have the time and resources available for you (or the equivalent person in your position) to fulfill your working group responsibilities changed over time?

GAVI's Added Value

- 8. What do you consider to be the major value added of the partnership? (E.g. bringing international and country-level attention to the need for immunization; bringing additional resources to the problem; being innovative in approach?)
 - How has it changed over time?
 - How can it be enhanced?
 - How effective has GAVI been in its advocacy role and why?
- 9. Are there other concerns on your mind you we haven't asked you about?

Questions for Reviewers of Investment Case Approach

Introduction:

The GAVI Alliance has commissioned Abt Associates to evaluate the performance of GAVI during Phase 1 (2000-2005) to identify lessons that may be useful for strengthening performance and the attainment of long term strategic objectives. GAVI identified 20 evaluation questions to be addressed in broad areas of governance, fiduciary responsibility, vaccine supply and pricing, country responsiveness, value and effectiveness of the partnership, and program impact.

One of the questions is to evaluate the effectiveness of GAVI's strategic decision-making approaches, and whether the investment case approach has resulted in a balanced portfolio overall.

We are aware of the findings of the Lessons Learned study that HLSP undertook in late 2005, and the differing opinions on when and how Investment Cases should be used. We also understand that in 2007 the Board decided that, rather than relying on individual investment cases, GAVI would develop a comprehensive vaccine investment strategy for Phase II to guide its investments, and that individual investment cases will be undertaken when needed within this overall strategy.

Questions:

Why did GAVI decide to use the investment case approach to allocate funding? How was GAVI making these strategic funding decisions before adopting this approach?

- 1. Please comment generally on whether GAVI has used investment cases effectively to determine global funding priorities. Has GAVI used this approach in the way it was intended when it was adopted in 2003-2004? Has its use changed over time?
- 2. Can you compare the way GAVI applies investment cases to the way it has been done in the World Bank? What are the pros and cons of each?
- 3. Criticisms of GAVI's use of the investment case approach include the following. Can you comment on the legitimacy of these, and how GAVI has tried to address them?
 - The time and effort required to develop an investment case is inappropriate, either because the decision-making process does not give enough thought to the analysis, or because in some cases there is already a rich base of evidence so that such detailed analysis is not warranted.
 - Certain issues are not covered well-enough; e.g. implementation issues, sustainability, country demand, harmonization.
 - There is lack of clarity on when investment cases should be developed.
 - They are used only to make decisions within a specific investment "bucket", but no across sectors.
- 4. From review of board reports, it is not clear that investment cases have been applied consistently to determine large, global funding priorities. Is there clarity as to why investment cases are used for some investments but not for other? For example,
 - 2004 \$37 million envelope for programmatic support to countries that wish to continue using or exploring using Hib vaccine.
 - 2006 \$22 million to support civil society groups (within HSS funding envelope)

• 2007 - \$50 million to explore GAVI's contribution to pandemic preparedness; and reprogrammed \$104.6 million from polio stockpile investment case for one-time intensive eradication activities.

Questions for Senior Management of the Secretariat

The following set of interview questions applies to selected key staff (Director of External Relations, Chief Technical and Policy Officer, Head of Country Support, and possibly Chief Financial and Investment Officer).

Introductory comments:

- The GAVI Alliance has commissioned Abt Associates to evaluate the performance of GAVI during Phase 1 (2000-2005) to identify lessons that may be useful for strengthening performance and the attainment of long term strategic objectives. GAVI identified 20 evaluation questions to be addressed in broad areas of governance, fiduciary responsibility, vaccine supply and pricing, country responsiveness, value and effectiveness of the partnership, and program impact.
- The evaluation team is aware of the recent decisions regarding changes in GAVI's governance structure. Our focus today is on somewhat related issues that may not be addressed by the new structure: GAVI's strategic decision-making processes, how well the partnership has worked, GAVI's added value, and effectiveness of its communications and advocacy efforts.
- Our focus in on Phase I, though it is important for us to understand changes and events that have occurred since then, in order for us to make timely and relevant recommendations.
- Our evaluation report will not identify who made specific comments, though we may use anonymous quotes to illustrate certain points, so please speak freely.

Leadership and Strategic Decision-making:

- 1. How do you perceive that the Board exerts its leadership on GAVI strategic direction and operations? How are the strategic objectives set (who drafts, vets, reviews, revises)?
 - Has this changed over time?
 - Do Board members have the time and resources they need to aid in decision-making? If not, what more do they need?
 - What is the Secretariat's role in decision-making; and in facilitating Board decision-making?
- 2. Are all the strategic objectives equally important? How were/are the relative importance of the strategic objectives then translated into funding allocation? (and has that changed over time)
- 3. How do Board decisions on policies and programs get interpreted and operational zed? What is the Secretariat's role in this? Who else is involved? Do other partners play a role?

What role does the Secretariat play in deciding the priority issues to bring before the Board (governance structure vs new strategic direction vs new funding commitment)? How do the partners provide input into what those important issues should be or how they should be framed?

- 4. How important are the strategic plan and annual workplan in Board decision-making?
 - What is the Secretariat's role in preparing these documents? Do you find them to be a good blueprint for achieving GAVI's strategic objectives?
 - Board meeting notes reveal that at various times the Board has found the workplans that are derived from the strategic plans to be more strategic and outcomes-focused. Has this occurred, and has it been helpful in directing GAVI's resources effectively to the strategic objectives?
- 5. Can you comment on adequacy of communications channels outside of board meetings both to get inputs for decision-making and to relay decisions to partners outside the board.—i.e. is the decision-making process inclusive and transparent?
- 6. GAVI has both global and country-based strategic objectives. What process does GAVI use to GAVI achieve a balance between these (e.g. promotion of new and underused vaccines versus health systems improvement and sustainability at the country level); and to arrive at decisions when country vaccine priorities seem to conflict with GAVI's global priorities?
 - What is the Secretariat's role in this?

Value-added of partnership:

- 7. What do you consider to be the major value added of the partnership? (E.g. bringing international and country-level attention to the need for immunization; bringing additional resources to the problem; being innovative in approach)
 - How has it changed over time?
 - How can it be enhanced?
- 8. Is there sufficient representation of the stakeholder constituencies in the board and other governance structures?
 - Do you feel they are adequately representing their constituencies?
 - How does the Secretariat facilitate partner contributions? Or should it have that role?

According to documentation, over the years the secretariat has assumed an increasing role in strategy, policy, and technical issues, taking over roles previously held by partners. There is some indication in the documents that this may have led to a diminution of the roles of some partners (e.g. research institutions, pharmaceutical industry). Can you comment on this? Is there a need to strengthen the technical role of partners? How might this be done?

- 9. One of the chief advantages frequently cited about GAVI's partnership structure has been its ability to make decisions, mount programs, and adapt to new requirements quickly. How would you rate GAVI on its ability to identify issues and to find good solutions in a timely manner?
 - To what factors do you attribute this?
 - Can you provide some specific examples?

Questions for the Director of External Relations

What is the working relationship between your division and the Board committees (past or present) on Advocacy, Civil Society, and Fund Raising?

What could GAVI be doing better to improve its track record in advocacy and in fund raising? What is your strategy to achieve this? Whom is it targeting? Who has been involved in formulating the strategy? How has it changed over time?

What have been the more effective advocacy approaches? How do you monitor effectiveness of your advocacy efforts?

How does GAVI communicate to countries about new programs and policies? How does GAVI become aware when there is confusion (e.g. between HSS and CSO support), and how do you make sure these issues are cleared up?

What do you view as the role of the RWG, and how do you communicate with them?

Questions for the Chief Technical and Policy Officer

What are the advantages and disadvantages of the workplan – does it give you the flexibility you need to be innovative? Does it ensure that annual activities maximize contribution to GAVI's strategic goals? Does it enable the Board to provide sufficient direction?

Are you satisfied with use of investment cases to determine global funding priorities?

- Have they been used consistently and appropriately?
- Have they been helpful to board members in making their decisions?
- What has been the Secretariat's role in determining when investment cases are needed, reviewing them and operationalizing Board recommendations?
- Will this change now that a long-term Vaccine Investment Strategy will be developed?

How does GAVI communicate to countries about new programs and policies? How does GAVI become aware when there is confusion (e.g. between HSS and CSO support), and how do you make sure these issues are cleared up?

What do you view as the role of the RWGs? How do you communicate with them? Do the RWGs have the resources they need?

Can you comment on the roles currently played by the ICCs and how these can be improved?

Questions for the Head of Country Support

What are the primary formal and informal means of communications with RWGs, country representatives and ICCs? How do you ensure that their perspectives are considered in GAVI's strategic planning? (We are already familiar with the Country Consultation Process used in preparation for Phase II.)

What do you view as the role of the RWGs? Do the RWGs have the resources they need?

How does GAVI communicate to countries about new programs and policies? How does GAVI become aware when there is confusion (e.g. between HSS and CSO support), and how do you make sure these issues are cleared up?

What is the process to review country progress (the monitoring IRC reviews APRs)? How does the Secretariat followup on recommendations of the IRC? What does GAVI do to assist those countries that are not improving? What more should it be doing?

What role have civil society organizations played at the country and regional level? Should these be strengthened, and if so, how?

What is GAVI's advocacy strategy? Whom is it targeting? How has it been formulated?

What have been the more effective advocacy approaches? How do you monitor the effects of your advocacy?

Questions for Chief Financial and Investment Officer

GAVI has made use of some very creative financing methods, such as IFFIm and AMCs, to assure long-term demand for new and developing vaccines.

- What were the factors that have enabled GAVI to be so innovative? How did its decision-making processes affect this?
- How involved have the various GAVI partners been in developing, analyzing and pushing forward these ideas?

Are you satisfied with use of investment cases to determine global funding priorities? Would you like them to continue to be used? In what situations?

As GAVI has grown and evolved, it has become necessary to increase staffing and financing of management costs and to support the technical assistance functions of partners such as WHO and UNICEF. In your view, have the cost increases been appropriate and sufficient? Has GAVI been able to retain its anticipated added value of efficiency in operations? Do partners have the resources they need?

What are the major financial issues you grapple with as they relate to achievements of GAVI's strategic objectives - including its value added as a public-private partnership?

Questions for Researchers and Expert Leaders

Introduction:

The GAVI Alliance has commissioned Abt Associates to evaluate the performance of GAVI during Phase 1 (2000-2005) to identify lessons that may be useful for strengthening performance and the attainment of long term strategic objectives. GAVI identified 20 evaluation questions to be addressed in broad areas of governance, fiduciary responsibility, vaccine supply and pricing, country responsiveness, value and effectiveness of the partnership, and program impact.

The GAVI evaluation steering committee asked the team to garner perceptions from stakeholders who have followed GAVI's evolution over the years about its strategic decision-making processes, how the partnership has worked, effectiveness of advocacy and communications systems, and GAVI's added value as a public-private partnership.

Our conversation is confidential. We will not quote you or attribute opinions to you in the report.

How the partnership has worked:

- 1. Based upon your deep knowledge of GAVI's beginnings, its growth, (and previous immunization initiatives), can you comment on the strengths and weaknesses of the partnership aspects of GAVI Alliance and the GAVI Fund as they have evolved over the years? Has GAVI been able to maintain the advantages (flexibility, quick decision-making) that were envisioned for it as a loose alliance of partners?
- 2. Can GAVI maintain its momentum? Is there a risk that GAVI pushes its partners and recipient countries too hard?
- 3. Has GAVI adequately addressed criticisms that have been raised about problems with global health partnerships? (These are general criticisms, not necessarily directed at GAVI. They include (1) skewing of country priorities by imposing those of donor partners; (2) depriving stakeholders enough of a voice in decision-making; (3) failure to compare the benefits of public vs private sector approaches; and (4) waste of resources through poor harmonization.)
- 4. Do all GAVI partners contribute to the Alliance in the way that was intended? Are all stakeholders and constituency groups adequately represented? How could this be improved?

Strategic decision-making:

- 5. From your observation of and participation in GAVI over the years, how do you believe most important decisions get made in practice? How has that changed?
 - How great a role do the different partners play in decision-making?
 - Are the views of various constituencies adequately represented?
 - On whom does the Board rely for analysis and recommendations? (Some say the Board's role is to rubber stamp decisions already made. Should this be changed?)
- 6. Has GAVI had adequate systems in place to ensure that funding decisions contribute effectively to achievement of its strategic objectives? How are its strategic objectives set?
- 7. How in your view has GAVI achieved an appropriate balance between global priorities and country-based priorities? Please explain.

Added value:

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8. What do you think has been GAVI's chief value-added as a global public-private partnership? Have there been areas where its success was greater or less than anticipated? If funding were immediately discontinued, what would GAVI leave behind?

Communications and Advocacy:

- 9. Has GAVI's advocacy strategy been effective? Why or why not? Can you offer any examples?
- 10. Can you comment on the adequacy of GAVI's communications channels? For example,
 - Is there a clear understanding, both inside and outside the Alliance, of its objectives and procedures?
 - Are new policies relayed to countries quickly and effectively?

 Are there adequate means for recipient countries and other constituency groups to make input into GAVI's policy decisions and implementation procedures?
11. Does the decision-making process appear to be inclusive and transparent?
Overall:
12. How has GAVI changed the landscape for immunization programs? Who benefits and loses?

ANNEX D: INTERVIEW GUIDES FOR ADIPS, AND VACCINE SUPPLY AND PRICING

Section 1: What have the ADIPs achieved and how useful a model is this for the future?

- 1. Thinking about both the RVP and the PneumoADIP and their work on establishing disease burden for pneumococcal disease and rotavirus, communication and awareness activities at both a global and country level and industry relations for supplying affordable vaccine for developing countries, what in your opinion have the ADIPs collectively achieved during GAVI Phase I?
- 2. What would you consider the ADIPs greatest strengths and weaknesses?
- 3. The structure for the ADIPs was built around three areas, 'Establish Value, Communicate Value, and Deliver Value'. Could you please comment on the structure;
 - a. Is this the appropriate structure to meet the goals of the ADIPs?
 - b. Did the structure support or hinder the work of the ADIPs?
 - c. What changes or recommendations would you suggest for future ADIPs
- 4. The governing body for the ADIPs is the Management Committee (MC), do you feel the MC s role was supportive of the ADIPs, if supportive please explain why, if not please explain why?
- 5. What were the strengths and weaknesses of the MC in managing the ADIPs? Would you recommend this governance structure for future ADIPs?
- 6. Can you comment on the GAVI resources for the ADIPs, such as funding, personnel, partner support and engagement? Do you feel the ADIPs had sufficient resources to complete the goals of the project, if yes, please explain why, if no, please explain why.
- 7. Were the ADIPs successful in your opinion in bringing together a collaborative effort of the public/private sector? If not why? What could the ADIPs have done differently to align the public/private sector collaboration?
- 8. The ADIPs worked for 5 years to accelerate 'close to market products', what gaps, if any, can you identify in the ADIPs work. Please explain.
 - a. Why do you think these gaps occurred?
- 9. In your opinion how successfully did the ADIPs work with GAVI in terms of meeting GAVI's strategic objective of accelerating new vaccine introduction, contributing to the inclusion of additional suppliers for GAVI markets, and affecting affordable pricing for low income markets?
 - a. How successfully did GAVI work with the ADIPs to achieve their goal of accelerating new vaccine introduction in developing countries?
- 10. Each ADIP was initially funded with \$30 million dollars over 5 years and then extended for 1 more year with additional investment from GAVI, do you think that the ADIP 'value' equaled GAVI's investment? Please explain.
- 11. What would you suggest the ADIPs could have done differently to achieve their goals?
- 12. In your opinion would you recommend future ADIPs for new vaccines in the pipeline? If so why? If not why?

Section 2: To what extent have the ADIPs made it more likely that there will be a more rapid country uptake of new vaccines when they are ready for introduction

- 1. In your opinion what are the major contributions of the ADIPs for new vaccine introduction in low income countries?
- 2. Have the ADIPs successfully addressed the factors such as appropriateness of vaccine, disease burden, advocacy, and country readiness to assure accelerated uptake of new vaccines?
- 3. Have the ADIPs adequately addressed regulatory issues to accelerate vaccine adoption? Please explain.
- 4. Given what you know about the ADIPs work, have they worked successfully with manufacturers in influencing vaccine supply and pricing to achieve a more rapid country uptake?
- 5. How have GAVI and its partners worked with the ADIPs to assure country-level readiness for new vaccine adoption?
- 6. In the absence of the ADIPS, please comment on how GAVI and its partners would have achieved a rapid country uptake of new vaccines

Section 3: To what extent has the GAVI Fund & GAVI Alliance been successful influencing vaccine pricing and supply? What can be learnt from the Phase I experience to strengthen and improve the future strategic response in this area?

- 1. Focusing on developing country markets how has GAVI and their partners influenced vaccine supply and pricing?
- 2. During Phase I, 2000-2005, in your opinion has GAVI effectively signaled to industry to influence or change the market?
 - a. What GAVI signals or activities in your opinion have influenced vaccine supply during Phase I?
 - b. What GAVI signals or activities in your opinion have influenced vaccine pricing during Phase I?
 - c. What GAVI signals or activities ensured affordable pricing for vaccines for developing countries?
 - d. In your opinion, has GAVI encouraged additional suppliers to enter the market for existing vaccines? If so what activities or signals were used to encourage the suppliers? If not what could GAVI have done differently?
- 3. Has GAVI and their partners addressed the issues of demand creation and credible demand forecasting to influence vaccine supply and pricing?
- 4. Thinking about Hep B, what role did GAVI play on influencing vaccine supply and pricing for Hep B vaccine?
- 5. Thinking about HIB, what role did GAVI play on influencing vaccine supply and pricing for HIB vaccine?
 - a. Thinking back about the shortage of pentavalent vaccine for GAVI countries, what in your opinion was the reason of the shortage? Were there any activities GAVI could have done to prevent the shortage in developing countries?
 - b. What could GAVI have done differently to avoid this situation?
- 6. In your opinion is it possible for the Alliance to influence suppliers to be more responsive in the developing country markets? If so in what ways?

- 7. Thinking about the Alliance partners, specifically UNICEF, how have UNICEF procurement activities during Phase I influenced the market and suppliers? Have they contributed to lowering prices for vaccines? In what ways have they influenced suppliers' behavior in the market?
- 8. Do you feel the donors in the Alliance have influenced suppliers' behavior during GAVI phase I? If so, in what way? If not what could the donors have done differently to encourage suppliers in the market? In what ways could the donors have they influenced pricing of vaccines?
- 9. In what ways does the size the GAVI Alliance fund, billions of dollars, impact supplier behavior? Do you feel it is an incentive for manufacturers to enter the market? Lower prices to remain in the market? Increase capacity to supply the market?
- 10. Can you give several ways in which the Alliance influenced either positively or negatively vaccine pricing?
- 11. What lessons learned in GAVI Phase I could be used to strengthen and improve GAVI's response to the market in the future?
- 12. What additional activities in your opinion could GAVI implement to influence vaccine supply and pricing of existing vaccines?
- 13. Overall what was GAVI's most valuable contribution in developing the market in low income countries?

ANNEX E: LIST OF INTERVIEWEES

Name and contact info	Position	Years in position	Constituency
G	AVI Alliance and GAVI Fund Boa	ırds	
David Fleming	Board member, GATES	2005 – present	Foundation
	Board member, Tech Institute (CDC)	2001 – 2003	
Jean-Marie Okwo-Bele	Board member, UNICEF	2002-2003	UNICEF
Joy Phumaphi	Board member, WHO	2003 – 2006	WHO
	Board member, WB	2007 onward	
Jean-Louis Sarbib	Board member, WB	2003 – 2006	WB
	Fund board member	2007 onward	
Dr. Sigrun Mogedal	Board member, Ind. Country (Norway) Working group member Board member, Ind. Country (Norway)	2001 – 2002 2002-2004 2005 - 2006	Ind. Country
Dr Francisco Songane	Board member	2003-2004	Dev. Country
Ann Peterson	Board member, Ind. Country (USA)	2002-2003	Ind. Country
Carol Bellamy	UNICEF	2000-2003	UNICEF
Gordon Perkins	Board member, Vaccine Fund	2001	Vaccine Fund
George Wellde	Board member, Vaccine Fund	2002 - present	Vaccine Fund
Marijke Wijnroks	Board member, Ind. Country (Netherlands)	2000-2001, 2005	Ind. Country
Montasser Kamal	Board member, Ind. Country (Canada)	2003-2006	Ind. Country
Rick Klausner	Board member	2002-2004	Gates Foundation
Charles Lyons	Chair of Vaccine Fund Executive Committee and member of Vaccine Fund Board	2000-2007	Gates Foundation

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Name and contact info	Position	Years in position	Constituency	
W	ORKING GROUP and TASK FOR	CES		
Steve Landry	Working Group, formerly on Financing Task Force	2001 - present	Foundation	
Michel Zaffran	Working Group member	1999-2002	WHO	
	Former Deputy Exec Sec of GAVI, now at WHO	2006-2007		
Dr. Paul Fife	Working Group, UNICEF		UNICEF	
Dr. Suresh Sakharam Jadhav	Working Group, Devel. Count. Vaccine	2005 – 2007	Manufacturer	
Nihal Abeysinghe	Working group, Devel Country (Sri Lanka)	2005 – 2007	Dev. Country	
Logan Brenzel	Advocacy Task Force, Task Force on Country ccoordination, Financing Task Force, World Bank		WB	
Amie Batson	Working Group, World Bank	2000-2002	WB	
	INVESTMENT CASE EXPERTS			
Maureen Law				
SECRETARIAT				
Julian Lob-Levyt	Ex. Sec	2004 onward	GAVI secretariat	
	Board member	2001 – 2003		
Alex Palacios	Dir., External Relations, GAVI Secretariat		GAVI secretariat	
Bo Stenson	Former Secretariat staff	1999-2005	GAVI secretariat	
Mercy Ahun	Head, Country Support, GAVI Secretariat	2000 onward	GAVI secretariat	
Lisa Jacobs				
Tore Godal	Ex Sec of Secretariat,	1999 – 2004	GAVI secretariat	
	Special Advisor to Norwegian Prime Minister GAVI	2005 onward		

Name and contact info	Position	Years in position	Constituency
Alice Albright	Chief Financial and Investment Officer		Vaccine Fund
07	THER KNOWLEDGEABLE INFORM	MANTS	
James Maynard	Knowledgeable about Children's Vaccine Initiative		Foundation/CSO
Robert Steinglass	IRC member		Tech Inst
	Tech. Director, IMMUNIZATION Basics		
Dr. Mark Kane	Working group member	1999-2001	CSO
	Board member, CSO (Children's Vaccine Program/PATH)		
William Muraskin	Queen's College, CUNY		Other
Mary Starling	Save the Children		Other
Gustav Nossal	University of Melbourne		Other
Veronica Walford	HLSP		Other
Ruth Levine	Center for Global Development		Other
INFORMANT	S ON ADIPS and VACCINE SUPP	LY AND PRICING	3
Jacqueline Keith	Wyeth		Multinational Supplier
Elaine Esber	Merck		Multinational Supplier
Walter Vandersmissen	GSK		Multinational Supplier
Shawn Gilcrest	Sanofi Pasteur		Multinational Supplier
Dr. Suresh Jadhav	Serum Institute of India		Emerging Market Supplier
Dr. Varaprasad Reddy	Shantha (India)		Emerging Market Supplier
Summana Khomvilai	Bio Farma (Indonesia)		Emerging Market Supplier
Ling Jiang	Cheng du (China)		Emerging Market Supplier
Orin Levine	Johns Hopkins University		Pneumo ADIP
John Wecker	PATH		Rota ADIP

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Name and contact info	Position	Years in position	Constituency
Professor Jan Holmgren	Chair of ADIP MC		ADIP Management Committee
Mr. Kevin Reilly	Wyeth		ADIP Management Committee
Dr. Brian Greenwood	London School of Hygiene and Tropical Medicine		ADIP Management Committee
Dr. Harry Greenberg	Stanford University		ADIP Management Committee
Dr. Mathuram Santosham	Johns Hopkins University		Permanent Observers for MCM
Shanelle Hall	Director, SD		UNICEF
Thomas Sorensen	Chief Immunization, SD		UNICEF
Dr Osman David Mansoor	Senior Advisor, EPI		UNICEF
Julie Milstien	Independent consultant		Independent consultant
Susan McKinney	Senior Technical Advisor for Immunization		USAID

ANNEX F: QUESTIONS FOR EPI MANAGERS AND RWG MEMBERS

Introduction

The GAVI Alliance has commissioned Abt Associates to evaluate the performance of GAVI during Phase 1 (2000-2005) to identify lessons that may be useful for improving performance and the attainment of long term strategic objectives. The findings of this evaluation will also serve an important function in terms of accountability to donors and GAVI eligible countries. The 2007 – 2010 strategy reflects some but possibly not all lessons from Phase 1. This evaluation should therefore help identify additional lessons that could further improve GAVI's future performance.

