SEVENTH GAVI BOARD MEETING
Stockholm, 11 March 2002
Executive summary

1. Performance-based grants disbursement strategy

Discussion

- The Data Quality Audit (DQA), developed by WHO and the Children's Vaccine Program, was field-tested in eight countries in 2001. Through this process it was found that the information systems, especially the retention of primary data at the health centre level, is weaker than anticipated, making the level of consistency in countries' immunization reporting system too low to satisfactorily provide a 'correction factor'.
- The main findings of the field test were that the DQA:
  - can evaluate quality of reported data;
  - can identify problems with reporting systems;
  - is relatively expensive ($60,000 average per country)
  - can be used as self-assessment tool;
  - cannot provide a mathematical formula to adjust share calculations due to its low precision but could be used to classify reporting system as 'validated' or 'not validated'.
- A particular concern is that the reliance on reported data as the means for payment will lead to inflation of reported figures. Although the ICC is expected to validate the reported figures, the point was made that many ICC members have not been able or willing to jeopardise partnerships (which go way beyond immunisation) by challenging reported coverage data, even if they suspect it is inaccurate.
- Some Board members felt that the assessment of performance should make use of indicators that are already available and include indicators other than just DTP3 coverage, since this could provide a broader view of progress. Others felt that increasing the number of indicators could increase imprecision and burden on countries.
- The problems identified in the pilot test of the DQA are not new. Furthermore, even if the DQA is not the most powerful tool in terms of precision, it may give countries the opportunity to look at the problems and identify strategies to assess them.
- The DQA is an excellent opportunity to build capacity, but some saw the proposed approach as overly prescriptive, and called for easing of restrictions on the use of coverage surveys to measure performance.

DECISIONS

The Board:

1.1. Agreed that GAVI must retain its focus on performance-based systems. However, in recognition of the realities facing countries and the intention of GAVI to be equitable, this system will need to be modified from its original design.

1.2. Approved the proposal that the first planned ISS reward (for DTP3 increase over baseline) be converted to a third investment ($10/child projected DTP3 increase) for all countries, providing one full year of ISS investment. All subsequent reward payments for all countries will be based on validated increases in DTP3.

1.3. Endorsed changing the DQA methodology so that instead of calculating a mathematical adjustment to the reported coverage figures, the DQA would result in a classification of the immunization reporting system as 'validated' or 'not validated' so that:

1.3.1. in countries where reporting systems are classified 'validated' by the DQA conducted during the third year of investment, the reward payment in the subsequent year will be based on reported DTP3 figures endorsed by the ICC; and

1.3.2. in countries where reporting systems are classified 'not validated' by the DQA conducted during the third year of investment, a second DQA will be conducted in the subsequent year. If the system is again classified as 'not validated', the reward payment will be deferred until reporting is improved or validated by another method (vaccine coverage surveys) as outlined in the methodology.

1.4. Agreed that the performance-based disbursement should be assessed after the system has had a chance to be implemented (i.e., at the end of 2003). This assessment should consider the costs, opportunity costs and benefits of the scheme (in terms of both increased coverage and health systems development).

1.5. Requested that investigation into alternative methods of assessing performance should be initiated simultaneously with the ongoing implementation of the DQA.

1.6. Requested that further analyses be made on how the confidence interval of DQA can be reduced (impact of complete reporting, larger sample size, etc.) and report this back to the Board as soon as possible.

1.7. Requested that GAVI partners with presence in countries emphasize the message about the importance of keeping primary immunization records.

2. Monitoring and reporting of country performance

Discussion

- Accountability is a key principle for the Alliance, in terms of country performance as well as the performance of GAVI and the Vaccine Fund in raising awareness of and catalysing improvements in immunization systems.
- The Annual Progress report is designed to give responsibility of reporting and implementation to governments, and empower ICCs to have more strength in the system. It should be an opportunity to identify problems with health and immunization systems, and stimulate action to resolve them.
- Some Board members questioned whether it was appropriate that Ministers of Health would need to be involved in reporting to GAVI and the Vaccine Fund; does requiring this signature add an unnecessary political burden to the process? Or does it enhance the commitment of the government to improving its system?
- Information received from countries on use of immunization services funding could be useful for identifying best practices and sharing information between countries.

DECISIONS

The Board:

2.1. Confirmed the following principles:

2.1.1. The monitoring and reporting system should be designed to minimize burden on countries and support country's own systems and needs.

2.1.2. The GAVI/Vaccine Fund Annual Progress Report will include a request for information about financial sustainability plans, and outcomes of DQAs in countries where they are conducted.

2.1.3. The responsibility for conducting mid-term reviews – in-depth assessments of the processes and functions of country immunization programs – will be delegated to ICCs and regional working groups.

2.1.4. The monitoring and reporting system should be flexible enough to be revised as needed.

2.2. Approved the draft Annual Progress Report, with the following amendments:

2.2.1. In the section that requests information on the use of immunization services funding, add space for countries to report whether the money was placed in a sector-wide account.

2.2.2. Change the wording in the section requesting information about the financial audit to better reflect the role and autonomy of governments.

2.3. Formed a subgroup – Mali (Nafo-Traore), Norway (Mogedal), UNICEF (Fife) and the Vaccine Fund (McKinnon) – to propose new text on financial audit requirements and report back to the Board at its next teleconference.

3. GAVI Review

Discussion

- The aim of the GAVI Review is to look at the structures and mechanisms developed to pursue the common goals of the Alliance, particularly the Board, Working Group and Secretariat, in order to assess whether they are effectively meeting the objectives.
- The Review will be most effective if it maintains focus and specificity.
- The consultants contracted to conduct the review plan to deliver the product in time for discussion at the next Board meeting in June. Most of the work would be done in April, with the first draft delivered to the Board by the end of May; final report would be sent to the Board early June.

DECISIONS

The Board:

3.1. Approved the terms of reference for the review of the functioning and inter–relationships between the GAVI Board, Working Group and Secretariat, and requested that the relationship with the Vaccine Fund also be included.

3.2. Agreed to the proposed timeline for the delivery of drafts and final product;

3.3. Confirmed its willingness to contribute to the review process as needed by the consultants.

4. Guidelines for use of Window #3 of the Vaccine Fund

Discussion

- The GAVI research agenda needs to be focused on implementation: what kind of research is required to get more vaccines to more children in the shortest time?
- As we advocate for the development of new vaccines it will be important to consider how vaccine standards have changed – even in the last 20 years – and whether today's regulatory hurdles are too high to encourage new product development. This may warrant further exploration and discussion at a future meeting.
- The involvement of developing country researchers and manufacturers is essential in the GAVI research agendas.

DECISIONS

The Board:

4.1. Took note of the proposal to establish Accelerated Development and Introduction Plans (ADIPs) to better address GAVI priorities to speed development and introduction of pneumococcal and rotavirus vaccines, and new technologies and management strategies to improve immunization coverage. The meningococal vaccine is not included as this project is already managed through the Meningococcal Vaccine Program (MVP).

4.2. Requested more in-depth information on the management structure and arrangements for accountability for the proposed ADIPs, and on the selection process for the ADIP managers.

4.3. Agreed that more work needs to be done to elucidate the ADIP process, particularly for managing R&D work once it has been commissioned, how developing countries will be involved, and how it will incorporate the efforts of all of the relevant GAVI task forces, before guidelines for using Vaccine Fund resources for R&D can be approved.

4.4. Will review the ADIPs for the pneumococcal and rotavirus vaccines at its next Board meeting in June and consider the need for opening Window 3 of the Vaccine Fund to support the implementation of these plans.

5. Priority Technologies and Operational Strategies to Increase Access to Immunization

Discussion

- Increasing access to immunization is fundamental to reaching the GAVI milestones.
- The process of identifying priority strategies to improve access highlighted the need to separate potential management solutions from technology solutions.

DECISIONS

The Board:

5.1. Took note of the three technology project areas proposed, and asked that further development of the plans be presented to the Board at its next meeting, or at its November meeting. The proposed priority technology project areas are:

5.1.1. Decreased dependence upon and streamlining of the cold chain

5.1.2. Improved tools to measure immunization services performance.

5.1.3. Reducing infectious wastes and ultimately eliminating the use of sharps (needles and syringes).

5.2. Requested that the Working Group examine ideas that would enhance efforts and focus on access and equity issues, to present to the Board as soon as possible.

6. Immunization Financing Database

Discussion

- The main objectives of the Immunization Financing Database are to:
  - Monitor trends in expenditure and financial flows at the country, region and global levels
  - Measure the influence of GAVI and the Vaccine Fund on immunization programmes and their sustainability

- To serve as a tool to help strengthen strategic planning for immunization services and to mobilize resources for improvement and expansion
- To serve as a reference tool to answer policy relevant questions

- The main sources of data are the UNICEF/WHO Joint Reporting Form and the countries' financial sustainability plans (for which guidelines are currently being developed). The exercise will strive to use existing data sources and report it in a consistent manner.
- The database will be fully functional and presented to the Board in June.

7. Lessons Learned on GAVI Procurement

Discussion

- The Lessons Learned on GAVI Procurement study is being conducted by Piers Whitehead of Mercer Management, building upon a 1993 vaccine industry study of a similar nature, also prepared by Mercer Management.
- The Lessons Learned study will provide a trend analysis of the vaccine industry since the 1993; outline the implications of changes on the economics and current and future developing country vaccine supply and pricing. The study will also include recommendations for meeting the short, medium and long-term public sector goals.
- The study will also explore how the industry and other partners experienced the process to support the forecasting, procurement, purchasing, and delivery of vaccines on behalf of GAVI and The Vaccine Fund, and the impact it had on their decisions. In particular the study will review the security of near term vaccine supply for the poorest 74 countries and suggest options for improvements

8. Recommendations of the Independent Review Committee on Indonesia

Discussion

- The GAVI Board had previously granted the Indonesian application for birthdose hepB vaccine conditional approval with the following two conditions:
  - To provide a detailed plan of action for the proposed nation-wide expansion hepB birth dose vaccine for the first two implementing years;
  - To provide plans to strengthen the function of ICC.
- After reviewing the responses and information reck)ved by Indonesia to the above conditions, the IRC recommends approval for the application for birth dose hepB vaccine for 5 years. In addition, Indonesia has made a request for injection safety support, a request that the IRC recommends be resubmitted.
- Concern was expressed regarding reports that Biopharma is experiencing high wastage rates in filling Uniject (the brand name of Biopharma's pre-filled monodose technology), which may be an indication that the technology is not completely ready for industrial use. This will need to be monitored.

DECISIONS

The Board:

8.1. Approved the recommendations of the IRC: one year of support to Indonesia for a birth dose of pre-filled monodose hepatitis B vaccine. The vaccine will be procured nationally at a price in 2002 of $0.80 per dose, at a total estimated cost for 2002 of $2,508,000, and a potential five-year commitment of $16 million. The vaccine price will be re-negotiated after one year.

9. China MOU

Discussion

- The draft MOU was prepared by the Government of China with its national partners, in consideration of the concerns expressed by the GAVI Board at its last meeting in Ottawa in October 2001. To facilitate the finalization of the MOU, the Board sub-group identified for the Ottawa meeting – Norway (Chair), DFID, UNICEF, CVP, Mali, and the GAVI Secretariat – considered the draft prepared by China and provided its input to the draft.
- The sub-group had chosen to refer to the Vaccine Fund throughout the draft as the provider of funds and support. Discussions between the UNICEF and Vaccine Fund lawyers may result in wording changes in those sections that refer to the Vaccine Fund.
- The sub-group further recommended that the MOU be signed jointly by the Chair of the GAVI Board, the President of the Vaccine Fund and a representative of the Chinese government. However, this may also change as a result of legal considerations.

DECISIONS

The Board:

9.1. Approved in principle the draft MOU submitted by China, with the proviso that changes relating to the above areas may need to be incorporated into the final draft.

9.2. Approved a recommendation of a five year financial commitment from the Vaccine Fund of $38.7 million to support the program, conditional on receipt of satisfactory annual progress reports.

9.3. Requested the Vaccine Fund and UNICEF to finalize the MOU within two weeks.

10. Next Teleconference and Meetings

DECISIONS

The Board:

10.1. A teleconference will be held during the week of 15 April.

10.2. The Board welcomed the invitation from the Pasteur Institute to hold its next meeting in Paris 19-20 June.

10.3. The Board welcomed the invitation to hold the next Partners' meeting in Dakar 20-22 November. A Board meeting will be held in conjunction with this meeting, on 18-19 November.

Report by the London School School of Hygiene and Tropical Medicine: Summary of Presentation and Discussion

- Gill Walt of the London School of Hygiene and Tropical Medicine presented the main findings of the report, "New Products into Old Systems: Initial Impact of GAVI in Countries". The study caveats included the fact that only four countries were visited and these were not necessarily a representative sample – selection of the countries was based on those which the researchers knew, had previous experience in, and were accessible.
- The main report findings were:
  - Countries welcomed the renewed focus on immunization, the opportunity to introduce hep B vaccine and auto-disable syringes and disposal boxes, and the flexibility of funding for systems support.
  - Immunization systems in the countries studied showed serious weaknesses, including staff shortages and inadequate allowances which compromised their ability to achieve targets; cold chain problems; poor standards of supervision; inadequate waste disposal and inaccurate data reporting.
  - There was some concern that countries received pressure to accept sub-optimal second choice of vaccine formulations, due to vaccine shortages, and whether Hib was appropriate for introduction.
  - The cost of Hib vaccine (at current prices) has a major impact on the cost of the immunization program in Ghana, raising questions over future sustainability.
- Professor Walt recommended that GAVI needs to take steps to ensure:
  - Introduction of new products does not unduly distort countries' immunization priorities
  - Quantitative performance monitoring is complemented by the addition of other indicators
  - Sufficient systems support is available for implementation of routine EPI, managing information systems, safe disposal
  - Other players are involved in the above, to ensure coordination with existing national processes, to widen the constituency of support
  - Sustainability, by working at a pace which allows change to be consolidated (and costs to be met)
- The report is an important opportunity to consider the progress and future challenges for GAVI and the Vaccine Fund. in enhancing collaboration at the country level. Many of the report's findings will be helpful to the GAVI alliance
- Dr Sam Adjei, Deputy Director-General of Health Services in Ghana expressed some concerns about the design and implementation of the research, having also consulted with the EPI manager in Tanzania – one of the other countries included in the report. While they welcomed the report for raising pertinent and important issues, according to Dr Adjei:
  - The researchers did not adequately convey the process to EPI staff in either country, or brief them on the findings before leaving the country.
  - Some of the descriptions of Ghana's situation were inaccurate. The ICC in Ghana was not under undue time pressure do decide whether to accept pentavalent DTP-hepB+Hib vaccine, nor was the vaccine's epidemiological appropriateness in question. In fact, the country had planned to introduce this vaccine in 2003; its decision was whether it would be able to introduce the vaccine earlier than planned.

  - Many of the issues raised in the report pre-date the emergence of GAVI and the Vaccine Fund, e.g., the challenges of securing sustained financing and staffing of health services. What is important is to integrate sector-wide approaches and global initiatives to produce and sustain better health outcomes.

- Many of the long-standing issues raised in the report were in fact reasons for establishing GAVI. What is critically important for GAVI is to assess whether its support is succeeding in addressing these weaknesses and making immunisation systems effective.
- Minister of Health Fatoumata Nafo-Traore from Mali, reporting feedback received from her colleagues in Africa, said that for many countries, the GAVI application and disbursement process has not been too fast, and in some cases it has even been too slow. She also noted that before introducing more expensive new vaccines support should be secured from national decision-makers who control the health budget.
- It will be important to consider how best to integrate ICC efforts with broader health partnerships in countries. Some partner constituencies such as the bilateral donors and development banks are more involved in these broad partnerships than in immunisation or ICCs; they have a strategic advantage in this regard.
- It will be important to include the impact of introduction of AD syringes on health care waste management as a part of countries' annual progress report to GAVI and the Vaccine Fund.

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Proposal on calculating GAVI reward shares

Executive summary

Principle of GAVI share allocation

GAVI funding to strengthen immunization services is designed to be performance-based. The Vaccine Fund's immunization services sub-account is designed to pay a "reward" of $20 for each additional child who receives the third dose of diphtheria-tetanus-pertussis vaccine (DTP3) compared to the previous year (see Annex 1b). Countries will receive funding based on demonstrating an increase in the reported number of children who receive DTP3 before one year of age, compared to baseline DTP3 coverage, and verified by an external audit.

Background on the immunization Data Quality Audit (DQA)

At the request of the GAVI Secretariat, WHO developed an external audit tool, the immunization Data Quality Audit (DQA), to evaluate the quality of immunization reporting and verify the accuracy of reported data. After reviewing the outcomes of audits completed in 8 countries in 2001, the TFCC has concluded the following:

1. No method is available (or ever likely to be available) that is both affordable and can be used to validate reported DTP3 coverage with high precision. Neither DQAs nor coverage surveys can validate reported immunizations to closer than 5-10% of the reported value.

2. The Data Quality Audit (DQA):
   - Is a valid tool for evaluating the quality of reported coverage data and can assist countries in identifying and correcting problems with immunization reporting systems;
   - **Cannot** provide a mathematical adjustment to reported DTP3 data for share calculations due to the low precision of the measurement;
   - Can be used to broadly classify the reporting system of a country as "reliable-unreliable";
   - Is expensive ($60,000 average cost) relative to Vaccine Fund support in some countries;
   - Has been successfully modified as a self-assessment tool and should be encouraged as a valid capacity building tool for countries to evaluate the quality of their reporting systems.

3. Most countries have significant weaknesses in their national reporting systems and correction of these weaknesses will require sustained efforts by the national immunization program.

