18th February, 2000

IMMUNIZE EVERY CHILD

GAVI STRATEGY FOR SUSTAINABLE IMMUNIZATION SERVICES

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EXECUTIVE SUMMARY

Nearly 30 million of the 130 million children born every year are not receiving basic immunization. The great majority of unreached children, or 28 million, live in developing countries, and of those, 25 million are in the poorest countries, defined as countries that have less than 1,000 USD per capita GNP.

A major priority for the Global Alliance for Vaccines and Immunization (GAVI) is to see that all countries of the world achieve at least 80% immunization coverage by 2005. To achieve that milestone, immunization services must expand to reach 11.3 million more children in the poorest countries.

This discussion paper outlines a strategy for increasing immunization coverage to reach these children. It was reviewed and its main principles were approved by the Board of GAVI at its meeting on 31 January 2000 in Davos, Switzerland. It is now being sent out to a large number of concerned organizations, institutions and individuals for further comments. After that it will be presented to the GAVI Board at its June 2000 meeting for final approval.

The paper is organized into three main sections. The first part proposes general policy directions for the Alliance to achieve its first objective "to improve access to sustainable immunization services". The strategy framework highlights immunization as an essential component in international development efforts; as a global public good; its relation to health sector development; and its connection with the polio eradication effort. Issues to be considered in relation to delivery, access and monitoring of immunization services are also discussed.

The second part of the document describes the operations of the Alliance that will basically be carried out by the partners: governments, UNICEF, World Bank group, WHO, foundations, industry, public health institutions, and NGOs. Their respective efforts are outlined. The essential roles of the GAVI partners include:

- fundraising;
- working with national governments to increase support;
- advocating for increased commitment and allocations to immunization;
- working with new partners to increase their efforts in delivery and outreach.

The third part of the document deals with the principles of financing of strategies to improve access to sustainable immunization services. It also presents the general principles and priorities for the use of sub-account 2 (immunization services) of the Global Fund for Children's Vaccines (GFVC, or the Fund).

Based on current assumptions of vaccine delivery costs it is estimated that an additional 226 million USD annually is needed to reach at least 80% coverage in the poorest countries with the

traditional EPI vaccines.To cover the same number of children with the newer vaccines, according to the guidelines adopted at GAVI's first board meeting, would require an additional 352 million USD.

It is likely that most of the funding for immunization services will have to continue to come from national budgets and traditional external sources (bilateral and multilateral funding). Sub-account 2 of the Fund might attract additional funding for this purpose. The mechanism for access to sub-account 2 is proposed to be the same as that for sub-account 1: country funding proposals based on national immunization plans that are endorsed by the national Interagency Coordinating Committee.

TABLE OF CONTENTS

INTRODUCTION

The mission of the Global Alliance for Vaccines and Immunization is "to save children's lives and protect people's health through the widespread use of vaccines". To achieve this mission, three widening gaps need to be addressed:

- the children who are still not receiving the 'basic six' immunizations as compared to those who are reached through the polio eradication initiative (Table 1);
- the growing disparity in the number of vaccines available to children in industrialized and developing countries (Fig 1);
- the lack of investment in vaccine research and development for diseases that are prevalent in poorer countries.

At its first Board meeting, GAVI adopted basic principles on the use of the Global Fund for Children's Vaccines which will contribute to filling the second gap – providing newer vaccines to children living in the poorest countries of the world (Report of the First Board Meeting, GAVI/99.02). A strategy for closing the third gap is under development and is expected to be considered by the GAVI Board at its third meeting in June 2000. The aim of this document is to outline GAVI's strategy to start addressing the first gap.

Since 1990, a declining proportion of the approximately 130 million children born every year becomes fully immunized with the original six EPI vaccines (measles, polio, tuberculosis, diphteria, pertussis, tetanus). While in the early 90s, four out of five children were fully immunized, in 1998 only three out of four children were reported to receive full immunization (see Figure 2). In addition, newer vaccines, such as those for Hepatitis B, Haemophilus influenzae *type b (Hib)*, and yellow fever have existed for years but are not widely incorporated into immunization programs in much of the developing world. Thus over 30 million children born every year will not be adequately protected against vaccine preventable diseases. Of those, 25 million live in countries with less than 1000 dollars USD GNP per capita (see Table 2).

This immunization gap represents a devastating toll on the world's population. Every year, there are three million unnecessary premature deaths, because too many children have not been given the vaccine that could have saved their lives (see Table 3). This is not only a health issue; it is an issue of fundamental equity and human rights.

The challenge facing us is how to expand immunization services to these unreached children, to recognize the obstacles that countries now face and identify creative strategies for overcoming those obstacles. From the Polio Eradication Initiative (PEI), we have seen countries as large as India give nearly every child under 5 a vaccine during National Immunization Days (NIDs). Recognizing that other vaccines are not as simple to administer as the oral polio vaccine, there are still important lessons to learn from the success of the PEI.

GAVI's Objectives

- Improve access to sustainable immunization services.
- Expand the use of all existing, safe and cost-effective vaccines where they address a public health problem.
- Accelerate development and introduction of new vaccines and technologies.
- Accelerate R&D efforts for vaccines needed primarily in developing countries.
- Make immunization coverage a centerpiece in international development efforts.

I. OVERALL POLICY DIRECTIONS

Strategy Framework

The Case for Immunization in International Development and Poverty Reduction

The shift in international policy now taking place from economic development to poverty reduction has important implications for immunization. The case for health as a key element of poverty reduction is gaining ground (G7 Köln Summit, London "World Health Opportunity" meeting report). In addition, there have been increasing calls for debt relief for the poorest countries, with the idea of channelling those savings into national health and social programs. These directions imply giving priority to combating conditions that are causing excess disease burden in poor populations. In this context the case for immunization is:

- Infectious diseases are among those diseases showing the highest differentials between poor and non-poor;
- Vaccine-preventable diseases account for over 20% of that "excess" burden (Table 4);
- Immunization is among the most cost-effective interventions (Table 5); and
- Among health interventions, immunization has demonstrated high potential for reaching the poorest populations even in the absence of other aspects of health services.

Since it can be monitored more easily than most other services, immunization lends itself as an important outcome measurement to highlight progress in global poverty reduction.

Policy direction*: Immunization services should be given a high priority in poverty reduction efforts.*

Immunization as a Global Public Good

Immunization leads to reduced transmission of diseases within and between countries. As travel and contacts across borders increase, immunization in one country tends to become more important in the reduction of transmission to other countries. Thus immunization has impacts that reach far beyond the individuals immunized.

In addition, immunization can lead to disease eradication. Eradication of a disease, as was the case with smallpox and will soon be a reality for poliomyelitis, can be considered an ultimate

example of a global public good. While the total cost of eradication smallpox has been estimated to 300 million USD the annual savings amounted to some 250 million USD, in addition to the reduction of extensive human suffering. Likewise polio eradication which may cost the global community 1.8 billion USD over almost twenty years will save 1.5 billion USD annually in averted treatment and immunization costs.