The evaluation encompasses all aspects of GAVI operations and programs. It will evaluate its decision making processes, its effectiveness as a partnership of stakeholders, program design, and overall impact. It will rely on qualitative and quantitative data, including information from GAVI partners at regional and country level. Our final report will not identify who made specific comments, so please feel free to respond openly. You can also address any follow-up comments outside of this meeting to vmolldrem@aol.com.

Questions

1. Communications:

- How are policy decisions and country program decisions communicated to you?
- Do you receive understandable, on-time information?
- Are the rationales for decisions clearly explained and transparent?
- Do you have an opportunity to make input into these decisions?
- How do RWG members provide feedback, either through their institutional channels or directly to GAVI?
- What role does the RWG play in informing and interpreting decisions that affect countries and programs in your region?

2. Program design issues:

- Is there more effective technical support at country level since GAVI? Why or why not? What is the source of this support? What role, if any, does the RWG play in this?
- Is there sufficient M&E at the country level to measure progress and meet GAVI's requirements? Is there more that should be done? Does the RWG have a role to play?
- How harmonized/aligned is GAVI funding and programs with other funding and activities in country? What can be done to improve harmonization?
- What are the primary functions of the RWG in furthering GAVI's programs and objectives? How has this changed over time?

3. GAVI Decision-making Processes:

- Do you find that GAVI gives adequate consideration to priorities and needs for countries in your region in its policy-setting (both programming NVS, INS, ISS, etc and choice of new vaccines to support) and country decision-making? What should be done differently?
- Does GAVI's emphasis on promotion of underused and new vaccines sufficiently address the needs and priorities for countries in your region?
- Have you found GAVI to be responsive and adaptable as conditions change over time?
- 4. Working relationships among partners at regional and country level:
- What are the roles and responsibilities of various partners within the RWG and country level?
- Are the major stakeholder groups represented in the RWG and country ICCs? Which groups are the most active? Which might be underrepresented? Are there any changes you would recommend?
- How do you ensure coordination among the partners at regional and country level?
- How harmonized/aligned is GAVI funding and programs with other funding and activities in country? What can be done to improve harmonization?

5. Advocacy:

• Has GAVI or have GAVI partners been effective advocates for immunization in your region or countries in your region? What were activities that were particularly effective? Is there room for improvement? How?

6. GAVI's Added Value:

- What has GAVI brought to the immunization program in your country or to countries in your region, beyond programs financed, that would not have occurred without GAVI?
- What do you see as the chief strengths and weaknesses of GAVI's programming?

7. Sustainability

- What are the challenges for countries in maintaining the improvements made? Is GAVI adequately addressing those challenges?
- Are the challenges primarily financial ones, or is programmatic/technical sustainability also an issue?
- 8. Do you have other comments?

ANNEX G: SUMMARY OF RWG AND EPI MANAGERS MEETINGS

Meeting attended	Location	Date
SEARO RWG	Jakarta, Indonesia	29 January, 2008
East Africa EPI managers meeting	Dar es Salam, Tanzania	27-29 February, 2008
West Africa RWG	Ouagadougou, Burkina Faso	8 March, 2008
West Africa EPI managers meeting	Ouagadougou, Burkina Faso	5-7 March, 2008
Central Africa RWG	Douala, Cameroon	17-18 March, 2008
Central Africa EPI managers meeting	Douala, Cameroon	19-21 March, 2008

	Participants
SEARO RWG	RWG members, Indonesia NIP and NIP partners
CA RWG	Gabon and DRC regional offices
EA EPI Mgrs and RWG	Zambia, Uganda, Tanzania, Kenya, Comoros, Mozambique, Lesotho, Malawi – includes national EPI managers, WHO and UNICEF focal points for immunization
WA EPI Mgrs and RWG	Mauritania, Benin, Cote d'Ivoire, Niger, Guinea Bissau, Togo, Liberia, Guinea, Gambia, Sierra Leone, Ghana – includes WHO and UNICEF focal points for immunization. This summary also includes Burundi, which is in the Central Africa region.

Topic 1:	GAVI communications at the regional and country level
Summary findings	Communications have improved during Phase 1, but there are still ongoing issues – though these are not consistent problems, GAVI communications are not always directed to the right people, and GAVI sometimes does not clearly explain its decisions. Lack of timely information about funding disbursed remains a chronic problem.
SEARO RWG	GAVI's communications have improved – esp formal communications and GAVI website – informal communications still has problems – RWG sometimes bypassed, GAVI country support person does not always get information out to them.
CA RWG	Often "informed by chance" – GAVI's mailing lists are incomplete. Sometimes participants were able to get info quick because of their own connections. However, when they provide feedback, GAVI does take it into consideration.
EA EPI Mgrs	Mostly good, in both directions, during Phase I. In a few countries, informal communications (e-mail, copies of official letters) did not occur evenly so info. did not get to action officers until near the deadline. Sometimes rationales for decisions were not adequately explained. As ICCs are subsumed under broader technical coordination committees, GAVI communications have not always gone to the right people.
	Some countries are not notified when GAVI transfers funds or advise how much is transferred, causing spending delays.
WA EPI Mgrs	Generally good to excellent, no single system (sometimes communications go through MOH, other times through WHO). However, some felt they were not adequately consulted

about decisions affecting them. E.g. new financing structure for vaccines – two EPI managers were not consulted before decision and do not understand rationale. There may be lack of conformity to documentation from GAVI.

Chronic problem is with transfer of funds – EPI managers are not getting the information about when funds are transferred and how much.

Topic 2:	How the GAVI partnership functions at the regional and country level
Summary Findings	Partnership mechanisms (e.g. RWG, ICC) function well, but GAVI itself is viewed as a separate donor rather than a partnership. Most EPI reps were satisfied that ICCs were active, helpful in advocating, harmonizing, vetting proposals.
SEARO RWG	GAVI gets more attention than individual partners, because it controls so much money. It is viewed as a separate entity (rather than an alliance) at the country level – and seems to consider itself a separate partner centrally as well.
	There is competition between GAVI and its partners, causing some tensions. There is conflict of interest with WHO as both a recipient of GAVI funds and board member
CA RWG	At regional level, all the major partners are in the RWG. The RWG coordinates West African technical assistance.
	At country level, GAVI is seen as complementary activity, aligned with national policies. Generally, country coordinating groups (e.g. ICC) coordinate TS in country,
EA EPI Mgrs	ICCs were quite active during Phase I, though participation could have been broader – with more bilaterals and more CSOs.
	ICCs vetted proposals, harmonized donor activities, and added clout in country negotiations with GAVI. WHO and UNICEF, who were expected to be GAVI reps in country, had too many other responsibilities to do this function well, and were limited by the need to maintain good relations with the Ministry. In recent years, as sector-wide coordinating committees have been established, partner membership on ICC is at a lower level so it has lost influence
WA EPI Mgrs	The ICCs were quite active and had membership including international donors and local NGOs. They played a role in advocacy, donor coordination, review of proposals and as a check and balance on how funds are spent. Participation is generally good.

Topic 3:	Roles and Responsibilities of the RWG
Summary	RWGs support country programs by coordinating and providing TA and reviewing GAVI proposals, but since WHO generally acts as an interface between EPI Managers and the RWG, EPI Managers are mostly unaware of the RWG's role. RWG role in improving quality of proposals, other than through TA provided, appears very limited.
SEARO RWG	The RWG reviews coverage, coordinates TA, offers support to countries in reviewing applications. It is essential for providing a mechanism to follow up on technical problems. Once TA needs are determined, partners to the RWG agree who will provide the TA; but the RWG is dominated by WHO and UNICEF. The RWG has no official role – it provides input to GAVI through the individual agencies of the partners, so the process of making inputs is ad hoc.
CA RWG	The RWG follows programs in countries of the region, informs them of GAVI policy, and, when asked, provides TA. TA is often to prepare required documents and ensure they are submitted on time, and to review monitoring and evaluation.
	When the TA is to be provided in a contiguous country the provider must pay up front, then be reimbursed by GAVI, this can sometimes cause problems in financing the TA
EA EPI Mgrs	Only one EPI group interviewed had ever heard of the RWG. None saw it as a source of

	technical support. None mentioned its role in reviewing proposals.
	Countries rely on WHO or other donors to provide technical support.
WA EPI Mgrs	One country said the RWG plays a role in technical support.
	Countries rely on WHO and UNICEF to provide appropriate TA.

Topic 4:	Perceptions of GAVI Decision-making
Summary	Although GAVI's initial strategic decisions were less transparent (types of vaccine supported, different funding windows) GAVI's decision making process has improved over time. GAVI's key decisions are set centrally, but GAVI does take country needs into consideration and gives opportunities for country inputs. GAVI cannot always accommodate these.
SEARO RWG	In Phase I, GAVI's decisions on what vaccines to support was ad-hoc – focused on what was already available. Decisions on the portfolio of vaccines were not transparent.
	The GAVI WG was very influential but it is not clear how people were appointed, what were the criteria and what was the TOR.
	Developing countries have two members on the Board, but there is no mechanism for them to get feedback from developing countries (until recently).
CA RWG	GAVI's decision-making process has improved over time. GAVI seems up to date on the situation in countries, and has taken country opinions into consideration when setting policy and making decisions. There have been exceptions, however.
	Partners have adequate ways to provide inputs into GAVI decisions
EA EPI Mgrs	GAVI presented funding windows after decisions were already made, but GAVI's vaccine priorities were in line with those of the countries and enabled them to introduce vaccines earlier. While GAVI influenced country decisions, it was generally to improve them – e.g. to focus on vaccine safety. Most agreed that GAVI takes country situations into account and enters into on-e-on-one discussions with them to resolve issues.
	Further, GAVI is quite flexible in adjusting its requirements for specific country needs
WA EPI Mgrs	GAVI made a real effort to understand country situations and did not impose vaccine programs on them. However, sometimes the vaccine available from GAVI was not the one the country preferred (e.g. monovalent vs. polyvalent). Biannual partners meetings, Ministers meetings, and other forms of country consultation have provided the opportunity for countries to make inputs into GAVI decision making. These should continue. GAVI's strategic policies & flexibility have made a real difference in the work of recipient countries.

Topic 5:	GAVI's Role in Technical Support
Summary	GAVI technical support primarily was targeted to meeting GAVI requirements (FSP, DQA, etc), however, countries were satisfied with and appreciative of technical support provided by GAVI.
EA EPI Mgrs	Countries were satisfied with the technical support they received. Most TS requested related to meeting a GAVI requirement (project design, FSP, DQA)
WA EPI Mgrs	Through WHO and UNICEF GAVI provides effective technical support, including required GAVI documents but also improving vaccine safety and preventing vaccine loss. GAVI tries to facilitate the countries' own processes, so that the results are country-owned – so the country determines what TS is required. Flexibility in GAVI funding enables countries to obtain expertise locally.

CA EPI Mgrs	No response
9.0	

Topic 6:	Topic 6: GAVI's Monitoring and Evaluation Requirements	
Summary	GAVI's M&E requirements are not too onerous, but the reporting demands are increasing, the requirements are time consuming, and it is not apparent that GAVI follows up on what countries say they will do.	
EA EPI Mgrs	GAVI requirements are not too onerous, and GAVI has been flexible in allowing for adjustments. The recommendations flowing from the DQAs are considered quite difficult and will take some time to complete.	
WA EPI Mgrs	No one complained about GAVI's monitoring and evaluation requirements. However, GAVI seems to demand more and more information in their forms. This is very time consuming. Yet there is no formal mechanism for monitoring what we said we would do – this makes the forms just a formality. GAVI does not ask if we did what we said we would do and, if not, what was the obstacle, even if we note the same problem in application after application.	

Topic 7:	Topic 7: Harmonization	
Summary	There is general agreement that GAVI has helped harmonize donor and government programs for immunization	
SEARO RWG	A key accomplishment of Phase I was harmonization among the immunization players. HSS is the next step, to now harmonize with other programs.	
CA RWG	GAVI is aligned with national policies, and within countries coordinating bodies work to coordinate partners	
EA EPI Mgrs	Programs are well harmonized because of the ICC, the FSP, or the cMYP.	
WA EPI Mgrs	ICCs play a role in donor coordination.	

Topic 8:	Topic 8: Effectiveness of GAVI's Advocacy	
Summary	All agree GAVI's advocacy has resulted in greater awareness by governments of the importance of immunization, but there remains a need to maintain the focus on immunization, particularly with high level officials, and to translate that into funding commitments.	
SEARO RWG	GAVI has brought a much higher profile to immunization. Ministers are much more aware.	
CA RWG	Advocacy has moved from convincing governments of the need for immunization to convincing them to include funds in the national budget.	
EA EPI Mgrs	GAVI has brought greater attention to immunization in recipient countries. Visits by GAVI board or secretariat to the country, GAVI-sponsored meetings of ministers have helped maintain visibility. The ICC can do advocacy at lower levels, but GAVI could find ways to put pressure on higher levels of gov't to keep focus on immunization, and to help countries develop and fund advocacy strategies. Funding surveillance studies would enable advocates to make the case that incidence of disease justifies immunization spending.	
WA EPI Mgrs	GAVI made the case for need for new vaccines. Visiting countries and debating issues helps. GAVI could do more to relate directly to high-level government policy makers. Advocacy is needed at level of President, Prime Minister, and MOF as well as MOH.	

Topic 9:	Effectiveness of GAVI's Advocacy
Summary	All agree GAVI's advocacy has resulted in greater awareness by governments of the importance of immunization, but there remains a need to maintain the focus on immunization, particularly with high level officials, and to translate that into funding commitments.
SEARO RWG	GAVI has brought a much higher profile to immunization. Ministers are much more aware.
CA RWG	Advocacy has moved from convincing governments of the need for immunization to convincing them to include funds in the national budget.
EA EPI Mgrs	GAVI has brought greater attention to immunization in recipient countries. Visits by GAVI board or secretariat to the country, GAVI-sponsored meetings of ministers have helped maintain visibility. The ICC can do advocacy at lower levels, but GAVI could find ways to put pressure on higher levels of gov't to keep focus on immunization, and to help countries develop and fund advocacy strategies. Funding surveillance studies would enable advocates to make the case that incidence of disease justifies immunization spending.
WA EPI Mgrs	GAVI made the case for need for new vaccines. Visiting countries and debating issues helps. GAVI could do more to relate directly to high-level government policy makers. Advocacy is needed at level of President, Prime Minister, and MOF as well as MOH.

Topic 10: Effectiveness of GAVI's Advocacy	
Summary	All respondents are concerned about financial sustainability, and some feel GAVI needs to commit to a longer financing period.
CA RWG	There are two issues: (1) gov't need to increase financing of EPI and (2) GAVI need to realize that longer financing will be required in post-conflict countries
EA EPI Mgrs	Financial sustainability is the key issue. Countries do not expect to be able to achieve sustainability without extension of GAVI support. The FSP makes assumptions about government future funding levels for immunization which may not be correct.
	There is also an issue as to how to balance initiation of new vaccines against full implementation of existing vaccine programs.
WA EPI Mgrs	For most countries financial sustainability remains problematic. It's a great idea, but it's difficult to write a plan and fund it.

Topic 11:	Topic 11: GAVI's strengths	
Summary	Major strengths identified were (1) GAVI's flexibility to make adjustment for country situations and to allow countries alternatives in implementing country programs, and (2) conditionality that all ICC partners agree to, providing substantial leverage to ensure government action.	
CA RWG	Flexibility	
	Conditionality that makes all partners sign	
	Report requirements	
EA EPI Mgrs	Flexibility to take country situations into account	
	Absence of earmarking which gives countries ability to make adjustments	
WA EPI Mgrs	Flexibility – allows us alternatives in implementing programs and is structured so that support is country driven	

Topic 12: GAVI's Weaknesses	
Summary	There was no single weakness highlighted – each group cited different areas for improvement, ranging from greater clarity on certain issues to increased complexity of reporting forms.
SEARO RWG	Lack of clarity from GAVI on certain issues – e.g. the HSS program and RWG's responsibilities towards it,
	Some board members have more influence than others, and there are conflict of interest with certain partners
	Lack of clarity on role of the RWG.
CA RWG	Insufficient background analysis prior to agreeing to support grant proposals.
EA EPI	Flow of funds problem cited earlier.
Mgrs	Perhaps too much funding flexibility.
WA EPI	Lack of realism by GAVI about what countries can really achieve (re. financial sustainability)
Mgrs	Period of support is too short
	GAVI changes its form too frequently – increase in complexity of forms with no apparent review by GAVI.
	One comment: GAVI should remember that many people in their countries have a vision of how to improve the health situation, but don't have the funds"
	Lack of formal mechanism for monitoring what countries say they will do.

Topic 13:	GAVI's Added Value
Summary	The primary added values listed by respondents were increased knowledge by countries of importance of immunization; increased resources for immunization; capacity building through management tools and other innovations; better partner coordination; and vaccine safety.
SEARO RWG	A higher profile for immunization; getting immunization back on the national agenda. Organizing the conversation: getting all the partners involved.
	Provision of new resources for immunization.
CA RWG	New money for vaccines; improved geographic coverage for immunization; and vaccine security.
EA EPI Mgrs	Increased understanding of the importance of immunization and country ownership of immunization programs; better coordination of partners; innovations like AD syringes and new tools for management; better coordination among partners; new resources.
WA EPI Mgrs	Building of country capacity to manage EPI programs; including identifying system-wide barriers, improved logistics and program management, and vaccine safety.

ANNEX H: RESEARCH GUIDE FOR COUNTRY VISITS

GAVI Phase 1 Evaluation Guide for Country Visits

The GAVI Alliance has commissioned Abt Associates to evaluate the performance of GAVI during Phase 1 (2000-2005), in order to strengthen GAVI's continued development in its second phase (2006 - 2010). The 2007 - 2010 strategy reflects some but possibly not all lessons from Phase 1. This evaluation should help identify additional lessons that could further improve GAVI's future performance.

The objectives of the evaluation are:

- To identify and learn from the successes and weaknesses of the GAVI in Phase 1, including how well it has evolved and learnt from experience over the period 2000-2005.
- To contribute to refinement or adjustment of GAVI policies in its next strategic phase of work.
- To document impact and to evaluate the efficiency and effectiveness of the GAVI Alliance's use of resources during Phase 1.

Stakeholder interviews at the country level are meant to elicit country responses from a wide range of people who were involved with GAVI support during the period of 2000-2005. GAVI has changed significantly since 2005, so whenever possible, we want to contact the persons who were involved during the period of 2000-2005 in order to assess the situation during GAVI phase 1.

People to be Interviewed

Group or	Types of People to be Interviewed
Institution	
MOH (central	 Overall MOH manager – Director General level
level)	 Manager of Directorate in which NIP falls – Director of
	Preventive Services level or Secretary General
	Planning Unit
MOF	 MOF manager responsible for oversight of and allocations to the
	health sector
	 MOF manager responsible for oversight of and allocations to the
	immunization program
	 MOF staff represented on the ICC
NIP	Current NIP manager
	 NIP managers from 2000 - present
	 Others identified by the NIP manager, ICC, or MOH
ICC	 WHO and UNICEF representatives on the ICC, and technical
	staff
	 Other ICC members – particularly NGOs
Donor	 Donor representatives on the health sector coordinating group,
Representatives	SWAp or similar coordinating body.