Summary of proposal to calculate reward shares

On the assumptions that a) the performance-based approach must be retained as a GAVI principle and that b) the GAVI Board chooses to preserve the vision of linking rewards to reported DTP3 coverage, *the TFCC proposes a modified approach for verifying reported DTP3*:

- The DQA should be carried out in all countries receiving GAVI immunization services support funding at least once (before the first GAVI reward) to assess the quality of immunization reporting.
- The reporting system can be considered "reliable" where the verification factor (VF) generated by the DQA is at least 0.8 ($\geq$ 0.8) and "unreliable" where it is less.
- The verification factor cannot and should **not** be used to adjust reported DTP3, or be applied in a manner that proportionally calculates sizes of rewards.

For awarding GAVI shares, the TFCC further proposes that:

- The first planned reward (for DTP3 increase in first year) be converted to a third investment ($10/child projected DTP3 increase) for all countries, providing one full year of immunization services support investment.
- All subsequent reward payments for all countries are based on validated increases in DTP3.
- In countries where reporting systems are classified "reliable" (assessed by DQA), reward payments are based on reported DTP3 figures endorsed by the ICC.
- In countries where reporting systems are classified "unreliable" (assessed by DQA), rewards be deferred until reporting is improved or validated by another method (vaccine coverage surveys) that meets strict criteria on frequency, methodological consistency and proper oversight.

Rationale for proposal

This proposal is based on the following realities:

1. Most countries have weak reporting systems that will initially be unable to demonstrate valid reported DTP3 data; it is expected that most reporting systems would be classified as "unreliable" in terms of accuracy of data.
2. GAVI did not previously specify that all records should be kept at least 24 months at the health center level to allow verification of DTP3 doses.
3. The initial GAVI immunization services funds (first disbursed late 2000/early 2001) will only have been available for part of the year for which coverage is being measured at the time that rewards are originally planned (reward measurement in late 2002 based on 2001 data).
4. The current GAVI investment in immunization services is a small proportion (10%) of expected immunization services funding.
5. The conversion of the original reward to an additional investment can be applied to improve the immunization system and to correct weaknesses of the reporting system.

This proposal is endorsed by the TFCC on the principles that:

- The method to determine GAVI immunization services funding is equitable across all countries.
- The approach is as simple as feasibly possible given the inability to accurately validate reported DTP3 coverage with high precision.
- The mechanism preserves the ultimate intent to nurture weak immunization programs.
- Incentives will continue to be provided to countries to strengthen monitoring and reporting systems for immunization coverage.

Outstanding issues for consideration

Although the TFCC believes that this proposal is currently the most suitable option to meet the original GAVI immunization services support specifications, concerns about its drawbacks remain. In particular:

- The cut-off point for classifying whether the reporting system is "reliable" is essentially arbitrary – wide confidence intervals mean that the verification factors remain quite imprecise.
- Linking financial rewards to reported coverage may encourage false reporting and over-emphasize improving reporting at the expense of improving immunization coverage.
- GAVI's primary objective is to encourage overall strengthening of immunization programs, but basing rewards on DTP3 coverage alone insufficiently addresses this.
- The DQA is relatively expensive to apply as an external audit ($60,000 per country), while having limited value in verifying actual immunization program performance.
- Some countries execute coverage surveys routinely and rely on them for assessing coverage rates. Incorporating coverage surveys in the proposal acknowledges this reality, yet weakens the message that improving reporting systems and generating reliable data is valuable.

TFCC recommendations

Recognizing the imperfections in the reward based funding approach, the TFCC recommends:

- An assessment of the GAVI reward system be conducted as soon as possible to determine whether funding should remain entirely performance-based, but only after trends in the reporting system can be assessed (i.e., not prior to end 2003).
- The TFCC should begin examining *options and means* to reward countries that report program progress, but are unable to demonstrate an increase in DTP3 numbers. This would include identifying qualitative indicators used in conjunction with DTP3 so that performance rewards rely on a broader assessment of performance.
- The timing of GAVI monitoring tools (annual report and mid-term review) should be adapted to fit adequately with the proposed changes.

Proposed approach for calculating GAVI shares during 2002-2003

This proposal maintains the current approach of providing GAVI immunization services funding based on verification of the absolute increase in reported DTP3 administered, but suggests changes in the method for determining the reward shares. Rather than using the DQA correction factor as a multiplier, as originally envisaged, **the TFCC recommends using the DQA Verification Factor (VF) as an indicator of the reporting system in a "***pass/fail***" manner ("reliable"/"unreliable").**

"Reliable": **When VF $\geq$ 0.8**
- Indicates an acceptably reliable reporting system
- Reported coverage considered reliable

"Unreliable": **When VF < 0.8**
- Indicates a flawed reporting system
- Reported coverage considered unreliable

The principal steps for determining GAVI reward shares during 2002-2003 are proposed to be:

1. **Use the DQA to evaluate the quality of each country's reporting system within the first 2 years of immunization services funding, but do not base GAVI payments on the first DQA.**
2. **Convert the first reward, scheduled to be given at the end of the second year for increases in DTP3 achieved during the first year, to a third investment for all ISS countries, regardless of whether the system is classified as "reliable" or "unreliable".**
3. **Base future payments on reported DTP3, verified by a DQA that shows reliable reporting. reward payments will be deferred in countries where the reporting system is not reliable and no survey results are available.**
4. **The need for repeated DQAs to validate reported data is determined by the results of the first DQA. Countries with unreliable reporting systems will require a subsequent DQA to show "reliable" before using reported DTP3 for reward shares. Those with reliable systems may be requested to undergo another DQA on a random basis, or in certain instances, for other legitimate reasons.**
5. **The use of coverage surveys to verify or calculate DTP3 will be permitted under strict conditions, and only after a DQA has been executed twice, reflecting an "unreliable" reporting system both times.**

This approach was selected among several options as being the most practical and equitable. The proposal is based on the principles of giving countries an opportunity to define weakness and to encourage efforts both to improve immunization coverage and strengthen reporting systems.

DQA process and share rewards: first year (see Figure 1)

1. **A DQA will be completed in all countries that receive immunization services funds, during the first or second year of funding**.[1] This will establish the baseline quality of the immunization reporting system. DQA results will be shared with the country; weaknesses in their reporting system will be clearly communicated and recommendations for improvement will be provided. Countries should be informed that GAVI audits will necessitate that all records should be kept at least 24 months at the health center level to allow verification of DTP3 doses.[2]

2. **The first reward (due at the end of the second year) should be changed to a 3rd investment payment, which is provided to all countries based on their *projected first year increase in DTP3* rather than the reported DTP3**. This is based on several realities: (1) most countries have weak reporting systems which will not be able to validate reported DTP3 during the first year; (2) GAVI did not specify that all records should be kept at least 24 months at the health center level to allow verification of DTP3 doses, and (3) the initial GAVI funds will only have been available for part of the year for which coverage is being measured. Furthermore, the current GAVI investment in immunization services is a small proportion (about 10%) of expected immunization services funding. The additional financial support will be considered an additional investment to improve the immunization system and to correct weaknesses of the reporting system. The actual quantity of funding could be modified or deferred based upon whether the first GAVI investment payments have been fully utilized.

[1] First DQAs are done in 2002 for Round 1, 2 and 3 application rounds (numbers 19 countries). First DQAs for Rounds 4 and 5 would be conducted in 2003. Highest priority for DQA execution will be given to countries receiving greater than $100,000 support in first disbursement.

[2] Letter distributed by GAVI Secretariat December 2001

3. If the first DQA indicates "reliable":

- The country will be given a 3rd investment payment, equal to the value of the first two investment installments, based on projected targets as stated in the original application, regardless of whether projected DTP3 target is unmet or exceeded.
- The DQA may be repeated again before the end of the 5-year cycle. This will be determined primarily on a random basis, but may occur based upon other legitimate reasons. However, in these countries, a DQA will not be executed during two consecutive years.

4. If the first DQA indicates "unreliable":

- The country will be given a 3rd investment payment, equal to the value of the first two investment installments, based on projected targets as stated in the original application.
- The country will be requested to submit to GAVI a 12-month plan of action to improve the reporting system based on the DQA recommendations, and endorsed by the ICC.
- The DQA will be repeated for a second time in the following calendar year.

Share rewards and DQA process: second-year and subsequently (see Figure 2)

1. Countries where the first (or previous) DQA classified the system "reliable" will receive GAVI reward ($20 per child) based on reported DTP3 increase (endorsed by national ICC), compared to DTP3 originally projected to be reached by end of year 1 (or to previous year's DTP3).
2. Countries where the first (or previous) DQA classified the system "unreliable" will have GAVI rewards based upon the outcomes of the 2nd DQA.

If a 2nd (follow-up) DQA indicates "reliable":

- Reward shares are granted at $20 per child. The number of supplementary children is calculated from the number of reported DTP3 in the audited year minus the number of children originally projected to be reached with DTP3 by end of year 1.
- Future fund disbursements can be based on reported data. The annual figures reported by the country (and approved by ICC) will be considered valid and used to calculate the size of reward shares.

If a 2nd (follow-up) DQA indicates "unreliable":

- Countries may elect either to a) defer reward payments and request a 3rd execution funded by the GAVI Secretariat when they deem themselves ready **OR** b) conduct and finance a vaccine coverage survey to validate reported DTP3, in observance of criteria (see Annex 1a).
- In the interim, all GAVI partners should help countries improve and correct weaknesses in the reporting system.

If a 3rd DQA indicates "unreliable":

- Share rewards will continue to be deferred, unless an independent vaccine coverage survey is permitted to validate DTP3 (see below).
- The country may not request a 4th DQA funded by the Secretariat but would be required to use its own or partners funding for additional DQA.

Conditions for using coverage surveys for share rewards

Vaccine coverage surveys may be used to validate increases in DTP3, provided that:

a) The DQA has already been executed twice and demonstrated "unreliable" both times.

b) The cost of the coverage survey is financed by the country or country partners.

c) The design and conduct of the survey is lead and supervised by international partners.

d) The results of the survey are endorsed by all ICC members and sent to the GAVI Secretariat.

e) The coverage survey is followed by a DQA the next year; that is, vaccine coverage surveys cannot be administered in consecutive years for the purpose of calculating reward shares.

Subsequent use of coverage surveys to calculate share rewards (after the first survey) will not be pre-determined, but rather will be judged on a case-by-case basis. The appropriateness of permitting multiple surveys will be made after consideration of several factors, including demonstrated progress between the DQA interventions and clear commitment to the 12-month plan of action to improve the reporting system. For more specifics on criteria, see Annex 1a.

Outstanding issues for consideration

This review has identified fundamental weaknesses in implementing GAVI funding solely based on precisely measuring increases in DTP3 coverage. Among these weaknesses are incentives to "beat the system" and greater focus on improving reporting than on improving DTP3 coverage. The TFCC Core group agreed that the strict performance basis of GAVI funding should be reconsidered, looking toward developing a broader approach designed to measure progress in various components of the immunization program. The group suggests a proposal should be developed during 2002, and linked to an independent review of the share based funding system after the first GAVI rewards (under this proposal) have been made. Specifically, the group recommends:

- The primary objective of GAVI is to encourage overall strengthening of immunization programs, which cannot be measured by DTP3 coverage alone. The TFCC should develop a proposal for an additional funding mechanism by which countries are monetarily rewarded for demonstrating that they have achieved program progress.
- After DQAs are re-executed in 2003, GAVI should review the impact and success of DTP3 based funding and give consideration to alternative funding mechanisms, including ones that include a broad range of program indicators.
- The timing of GAVI monitoring tools (annual report and mid-term review) should be adapted to fit adequately with the proposed changes.

Figure 1. Proposed DQA and GAVI share rewards – first reward year
(year 2, based on original ISS guidelines) (DQA conducted in year 2)

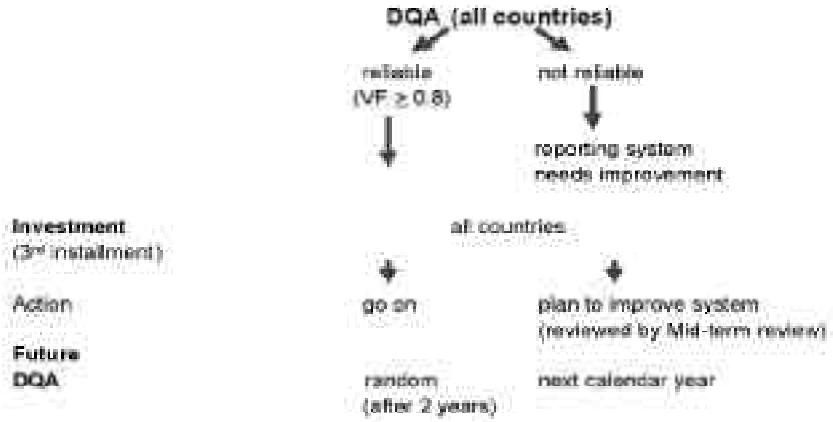
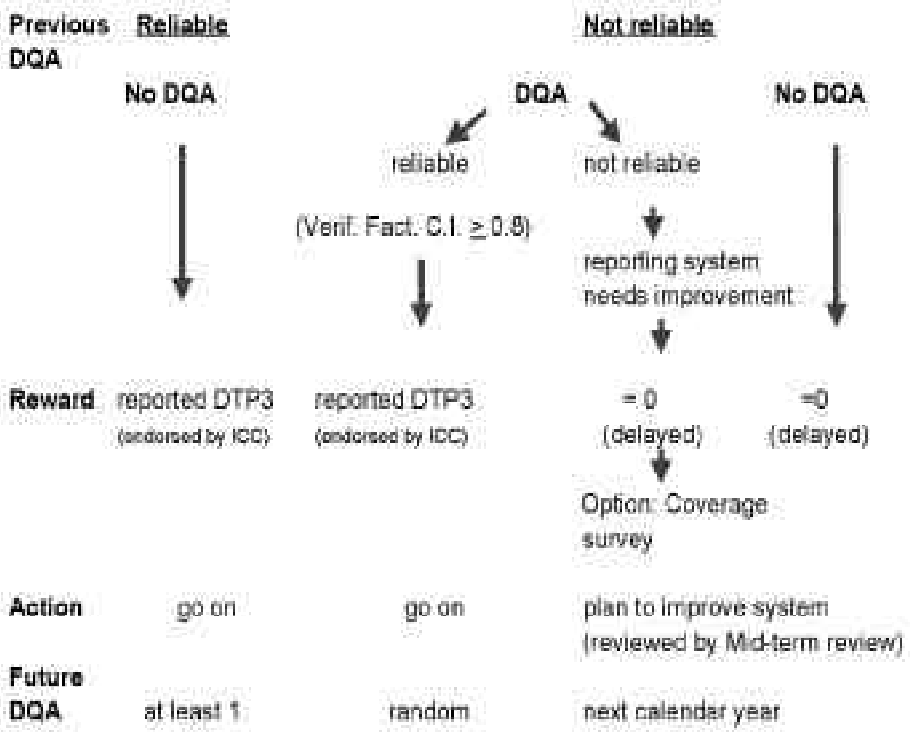


Figure 2. DQA and GAVI share rewards – subsequent years



Annex 1a:
Use of vaccine coverage surveys

Vaccine coverage surveys do not help countries improve their routine immunization reporting system, an important goal of GAVI partners. However, vaccine coverage surveys are used regularly in many countries to validate immunization levels. When conducted properly, coverage surveys are a valid approach to measuring immunization coverage and can be used to estimate DTP3 doses administered, provided that consistent rules are applied. Coverage surveys have been used in some GAVI funded countries to establish the DTP3 baseline.

For measuring share allocations, countries permitted to use coverage surveys to verify their coverage level should be held to the following criteria:

1. **Coverage survey methods**: Use of one of the 3 main methods of survey (MICs, DHS, or WHO EPI coverage cluster survey) with a representative sampling of the country population (national level).

2. **Minimum sample size**: For a cluster survey, the minimum sample size will be 1,470 children (e.g., 49 children by 30 clusters, or 7 children by 210 clusters), so that at 50% DTP3 coverage, the 95% confidence interval is 50%, plus or minus 5%. A smaller figure may be proposed for small countries. MICs and DHS have larger sample sizes and tighter confidence intervals.

   Stratified surveys (urban/rural; different areas…) may be accepted provided that the results at national level are properly weighted.

3. **Operational issues**: The design/conduct of the survey should be supervised by international partners. International partners (e.g. WHO, UNICEF, or bilateral partners at country or regional level) should assure sampling and data collection methods are representative and scientifically valid, that the survey is conducted by an independent party (not associated with EPI), and that the survey is conducted honestly (e.g. avoidance of prior knowledge of sample sites). The report of the survey will be signed off by the ICC and sent to the GAVI Secretariat.

4. **Estimates**: The vaccinations given to children under one year during the year to be verified should be measured by the coverage survey. However, this is impossible (or extremely difficult) because two cohorts of children under one are vaccinated during one year. Vaccine coverage surveys usually measure coverage from approximately age 2 and under (e.g., a survey in 2002 would measure coverage among children vaccinated mainly in 2000 – if coverage is ascertained in 12-23 month old children). As a proxy for the number of immunizations given to under ones, coverage among 12-23 month old children using an immunization card + history will be acceptable (including vaccinations given at any time before the survey). The point estimate (not the confidence intervals) will be used for calculating DTP3 doses given.

5. **Use of birth cohort denominators**: Denominator data which have been submitted with the original GAVI application will be used unless there is compelling reason to use new data (e.g., new census). These denominators should already include previsions of population increase and infant mortality rate correction. If a new denominator is proposed (signed off by the ICC) and accepted by GAVI, the supplementary number of children will be calculated with retrospective extrapolations from the new census.

Example:

Old census 2001: 100,000 children under one, coverage 70% (70,000)
New census in 2002: 150,000 children under one, and coverage (from survey) is 75% (112,500).

According to the old census in the application form, population under one was 110,000 in 2002. Then the basis for share calculation would NOT be (112,500 less 70,000)= 42,500 additional. It would be: (112,500) less [(70,000) x (150,000/ 110,000)] = 17,045 additional.