Policy direction: *Immunization must be maintained as a global public good since it benefits every community, country and region of the world.*

Immunization in Health Sector Development

Immunization is provided through facilities, staff and operations dedicated to public or private health services. Thus, the overall performance of the health sector has a strong influence on the quality and coverage of immunization services. Conversely, appropriately planned immunization services can also contribute to the overall development of the health sector. Traditionally this relationship has been viewed as contentious as an either "horizontal" or "vertical" issue.

Analyses of health sector reforms undertaken during the 1990s show that this does not need to be the case (Health sector reform and priority health interventions: The case of immunization services. Washington, 1999-11-15-16). In fact, profound reforms including sector wide approaches can contribute to higher immunization coverage levels (S. Adjei 99). Moreover, a recent review of the impact of polio eradication on health systems shows that synergies can be achieved, provided that the eradication efforts are adequately planned (Stenson & Mogedal 99).

Any increased investments in the health sector, as part of a poverty reduction strategy, must address the need for health services to reach out to populations remote areas. This outreach should strengthen opportunities for synergies in the delivery of basic health care to poor populations, such as combining immunization with nutrition and family planning programs.

Thus, health sector reforms need to improve people's health by responding to legitimate needs. As a public good, immunization requires strong public policies and finance. However, the delivery of services is increasingly segmented into different kinds of public and private sectors (World Development Report 1993, HNP white paper 1997). This increased complexity require increased central and peripheral managerial capacity, and increased emphasis on outcomes rather then specific inputs (Washington meeting).

There is also a need to further analyze the cost of immunization programmes in relation to broader healthrelated investments.

Policy directions:
Strengthen immunization services to synergize within overall health sector plans and development.
Shift emphasis pragmatically, as health systems development permit, from specific inputs to specific outcomes.
Respond to urgent need to strengthen national capacity to plan and manage immunization services in the broader context of health sector development.

The Polio Eradication Initiative and GAVI

In 1988, the World Health Assembly resolved to eradicate polio from the world by the year 2000. This goal is within our reach and the Polio Eradication Initiative (PEI) is now among the highest priorities for the global immunization community.

This initiative received some 300 million USD in external support during 1999, in its final phase of operation, according to WHO. Transmission is expected to be interrupted by the end of year 2000 or shortly thereafter. Financing requirements are expected to start to decline by 2001, but in order to reach the goal, continued selective field operations will be needed for several years, at least until 2005, requiring an additional estimated total of 1 billion USD.

The polio eradication initiative is an effective global effort that reaches virtually every child in the world. Political commitment and mobilization of civil society has proven to be instrumental in the initiative's ability to reach the unreached. With contributions to the campaign ranging from Heads of State making national radio appeals, to football stars and other celebrities involved in public events, to local volunteers making community appeals, the global momentum achieved is a model for immunization activities.

PEI has developed clear roles and responsibilities for different partners at global, regional and national levels, and managerial and communications mechanisms between all these levels and partners. These represent important opportunities for GAVI that will materialize only if there is close collaboration between GAVI and the Polio Eradication Initiative (PEI) at all levels.

- At country level: GAVI will build on polio activities in several ways:
  1. Improving access to all vaccines based on lessons learned from NIDs. Feasibility studies are in progress with support from the UN foundation.
  2. The PEI is a major investor in cold chain equipment and GAVI partners could complement these activities.
  3. During year 2000, staff currently involved in EPI/polio will do broader work for immunization related activities which will benefit GAVI, such as helping develop five-year plans, contributing to the strategic vision, helping in priority setting and microplanning, etc.
  4. In many countries the polio initiative is co-ordinated through an Interagency Coordination Committee (ICC). Its mandate must be broadened to encompass all immunization efforts which can be used for GAVI's objectives.

- At regional level: the EPI/PEI has strong regional teams that provide leadership for field operations – a network upon which GAVI should build upon. Regional ICC mechanisms, which bring in many partners and address the full immunization agenda, already exist and can be also integrated into GAVI efforts.

- At global level:
  1. Global polio partners provide technical assistance (CDC, RIVM, NIBS a.o), carry out research (universities a.o), provide fundraising, advocacy, in-country volunteers (Rotary a.o), financing (donor agencies, World Bank a.o), and staff (CDC, US, Canada etc). As country specific plans are being developed for GAVI related activities they will be available for partners through the same channels as for polio and vice versa. The activities will be closely co-ordinated in order to ensure that competition in resource mobilization is avoided.

2. Advocacy and communication activities will also be co-ordinated at the global and country levels to ensure synergy and avoid simultaneous media action and conflicting messages.

Policy direction: *Polio is a time limited initiative. Its external financial requirements will start to decline by 2001. GAVI has broader and longer term goals. The Polio eradication initiative and GAVI seek to maximize this complementarity through close collaboration to fulfil their respective missions. This collaboration will be considered on a country-by-country basis, strongly respecting the needs of the final polio eradication efforts. As it has been clearly shown that polio eradication benefits from a strengthening of immunization infrastructure and increased access to routine immunization GAVI encourages support to these components in all countries, including those taking part in the intensified polio eradication effort.*

Immunization Services

Delivery

While vaccinations are remarkably effective and provide longer term protection in comparison to many other health interventions, the delivery of effective services rely on the existence of a number of essential components that require rigorous attention (WHO, doc. in preparation). They include:

- Supply and quality of vaccines (forecasting, procurement, production)
- Logistics support (transport, cold chain, supplies, waste management)
- Communication (advocacy, social mobilization, programme communication)
- Surveillance (routine reporting, case investigation, diagnostics, active surveillance)
- Service delivery (policy and strategy development and guidelines, planning, coordination and budgeting, supervision and monitoring).

GAVI Milestones

During 2000, GAVI will present an analysis of current market and policy failures levels of research, development and commercialisation of candidate vaccines for HIV/AIDS, malaria and TB and make recommendations to overcome these problems.

By 2005, 80% of developing countries will have routine immunization coverage of at least 80% in all districts.

By 2002, 80% of countries with adequate delivery system will introduce Hepatitis B vaccine and all countries by 2007.

By 2005, 50% of poorest countries with high burden of disease and adequate delivery systems will have introduced Hib vaccine

By 2005, the vaccine efficacy and burden-of-disease will be known for all regions for rotavirus and pneumococcal vacines, and mechanisms identified to make the vaccines available to the poorest countries.

Some components require central national attention that can be shared with other similar functions, but not be de-centralized (vaccine procurement, policy development). Others need to be de-centralized in harmony with reforms (staff costs, distribution, etc.), while most require both

central and peripheral attention to operate effectively. Experience from the Americas has shown that an effective execution of immunization services requires forward planning. GAVI partners recognize how crucial it is for countries and districts to develop multi-year health plans in which immunization is a key priority, and build the adequate capacity for management of immunization services. The importance of good management can hardly be overemphasized and strengthening the management capacity of countries thus becomes one of GAVI's major challenges.