Group or Institution	Types of People to be Interviewed
	 Donors with large health projects
	 Representative of GFATM, if they are receiving GF grants
	Aim to meet with at least 2-3 big donors in the health sector.

General Guidelines

Pls note some items that you should request and clarify earlier in your visit – under the sections *Beneficiaries of GAVI* and *Harmonization*. You may not get very good data on how GAVI funding was distributed, but try for as much specificity as possible. You need not have written documentation on the planning and funding process, but should feel you have sufficient clarity regarding key differences between various funding sources.

All topics should be covered with the core technical group (NIP Manager and team, WHO technical staff, and UNICEF technical staff). You should aim for at least 2-3 hours of time with these folks during you visit – some discussions may take place as a group (harmonization, ADIPs, etc), but other topics may be best for individual discussions (M&E, coordination of TA, value-added of GAVI). Only selected topics are suitable for other MOH staff, MOF, and other health donors, as noted. Lastly, you will not be able to cover all topics with all ICCs members – what you discuss with whom will depend on their interests, involvement in the ICC, and how long they have been in country.

Topic	MOH Outside NIP	MOF	NIP Mgr & staff	WHO Tech Staff	UNICEF Tech Staff	ICC Member s	Other Health Donors
Communication and advocacy	XX	XX	XX	XX	XX	XX	Donors
Monitoring and evaluation	XX	XX	XX	XX	XX	XX	
Coordination of TA			XX	XX	XX	**	
Beneficiaries of GAVI			XX	XX	XX	**	
Sustainability of improvements	XX	XX	XX	XX	XX	XX	
Impact of ADIPs of uptake			XX	XX	XX	**	
Harmonization with other programs	XX	XX	XX	XX	XX	XX	XX
Value added of GAVI Alliance	XX	XX	XX	XX	XX	XX	XX

Introductory questions:

- What is your current position? What are your responsibilities?
- How long have you been in this position?
- What other positions have you held related to your current post (e.g. same position in different country, different agency same country, etc)?

Communication and advocacy

Reference to question #12 of RFP: How effective has the GAVI Alliance & GAVI Fund communication and advocacy systems been at all levels (i.e. between governance entities, partners and countries), and how well are they coordinated with other partners? Some questions are also related to RFP Question #2 regarding GAVI decision making processes, and consideration of country needs and priorities.

- How were GAVI policy decisions, new program requirements (DQA, FSP, HSS, CSO), and country program decisions communicated to you? Were the communications timely and clear? Pls give specific examples.
- Who was the official contact for GAVI communications during Phase 1? Did information get communicated to all members of the ICC, or were there delays then in-country?
- Did the RWGs play a role in communicating or interpreting GAVI decisions to recipient countries? Conversely, what role does the RWG play in communicating country concerns and feedback to GAVI?
- How did these communications processes change over the course of Phase I? Did it improve and what are areas still in need of improvement?
- How do you respond to GAVI decisions and policies? Do you feel you have adequate input into GAVI decisions and policies? Do GAVI's programs meet the most acute needs of the NIP in your country?
- What currently is your primary source of information regarding GAVI programs and policies?
- Has GAVI or GAVI partners been effective advocates for immunization in your country and globally? What were activities that were particularly effective? What were the results of those activities? What more can be done?
- Has the ICC been an effective advocate for immunization in your country? What has been accomplished? What more can be done?
- What is needed to ensure commitment to immunization, given all the other competing health needs?

Monitoring and evaluation

Reference to question #5 of RFP: How adequate and appropriate has the GAVI Alliance approach to monitoring and evaluation at country level been?

Questions to ask NIP donors/partners/MOH:

- What mechanisms are in place to monitor funding from GAVI? Who prepares reports of expenditures? Who reviews these? How often?
- Are GAVI funds audited? When was the last time an audit was conducted?
- Who is responsible for monitoring the progress of the immunization program?
- What is the role of the ICC (and the TWG or technical subcommittee) in monitoring and evaluation? Does the ICC receive performance reports from the NIP beyond what is required for GAVI (give examples)?
- Thinking about new strategies implemented, or additional funds committed to support existing activities – how did you evaluate the performance and results?
- Is GAVI's approach to monitoring and evaluation appropriate (are they insufficient, overly burdensome)? What more should be done – at global level, and at country level? Or, what should be eliminated or simplified?

Questions to ask NIP manager:

Can you pls comment on the GAVI reporting requirements (are they appropriate, too burdensome, confusing)?

• Have the changes in the reporting format been helpful? Have they clarified/simplified reporting? Do you use the reports as part of your internal planning and evaluation?

Technical assistance (core group)

Reference to question #13 of RFP: To what extent has GAVI enabled an effective, efficient and acceptable approach to technical assistance provision at country level? *Answers may tend toward TA to support GAVI requirements, such as to develop an FSP or HSS application, but we want to be sure they talk about TA for NIP – to assess cold chain equipment, to develop IE&C strategy targeting low-performing districts, etc.*

Questions to NIP managers:

- What is the role of the ICC or the TWG in identifying TA needs and coordinating TA response?
- What kinds of technical assistance have you requested for the immunization program, and have the partners been responsive?
- Has GAVI provided any technical assistance to your immunization program? Was the technical assistance related to meeting GAVI requirements (new proposal, FSP, DQA, etc)? Please give examples of technical assistance provided during 2000-2005.
- Do you believe you get adequate technical support (both long-term in-country staff and for specific assignments as necessary? Can you think of unmet technical needs? (think broadly, training for supervision, database for coverage data, review vaccine wastage, coverage survey, etc)
- What could be improved related to the process of accessing technical assistance?
- Has GAVI improved coordination among NIP partners, in a way that improves technical support to NIP?

Questions to NIP donors/partners:

- What is the process for obtaining technical assistance? Who pays for it? What have you done when you identify a TA need, but have no funding for it?
- Has GAVI enabled a more efficient approach to technical assistance?
- Has GAVI improved coordination among NIP partners, in a way that improves technical support to NIP?

Beneficiaries of GAVI funding and assistance

Reference to question #18 of RFP: Who has benefitted from GAVI Alliance Initiatives – including the extent to which fragile states, the poorest countries, and the poorest of poor within countries are reached? What are the comparative 'inputs' and 'outcomes' between countries receiving support?

- **Obtain data** on how funds were allocated to districts (we don't need to know exactly how they spent it), but of the ISS funding that were to district level how much went to each district? Also obtain data on annual coverage rates by district.
- Are ISS funds allocated to all districts or only selected districts? What criteria are considered in allocation to districts? Did the criteria change over time, and why?
- Were ISS funds allocated toward harder to reach children or toward lower coverage districts? How important was improving equity in your criteria for allocating ISS funds?
- Have there been improvements in the traditionally lower coverage districts over the last 5 years?

Sustainability of GAVI support

Reference to question #20 of RFP: Are countries likely to be able to sustain the improvements in immunization achieved with support from GAVI?

- What are the challenges for sustaining the improvements achieved with support from GAVI? Are the financial challenges or the technical challenges more difficult?
- What actions have been taken (over the last five years) that demonstrate a commitment to sustaining the improvements achieved with support from GAVI? What more needs to be done?
- If ISS support were to end, would you be able to maintain your existing coverage rates? What would be most at risk? How would you cover the shortfall in funding?
- When did your country start to co-finance new vaccines? Was this prior to the new vaccines cofinancing policy (2006)? What led to that decision?
- Are you satisfied with GAVI's co-financing policy under Phase 2? Do you think it is fair and reasonable? What suggestions would you make for co-financing rules?
- How will the co-financing policy affect your decision to apply for new vaccines as they become available?

ADIPs (core group)

Reference to Question #17b of RFP: To what extent have the ADIPs made it more likely that there will be a rapid country uptake of new vaccines when they are ready for introduction?

- Has any work been done to prepare for introduction of Hib vaccine into the NIP? How about pneumococcal or rotavirus vaccines? What else needs to be done?
- How does the cost of these vaccines impact the decision to use them, particularly given the cofinancing guidelines?
- Is there a plan for introduction of Hib vaccine?
- Do you foresee these pneumo and rota vaccines being incorporated in the NIP once they are available (availability is anticipated in the next 1-2 years)?

Harmonization of GAVI funding and programmatic support with other programs

Reference to question #3 of RFP: How harmonized and aligned is GAVI Alliance funding and programmatic support (including monitoring & evaluation) with other funding and activities at country level, including in federal systems? Be sure to talk with some donors not focused on immunization here. Goal is to find out the programming and funding process for other health sector funds, including government budget, other global initiatives (GF) and other donors (WB and bilaterals). We know NIP is not very well harmonized with other programs, but why – does NIP tend to be in different branch/directorate of MOH compared with these other programs? Do other donors require specific financial management arrangements?

Information to obtain from MOH and MOF:

- Identify early on the large bilateral and multilateral health programs in country World Bank, USAID, DFID, GFATM, etc – and arrange meetings.
- Identify the key counterparts within MOH for these other programs.
- Obtain organogram of Ministry of Health, and identify the placement of the NIP.
- Planning process and funding flows for health, child health and immunization does it originate at facility level (in theory and practice).
- Find out how funding for vaccines, injections supplies, other equipment, and operational expenses flow for EPI, and other health programs.
- Find out how districts obtain funding for health programs, and how health workers would get funded for activities at the district level such as supervision and outreach activities.

Questions directed to MOH higher level than EPI, and EPI donors/partners:

How is GAVI funding treated within the MOH budget? Is it recognized in the budget?

- If your country received ISS funding, how were the funds programmed and who managed the funds (disbursements, reconciliation with budget, audit, etc)?
- Who are the major donors in the health sector and how (budgetary vs. project support) is the support treated within the MOH budget?
- What are the advantages and disadvantages of GAVI funding?
- How do other health projects support the NIP?

Questions for non-EPI donors:

- How is GF/DFID/*insert other donor* money treated within the MOH budget? How are finds programmed and who manages and monitors the funds?
- Is there funding provided to districts? How is that administered?
- Do donors provide any commodities? What? Are the procurements in-country?

Added value of GAVI

Reference to question #9 of RFP: What added value have the GAVI Alliance and GAVI Fund brought to international efforts in immunization, beyond programmes funded? Has the GAVI Alliance enabled partners to 'do more' and 'do it better?' What has the Public Private Partnership dimension of GAVI achieved – what is its added value? The answers here may tend toward what GAVI has done, but the question is what has it done that just having bunch of money could not have accomplished. Some questions are also related to RFP Question #4 (how well has the partnership worked), although the RFP question is targeted toward global level, we're also interested in documenting the experience at country level.

- The GAVI Alliance has provided new funding to immunization programs. Beyond this funding, what, if any, additional value has GAVI brought to the immunization program in your country? Pls give specific examples.
- The GAVI Alliance is comprised of partners in immunization who were working together on immunization prior to the advent of GAVI. For example, WHO and UNICEF were on the ICC even before GAVI. Thinking specifically about the NIP, how has the relationship between the NIP and WHO and UNICEF changed since GAVI came along? How has the relationship between the donors (ie, WHO and UNICEF, WHO and USAID, etc) changed since GAVI?
- What value, beyond funding, has GAVI brought to immunization at country and global level?
- Non-traditional partners such as manufacturers and civil society organizations are also part of the GAVI Alliance are these groups active partners in the NIP in your country? Do you think that is beneficial to countries? What are some tangible results from partnering with these non-traditional partners?
- Have there been any problems with the way the NIP partners work together? Lack of clarity in the roles and responsibilities, competing interests, differences in technical/strategic approach? How have you resolved those issues?

ANNEX I: COUNTRY REPORTS

GAVI Phase 1 Evaluation Country Visit Report – Democratic Republic of Congo 21 April-1 May, 2008 Stephanie Boulenger

1. Basic Information

Population (2005)*	57,549,000
Number of surviving infants (2005)*	2,542,000
Total health expenditure per capita 2005 (PPP international \$)**	\$64
Govt. health expenditure per capita 2005 (PPP international \$)**	\$46
EPI expenditures (2006) ***	\$19,234,808
GAVI applications	NVS for YF – June 2002
	INS – June 2002
	ISS –June 2002
	NVS for DTP-Hep B – June 2002
	NVS for DTP-Hib – November 2007
	HSS – November 2007
	CSO – November 2007
Total GAVI Support	NVS - \$23,611,417
	INS \$3,258,400
	ISS - \$21,931,280
DTP3 Coverage Rate 2000*	40%
DTP3 Coverage Rate 2005*	73%

^{*}UNICEF Immunization Summary: The 2007 Edition

2. GAVI Management and Operations

• Is monitoring and evaluation appropriate at country level?

Monitoring and evaluation of funds and activities in DRC was very weak between 2003 and 2007. This was outlined by the results of an external audit and an ISS evaluation¹³⁴. The audit showed that some expenditure were misclassified, or could not be justified due to absence of receipts and accounts. See Annex 1 for main results of the audit. The ISS evaluation quotes for example "Districts are required to send justifications of funds to the central level once activities have been implemented. However, it was extremely difficult for this mission to trace financial documents rendering it impossible to evaluate the fund justification process. (...) According to the financial manager of the NIP, only about 50% of

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^{**} WHO Statistical Information Systems, WHO Health Statistics 2008.

^{*** 2006} GAVI Annual Progress Report

 $^{^{134}}$ GAVI ISS Evaluation in DRC. Dr Jean Michel NDIAYE and Dr Claude KONAN, Consultants. Kinshasa, April 2 - April 14, 2007

justifications are received in time." It was also noted that health zones do not usually receive the full amount for their planned activities, and that the provincial ICC which is supposed to coordinate all EPI activities at the district level is non functional in most provinces. See Also, the reporting system of GAVI was not seen as a burden or additional work.

Table 1 for the low number of ICC meetings per province.

In terms of surveillance, there is a big controversy about coverage data because UNICEF reported DTP3 coverage of 77.2% in 2006 and the Demographic and Health Survey, 45%. One source of difference that several respondents quoted is the fact that the DHS used vaccination cards which are not necessarily kept by mothers or households, can be lost or not given by the vaccinator. This factor can explain the difference but it's real impact is not known.

The reporting, surveillance and M&E systems are there in theory, but not in practice, and the lower you go in the system (from the central to operational level), the more true it becomes. This is probably emphasized by the fact that the government wants to decentralize the health care system and the fact that the country is very big. But a question remains. It seems like the ICC members knew that M&E was weak since 2003 (as reported by some respondents), but they still signed every year the situation analysis reports sent to GAVI. So it seems that there is not only a problem at the programmatic level but also at the ICC level.

In summary, a lot of problems with M&E were noted. In front of this problem, all the respondents agreed that the flexibility of GAVI funds and the fact that GAVI funds were managed by the NIP, and overseen by ICC, is not appropriate for DRC. There needs to be tighter control of activities and funds.

In contrast, and perhaps in response to some of the failures of the M&E system for GAVI ISS funds, the HSS funding will be monitored much more closely and the government and partners involved in HSS are now in the process of identifying an external firm to do the financial management by implementing an accounting system.

Also, the reporting system of GAVI was not seen as a burden or additional work.

Table 1: Number of ICC meetings per province in 2005

Provinces	Number of meetings with a summary report	Transmission of M&E Indicators
Bas Congo	0	0
Bandundu	0	0
Equateur	1	1
Kasaï Occ	3	3
Kasaï Or	4	4
Katanga	0	0
Kinshasa	0	0
Maniema	0	0
Nord Kivu	0	0
Orientale	4	3
Sud Kivu	0	0
Total	12	11

• Has GAVI enabled effective coordination of technical assistance?

There is no formal process for identifying TA needs or for answering TA needs when identified. Usually, WHO will take the lead in identifying the needs and the consultants who will provide TA. If a person at the NIP identifies a need, they will ask the NIP manager to share this with the ICC, who will then decide of the relevance of providing TA and will identify a way to obtain it.

The main TA provided was for elaborating the FSP, Hib introduction plan, DQA, CMYP, HSS, cold chain rehabilitation plan, pneumococcal vaccine introduction plan. In general, people were satisfied with TA received. A respondent said he would like to have more long-term TA that could train people at the NIP or for management.

If TA is an important aspect for GAVI, they should maybe request countries to develop a formal process at different levels of operations.

• How effective and clear are GAVI communications and communications systems?

GAVI communication and information goes through the Ministry of Health and NIP. The ICC is either copied on these communications or information is transmitted by NIP to ICC. ICC members felt that communication from GAVI was good and timely. It is important to note that the General Secretary is not included in this channel of communication which is a problem because he is key in the health care system and in the decision-making process. This omission can delay some decisions and release of funds.

Then there are the communication channels between the different MOH offices and/or Departments receiving GAVI funds (i.e. HSS, ISS, CSO) that are non-existent. Some respondents felt this should be corrected as the NIP, which is supposed to be at the center of those funds since they are there to also strengthen immunization services, does not know anything about them and if they will receive some support from those funds. They cannot be part of the programming of funds or activities if they don't know anything.

Respondents felt GAVI should put more efforts into communicating and advocating with higher levels of government, such as the Parliament and the President to ensuring sustainability of GAVI investments and creating line items for immunization because health and immunization are not government priorities. But one problem noted is that in DRC, Ministers change often. For example, the Minister of Health changed 4 times in a year, so advocacy needs to be re-done constantly.

RWG were very much appreciated by all people who attended them. They like the concept of exchanging ideas with other countries facing similar problems and to learn from others.

• Is GAVI harmonized with other funding and programs?

The NIP is financed by UNICEF, WHO, GAVI, USAID and Rotary. There is a separate GAVI account. It is a program that is under the 4th Directorate (Disease Control), but which is not integrated with the MOH structure, planning process, or budgeting process. But that's true for most health programs. The organogram of the MOH is there in theory, but not much is done through the MOH besides the payment of salaries (which are low and infrequent). The health care system is run by donors, implementing agencies and NGOs, who in turn try to have their programs fit with MOH policies and do make efforts to coordinate between them. But there is no coordination taking place with the 4th Directorate or other programs that fall under it; it is completely vertical. The Planning and Programming Department (DEP)¹³⁵ is not involved either with the NIP activities. The link between DEP and GAVI is that DEP coordinated the GAVI HSS proposal, helped with CSO proposal and is the coordinating assistant for the elaboration of the CMYP.

¹³⁵ Role of DEP: Develops policies and strategies, pilots sectoral strategies, is the memory of the sectoral strategy.

NIP Macroplans (for planning activities and funding) are elaborated every year with members of the ICC (UNICEF, WHO, USAID, Rotary) and a representative from the Ministry of Budget and Ministry of Finance. But these macroplans are not integrated with other MOH programs or activities.

So in that sense, GAVI is not a burden and is very well integrated with other donor activities. The GAVI activities are well harmonized with other immunization donors. But more harmonization is needed with other donors not putting money directly in NIP.

It's important to note that the concept or term "harmonization" does not resonate much with the respondents (especially respondents working for MOH or NIP) and is not really seen as an important or relevant issue. Respondents from international organizations had a better knowledge of the term harmonization.

3. GAVI Impact on Immunization Program

• Who has benefitted from GAVI assistance?

The different funding flows are: (starting all from the GAVI bank account)

- Directly to central
- Directly to intermediate
- From Intermediate to operational
- From central to operational

Theoretically, the first criteria for the use of GAVI funds is: 15% national, 20% intermediate (province, coordination et antennas), 65% operational level (i.e. health zones). In practice, this criteria was not applied. The distribution of GAVI funds between 2004 and 2007 shows that the proportion, on average, was not followed exactly: 43% national, 21% intermediate, and 36% operational.

When the macroplans are elaborated, the criteria for distribution of HAVI funds are (1) amount of other donor funds and (2) presence of donors in a zone. To allocate between provinces, the team determines: (1) which activities do they need to carry out? (2) Number of health zones in the province (3) other sources of funding/donors.

Now when looking at the distribution of GAVI funds by province in 2007, we see that it follows population. But there is no link with poverty, even when controlling for population.

Province	Population Rank	GAVI funds in 2007 per capita (rank)	% of population living under poverty index ¹³⁶	Poverty Rank
Bas Congo	10	11	69.8	6
Kinshasa	4	10	41.6	11
Bandundu	3	9	89.1	2
Nord Kivu	7	8	72.9	5
Katanga	1	7	69.1	7
Maniema	11	6	58.5	9
Oriental Province	2	5	75.5	4
Kasai Occidential	8	4	55.8	10
Sud Kivu	9	3	84.7	3
Kasai Oriental	6	2	62.3	8

¹³⁶ Source: 1-2-3 Survey 2004-2005.

Province	Population Rank	GAVI funds in 2007 per capita (rank)	% of population living under poverty index 136	Poverty Rank
Equateur	5	1	93.6	1

• Have ADIPs impacted likelihood of country uptake of new vaccines?

DRC is preparing for the introduction of the Hib and is waiting to obtain pre-qualification for rotavirus. For pneumococcal, they manifested interest and elaborated an introduction plan.

The thinking is to take advantage of the funding while it's there and see later for the costs. The respondents also underlined the fact that there is high child mortality in DRC and they cannot not apply. But the introduction of Hib comes with its lot of challenges. First, DRC has a limited stocking capacity (the vaccines are too voluminous), so they took the decision to postpone the introduction to 2009 in order to strengthen the cold chain capacity first. Second, the cost of the vaccines is high.

So DRC is no doubt planning on introducing Hib, pneumococcal and rotavirus in the NIP when they become available. But this vision is very short term and the long term perspective of having to pay for them is far from being on the agenda. Right now, DRC will take what they can get.

• How effective are GAVI advocacy efforts?

Right now, immunization is funded almost entirely by donors. If the goal is to slowly increase the share of the government in funding immunization, GAVI needs to be more active in advocating with the Ministry of Budget, the Ministry of Finance, and even Parliament and the President, to start having a line item for vaccines or even putting immunization on the agenda.

One problem noted by respondents is that certain donors decided to pull out of vaccination since GAVI arrived.

• Can countries sustain the improvements achieved?

With government expenditure representing less than 8% of total health expenditure in DRC, no one interviewed thought that the government could sustain the improvements achieved alone. DRC is in a phase where it's building the foundations of its health care system and cannot afford to pay for vaccines. It will continue relying heavily on donors for at least 5 years. So RDC can sustain improvements but with the help of external funding.