6. **Timing**: The survey should be done during the year that *follows* the year for which shares are calculated.

Annex 1b:
Current method for GAVI immunization services sub-account (ISS) funding

GAVI Immunization Services share Funding is based on the increase in number of children receiving DTP3 by age 12 months relative to an agreed baseline submitted at the time of the GAVI/Vaccine Fund application. Each country projects the number of additional children that will be immunized with DTP3 within a two year period, and, based on these targets, the total funding is calculated at a rate of US $20 "*share*" per child. Total calculated funding of "X" is disbursed as follows:

- **Investments** – 50% of X calculated funds given as *up-front* investment, equivalent to $10 per child for *projected* increase in children receiving DTP3.
- First half of investment is given at beginning of first year (X/4)
- Second half of investment given at beginning of second year (X/4)
- **Rewards** – rewards based on reported DTP3 doses administered, externally validated, compared to baseline DTP3 (1999 for the first three rounds, 2000 for rounds 4 and 5).
- First reward to be given at end of second year (e.g. during 2002 for countries funded in 2000/early 2001) for improvement in coverage (2001 minus baseline), and would include the remaining $10 per child increase in DTP3 doses. If DTP3 targets are met, then the size of the first reward is equivalent to "X"/2.
- Subsequent rewards are disbursed at the end of each following year, up to the end of the five year funding cycle, at a rate of US $20 per child increase (Figure 1).

Figure 1: Key elements and timetable of the current immunization services sub-account process

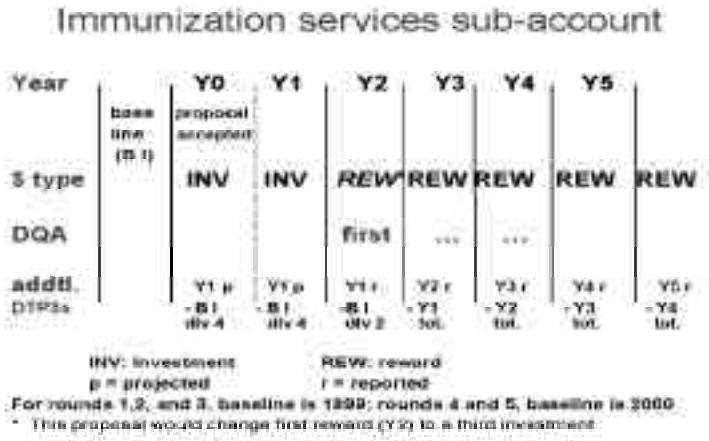


Table 1. Results of verification factors in 8 audited countries from the DQA (June-September 2001) and estimated rewards

Country	Verification factor		Size of reward (2002) if calculation based on:	TFCC PROPOSAL: PROJECTIONS BASED ON AUDIT RESULTS			
				Classification of reporting system	Size of 3rd investment (2002) if calculation based on:	Reconduct 2nd DQA in 2003?	Size of 1st reward (2003) calculation:
	Point Estimate	(+95% CI)*	Point Estimate (original intent)		Projected DTP3**		
Pakistan	.67	(.33-1.01)	None	Unreliable	$5,010,000	Yes	Dependent on results of 2nd DQA
Uganda	.71	(.50 -.92)	None	Unreliable	$910,000	Yes	Dependent on results of 2nd DQA
Mali	.75	(.10-1.43)	$67,400	Unreliable	$858,000	Yes	Dependent on results of 2nd DQA
Tanzania	.57	(.24-.90)	None	Unreliable	$1,214,000	Yes	Dependent on results of 2nd DQA
Kenya	.40	(0.0-.80)	None	Unreliable	$1,289,000	Yes	Dependent on results of 2nd DQA
Côte D'Ivoire	.87	(.57-1.18)	$551,220	Reliable	$1,026,000	No	Actual reported less projected
Liberia	.60	(.25-.95)	$101,116	Unreliable	$611,000	Yes	Dependent on results of 2nd DQA
Rwanda	.71	(.54-.88)	$230,180	Unreliable	$908,000	Yes	Dependent on results of 2nd DQA

* based on the T distribution

** as estimated from application

Annex 1c
Data Quality Assessment (DQA) – What is the ability to verify reported data?

- The DQA generates a "verification factor" (VF), which represents the proportion of reported DTP3 doses that can be verified by the audit (comparing DTP3 doses whose report is available at the health center level to the ones reported at a higher level [district]).
- The DQA verifies the last DTP3 tabulation available at national level, which can be compared to the figure reported in the WHO/UNICEF Joint Reporting Form (JRF).

Outcomes:

- DQA shows substantial deficiencies in the quality of reported data in all countries.
- DQA verified only 40-87% of reported immunizations. VFs for most countries are well below 1. Confidence intervals are very wide.
- The most important reasons for low verification rates are missing records at the clinic level and incomplete reporting to district and national level (all countries). Other reasons include inflated values from some clinics/districts, falsified reports substituted for missing reports, and availability of updated reports (after sent to national level).

Implications:

- From the 8 audit field tests, only 1 of 8 countries were found to have "reliable" systems — almost a 90% failure rate. Based on the TFCC proposal, this means most of the countries would require DQAs in the following year.
- For 2002 the current plan is to schedule 19 DQAs (round 1, 2, 3 countries). If 90% of these DQA outcomes are "unreliable", the TFCC proposal requires audits to be re-executed in 2003 — translating into the execution of 17 "2nd time" DQAs. A hypothetical scenario could be, therefore, that 17 "2nd time" DQAs would occur *in addition to* the 14 "1st time" DQAs (round 4, 5 countries), reaching a total 31 DQAs for 2003.

Annex 1d

From the report of the GAVI Board Teleconference, 31 March 2000

Sub-account for strengthening of immunization services:

- The basic concept is, at the outset, to invest in a government's commitment to strengthen immunization services, and, thereafter, to reward a government for the increase it has actually achieved over the past year.
- Support would be disbursed in the form of "shares", initially valued at US $20, with one share representing one un-immunized child. There would be no prescribed conditions on the use of the shares disbursed; the only condition is that immunization rates rise.
- For example, if a country were to set a goal of increasing immunization coverage by 10,000 children over baseline, and the local ICC and GAVI accepted this as a reasonable goal, the country would receive US$ 200,000 as an investment. Then, after the first year, if the country meets the goal by reaching 10,000 more children, the government will be compensated with another 10,000 shares, or US$ 200,000.
- It is a quite revolutionary concept – a performance-based system that relies on local Inter-agency Coordinating Committees (ICCs) to set goals and monitor progress, but does not prescribe input monitoring systems.
- DTP3 coverage would be used to measure immunization rates; while an imperfect measure, it is widely recognized as the best tool that is available at this time. Improvements in indicators are envisioned as implementation proceeds.
- Due to their large populations and their relative strength in local vaccine production, individual negotiations will be held with China, India and Indonesia to discuss the most appropriate support for these countries from the Fund. In fact, a mission to India is now being planned for the end of April, and one to Indonesia for the second half of May.

The Board gave its general endorsement of the proposal outlined above for the use of the Fund to support the strengthening of immunization services.

Because this is such a revolutionary idea, in order to consult with regional and country-level partners and the countries themselves, the Board endorsed the proposal that the timeline for the distribution of proposals to countries and the disbursements of funds be pushed back. It was stressed that seeking and obtaining buy-ins from countries will be especially important, as they are the most important partners in this effort.

Therefore, the country proposal package will be sent to countries on 15 May with a deadline of 1 July for receipt of proposals at the GAVI Secretariat. The proposals will be reviewed by an expert panel in early July, with their recommendations provided to the Working Group and the Board by mid-July. The first round of disbursements from the Fund would be made immediately thereafter.

Annex 2
Monitoring and reporting of country performance

Introduction
Strategic objectives and milestones have been adopted by the GAVI Board to guide the collective efforts of GAVI Partners to expand the use of vaccines in the world's poorest countries, thereby reducing the human and economic burden caused by vaccine-preventable diseases.

A results-based approach to country support is also being promoted, most explicitly through The Vaccine Fund's immunization services support mechanism. In order to accurately assess country progress and results, appropriate indicators that relate to GAVI's strategic objectives and milestones need to be tracked.

This document provides an update on GAVI's monitoring framework and describes in particular how progress of countries approved for support will be monitored, reported, and used for allocation of for immunization services support.

Principles
- GAVI monitoring and reporting systems should be based on existing national systems to minimize burden, avoid duplication and encourage consistency of data. This will help reinforce national capacity and country ownership.

- Monitoring systems should promote use of data at the local level, leading to corrective action and effective support. Collected information should be reported to the level where such data is needed and used for clearly defined purposes.

- The WHO/UNICEF Joint Reporting Form (JRF) is the principal tool for collecting country performance data. All countries are expected to complete and submit to WHO and UNICEF the JRF by 15 April of each year for activities in the previous calendar year. The JRF is certified by the government and should when applicable be presented and endorsed by the national coordination mechanism (ICC or similar). WHO and UNICEF headquarters have systems in place for analysis of JRF data. Feedback systems to countries should be reinforced.

Purpose of country performance monitoring
Within the GAVI process three distinct purposes for monitoring country performance can be identified. Each one requires its own data management process and its own set of indicators (although some are shared).

1. Assessment of programme performance to enhance corrective action and support
This information is collected and used at the local level (sub-national and national) to monitor and improve program performance. It is usually not necessary to report such information to the global level but it may be tracked by GAVI Partners at a regional/sub-regional level to help target country support activities.

Countries applying for support have been requested to identify and monitor three quality indicators: management (e.g. drop-out rate of DTP1 to DTP3), disease surveillance (e.g.

AFP surveillance rate), and immunization/injection safety (e.g. utilization of AD syringes and safety boxes). Progress against these indicators will be assessed at the time of the mid-term review [1].

In addition, WHO, UNICEF and other GAVI Partners are developing a set of national-level "Core Indicators" that will allow tracking of country performance and development of country profiles in accordance with the capacity-building framework [2]. The monitoring and evaluation sub-group of the re-organized Task Force on Country Coordination will finalize this work, which in the future may complement or replace the three quality indicators.

2. Monitoring of progress against global GAVI strategic objectives and milestones

Strategic objectives and milestones have already been adopted by the GAVI Board. At the London Board meeting in June 2001, the GAVI Board approved the revision of the GAVI strategic objectives, and placed emphasis on improving access to sustainable immunization services and integrating all immunization initiatives. This overall monitoring framework for GAVI needs to be completed including methodology for collection and source of data. This framework will be presented to the GAVI Board at a later meeting.

Consultation with other global initiatives (e.g. Global Fund to Fight AIDS, Tuberculosis and Malaria, Roll Back Malaria) aiming at coordinating the monitoring of broader health systems performance will also occur.

3. Allocation of support in accordance with the GAVI Guidelines on Country Proposals

The GAVI Guidelines on Country Proposals clearly describe eligibility criteria and application procedures for support from The Vaccine Fund.

- Support for new and under-used vaccines is approved by the GAVI Board for a period of five years (or five birth cohorts). Based on actual implementation of activities, each country will each year submit vaccine and safe injection supplies needs for the following year within their approved entitlement for shipment by UNICEF Supply Division.
- Support for injection safety is provided for a maximum of three years upon approval of a plan to improve injection safety and waste disposal for immunization, either through the provision of auto-disable (AD) syringes and safety boxes or an equivalent cash grant.
- Support for immunization services is performance-based, initially through investments based on targets in the national plan for the additional number of children to be immunized with DTP3, and from year 3 through rewards based on actual performance[3].

The following section describes annual reporting procedures for countries approved for support from The Vaccine Fund.

[1] GAVI/Vaccine Fund Guidelines on Country Proposals (Revision 3, August 2001)
[2] "Monitoring national immunization systems through establishing core indicators", WHO draft February 2002
[3] Refer to GAVI Board paper "Proposal on calculating GAVI reward shares", TFCC January 2002

Country monitoring and reporting requirements

Annual report

The government is responsible for completing and submitting an annual progress report to GAVI by 30 September. The ICC must endorse the annual report prior to submission to the GAVI Secretariat.

The GAVI Secretariat is responsible for the collection of annual reports from countries that receive support. The Independent Review Committee (IRC) will review the annual reports and provide recommendations for approval to the GAVI Board[4] . Decisions on vaccine and supplies needs will be communicated to UNICEF Supply Division by 15 November.

The Data Quality Audit (DQA)

The DQA has been developed by WHO and helps to evaluate the quality of a country's health information system and verify the accuracy of reported administrative data. DQAs will be conducted in countries receiving immunization services support during the first or second year of funding[3].

In the case of countries where the DQA found the health information system not to be reliable, an ICC-endorsed plan to improve the system, based on the DQA findings and recommendations, should be prepared within three months. The plan must be forwarded to the regional working group for supportive action and to the GAVI Secretariat for information and future reference.

The DQA report will be forwarded to the GAVI Secretariat by the contracted audit company within three weeks of completion of the audit. Information on whether a DQA has been conducted in the previous calendar year is included in the JRF.

Financial sustainability plans

Development of a financial sustainability plan during the second year of support is a requirement for all countries approved for GAVI/Vaccine Fund support[5] . Country guidelines are being finalized and country support systems strengthened.

A financial sustainability plan should be attached to the first annual progress report. The plan should show clear evidence of Ministry of Finance participation and partner involvement. This could be achieved through the provision of signed comments by partners. The plan should present core expenditure data and resource requirement projections with a clear statement of the assumptions. The plan should describe how the country will monitor its own progress toward improved financing.

In subsequent years, the financial sustainability plan will be integrated into the national multi-year plan and annual workplans. Progress will be monitored by the government and partners and described in the annual reports.

The GAVI mid-term review (MTR)

A mid-term review will be required in all countries approved for any GAVI/Vaccine Fund support within 24-30 months of first support. The main purpose of the MTR is to identify progress and problems in implementation at an early stage for corrective action and

[4] The GAVI Board will provide guidance on which type of decisions that need to be submitted to the Board.
[5] *Refer to Guidelines for Financial Sustainability Planning draft document, FTF November 2001(Correct title and date of latest draft)*

adjustment of workplans. The MTRs will be tailor-made to the particular context and relevant issues in each country.

The MTR will not be directly linked to share disbursements. The MTR will however look at the way support has been used; the relation to and impact on health systems development; progress against other performance measures (e.g. three selected indicators and "Core Indicators"); capacity constraints and how to address these; and progress toward improved financing as described in the financial sustainability plan. When possible the MTR should be linked to a broader review of the health sector.

The regional working groups are responsible for initiating and supporting ICCs to undertake the MTR. GAVI Partners will provide the necessary funding.

The outcomes of the MTR will be forwarded to the GAVI Secretariat and reviewed as part of the country documentation by the Independent Review Committee at the time of the annual report review.

Summary of roles and responsibilities – GAVI/Vaccine Fund annual reporting process

Government	• Preparation and submission of annual reports
ICC	• Signed endorsement of annual reports
Regional working groups	• Monitoring of country performance and technical assistance • Responsible for initiation of mid-term review and provision of country support
GAVI Secretariat	• Compilation of annual reports and submission to the IRC • Submission of IRC recommendations to GAVI Board • Tracking of GAVI Board approvals • Feedback to countries • Management of the DQA
WHO and UNICEF	• Responsible for validation of country data (in particular JRF)
Independent Review Committee (IRC)	• Review and preparation of recommendations to the GAVI Board
UNICEF Supply Division	• Information on global vaccine and supply availability and delivery of vaccines and products to countries in accordance with approved annual requests

Annex 3

Final Terms of Reference for an external review of the functions and interactions of the GAVI Working Group, Secretariat, and Board

1. Purpose

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

2. Context

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

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

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

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

1. Management and monitoring of Vaccine Fund funding provided to up to 74 countries to help them improve immunization services, introduce new vaccines and increase safety of injections.
2. Monitoring progress in increasing levels of immunization coverage, as well as identifying barriers to increasing coverage and how to address these.
3. Monitoring and optimising the impact of GAVI policies and Vaccine Fund support on routine immunization coverage and the broader health systems in low-income countries.

4. Promoting sustainable financing and delivery of immunization programs.
5. Considering whether and how to expand the scope of Vaccine Fund funded activities to include other new vaccines and research and development.
6. Identifying GAVI's role with respect to middle income countries.
7. Facilitating the alignment of GAVI goals and activities with those of accelerated disease reduction initiatives (e.g. polio eradication, measles burden reduction), with the new Global Fund for AIDS, TB and Malaria (GFATM), and with national health system development.

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

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

3. Outcomes of the review

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

Prepare a report and make a presentation to the Board.

4. Specific activities

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

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

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

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

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

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

Identify options for reform.

5. Review methods

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

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

6. Timing

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

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

7. Management of the review

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

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

KEY DOCUMENTS FOR THE REVIEW

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

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

Annex 4
Guidelines for optimal, effective and catalytic use of resources from "Window 3" of The Vaccine Fund

Introduction
Focused research and development (R&D) projects play a key role in addressing glaring gaps in the equitable access to priority vaccines needed to immunize the world's children against vaccine-preventable infections. Accelerating the development and introduction of new generation pneumococcal vaccines, live oral rotavirus vaccines and meningococcal* conjugates that include group A into the world's least developed countries will enhance **equity**. The "vaccine technologies" projects (currently under selection) will expand **access** by improving the practicality and efficiency of immunization.

Accelerated research/development/introduction project agendas
Under auspices of the GAVI Task Force on Research & Development (in conjunction with GAVI Partners such as WHO, the Bill and Melinda Gates Foundation, Rockefeller Foundation and NIH), leaders of the global research communities involved with pneumococcal, rotavirus and meningococcal vaccines from industrialized and developing countries drafted agendas to accelerate research, development and introduction of these vaccine products into immunization programs of developing countries.