In the past, governments have functioned as if the financing, management and execution of health services were the sole responsibility of the central health ministries. In recent years, a shift has occurred toward recognizing the role that the *delivery* of health services quite often falls to community organizations, the private sector, and NGOs. With this revision of roles and responsibilities in service delivery, there is new pressure for governments to increase their emphasis in quality control, monitoring, surveillance and assessment. Current critical indicators are set out in Table 6; a common assessment toolbox for use by all GAVI partners is being developed and tested (expected to be available by mid 2000).

With the policy adopted at its first board meeting, GAVI committed itself to take newer vaccines to populations in need.Specifically, Hepatitis B vaccine should be introduced into all eligible countries, Hib vaccine into Africa and other countries in which the disease burden has been demonstrated, and Yellow Fever vaccine in countries at risk. The introduction of the newer vaccines can only been done in countries with reasonably functioning routine immunization services. In particular it is of high priority for GAVI that the mortality from measles (presently 900,000 children's deaths per year) is brought down by reaching every child with measles vaccine.

In order to reach out to the target population it is important that vaccines be deliverable in a safe, simple and most effective fashion. The simplest way to provide them and to reach out to the target population is by using a combination of four (DTP+Hep B) or five (DTP+Hep B+Hib) vaccines together, administered through a safer technology such as monodose delivery devices. The packaging and formulation of these new vaccines need to fit within the logistical limitations of the low-income countries.

Policy direction:
GAVI recognizes that immunization services can only be effectively delivered if all components are fully operational. That should be assured through a judicious mix of central and de-centralized functions.
The increased number of players involved in service delivery require that the public sector strengthens its function for monitoring, surveillance and assessment and establishes mechanisms for collaboration with private providers.
GAVI promotes the use of new and safe technologies such as vaccine combinations and monodose delivery devices that will facilitate reaching the un-reached.

Access

The greatest challenge to fulfill GAVI's mission is to increase access to immunization services for the currently unreached children, especially the 25 million born every year in the low income countries.

Practical experiences over the last few years have pointed to a variety of mechanisms that can be used to improve access.

Health sector reforms
Reforms can work in both directions with regard to access to immunization services. There is a need for further analysis of the impact of health sector reforms on immunization coverage. Positive reforms have been found to include:

1. Shifting resources from tertiary to primary care.
2. Engaging privately practising health workers in immunization services
3. Protecting and increasing financing of outreach activities, especially for travel and subsistence allowances
4. Making access to immunization a performance indicator in health systems financing

Community based action
The importance of communities in health activities has become increasingly apparent:

1. Community directed distribution of ivermectin has proven superior to health services based distribution.
2. Communities can facilitate transport and other support functions
3. Community created demand through active involvement in disease surveillance such as measles.

Combined community and health services based action
The most effective approach in reaching the highest coverage is the polio national immunization days, which combine community mobilization with health services outreach. An added important aspect of NIDs is their regular campaign modes (i.e. focussed on a certain day). This does not necessarily need to be a national day but could be a regional or district day(s).

Combining various interventions
There may be advantages in combining interventions that can be delivered simultaneously at the most peripheral level. They could include vitamin A supplementation, intermittent administration of drugs (such as ivermectin for river blindness, albendazole for intestinal helmints, drug combinations for lymphatic filariasis), distribution of insecticide treated mosquito-nets, and the kit for their re-impregnation.

Through operational research, each country will identify the most effective means of improving access to the most appropriate combination of interventions. In this operational research attention should be paid to a possible transfer of relevant technologies and the effectiveness thereof.

Policy directions:
GAVI promotes health sector reforms that increase sustainable access to vaccinations and other health interventions.
Through advocacy and other mechanisms GAVI will support work that promotes community demand, ownership and action.
GAVI will collaborate with other initiatives like Roll Back Malaria, African Program for Onchocerciasis Control and Micronutrient Initiative to develop effective campaign strategies to reach the most inaccessible populations.

Monitoring and evaluation

The need for monitoring and evaluation extends to the whole of the immunization services as part of the health system. The main role of GAVI is to promote and ensure the introduction

of comprehensive and joint monitoring systems in the countries concerned. Harmonization with other reviews and health sector evaluations is essential.

New monitoring and evaluation instruments are now being developed and piloted by the partners. These tools are being expected to be ready for large-scale use during year 2000.

The basis for monitoring and evaluation will be the national multi-year immunization plan into which the monitoring system should form an integral part, and implementation by the ICC. In addition there may be a need for in-depth reviews to be undertaken intermittently as required, most commonly at mid-term and at the end of a five year plan.

All country support from the GFCV will be allocated on the basis of one comprehensive country proposal. Contributions from the GFCV will be included in the comprehensive monitoring system with particular responsibility given to one of the GAVI partners at the national level. This partner will also be responsible for accounting as required. The focus of the evaluations will be on outcomes and achievements.

Policy directions:

GAVI promotes comprehensive, outcome-oriented monitoring and evaluation systems as integral parts of the national multi-year immunization plans.
GAVI will seek joint monitoring action together with all other concerned partners including the national governments.

II. GAVI IMPLEMENTATION MECHANISMS

The main responsibility for immunization services – as an integral and essential part of health sectors – rests with national governments. A major responsibility for supporting countries to improve and extend immunization services lies with those international, multilateral, bilateral and other organizations that are active in international development cooperation in health.

GAVI does not change that. As an international alliance of operational partners, the GAVI Board, working group and task forces will work to identify overall needs to strengthen immunization, and encourage members of the alliance to increase their activities in order to fill the gaps. GAVI partners will strive to work through existing regional and national Interagency Coordination Committees (ICC), to identify needs and plan activities.

The role of GAVI is therefore to strengthen the explicit and complementary roles of each individual partner in the alliance, as they are described below.

<u>Governments of low- and middle-income countries</u>

Primary
To ascertain that the health sector develops effective measures to reach out and provide health services to those most in need.

Supportive
- To assure that health in general and immunization in particular receive a justified and identifiable proportion of the government budget.

- To coordinate external inputs to immunization, develop, monitor and evaluate multiyear immunization plans,
- To collaborate with communities and private providers.

Governments of high-income countries

Primary
To ensure that health gets an adequate proportion of external aid channelled through the sector coordination mechanisms.

Supportive
- To ascertain that pro-poor global policies are made and implemented.
- To ensure that health is given adequate priority in the context of poverty reduction as well as a global public good.
- To facilitate global health challenges including immunization receive priority in their national health institutions and facilitate their participation in international efforts.
- To support the strengthening of immunization services through broad sectoral approaches.

UNICEF

Primary
Advocate and mobilize leaders from global to community levels to place immunization of children a key priority for development.

Supportive
- Provide mechanisms for procurement of vaccines and equipment.
- Facilitate functioning of mechanisms for national coordination of immunization services.
- Provide technical and logistics support for expansion of outreach services.
- Provide technical and financial support to enhance community action for access to immunization services.

World Bank Group

Primary
Within a broader perspective of poverty reduction and economic development to take primary responsibility with national governments to work toward sustainable financing mechanisms in the longer term for immunization services including vaccine purchase and infrastructure support.

Supportive
- Enhance more effective involvement of Departments of Finance, Economics and others to become full partners in reaching full immunization coverage.
- Support and carry out analyses relating to the economics of immunization.