Thus, DRC cannot follow GAVI's cofinancing policy. Although it cannot pay the full amount planned, they can still pay a symbolic amount which will at least be a way of getting other ministry's attention and might lead to the creation of a budget line. The government of DRC paid in 2004 (261 million CFA Francs) and 2006 (unknown amount) and is planning on paying something in 2008. GAVI's co-financing policy should be revised to take into account the financing capacity of a country. One way of assessing that is considering more in the proposal review process the share of the government in health expenditure.

Several respondents also disagreed with the use of the number of children immunized as a criteria for measuring bonuses. The main reason being that GAVI funding is decreasing since the additional number of children is decreasing.

• What is the value-added of GAVI?

GAVI was a catalyst for exchange, coordination and complementarity between partners. GAVI sets a long term vision through the development of FSPs, CMYP, vaccine introduction plans, etc. It also made people aware of injection safety. They target issues that are in need of attention. For some respondents, there is no value-added in terms of financing mechanism because it's just one more transaction and just adds to

the number of financing sources. To make aid more efficient, there should be a decrease of the number of financing sources. Although HSS funding is part of Phase 2 of GAVI, its important to mention that the management system of those funds will be used as a pilot-test and to see to what extent it can be a model for the Health care system. It was felt that if HSS works, other donors will be more confident to invest and fund DRC.

For the NIP personnel, GAVI is an opportunity to have a better quality of life and working conditions (e.g. GAVI funds are used to finance a bus that takes workers home). It ensured no shortage of spare parts and fuel.

But the equilibrium and what was achieved with GAVI funds is very fragile and more could have been done with the funds had they been managed better.

4. Conclusions – Key Strengths and Areas for Improvements

- Advocacy at higher levels of government is needed
- Tighter control of GAVI funds and activities are needed
- Co-financing policy is not appropriate for DRC
- Continue promoting and financing RWGs and sub-RWGs.
- Communication should be better tailored to government structures and decision-making bodies and processes should also be ensured between GAVI funding windows.
- Ensure that lower levels (or decentralized units) are strengthen
- Better integration of programs
- Better adapt GAVI funding to countries like DRC who cumulate a weak health care systems and a very vast territory to cover (huge means for transportation, poor road and communication infrastructure, insecurity, difficult geographical accessibility).

5. Contact List

Organization	Name	Position/Role
Ambassade de Belgique. Direction Generale de la Cooperation au Developpement	Dr. Martinus DESMET	Attache de la Cooperation au Developpement, Secteur Sante
Association des Rotary Clubs Belges pour la Cooperation au Developpement	Dr Valentin Mutombo	Coordinator
AXXESS Project	Dr. Jean Kaseya	Project manager, VPD specialist
Direction d'Etude et Planification (DEP)/Planning and Programming Department.	Dr Hyppolite Kalambay Ntembwa	Director
European Union	Barth Caellouart	
Government of Canada, Embassy of Canada	Luc St-Laurent	2nd Secretary (Cooperation)
MOH, 4th Direction (Lutte contre la maladie)	Dr. Vital MONDONGE MAKUMA	Director
NIP	Dr Mabiala Eleyi Micheline	PEV director
NIP	Dr Paul	Chef Service Immunization
NIP	Ingenieur Claude Mangobo	Chef de Service/Chaine

Organization	Name	Position/Role
	Molanga	du Froid
NIP	José Mbo	Budget
NIP	Ferdinand WOTO	Chef de service des finances PEV
NIP	Pascal Mukenyi	Chef de Service/Statistique
NIP	Dr Michel Nyembwe	Chef de Service/PEV routine
NIP	Mme Didine	Communications
NIP	Dr Andre Kasogo Mulamba	Chef de Division, Surveillance epidemiologique des maladies-cible du PEV
UNDP	Dr Zina YACOUBA	Chef d'équipe portfolio des Projets. Chef du Projet Paludisme
UNICEF	Celestino Costa	Regional Senior Health Advisor, Chief of Survival Division (Section Survie)
UNICEF	Bonny Sumaili	Health Officer
UNICEF	Dr Paul Adovohepke	Interim Health Specialist (Immunization)
UNICEF	André Yameogo	Health Specialist (Polio)
UNICEF	Rémy Mwamba	
USAID	Astrid Lina MVUMBI PIRIPIRI	Child Survival Specialist
WHO	Yolande Masembe	Chargee du PEV de routine
WHO	Dr Mayenga	
WHO	Jean-Pierre Lokonga	Chef EPI et polio
World Bank	Jean-Pierre Manshande	Sr Health Specialist
World Bank	Tomo Morimoto	Consultant

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GAVI Phase 1 Evaluation Country Visit Report – *Indonesia* 9-23 April2008 Allan Bass

1. Basic Information

Population (2005)*	222,781,000
Number of surviving infants (2005)*	4,324,000
Total health expenditure per capita 2005 (PPP international \$)**	\$78
Govt. health expenditure per capita 2005 (PPP international \$)**	\$36
EPI expenditures (2007) ***	\$ 313.79 million (\$109.14 million for campaigns)
GAVI applications	NVS Hep B – March 2002
	INS – September 2002 ISS – June 2003
Total GAVI Support	NVS - \$16,029,000
	INS - \$11,227,000
	ISS - \$12,636,000
DTP3 Coverage Rate 2000*	75%
DTP3 Coverage Rate 2005*	70%

^{*}UNICEF Immunization Summary: The 2007 Edition

Indonesia is a middle coverage country with declining DTP3 coverage and a large population of unimmunized children. There was a polio outbreak in 2005, measles cases and diphtheria deaths continued in 2007. It had an excellent EPI in 1990 and moderate DTP3 coverage was maintained during the economic crisis and democratic change of the 1990s, but rapid decentralization and health reform in 2001 marked the beginning of declining immunization coverage. Multiple large scale vaccine and AD syringe stock-outs occurred during phase 1.

2. GAVI Management and Operations

• Is monitoring and evaluation appropriate at country level?

Monitoring the management and use of GAVI funding appears appropriate. The NIP assists provinces in planning annual immunization activities. Provinces and districts conduct operational micro-planning. The NIP monitors and provides technical support to workshops and other planed activities. Directed by the NIP manager, the NIP's GAVI Secretariat is effectively the operational management executive for the NIP Manager and is well integrated in the NIP. It coordinates GAVI funded activities and supports 13 field supervisors representing the NIP in 4 provinces. The secretariat is led by a mandatorily retired, at age 55, senior NIP medical officer and her similarly retired deputy NIP epidemiologist - more recently, the WHO National EPI Officer Indonesia. The Secretariat is supported by a junior MO and 3 administrative staff.

The Immunization Interagency Coordinating Committee (IICC) and IICC Technical Working group (TWG) share reports and review the progress of the immunization program. The NIP GAVI secretariat,

^{**} WHO Statistical Information Systems, WHO Health Statistics 2008.

^{*** 2007} cMYP

along with donors, coordinated through the Immunization ICC TWG, pay the agreed costs against the planned activities and maintains accounts of expenditure for submission to auditors. The NIP Manager manages and monitors GAVI funded expenditure.

The monitoring and evaluation of immunization service performance appears to be generally very good. Program performance is monitored using routine, administrative coverage, AEFI surveillance, and disease surveillance data. Immunization coverage cluster and DHS surveys have been conducted in 2002-3 and 2007. The DHS demonstrated greatly inflated reported administrative coverage data. The 2007 multiple province coverage surveys are expected to show declining DTP3 coverage. Administrative and coverage survey data are compared, though the clear over-reporting of immunizations through the HIS has not been addressed. Private sector immunization provision (estimated 40% in the capital) performance is not routinely monitored except in the periodic coverage surveys. Anecdotal reports suggest that private providers are numerous, frequently also holding government positions, are widely spread throughout the country, use MOH provided vaccines, and reportedly provide low quality services with poor vaccine management.

Vaccine availability is a key element of sustainability. Multiple large scale vaccine and AD syringe stockouts occurred in 2003 - 2007 and in large part are an outcome of the national GoI's unmet commitment to the timely funding of all routine vaccines. UNICEF Indonesia called for urgent action in March 2007. Although the situation has been reported in the WHO/UNICEF Joint Reporting Form (JRF), it has led to no effective high level partner or GoI action during the last four years. There have been numerous vaccine stock-outs due to unreliable financing, and outreach activity has been severely constrained. Local Level Government's commitment to fund operational costs in districts appears to be declining and is poorly monitored.

• Has GAVI enabled effective coordination of technical assistance?

GAVI and the IICC process have generally provided very effective mechanisms for the coordination of technical assistance. However, the IICC TWG role in coordinating technical assistance should be formalized. GAVI ISS funding enables local university based consultants to be employed to provide specific technical services otherwise unavailable under government rules. Indonesia has capable human resources. The use of developing country international consultants, with limited EPI experience, was seen as politically imposed and of limited value. To be useful, external consultants must bring additional skills and professional experience to TA.

• How effective and clear are GAVI communications and communications systems?

Individual donors' officers described the GAVI Regional Working Group (RWG) as useful while NIP did not. RWG participation did not appear broad or inclusive of regional countries key NIP staff or key CSOs.

The IICC is very inclusive with wide donor, government, and civil society participation. Uniquely, the national vaccine manufacturer is an active member of the IICC. The IICC is respected and seen as extremely useful for endorsements and dissemination of progress reports. Its evolution to the broad discussion of immunization was appreciated. The narrower IICC Technical Working Group (TWG), convened by WHO, usually meets monthly, and has similar technical membership as the main IICC.

NIP's GAVI Secretariat is the primary point of contact for disseminating GAVI policy and strategy information, often through the IICC. Secretariat staff did not feel well informed. NIP managers were concerned by a lack of clarity, particularly on expected outputs.

WHO/Indonesia received GAVI programs and policy information from WHO/SEARO, with delays. SEARO became more proactive as calls for proposals arose. PATH and CVP provided key support and information to the NIP, particularly during phase 1 application processes. PATH Indonesia obtained information on GAVI programs, policies, and program requirements from PATH's head office.

• Is GAVI harmonized with other funding and programs?

Donor and GoI collaboration and harmonization intent and effort appear excellent, with some progress achieved. In the context of health sector reform, Indonesia continues to undergo major structural change begun during GAVI phase 1, creating an uncertain harmonization environment for all partners as GoI evolves. The different roles of WHO and UNICEF are not clearly understood by MOH and BAPPENAS planners and senior officials, particularly in setting priorities in health sector planning and finance.

MOH uses Log Frame planning versus the GAVI cMYP approach, seen by the MOH Planning Bureau as requiring extra work. Misalignment of the GoI 2004-2009 planning cycle and the GAVI cMYP requires additional effort. New short duration GAVI applications are expected to realign planning cycles, though will require additional applications.

The GoI National Development Planning Board (BAPPENAS) is adopting the ICC mechanism for the health sector - with the IICC as a sub-group of the health sector ICC. Indonesia's GF CMC Country Coordinating Mechanism and the IICC are similar in membership. In 2007 GF funding to Indonesia was suspended after an audit by Price Waterhouse Coopers.

GAVI funds are managed off of the regular national budget. BAPPENAS and MoH intend to bring GAVI funds into the budget in the future, while "not removing the current flexibility". Fund management procedures are based on GoI State Budget (APBN) rules. GAVI funds are received in a bank account operated by the NIP GAVI Secretariat, acting as treasurer under the NIP manager, and the Director General of Disease Control and Environmental Health (DG DC&EH). Monthly financial reports are provided to the DG DC&EH and SD MOH. Bank interest is returned to GoI Treasury. Annual audits are conducted by the BPK Supreme Audit Agency with periodic external audits by Price Waterhouse Coopers.

A similar mechanism is used for disbursements to Provinces and District health authorities for specific EPI activities through a provincially appointed treasurer. The provincial and district treasurers provide monthly financial reports to the GAVI Secretariat Treasurer. Each province develops an operational plan and budget (PO), in consultation with NIP, to guide annual activities using GAVI ISS or other funds. Funding to districts appears to be population proportional. It should be noted that much of the funding is allocated to transport costs. Provincial and district activity expenditure is based on the PO. Quarterly technical reports are provided to the NIP.

3. GAVI Impact on Immunization Program

• Who has benefitted from GAVI assistance?

- GAVI support has ensured that more than half of Indonesia's infants are fully immunized. The introduction of HepB birth dosing and routine HepB immunization will rapidly reduce HepB population prevalence.
- With donor support, TA, and GAVI procurement, Bio Farma, the parastatal national vaccine manufacturer, has gained the capacity to produce monodose Hepatitis B vaccine in innovative 'pouch and needle' devices (Uniject) for use beyond the cold chain by rural village midwives. Through GAVI procurement and the WHO vaccine prequalification

process, BIO Farma has gained some access to international vaccine markets. It gained a domestic market for its DTP-HepB vaccine.

- o Districts have gained operational funding allocation allowing some activity in the face of local government funding reductions.
- Recent reports suggest that *Posyandu*, (scheduled routine maternal and child health outreach services operated in partnership with civil society), formerly provided some 70% of immunization services, are currently operating at about 30% of previous levels, leaving infants and their mothers in underserved urban settlements and remote and rural districts with some limited benefit.
- o GoI has learned a new mode of interagency coordination and cooperation in the health sector.

Have ADIPs impacted the likelihood of country uptake of new vaccines?

A national Technical Advisory Group (TAG) on vaccines has been officially established, in response to ADIP, to guide new pediatric vaccine introduction. Preparations for pneumococcal and rotavirus vaccine are underway.

The Pneumo ADIP is funding the Indonesian Pediatric Society (IDAI) to do a six-province hospital based surveillance study on Indonesian serotypes. Introduction studies are planned for 2009 focusing on immunogenicity and safety, effectiveness, acceptability, and efficacy, with phased introduction from 2010 reaching 50% coverage in 2011.

Rotavirus incidence and genotypes were identified in a 2001-2004 two province hospital based study with the support of PATH and US CDC. From 2006-2007 the Indonesian Rotavirus surveillance network was expanded to 6 provinces. Bio Farma is developing Rotavirus production capacity in collaboration with The Murdoch Childrens Research Institute, Melbourne Australia. Following phase 1 and 2 trials planned for 2009, NIP is planning to pilot Rotavirus vaccine introduction in 2011 with GAVI support.

Indonesia has adequate data on Hib disease burden and cost effectiveness from the 1998-2000 Hib pilot project, supported by PATH/WHO/AMP. Bio Farma is producing DTP/HB/Hib vaccine, and NIP plans to introduce Hib vaccine in 2010 with GAVI support.

How effective are GAVI advocacy efforts?

"If it had not been for GAVI - Immunization would have been forgotten"

Immunization competes for policy priority and constrained national and district resources. GAVI advocacy was seen as limited in national extent and effect, with, exceptionally, the 2007 visit of Julian Lob-Levyt, GAVI Alliance Executive Secretary, seen as extremely helpful. BAPPENAS and the MOH Planning Bureau, and others appreciated the high level contact with GAVI. Other recent GAVI visitors were unable to address NIP questions on procedural and application submission issues.

A widely distributed monthly electronic newsletter containing advocacy tools, and information on policy, programs, programme requirements, and strategies targeted at country implementers was suggested, as an additional e-publication to the already established *Global Immunization News* (GIN).

Can Indonesia sustain the improvements achieved?

While administratively reported immunization coverage is high, recent survey data and the vaccine preventable disease patterns suggests that actual coverage is low and declining. There was a polio outbreak in 2005, and measles (despite SIAs), diphtheria, and neonatal tetanus continue as public health problems. Preliminary results from the 2007 six province coverage survey suggest further declining DPT3 coverage. It is considered likely that 2005-2006 DTP3 coverage will be revised downward to around 50%.

All informants agreed that GAVI ISS funding supported the maintenance of immunization coverage against declining service provision as a result of the competition for district spending priorities – the unintended consequences of decentralization to districts from 2001. The specialized vaccinators of the 1980s and 1990s have been replaced with multirole health workers with greater turnover and mobility, requiring a greatly increased national training effort to maintain acceptable immunization services quality and performance.

It is not possible to have an immunization program without vaccine in districts. Stock-outs of the routine vaccines BCG and TT, and autodisable syringes have been reported in districts in 2004, 2006, and 2007. In 2007 the UNICEF JRF data indicated that stock-outs caused the interruption of immunization services in districts: In 2007 there was no BCG vaccine in 176 to 440 districts in February through April, in January through April 132 districts reported stock-outs of TT, and 352 reported stock-outs of AD syringes in December.

A longer term corollary risk is the loss of trust by health workers causing poor morale impacting on services, and by beneficiary families, mothers and communities resulting from wasted visits and continued vaccine preventable disease, and its possible detrimental effect on the utilization of immunization services in particular and primary health services in general.

Recent vaccine management studies (UNICEF & MCC) indicate that national vaccine supply requirement procurement requests underestimate actual program needs by some 3 to 5 months usage. Critically, no buffer stocks for enabling immunization during periods of interrupted supply are ordered or maintained. Supply chains without steady periodic commodities replenishment cannot be effectively or efficiently managed.

GoI vaccine procurement contracts issued on release of funds have been delayed in each of the last four years 2004-8. In 2007 the release of funds eventuated in July. This stop start procurement cycle greatly adds to the problem of poor vaccine management in most districts. 2007 procurement was also reduced under a 20% sector budget reduction. In 2007 it was estimated that only 4.5 months of the actual annual need was supplied in the last 5 months of the year. In 2008 vaccine procurement is, for the first time, being conducted by the MOH Procurement directorate, with additional procedural delays expected. 2008 vaccine procurement funds were released in June 2008. Expert estimates suggest that as much as 3 to 6 months of immunization activity and coverage may be lost due to stock-outs.

The apparent lack of district and local level government investment in health sector infrastructure and funding of operational costs is of great concern. Mandated district health expenditure is 15%, with actual expenditures reported below 4% or less in some district. Immunization operations are a small proportion of total district health sector expenditure – with less than the equivalent of US\$ 600.00 spent annually in some districts.

• What is the value-added of GAVI?

A key value added by GAVI is the structural improvement in donor and GoI coordination. Based on the phase 1 experience of the Immunization ICC, and stimulated by the HSS application process, the GoI

National Development Planning Board (BAPPENAS) is adopting the Interagency Coordinating Committee mechanism for the health sector - with the Immunization ICC to operate as a sub-group of the Health sector ICC.

The prevention of the effective collapse of immunization services, and going forward, the possibility of coordinated rehabilitation and revitalization of Indonesia's once highly competent and effective national program, can be a key added value.

4. Conclusions – Key Strengths and Areas for Improvements

• Risks going forward

Key among the structural risks to immunization in Indonesia is that the GoI does not prioritize immunization as an essential program. It is not seen as a health 'best buy'. Immunization is considered a project and subject to short term funding arrangements, local level government priorities, and the continuing need for external funding support. The unclear financial and budgetary environment and unresolved funding for routine and new vaccines and local level operational costs, and the serious decline in outreach services threatens the collapse of routine immunization in Indonesia. The unexpected and unintended outcomes of the developing health reform and decentralization process present a continuing program management and vaccine financing risk.

Generational change in the NIP will weaken NIPs technical competence. The 9 year hiring freeze and mandatory retirement at age 55, is leading to the rapid replacement of the highly experienced senior management team with much younger, but vastly more inexperienced, new staff. A new NIP manager was appointed in February 2008.

• Key Strengths

- GAVI is highly respected by Government and by partners, and is well positioned to advocate for the political and national budgetary support necessary for the success of immunization in a highly decentralized country.
- GAVI and its partner organizations work in close collaboration in immunization, child health, and other health programs, and are clearly making efforts on harmonization.

• Areas for improvement

- Critical sustainability issues have been identified in country and reported to GAVI and
 partners through the WHO/UNICEF JRF since 2004. There was no evidence to suggest that
 GAVI or its partners took high level action to address these critical issues.
 - o Immunization programs require vaccine availability and fully funded local level operational costs for immunization service delivery. These government commitments do not appear to be monitored or acted upon. While these critical elements are reported in some form, monitoring is weak.
- Evaluation should be used to identify and improve the accuracy of performance monitoring.
 - o Monitoring should lead to decisions for actions to address critical path obstacles.
 - o GAVI should develop and implement a criteria based monitoring mechanism that leads to remediation action if critical sustainability criteria are not met.
- GAVI communications and its advocacy messages do not reach all decision makers beyond the NIP, and unevenly, through the NIP and the ICC, donor partners.

 Additional communications channels must be utilized to support advocacy and decision makers at all levels of the decentralized health system.

Conclusions

GAVI, its partners, programs, communications and advocacy are well received and appreciated in Indonesia. GAVI process and mechanisms have been effective in generating interest and donor collaboration and support for immunization in Indonesia, but has failed to generate adequate or increased GoI support. The GAVI monitoring process has not identified the critical sustainability failures reported and needs to be improved.

