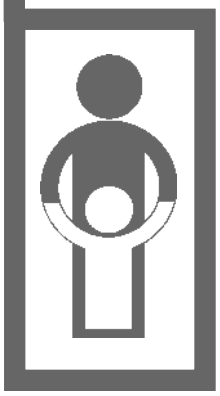
WHO/V&B/99.13
ENGLISH ONLY
DISTR.: GENERAL

Options for a Global Fund for New Vaccines



DEPARTMENT OF VACCINES AND OTHER BIOLOGICALS

World Health Organization
Geneva
1999

The Department of Vaccines and Other Biologicals
thanks the donors whose unspecified financial support
has made the production of this document possible.

This document was produced by
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Access to Technologies Team
of the Department of Vaccines and Other Biologicals

Ordering code: WHO/V&B/99.13
Printed : June 1999

This document is available on the Internet at:
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List of acronyms

ADB	Asian Development Bank
BCG	Bacille Calmette-Guerin (vaccine)
CDC	Centers for Disease Control and Prevention
DALY	Disability Adjusted Life Year
DT	diphtheria and tetanus toxoids
DTP	diphtheria and tetanus toxoids and pertussis vaccine
EPI	Expanded Programme on Immunization
GEF	Global Environment Facility
Hep B	hepatitis B (vaccine)
Hib	*Haemophilus influenzae* type b (vaccine)
IBRD	International Bank for Reconstruction and Development
ICG	International Coordinating Group on Vaccine Provision for Epidemic Meningitis Control
IDA	International Development Association
IFRC	International Federation of Red Cross and Red Crescent Societies
IPG	Interagency Planning Group on Environmental Funds
NATO	North Atlantic Treaty Organisation
NGO	non-governmental organisation
OPV	oral polio vaccine
PAHO	Pan American Health Organization
STI	Swiss Tropical Institute
TT	tetanus toxoid
UN	United Nations
UNDP	United Nations Development Programme
UNHCR	United Nations High Commission for Refugees
UNICEF	United Nations Children's Fund
US	United States
WHO	World Health Organization

Executive summary

Trust funds are flexible financial instruments that can take many forms and perform a variety of functions. The choice of form, function and mechanisms for a trust fund depends on what the trust fund is meant to achieve. Goals for a trust fund are policy goals and are based on values. In a world of resource constraints and where a range of viewpoints is expressed, trade-offs must be made between one or more goals. Because these trade-offs are themselves policy decisions, they should be explicit and justifiable, and ideally, they should represent a consensus among key stakeholders.

Currently, a Global Fund for New Vaccines is being put forward as one possible part of a system for expanding and improving vaccination. In this paper, five parameters of such a fund are explored. These five parameters are: equity, impact, feasibility, sustainability and scope. For each, goals such as access, effectiveness, and independence are discussed. The discussion includes an analysis of which other goals are compatible and which would involve trade-offs. Arguments are presented both in favour and against each.

Examples of real and proposed funds are presented as illustrations. These scenarios include details of eligibility, vaccines to be provided, mechanism, payment, sources of capital, order of magnitude estimates of capital requirements, administrative structure, and implementation. Each of these is analysed to show how well they fulfill each of the potential goals of a fund.

Opportunity costs of a Global Fund for New Vaccines are examined. Investment of fund capital is expected to provide returns of approximately 8% per year (Levine, Batson and Sakai, 1999). However, measures of burden of disease that take into account discounting, such as the Disability Adjusted Life Year (DALY), discount human life at 3%. Therefore, the economics of the opportunity cost analysis degenerates into a battle over the arbitrary nature of the DALY discount factor.

Opportunity costs are therefore best expressed in terms of the potential gains in influence over supply issues and in advocacy for improved and expanded vaccination that a Global Fund for New Vaccines would offer, as compared with the advantages of a more tailored country level approach. Examples such as the Global Environment Facility have shown, however, that it is possible to establish a global fund with global goals that would seed country level funds and thereby exert influence on policies without impairing autonomy, sustainability and ownership at the country level. It is expected that all of global, regional and country level initiatives would result in the leverage of further financing for vaccination.

Conclusions include quick reference tables on potential goals for a Global Fund for New Vaccines, lists of compatible goals, and lists of potential trade-offs. Recommendations are to pay special attention to lessons learned in innovative financing in other sectors, to continue to explore financing options, to build consensus among stakeholders on goals and trade-offs for a possible Global Fund for New Vaccines, and to move forward to the preparation of a proposal for such a fund.

1. Introduction

This paper is a discussion of options for a Global Fund for New Vaccines, which is considered as a possible mechanism to address financing issues for "new" vaccines, such as *Haemophilus influenzae* b vaccine (Hib), Hepatitis B vaccine (Hep B), and future vaccines against rotavirus and *Streptococcus pneumoniae* (pneumococcus). Vaccines against yellow fever and rubella might also be considered part of this group.