World Health Organization

Primary
Developing global policies and strategies for immunization and vaccine development and advocacy for these.

Supportive

- Provide technical and financial support to governments to strengthen the health sector capacity to improve access to immunization services and surveillance systems.
- Facilitate functioning of mechanisms for national coordination of immunization services.
- Provide national and regional capacity networks to promote technical efficiency and capacity through the development of common policy frameworks.
- Provide support for disease burden studies and effectiveness trials to assess the importance of newer vaccines at the country level.

Foundations

With their flexibility and rapid response potential, Foundations will:

- Provide financial support to the Global Fund for Children's Vaccines
- Mobilize new resources for the Fund
- Provide support to lead agencies in support of analytical, policy and operational work
- Support catalytic action at country level

Pharmaceutical Industry

The developers and producers of vaccines and immunization supplies will:

- Contribute actively to supply high quality vaccines to the poorest population,
- Contribute actively to the development and supply of new breakthrough vaccines on a worldwide basis,
- Develop technologies to facilitate the distribution and administration of vaccines within countries,
- Contribute to the education of immunization providers in these countries,
- Engage every private sector in the mission of GAVI.

Public Health Institutions

In relation to access and infrastructure, these institutions (eg MOH public health institutions like CDC, NIH, NIBS, State Serum Institute etc.) will:

- Facilitate setting global policies
- Work as reference laboratories for surveillance and quality control
- Provide technical staff for operations and capacity building.

Non-governmental organizations (e.g. Rotary International)

As part of the civil society and in view of its growing role, NGOs are expected to:

- Support immunization in countries as part of their health programmes,
- Advocate for the need to strengthen immunization and health systems,
- Contribute to fundraising for immunization in various forms.

III. FINANCING THE GAPS

Assumptions

There are limited data available for the costs of immunization services in countries and development assistance resource flows for immunization (except for polio eradication), making it difficult to calculate global costs and financial gaps.

Therefore, the calculations below are based on average standard costs for immunization services as defined through previous studies (Brenzel and Claquin, 1994; WHO-V&B, Cost estimates of expanding immunization services in selected HIPC countries, 1999), and knowledge of vaccine prices (based on current prices). As the costs range considerably between countries, these calculations cannot be applied to individual countries without making further assumptions about their specific cost structure. However, we anticipate that more precise data can be derived from the forthcoming country proposals, country by country, to be compiled on a regional and global basis.

It is assumed that the expansion of services will necessarily incorporate a share of the capital and indirect costs, also based on the fact that we do not know the breaking points between fixed and variable costs.

The most important cost elements required to increase access are recognized to be:

- Management and operations
  - -training and capacity strengthening
  - -salaries and allowances
  - -monitoring and evaluation
  - -operational research for innovation
  - -communication, social mobilization and community participation
- Supplies and maintenance
  - -vaccines and safe injection materials
  - -fuel
  - -spare parts and services
- Capital investments: equipment for
  - -cold chain
  - -telecommunications
  - -computing
  - -transport

The birth cohort is projected to be roughly constant over the next ten years. This does not necessarily hold true for individual countries although it is correct for the group of countries "less developed regions" (1998 revision of the United Nations World Population Estimates and Projections). This year's birth cohort in the countries with below 1,000 USD per capita GNP is 91 million. Of these, 66 million are being immunized through routine immunization programmes. Thus, 25 million children remain unimmunized. To achieve at least 80% coverage in all countries, 11.3 million of these children have to be reached (see Table 7).

The cost of fully immunizing a child with the six traditional EPI vaccines through routine health services were estimated to be approximately 15 USD per child in the 1980s and approximately 17

USD per child in the 1990s. Thus, with an annual birth cohort of approximately 91.4 million in low-income countries, estimates of total immunization costs in 1998 were 1.123 billion USD.

To reach inaccessible populations costs more than static services with a progressive increase in the marginal cost for every new child as coverage approaches 100%. Outreach services have been estimated to cost on average 26 USD per fully immunized child, with a range of 16 USD to 48 USD. Thus the marginal cost to immunize children up to a coverage of 80% has been calculated to increase by 3 USD (i.e. from 17 to 20 USD per child) and by 8 USD (i.e. from 17 to 25 USD per child) above 80% coverage.

Financial Requirements

Out of the annual birth cohort in the developing countries of 117.7 million, 28.0 million children are currently unreached by immunization. Of these 25.3 million live in the low-income countries[1].

The cost of immunization for all developing countries is shown in Fig. 1. The current investment in immunization in these countries is 1.564 billion USD annually. To reach 80% coverage with the traditional and newer vaccines would require 2.310 billion USD and to reach all children would require a total of 2.808 billion USD.

The cost of immunization for the low-income countries only is shown in Fig. 2. The current investment in immunization in these countries is 1.133 billion USD annually. To reach 80% coverage with the traditional and newer vaccines would require a total of 1.711 billion USD and to reach all children would require a total of 2.132 billion USD.

The cost of adding the new vaccines against Hepatitis B, Haemophilus influenzae type b, and Yellow Fever (vaccine cost + 1 USD per child for administration) has been calculated according to the country specific patterns of disease burden.[2] For further information see Table 8.

In summary about 95% of the costs for expanding access to the traditional vaccines would fall on the low-income countries. For the introduction of the newer vaccines about three quarters of the costs would be required for the low-income countries.

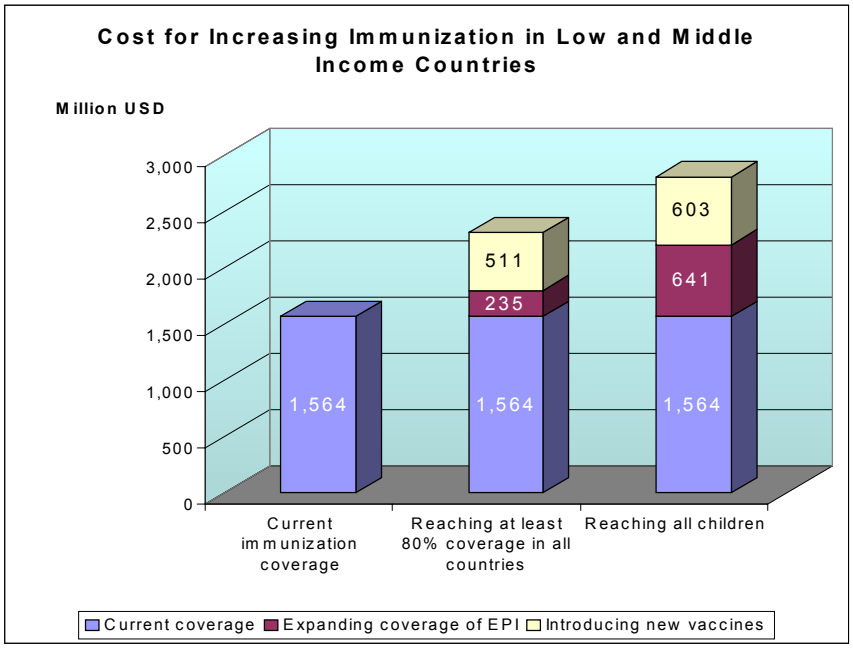
If the national governments of low-income countries continue to bear at least the costs of fixed facilities and staff of immunization services (estimated to be some 50% of total costs), external assistance requirements to increase access to the traditional vaccines will be roughly half of these figures. Achieving coverage goals with the new vaccines will require a greater proportion of external assistance.