Contact List

Organization	Name	Title
MOH	Dr I. Nyoman Kandun,	Director General of Communicable Disease
	MPH	Control and
		Environmental Health,
МОН	Dr. T. Marwan Nusri,	Secretary Directorate General
	MPH	DGCDC&EH
МОН	Dr. Carmelia Basri	NIP EPI - Manager
МОН	Dr. Julitasari Sundoro	Medical Epidemiologist
		NIP GAVI Secretariat
МОН	Mr. Sayuti, Magister	Coordinator
		NIP GAVI Secretariat
MOH	Dr. H. Andi Muhadir	Director Surveilans Immunization & Matra
		Health
МОН	Dr M. Lutfi Dayan	NIP GAVI Secretariat
МОН	Dr. Prima Yosephine	Chief of Planning , Monitoring, Evaluation EPI,
MOH	Dr. Jane Soepardi	TB Control Program Manager (ex EPI
	1	Manger until Last Feb 2008)
BAPPENAS National	Dr. Hadiat	Deputy Director, Community Health
Development Planning Agency		Planning
MOH	Dr Imam Subekti	Head, International Cooperation Division
		MOH Bureau of Planning and Budgeting
PATH	Dr A. Widjaya	Sr. Technical Director
University of Indonesia	Prof. DR Dr Sri Rezeki	Chair, Vaccines Technical Advisory Group
	S. Hadinegoro	expert for immunization .
		Division of Infection & Tropical Pediatric,
		Department of Child Health
University of Indonesia	Dr. Hindra Irawan Satari	Secretary, National Committee AEFI
		(adverse Event Following Immunization)
		Department of Child Health

Organization	Name	Title
Bio Farma	Drs Mahendra	Production Director
	Suhardono	
Bio Farma	Dr Iskandar	Planning & Development Director
Bio Farma	Sarimuddin Sulaeman	Marketing Director
Bio Farma	Mohammad Sofie A. Hasan	Finance and HRD Director
Bio Farma	Juliman	Senior Manager for International Marketing
WHO Jakarta	Dr. Bardan Jung Rana	WHO Medical Officer
WHO Jakarta	Asmaniar, SKM	EPI Project Officer
WHO SEARO	Dr Stephan Guichard	
The World Bank	Dr Puti Marzoeki	Senior Health Specialist
MOH Bureau of Planning and Budgeting	Dr. Kazuhiro Kakimoto	Health Policy Advisor (JICA)
UNICEF	Dr. Vinod Bura	Health Specialist, EPI
UNICEF	Dr. Wibowo	Project Officer, EPI
UNICEF	Anne H. Vincent	Chief Health and Nutrition section
UNICEF	Dr. Kenny V. Peetosutan	Project Officer EPI
USAID	Gregory J. Adams	MCC Immunization Team Leader
The Partnership for Child Health Care Inc.	James C Sonnemann	Chief of Party, MCC Immunization Project
USAID	Jason K. Singer	Director, MCC Threshold Program
The Partnership for Child Health Care Inc.	E.G. P. Haran	Technical Director, MCC Immunization Project
The Partnership for Child Health Care Inc.	Farida Aprilianingrum	EPI Technical Officer MCC Immunization Project
The Partnership for Child Health Care Inc.	Marko Weeks	Local Area Monitoring TA Technical Director MCC Immunization Project
	Ms. Luwu	Senior Regional supervisor/GAVI
CDC	Dr Vita Rosemary	CDC Manager West Java Province
МОН	Mr. Yudi	Technical Officer EPI Supervisor

Organization	Name	Title
		West Java Province
МОН	Mr Odang Kusmana	Staff logistic EPI West Java
МОН	Dr. Nyoman Supartha	NIP Clinical Epidemiologist
MOH	Syarifudin, , Magister PH	EPI manager Povince Central Java
MOH	Dr Widodo	EPI manager Semarang Municipality,
		Central Java
МОН	Dr Jauhari Angkasa	EPI manager ,Distric Grobogan, Central
		Java
MOH	Dr Agus	EPI manager District Klaten, Central Java

GAVI Phase 1 Evaluation Country Visit Report – *Laos* May 12-16, 2008 Grace Chee

1. Basic Information

Population (2005)*	5,924,000
Number of surviving infants (2005)*	188,000
Total health expenditure per capita 2005 (PPP international \$)**	\$78
Govt. health expenditure per capita 2005 (PPP international \$)**	\$16
EPI expenditures (2006) ***	\$3,054,810
GAVI applications	NVS for DTP-Hep B – July 2000 ISS– November 2001
	INS – November 2001
Total GAVI Support	NVS - \$3,682,548
	INS - \$258,000
	ISS - \$1,431,200
DTP3 Coverage Rate 2000*	53%
DTP3 Coverage Rate 2005*	49%

^{*}UNICEF Immunization Summary: The 2007 Edition

2. GAVI Management and Operations

Is monitoring and evaluation appropriate at country level?

The TWG and the ICC are responsible for overall monitoring of EPI program performance. The EPI Manager prepares regular coverage reports to the TWG and the ICC. Key issues are discussed in these forums, but there has not been adequate resolution of some of the most pressing issues, such as lack of operational funding and reliable target population.

While many respondents agreed with the principle behind GAVI's monitoring and evaluation approach of allowing countries to establish their own procedures and mechanisms, they believe more stringent oversight at country level would be appropriate. There were also some criticisms of the usefulness of the DQA tool in actually verifying coverage information and identifying related problems – such as vaccine management. Some suggestions include having a local coordinator, or requiring annual audits of both coverage and expenditures.

The reports required by GAVI are thought to be time consuming, though not necessarily inappropriate or unreasonable. It was suggested that the burden could be eased somewhat if year to year changes in the APR could be limited (same comment was made for the UNICEF WHO JRF though that is not a GAVI requirement).

Has GAVI enabled effective coordination of technical assistance?

^{**} WHO Statistical Information Systems, WHO Health Statistics 2008.

^{*** 2006} GAVI Annual Progress Report

Many respond that GAVI was effective in promoting collaboration among the partners. The core team members discussed technical support needs and worked collaborative to identify needed resources. However, various persons interviewed reported different gaps in technical support – ranging from tasks that remain unsupported, to low quality consultants and advisors provided – at various time. Examples were given that span various timeframes, individuals, and types of inputs (or inputs lacking). There were respondents who questioned the level of commitment demonstrated by EPI's core partners (WHO, UNICEF, and MOH) during Phase 1. It appears that there were gaps in the level of technical inputs, both from partners and the EPI program.

In the last few years, there is a strong core team (EPI Manager, WHO EPI Officer, and TBD UNICEF EPI Officer). The level of commitment from the partner agencies also appears stronger.

How effective and clear are GAVI communications and communications systems?

There were mixed messages regarding the communications systems at the beginning of Phase 1. Communications went directly to the Minister, while the implementation level and the partners were not copied. Sometimes these messages and requests would be disseminated among key stakeholders relatively quickly, but at other times the partners had to spend a lot of time getting a copy of the GAVI communication.

Even today there are communications problems cited, especially related to GAVI visits to country or GAVI invitations. Two examples cited include a GAVI mission to discuss HSS, when not all partners were included in preparations for the mission, nor were they notified of the mission in advance. Another example was a GAVI invitation to a meeting regarding new vaccine policy, scheduled around the World Health Assembly. Although the EPI Manager was to be copied, he did not receive the communication until several days before the meeting.

GAVI was not very active in seeking out appropriate counterparts at implementation level. Only recently does the EPI Manager communicate directly with GAVI. The WHO EPI Officer has been in country approximately six months, and he is not copied on any communications (presumably because GAVI does not know he is in Laos).

The RWG played a key role in disseminating information about GAVI and providing a collective voice for the countries in the beginning. However, the level of support that can be provided by the partners at regional level is only as effective as the local staff of these organizations – if the local advisor is not strong and does not understand how to make use of the regional support, then it is not accessed.

Overall, the respondents did not feel empowered, nor had clear channels, for voicing feedback regarding GAVI requirements or policies. Even very senior officials at core partner agencies did not have a clear channel for voicing concerns. From the MOH perspective, they simply accepted GAVI policies without question.

• Is GAVI harmonized with other funding and programs?

The health system in Laos is very fragmented. There is little donor coordination, with various health projects managed from different departments and program offices (such as EPI) within the MOH, as well as other Ministries, such as the Ministry of Foreign Affairs. Even under specific directorates, there is limited coordination across programs. Core components of health planning, such as an overall health plan, with clear priorities and strategies, a health financing strategy, and mechanisms for coordination are only underway in recent years. Work is underway to promote a MCH-EPI package of services and to define an essential healthcare package.

Laos is only just beginning to take a more sectorwide approach to planning and delivering health services. This effort is being supported directly and indirectly by donors. For example, JICA began implementation of a sector coordination project in 2006, and has established a mechanism for dialogue and coordination. The WB HSIP project allows provinces and districts much latitude to plan activities as they deem appropriate. However, the capacity within the MOH is limited, and the structures are not yet in place to fully support an integrated approach to service delivery. Progress is being made, but it is slow.

In this environment, many praise GAVI for working within the existing government system, following government procedures, and allowing the MOH and the EPI program significant authority in programming funds. Further, GAVI's new HSS window will allow the MOH to take a broader approach to supporting the EPI program, and is well-aligned with the MOH approach of promoting an MCH-EPI package.

3. GAVI Impact on Immunization Program

• Who has benefitted from GAVI assistance?

New vaccines introduced with GAVI support were not targeted in any way, so all regional and socio-economic groups benefited equally.

• Have ADIPs impacted likelihood of country uptake of new vaccines?

The Accelerated Development and Introduction Plans (ADIPs) have not had any impact on Lao PDR's decisions regarding introducing new vaccines.

• How effective are GAVI advocacy efforts?

In general, respondents thought GAVI has been a good advocate for immunization in Laos, although more could have been done. GAVI, and its requirement for a high level ICC, renewed focus and interest in immunization. The broad representation on the ICC was a forum for increasing awareness, but actual follow-up by the ICC members varied. For some ICC members, it is not clear what concrete actions they are to take.

The level of government commitment has improved – the measles campaign was cited by many respondents as an indication of progress. The most senior leaders in the country were involved and called upon all sectors to participate in the effort. The coverage rate in 2007 was 96%, while the coverage rate in the last measles campaign (2003/2004) was 70% - 80%.

Translating commitment into funding allocation continues to be a challenge, but there has been some progress in that area. Last year, the government provided \$150,000 for the measles campaign, and has committed to the annual budget of \$100,000 to cofinance pentavalent vaccine. Many provinces also provided small amounts of funding (up to \$10,000). ICC members were also active in securing new donors for immunization – Luxembourg and Korea. Some also cite that the level of information for the general public has increased significantly, with regular media attention to the subject.

• Can countries sustain the improvements achieved?

Funding for health in Laos is extremely limited. The total MOH budget (funded from government resources) is approximately \$5.5 million, representing approximately 4% of the national budget. This percentage is expected to increase, particularly after revenues from a new hydropower dam become available (2010-2011). The government has committed to apportioning more funding to social sectors as the economy grows and its revenues increase. It is estimated that government funding for health represents approximately 20% of total funding, with the remainder coming from donors.

GAVI has provided DTP-HepB vaccine for Laos since its introduction in 2001. GAVI ISS funding also supported the EPI program from 2002-2006. Lao PDR has always relied on donors to fund the EPI program. Respondents agree that although it was understood relatively early on that government was to take over the cost of the vaccines, there was little expectation among government officials and EPI partners, that this was feasible. Most respondents believe the current co-financing policy to be fair and reasonable.

The suspension of ISS funding is not clearly associated with the lack of increase in number of immunized children, and low DQA verification factor. Many respondents seemed bitter that GAVI suddenly ended its support with no notice, and no transition period. Some of the core GAVI principles of sustainability and performance incentives seemed not to have resonated in Laos.

Since the end of ISS funding, coverage continues to be weak, with reported data indicating DTP3 coverage rate of 51%, ranging from 18% to 67% on a provincial basis. ISS funding had been used for outreach services in 11 provinces representing approximately 65% of the population – those provinces have had no reliable funding for outreach since the beginning of 2007. It was estimated that approximately 65% of immunization services are provided through outreach. Not only has the immunization program seen minimal improvement under GAVI Phase 1, but is currently poised to further lose ground.

• What is the value-added of GAVI?

Respondents felt that GAVI added value in several ways – promoting greater coordination and a consultation process in planning, increasing advocacy and awareness of immunization, and promoting new agendas, such as sustainability and system-wide approach. Respondents also cited many GAVI achievements, including providing the platform for real improvement in injection safety, and increasing country level capacity in planning.

4. Conclusions – Key Strengths and Areas for Improvements

Strengths

- The Lao government has demonstrated increased commitment in the last few years, including providing \$150,000 for the measles campaign in 2007, and another \$100,000 for this year. They had never previously provided funding for immunization.
- GAVI has promoted greater coordination among the partners, and increased awareness of the importance of immunization.

Areas for Improvement

- Oversight of management and use of funds was not always strong enough.
- There were weaknesses in technical inputs both from GAVI partners and within the EPI program.
- Respondents generally do not feel they have a voice in GAVI decision-making.
- In country partners relied on ISS funding for service delivery costs, and with the end of ISS funding, many parts of the country do not have reliable immunization services.
- End of ISS funding is not clearly linked to data quality of coverage increases either GAVI, including its local partners, have not made that message clear enough, or local officials have not taken it seriously.

5. Contact List

Organization	Name/Title	Background	
Ministry of Health, EPI Program	Dr Anonh Xeuatvongsa, EPI Manager	In current position since 2006	

Organization	Name/Title	Background	
Ministry of Health, EPI Program	Sisouveth Norasingh, Data Manager, NIP	In current position since 2004	
Ministry of Health	Dr Somthana Douangmala, former EPI Manager	EPI Manager for 18 years, ending in 2006	
Ministry of Health	Dr Khamphet, Director, Dept of Planning and Budgeting	In current position since 2006, officially on ICC since then, but involved in EPI before	
Ministry of Health	Dr Sisamone Keola, Project Manager, Health Service Improvement Project (WB), Dept of Planning and Budgeting	Since 2006	
Ministry of Health	Dr Chanpheng Southivong, Depy Project Manager, Health Service Improvement Project (WB), Dept of Planning and Budgeting	Since 2006	
Ministry of Health	Dr Soulivanh Pholsena, Senior Health Planner, Dept of Planning and Finance	Since 2006	
Ministry of Health	Dr Kaisone Chounramany, Director, Mother and Child Health Center	In her position since 1989, but only directly involved in EPI since 2006	
Ministry of Health	Dr Khampuoi, Director, Mother and Child Health Center		
Ministry of Health	Dr Chanphomma Vongsamphanh, Depy Director General, Dept of Curative Medicine	ICC member since 2004	
Ministry of Planning and Investment	Bounsamack Sayaseng, Depy Director general, Planning Dept		
Ministry of Finance	Bounleua Sinxayvoravong, Depy Director General, External Finance Dept		
Ministry of Finance	Angkhansada Mouangkham, Director International Financial Cooperation Division		
WHO	Dong Il Ahn, Representative	in current position 18 mos	
WHO	David Bassett, Technical Officer, EPI	2000-2003	
WHO	Keith Feldon, Technical Officer, EPI In current position 6 mo previously similar position Cambodia and Indonesi		
UNICEF	Laila Ismael Khan, Representative	in current position 1 years	
UNICEF	Dr Aboudou Karimou Andele, Health and Nutrition Section Chief	In current position 15 months	
UNICEF	Dr Samphanh Khamsingsavath, Asst in current position 5 years Project Officer for EPI		
JICA	Asaoki Hiroaki, Asst Resident In current position less than Representative years		
JICA	Noda Shin-ichiro, Chief Advisor	In current position less than 2 years	

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Organization	Name/Title	Background
JICA	Tsunoda Kenichi, Project Coordinator	In current position less than 2 years
JICA	Okabayashi Hironori, Advisor on Child Health	In current position less than 2 years

GAVI Phase 1 Evaluation Country Visit Report – Malawi April 15-24, 2008 Grace Chee

1. Basic Information

Population (2005)*	12,884,000
Number of surviving infants (2005)*	495,000
Total health expenditure per capita 2005 (PPP international \$)**	\$64
Govt. health expenditure per capita 2005 (PPP international \$)**	\$46
EPI expenditures (2007)	\$19.7 million (estimated)
GAVI applications	NVS for HepB+Hib – Sep 2000
	INS – June 2005 to 2007
	ISS - May 2007
	HSS - Nov 2007
Total GAVI Support	NVS - \$48,790,597
	INS - \$552,605
	ISS - \$993,000
DTP3 Coverage Rate 2000*	75%
DTP3 Coverage Rate 2005*	93%

^{*}UNICEF Immunization Summary: The 2007 Edition

2. GAVI Management and Operations

Is monitoring and evaluation appropriate at country level?

All respondents believed that GAVI's M&E requirements related to NVS and INS were reasonable and appropriate. The Annual Progress Report is manageable because all the information is already being collected. It is generally completed after completion of the UNICEF-WHO Joint Reporting Form (JRF). In earlier years, there was confusion because of the distinction between newborns and surviving infants, but that is now clear. Changes in the APR format did not present a problem, although it was noted that if change is too frequent, it is hard to keep up.

The ICC has been active in monitoring the progress of activities and program performance during Phase 1. The ICC was less active in 2007, as the SWAP governance structures took over and it was unclear how the ICC fits into that structure. It is now agreed that the ICC will be transitioned into a sub-TWG under the Essential Health Package (EHP) TWG of the Health Sector Review Group (HSRG) that oversees the health sector as a whole. Some partners believe reactivation of this form of review committee would be useful.

Malawi was only approved for HSS and ISS funding in 2007, and has not begun to program or spend these funds. Both HSS and ISS funds are channeled through the MOH, and handled in accordance with the procedures used for all discrete (non-pooled) donor funds. There is no experience to-date of the role of the ICC in overseeing the expenditures under ISS or HSS funding.

• Has GAVI enabled effective coordination of technical assistance?

^{**} WHO Statistical Information Systems, WHO Health Statistics 2008.

All of the Malawi EPI partners believe there has been good coordination and good working relationships between partners even before GAVI. The partners work together to resolve technical issues in a collaborative manner. The EPI program believes that all partners have been very supportive, and are essential to program success. There seems to be good teamwork between the partners, with each aware that their contributions are critical to the whole, and recognizing the importance of the others' inputs. The partners also provide checks on each other, reminding others of their appropriate responsibilities as necessary. The EPI program also is very cognizant of maintaining good relationships with all donors, even ones who may not be actively supporting EPI at any given time.

All respondents believed that there were no unmet technical assistance needs before, or during Phase 1. Some respondents mentioned some delays to obtaining TA due to logistics of bureaucratic procedures, but overall these were not serious issues.

• How effective and clear are GAVI communications and communications systems?

During the first years of Phase 1, Malawi relied on the RWG for information about GAVI, and application procedures. The regional offices of WHO and UNICEF also assisted by providing consultants More recently, however, GAVI sends information on new programs, policies, and requirements directly to EPI. Officials in country feel the information they receive is generally clear, and seldom do questions go unanswered. Any questions they have now can also be directly addressed to the Secretariat. Partners obtained necessary information from a variety of sources, including directly from GAVI, from the EPI program, and from regional or headquarters offices of their own organization. Other government officials generally relied on the EPI program for information related to GAVI.

The primary contact person for correspondence from GAVI was and is the Minister of Health, with copies to the EPI program, UNICEF, and WHO. Although implementation is the responsibility of the Permanent Secretary, this has worked reasonably well as long as requests are also duplicated to the EPI partners, allowing them to act upon requests as necessary.

• Is GAVI harmonized with other funding and programs?

Malawi moved to a SWAP for funding the health sector in 2004. The initial donors to the SWAP were Norwegian Embassy, DFID, and World Bank. Since then, other donors have joined, including Global Fund (GF), Germans, UNICEF, etc. USAID, JICA, and WHO remain some of the donors that continue only to fund discrete programs.

The SWAP is guided by a Program of Work (POW) endorsed by all health sector donors. The immunization program is well-harmonized within the POW, as EPI is one of the key interventions in the Essential Health Package (EHP). While UNICEF and WHO funded immunization activities outside of the SWAP, there was also funding for routine immunization through the SWAP mechanism, as immunization was part of district health plans and district health budgets.

Soon after the SWAP mechanism was established, Malawi also decentralized fiscal responsibility to district level. As part of this process, District Health Offices were delinked from the Ministry of Health, and report to the District Assembly, who in turn report to the Ministry of Local Government. Thus funding for district health activities is disbursed directly from MOF to District Assemblies, although the health budget is earmarked. Although it was not a pervasive problem, some respondents report occasional delays when the central EPI program and district EPI officers were accessing funds already budgeted for activities.

Under Phase 1, assistance from GAVI consisted of new vaccine and injection safety support. While these items may not have been at the top of the priority list prior to GAVI, partners felt that it has been beneficial for GAVI to implement these important changes to the EPI program. Given the nature of

GAVI support under Phase 1 (non-cash), it was easily integrated into the health system, both administratively and technically. The MOH budget includes a line-item for vaccines, with indications of the amount contributed by GAVI, and the amount contributed by government budget. Addition of the two new vaccines was easily delivered using a pentavalent DTP-HepB-Hib vaccine, based on the same immunization schedule as the earlier DTP vaccine. Little adjustment was required to incorporate delivery of the new vaccines, or to adjust planning or reporting mechanisms.

Malawi was approved for ISS and HSS funding within the last year. The planned HSS activities are based on the POW for the health sector, and fully support the overall health plan. The HSS and ISS funds will be managed subject to provisions applicable to all other government funding, including the appropriate procurement and review mechanisms. However, it is unclear whether adjustments will need to be made to meet GAVI's reporting requirements. HSS and ISS funding will be treated as discrete funding, with a separate account ledger, as is done for all other discrete donors.

3. GAVI Impact on Immunization Program

Who has benefitted from GAVI assistance?

Malawi has maintained strong coverage during the GAVI period. Malawi only applied for new vaccines and injection safety supplies during Phase 1, because its high DTP3 coverage rate made it ineligible for ISS funding. After GAVI revised its policies allowing countries with coverage rates over 80% to apply for ISS, Malawi applied for ISS funding and was approved in 2007. It intends to target some lower performing districts with ISS funding, but has only just begun to program the funds. New vaccines introduced with GAVI support were not targeted in any way, so all regional and socio-economic groups benefited equally.

DFID supported a series of five studies analyzing the equity of five health sector programs – malaria, tuberculosis, HIV/AID, maternal mortality, and immunization. Immunization services were found to be very equitable, with relatively modest differences in coverage rates between poorer and better off groups. Further, these studies found that in comparison to an average of 56 other countries, full immunization among the poorest quintile of the population was significantly higher (approximately 25 percentage points) in Malawi.

• Have ADIPs impacted likelihood of country uptake of new vaccines?

The Accelerated Development and Introduction Plans (ADIPs) in particular have not had a specific impact on Malawi's decisions regarding introducing new vaccines. The Wellcome Trust has been collecting disease data for many years that provides documentation of the burden of pediatric meningitis and rotavirus diseases. This data is sufficient evidence to support introduction of pneumococcal vaccine, when it is available. Malawi intends to introduce pneumococcal vaccine in the next two years, although the MOH and MOF have not yet made a firm commitment based on detailed projections of cost implications.

How effective are GAVI advocacy efforts?