GAVI has a number of mechanisms at its disposal to assure that high priority research and development activities are successfully resourced and completed. Window 3 is a new mechanism that will work catalytically with other available mechanisms that include:

- Partners working in a coordinated fashion to increase efficient use of existing resources.
- Individual Partners assuming responsibility for specific high priority tasks or activities, according to their interest, expertise and funding capacity.
- Individual Partners directly financing others to carry out all or part of the project agenda.

Guidelines for use of Window 3 monies

Assuring that Window 3 monies are complementary to existing resources and that Window 3 functions as both a funding source and advocacy tool

Window 3 funding will aim to co-fund projects to a maximum of 75% of the total required. Through meetings and other modes of communication with investors, efforts will be made to match investors to unfilled gaps in the project agendas and to help raise initial capital to fill the gaps. These efforts to ensure matching funds for specific activities, as well as the general funding of The Vaccine Fund itself, serve as an advocacy tool in two distinct ways. First, financial support from The Vaccine Fund sends a strong message about the global priority accorded to the activities and projects to be supported. Second, some prospective donors are interested in supporting GAVI's R&D objectives. For such donors, Window 3 of The Vaccine Fund assures a conduit to channel their contributions to further the R&D objectives of GAVI.

Types of R&D activities that should be supported.[1]

The prioritized tasks and activities that will be supported by Window 3 are integral components of global agendas that have been prepared to accelerate the development and introduction of projects specifically approved by the GAVI Board, beginning with the three vaccine projects and expanding to include future vaccine technologies projects.

Two activities that are particularly critical to move the project agendas forward are:

- Epidemiologic measurements of the **burden** of pneumococcal, rotavirus and meningococcal vaccine-preventable disease, and
- **Clinical trials** that assess the safety, immunogenicity, practicality, efficacy and effectiveness (including cost effectiveness) of the vaccine (and vaccine technologies) in target populations in developing countries.

Disease burden studies generate the evidence base to guide countries in prioritizing vaccine introduction. Disease burden data do not favor manufacturers of individual products but benefit all Partners, public and private.

In contrast, support for clinical trials of specific products might benefit manufacturers of particular products. To minimize any implications stemming from use of Window 3 monies on competition in industrialized country markets, Window 3 will:

- Wherever possible, engage multiple manufacturers as partners rather than a single manufacturer, taking into account that some candidate vaccines are further along in development than others and manufacturers may vary in their degree of engagement with GAVI.
- Be transparent in all funding, allowing all firms to respond to public advertising of requests for proposals.
- Limit funding to clinical trials that are structured to minimize licensing benefits in industrial country markets. In situations where both an obvious industrial market benefit may arise because of the design of the clinical trial and the level of Window 3 funding surpasses the level of $\geq$ US$ 5 million (over a period of three years), then an analysis of the potential commercial benefits and the appropriate returns to the public sector will be required. These returns to the public sector may include, for example:
  - Negotiating in advance an appropriate and “affordable” price for Vaccine Fund-eligible countries.
  - Negotiating in advance a guarantee that a certain number of doses of vaccine will be made available for Vaccine Fund countries.
  - Negotiating access to the patents and (or) a transfer of technology if the manufacturer chooses not to develop the product or not to manufacture sufficient quantities to supply the countries.

The portfolio supported by Window 3 for each project agenda will represent a balance of “downstream” activities as well as some activities involving products that are further upstream in the development pipeline but that may have specific advantages over the more advanced products with respect to use in developing countries.

Other priority activities required to accelerate the introduction of these new vaccines and technologies into public health use in developing countries, such as investment in additional production capacity to meet the needs of developing countries, will be handled separately and brought to the GAVI Board on a case-by-case basis.

[1] Since the meningococcal conjugate vaccine research agenda has already been fully funded, it is not included in this exercise.

Once disease burden and clinical trials have been completed, the commitment of affected countries to invest in the use of these vaccines can be addressed.

A transparent lean management structure to support the research agendas
Accomplishing the research project agendas will require the investment of considerable resources. For each activity or task included in the global agendas, a priority level has been assigned, a timeline has been established and a cost has been estimated. In a systematic fashion, a process has been initiated to document current commitments of donors and to highlight funding gaps. Following completion of that process, a more precise picture of the extent of additional investment that will be required to complete the specific activities of the project agendas will be available. GAVI will seek the most competent, efficient and cost-effective management approach to undertake and complete the activities of the project agendas within the shortest possible time. For the initial activities, i.e., disease burden and clinical trials in the developing countries, we suggest:

- **Project Agenda Managers** for each product area, who are responsible for creating the prioritized product agendas, supporting key activities and monitoring action as outlined below. These Project Agenda Managers will be supported by the GAVI R&DTF, with technical and administrative input from relevant partners (including WHO's Initiative for Vaccine Research, which already provides secretariat support for the overall R&DTF). The process would include the following 5 steps:

- Create detailed product agendas.
- Generate "requests for proposals" ("RFPs") for priority activities.
- Review proposals submitted in response to the RFPs.
- Make recommendations for funding.
- Provide oversight to assure that the projects adhere to their timetables.

This process will primarily address the pneumococcal and rotavirus vaccine projects and the vaccine technologies project. Since the meningococcal conjugate vaccine research agenda has already been funded, it is not included in this structure.

- **Detailed project agendas.** Detailed project agendas will be created addressing the scientific (e.g. disease burden and clinical trials), financial, advocacy, policy and programmatic actions needed to accelerate the development and introduction of the priority products. These agendas will be prepared with input from experts in the immunization community. The agendas will outline the targets and prioritized list of activities providing information on the timelines, budgets and responsible parties.

- **Request for Proposals.** Highly focused RFPs that address specific project agenda activities will be prepared by the rotavirus and pneumococcal vaccine Project Agenda Managers, in conjunction with appropriate technical consultants. The RFPs generated will be widely advertised in order to solicit the best specific proposals from potential implementers worldwide. An important component of each submitted proposal will be a detailed timeline for completing the work scope.

- **Transparent selection of the best proposals by an Independent Review Panel.**
  - Independent Review Panels composed of 6-8 acknowledged experts (with minimal conflicts of interest) will review the proposals and select those that will be recommended for funding. This will be done by vote, with each member of the panel having an equal vote. The Project Agenda Managers, with support from the R&DTF will be responsible for selecting the experts for the Independent Review Panel and will act as the secretariat for their respective Independent Review Panel.

- Separate panels will be convened to review the rotavirus, pneumococcal and vaccine technologies proposals. However, for common areas, such as epidemiology and disease burden measurements, some technical experts may review proposals that relate to more than one project agenda.
- If a panel member perceives that she/he or another member may have a conflict of interest with respect to a specific proposal, she/he will absent herself/himself from discussions or votes on that specific proposal.
- The procedures to be followed by the panels will be drawn from the modus operandi of prior WHO steering committees, NIH study sections, MRC review committees, etc. The timelines associated with each proposal will be carefully considered as part of the review process, balancing proposed speed versus feasibility.
- The Independent Review Panel will review the design of each study to determine if results of that study might have a noteworthy impact on industrial country markets of the vaccine. If the proposed activity is greater than the $5 million over three years threshold and has commercial implications, the Project Agenda Manager will request that the Financing Task Force, or another GAVI Partner involved in commercial negotiations, undertake a due diligence business plan to assess the implications of The Vaccine Fund's investment.

- Four members of the R&DTF (including the co-chairs from academia and from WHO-IVR and two other R&DTF members) will work closely with the project managers to both provide secretariat support and to share oversight responsibilities. This core will strive to assure that the Independent Review Panels function in a consistent manner. The core will provide continuity to the process, and will act as a liaison to the full R&DTF. In order to maximize their independence, these members of the core will not have voting privileges.

- **Minimizing conflicts of interest.**
  - To minimize conflicts of interest with respect to the status of individual manufacturer's products, R&DTF members who represent industry will not serve as members of the core entity when studies of specific products are to be considered. Industry members may participate in the review of projects related to disease burden measurement or other activities that are generic and not related to specific products.
  - All members of the R&DTF as well as technical experts who serve on the Independent Review Panels will fill out a form in which they must declare equity holdings, paid consultancies, collaborations, etc. that might be construed as constituting a potential conflict of interest with projects that will be under review.

- **Rapidity of transfer of funds**. Disbursement of funds will follow procedures similar to those set by the GAVI committee that reviews country applications for support from The Vaccine Fund for strengthening of immunization services infrastructure or "new vaccines". Once the specific proposals have been selected and the recommendations for awards have been approved by the GAVI Governing Board, The Vaccine Fund Board will review the recommendations and authorize the rapid transfer of funds to the implementers. An important facet of these grants is that the projects' progress will be closely followed by the R&DTF, making sure that timelines are being met.

To summarize, the Requests for Proposals, reviews of the proposals, and announcement of awards are designed to ensure a rapid, transparent competitive process.

Commitment of The Vaccine Fund to purchase specific products

The commitment of Window 3 resources to support clinical research involving a specific vaccine or vaccine technology product does not necessarily obligate The Vaccine Fund to procure that vaccine or product in the future. It is anticipated that support of clinical trials of specific pneumococcal, rotavirus or meningococcal vaccine products or vaccine technologies by Window 3 of The Vaccine Fund will generate invaluable information about the use of those products in developing countries. In general, however, once these products become licensed, the actual procurement of vaccines or related products by The Vaccine Fund will take place through the same transparent, competitive procurement process that currently exists for other vaccines purchased by GAVI. Nevertheless, should it become obvious that development of a vaccine or modifications of a vaccine or technology for developing country use (e.g., changes in vaccine formulation to include additional serotype antigens) is contingent upon some level of future guaranteed purchase by The Vaccine Fund. Such situations will be handled separately and brought to the GAVI Board on an individual case basis.

The amount of monies from Window 3 to be allocated annually

It is proposed that the total allocation of monies from Window 3 of The Vaccine Fund shall not surpass US$30 million per year for the first 3 years. After 3 years, Window 3 will be reviewed and the ceiling may be increased or decreased. Precise apportionment among the projects will depend on the activities prioritized in each agenda and the degree of direct financing from partners.

Annex 5
Priority technologies and operational strategies to increase access to immunization

Executive summary

- At its meeting in the Netherlands in November 2000, the Board requested that the Task Force on Research and Development (R&DTF) recommend up to three non-vaccine related research projects to improve immunization systems and especially to increase access. These would be in addition to the three vaccine related R&D priorities that were proposed and approved by the Board at that meeting: pneumococcus, rotavirus and meningococcal A.

- Subsequently, the R&DTF undertook an extensive process of information gathering, evaluation, rationalization and prioritization to identify key technologies or improved management or operational strategies that could have a favorable impact upon immunization services in developing countries.

- The R&DTF sought the involvement of a wide range of individuals in order to tap the necessary expertise. Three teams were formed to look at different potential research areas:
  - "Hardware" solutions, with particular emphasis on safety and waste management.
  - "Software" solutions and operational research focusing on management and outreach strategies.
  - "Formulation and process" solutions.

- Using the criteria of: potential programmatic impact, technical feasibility, probability of successful introduction, and cost-benefit ratio, the recommendations of the three teams were merged into a short list of **seven** different problem areas that could potentially be addressed through research project agendas that focus on new technological solutions or operational strategies.

- The three priority **technology project agendas** identified were:

  1. Decreased dependence upon and streamlining of the cold chain.
  2. Improved tools to measure immunization services performance.
  3. Reducing infectious wastes and ultimately eliminating the use of sharps (needles and syringes).

- It was understood that the technology-related projects should be focused on those which could be introduced into services within a 5-10 year timeframe. Within that context specific promising **technologies** were identified under each project agenda:

1. Decreased dependence upon and streamlining of the cold chain:
   - Sugar glass stabilization technology (highest ranked technology in this agenda) – *Long term*
   - Refrigeration products with improved efficiency, temperature regulation and monitoring – *Short & medium term*
   - Re-evaluation of the effect of freezing on vaccine potency – *Short & medium term*

   – Reduced risk of harming vaccines outside the cold chain (VVMs) – *Short term*

2. Improved tools to measure immunization services performance:
   – Non-invasive (oral fluid) antibody tests to measure immunization coverage (only priority technology in this agenda) – *Medium term*

3. Reducing infectious wastes and ultimately eliminating the use of sharps (needles and syringes).
   – Devices to "defang" syringes (highest ranked technology in this agenda) – *Short term*
   – Aerosol administration of measles vaccine during mass campaigns – *Short & medium term*
   – Urban disposal of needles & syringes (incinerators and grinders) – *Medium term*
   – Multi-dose jet guns – *Medium term*

- If the Board approves these three project agendas, specialist teams will work under the auspices of the R&DTF to develop full proposals for Board consideration at a later meeting – most likely in November 2002.

- The four priority **operational project agendas** identified were:
  1. Increased access to immunization through outreach and demand creation efforts.
  2. Impact of monodose vial sizes on program operations and safety.
  3. Alternative solutions to meet program running costs.
  4. New tools to monitor immunization coverage and service quality at district level.

- Since operational research differs so greatly from research into new technological solutions – in the skill-base required and in the design and implementation of the research – it is recommended that the operational research project agendas be further explored by a new group or special project that focuses on access issues. If acceptable to the Board, the Working Group will develop a more comprehensive proposal on this new access focus and present it to the Board at its June 2002 meeting.

Annex 5a
Overview paper developed by the Task Force on Research and Development

Introduction
In the last years of the 20th century three glaring gaps became apparent with respect to immunizing the world's children against vaccine-preventable diseases:

1. Globally, immunization coverage had stagnated from the peak reached circa 1990 and had even begun to fall in certain areas. This constitutes an **ACCESS** gap.
2. Some relatively new vaccines that were routinely being given to infants in industrialized countries (such as *Haemophilus influenzae* type b conjugate and hepatitis B) were not being expeditiously introduced for routine use in developing countries. This constitutes an **EQUITY** gap.
3. Inadequate resources were being channeled to develop vaccines of particular importance for populations in developing countries. This constitutes an **INVESTMENT** gap.

It is against the above background that the Global Alliance for Vaccines and Immunization (GAVI) came to exist to address the perceived gaps. To understand the **ACCESS** gap, one must appreciate how immunization services in developing countries operate.

Providing immunization services
To operate a high performing immunization service in a developing country requires a coordinated effort that successfully incorporates a series of components that include:

- **Advocacy and communication**
  - At the national and local level, health officials must clearly communicate their strong commitment to make immunization services a high priority. Among countries with similar mean per capita incomes, surprisingly wide discrepancies in immunization coverage can be observed. In some instances, these differences reflect the relative priority that health officials accord to the operation of immunization services.
  - Various modes of communication must be harnessed to create a demand for immunization services within the general population and to mold public perception to appreciate the value of vaccines.

- **Supply of quality vaccines**
  - A reliable supply of quality vaccines must be assured. No matter how competent immunization services may be with respect to reaching target populations, if quality vaccines are not consistently available, immunization coverage will be compromised. Problems relevant to assuring a supply of quality vaccine are faced at the international, national, regional and local level.
  - Ultimately, the success of immunization services lies at the local level. Thus, a reliable infrastructure must exist to deliver the appropriate types and quantities of vaccines from central and regional supply depots to providers of immunization services at the local level.

- **Logistics**
  - ***Cold chain:*** All vaccines currently used in infant immunization globally have some degree of temperature instability which, if exceeded, may result in loss of vaccine potency or possibly of decreased safety (e.g., because of administration of an altered protein). For attenuated virus vaccines such as measles and oral polio, increased ambient temperature constitutes the main risk. For protein vaccines such a diphtheria and tetanus toxoids and *Haemophilus influenzae* type b (Hib) conjugate, excessively low temperatures may denature the protein, possibly diminishing the immunogenicity of the vaccine. Because of these constraints, the EPI organizes a cold chain that aims to maintain vaccines within a tolerant range of temperatures from their point of storage at central or regional level, through transport to the local level to the point where they are used by fixed health facilities, mobile immunizing teams and implementers of mass immunization campaigns. Maintenance of the cold chain is always a logistical challenge. However, in certain geographical areas and under some climatic conditions, the hurdles faced by immunization personnel in maintaining the cold chain are daunting.

It is obvious that the number of different vaccines that must be administered and the size of vials can have major impact on the logistics of the cold chain (e.g., the volume of cold storage required for 10 mono-dose vials is more than for a single 10-dose vial of vaccine). Thus, the decision to introduce new vaccines into the immunization schedule to address the EQUITY gap or changes in the size of vials (e.g., from multi-dose to mono-dose) have logistical consequences on the cold chain that must be taken into account. On the other hand, the introduction of some combination vaccines that contain multiple vaccine antigens within a single dose can potentially reduce pressures on the cold chain.

  - ***Sterile needles and syringes:*** A well run immunization service assures that all health workers who administer vaccines to target populations have at their disposal an adequate supply of sterile syringes and needles so that every parenteral inoculation involves a sterile syringe and needle that has not been used on any prepvious subject.
  - ***Disposal of infectious waste:*** Immunization services in developing countries that successfully reach their target populations with quality vaccines administered using sterile needles and syringes generate, as a by product, a corresponding quantity of used needles and syringes that have been exposed to human tissue and blood. These potentially infectious “sharps” must be properly handled whether they are of the re-sterilizable, disposable or auto-disable type. Re-usable needles and syringes must be carefully collected and sterilized. Disposable and auto-disable needles and syringes must be incinerated or otherwise rendered non-infectious and disposed of in a safe manner.
  - ***Combination parenteral vaccines:*** Some combination parenteral vaccines diminish the number of needles exposed to human tissue and blood.

- **Service delivery:** To receive the benefit of vaccination, individuals within target populations must be physically contacted. Moreover, since most vaccines in the EPI schedule require the administration of multiple doses with correct spacing between the doses, multiple contacts are required at appropriate time points. Various barriers may impede reaching target populations.
  - ***Distance, isolation and population mobility*:** In some developing countries, populations live far from fixed health care facilities. During certain times of the year (e.g., the rainy season, with the appearance of seasonal rivers) temporary barriers may make it difficult to reach otherwise accessible facilities. For such isolated populations, alternative strategies must be employed to reach the isolated population and they must be compatible with local conditions, culture and resources.