[1] Low-income countries are defined as those with a GNP/capita below 1,000 USD, middle-income countries with a GNP/capita between 1,000 USD and 9,360 USD. The notion of developing countries is used for these two categories together.

[2] These amounts are based on existing policy for which Hib vaccine is not introduced in Asian countries, and the Yellow Fever vaccine is introduced only in endemic countries.

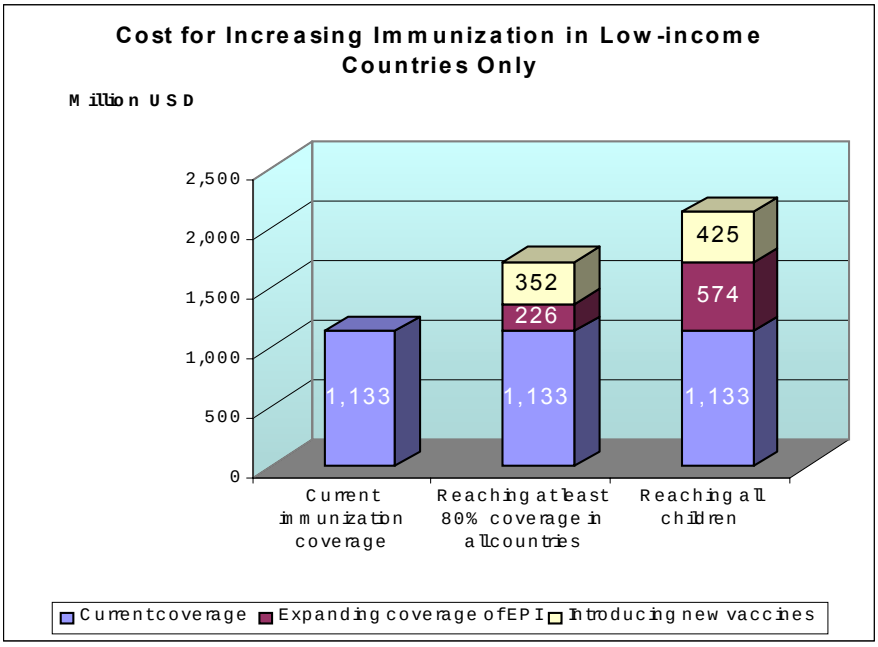
In addition to the requirement to finance an extension of the coverage with the traditional vaccines and the introduction of the new vaccines the polio eradication initiative will continue to require funding to the tune of 1 billion USD (out of which some 700 million USD have already been committed) over the next six years.

Figure 1



*The costs of introducing new vaccines in middle income countries may represent an over-estimate, because of under-reported introductions

Figure 2



The role of GAVI partners in closing the gaps

National governments bear the main financial burden of health and immunization services in their respective countries. The responsibility for ensuring an expansion of current services to underserved groups, and including the new vaccines in their immunization schedules, will continue to fall mainly to governments. Many countries have demonstrated that substantial parts of infrastructure expansion can be met through their own budgets and through sector wide financing; this is the preferred mode of financing. In addition, strategies (including operational research) to reduce wastage and contain costs should be a natural part of the national immunization plan. Thereby a more cost-effective delivery of immunization services will be achieved.

Even so, in many instances there appears not to be sufficient resources currently to meet the cost of expansion of immunization services that has been outlined above; in early discussions with countries, a number of them have indicated a need for external support for infrastructure development. This external support should be sought primarily from increases in bilateral assistance to countries, new loans from the World Bank and regional development banks, and increases in funding from multilaterals (mainly UNICEF and WHO). GAVI Secretariat and partners therefore will work to encourage and assist in:

- fundraising by coordinated appeals;
- supporting national governments in loan requests;
- advocating for increased allocation of international development funds for immunization;
- working with governments to ensure that immunization is among the highest priorities of the national health system and that it receives appropriate internal resources;
- working with NGOs and community organizations to increase funding for health service delivery and outreach efforts.

The national ICCs will play a crucial role in providing an opportunity for the partners to consider support to specific items and in the co-ordination of external financial assistance.

Global Fund for Children's Vaccines

The Global Fund for Children's Vaccines (GFCV) is a new experiment in the international public health community. The Fund has three sub-accounts (or windows) for disbursements: 1) vaccines and safe injections materials; 2) vaccine access and infrastructure; and 3) vaccine research and development.

The Bill and Melinda Gates Foundation has provided the first contribution to the Fund through a commitment of 750 million USD over five years. This contribution is primarily targeted for sub-account 1 – the procurement of new vaccines (see GAVI Report of First Board Meeting, 1999). This contribution will provide approximately 40% of the resources required to cover the target population > 80% with the newer vaccines (Tab. 2).

Should contributors and recipient countries wish resources to be channelled to sub-account 2, these funds will be used to fill resource gaps not covered by other partners for strengthening access and infrastructure in low income countries (<1000 USD per capita GNP) to increase their immunization coverage. The proposed general priorities for funding from sub-account 2 are:

- to help countries meet the assessment criteria required to receive support for procurement of newer vaccines under sub-account 1 of the Fund;
- to facilitate multi-partner collaboration;
- to fund cost elements critical to increase access.

The basic mechanisms for providing financial support from sub-account 2 of the Fund will be the same as for sub-account 1:

- country funding proposal submitted to GAVI need to be based on a multi-year plan including strategies to achieve increased immunization coverage;
- the country plan needs to be endorsed by the National Interagency Coordination Committee and be explicit about contributions from partners.

In using sub-account 2 resources concerns that have been raised about monitoring mechanisms, the risk of substitution of other funds, and raising unrealistic expectations will be taken into consideration..

The following procedures for applications to the Fund are foreseen:

- that country proposals will first be reviewed by ICCs;
- that ICC partners will consider how they can contribute to meet the financial gaps of the plans;
- that only unmet needs will be forwarded to GAVI to be considered for financing from the Fund.