Choices for directions a Global Fund for New Vaccines could take are examined in an effort to make explicit the values and trade-offs that go into choosing goals. The paper illustrates some of the possible trade-offs. The paper does not make recommendations for the goals of a Global Fund for New Vaccines, but is meant as a tool for policy-makers and their technical advisers to make choices on possible fund goals and to build consensus. Reaching a consensus on the utility of a Global Fund for New Vaccines and its goals is seen as a vital first step in determining mechanisms and management structures.

This paper limits itself to a discussion of directions for use of returns from such a fund. Strategies for raising the capital and for investing the capital are not considered here. Procurement strategies and other vaccine supply mechanisms are not discussed in depth but influence over these issues is considered in relation to different possible fund mechanisms. It is assumed that a possible Global Fund for New Vaccines would be part of a system for improvement and expansion of vaccine programs, and could include finance for new vaccine development, infrastructure development and maintenance, the development of human and infrastructural capacity.

1.1 Background

In a world of decreasing support for publicly funded development initiatives, strong coalitions are needed to build the confidence of financier agencies and individuals. These coalitions should work wherever possible to attract funds through sound proposals based on cooperation between key players to optimise the productivity of available resources. This requires consensus building between stakeholders.

Policies are based on goals. Goals are based on values. Rationing of health services, priority setting and health resource allocation decisions are policy decisions that are ultimately value based. Financing is a resource and its management is therefore also value based. This paper aims to make explicit the value choices that always underlie the definition of goals. This is meant as a first step in consensus building, and ultimately the preparation of a proposal to expand financing for vaccination.

The intended product is a tool for policy-makers and their technical advisors in making decisions and building consensus about the goals and policies associated with a possible Global Fund for New Vaccines. Decisions on the mechanisms and implementation of such a fund flow from goal choices, as is illustrated here.

1.2 Approach

This paper is designed as a toolkit for use in moving towards creating financing for improving and expanding vaccination. The focus here is on financing new vaccines, but it is recognised that such financing must be part of a broader system. First of all, critical success factors as determined by experience in vaccine finance as well as by experience in other sectors are reviewed and compiled. Secondly, options for new vaccine finance are explored systematically.

Five parameters have been identified that can guide fund design. These five parameters are equity, impact, feasibility, sustainability and scope. Each of these parameters encompases goals for fund design, such as effectiveness, transparency and sustainability. Clearly, each of these goals can be rendered absurd when taken to its logical extreme, and it is expected that trade-offs will occur. However, it is useful to consider each to see how favouring one goal or set of goals will affect fund design, and ultimately, the outcome of investment.

It is also useful to consider what trade-offs would have to be made to accommodate two or more goals that are not directly compatible, for example, between equity and efficiency. In discussing these trade-offs, it is assumed that there is a "utility curve" of possible outcomes that would all be equally acceptable. In other words, different combinations of equity and efficiency may all have the same utility (desirability) for the "global coalition". However, the shape and position of such utility curves are determined by values that cannot be ascertained through theoretical analysis.

Examples of real and proposed financing mechanisms are analysed and compared to show how they emphasize a certain goal or goal set. This illustrates how the choice of goal can affect performance. The illustrations are aimed at making explicit what are often hidden value choices.

Finally, the opportunity costs of the fund are considered, in terms of the potential impact on burden of disease of the fund interest over time, compared with the impact on burden of disease should the fund capital be immediately invested in the management of vaccine preventable disease. It is assumed that the a Global Fund for New Vaccines will have similar potential for leveraging additional finance as other vaccine finance mechanisms.

Conclusions consist of a set of quick reference tables and suggestions for next steps. The aim here is not to propose which options to select, but to provide a tool that will clarify the selection process.

1.3 Assumptions

The following assumptions have been made in formulating arguments and in modeling possible fund characteristics:

- Resources for vaccination are scarce and may be subject to rationing.
- Country contributions to vaccination will remain stable or grow.
- Financier and other partner contributions to vaccination will remain stable or decrease.
- A Global Fund for New Vaccines would not address research and development costs for new vaccines.
- A Global Fund for New Vaccines would not finance purchases of the basic six EPI vaccines: BCG, DTP, DT, TT, polio and measles.
- A Global Fund for New Vaccines would finance infrastructure only in exceptional circumstances.

1.4 Five parameters of vaccine finance and related goals

The five parameters of new vaccine finance to be considered in this paper are equity, impact, feasibility, sustainability and scope. In some cases, several goals are relevant for a given parameter, as described below.

1.4.1 Equity

Access: Everyone has a right to vaccines and those who are most at risk of infection and its complications, the poor, the malnourished, the sick, should have priority in accessing vaccine financing. This could mean that resources would go into providing vaccines in the poorest, most remote and the most war-torn areas, even where such work is difficult, risky and expensive and co-financing is required for vaccine-related infrastructure and personnel.