All respondents believe that GAVI has been a very effective advocate for immunization in Malawi. The most important efforts repeatedly cited are visits from GAVI officials including the Executive Secretary, the conference including the Ministers of Finance to support the FSP, and GAVI creating general awareness of the importance, as well as the cost of vaccines. The immunization program continues to be one of the successes of the health sector in Malawi – GAVI was an important contributor to that success. Currently under the SWAP, donors cannot push EPI over other programs, but GAVI continues to maintain the necessary focus. The government and donors all see immunization as a core service, as demonstrated by using DTP3 as a core indicator under the SWAP.

One important indicator of government commitment is budget contribution of \$1.0 million for vaccines in 2006, prior to the official GAVI co-financing requirements. GAVI also solidified government ownership of the EPI program, which many believe is evident at all levels of the health system.

GAVI also brought the partners together, using an existing structure (the ICC) to coordinate efforts and develop solutions to program problems. The ICC was effective as an advocate for EPI, but under the SWAP governance structure, it will be important to ensure continued resource commitments to immunization. The ICC partners, particularly the core technical partners (EPI program, UNICEF, WHO) have worked collaboratively to maintain the success of immunization, and it is easier to generate ownership for a program with proven success.

• Can countries sustain the improvements achieved?

GAVI has provided the pentavalent vaccine for Malawi since its introduction in 2001, and all partners agree that this vaccine could not be sustained without GAVI support. The cost of the vaccine has not decreased during Phase 1, and remains unaffordable for Malawi. While the GOM co-finances this vaccine as required by GAVI, it would be difficult for GOM and its donors to take over this cost.

From a technical perspective, Malawi should be able to sustain the improvements achieved under GAVI. Malawi was not an ISS recipient, so has not relied on GAVI funding for the core of its EPI operational expenses. Through both targeted funding from UNICEF and WHO, as well as through SWAP funding, Malawi is capable of managing the recurrent costs of the EPI program. The SWAP has provided much more flexibility to the Malawi government in prioritizing its activities. Malawi contributed \$1.0 million for vaccines prior to GAVI's adopting its co-financing policy, coinciding with the initiation of the SWAP that provided more flexible funding options for the MOH.

GAVI support for AD syringes ended in 2007, and Malawi has now taken over procurement and funding of AD syringes. The cost of syringes is part of the SWAP budget, so much of the funding is dependent on donors, however, it is an indication that the GOM and donors place continued high priority on safe injections.

Resources are very limited in Malawi – the EHP agreed under the health SWAP is underfunded. The government has increased total expenditures for health in recent years, and has committed to minimum budget allocations for health (10.7%), but total resources are still very constrained. While Malawi has strong technical capacity (with support from its partners as needed), it will continue to rely on GAVI or other donors for funding.

While GAVI's contributions were limited to new vaccines and injection safety supplies, partners do credit it for improvements in coverage. The establishment of GAVI reinvigorated the program, and facilitated improved partner coordination. Sustaining enthusiasm and coordination will be important for continued success of the program.

• What is the value-added of GAVI?

It is difficult to separate the value added of GAVI from the financial resources (in the form of vaccines and syringes) it brought to Malawi. The three factors respondents mentioned most often mentioned were increasing advocacy and awareness of immunization, promoting coordination and collaboration, and changing the approach to considering new vaccines based on cost effectiveness and not only cost.

Malawi was a country where GAVI advocacy efforts were quite effective. The visit by the GAVI Executive Secretary, the Financial Sustainability Plan commitment from the Minister of Finance were often cited as events that really raised the awareness of immunization, and the cost of immunization to the

highest levels. This could not have been achieved by the existing partners in country. The awareness and commitment leads to success, further reinforcing ownership and commitment to the program.

While the core partners (UNICEF, WHO, and EPI program) had strong relationships historically, the change facilitated by GAVI was inclusion of a broader group of voices and advocates. Most importantly facilitated by GAVI were relationships with other directorates in MOH (planning, finance, etc), and the Ministry of Finance. EPI would never have thought to talk with MOF, but as a result there is now commitment to EPI within MOF.

Lastly, GAVI allowed countries to consider new vaccines in an entirely new way – not only looking at cost but at cost effectiveness. Without GAVI support, these new vaccines would never have been considered because of their prohibitive cost.

4. Conclusions – Key Strengths and Areas for Improvements

Strengths

- GAVI allowed Malawi to introduce Hepatitis B and Hib vaccine without GAVI, these vaccines could not have been introduced.
- While there was good donor coordination before, GAVI strengthened collaboration among the partners, bringing in new partners, and strengthening the immunization program.
- GAVI has also been a strong advocate for immunization, generating political and financial commitment at the highest levels.
- As a result, the EPI program has strong support from government, from donors, and from key implementation drivers (DHOs).
- GAVI has been a flexible and responsive donor it has provided channels for countries to provide feedback and has revised its policies based on country input. This characteristic distinguishes it from many other donors and programs.

Areas for Improvement

• While the ICC was initially very active in reviewing the EPI program and in resource mobilization, it has become less active recently. As it transitions to a sub-TWG of the EHP TWG, more effort should be made to improve this forum for discussion and review.

Contact List

Organization	Name/Title	Background
Ministry of Health, EPI Program	Agnes Katsulukuta, EPI Manager	In current position since 1999
Ministry of Health, EPI Program	Musavali , Logistician	
Ministry of Health, EPI Program	Tambule Chirwa, Data Manager	
Ministry of Health	Medson Kasambarra, Director of Procurement Unit	
Ministry of Health	Mr Chincocomo, Procurement Unit	
Ministry of Health	Bentley Nhlema, Controller	
Ministry of Health	Ann Poya, Head of SWAP Secretariat	
Ministry of Health	Edwin Katayika, Dep Director, Planning Directorate	
Ministry of Health	Hetherwick Ntaba, former Minister of Health	Minister during Phase 1, currently on GAVI Executive Committee, and GAVI

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		Evaluation SC
Ministry of Finance	Alfred Nyasulu, Asst Director, Head of Disbursement and Debt Financing	sits on CCM, and health SWAP
Ministry of Finance	Jonathan Kamtaeni	involved during the last 2 years, including development of HSS application
WHO	Dr Chiwaya, EPI Officer	in current position 8 mos
WHO	Felicitas Zwaira, WHO Rep	
WHO	Dr Banda, former EPI Officer	from end 2004 to 2007
World Bank	Alfred Chirwa, Population and Health Specialist	With WB since 2004, previously at USAID from 2001 focusing on HIV
UNICEF	Allan Macheso, EPI Officer	in current position 1.5 years
UNICEF	Aida Girma, UNICEF Rep	In current position 5 years
UNICEF	Katemah Bizuneh, Acting Head of Health and Nutrition	in Malawi 5 years
JICA	Grace Funsani, Aid Coordinator (Health)	less than1 year in current position
JICA	Nathan Mwafulirwa, Senior Program Officer (Health)	less than1 year in current position
USAID	Catherine Chipazi, Child Health Specialist	
Christian Health Association of Malawi	Desire Mhango, Director of Health Programs,	
Christian Health Association of Malawi	Francis Gondwe, Executive Director In current position since A 2007, also Chair of CSO team since Sep 2006	
DFID	Julia Kemp In Malawi 9 years, 4 years DFID	
Royal Norwegian Embassy	Ragnhild Seip, Second Secretary Development	in current position 1.5 years

GAVI Phase 1 Evaluation Country Visit Report – Mali 4-14 May, 2008 Stephanie Boulenger

1. Basic Information

Population (2005)*	13,518,000
Number of surviving infants (2005)*	575,000
Total health expenditure per capita 2005 (PPP international \$)**	\$60
Govt. health expenditure per capita 2005 (PPP international \$)**	\$31
EPI expenditures (2006) ***	\$ 11,219,641
GAVI applications	ISS – September 2000
	NVS for YF – November 2001
	INS – November 2002
	NVS for DTP-Hep B – June 2002
	NVS for DTP-Hib – November 2004
Total GAVI Support	NVS - \$13,838,719
	INS - \$710,600
	ISS - \$5,376,560
DTP3 Coverage Rate 2000*	40%
DTP3 Coverage Rate 2005*	73%

^{*}UNICEF Immunization Summary: The 2007 Edition

2. GAVI Management and Operations

• Is monitoring and evaluation appropriate at country level?

In order to access ISS funds, districts prepare a microplan every year for submission to the ICC along with a performance contract. Follow-up of activities during the year are done through supervision visits by NIP and WHO. Although it was reported that some districts that get GAVI support have not received any supervision visits in the last 2-3 years because funds were not released in time.

During the implementation of activities, the original receipts are sent by districts through the DNS to the DAF for verification and reconciliation of expenditure. But there isn't a process to monitor specifically the use of GAVI funds, besides the situation report produced every year for GAVI. It should be noted, and this was outlined by several respondents, that since 2004-05 it is not known how the bonuses/rewards are used. The holder of financial data is the DAF and it is difficult for the NIP to obtain information from them. GAVI funds were audited in 2001 and 2003, but the audit reports were not available.

Consequently, it is difficult for the NIP to have a control and oversight over financing or know what has been disbursed because of this separation of responsibility between NIP and DAF. Besides the poor communication between NIP and DAF, this can also be explained by the position of the NIP in the MOH organogram (see file "Organogram_Mali MOH and NIP.ppt"). As it is, it is considered a section and it depends of the Prevention and Disease Control Division.

^{**} WHO Statistical Information Systems, WHO Health Statistics 2008.

^{*** 2006} GAVI Annual Progress Report

Also noted as a source of problem for many issues (M&E, slow decision-making, slow implementation) was the fact that the ICC does not meet on a regular basis and when it meets it is often delegates (who have no power to take decisions) who attend the meetings. This delays the release of funds once microplans are agreed by all ICC members. It should be noted that between 2001 and about 2004, the ICC was working very well and was very active. Since 2004, it has been slowing down quite substantially. ICC is a good coordination mechanism for planning and management but needs to be faster and more transparent. ICC should be aware of the funding received by MOH from GAVI, including rewards and how they are used.

Majority of respondents thought that GAVI funds should be more tightly monitored to improve oversight and ability to plan and supervise. This could be done by requesting more information in the situation report (e.g. bonuses) and more often.

As for the GAVI annual Situation Report, there was a large range of answers and feedback regarding its appropriateness. Some felt it was appropriate and necessary but that it should be better harmonized with the reporting systems in place (why not include it in the JRF?). For some, the situation report is very difficult to complete and takes time (for example, it is very difficult to calculate the number of surviving infants because this is not measured through their HIS or to report for certain expenditure categories like personnel). In several instances, the problem of translation and understanding of terms was also an issue.

One thing noted is that several problems or issues to correct that were identified during this country visit were identified also during the ISS evaluation in 2004, but it seems that there was no follow-up or action taken to correct any of them.

• Has GAVI enabled effective coordination of technical assistance?

Mali received TA, among others, for the preparation of yellow fever campaign, MAPI (Manifestation post vaccinale indésirable) management for yellow fever, and Hib introduction plan.

There is no formal process for identifying needs for or TA. It is usually WHO who will identify TA.

NIP is in demand of TA, but the choice is made at other levels. They would like to be more involved in the definition of the TA profile and in the identification of the person who will provide TA.

• How effective and clear are GAVI communications and communications systems?

Communication between GAVI and ICC members is effective, timely and clear but several issues were noted. One of them had to do with the vocabulary used in some of the technical documents which is sometimes difficult to understand because not adapted to the Mali context. The other one was that there was not enough information communicated to ICC members about GAVI funds received by the MOH. At last, since the ICC is not functioning as it should, it creates some delays and inefficiencies in communication.

Below the ICC members, communication is weaker. Perhaps there needs to be more formal communication channels implemented for communicating to NIP personnel and regional/district directorates. Communication is also weak between the different GAVI funding windows, i.e. ISS and HSS.

Communication between GAVI and other health donors and partners outside the ones involved in the NIP is non existent; some donors do not know about GAVI. Some respondents said they would like to be more informed. On the other, several people involved with the NIP mentioned that other health donors were regularly invited to attend NIP review meetings, but often did not show up.

There was very positive feedback about RWGs. They are a great mechanism for peer-review of proposals and documents, and for exchange.

The information sent by GAVI is not always clear. For example DQA, HSS proposal guidelines and requirements, situation report, etc. In that sense, it's important to have a GAVI contact who can clarify those things. Furthermore, some people from the NIP mentioned that the customs and shipment papers for vaccines that they receive are unclear (not readable) and in English, which creates some problems for knowing the quantity of vaccines the NIP received.

• Is GAVI harmonized with other funding and programs?

GAVI ISS represented 0.2%, 0.3% and 0.3% of the total health expenditure in 2001, 2002 and 2003, respectively.

GAVI funds are flexible in their use, but not necessarily well harmonized with the systems in place. But the question of harmonization of GAVI depends largely on the perspective. From the point of view of the health care system, GAVI (and the NIP) remains a vertical program. GAVI funds are in a separate account (The project Account), and they are programmed and monitored separately. So in a way, release of funds is not really harmonized, but planning of activities is since it is integrated in the NIP and each year microplans are done at the districts with other donors. From the point of view of the Ministry of Finance (MOF), GAVI is not harmonized either and is outside the MOH budget. According to the MOF, to be harmonized, GAVI funds should be aligned with other donors and channeled through MOF. For example, the World Bank, Canada, the Netherlands and Sweden give sectoral budget support since the Paris Declaration. This would also avoid risks of redundancy and duplication. To other health donors and partners, GAVI funds are generally not harmonized. For example, GAVI is not part of the PRODESS (Program for Health and Social Development, Programme Décennal de Développement Sanitaire et Social).

It seems like the question of harmonization should be better defined by GAVI for the countries:

- Harmonization with who? Donors and partners involved health, donors and partners involved in immunization only, the MOF, the planning and programming department?
- Harmonization with what? With government or donor disbursement procedures, reporting requirements, M&E, HIS?

Another question that came up was: In a country where the systems are weak, why promote harmonization? Should we sacrifice harmonization for efficiency and effectiveness? Is there confusion between harmonization, coordination, alignment, and uniformisation?

3. GAVI Impact on Immunization Program

• Who has benefitted from GAVI assistance?

When the NIP decides which regions and circles will receive GAVI funds, they select the poor performing districts. The criteria for selecting districts are: presence of partners, are the district team active, are the community team active, geographic access, access to services, drop-out rates and DTP3 coverage. (See file "sélection cercles.xls" for an example of district selection) The DAF or NIP did not have readily available the distribution of GAVI funds and equipment by districts per year.

• Have ADIPs impacted likelihood of country uptake of new vaccines?

The introduction of the Hib vaccine was done step by step. It first started with Bamako and was scaled-up in 2007. Co-financing of Hib will start in 2012. For the pneumococcal vaccine, Mali submitted a proposal and foresees this vaccine being incorporated in the NIP in 2009. For Rotavirus, the country is still awaiting the results of the clinical trials and is working with the vaccine development center in Bamako

on this issue. A priority that was identified in Mali was the meningococcal conjugated vaccine which will be introduced in 2010. The cost of these vaccines did not impact the decision to use them.

Access to these vaccines is a great opportunity but there needs to be more attention towards preparing their introduction which means addressing human resources and cold chain equipment constraints. Also, some respondents felt that there needs to be more coordination with other donors when the decision to introduce a new vaccine is taken.

• How effective are GAVI advocacy efforts?

On one hand, GAVI or the ICC have not been very active advocates. On the other hand vaccination and immunization are priorities in Mali, and it is reflected in the political involvement and commitment of the MOH, so there is not a great need for defending vaccination. But it was still felt that more advocacy is needed with the Ministry of Finance and with other ministers.

Advocacy for the NIP is limited by its position in the organogram of the MOH which limits its impact and power. Several respondents felt it should become a division or a direction. The ICC, whether for advocacy or other topics, needs to be revived and more active. There is maybe a role there for GAVI.

Advocacy could be more evidence-based oriented (with power point presentations, graphs, numbers) to show the benefits of investing in vaccination programs and services that support them. An example would be to show the impacts of vaccination on the economy, on mortality, etc.

• Can countries sustain the improvements achieved?

Mali has a budget line-item for vaccines so it can finance part of the NIP. The country can also pay a percentage of the cost of new vaccines, but they cannot take on the full price of all vaccines provided trough GAVI. So sustainability would surely be at risk if GAVI funds were to end.

To improve sustainability and the future of vaccination, several issues need to be tackled in Mali:

- Human resources: lack of, quality, training, repartition.
- Increase institutional visibility of the NIP (i.e. have it as a direction).
- Get political support to maintain budget line-item, because co-financing will require more resources.
- Reinforce partnerships (WHO, UNICEF, USAID) and identify other partners.
- Involve community who are also involved in immunization.
- Increase accountability of government with regards to FSP. It was felt that a lot of effort was put into developing the FSP, but no follow-up or implementation was done.

It is worth noting that in 2006 the NIP reported a DTP3 coverage rate of 95% versus 67.6% reported by the DHS.

	DTP3 Coverage Rates, 2006			
	National Estimates		Dł	1 S
	%	Rank	%	Rank
KAYES	78	7	49.4	7
KOULIKORO	96	3	74.3	2
SIKASSO	107	1	73.5	4
SEGOU	99	2	73.7	3

MOPTI	89	5	58.7	6
TOMBOUCTOU	75	8	48.9	8
GAO	82	6	68.3	5
BAMAKO	92	4	(24.8) ¹³⁷	9
KIBAL	73	9	79.6	1
TOTAL	95		67.6	

• What is the value-added of GAVI?

GAVI provides funding, better partnerships, motivation to improve vaccination services and a flexible funding mechanism that's adapted to the system. GAVI allowed better support for operational costs, strengthening personnel capacity. GAVI introduced good concepts like injection safety.

4. Conclusions

Key Strengths

- Increase in vaccine coverage
- GAVI helped build capacity for planning (through the development of microplans)
- GAVI allowed sustaining the country's commitment to vaccination and attain vaccine independence (started with ARIVA in)

Areas for Improvements

- More follow-up with ICC to see if its functioning well. GAVI could commit to help reviving the ICC.
 - Modify (adapt it better to country-context) or get rid of situation report
- Implement tighter control or closer follow-up of GAVI funds to ensure that more is done with money available.
- Perhaps modify the way GAVI funds flow or are managed so that the NIP has better control and oversight.
- GAVI could work at decreasing the unit costs of new vaccines so that countries are able to pay for them.
- FSP remained an intellectual exercise, but nothing was done beyond signing the document. There should be implementation plans and implementation.
 - Redefine harmonization and make it more country specific.
 - GAVI could participate in advocating for changing the status of the NIP.

Contact List

Organization	Name	Position/Role
USAID	Robert de Wolfe	Deputy Team Leander/Child Health Advisor
USAID	Alexander D. Newton	Director
WHO	Dr Diallo Fatoumata Binta T.	Representative
NIP (Centre National d'Immunisation - CNI)	Dr. Kone Nouhoum	Director

¹³⁷ () Based on a low number of weighted cases (43 children).

Organization	Name	Position/Role
NIP (Centre National d'Immunisation - CNI) / GROUPE 1	Nama Magassa	Director of the Planing, Traning and Health Information Unit at the National Health Directorate
NIP (Centre National d'Immunisation - CNI) / GROUPE 1	Dr Mady KAMISSOKO	Focal person for acute flaccid paralysis surveillance
NIP (Centre National d'Immunisation - CNI) / GROUPE 1	Ibrahim TRAORE	Ministry of Budget
NIP (Centre National d'Immunisation - CNI) / GROUPE 1	Mammadou TRAORE	Program Supervisor
NIP (Centre National d'Immunisation - CNI) / GROUPE 1	Bani DIABY	Medical Assistant. Vaccination Data Management
NIP (Centre National d'Immunisation - CNI) / GROUPE 1	Dr. Malle	Support Doctor
WHO	Dr. Ndoutabe Modjirom	Focal Point IVD
ATN/USAID	Cheick H.T SIMPARA	Assistand Director and Health Reform Advisor. USAID Health Program / Assistance Technique Nationale (ATN)
ATN/USAID	Lisa NICHOLS	Chief of Party
ATN/USAID	Boubacar GUINDO	NIP and Malaria Advisor
UNICEF	Etienne Dembélé	Immunization Officer
WHO	Baba Tounkara	Focal person for measles
MOH/Administrative and Financial Direction	Koniba DIARRA	Economic Services Inspector (Directeur Admin et Financier Adjoint)
WHO	M. Idrissa Yalcouve	Logistics Officer for NIP
NIP (Centre National d'Immunisation - CNI) / GROUPE 2	Dr Zankoura Coulibaly	Logisitics Officer
	M. Seydou KOUYATE	Routine Immunization Data Manager/NIP
	M. Moussa BATHILY	PFA Data Manager/NIP
	Mme Diarra Hamsatou Dicko	Public Health Medical Assistant/NIP
	Dr. Sekou Kone	Vaccination Strategies Advisor/NIP
MOH/Planning and Statistics Department	Dr Salif Samake	Director
Prevention and Disease Control Division (Division Prevention et Lutte contre la Maladie - DPLM)	Dr Sory Ibrahima Bamba	Director
WHO	Dr Ignace Ronse	HSS focal point
World Bank	Tonia Marek	Main Public Health Specialist
Belgian Cooperation	??	Director of health
Canadian Embassy	Christiane Vickeman	
Ministry of Finance/General Budget Directorate	Abdoulaye Toure	Director General of Budget

Organization	Name	Position/Role
Ministry of Finance/General Budget Directorate	Boubacar Timbo	
USAID	Sixte Zigirumugabe	
Global Fund/UNDP	Marc Wajnsztok	
UNICEF	Dougoufana Bagayoko	

List of Acronyms

Appui au Renforcement de l'Indépendance Vaccinale ARIVA

Support for the Strengthening of Vaccine Independence

Association de Sante Communautaire **ASACO**

Community Health Association

Le Centre de Santé Communautaire **CESCOM**

Community Health Center

Direction Administrative et Financière **DAF**

Finance and Administration Directorate

Direction Nationale de la Santé **DNS**

National Health Directorate

Fédération nationale des associations de santé communautaire **FENSACOM**

National Federation of Community Health Association

International Health Partnership **IHP**

Ministry of Finance **MOF**

Programme national de développement sanitaire et social **PRODESS**

National Health and Social Development Program

GAVI Phase 1 Evaluation Country Visit Report – *Uzbekistan April 1-10, 2008 Slavea Chankova*

1. Basic Information

Population (2005)*	26,593,000
Number of surviving infants (2005)*	580,000
Total health expenditure per capita 2005 (PPP international \$)**	\$171
Govt. health expenditure per capita 2005 (PPP international \$)**	\$82
EPI expenditures (2006)***	\$13,101,694
GAVI applications	NVS for HepB – November 2000 INS – August 2001
Total GAVI Support	NVS - \$4,575,547 INS - \$853,300
DTP3 Coverage Rate 2000*	96%
DTP3 Coverage Rate 2005*	99%

^{*}UNICEF Immunization Summary: The 2007 Edition

2. GAVI Management and Operations

• Is monitoring and evaluation appropriate at country level?