ANNEXES

Table 1: Comparison of Polio3 routine coverage and Polio NID coverage

Country	1997 Coverage with third polio dose in routine services	Highest coverage achieved during polio NIDs	Percent new-borns remaining without a single contact with routine EPI services
Dem. Rep. of Congo	18	95	**na**
Congo	21	91	**71**
Chad	24	108	**55**
Sierra Leone	26	na	**62**
Mauritania	28	95	**71**
Niger	28	103	**66**
Togo	33	104	**47**
Kenya	36	82	**58**
Angola	38	90	**32**
Nigeria	45	95	**47**
Cameroon	47	103	**47**
Comoros	48	na	**45**

From: World Health Organization

Table 2a: The "unreached" children in low-income countries

	Country	GNP per capita	Public health budget as % of GDP	Birth cohort (in 2000)	DTP3 coverage	Unreached children	
#		(USD)	(Percent)	(Thousand)	(Percent)	(Percent)	(Thousand)
1	**Afghanistan**	n.a.	n.a.	1,157	34	66	764
2	**Albania**	810	2.5	60	96	4	2
3	**Angola**	340	3.3	607	36	64	388
4	**Armenia**	480	3.1	47	82	18	8
5	**Azerbaijan**	490	1.1	121	97	3	4
6	**Bangladesh**	350	1.2	3,524	78	22	775
7	**Benin**	380	1.7	247	81	19	47
8	**Bhutan**	n.a.	2.3	77	86	14	11
9	**Bolivia**	1,000	4.1	266	76	24	64
10	**Bosnia & Herzegov**	n. a.	n.a.	41	89	11	5
11	**Burkina Faso**	240	2.3	541	*70	3	162
12	**Burundi**	140	0.8	276	50	5	138
13	**Cambodia**	280	0.7	355	64	36	128
14	**Cameroon**	610	1	583	48	52	303
15	**Central Afr Rep**	300	1.9	134	45	55	74
16	**Chad**	230	3.7	329	23	77	253
17	**China**	750	2.1	19,497	98	2	390
18	**Comoros**	370	0.9	25	75	25	6
19	**Congo, Dem Rep**	110	0.2	2,316	18	82	1899
20	**Congo, Rep**	690	3.2	125	*23	77	96
21	**Côte d'Ivoire**	700	1.4	546	64	36	197
22	**Cuba**	n.a	7.9	137	99	1	1
23	**Djibouti**	n. a.	n.a.	23	*62	38	9
24	**Eritrea**	200	1	150	60	4	60
25	**Ethiopia**	100	2	2,746	57	43	1181
26	**Gambia**	340	2	51	96	4	2
27	**Georgia**	930	0.6	68	86	14	10
28	**Ghana**	390	1.4	736	68	32	236
29	**Guinea**	540	1	313	56	44	138
30	**Guinea-Bissau**	160	1.1	50	*63	37	19
31	**Guyana**	770	4.3	17	90	10	2
32	**Haiti**	410	1.3	257	22	78	200
33	**Honduras**	730	2.8	206	96	4	8
34	**India**	430	1.2	24,316	73	27	6565
35	**Indonesia**	680	0.6	4,539	65	35	1589
36	**Kenya**	330	1.6	994	64	36	358
37	**Korea, DPR**	970	n.a.	456	37	63	287
38	**Kyrgyz Republic**	350	3.5	114	97	3	3
39	**Lao PDR**	330	1.3	207	55	45	93
40	**Lesotho**	570	4.1	74	*57	43	32

	Country	GNP per capita	Public health budget in % of GDP	Birth cohort in 2000	DTP3 coverage	Unreached children	
#		(USD)	(Percent)	(Thousand)	(Percent)	(Percent)	(Thousand)
41	**Liberia**	n. a.	n.a.	142	19	81	115
42	**Madagascar**	260	1.1	608	68	32	195
43	**Malawi**	200	2.3	505	96	4	20
44	**Mali**	250	1.2	515	53	47	242
45	**Mauritania**	410	1.1	106	*28	72	76
46	**Moldova**	410	4.9	56	97	3	2
47	**Mongolia**	400	4.4	58	94	6	3
48	**Mozambique**	210	4.6	832	77	23	191
49	**Myanmar**	n.a.	0.4	938	87	13	122
50	**Nepal**	210	1.2	793	76	24	190
51	**Nicaragua**	390	5.3	176	86	14	25
52	**Niger**	190	1.6	506	25	75	380
53	**Nigeria**	300	0.3	4,239	21	79	3349
54	**Pakistan**	480	0.8	5,390	79	21	1132
55	**Papua New Guinea**	890	2.8	150	58	42	63
56	**Rwanda**	230	1.9	309	*77	23	71
57	**São Thomé**	280	6.2	6	73	27	2
58	**Senegal**	530	2.5	370	65	35	130
59	**Sierra Leone**	140	1.5	218	56	44	96
60	**Solomon Islands**	750	4.8	15	69	31	5
61	**Somalia**	n. a.	n.a.	517	24	76	393
62	**Sri Lanka**	810	1.4	329	94	6	20
63	**Sudan**	290	n.a.	955	72	28	267
64	**Tajikistan**	350	5.8	187	94	6	11
65	**Tanzania**	210	2.5	1,347	74	26	350
66	**Togo**	330	1.2	188	36	64	120
67	**Turkmenistan**	n.a.	1.2	120	99	1	1
68	**Ukraine**	850	5	482	98	2	10
69	**Uganda**	320	1.8	1,107	46	54	598
70	**Uzbekistan**	870	3.5	653	99	1	7
71	**Vietnam**	330	1.1	1,638	94	6	98
72	**Yemen**	300	1.1	831	68	32	266
73	**Zambia**	330	2.6	382	*70	30	115
74	**Zimbabwe**	610	2.2	355	70	30	107
	Total			91,351			25,276

(*) reported coverage prior to 1998

Table 2b. The "unreached" children of the middle-income countries*

#	Country	GNP/capita 1997 (USD)	Public health budget as % of GDP (percent)	Birth cohort 2000 ,000	1998 DPT3 (percent)	Total unreached children (percent)	,000
1	**Algeria**	1,490	3.3	885	80	20	177
2	**Argentina**	8,570	4.3	721	83	17	123
3	**Bahrain**	7,820	……	11	98	2	0
4	**Barbados**	6,590	4.4	3	93	7	0
5	**Belarus**	2,150	5.3	101	97	3	3
6	**Belize**	2,740	6.0	7	87	13	1
7	**Botswana**	3,260	1.6	53	82	18	10
8	**Brazil**	4,720	1.8	3,350	94	6	201
9	**Bulgaria**	1,140	5.5	71	96	4	3
10	**Cape Verde**	1,090	3.4	13	80	20	3
11	**Chile**	5,020	2.5	288	92	8	23
12	**Colombia**	2,280	2.9	987	70	30	296
13	**Costa Rica**	2,640	6.3	91	85	15	14
14	**Croatia**	4,610	8.5	47	93	7	3
15	**Czech Rep**	5,200	7.4	89	98	2	2
16	**Dominican Rep**	1,670	1.8	194	74	26	50
17	**Ecuador**	1,590	2.0	309	85	15	46
18	**Egypt**	1,180	1.6	1,712	96	4	68
19	**El Salvador**	1,810	2.4	167	99	1	2
20	**Equatorial Guinea**	1,050	5.2	18	*81	19	3
21	**Estonia**	3,330	6.4	12	94	6	1
22	**Fiji**	2,470	2.3	18	86	14	3
23	**Gabon**	4,230	0.5	44	*54	46	20
24	**Guatemala**	1,500	1.7	404	89	11	44
25	**Hungary**	4,430	6.8	95	100	0	0
26	**Iran**	1,780	2.8	1,414	100	0	0
27	**Jamaica**	1,560	2.5	54	85	15	8
28	**Jordan**	1,570	3.7	227	91	9	20
29	**Kazakystan**	1,340	2.2	286	98	2	6
30	**Latvia**	2,430	4.4	20	94	6	1
31	**Lebanon**	3,350	2.1	71	96	4	3
32	**Lithuania**	2,230	4.8	36	93	7	3
33	**Lybian Arab Jam.**	5,540	……	162	97	3	5
34	**Malaysia**	4,680	1.5	515	95	5	26
35	**Maldives**	1,150	4.9	10	97	3	0
36	**Malta**	8,630	…..	5	92	8	0
37	**Mauritius**	3,800	2.3	18	90	10	2
38	**Mexico**	3,680	2.4	2,310	96	4	92
39	**Micronesia**	1,980	….	19	80	20	4
40	**Morocco**	1,250	1.6	694	93	7	49