- ***Under-utilization of immunization services despite close proximity:*** In some areas of developing countries, particularly in peri-urban slums, target populations may not use fixed health care facilities even though there exist no distance or physical barriers. Poverty, illiteracy, inadequate advertisement of the availability of health services and local cultural attitudes may each play a role.
- ***Immunization schedules:*** Obviously, the more doses of a vaccine antigen required to successfully immunize a child, the greater the pressure on the immunization services. Thus, DPT, hep B and Hib which require three doses to immunize an infant require three spaced contacts; in contrast, measles vaccine, which is given as a single dose in infancy, requires a single contact.
- ***Route of administration:*** Live oral polio vaccine is extraordinarily simple to administer (a couple of drops into the subject's mouth), painless and poses no problems of injection safety. For these reasons, less sophisticated categories of health personnel can be readily taught to administer oral polio vaccines.

• **Surveillance**

- ***Incidence of vaccine preventable diseases:*** The ultimate measure of the efficacy of local immunization services is the demonstration of a low incidence of vaccine-preventable infections. However, surveillance for certain infectious diseases is notoriously difficult because of lack of specificity, since other etiologic agents may cause similar clinical syndromes. Moreover, laboratory support for surveillance activities is extremely constrained in most developing countries.
- ***Estimates of coverage of target populations:*** In the past, considerable reliance was placed on immunization surveys as a way to estimate vaccine coverage and the effectiveness of immunization programs.
- ***Objective measures of immunoconversion:*** Serosurveys can be used to help monitor the prevalence of immunity in populations and to help health authorities decide when to undertake mass vaccination campaigns. For example, several Latin American countries use serological monitoring to determine the immune status of the pediatric population to measles and schedule mass measles immunization campaigns based on these data.

Characteristics of ideal vaccines

The constraints currently faced by immunization services in developing countries would be drastically diminished if all future vaccines had the following characteristics:

- Could be administered by non-parenteral (oral, nasal or transcutaneous) routes.
- Would require only one dose (or at most two doses) to elicit protection.
- Could successfully immunize very young infants (< 3 months of age).
- Could confer long-lived protection.
- Would be available in formulations already combined with multiple other vaccines or would be combinable with other vaccines at the moment of administration.
- Would exhibit temperature stability to minimize (or perhaps even eliminate) the stringency of cold chain requirements.

Vaccines with the above characteristics would greatly enhance access to immunization services by making them much more practical and efficient. Moreover, by eliminating the need for sharps, such vaccines would also increase safety. It will be many years before vaccines with these characteristics become routinely available. Accordingly, in the intervening time, other means must be sought to increase access to immunization services.

Selecting vaccine technologies and operational strategies to increase access to immunization services

At the behest of the GAVI Board, the R&DTF undertook an extensive process of information gathering, evaluation, rationalization and prioritization to identify key technologies or improved management or operational strategies that could have a favorable impact upon immunization services in developing countries. The accelerated development and introduction of these technologies and managerial/operational approaches hold great potential to improve the current state of immunization services.

As a first step, a questionnaire was sent out to a sample of 50 experts to gauge what they considered to be the technology areas on which to focus. This led to three study teams being set up to consider different areas of technology and operational strategies:

- Team A – "hardware" solutions, with particular emphasis on administration safety and waste management.
- Team B – "software" solutions and operational research focusing on management and outreach strategies.
- Team C – "formulation and process" solutions.

Only technologies that could be implemented in the field within 10 years were considered. This eliminated otherwise promising and interesting work being done on new delivery technologies such as transcutaneous and "edible" (transgenic plant) forms of vaccines. Each study team presented their recommendations on what they considered to be the priority technology or operational research areas within their scope. Two workshops were then held to merge the recommendations and rank them against a set of agreed criteria.

Process of selection

The recommendations of the three teams were merged into a short list of 3 priority technology agendas and 4 operational strategy agendas. Various specific short-term, medium-term and long-term solutions fell within these priority agendas. Four equally weighted criteria were then used to rank the short list items, including:

- Program impact
- Technical feasibility
- Probability of successful introduction
- Cost-benefit ratio

Note— The prioritized vaccine technology agendas and the specific vaccine technologies that fall within each agenda are listed in Table 1 below. Similarly, Table 2 lists the operational strategies agendas and the specific strategies that fall under each agenda. Within each Table the order of presentation of the agendas and of the specific technologies (Table 1) or the specific strategies (Table 2) reflects the relative prioritization worked out at the final joint meeting of Teams A, B and C in London in February 2002. The agendas, technologies and strategies that received the highest overall ranks in this process are shown in italics accompanied by an asterisk.

RECOMMENDATIONS:

TABLE 1. The selected vaccine technology agenda

***** These specific vaccine technologies received the highest rank.

DESCRIPTIONS OF THE VACCINE TECHNOLOGIES

DECREASED DEPENDENCE UPON AND ULTIMATE AND ELIMINATION OF THE COLD CHAIN

Current cold chain systems are inadequate and are causing freezing of vaccines. A number of strategies and technologies now exist for streamlining the cold chain and for progressively removing vaccines from the cold chain. By reducing dependence on the cold chain more children will be reached and costs of immunization will be reduced.

Agenda	Technology solution	Time frame
Decreased dependence upon and ultimate elimination of the cold chain	Sugar glass preservation technology*	Long term
	Eliminate the risk of freezing vaccine	Short term
	New refrigeration, monitoring and eutectic products	Short & medium term
	Re-assess the impact of freezing on vaccine immunogenicity/efficacy	Short & medium term
	Impact of vaccines out-of-the-cold	Short-term
Refined tools to measure progress in improving immunization services	Non-invasive (oral fluid) field assay to measure protective levels of tetanus antitoxin in infant & toddlers as an objective assessment of coverage*	Medium term
Reducing infectious wastes and ultimately eliminating the use of sharps (needles and syringes)	Devices to "defang" syringes*	Short-term
	Aerosol administration of measles vaccine during mass campaigns	Short and medium term
	Urban disposal of needles and syringes (incinerators and grinders)	Medium term
	Multi-dose jet guns	Medium term

Sugar glass preservation technology

Liquid bacterial vaccines that are currently sensitive both to heat and to freezing may be stabilized to the extent that they no longer need to be kept in the cold chain. Stabilization would allow new vaccines in mono-dose format to be integrated into vaccine distribution systems at the lowest possible cost, eliminating wastage, maximizing potency and permitting access for immunization services to more children.

Table 2. The selected operational strategy agendas

Agenda	Strategy solution	Time frame
Service delivery strategies to improve access	Impact of sustained outreach*	Short term
	Stimulate demand for immunization	Short & medium term
Impact of smaller vials on immunization services	Impact of mono-dose on safety and operations*	Short-term
Sustainable solutions for paying running costs	Minimizing recurrent costs/implementing "best practice"	Short & medium term
	Sustainable solutions for paying running costs	Short & medium term
	Cost effectiveness of increasing budget for running costs	Short & medium term
Solutions for program monitoring	GAVI performance measurement for share allocation	Short & medium term

* These operational strategies received the highest rankings

Eliminate the risk of freezing vaccine
Vaccine wastage cause by freezing probably runs to many millions of dollars per year. In an environment of vaccine shortages and the simultaneous introduction of new, more expensive vaccines, this is unacceptable. This heading has three areas of work aimed at reducing this waste.

New refrigeration, monitoring and eutectic products
Current cold chain equipment permits freezing and fails to regulate and monitor vaccine storage temperatures. Technology now exists with higher efficiency and better regulation, using solar energy at lower cost and with longer maintenance autonomy – a vital factor in remote areas. The application of this technology to the cold chain will assure that protected against freezing and high ambient temperatures

Re-assessing the impact of freezing
Freezing of vaccines, which is widespread in the cold chain according to many field studies, is now causing the loss of large quantities of high value new vaccines. The effect of freezing on the potency of vaccines needs to be evaluated and strategies and technologies for reducing the risks of freezing need to be developed.

Impact of vaccines out-of-the-cold chain
Vaccine Vial Monitors now enable some vaccines to be transported out of the cold chain and they enable certain refrigerated storage standards to be relaxed. Studies will demonstrate the feasibility of new policies for vaccine handling and distribution. The new policies will result in lower cold chain costs and more children reached in areas of difficult physical access while also facilitating new vaccines to be introduced at minimum additional cost.

REFINED TOOLS TO MEASURE PROGRESS IN IMPROVING IMMUNIZATION SERVICES

Non-invasive (oral fluid) field assay to measure antibodies

In the absence of effective surveillance, antibody tests provide an indisputable outcome measure for success or failure of an immunization program. If possible, oral fluid tests that are useable in the field are needed for, particularly tetanus (but perhaps also for meningococcus A, measles, and hepatitis B).

REDUCING INFECTIOUS WASTE AND ULTIMATELY ELIMINATING THE USE OF SHARPS (NEEDLES AND SYRINGES)

Estimates indicate that more than 50% of developing country injections are unsafe, with by far the biggest problem being the re-use of contaminated needles and syringes, though accidental needle stick is also an issue. The medium to long term vision is a significant reduction in the use of sharps. The wide-scale introduction of auto-disable (AD) syringes are addressing this problem of needle safety, but AD syringes increase the volume of infectious sharps waste. Current options for waste disposal (open pit burning, incineration, burying and disposal in community garbage) are inadequate, particularly in urban areas, and casual discarding of used syringes and needles outside health facilities is all too common.

Defanging technologies

Simple and inexpensive field tools to remove needles from syringes and deposit them into safe boxes for disposal. These systems are already undergoing field testing and may be implementable in a relatively short time frame.

Urban syringe waste disposal

New technologies to deform (melt or grind to powder), disinfect and compact syringes ready for municipal waste disposal or plastic recycling.

Measles aerosol

We recommend the development of a practical aerosol administration system as a needle-free and simple delivery tool, making use of existing liquid formulations of measles vaccine.

Multi-dose jet guns

We will focus in the medium term on the validation and introduction of new jet injectors as a high-throughput, needle-free system for use in mass campaigns, with safety features to prevent cross-contamination**.** Their development and introduction will be linked to the global measles elimination program.

DESCRIPTIONS OF THE OPERATIONAL STRATEGIES

SERVICE DELIVERY STRATEGIES TO IMPROVE ACCESS

Physical, communications and managerial barriers account for children who are un-reached by immunization services or who do not complete the immunization schedule. These barriers may be removed by outreach strategies, by more effective communications, by management of sessions and by more appropriate presentation of vaccines. Operations research will reveal the best strategies to be applied in appropriate conditions and will enable this evidence to be shared between countries.

Impact of sustained outreach

Various outreach strategies such as “SOS” are already in operation to increase access. These require intensive allocation of human, vehicular and cold chain resources. It is important to document the impact of these programs.

Stimulate demand for immunization
The potential value of immunization is not fully appreciated or at best misunderstood in several settings. Improved understanding is critical to the success of any immunization program. Understanding population knowledge and attitude towards vaccine program is a powerful tool for the development of local advocacy programs.

IMPACT OF MONO-DOSE ON IMMUNIZATION SERVICES

Impact of smaller vial sizes on program operations
Fear of high vaccine wastage results in children often being refused immunization if the session is not large enough to utilize a multi-dose vial of vaccine. Many other issues including vaccine wastage, safety and the possibility of thimerosal no longer being used suggest that smaller vial sizes and mono-dose presentations of vaccine will be used more in developing countries in the future. Research will determine the impact of this change on vaccine utilization, on safety and on immunization coverage.

SUSTAINABLE SOLUTIONS FOR PAYING RUNNING COSTS
Resolving the issue of shortages of running costs in the 'field' is probably the most cost-effective way of increasing coverage for the least cost. Little work is being done by others to address this problem. Two strategies are proposed: First, working to encourage the buyers of capital equipment to procure material with low running costs and, second, to provide evidence of the impact of increasing local expenditures.

Minimizing recurrent costs/implementing "best practice"
All equipment has a purchase price and a "whole life" cost. Increasing the first can often reduce the second. However, many procurement agencies are reluctant to change their "lowest bidder" policy – even at the expense of the program stalling because of shortages of funds for running costs. The work would aim at quantifying the trade-offs between capital and running costs and provide evidence for procurement agencies to purchase equipment with minimum running costs.

Comparing sustainable solutions for paying running costs
Detailed analyses and comparisons are needed to assess the advantages of different options paying running costs.

Cost effectiveness of increasing budget for running costs
Building on work in Uganda, studies are needed to demonstrate the high cost effectiveness of even marginally increasing running budgets. The purpose is to provide evidence to ministry planners that increasing running cost budgets may be their best strategy for increasing the effectiveness of their program.

SOLUTIONS FOR PROGRAM MONITORING

GAVI's focus on performance requires more accurate, less expensive methods for tracking the number of children immunized than the current Data Quality Audit and National Cluster Coverage Surveys. District level survey methods for accurately determining immunization coverage and service quality would provide local managers and international auditors with the evidence they need to assess performance.

GAVI performance measurement for "share" allocation

The success of vaccination programs differs considerably from country to country and even within districts in a given country. It is critical to develop simple and objective system that can be implemented step by step to evaluate the success of the program. This would be invaluable both for instructing program planners and product consumers.

Annex 6
Update on the Immunization Financing Database

Background
The work of GAVI and The Vaccine Fund has brought an increased recognition of the importance of accurate and up-to-date information on the financing of immunization programs. At the country level, governments and their development partners require believable information about how much is being spent, on what, from what source, and how much will be needed in the future to achieve programmatic objectives of expanded coverage and higher quality. At the international level, both multilateral and bilateral funding agencies need data to inform priority setting and planning for future support for immunization. And GAVI specifically requires information on trends in immunization program financing to assess progress toward financial sustainability aims.

The appreciation for the value of information on immunization program financing is, at least in part, being matched by renewed attention to and opportunities for data gathering, both specifically for immunization and for the larger health sector. The recent proliferation of in-depth country studies of the costs of delivering immunization services, as well as several financial assessments, have awakened an appetite for similar levels of detail on regional and global levels. At the same time, through the UNICEF-WHO joint reporting form, the GAVI/Vaccine Fund application and the upcoming financial sustainability plans, there are opportunities to obtain information on immunization financing for a large number of countries over several years.

Objectives of the Immunization Financing Database
Under the auspices of the Financing Task Force, GAVI has undertaken the development of an Immunization Financing Database (IFD), which, once fully established, will provide an updated time series of consistent and comparable data on the sources and uses of immunization program financing. It currently is envisioned that the database will be publicly available, endorsed by GAVI Partners and using a common structure and information system as other data collection efforts under the GAVI effort. The objectives of the IFD are:

- **To monitor trends in expenditures and financial flows at the country, regional and global levels**. The IFD will capture information on the volume of resources that countries, regions and the international community are dedicating to immunization services and supplemental activities; it will also compile information on the sources of those resources, and their allocation of those resources across inputs.

- **To monitor trends in Vaccine Fund support for immunization, and its effect on countries' financial sustainability.** The IFD will permit assessment, in a limited way, of the effect of Vaccine Fund support on government and donor financing patterns.

- **To serve as a tool for strategic planning and resource mobilization.** At the country level, financing information is needed to assure coherence between program objectives and activities, on the one hand, and resource availability, on the other. At the global level, development partners require solid information to assist them in setting priorities and planning for current and future support for immunization services in middle- and low-income countries.
- **To provide empirical information on financing patterns and mechanisms, program efficiency and sustainability**, answering specific policy questions such as:
  - How far is current spending from a defined "ideal" that might be estimated based on norms (e.g., cost per fully immunized child)?

– What is the relationship between financing patterns and immunization program performance?

Data inputs

Three types of data currently are available to partially meet the requirements of the database; though collected for other purposes, these have been compiled under the auspices of the database and their usefulness of the database effort has been assessed. The three types of data include:

- **Primary data:** Information from in-depth costing and financing case studies or country-specific financing assessments. These data frequently are of high quality and comprehensiveness, but the studies have not all used consistent methodologies (e.g., definition of cost elements) and have been conducted in a relatively small group of countries, not representative of all low- and middle-income settings.

- **Secondary data.** Limited data are available from a variety of databases held in bilateral or multilateral partner agencies (USAID, World Bank, WHO, UNICEF, PAHO, OECD). The quality of the data is difficult to assess because, in many cases, there is little information available about the data collection methodologies used. In some cases, the information is known to represent "best guesses" developed for specific institutional purposes.

- **Country data.** Through the PAHO and UNICEF-WHO reporting forms and the GAVI/Vaccine Fund application, many countries routinely provide information about, for example, annual expenditures on vaccines. Again, information on data collection methodologies typically does not accompany the figures submitted by countries, and forms are not always completed. In the case of the GAVI/Vaccine Fund application, for example, a large share of the first-round applications lacked even the most basic financial information.

If the database were to depend solely on existing sources of data it would be unable to meet its objectives because of lack of comparability and comprehensiveness of the information across countries and over time. Therefore, a significant share of the database-related activities are devoted to establishing standards for the collection of data in the future, particularly through the Financial Sustainability Plans and other GAVI/Vaccine Fund instruments.

Priority activities

To date, database development activities have focused on: (a) identifying the existing sources of information, and compiling all available data; (b) developing a structure and user interface for the database; (c) establishing a technical group to serve as the database development team; and (d) examining a set of key variables (e.g., percent of spending devoted to vaccines) for a set of countries that have information deemed to be reasonably comparable; and (e) exploring opportunities for prospective data collection.

Three activities will be undertaken during the next six months to advance the database development:

- Prepare methodologies and guidelines that can be used for future data collection efforts (e.g., GAVI financial sustainability plan, WHO-UNICEF Joint Reporting Form, PAHO reporting form) [April 2002].

- Calculate baseline estimates of immunization expenditures and financing for a limited number of countries, including baseline financial sustainability indicators to present to the GAVI Board [June 2002].