All respondents were of the opinion that GAVI's M&E requirements related to NVS and INS were reasonable and appropriate, and did not require collection of data that EPI did not already collect as part of its routine operations. All of those involved in preparing the APRs said they had no problems with the design of the report form. ¹³⁸

• Has GAVI enabled effective coordination of technical assistance?

The ICC in Uzbekistan was established as a result of GAVI requirement, and most of those on the committee are from MOH and other government agencies. EPI partners on the ICC during GAVI Phase 1 included WHO, UNICEF, USAID, JICA, World Bank, and ADB. In the past few years, however, there has been a reduction in the number of bilateral donors in the health sector in general, as well as in immunization. The representatives of the bilateral donors and development banks now attend ICC meetings primarily to get an update on EPI activities, and not because they are actively involved in assisting EPI. WHO and UNICEF are the only partners providing technical assistance, and they have other mechanisms for planning technical assistance: WHO has a rolling two-year plan for technical assistance to EPI that is prepared in coordination with UNICEF; while UNICEF has a five-year strategic plan of support to Uzbekistan, and a corresponding annual workplan that it develops with MOH (which includes financial and technical support to EPI). As a result, ICC has not served as a venue for deciding on and coordinating technical assistance corresponding to the EPI strategic plan, but has helped

^{**} WHO Statistical Information Systems, WHO Health Statistics 2008

^{*** 2007} GAVI Annual Progress Report

¹³⁸ The APRs are prepared by the EPI manager, the Chief of Immunological Unit at Republican Center for State Sanitary and Epidemiological Surveillance (where he data on vaccine supplies and coverage is processed), and WHO officers working with EPI.

coordinate assistance for new/ad-hoc activities (such as GAVI applications or SIAs). Several respondents noted that ICC has served as an innovative problem-solving venue, where experts from government institutions that tend to work in isolation of each other could sit at the same table and brainstorm how to address EPI issues together. There has been no direct technical assistance from GAVI. Technical support for preparation of GAVI applications came mostly from WHO.

• How effective and clear are GAVI communications and communications systems?

While the EPI manager is the focal point on behalf of the government for receiving GAVI communications, she had requested that all GAVI communications go through WHO country office (WHO's program officer and advisor for EPI), due to the fact that GAVI sent communications only in English, and there was no capacity at MOH for quick translation. While this system has worked well (according to EPI manager), it seems to cause delays in GAVI communication reaching her. Other deficiencies in GAVI communication system that were pointed out by those interviewed include:

- substantial delay in the translation of many GAVI documents to Russian (e.g. instructions on how to apply for new types of GAVI support¹⁴⁰)
- organization and contents of GAVI website is not very user-friendly (difficult to find instructions on how to apply for various funding mechanisms)
- instructions on what a successful country application looks like are not very clear it was suggested that posting a "model application" submitted by another country will be very helpful (the way GFATM does).
- there is a delay in posting the APR forms for the year on the website (e.g. the form that needs to be filled by mid-May was not there at the beginning of April)

The RWG facilitated communications from GAVI – it sent documents to WHO country office, which translated them for NPI/MOH.

None of the EPI stakeholders we interviewed in Uzbekistan had been ever asked by GAVI to contribute or comment on GAVI's new policies or requirements for existing programs as those were developed by GAVI. Accordingly, respondents did not feel that they had a say in those areas.

• Is GAVI harmonized with other funding and programs?

The type of support provided by GAVI to Uzbekistan, HepB vaccine and injection safety support, was in areas that were relatively new to EPI, so there were no other donors who were financing them when GAVI support started¹⁴². However, during the years when GAVI supplied HepB vaccines for infants, in some areas the government and donor projects (World Bank's Health Project and USAID's Project Hope) financed HepB vaccines for catch-up campaigns for older age groups. As stated by NIP/MOH respondents, GAVI financing of HepB vaccines for infants allowed the government to use their available funds for purchase of HepB vaccine for other age groups.

142 With the exception of some local corporate donors who financed HepB vaccination of their employees.

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¹³⁹ For example, the consultant attended an ICC meeting at which the WHO officer announced that GAVI's review committee had approved the country NVS application for pentavalent vaccine. The EPI manager did not appear to have received this information at the same time as WHO country office.
¹⁴⁰ For example, there is currently no Russian version of the HSS application instructions on GAVI's website and

 ¹⁴⁰ For example, there is currently no Russian version of the HSS application instructions on GAVI's website and
 Uzbekistan is considering applying for HSS, following in the footsteps of several other countries in Central Asia (which also use Russian as one of their official languages).
 141 The only person asked for some form of feedback was the EPI manager at the time when Uzbekistan was preparing its

GAVI application – she was asked to fill out an evaluation questionnaire on the contents and quality of the training/information package GAVI used at seminar on how to prepare GAVI applications (that she attended).

While the government of Japan helped finance vaccines for routine immunizations at certain times before and during GAVI years, no other donors had financed new vaccines or injection supplies for routine immunization. In 2007, there were no external donors for vaccines, and the current cMYP lists GAVI as the only expected donor through 2010.

3. GAVI Impact on Immunization Program

Who has benefitted from GAVI assistance?

Uzbekistan has maintained impressively high immunization coverage since the late 1990s. Coverage with DPT3 ranged between 96 and 99% in 2000-2006. The main factors behind this success are high political commitment to immunization, the legacy of the soviet system of universal health care coverage and compulsory immunization, and cultural acceptance of immunization. Immunizations for children under 2 are free and provided almost exclusively through the public sector. At introduction of HepB into the immunization schedule for infants, coverage with the new vaccine immediately started to trail the coverage for the other antigens. Coverage is consistent across geographical regions and population groups, and the small percent of those not immunized is mostly due to medical reasons. ¹⁴³

• Have ADIPs impacted likelihood of country uptake of new vaccines?

In 2004, the Norwegian Institute of Public Health, operating under an agreement of the Norwegian government with GAVI, partnered with the Institute of Virology in Tashkent to conduct a study to estimate the disease burden and cost-effectiveness of introducing rotavirus vaccine in Uzbekistan. This work was performed under a collaborative arrangement with the Rotavirus Vaccine Program at PATH. The study revealed that rotavirus is a main cause of severe diarrhea among children (35-40 %), and that the vaccine will be cost-effective even at a high price.

Introduction of rotavirus vaccine was discussed at the ICC meeting in August 2007. The study findings were presented by the leading researcher, and a representative of RVP/PATH made a presentation on the experience of implementing rotavirus vaccine. A GAVI application for rotavirus vaccine is planned for 2008, and introduction of the vaccine for 2010.

How effective are GAVI advocacy efforts?

Immunization has had high political priority in Uzbekistan and the country has not had problems with demand for immunization services. Therefore, there was limited space/need for GAVI advocacy efforts but there were two areas that respondents felt were particularly influenced by the presence of GAVI support in Uzbekistan:

■ reaffirming a positive image of immunization as such among the general public, as HepB incidence visibly declined¹⁴⁴ with the introduction of the vaccine in EPI¹⁴⁵;

ICC brought together government agencies that otherwise work in isolation, and involvement of MOF at the table has been particularly beneficial for positive developments in EPI financing (such as the introduction in 2003 of a separate line for vaccines and related injection supplies in the government

¹⁴³ The 2006 MICS survey by UNICEF showed coverage of 90% for DPT3 and 86% for HepB3. Some respondents (none of them from a govt organization) expressed concerns that there was some degree of over-reporting coverage in official statistics, but did not believe that those not covered were predominantly from particular geographical areas.

¹⁴⁴ Incidence steadily declined from 23.2 to 3.1 cases per 100,000 population between 2001 and 2007.

As one respondent pointed out, since the diseases corresponding to the routine EPI vaccines have not been seen by current generation, there was a potential danger of the population forgetting the importance of maintaining vaccination against them. In fact, a slogan used by EPI in media/social mobilization campaigns is "Immunization is not only compulsory, it is also necessary."

budget¹⁴⁶; faster approval by MOF of documents submitted to GAVI such as the recent pentavalent application, and the FSP¹⁴⁷)

■ The cMYP and FSP were used for advocacy with MOF for increased vaccine resource allocation.

• Can countries sustain the improvements achieved?

During the years of GAVI support, the government did not finance any share of the cost of HepB vaccine for infant immunization or for AD syringes. While the government did not begin co-financing of HepB vaccine costs for infants during the years of Phase 1 GAVI support, notes from ICC meetings, opinions of those interviewed in-country, and APR notes indicate that the government was prepared for the end of GAVI support and committed to reaching self-financing of vaccine purchases at that time. Respondents said that each GAVI application involves long deliberation by the government over the sections related to government financing, indicating that the government takes seriously its commitments to the share of vaccine costs it had to finance in the future.

The government share of vaccine expenditures increased from 23% in the first year of GAVI support (2001) to 84% in the last year of HepB GAVI support (2006). In 2007, the government paid the full cost of vaccines and supplies for routine immunizations, as shown in the figure below.¹⁴⁸

100% 8.1 11.5 15.8 16.0 90% 36 3 ■ World Bank 80% 70% 55.1 □ WHO 36.0 37.8 60% ■ Japan 53.8 50% 100.0 GAVI 84.2 40% ■ Government 63.7 25.0 30% 54.1 20% 38.0 34.7 23.0 10% 2002 2003 2005 2006 2004 year

Figure J1: Financing of Vaccines and Injection Supplies for Routine Immunization 2001-2007

Source: EPI data

While Uzbekistan demonstrated ability to self-finance HepB vaccine in 2007, and there was strong government commitment to continue it, the country does not have the ability to self-finance additional new vaccines at current vaccine prices. According to the 2007-2010 cMYP, Hib and rotavirus vaccines are not currently affordable for Uzbekistan.

Annex I: Country Reports

¹⁴⁶ Until then, vaccines were sharing a budget line with all other drugs and medical supplies and that created a problem for ensuring financial priority and sufficient funding for vaccines.

¹⁴⁷ As respondents pointed out, the MOF representative on ICC (who is in charge of health budget) has improved her understanding of the specific financial issues faced by EPI as a result of her ICC participation, and accordingly has acted as an advocate for EPI at MOF.

advocate for EPI at MOF.

148 According to data from the most-recent cMYP, in 2005 vaccines represented 14% of routine immunization costs, and a quarter of vaccine costs were for HepB. Vaccines for SIAs are typically financed by donors (USAID, WHO, UNICEF, and others).

The recent approval of the country application for pentavalent vaccine (at \$0.30 co-financing) means that GAVI will again become a major source of vaccine financing. If Uzbekistan is also approved for GAVI rotavirus vaccine support, GAVI's share of vaccine costs will increase further in 2009/2010. There are concerns that if there is a higher co-financing requirement, Uzbekistan will have difficulty financing these new vaccines.

After INS ended in 2005, EPI considered procurement of AD syringes with government funding but decided against it due to the high cost offered by the supplier they contacted and the complicated logistics of procuring AD syringes on its own. The possibility of local manufacturing of AD syringes was also explored but this option did not prove viable. From 2006 on, all immunizations are administered with disposable syringes. There is strict monitoring of injection safety practices, continued training of vaccinators and pediatricians (including annual certification of vaccinators), and education campaigns for the population on the dangers of syringe reuse. In recent years, the results of routine monitoring and assessments, including a special assessment by WHO, indicate that there have been no serious program lapses in injection safety.

• What is the value-added of GAVI?

According to most of those interviewed, the main contributions of GAVI in Uzbekistan beyond the HepB and ADS supplies were: (1) initiation of long-term planning for financial sustainability of EPI through the requirements to produce cMYP and FSP¹⁵⁰; (2) bringing the organizations related to immunization at one table through the ICC, especially the government agencies which tend to work in isolation of each other.

4. Conclusions - Key Strengths and Areas for Improvements

Strengths

- GAVI gave a head-start opportunity to Uzbekistan to introduce HepB in the EPI schedule at a time when the country could not afford the new vaccine; and provided support until the government was ready to finance the vaccine on its own (as a result of better economic situation and increased mobilization of resources for immunization).
- GAVI helped initiate long-term strategic planning for financial sustainability of vaccines, as a result of the requirements to produce cMYP and FSP;
- Establishment of ICC, due to GAVI requirement, brought MOF to the table where immunization issues were discussed, and thus helped with advocacy for resource mobilization for EPI vaccines.

Areas for Improvement

Positive developments in EPI strategic and financial planning due to GAVI (e.g. FSP and cMYP) are not likely to be sustained if they are not linked to GAVI funding

¹⁴⁹ The price quote for ADS was \$0.57 per syringe, which translated to about \$1 total cost per syringe with all procurement costs. The EPI manager pointed out that the total cost of the set of basic vaccines per infant is about \$1. In Uzbekistan, controls on hard currency exchange place an additional burden on procurement of supplies from abroad; whereas unpredictable fluctuations in the exchange rate pose difficulties for accurate budget forecasts for such supplies.
150 However, most interviewees thought that while EPI and MOF realized the benefits of such planning, it was unlikely to become institutionalized in the absence of GAVI requirements. The reasons given were: culture to only produce documents and data that are strictly required by law/regulation; significant amount of time and effort necessary to produce and get all approvals for these documents. It is also unclear how much GAVI requirements contributed to building local capacity to produce such documents: EPI and partners had used WHO consultants for preparing the financial parts of all applications submitted to GAVI so far, and appear inclined to use outside consultant assistance with the applications currently planned (rotavirus and HSS).

- Nearly all respondents saw a need for GAVI to get involved more directly, hands-on, in providing technical assistance to EPI focused on capacity building
- NIP/MOH representatives stated that GAVI, as a prominent global figure in immunization, should also provide technical assistance for new vaccine implementation, and some form of a knowledge database that disseminates the latest technical information on vaccines (including Russian translation).
- Delayed or no translation of GAVI documents into Russian (including correspondence with country, and website contents) impedes the timely communication of GAVI's requests, decisions, and information on new policies and programs to EPI/MOH
- Need to improve the provision of information on new types of support, especially instructions and examples of successful country applications
- GAVI should consider ways to improve advocacy with MOF officials in order to increase resource mobilization for immunization from government sources¹⁵¹

Contact List

Organization	Name, position	Background	
EPI	Dilorom Tursunova	At MOH for 19 years; EPI	
	EPI Manager	manager since 2002	
	Leading Specialist at MOH		
Republican State Sanitary and	Lucia Kim	At current position since 2004;	
Epidemiological Surveillance Center (RSES)	Chief of Immunological Unit	has worked for SES since 1980s	
Republican State Sanitary and	Dr. Sanat Shoumarov	At this position since 2000	
Epidemiological Surveillance Center (RSES)	Chief Doctor		
(NOLO)			
Republican State Sanitary and Epidemiological Surveillance Center	Dr. J. Baratova	In this position since 2004	
(RSES)	Deputy Director		
МОН	Saidmurad Saidaliev	In this position since 2004.	
	Head of Department of State Sanitary and Epidemiological Surveillance	Chairs the ICC when Deputy Minister is away	
МОН	Dr. K. Yadgarova	In this position since 2004	
	Chief of MCH Department		
WHO	Dr. Shahin Huseynov	At WHO/Uzb since 2007, was at	
	Technical Officer, Vaccine Preventable Diseases and Immunization, Central Asia Republics	other WHO country offices before then	
WHO	Dilafruz Hudaykulova	At this position since 2004	
	National Professional Officer		
	Vaccine Preventable Diseases, WHO Country Office		
WHO	Dr. Shukhrat Aripov	Recently moved to WHO,	

¹⁵¹ For example, MOH cannot nominate someone in another ministry to attend GAVI seminars. So GAVI can perhaps invite directly MOF officials in charge of immunization financing to such seminars. Respondents indicated that such initiatives to educate MOF officials on the intricacies of immunization financing will be very helpful for many countries.

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Organization	Name, position	Background	
	National Professional Officer, Avian Influenza and the IHR	involved only in avian influenza(epidemiological	
	WHO Country Office	control)	
UNICEF	U. Hudaykulov	At UNICEF since 2006	
	Officer for Health and Education		
JICA	Dr Angela Rakhimova	At JICA since mid-2005; not	
	In-house Consultant in Health Sector	involved with other immuniz related programs before then	
USAID	Benjamin Mills	At this position since end-2005;	
	Health Advisor	consultant for USAID health projects in the country before then	
World Bank	Flora Salikhova	On ICC since 2005; involved	
	Human Development Operations Officer	with other health projects in country before then	
ZdravPlus Project (USAID)	Peter Campbell, MD	6 yrs with the project; has also worked as consultant for WB and ADB (appraisal for project loans in health sector)	
	Regional Director Quality Improvement in Health		
Other	Inessa Ashirova, former EPI manager and UNICEF APO	EPI coordinator until 2002 (as Chief of Immunological Unit at RSES); UNICEF APO 2002- 2005; then at Institute of Immunology as Coordinator for Rotavirus Program. Prepared both INS and NVS application	
Other	N. Atabekov	Head of MOH Department of State Sanitary and Epidemiological Surveillance until 2004. Oversaw preparation of NVS and INS applications. Now at Institute of Epidemiology and Microbiology	

ANNEX J: INFORMANTS' COMMENTS TO DRAFT REPORT

Comments Related to Report Content and Discussion

- I have no problem with the summary and recommendations. Historically, the only thing I would add is a paragraph or two on where the immunization world was in 1999 before the proto GAVI Board meeting in Seattle. The CVI was in ruins following a disastrous meeting in Bellagio, Carol Bellamy and UNICEF were systematically cutting back each year on the dollars they would commit to vaccine purchases. Donor, industry, and international agencies did not trust each other. I believe the \$100 million commitment for CVP at Path from the Gates Foundation followed by the establishment of the Global Fund for Children's Vaccine (\$750 million over 5 years) was the tipping point that made everything else possible. It's like Samuel Johnson's dancing dog - the question is not how poorly he dances but that he dances at all.
- For the most part, the evaluators maintained boundaries between Phase 1 and Phase 2 issues and policies, which must have been a difficult task given that this evaluation was begun at the end of 2007-- well into Phase 2. However, the report includes discussion of co-financing which is a Phase 2 policy. Since they did not have the mandate to look at this and co-financing will be evaluated next year, the assessment of cofinancing should be limited at this time.
- The presentation and discussion of the FTF and work on financial sustainability could be strengthened. There is no discussion of Bridge Financing (there was an investment case) -- why it was created and what led to its demise/transformation into co-financing discussions. It was a major accomplishment of GAVI to be the only GHP to have a definition of sustainability and to work on this issue (which is not mentioned).
- There is need to highlight that like the WG, the FTF operated with a high level of trust and focus on problem solving of technical issues.
- The evaluation is very thin on the role of the RWG in the GAVI governance/decisionmaking/implementation structure. It would be useful to have more information here.
- GIVS is not really mentioned in the report and probably needs to be highlighted as something that UNICEF & WHO did together, while being in the GAVI partnership. What are the implications of this?
- The report touches on the apparent tension between the roles that GAVI partners play at country level as representative of their own institutional interests and how much they can represent and attend to GAVI-specific needs. It would be useful to have further elaboration on this point here and to what extent the intended model of GAVI at the country level actually "works".
- p. 83, It was our understanding that these [Task Teams or Task Forces] would always be short term, although it is true that some of the task forces were dissolved sooner than others, and some had lots of issues with the Board and Working Group, such as Advocacy, as you point out, but also that on R&D, and that on Country Coordination, which was later replaced by the same group under a different name. FTF work is summarized in a recently published paper now available online: Milstien, J.B., Kamara, L., Lydon, P., Mitchell, V., Landry, S. The GAVI Financing Task Force: One Model of Partner Collaboration. Vaccine 2008, 26: 5296-5302. doi 10.1016/j.vaccine.2008.07.061.
- The report rightly points out that innovation and speed was fundamental under Phase [1]. The ISS is mentioned as perhaps most important. I would like to emphasize 3 others:

- o a) We based the allocations on country proposals and open up immediately for all eligible countries to apply. Big discussion about that. Some wanted to start with a handful of pilot countries like Ghana and alike. I believe this was a "first", later followed by the GF.
- b) Independent assessment of proposals by an expert group (majority from developing countries to have south assessing south) to de-politicise the review process. It worked.
 The GAVI board rarely interfered in the recommendations by the expert group. Principle later followed by GF.
- o c) We established from the start a policy of not committing funds that we did not already have commitments for. Thus the policies would have to be made at start so that they would fit within the USD 750 million and a 5 year commitment to each country. This was the reason why China, India and Indonesia (initially) was excluded from ISS funding. The principle was later followed by GF and used effectively by them for fundraising.
- It was important at start to focus on a niche in order not to be in competition with others. The niche identified initially was new and underutilized vaccines. ISS came as an addition to that. We could project what the likely distribution among the different components, but not be very accurate because it was up to the countries to determine what they would apply for and how ambitious the increases in coverage would be. To set precise funding allocations would be a top down approach.
- It is often difficult to define what is meant by a strategic framework unless one specifies more precisely what is meant. I do not know if we had what you have in mind or not. But at least as reported in the Tenth GAVI Board meeting we developed a Strategic Framework of Added value to guide work plan development. That was very important to get agreement of GAVI role and responsibility versus that of partners. A very tense process!
- At least I believe our minds were clear on evaluation policy. In the beginning be assessed on outputs: the speed of country proposals being approved and funds disbursed; and timely specific reviews as required on specific issues. Later on outcomes. It was decided that we should not set up something separate but use the annual assessment of vaccination by WHO and UNICEF. The added value of that was that it was independent of GAVI Secretariat. Thus it is now WHO (primarily) and UNICEF that assess annually how many lives GAVI are or will save. One can hold that up against disbursements to assess the total cost-benefits of GAVI. This principle of ongoing independent evaluation is very important as most ongoing evaluations are internal.
- It is true that combo vaccine price was not reduced during phase 1 but it happened for Tetravalent in 2007 as a result of phase I (see page 22 of GAVI Progress Report) On the same page you also see that the Hep B vaccine price dropped by 75% from 1999 to 2007 coinciding with a step increase in volume as a result of GAVI starting in 2001 and more competition. Thus I do not believe it is correct to state GAVI had no impact on reducing the prices of the two vaccines.
- No strategy for influencing vaccines markets we knew already in 2000 that vaccine
 manufacturers started to develop combo vaccines as a result of GAVI and the gift of USD 750
 million from Gates. Many of them in developing countries. Thus our strategy for influencing
 vaccine markets was clear: Through credible demand to create competition in the market by a
 global procurement mechanism.
- You present probably correctly the donations through the first 6 years although I cannot remember the Danish contribution in 2001. More importantly, the table do not cover the point that Norway's commitment made at the Board meeting in Oslo June 2000 was the first multi year commitment (1 billion kr over five years, USD160 million) quelling the anxiety at Gates [Foundation] at that time that nobody else would join. Thus Norway was the second big contributor to join.