#	Country	GNP/capita 1997 (USD)	Public health budget as % of GDP (percent)	Birth cohort 2000 ,000	1998 DPT3 (percent)	Total unreached children (percent)	,000
41	**Namibia**	2,220	3.7	60	74	26	16
42	**Oman**	4,950	2.5	90	100	0	0
43	**Panama**	3,080	4.7	61	98	2	1
44	**Paraguay**	2,010	1.8	167	84	16	27
45	**Peru**	2,460	2.2	608	98	2	12
46	**Philippines**	1,220	1.3	2,062	87	13	268
47	**Poland**	3,590	5.0	420	*95	5	21
48	**Romania**	1,420	3.6	201	*97	3	6
49	**Russian Feder.**	2,740	4.1	1,455	97	3	44
50	**Samoa**	1,150	3.1	5	100	0	0
51	**Saudi Arabia**	6,790	……..	713	94	6	43
52	**Slovakia**	3,700	4.6	58	99	1	1
53	**South Africa**	3,400	3.6	1,051	*73	27	284
54	**Suriname**	1,240	2.0	8	90	10	1
55	**Swaziland**	1,440	2.8	37	76	24	9
56	**Syrian Arab Rep.**	1,150	…..	481	97	3	14
57	**TFYR Macedonia**	1,090	7.3	32	97	3	1
58	**Thailand**	2,800	1.4	993	*95	5	50
59	**Trinidad & Tobago**	4,230	2.1	18	91	9	2
60	**Tunisia**	2,090	3.0	192	96	4	8
61	**Turkey**	3,130	2.7	1,396	79	21	293
62	**Uruguay**	6,020	7.0	58	87	13	8
63	**Vanuatu**	1,310	3.3	6	*93	7	0
64	**Venezuela**	3,450	3.0	575	39	61	351
				26,278			2,772

*** GNP/capita 1,000 - 9,360 USD**

Table 3: Mortality from Vaccine Preventable Diseases

Disease	Estimated Annual Deaths
• Polio	720
• Diphtheria	5,000
• Pertussis (whooping cough)	346,000
• Measles	888,000
• Tetanus (including 215,000 neonatal tetanus)	410,000
• Haemophilus influenzae b (Hib)	400,000
• Hepatitis B	900,000
• Yellow Fever	30,000
Total	**2,979,720**

From: The World Health Report, 1999

Table 4: Annual Global Mortality from Diseases that Disproportionately Affect the Poor

Disease	Estimated annual deaths in millions
• TB	1.5
• HIV/AIDS	2.6
• Maternal	0.5
• Malaria	1.1
• Diarrhea	2.2
• Respiratory Infections (-Hib)	3.1
• Vaccine Preventable (+Hib, HepB)	3.0
Total	**14.0**

From: The World Health Report 1999; AIDS epidemic update: December 1999

Table 5: Cost-effectiveness of immunization vs. select other interventions

Intervention	Cost per DALY/life-year gained in USD	Cost per death averted in in USD	Comments and sources
Measles immunization	<11.7 (2-15)	351	Foster, *et al* in Jamison 1993
Tetanus immunization Campaigns Routine	 2.3 → 11.7	 115 (52-2,750) 89 (27-205)	 Steinglass, *et al* in Jamison 1993
OPV	23 – 49	784-1,872	Jamison, *et al* in Jamison 1993
BCG	8.2		In high infection risk environment
EPI+ Cluster of interventions (micronutrients & Hep B) In low-income countries	 14-20		Jamison 1994
Meningococcal Meningitis 1 dose, Africa 4 doses, Africa	 11-318 24-693	 1,125-33,133 2,485-71,660	Miller, Wenger et al 1999
HepB immunization	29-59		Jamison 1993
HepB immunization - in low-income countries with >8% prevalence	 8-11		 Miller, McCann 1999
Hib immunization in Asia - overall - in low-income countries	 87 55	 3,010 1,475	 Miller, 1998
Hib immunization globally - low-income countries - middle-income countries - high-income countries	 17-236 46-5,360 119-7,831		 Miller, McCann 1999
TB short-course chemotherapy, Africa	3		Dejonghe
Malaria, impregnated nets, Africa	19.5		Goodman
Hypertension, different therapies, USA	4,340-87,940		Shephard
Osteoporosis, hormone replacement therapy, USA	25,244		Gabriel
Hip replacement	1,075		From Mooney, Creese in Jamison 1993
Heart transplantation	7,500		From Mooney, Creese in Jamison 1993

Table 6: Critical Indicators by Component

Overall system indicators:
- % of recommended vaccines being used in the immunization programme
- Proportion of districts with BCG coverage >=80%
- Proportion of districts with DTP3 coverage >=80%

Component	Planning Area	Indicators
Supply & Quality	Forecasting	Sufficient vaccines in health centres
	Procurement	Vaccines of assured quality at appropriate prices
	Production	Manufacturer viability >70%
	NRA functions	NRA functions filled appropriate to vaccine source
Logistics	Transport systems	% districts with stock-outs due to lack of availability of transport
	Cold chain	% doses lost due to failure of cold chain equipment
	Supplies distribution	% immunizations given safely and reliably
	Communication	Communication system responsive to programme needs
	Waste management	%immunization wastes disposed of in safety
Communication	Advocacy	Proportion of public dialogue on immunization issues and concerns
	Social mobilization	Proportion of civil society organizations promoting immunization of children
	Programme communication	Proportion of targeted mothers who know which disease the child was vaccinated against and when to return for next immunization
Surveillance	Routine reporting and notification	Completeness/timeliness of reporting
	Case investigation	Percent of reported cases investigated
	Diagnostic labs	Proportion of laboratories accredited or passing proficiency test
	Active surveillance	Proportion of all active surveillance sites visited according to schedule
Service Delivery	Policy development & guidelines	Availability of 3-5 year immunization plan
	Planning, co-ordination & budgeting	ICC met on routine system at least once previous year to leverage resources
	Supervision & monitoring	Proportion of districts having immunization coverage as a priority indicator
	Intervention at point of use	Proportion of districts with sufficient health workers as indicated by immunizaiton plan