- Analyze comparability of available primary data, document methods and determine potential for extrapolation [September 2002].

Team

The database development team currently includes technical specialists from the World Health Organization, UNICEF, Abt Associates, PAHO and the World Bank, with the daily work being done by a consultant economist at WHO.

Annex 7
Framework for the study on Lessons Learned: New Procurement Strategies for Vaccines

Background
The world immunization community has joined forces through the Global Alliance for Vaccines and Immunization (GAVI), which is supported by a $1 billion Vaccine Fund. GAVI and The Vaccine Fund are strengthening immunization programs and supporting the development and introduction of new vaccines and immunization technologies. As part of this effort, GAVI/The Vaccine Fund is expected to purchase over $600 million of priority vaccines in the next 5 years.

The public sector must work with the private sector to assure three objectives which support developing country needs: 1) to ensure sufficient supply of existing vaccines at a reasonable price 2) while also encouraging private investment in adequate production capacity for priority products to meet the needs of developing countries and 3) while also encouraging adequate investment in research and development of new products particularly relevant for use in the developing world. The GAVI partnership provides new opportunities for ensuring the more rapid access to and use of priority vaccines through strategies that empower national decision makers with appropriate disease burden and vaccine efficacy data, improve forecasting, assure longer time financing of immunization programs and vaccines, and establish new supply relationships with manufacturers through procurement. Given these new opportunities, the GAVI partnership wishes to explore the potential impact of different forecasting and procurement strategies as well as the optimal roles and responsibilities of different players involved in the process.

GAVI Partners have also recognized that the immunization market is evolving as demonstrated by the increasing divergence in products produced for and used in industrial and developing countries. Partners are aware that the changing markets will have an impact on the effectiveness of procurement strategies and that procurement strategies will have a major impact on the vaccine market.

Study objective
The study will provide the GAVI Partners a better understanding of the changing economics and structure of the vaccine industry and an organizational review of the GAVI-industry relationship, particularly as it relates to forecasting, procurement and purchasing strategies for vaccines and other technologies. The study will also enable GAVI Partners to make appropriate, data-driven decisions on optimal procurements strategies to achieve GAVI's goals (e.g. guaranteed purchases).

Study structure and deliverables

Part 1. Vaccine industry study describing size, share, and dynamics of the global vaccine market:
Building on the 1993 industry study prepared by Mercer Management, the study will provide an analysis of the size, structure and economics of the vaccine market. The study will perform a trend analysis of the industry since 1993 — outlining the implications of changes on the economics of current and future developing country vaccine supply and pricing. The study will also include recommendations for meeting the short, medium and long-term public sector goals.

Part 2: Study of experiences, organizational roles and optimal strategies for forecasting, procurement and purchasing of vaccines and other technologies

Given the recent cycle of forecasting, procurement, purchasing, and delivery the study will explore how the industry and other partners experienced the process and the impact it had on their decisions. The study will map out the procurement cycle from initial demand forecasting through the RFP, tender, awards, purchasing, offtake and shipment of orders. The analysis will identify each organization's (or group's) contribution at each step, and recommend possible ways to improve the efficiency and effectiveness of the process. In particular the study will review the security of near term vaccine supply for the poorest 74 countries and suggest options for improvements.

Annex 8
Recommendation on Indonesian proposal to GAVI and The Vaccine Fund

Based on the recommendations from the IRC the GAVI Board decided in its teleconference 8 January 2002 to grant the Indonesian application for birth dose hepB vaccine conditional approval with the following two conditions:

1. To provide a detailed plan of action for the proposed nation-wide expansion hepB birth dose vaccine for the first two implementing years;
2. To provide plans to strengthen the function of ICC.

After reviewing the responses and information received by Indonesia to the above conditions, the IRC recommends approval for the application for birth dose hepB vaccine for 5 years. In addition, Indonesia has made a request for injection safety support, a request that the IRC recommends be resubmitted.

The IRC also recommends that the GAVI Board request further information on targets for hepB immunization and to ask Indonesia in its inception report in September 2002 to report on progress in the development of the ICC workplan in accordance with the plans provided.

Another outstanding issue has been the price of hepB vaccine in pre-filled monodose formulation produced by BioPharma and procured directly by the Indonesian MOH, as this product is not yet prequalified and thus does not have an international market price.

Following discussions between the President of The Vaccine Fund, on behalf of GAVI, and BioPharma, the company has offered to supply hepB vaccine in UniJect for 2002 at a price of $ 0.80 per dose, to be renegotiated after one year.

Based on this agreed price the financial implications of an approval of the support to Indonesia will be as follows:

3,1 mill doses of hepB in UniJect at a price of $0.8 per dose	$2,490,000
34,600 safety boxes	$ 18,000
Total	$2,508,000

Projected costs for the five year period would be US$ 16 million.

Annex 9

MEMORANDUM OF UNDERSTANDING

Between
The Government of the People's Republic of China
and
The Boards of the
Global Alliance for Vaccines and Immunization
and
The Vaccine Fund

Whereas, hepatitis B virus (HBV) infection is endemic in China. More than one-third of the world's estimated HBV carriers reside in China and Hepatitis B is estimated to account for 280,000 deaths annually in China.

And whereas, in the 2001-2005 plan for the Expanded Programme on Immunization (EPI) in China, the Ministry of Health has established goals in four key areas: 1) achieving maximum coverage among all children for routine immunizations; 2) reducing morbidity and mortality due to vaccine preventable diseases, and placing the highest priority on maintaining China polio-free; 3) accelerating hepatitis B control and reducing the prevalence of chronic HBV infection among children <5 years of age; and 4) ensuring immunization injection safety.

And whereas, the State Council has approved a statement from the Ministry of Health and the Ministry of Finance that hepatitis B vaccine is to be integrated into routine EPI throughout all of China (see Appendix 1).

And whereas, the Interagency Coordinating Committee (ICC) serves as the technical advisory group for EPI and coordinates related international agencies to provide technical and material support for EPI in China.

And whereas, the Global Alliance for Vaccines and Immunization ("GAVI") is a partnership between national governments, UNICEF, WHO, The World Bank, the Bill & Melinda Gates Foundation, the vaccine industry, public health institutions and NGOs, focused on saving lives and protecting people's health through the widespread use of vaccines. The GAVI Board, composed of representatives of the members of the alliance, is the highest body of the alliance, representing the partners' commitment to ensuring the success of this initiative. Its role is, *inter alia*, to consider providing support to programmes that country governments develop in consultation with their national partners.

And whereas, The Vaccine Fund* has been established as an integral part of the GAVI process to help the Alliance meet its objectives. Responsible for raising the world's awareness of the need to support the GAVI immunization goals and for providing additional and catalytic resources necessary to fulfill the common mission.

And whereas, The People's Republic of China requested assistance from GAVI and The Vaccine Fund to 1) improve hepatitis B vaccine coverage in areas where hepatitis B vaccine coverage is currently low; 2) fully integrate hepatitis B vaccine into EPI; 3) ensure that immunization injections are given safely.

And whereas, the Boards of GAVI and The Vaccine Fund have approved the proposal for the Project, therefore we have agreed as follows:

Article I. Scope of Memorandum of Understanding

1. This Memorandum of Understanding sets out the basic conditions under which the GAVI partners operating in China shall, within the framework of their overall cooperation with the Government of China and in accordance with the Project proposal endorsed by the GAVI Board on 25 September 2001, assist the Government to carry out the Project on Hepatitis B Immunization within EPI in China (hereinafter called the Project) as specified in Document 11A and other documents of the Country Proposal for Support to GAVI and the Vaccine Fund (hereinafter called the Project Documents). This MOU also indicates the parties' understanding as to support provided to the Government for the Project from The Vaccine Fund.

2. The vaccines to be procured shall be used for routine immunization of children under 12 months of age and the principles of the WHO-UNICEF-UNFPA joint statement on safety of injections (WHO.V&B/99.25) shall apply to all immunizations provided with these vaccines, with the exception that the timeline of implementation for autodisable (AD) syringe use will allow for phased introduction of AD syringes, with full implementation by the end of 2005. Phased introduction will occur as rapidly as possible according to the capacity of the EPI system to implement this policy.

3. The Project will cover 12 western provinces and non-western national poverty counties of China.

Article II. Institutional Framework for Management and Implementation of Project

1. The Government shall remain responsible for the Project and the realization of its objectives as described in the relevant Project Document(s), and shall carry out such parts of the Project as are stipulated in the provisions of this MOU and such Project Documents.

2. The Ministry of Health and the Chinese Centers for Disease Prevention and Control (China CDC) will work closely with the GAVI partners involved in the Project (e.g. WHO, UNICEF, the World Bank, others) through all phases of the Project. In addition, an Operational Advisory Group, a subcommittee of the ICC, will be established to provide advice and guidance, endorse progress reports, approve the use of any savings from the GAVI fund contribution, and advocate for the Project. The Group will consist of two persons appointed by the Ministry of Health, one from China CDC, one from the Project Office, a representative of GAVI at the global level, and two persons appointed by the ICC. The Group will meet at least twice a year.

3. The Ministry of Health is ultimately responsible for the Project. The Director General of the Department of Disease Control will serve as the principal director of the Project. The responsibility of the principal director and the Ministry of Health will include determining major policy directions, approving any major funding changes from the government funding contribution, and coordinating with other ministries and international agencies in China.

4. A Project Office, located at China CDC within the Center for EPI, will be responsible for day-to-day management of the Project. This office will assist with and develop implementation plans, provide technical guidance for the Project, and conduct supervision, monitoring and evaluation. The office will have two co-Project managers (one from China and one international), administrative and support staff, and additional staff as necessary. The co-Project managers will provide to the ICC reports on Project progress, and will participate in the Operational Advisory Group.

5. At the province and lower administrative levels, responsibility for hepatitis B immunization is with the EPI Departments and the Epidemic Prevention Stations, and these units will also have responsibility for implementation of the Project. At the provincial and prefectural levels, responsibility for the implementation, management and coordination of the Project will reside with the Health Bureaus and the Epidemic Prevention Stations. At the county level, the Epidemic Prevention Station under the County Health Bureau will have responsibility for the planning and supervision of Project activities; training of township and village level health care workers; handling of vaccines; and administrative reporting (e.g., routine immunization coverage reporting).

6. The ICC will assist the Project by providing technical consultation, assisting in developing and advising on Project implementation plans, coordinating input of related projects, coordinating fundraising assistance, and advising on Project progress.

7. A summary of the management and advisory responsibilities described above is attached as Appendix 2.

8. The Government agrees that any changes in the above named institutions because of reorganization, including changes of responsibility, will not result in a loss of functional responsibility for implementation of this Project.

9. Each relevant administrative level will prepare annual implementation plans. For the 12 western provinces, this will include national, provincial, prefecture and county levels. For the other Project counties, the administrative levels are national, provincial and county. These implementation plans will specify activities, timelines, responsible parties and milestones for different aspects of the Project, including procurement, safe injection, waste disposal, reporting, county-level receipt of product and distribution to the lowest administrative levels, the amount of service fees, and the mechanism for communication and transparency of service fees to the public. The Project Office may revise the implementation plans as needed in consultation with MOH and the provincial level.

10. Implementation plans will be completed down to the county level within 3 months of the signing of this Memorandum of Understanding. Operational Advisory Group and ICC members may assist with development of these implementation plans as needed.

11. Provincial implementation plans will be reviewed by the Project Office and approved by the Ministry of Health and must include detailed information on co-funding, maximum allowed service fees, and indicators.

12. In the performance of their duties, advisory experts, consultants and volunteers shall act in close consultation with the Government and with persons and bodies designated by the Government, and shall comply with such instructions from the Government as may be appropriate to the nature of their duties and the assistance to be given.

13. Technical and other equipment, materials, supplies and other property financed or provided under the Project shall belong to the Government or to an entity nominated by it.

Article III. Project Monitoring, Evaluation and Information

1. This Project will be monitored employing maximum use of existing health information systems. In addition to reports agreed upon in the implementation plan, provinces will submit semi-annual progress reports to the Project Office for review and for identification of gaps and problem areas. Progress reports will include detailed information on how the vaccine and supplies have been distributed. Central Project staff will undertake visits on a periodic basis to provincial and local health departments.

2. The Government will report its progress toward achieving its performance goals annually and present strategies to improve performance of immunization in the following year. The report must contain records of the number of children reported to have received DTP3 and hepB3 by age 12 months, based on county bi-monthly reports to be reviewed by each province and submitted to the Project Office.

3. For the first year, an Inception Report, endorsed by the Operational Advisory Group, is required to be provided to the GAVI Board, to reach the GAVI Secretariat no later than 30 September 2002. In subsequent years, progress reports endorsed by the Operational Advisory Group shall be submitted to the GAVI Board, for receipt by the GAVI Secretariat by 30 September each year. These reports should be submitted using the standard format provided by the GAVI Secretariat. The progress reports shall contain definitive figures for the previous year and any preliminary information deemed relevant for the first part of the current year. The receipt of a satisfactory annual progress report is a condition for continued endorsement by GAVI and continued funding beyond the first year. If the report is deemed unsatisfactory, then areas for improvement will be noted and corrective actions agreed upon for funding to continue.

4. A Financial Sustainability Plan should be attached to the annual progress report in 2003. This plan should include a plan for sustainable procurement of hepatitis B vaccine. GAVI will propose guidelines for the Financial Sustainability Plan.

5. Before the end of the third year (from the signing date of this MOU), the Government in consultation with the Operational Advisory Group shall organize a mid-term review of the Project, with the participation of external experts agreed upon with GAVI. If possible, this review may be coordinated with the periodic EPI reviews conducted by the Ministry of Health and ICC partners. The review report will document county performance against planned targets as specified in the Project implementation plan, and will include the status of the following performance indicators:

    - The number of children reported, by county bi-monthly reports, to have received DTP3 and hepB3 by age 12 months.
    - % coverage with hepB3 by 12 month of age
    - % infants receiving the first dose of hepB vaccine within 24 hours of birth
    - % infants receiving hepB vaccine at or below the maximum stated price (including any service delivery fee)
    - % immunization injections given with AD syringe

Additional performance indicators and interim milestones, with targets to be determined in the implementation plan, will be developed and include:

- the percent of counties doing bimonthly reporting;
- the percent of counties reaching the target level of hepB3 coverage;
- the percent of counties that are using AD syringes for hepatitis B vaccine and for other EPI vaccines;
- the percent of counties that provide hepatitis B vaccine free at charge.

The above indicators will be reviewed for appropriateness on an annual basis, and may be adjusted by mutual agreement of the MOH and Operational Advisory Group.

The specific targets to monitor implementation of this Project are that by the end of the fifth year (from the signing date of this MOU):

- HepB3 coverage will reach 85% at the county level
- >75% of newborns at the county level will receive the first dose of hepatitis B within 24 hours of birth
- All immunization injections will be with autodisable syringes.

6. Before the end of the fifth year a final review will be organized along the same lines as the mid-term review.

7. Any information or material which the Government is required to provide to the GAVI Board under this Article may be made available by the GAVI Secretariat to the Vaccine Fund, any GAVI partner or designate if requested.

8. The Government and the Boards of GAVI and The Vaccine Fund shall consult each other regarding high level national and international public announcements, as appropriate, of information relating to this Project.

Article IV. Financial Support from GAVI and The Vaccine Fund

1. Through The Vaccine Fund, GAVI will provide financial support to the Project as identified in the Project budget attached to this MOU. This financial support will be provided through the Vaccine Fund, in keeping with standard procedures for the disbursement of funds from the Vaccine Fund.

2. More particularly, 50% of the estimated cost of the hepatitis B vaccine and safe injection equipment (AD syringes and safety boxes or equivalent) for hepatitis B vaccine and for other vaccines during the 5-year period beginning in 2002, up to a total of USD 38 million in accordance with the budgets set forth in Appendix 3.

3. In addition, an amount of up to eight hundred thousand US dollars (USD 800,000) will be provided to contribute to direct costs of a Project Office, such as for training, monitoring, supervision visits, and information dissemination (Appendix 3). Funding for the Project Office shall reside in a sub- account at China CDC, under the control of the Project Office.

4. For year one of the Project, the projections for need will be based on data from the State Statistical Bureau. In future years, the data source and assumptions will be determined by the Project Office, and used in the procurement process.

5. Any savings that is generated (for example by a lower price or lower birth cohort than was originally estimated, or from procurement timing or pricing) shall be applied to the Project activities (for example training, IEC and supervision). The Operational Advisory Group will determine the use of such saving from the Vaccine Fund contribution. This savings and resulting expenditure shall be reported to the GAVI Board.

6. The Government shall apply all interest earnings to the Project activities.

7. An initial disbursement of funds of the first year budget will be made to the Ministry of Health and China CDC after finalization and approval of this Memorandum of Understanding (see Appendix 4 for banking details). Subsequent disbursements will be based on the achievement of mutually agreed milestones and the receipt of satisfactory annual progress reports. As noted in Article III.3, if the GAVI Board determines that the report is unsatisfactory, areas for improvement will be noted and corrective actions agreed upon for funding to continue.

Article V. Contributions of the Government

1. The Government undertakes to finance 50% of the estimated cost of the hepatitis B vaccine and safe injection equipment for hepatitis B and other vaccines during the 5-year period beginning in 2002, up to a total of USD 38 million in accordance with the budgets set forth in Appendix 3.

2. Any savings that is generated by a lower price or lower birth cohort than was originally estimated shall be applied to the Project activities. This savings and resulting expenditure shall be reported to the GAVI Board.