Comments Related to Analysis Approach

- The evaluations includes a very narrow discussion about how well GAVI in Phase 1 was harmonized and aligned with country processes, and this is an area I think needs further work in the report. The evidence to conclude that GAVI Phase 1 was well aligned and harmonized is not provided in this report, though there were attempts to strengthen this during Phase 1 (FSP was a tool for integrating national EPI requirements, including new vaccines, into national plans and budgets). We know from Phase 2, that there is interest to align planning and budgeting cycles with GAVI application, approvals and monitoring processes which are currently not in alignment.
- The quantitative analysis (Chapter 3) of DTP3 coverage could be improved by using the same country groupings that GAVI currently uses for its cofinancing policy rather than using a pure income classification. This would help link the findings of Phase 1 into the policies of Phase 2. The analysis needs to be population weighted if not already. It would be useful to highlight the regression findings on DTP3 coverage related to ISS funding in a Box.
- The report should be careful to characterize the unit cost analysis in Table 8 as a costeffectiveness analysis. Dividing total ISS expenditures by the number of pertussis deaths averted is misleading, because it is not only ISS expenditures but also expenditures on specific NVS related to pertussis that would affect this result. It is unfortunate that sufficient data were not available to undertake a cost-effectiveness analysis of GAVI assistance across various VPDs. This being said, it would be useful for the authors to place these figures within a context of other unit cost results for immunization -- are these figures higher, lower (they strike us as being much lower) than the literature. Use of the term "cost" should be replaced with "expenditure" per DTP3 to be more accurate. It would also be useful to compare the aggregate figure on expenditure/DTP3 child with the results of the 50 FSP analysis that has been conducted.
- The comparison between GAVI and other GHPs seems to be too superficial to be meaningful and we would like to see more details in this section.

Overall Comments

- Great review! Congratulations on a well written, carefully crafted, valuable analysis and report.
- The draft Evaluation Report for Phase 1 of GAVI is generally well-written and covers a lot of ground. The researchers have done a tremendous job of piecing together the story from reports and interviews. Congratulations are owed to the team.
- You have done well in outlining the key achievements and problems with GAVI in Phase

ANNEX K: GAVI COMMITMENTS BY COUNTRY AND PROGRAM

	Country	LICUS Status ^a	GDP quintile ^b	DTP3 coverage at first approval ^c	5 years Immunization Services Support	3 years Injection Safety support	5 years New and Under- used Vaccine Support	Other Support	Total commitment for five years	Eligible for ISS ^d	Eligible for NVS ^d
1	Afghanistan	Yes	1	31%	13,513,000	1,675,500	20,344,000	100,000	35,632,500	х	x
2	Albania		5	93%		100,500	347,500	100,000	548,000		х
3	Angola	Yes	3	50%	6,565,000	1,502,500	38,370,000	100,000	46,537,500	х	x
4	Armenia		5	63%	80,000	54,500	358,500	100,000	593,000	х	x
5	Azerbaijan		5	72%	496,000	145,000	698,500	100,000	1,439,500	х	x
6	Bangladesh		4	67%	26,974,000	8,116,500	27,305,000	100,000	62,495,500	х	х
7	Benin		1	61%		446,500	21,131,500	100,000	21,678,000		x
8	Bhutan		4	88%		25,500	487,500	100,000	613,000		х
9	Bolivia		4	93%		801,000			801,000		х
10	Bosnia & Herz		5	85%		56,500	316,000	100,000	472,500		х
11	Burkina Faso		2	42%	5,586,500	991,500	31,706,500	100,000	38,384,500	х	х
12	Burundi	Yes	1	57%	2,662,500	428,000	19,482,000	100,000	22,672,500	х	х

	Country	LICUS Status ^a	GDP quintile ^b	DTP3 coverage at first approval ^c	5 years Immunization Services Support	3 years Injection Safety support	5 years New and Under- used Vaccine Support	Other Support	Total commitment for five years	Eligible for ISS ^d	Eligible for NVS ^d
13	Cambodia	Yes	3	65%	2,392,000	667,500	9,759,500	100,000	12,919,000	Х	х
14	Cameroon		3	48%	5,505,000	1,082,500	18,423,500	100,000	25,111,000	х	х
15	CAR	Yes	3	23%	1,605,500	146,000	580,500	100,000	2,432,000	х	
16	Chad		1	32%	2,715,000	421,500	1,073,000	100,000	4,309,500	х	
17	China		5	93%		15,926,000	21,953,500	800,000	38,679,500		х
18	Comoros	Yes	2	67%	107,500	32,500	356,500	100,000	596,500	х	x
19	Congo DRC	Yes	1	31%	31,395,500	3,238,000	58,736,000	100,000	93,469,500	х	x
20	Congo Rep	Yes	2	50%	1,534,500	268,000	785,000	100,000	2,687,500	х	x
21	Côte d'Ivoire	Yes	4	56%	3,859,500		9,298,500	100,000	13,258,000	х	x
22	Cuba		5	89%		436,000			436,000	х	x
23	Djibouti		3	53%	205,000	32,000			237,000	х	x
24	Eritrea	Yes	2	61%	794,500	144,000	2,149,000	100,000	3,187,500	х	x
25	Ethiopia		1	45%	18,989,000	3,091,000	132,965,000	100,000	155,145,000	х	x
26	Gambia		2	74%	489,500	109,000	3,453,500	100,000	4,152,000	х	x
27	Georgia		5	61%	273,500	60,000	614,000	100,000	1,047,500	х	x
28	Ghana		4	73%	3,359,500	855,000	47,743,500	100,000	52,058,000	Х	x
29	Guinea	Yes	4	57%	2,100,500	650,500	4,002,000	100,000	6,853,000	Х	x
30	Guinea Bissau	Yes	2	47%	423,000	123,500			546,500	Х	х
31	Guyana		5	83%			873,000	100,000	973,000		х

	Country	LICUS Status ^a	GDP quintile ^b	DTP3 coverage at first approval ^c	5 years Immunization Services Support	3 years Injection Safety support	5 years New and Under- used Vaccine Support	Other Support	Total commitment for five years	Eligible for ISS ^d	Eligible for NVS ^d
32	Haiti	Yes	2	59%	2,171,000	455,000			2,626,000	х	х
33	Honduras		4	98%		456,500			456,500		x
34	India		3	55%		24,201,500	14,210,500	100,000	38,512,000		x
35	Indonesia		5	90%	16,005,000	10,745,500	13,249,500	100,000	40,100,000	х	x
36	Kenya		3	64%	6,063,500	1,244,500	68,175,000	100,000	75,583,000	х	x
37	Korea DPR		3	63%	2,340,000	761,000	3,087,000	100,000	6,288,000	x	x
38	Kyrgyz Rep		5	99%		178,000	1,091,500	100,000	1,369,500		x
39	Lao PDR	Yes	3	56%	2,251,500	279,000	4,480,000	100,000	7,110,500	х	x
40	Lesotho		4	56%	517,500	109,500	389,000	100,000	1,116,000	х	x
41	Liberia	Yes	1	23%	2,804,500	160,000	527,500	100,000	3,592,000	х	×
42	Madagascar		2	57%	4,277,500	794,000	11,650,000	100,000	16,821,500	x	x
43	Malawi		1	83%		858,500	37,665,500	100,000	38,624,000	х	×
44	Mali		1	45%	4,700,000	745,000	21,033,500	100,000	26,578,500	х	x
45	Mauritania		3	61%	1,062,000	203,500	827,000	100,000	2,192,500	х	x
46	Moldova		4	98%		91,000	349,500	100,000	540,500		х
47	Mongolia		4	98%		109,000	2,429,000	100,000	2,638,000		х
48	Mozambique		1	73%	3,291,000	941,000	16,300,500	100,000	20,632,500	х	Х
49	Myanmar	yes	3	70%	7,902,500	2,674,000	21,511,500	100,000	32,188,000	х	х
50	Nepal		3	72%	5,146,000	1,353,500	12,011,000	100,000	18,610,500	х	х

	Country	LICUS Status ^a	GDP quintile ^b	DTP3 coverage at first approval ^c	5 years Immunization Services Support	3 years Injection Safety support	5 years New and Under- used Vaccine Support	Other Support	Total commitment for five years	Eligible for ISS ^d	Eligible for NVS ^d
51	Nicaragua		5	86%		439,500			439,500	х	x
52	Niger		1	23%	6,944,500	1,007,000			7,951,500	х	x
53	Nigeria	yes	2	38%	53,020,000		4,835,500	100,000	57,955,500	Х	
54	Pakistan		4	58%	31,943,000	9,510,000	47,741,000	100,000	89,294,000	Х	x
55	Papua NG		5	62%	1,824,000				1,824,000	х	x
56	Rwanda		1	57%	2,585,000	369,000	21,434,500	100,000	24,488,500	х	x
57	São Tome		2	79%	61,000	21,500	79,500	100,000	262,000	х	х
58	Senegal		2	52%	3,987,000	749,500	18,966,500	100,000	23,803,000	х	х
59	Sierra Leone		1	39%	1,859,000	312,500	10,135,000	100,000	12,406,500	х	х
60	Solomon Islands	yes	4	82%						х	х
61	Somalia	yes	1	30%	3,399,500	311,000			3,710,500	Х	
62	Sri Lanka		5	99%		845,000	2,974,000	100,000	3,919,000		х
63	Sudan	yes	2	64%	7,274,500	1,828,000	4,651,000	100,000	13,853,500	х	х
64	Tajikistan		3	65%	1,322,000	349,500	928,000	100,000	2,699,500	х	х
65	Tanzania		1	74%	7,890,000	1,495,500	29,548,000	100,000	39,033,500	х	х
66	Timor Leste	yes	3	44%						х	х
67	Togo	yes	2	43%	1,658,000	374,500	1,095,000	100,000	3,227,500	х	х
68	Turkmenistan		5	96%		155,500	888,500	100,000	1,144,000		х
69	Uganda		2	54%	10,071,000	1,338,000	74,951,000	100,000	86,460,000	x	x

	Country	LICUS Status ^a	GDP quintile ^b	DTP3 coverage at first approval ^c	5 years Immunization Services Support	3 years Injection Safety support	5 years New and Under- used Vaccine Support	Other Support	Total commitment for five years	Eligible for ISS ^d	Eligible for NVS ^d
70	Ukraine		5	97%		791,500	3,163,000	100,000	4,054,500		х
71	Uzbekistan		4	95%		807,500	3,623,500	100,000	4,531,000		х
72	Viet Nam		4	93%		3,226,000	11,330,000	100,000	14,656,000	х	x
73	Yemen		3	73%	4,342,000	1,238,000	41,301,000	100,000	46,981,000	Х	x
74	Zambia		2	75%	4,641,500	762,500	39,170,000	100,000	44,674,000	Х	x
75	Zimbabwe	yes	4	78%	3,220,000	1,079,500			4,299,500	х	×

Notes and Sources:

(a) LICUS status determined by whether country was classified as "severe" or "core" LICUS in FY2006 by the World Bank

Source: http://www.worldbank.org/ieg/licus/docs/appendix_b.pdf

- (b) GDP quintiles based on GDP per capita in international dollars. Source: WHO online database, WHOHIS
- [c) Data provided by GAVI Secretariat
- (d) All countries that received a given type of GAVI support were counted as eligible. For the remaining countries, eligibility was determined based on DTP3 coverage (more than 50% for NVS, and 80% or less for ISS).

ANNEX L: ESTIMATES OF HEPB3 IMMUNIZATION ATTRIBUTABLE TO GAVI

This analysis is based on 45 countries that received GAVI assistance and reported hepatitis B immunization coverage to WHO/UNICEF in at least one year between 2001 and 2005, excluding China, India, and Indonesia, where GAVI policies were unique to those countries. GAVI began providing hepatitis B immunizations to 21 of these countries in 2001, increasing to 45 of the countries by 2005. Our analysis is based on Hepatitis B immunizations from 1996 to 2005. However, in 1996, only five of the 46 countries were reporting data on Hepatitis B coverage. Of the 450 country-years covered by our data, only 198 had reported data for immunization coverage. The missing years reduce the precision with which we can estimate the effects of GAVI's intervention, but the data are still sufficient to allow us to draw statistically rigorous conclusions.

We only know that coverage in unobserved years is that it was zero or higher. However, it seems reasonable to assume that coverage in the unobserved years was lower than in the observed years. This assumption is supported by two arguments. First, wherever we observe Hepatitis B coverage, levels have been increasing over time. Since the unobserved years occur before the observed years, they are likely to reflect periods of lower coverage. Second, providing the coverage and keeping records on it may be related, so that reported observations are likely to reflect increased attention and awareness. Our analysis is based on the assumption that unobserved coverage is known only to be between zero and the lowest coverage level actually reported in each country. In our analysis, we treat the unobserved years as being "left censored," meaning that we know only that they lie below some set value.

The unit of analysis for this regression is the country-year. That is, each of the 45 countries provides ten years of data, for a total of 450 observations. We used random effects time series regression¹⁵³ to model the correlation of observations within country.¹⁵⁴ The independent variable was an indicator of whether GAVI had shipped Hepatitis B vaccine to that country in that year. The dependent variable is *logit*(coverage). (Thinking of the equation from the child's point of view, the independent variable is whether the child reached one year of age during a period covered by hepatitis vaccine shipments. The dependent variable is the log of the odds that the child is immunized.)

¹⁵² China and India received HepB support from GAVI, but targeting only a small portion of the population. GAVI supported Indonesia to introduce HepB birth dose only using Uniject technology.

¹⁵³ Stata procedure xtintreg

¹⁵⁴ In our earlier analysis of the ISS, we used panel-corrected standard errors with these regressions. Panel-corrected standard errors are not available for regressions with censored observations, so we used bootstrap standard errors.

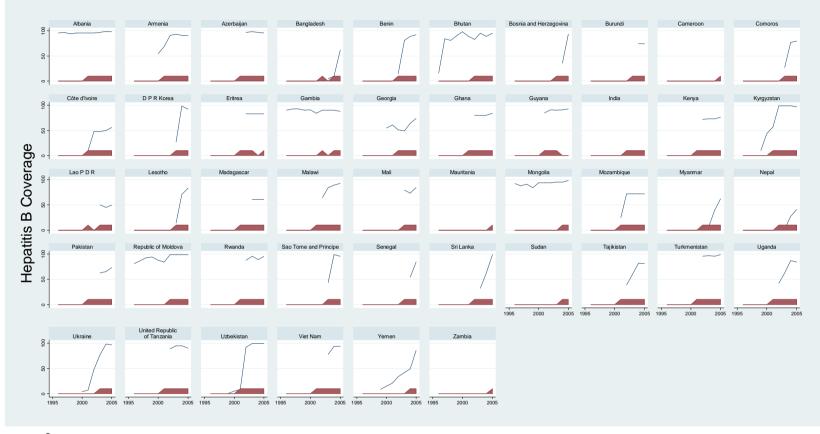


Figure L1: Hepatitis B Immunization Coverage 1995-2005, by country

^aShading along the horizontal axis shows years when GAVI shipped hepatitis B vaccine. Source: WHO-UNICEF Coverage Estimates.

We used the same covariates in this analysis as in our earlier analysis of the ISS: GDP per capita, and political stability. Because pre-intervention coverage levels were limited, we did not use pre-intervention levels of coverage as a covariate in this model. Instead we used DTP3 coverage. This allowed us to control for external factors that might have increased the general level of immunization even in the absence of GAVI intervention. Since GAVI also supported (through ISS) DTP3 coverage in some of these countries, the model estimate of GAVI's effect on Hepatitis B immunization excludes indirect effects that might have been attributable to ISS.

Our model was

 $\ln\left(\frac{p_t}{1-p_t}\right) = \alpha + \beta_0 G_t + \beta_1 G_{t-1} + \gamma_1 PS + \gamma_2 \ln(GDP) + \gamma_3 \ln\left(\frac{DTP3}{1-DTP3}\right) + f(t) + \mu + \varepsilon$

where

t = Year (1996 through 2005)

p = Probability that a child was immunized for Hepatitis B in year t

G = 1 if GAVI shipped Hepatitis B vaccine in year t

0 otherwise

PS = Political Stability

GDP = Inflation-adjusted GDP per capita in US dollars

DTP3 = Probability that a child received a third immunization for DTP in year t

 $\begin{array}{lll} f(t) & = & A \ cubic \ polynomial \ of \ t \\ \mu & = & The \ country-specific \ residual \\ \epsilon & = & The \ observation-specific \ residual \end{array}$

We included GAVI vaccine shipments in the year of immunization and in the preceding year because the time between shipment and immunization means that some shipments in a calendar year will result in immunizations in the next calendar year. However, the correlation between G_t and G_{t-1} is .75, which lowers the precision of the individual β estimates. We therefore also estimated a model with only the current year's shipments as an independent variable. The model that takes account of subsequent year immunizations shows a substantially larger effect of GAVI than the model based on shipments and immunizations that occur in a single year. It also fits the data significantly better.

Both models are shown in Table K1. Coefficients in the table are shown in exponential form. The dependent variable in each model is the log of the odds ratio, so the coefficients as shown can be interpreted as the factor by which the odds must be multiplied. For example, the 1.34 associated with the year in the first cell of the table means that we estimate that the odds of Hepatitis B immunization were increasing by about 34% per year apart from any GAVI effect. Because many countries did not report Hepatitis B coverage before GAVI intervened, this estimate has a relatively large standard error. A 95% confidence interval for the trend is 20% to 70%. We can be sure that some increase in coverage preceded GAVI's intervention, but we cannot be sure how rapidly the increase was proceeding.

¹⁵⁵ In two countries political stability indices were missing for a five year period. We replaced these missing values with the general mean for the political stability index. This had no material effect on our estimates.

Table L1: Regression Models of the Effect of GAVI Shipments on Hepatitis B Coverage

	Curre	ent and Prior year		rrent year only
	e ^b	se	e ^b	Se
Т	1.34	0.08	1.55	0.09
t²	1.07	0.11	1.30	0.13
t ³	1.00	0.09	0.89	0.09
GDP per capita	1.00	0.00	1.00	0.00
Political Stability	0.61	0.16	0.62	0.16
DTP3	1.89	0.26	1.98	0.28
GAVI at time t	2.12	0.64	2.63	0.81
GAVI at time t-1	4.24	1.14		
σ_{μ}	5.04	1.13	5.05	1.12
$\sigma_{arepsilon}$	3.19	0.21	3.42	0.23

Source: Analysis of WHO-UNICEF Coverage Estimates and other data.

This uncertainly is reflected in our estimates of the GAVI effect. If we consider only immunizations occurring in the year of shipment, the model shows that GAVI's effect was to multiply the odds of immunization by 2.6, with a 95% confidence interval of 1.0 to 4.2. Including immunizations in the year of shipment plus the following year, the effect is to multiply the odds of immunization by 9.0, with a 95% confidence interval of 2.3 to 15.7. This means that while we can be confident that GAVI had a positive effect on immunization, the scarcity of pre-GAVI data prevents us from saying precisely how large this effect was.

With this limitation in mind, we prepared our best estimate of GAVI's effect on the number of children immunized each year by comparing the model estimate of coverage with the model estimate of what coverage would have been without GAVI. (That is, we reset the GAVI indicator variable to 0.) We multiplied this difference by the target population of children age 12 to 23 months in each country. We summed these to estimate to total number of children whose immunization was attributable to GAVI.

Estimates that include immunizations that occur in the year after the vaccine was shipped are about twice as high as those that are limited to children immunized in the year of shipment. According to these higher estimates, GAVI is responsible for about half of all Hepatitis B immunizations that occurred in these countries. During each year from 2003-2005 about 10 million children who would not otherwise have been treated were immunized because of GAVI.

Table L2: Hepatitis B Immunizations 2000-2005

		Immunizations uted to GAVI		All HepB3 Immunizations		Countries with valid Hepatitis	
	year of shipment	year of shipment plus following year ^b	Children 12 to 23 months of age	lower limit ^a	upper limit	B Immunization Data	
2000			24.8	0.4	11.8	11	
2001	2.4	1.7	24.7	0.7	11.7	14	
2002	4.5	7.8	26.4	6.0	13.6	25	
2003	4.2	9.9	27.2	13.0	15.0	38	
2004	4.9	10.1	27.7	15.8	17.4	41	
2005	4.1	10.7	27.8	20.9	20.9	45	

^a Following year coverage refers to coverage that occurred in 2005 (for example) attributable to shipments

in 2004.

b Lower limits include only countries with valid reports. Upper limits include non-reporting countries. Source: Analysis of WHO-UNICEF Coverage Estimates and other data.

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