From: J. Milstien et al, WHO

Table 7: Number of Unreached Children in Low-Income Countries (Thousand)

Birth cohort 2000	**91,351**
Children vaccinated in 1998	**66,075**
Unreached children with at least 80% coverage in all countries	**11,337**
Unreached children from 80% to more than 95% coverage	**13,917**
Unreached children at more than 95% coverage	**25,276**

Table 8a: Estimates of Immunization Costs in Low- and Middle-Income Countries [1]

	Birth cohort year 2000 (thousand)	Cost at current coverage (USD million)	Cost to reach at least 80% coverage in all countries (USD million)		Cost to reach all children (USD million)	
			Additional	Total	Additional	Total
New Vaccines:						
--26 countries adding Hep B vaccine only[2]	**68,533**		**157**		**185**	
--69 countries adding Hep B and Hib[3]	**21,614**		**146**		**164**	
--43 countries adding Hep B, Hib and YF[4]	**27,482**		**208**		**254**	
Routine immunization with new vaccines[5]		**41**	**511**	**552**	**603**	**644**
Routine immunization with six traditional vaccines		**1,523**	**235**	**1,758**	**641**	**2,164**
Total cost of increased immunization coverage	**117,629**		**746**	**2,310**	**1,244**	**2,808**

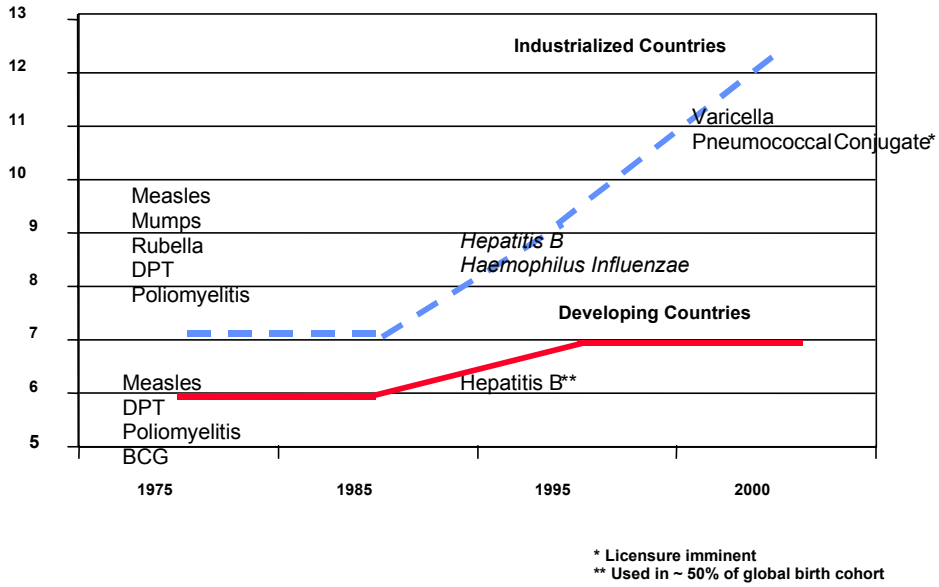
1. Equal or below GNP per capita 9,360 USD
2. Asian countries. Cost per child estimated to be 2.87 USD.
3. Cost per child estimated to be 8.50 USD.
4. African and Latin American countries at risk of yellow fever. Cost per child estimated to be 9.63 USD.
5. Introduction of Hib vaccine in all Asian countries would require an additional 333 million USD to reach at least 80% coverage and 386 million USD to reach all children.

Table 8b: Estimates of Immunization Costs in Low-Income Countries [1]

	Birth cohort year 2000 (thousand)	Cost at current coverage (USD million)	Cost to reach at least 80% coverage in all countries (USD million)		Cost to reach all children (USD million)	
			Additional	Total	Additional	Total
New Vaccines:						
--19 countries adding Hep B vaccine only[2]	**64,923**		**151**		**178**	
--22 countries adding Hep B and Hib[3]	**4,876**		**35**		**40**	
--33 countries adding Hep B, Hib and YF[4]	**21,552**		**166**		**207**	
Routine immunization with new vaccines[5]		**10**	**352**	**362**	**425**	**435**
Routine immunization with six traditional vaccines		**1,123**	**226**	**1,349**	**574**	**1,697**
Total cost of increased immunization coverage	**91,351**		**578**	**1,711**	**999**	**2,132**

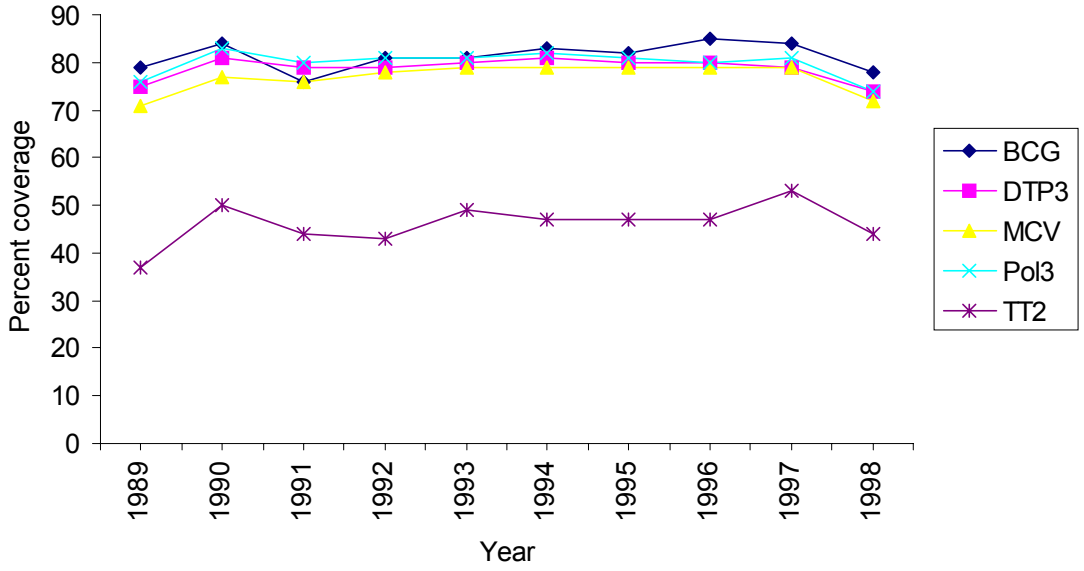
1. Equal or below GNP per capita of 1,000 USD
2. Asian countries. Cost per child estimated to be 2.87 USD.
3. Cost per child estimated to be 8.50 USD.
4. African and Latin American countries at risk of yellow fever. Cost per child estimated to be 9.63 USD.
5. Introduction of Hib vaccine in all Asian countries would require an additional 314 million USD to reach at least 80% coverage and 365 million USD to reach all children.

Figure 1: Number of Children's Vaccines Routinely Used in Developing and Industrialized Countries



(From the World Bank)

Figure 2: Global Coverage of EPI+ Vaccines, 1989 – 1998



(From WHO Vaccine Preventable Diseases Monitoring System, 1999 Global Summary)