3. The Government agrees that funding for hepatitis B vaccine and for injection equipment for hepatitis B vaccination will come fully from the central government in both the 12 western provinces and in the national poverty counties of six other provinces (Henan, Hubei, Jiangxi, Anhui, Shanxi, and Hunan). Funding for hepatitis B vaccine and for injection equipment for hepatitis B vaccination in the national poverty counties in the other nine provinces will come fully from the provincial finance bureaus of those provinces. For injection equipment for EPI vaccines other than hepatitis B in the 12 western provinces, financing will be provided 1/3 from the central government and 2/3 from the provinces. For injection equipment for EPI vaccines other than hepatitis B in non-western national poverty counties, financing will be provided 100% from the provinces. The Project implementation plans, prepared by the provinces and approved by the Ministry of Health, shall specify that the provinces will provide the necessary co-funding, will not pass down this financing cost to the Bureaus of Health or to lower administrative levels, and will not be at the expense of other health programs.

4. The Ministry of Health takes responsibility for arranging with the Ministry of Finance for the flow and management of funds for centrally-conducted procurement, and for coordination and monitoring of procurement by the provinces.

5. Activities to be supported (in part) by the government at all levels include the costs of routine EPI work now being conducted, such as the logistics system, health care workers, and surveillance. Additional funding will be contributed to support (in part) new training needs, information and communication, Project management, supervision and monitoring. The government also agrees to work towards improving the EPI reporting system at the county level as a monitoring tool.

6. The Government will ensure that the following in-puts are available to the Project:

   (a) local counterpart professional staff and other services, including national counterparts to operational experts;

   (b) land, buildings and training and other facilities available or produced within the country; and

   (c) equipment, materials and supplies available or produced within the country.

7. The Government shall meet charges relating to customs clearance of equipment and supplies, their transportation from the port of entry to the Project sites together with any incidental handling or storage and related expenses, their insurance after delivery to the Project site, and any installation and maintenance.

8. The Ministry of Health will collaborate with the Project Office to prepare an estimate of the funding needed for the Project activities for training, IEC, supervision, coverage surveys, and evaluation of vaccine outside the cold chain. This proposal will be brought to the ICC by 1 July 2002 for endorsement, contributions and fundraising coordination.

Article VI. Contributions of GAVI partners

1. GAVI partners and other ICC members in China have ongoing activities that overlap with the objectives and activities of the Project, including conducting safe injection training, improving hepatitis B coverage, supervision visits, immunization IEC activities, and other activities. To the extent possible, GAVI partners and ICC members will work together to coordinate their activities and Project activities. Related ICC activities and projects are described in Appendix 5.

2. To the extent possible, ICC members will work with the MOH, GAVI partners, the Project Office, and other institutions to mobilize new funding for Project activities by assisting with the Project funding proposal and providing fundraising coordination, and by identifying and providing expert consultants.

Article VII. Procurement of Hepatitis B Vaccines and Safe injection equipment

1. Hepatitis B vaccine, AD syringes and safety boxes (or equivalent) will be procured through a process to maximize competition; ensure cost effectiveness; assure quality, safety and efficacy; and provide accountability. The lead for procurement and ultimate responsibility will rest with the Department of Planning and Finance of the Ministry of Health. The Department will establish a procurement co-ordinating committee consisting of the Ministry of Health, the Ministry of Finance, the State Drug Administration, the Project Office, UNICEF, WHO, and a World Bank representative. The Committee will assist in coordinating the procurement process including reviewing, recommending and monitoring 1) eligible suppliers 2) criteria for awards 3) specifications (for vaccine, AD syringes, safety boxes and their equivalents), especially on quality 4) length of contract and 5) accountability requirements and procedures to be followed in implementing the procurement. Details concerning the procurement process are provided in Appendices 6 and 7. An expert consultant on procurement will be available to advise the Committee on options to consider and to make recommendations for procurement mechanisms that are appropriate given the Project circumstances and that incorporate the relevant experience of agencies collaborating on the Project.

2. Procurement for this Project, with funds from The Vaccine Fund, the central government and co-funding from the provincial governments will be conducted centrally. Regardless of the source of the funds, the designated central level procurement mechanism will be responsible for selecting a tendering agency responsible for all of the procurement, developing and approving the specifications, and approving the choice of suppliers. With the assistance of the Project office, the Procurement Coordinating Committee will review and the Ministry of Health will approve the estimates from each province for the amount of vaccine and injection equipment to be purchased.

3. For the Project procurement funded with province co-funds, each province will separately contract with each supplier, based on the result of the central procurement tendering. The provinces will send a copy of their contract(s) to the Ministry of Health for their information and review. After reviewing, the Ministry of Health will issue contracts to each supplier for those products to be purchased with central government and funds from the Vaccine Fund. Payment to the suppliers for these contracts will come through two channels: 1) the provinces, for their co-funding portion; and 2) the central government (with funds from either central level/Vaccine Fund or from The Vaccine Fund, depending upon the province and items procured).

4. All utilization of funds for the Project will be subject to audit according to Chinese Audit Regulations. Provincial audit departments will conduct audits yearly and will report results to the Project Office. The Operational Advisory Group shall have access to the results of the audits.

5. Domestic procurement is conditional on the existence of a fully functional National Regulatory Authority (NRA) and compliance with WHO recommended procedures. The State Drug Administration (SDA), the national regulatory authority, is an agency independent of MOH and is responsible for quality inspection of vaccines. The Government hereby agrees to meet the terms and provisions of the NRA's institutional development plan prepared by WHO in collaboration with, and endorsed by SDA (see Appendix 8). The plan specifically includes:

    - To start the implementation of lot release for EPI vaccines, including hepatitis B vaccine (began December 2001),
    - To document AEFI system, with implementation of a single national list during 2002, coordinating with Ministry of Health, and to carry on a personnel training program for surveillance of AEFI (underway),
    - To carry on a training program of GMP inspectors (began before the end of 2001), including the training of inspection for hepatitis B vaccine production. All the training will be completed before the end of 2002.

If WHO determines that the schedule is not being met, then it will inform the GAVI Board, and disposition of the vaccine procurement will be determined by the procurement coordinating committee, including consideration of the need for international procurement.

6. The maximum allowed prices for hepatitis B vaccine, AD syringes and safety boxes (or equivalent) purchased using funds provided from The Vaccine Fund has to be comparable or lower to the highest one of UNICEF's published prices for the same time period for equivalent presentation of vaccine or equipment. If the negotiated prices are higher than UNICEF's, the government may consult with the Operational Advisory Group to determine options including the need for international procurement. Alternatively, the government will pay the difference in order to purchase enough vaccine and safe injection supplies to reach the target population.

7. Regarding management of vaccine distribution, transportation equipment used for distribution of the hepatitis B vaccine from manufacturers to provinces will be specified in all vaccine contracts. Hepatitis B vaccine will be transported from provincial Epidemic Prevention Stations (EPSs) to villages using currently available cold chain equipment. To ensure quality control, evaluation and monitoring will be done at each administrative level.

8. Full implementation of AD syringe use will be completed according to the schedule in the implementation plan. Since AD syringe procurement may only be at a partial level in the initial years of the Project, the funding budgeted for AD procurement shall be applied to those systems needed to support safe injection and AD introduction, including training, waste disposal and bundling. If not qualified domestic supplier is available, then the option of international procurement will be considered. Exact use of any available funds from the GAVI contribution will be determined in consultation with the Operational Advisory Group.

9. The Government will implement a procedure for provinces to follow so that purchases of vaccines and safe injection equipment are distributed together. The Project Office will be available as a resource to assist with developing a bundling procedure.

Article VIII. Sustainability of Financing and User Charges

1. A major objective of the Project is to improve hepatitis B vaccine coverage by reducing the economic barrier to receiving hepatitis B vaccine. By the end of the Project, the Government will assume financial responsibility of providing hepatitis B vaccine in the same manner as other EPI vaccines are provided routinely to infants; that is hepatitis B vaccine will be provided free-of-charge with a nominal service fee no greater than that for other routine EPI vaccines (using DPT3 as the benchmark). No charges will be made by any administrative level for procurement, storage, transportation and distribution to lower levels.

2. As a transition during this Project, the Government agrees to establish a transparent and widely advertised pricing system for service delivery fees, stipulating the maximum fee that the immunization provider will be allowed to charge for providing HBV and for the syringe (and the AD syringe when available). This service delivery fee charged to parents in Project provinces, determined by the central government and each province, will not exceed 3RMB per injection. Provincial Project implementation plans, approved by the Ministry of Health, will specify that all levels of the government will agree to these fees. The pricing policy will be adhered to, monitored, enforced and communicated to parents as stated in the implementation plan. Evidence of compliance to the agreed fee structure will be provided as a milestone on which subsequent GAVI disbursements are based.

3. The Government agrees to monitor the impact that any service fee will have on access to hepatitis B immunization and vaccine coverage in general. China CDC and the Project Office will monitor the vaccine price at the end user level, and the delivery of the vaccine for infants in the target areas of the Project.

4. If necessary, the Government will take corrective action to ensure that the service fee is affordable enough to ensure access for all.
5. An expert consultant on financing will be available as a resource to the Government, to assist in evaluating the economic implications of hepatitis B vaccine integration into EPI on the public health system.

Article IX. Facilities for Execution of GAVI-Sponsored Assistance

1. In addition to the arrangements set forth in its basic agreements with individual GAVI partners who are operating in China and assisting the Government to implement the Project, the Government shall endeavor to take all measures within the Government's power and to the extent possible, which may be necessary for the speedy and efficient provision of assistance from the GAVI partners to the Project as follows:

   (a) prompt clearance of experts and other persons performing services on behalf of GAVI partners;

   (b) prompt issuance without cost of necessary visas, licenses or permits;

   (c) access to the site of work and all necessary rights of way;

   (d) free movement within or to and from the country, to the extent necessary for proper execution of GAVI assistance

   (e) the most favorable legal rate of exchange;

   (f) exemption from (or waiver of) any and all customs duties and import fees for all equipment, commodities and supplies imported for the implementation and support of this Project.

   (g) any permits necessary for the importation of equipment,

   (h) any permits necessary for importation of property belonging to and intended for the personal use or consumption of officials of the GAVI partners, or other persons performing services on their behalf, and for the subsequent exportation of such property; and

   (i) prompt release from customs of the items mentioned in sub-paragraphs (f), (g) and (h) above.

Article X. Research

1. It is understood that the Government will ensure that each public or private entity undertaking research in China relating to the Project shall be responsible for safeguarding the rights and welfare of human subjects involved in research relating to the Project. Said responsibility includes complying with all applicable national laws, regulations, and codes of ethics of the People's Republic of China. Certification of ethical review and approval for this research shall be obtained from the Institutional Review Board of the Agency conducting the research.

Article XI. Suspension or Termination of Assistance

1. The GAVI Board may, by written notice following consultation between the Government and the GAVI partners concerned, suspend or terminate the disbursements from The Vaccine Fund to support the Project if in the judgment of the GAVI Board circumstances arise which interfere with or threaten to interfere with the successful completion of the Project or the accomplishment of its purposes. The GAVI Board may, in the same or a subsequent written notice, indicate the conditions under which it is prepared to resume disbursements from The Vaccine Fund to support the Project and the period within which such conditions must be achieved in order for such disbursements to be resumed. If such conditions are not achieved to the satisfaction of the GAVI Board within the specified period, the GAVI Board may terminate all future disbursements from The Vaccine Fund to support the Project.

Article XII. Settlement of Disputes

1. Any differing viewpoints or interpretations between the GAVI Board and the Government arising out of or relating to this MOU will be settled amicably by consultation between the Parties. Any differing viewpoints or interpretations between individual GAVI partners and the Government arising out of or relating to the Project will be addressed in accordance with the basic agreement between the Government and the individual GAVI partner concerned.

Article XIII. General Provisions

1. In the event of any inconsistency or ambiguity between this MOU (on the one hand) and the basic agreement between the Government and an individual GAVI partner, or the programme of cooperation between the Government and an individual GAVI partner or associated document (on the other hand), then the basic agreement between the Government and an individual GAVI partner, or the programme of cooperation between the Government and an individual GAVI partner or associated document as the case may be, shall prevail.

2. This MOU may be modified by written agreement between the Parties hereto.

3. Both the Chinese and English versions of this Memorandum of Understanding shall be equally valid.

4. The obligations assumed by the Parties under Article III (concerning Project monitoring, evaluation and information) hereof shall survive the expiration or termination of this MOU.

5. This Memorandum of Understanding shall be effective from the date of signing and be valid for five years beginning with the start of the Project in 2002 and may be extended by mutual consent of the Parties.

Approvals:

For the Government (MOH):

For the GAVI Board:

For the Vaccine Fund Board:

Appendixes

1. **Statement Regarding Integration of Hepatitis B Vaccination into the Expanded Programme on Immunization**
2. **Management Matrix and Responsibilities**
3. **Detailed Budget For Hepatitis B Vaccine and Injection Equipment**
4. **Banking Details**
5. **Current activities of the EPI Interagency Coordinating Committee Members and GAVI Partners in China**
6. **Funds Management Guidelines for the MOH/GAVI Hepatitis B Project**
7. **Management Guidelines for Procurement of Hepatitis B Vaccine and Injection Equipment for the MOH/GAVI Hepatitis B Project**
8. **Text of October 12, 2001 Letter from LiLi Zhao, Deputy Director, Department of International Cooperation, State Drug Administration**

Appendix 1.
Statement Regarding Integration of Hepatitis B Vaccination into the Expanded Programme on Immunization

Ministry of Health and Ministry of Finance Document
MOH DDC Issue no. 339, 2001

Notice on Hepatitis B Vaccine Integration into the Expanded Programme on Immunization for Children

To Provincial, Autonomous Region and Directly-Administered Municipal Governments:

Endemic hepatitis B, with substantial health and economic impact, contributes greatly to ongoing poverty in poor regions. Every year in China, an estimated 500,000 persons become acutely infected with HBV, accounting for one-fourth of infectious disease cases. Furthermore, persons with HBV infection can develop cirrhosis and liver cancer. In China, an estimated 20 million persons suffer from chronic hepatitis B, and every year the estimated cost for treatment and general health care for patients with hepatitis, cirrhosis, and liver cancer is more than 100 billion RMB. Being a hepatitis B carrier can have consequences for preschool, school, employment, and marriage which can lead to serious social problems, therefore hepatitis B virus infection is a major public health problem.

Hepatitis B immunization of infants is the most important strategy for controlling hepatitis B. To protect children's health, hepatitis B vaccine will be integrated into routine EPI throughout all of China starting during 2002, implemented by provincial, autonomous region and municipal governments. As approved by the State Council, the following notice is issued:

1. High priority should be placed on integrating hepatitis B vaccine into EPI and associated activities including organization, coordination, and implementation. Funds for hepatitis B vaccine procurement for eligible children should be arranged by provincial, autonomous region and municipal governments.
2. The central government will support hepatitis B vaccine immunization activities in poor areas, especially in the western provinces. In the 10th 5 year plan, special funds from the central level have been allocated to support hepatitis B vaccine procurement in western provinces and state-level poverty counties in some middle provinces. Furthermore, in the above areas, additional funds for hepatitis B vaccine procurement will be sought through international cooperation, and provincial financial bureaus should also arrange necessary funds to ensure smooth implementation of hepatitis B immunization.
3. To obtain support for hepatitis B prevention from the society-at-large and to encourage public participation and support, the government at all levels should collaborate with relevant departments, agencies and mass media organizations to carry out wide-ranging, ongoing health education activities.
4. To promote management of hepatitis B immunization programs, health authorities at all levels should be responsible to the local government; should organize and implement hepatitis B immunization according to EPI requirements; and should integrate hepatitis B immunization into the EPI review system.

5. The hepatitis B immunization user fee must be uniform. Every province should consider the local situation to establish the standard for the user fee and implement it critically.
6. After integration of hepatitis B vaccine into EPI, each province, autonomous region and directly-administered city should adopt government competitive bidding procedures for procurement of hepatitis B vaccine and syringes.

cc: Ministries and committees of the State Council, provincial-level cities, Xinjiang Production and Construction Corps, health and financial bureaus of all provinces, autonomous regions, and directly-administered cities

Ministry of Health, General Office
December 10, 2001

Appendix 2.
Management Matrix and Responsibilities

Operational Advisory Group (meets minimum of 2 times/year)

Composition:

- Ministry of Health (2)
- China CDC (1)
- Project Office (1)
- GAVI Global Representative (1)
- Other ICC representatives (2)

Responsibilities:

- Project advice and guidance
- Project advocacy
- Review and endorse progress reports
- Approve use of savings from Vaccine Fund contribution

Principal Director (Director General of the Department of Disease Control of the MOH)

Responsibilities:

- Determining major policy directions
- Coordinating with other ministries and international agencies
- Approve major funding changes for Chinese funding contribution

There are two categories of health service institutions in China: administrative and technical. The Ministry of Health (MOH) acts under direction of the State Council of the central government and is the highest administrative level. Lower level administrative units include provincial, prefectural, and county health bureaus. The MOH, with lower level administrative units, are responsible for establishing health laws, regulations and policies and the organization and delivery of health services.

Co-Project managers (Project Office, Center for EPI at China CDC)

Responsibilities:

- Day-to-day management
- Implementation plan development, revision and approval
- Technical guidance
- Supervision, monitoring and evaluation
- Reporting

The Chinese Centers for Disease Prevention and Control (China CDC) is the highest technical level of health service institutions in China. Technical units are managed by corresponding administrative units at each level. The technical units are responsible for the delivery of preventive and curative health services, and for research and education. Epidemic prevention stations (EPS) at provincial, prefectural and county levels are administered by local governments and local administrative units, and are responsible for disease prevention and control at the local level. EPI departments in EPS are responsible for delivery of immunization services.

The Department of Planning and Finance of the Ministry of Health will be responsible for development of the procurement process. Further details are provided in Appendices 6 and 7.

ICC Project Responsibilities:

- Technical consultation, including assisting with periodic assessments of Project progress
- Advice on implementation plans
- Coordination of related projects and inputs
- Fundraising assistance and coordination, including evaluation of the efficient and effective use of available resources and mobilization of additional resources

Appendix 3.
Detailed Budget For Hepatitis B Vaccine and Injection Equipment

Category	2002	2003	2004	2005	2006	Total 2002-2006
Overall Project (Vaccine, Equipment)						
Hepatitis B Vaccine and Injection Equipment						
Hepatitis B vaccine	$7,311,208	$7,311,208	$7,311,208	$7,311,208	$7,311,208	$36,556,042
AD syringes (hepatitis B)	$1,316,478	$1,316,478	$1,316,478	$1,316,478	$1,316,478	$6,582,391
Safety boxes or equivalent (hepatitis B)	$153,589	$153,589	$153,589	$153,589	$153,589	$767,946
Subtotal	**$8,781,276**	**$8,781,276**	**$8,781,276**	**$8,781,276**	**$8,781,276**	**$43,906,378**
Injection Equipment for Other EPI Vaccines in Project Area						
AD syringes (other vaccines)	$5,704,739	$5,704,739	$5,704,739	$5,704,739	$5,704,739	$28,523,693
Safety boxes or equivalent (other vaccines)	$665,553	$665,553	$665,553	$665,553	$665,553	$3,327,764
Subtotal	**$6,370,291**	**$6,370,291**	**$6,370,291**	**$6,370,291**	**$6,370,291**	**$31,851,457**
Total (Vaccine, Equipment)	**$15,151,567**	**$15,151,567**	**$15,151,567**	**$15,151,567**	**$15,151,567**	**$75,757,835**
Percentage contributed by China	50%	50%	50%	50%	50%	
Percentage contributed by The Vaccine Fund	50%	50%	50%	50%	50%	
Contributions from The Vaccine Fund						
Hepatitis B Vaccine and Injection Equipment						
Hepatitis B vaccine	$3,655,604	$3,655,604	$3,655,604	$3,655,604	$3,655,604	**$18,278,021**
AD syringes (hepatitis B)	$658,239	$658,239	$658,239	$658,239	$658,239	**$3,291,195**
Safety boxes or equivalent (hepatitis B)	$76,795	$76,795	$76,795	$76,795	$76,795	**$383,973**
Subtotal	$4,390,638	$4,390,638	$4,390,638	$4,390,638	$4,390,638	**$21,953,189**
Injection Equipment for Other EPI Vaccines in Project Area						
AD syringes (other vaccines)	$2,852,369	$2,852,369	$2,852,369	$2,852,369	$2,852,369	**$14,261,846**
Safety boxes or equivalent (other vaccines)	$332,776	$332,776	$332,776	$332,776	$332,776	**$1,663,882**
Subtotal	$3,185,146	$3,185,146	$3,185,146	$3,185,146	$3,185,146	**$15,925,728**
Total amount from The Vaccine Fund	**$7,575,784**	**$7,575,784**	**$7,575,784**	**$7,575,784**	**$7,575,784**	**$37,878,918**
Amount provided by China	**$7,575,784**	**$7,575,784**	**$7,575,784**	**$7,575,784**	**$7,575,784**	**$37,878,918**
Additional funds GAVI (Project Office, see Article IV.2)	$160,000	$160,000	$160,000	$160,000	$160,000	**$800,000**
Total amount provided by GAVI	**$7,735,784**	**$7,735,784**	**$7,735,784**	**$7,735,784**	**$7,735,784**	**$38,678,918**

Note: All figures are USD

Assumptions:Cost of hepatitis B vaccine: 3 doses = 1 USD. Cost of AD syringes: 0.06 USD per syringe

Cost of safety boxes or equivalent: 1 box = 0.70 USD

Appendix 4.
Banking Details

Appendix 5.
Current activities of the EPI Interagency Coordinating Committee Members and GAVI Partners in China

Immunization activities of GAVI partners and other ICC members in China that overlap with the objectives and activities of the Project include:

- UNICEF: Immunization IEC activities, provision of hepatitis B vaccine, supervision visits in multiple provinces
- WHO: Implementation of activities funded by AUSAid and the Government of Luxembourg to support safe injection for immunization in Tibet, Qinghai, Ningxia, Gansu, and Inner Mongolia. Other projects address improving hepatitis B coverage, injection safety, reporting and monitoring, the cold chain, waste disposal and disease surveillance.
- World Bank (Health Projects VII and VIII, and the New TB Project with DFID): activities to support safe injections for immunization, immunization IEC, provision of hepatitis B vaccine, including monitoring, training and supervision visits in multiple provinces
- JICA: JICA EPI Strengthening Project: activities to support safe injections for immunization in multiple provinces, including monitoring and training, and recycling of immunization sharps waste.
- China Foundation for Hepatitis Prevention and Control: Provision of hepatitis B vaccine, training, IEC activities in selected counties in multiple provinces.
- China Foundation (U.S.): Immunization IEC, provision of hepatitis B vaccine, supervision visits in selected counties in multiple provinces
- ICC Safe Injections Working Group. A working group of the ICC focusing on the topic of injection safety, including safe disposal of syringe and needle waste.

Appendix 6.
Funds Management Guidelines for the Project

The Ministry of Health has established the following guidelines for its staff in connection with the Project.

1. Principles for Project funds management

1.1 Utilization of Project funds must strictly follow relevant provisions described in the Hepatitis B Implementation Plan and the MOU. All funds must be used for the Project.

1.2 Project provinces should allocate co-funds for the Project following the Hepatitis B Implementation Plan and the MOU, and develop detailed provincial guidelines for co-funds management.

1.3 Periodic supervision will be conducted during the Project. All Project activities should be carried out following national law, regulations, and financial rules. The scope and standards of expenditure should be strictly identified, and all financial documents should reflect the true utilization of Project funds.

2. Scope of funds utilization

All funds must be used for the Project in the selected Project provinces based on the principles and provisions in the MOU to ensure the implementation of the Project.

3. Allocation of central government funds and funds disbursed from The Vaccine Fund.

3.1 Funds from central government and The Vaccine Fund will be used together according to the agreement between both sides. The Procurement Coordinating Committee will review the estimates as provided by each province, in which there must be definite objective and accurate data, for hepatitis B vaccine and injection equipment and make definitive recommendations to the Ministry of Health. The Ministry of Health will contract with the selected suppliers according to the procurement plan and allocate and provide funds directly to the manufacturers for the amount of products to be paid for with central government and GAVI funds.

3.2 Each Project province receiving products funded by the central government or GAVI must periodically submit reports on Project progress. The Project Office will review the reports and arrange funds for future steps. If provinces fail to submit timely reports, central funds may be reduced or suspended.

4. Management of provincial co-funds

4.1 Each Project province must establish detailed fund management guideline to ensure timely allocation of provincial co-funds and to strengthen management of corresponding provincial co-funds for the Project.

4.2 Each Project province must follow Project management principles. Provinces may submit expense accounts after the Project or may allocate funds level-by-level before the Project.

4.2.1 To submit expense accounts after the Project, the process must follow financial regulations and requirements. The staff of the financial bureaus will participate in the management of funds, and strictly inspect the scope, standard and authorization procedure of the Project activities. Only those provinces whose disbursements meet the Project requirements will be reimbursed.

4.2.2 To allocate funds before the Project, the Project implementation plan submitted by lower administrative level must be carefully reviewed, according to which funds will be allocated. Lower administrative levels must submit timely reports on Project progress and fund utilization.

5. Supervision of Project funds

5.1 In order to guarantee the appropriate utilization of funds and achieve Project goals, periodic supervision and inspection will be conducted to identify problems and take corrective action during the implementation of the Project.

5.2 Each province must submit timely reports on funds disbursement and Project implementation, and accept inspection and evaluation.

5.3 Funds spent above the agreed upon amount will not be reimbursed. If Project units fail to reach Project goals or leave the Project unfinished, other health funds not for this Project may be reduced. The units or persons who make false statements or appropriate the special funds for other purposes will be subject to punishment according to related law and regulations.

All Project provinces should develop detailed implementation guidelines according to the local situation and submit these documents to the relevant departments of the Ministry of Health.

Appendix 7.
Management Guidelines for Procurement of Hepatitis B Vaccine and Injection Equipment for the Project

The Ministry of Health has established the following guidelines for the Project to ensure timely procurement and effective use of funds.

1. Organization of procurement

Hepatitis B vaccine and injection equipment for the Project will be purchased by the central and provincial governments from the centrally selected suppliers resulting from a central tendering process. A procurement coordinating committee established at the central level, will be responsible for the organization, coordination and monitoring of all Project procurement, regardless of the source of funds.

2. The principles of procurement

According to relevant government procurement guidelines and the requirements of the Hepatitis B Implementation Plan, procurement for Project activities will follow principles of accountability, fairness, maintaining the public interest, and selecting suppliers based upon objective evaluation.

3. The procurement procedure

3.1 The procurement coordinating committee will provide Project provinces with information on the types, specifications and budget estimates of hepatitis B vaccine and equipment to be procured for the Project. All information will follow requirements as specified in the Hepatitis B Implementation Plan.

3.2 After receiving the information on the types, specifications and budget estimates, Project provinces will submit their forecasts of the volume of product needed to the procurement coordinating committee for finalization and authorization.

3.3 With the assistance of the Project office, the The procurement coordinating committee will review the forecasts submitted by Project provinces. These forecasts will be approved by the Ministry of Health.

3.4 The procurement coordinating committee will make a recommendation for the selection of a national purchasing agency to conduct the procurement activities. All activities will be monitored by the procurement coordinating committee. The selected agency will provide consulting services, determine the appropriate purchasing method, organize activities (such as compiling specifications, inspection/testing procedures and contract clauses; soliciting applicants; evaluating offers and selecting suppliers), and review documents according to the guidelines of government purchasing.

3.5 The Ministry of Health and provincial administrative departments will separately contract with the selected suppliers. Each province will sign the contract for the procurement with co-funds provided by the province according to the forecasts approved by the Ministry of Health. After reviewing the provincial contracts, the Ministry of Health will sign their contract with the selected suppliers for procurement with funds provided by central government and GAVI

4. Funds allocation

The procurement must strictly follow relevant Chinese and Vaccine Fund financial guidelines. Project provinces must ensure timely allocation of co-funds and must pay attention to the effectiveness of funds and the social effects.

5. Supervision, inspection and evaluation

Relevant central departments will strengthen supervision and inspection of procurement and distribution of equipment following the procurement plan. Emphasis will be on the county level in the evaluation of the Project. The responsible units or persons will be subject to punishment in case of irresponsible action.

Each province must realize the importance and the challenges of the Project, and must make reasonable and detailed management and implementation guidelines that are suitable for the local situation to ensure smooth implementation of the Project.

Appendix 8.
Text of October 12, 2001 Letter from LiLi Zhao, Deputy Director, Department of International Cooperation, State Drug Administration

SDA
State Drug Administration
Department of International Cooperation
A 38, Beilishilu
Beijing 100810
China

Dr. Janos Annus
WHO Representative in China
World Health Organization

October 12, 2001

Dear Dr. Annuas,

This is referred to Dr. Lee's dated on 8 October regarding GAVI response letter, I would like to send you our Administration's working plan for strengthening regulation on hepatitis B vaccine.

The Assessment of Vaccine Regulation in China made by WHO in July has provided a clear profile of our current regulatory capacity on Vaccine. To implement the recommendations made by WHO in the Assessment and respond to GAVI's letter, we would like, according to our revised Drug Law, to commit ourselves:

1. to start the implementation of lot release for EPI vaccines including hepatitis B vaccine on 1 December 2001. All the documents for lot release including summary protocols, checklist and other lab work have been prepared by the National Institute for the Control of Pharmaceutical and Biological Products;
2. to document AEFI system by early 2002 with implementation of a single national list during 2002 coordinating with MOH; carry on personnel training program on surveillance of AEFI;
3. to carry on a training program on GMP inspectors before the end of 2001 including the training for inspection of hepatitis B vaccines production and all the training will be completed before the end of 2002.

We highly appreciate WHO's support to our vaccine program and would like to continue the cooperation with WHO in this field. If you have any further questions or concern, please let us know.

Best regards.

Yours sincerely,

Lili Zhao /s/

Lili Zhao
Deputy Director
Department of International Cooperation
State Drug Administration

cc: Dr. Lisa Lee VMD, Medical Officer, WHO/China
Dr. Alan Schnur, Technical

Annex A
List of participants

Board Members

Chair	1.	Ms. Carol Bellamy**, Executive Director, UNICEF**
Bill & Melinda Gates Foundation	**2.**	**Ms. Patty Stonesifer,** President and Co-Chair, Bill & Melinda Gates Foundation, U.S.A.
Governments: Developing countries	**3.**	**Dr. Fatoumata Nafo-Traore**, Minister of Health, Mali
	4.	**Dr. Gautam Basu**, Joint Secretary, Ministry of Health and Family Welfare, India
Governments: Industrialized countries	**5.**	**Dr. Sigrun Mogedal**, Senior Adviser, NORAD, Norway
	6.	**Dr. Julian Lob-Levyt**, Chief, Health & Population Department, Department for International Development (DFID), U.K.
	7.	**Dr. E. Anne Peterson**, Assistant Administrator for the Bureau for Global Health, U.S. Agency for International Development (USAID), U.S.A.
NGO	**8.**	**Dr. Mark Kane**, Director, Children's Vaccine Program at PATH, U.S.A.
Research and development	**9.**	**Prof. Philippe Kourilsky**, Director General, Institut Pasteur, Paris
Technical Health Institute	**10.**	**Dr. David W. Fleming**, Deputy Director for Science and Public Health, Centers for Disease Control and Prevention (CDC), U.S.A.
The World Bank	**11.**	**Mr. Jozef Ritzen**, Vice President of the Human Development Network, The World Bank, U.S.A.
UNICEF	**12.**	**Dr. Suomi Sakai**, Chief, Immunization Activities, UNICEF
Vaccine industry: Developing country	**13.**	**Mr. Kevin L. Reilly,** President, Wyeth Vaccines and Nutrition, Wyeth-Ayerst Global Pharmaceuticals, U.S.A.
World Health Organization	**14.**	**Dr. Gro Harlem Brundtland**, Director-General, WHO
	15.	**Dr. Yasuhiro Suzuki**, Executive Director, Health Technology and Pharmaceuticals, WHO

Other Participants

The Vaccine Fund	**16.**	**Mr. Jacques-François Martin**, President, The Vaccine Fund, Lyon

GAVI Working Group

17. **Dr. Paul Fife**, Health Adviser, UNICEF
18. **Dr. Tore Godal**, Executive Secretary, GAVI Secretariat
19. **Dr. Steve Landry**, Technical Advisor, Child Survival, Population, Health and Nutrition, USAID, U.S.A.
20. **Ms. Heidi Larson**, Senior Communication Adviser, UNICEF
21. **Dr. Mike Levine**, Director, Center for Vaccine Development, University of Maryland School of Medicine, U.S.A.
22. **Mr. Walter Vandermissen**, Government Affairs Director, GlaxoSmithKline Biologicals, S.A., Belgium
23. **Mr. Michel Zaffran**, Programme Manager, Vaccines and Biologicals, WHO

Presenter

24. **Dr. Gill Walt**, Professor of International Health Policy, London School of Hygiene and Tropical Medicine, U.K.

Reviewer

25. **Ms. Karen Caines**, Consultant, Department for International Development (DFID), U.K.
26. **Mr. Hatib Njie**, Consultant, Department for International Development (DFID), U.K.

Observers

27. **Dr. Yves Bergevin**, Chief of Health, UNICEF
28. **Ms. Michele Boccoz**, Executive Vice President, Institut Pasteur, Paris
29. **Mr. William O. Brisben**, Presidential Representative to the UNICEF Executive Board, U.S.A.
30. **Ms. Jacqueline Keith**, Assistant Vice President, Wyeth-Ayerst Labs, U.S.A.
31. **Ms. Marion Kelly**, Specialist in Child Health, Health & Population Department, Department for International Development (DFID), U.K.
32. **Dr. Marie-Paule Kieny**, Director, Initiative for Vaccine Research, WHO
33. **Mr. Jon Liden**, Office of the Director-General, WHO
34. **Mr. Bruce MacLachlan**, Deputy, GAVI Coordinating Activity, Global Immunization Division, CDC, U.S.A.
35. **Dr. Sudhansh Malhotra**, Assistant Commissioner (Child Health), Ministry of Health and Family Welfare, India
36. **Mr. Fabian McKinnon**, Executive Vice President, Operations, The Vaccine Fund, Lyon
37. **Mr. Sean Murphy**, Embassy of Ireland, Stockholm
38. **Ms. Violaine Mitchell**, Coordinator, GAVI Financing Task Force, The World Bank. U.S.A.
39. **Dr. Anders Nordström**, Interim Executive Director, Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM)
40. **Ms. Namita Pradhan**, Office of the Director-General, WHO
41. **Dr. Daniel Tarantola**, Director, Vaccines and Biologicals, WHO
42. **Ms. Veronica Walford**, Consultant, Department for International Development (DFID), U.K.

Observers	**43.**	**Mr. Piers Whitehead**, Vice President, Mercer Management, U.K.
GAVI Secretariat	**44.**	**Ms. Lisa Jacobs**, Communication Officer
	45.	**Ms. Corina Luputiu**, Senior Secretary
	46.	**Mr. Bo Stenson**, Principal Officer

Annex B:
List of presentations

Presentations may be viewed and downloaded from the GAVI website: www.vaccinealliance.org

Share allocation: TFCC analysis and proposal

Mr. Michel Zaffran, Programme Manager, Vaccines and Biologicals, WHO

Update on the Immunization Financing Database (IFD)

Dr. Steve Landry, Technical Advisor, Child Survival, Population, Health and Nutrition, USAID, U.S.A.

Framework for the study on Lessons Learned: New Procurement Strategies for Vaccines

Mr. Piers Whitehead, Vice President, Mercer Management, U.K

New Products into Old Systems: The initial impact of the Global Alliance for Vaccines and Immunization (GAVI) from a country perspective

Dr. Gill Walt, Professor of International Health Policy, London School of Hygiene and Tropical Medicine, U.K.