1.4.2 Impact

a) Effectiveness: Global vaccine finance should be allocated in order to maximize the reduction in burden of disease per dollar spent on new vaccines. This could mean that people with easy and cheap access to health services would be much more likely to have access to vaccine than people in remote, underserviced areas, and countries that are “risky” investments due to poor infrastructure or political instability would be avoided.

b) Coverage and speed: Global vaccine finance should be allocated in order to vaccinate as many children as possible with the new vaccines, as quickly as possible. This could mean that countries with highly functioning delivery systems and concentrations of population in urban areas would be favoured for financing, regardless of the risk of vaccine-preventable disease faced by these populations. Emphasis on speed of implementation may also bias programmes against capacity building, which takes time.

1.4.3 Feasibility

a) Feasibility: Global vaccine finance should be planned such that the capitalisation required is attainable, and the coalition of capitalisers, technical experts and participating governments is broadly supportive of the plan, and there are local champions with enough power to galvanise implementation. Local absorption capacity also needs to be assured. Further, financing should take into account population level demand for the vaccines based on perceived risk. The rationale behind this is that perceived risk is a key determinant of care-seeking behaviour and could have a significant impact on access and effectiveness. This could mean that the financing is severely limited in scope, perhaps due to artificial constraints, or is not cost-effective.

b) Transparency: Global vaccine finance should be seen to be fairly distributed among target groups, according to an explicit, transparent process. This could mean that mechanisms such as a ceiling for financing to any one country, or a minimum number of recipient countries would be used to ensure that one or a few countries do not monopolise financing.

1.4.4 Sustainability

Independence: From a global perspective, vaccine finance should be used to encourage the development of sustainable local finance mechanisms as well as to influence the expansion and improvement of vaccination, not to serve as a substitute for government financed vaccination. This could mean that governments would not have access to finance unless they can show that they have a plan to become self-sufficient in the purchase or production of quality vaccines. Such a plan may not be feasible for some of the least developed countries in the foreseeable future. From the country perspective, vaccines are a strategic resource and every sovereign nation should have the capacity to supply itself with vaccine through local production or through purchase from friendly nations. This could be construed to mean that global vaccine finance should be used to build up local or sub-regional new vaccine production capacity even where this is not cost effective.

1.4.5 Scope

a) Focus/Simplicity: Global vaccine finance should in the first instance be narrowly focussed, since it is known that success is inversely correlated with complexity. This could mean that financing would focus on providing access to one or a few vaccines only, to a select group of countries according to a set mechanism. This system would aim to increase the potential for success by reducing the complexity of the system.

b) Globalism: The vaccine finance system should be global, rather than regional, sub-regional, or country level. The rationale behind this is that the coalition that is acting to mobilise resources is global and potential sources of capital have global interests. Global scale financing may provide leverage to mobilise additional resources, influence supply issues, and motivate country level planning, expansion and improvement of vaccination. However, this may alienate potential regional or national funding sources, increase the complexity of the logistics, and ignore the possibility that some countries might be grouped according to shared finance needs. In addition, a global fund might result in the loss of country level “ownership”.

2. Lessons learned

Summarized here are lessons learned in World Bank projects as reported by Carvalho and White (1996) in "Implementing Projects for the Poor, what has been learned?" and by the Global Environment Facility (GEF) Secretariat (1998) in their review of thirteen conservation trust funds.

2.1 Development project critical success factors

Distilled from Carvalho and White's review of World Bank projects, critical success factors include the following:

- Quality of leadership and planning including analysis of socioeconomic factors;
- Use of culturally appropriate management techniques;
- Clarity on both objectives and targets;
- Relative prices;
- Government commitment;
- Specificity: project benefits clearly defined and identifiable;
- Targeting: project benefits a well defined group;
- Speed: project benefits materialise quickly;
- Competition: pressure on project managers to perform to a high standard;
- Politics: an appreciation of the interest groups that will influence project implementation; and
- Multiple viewpoints: the project must draw on all perspectives.

2.2 Critical success factors for trust funds

The most useful set of lessons may be the GEF Secretariat's conclusions on critical success factors for trust funds. Success factors that apply to a Global Fund for New Vaccines include the following:

- Absence of major, urgent threats/problems requiring mobilization of large amounts of resources in a short period. The presence of these threats would favour a project format or budgetary support rather than a trust fund. Trust funds work best where action is required over a long period, 10-15 years or more, and within the financial bounds of the revenue a trust fund can produce. This is a strong argument against using a trust fund to finance large one-off purchases such as cold chain infrastructure.

- The support of governments of the concept of a fund outside their direct control. Support may be manifested by financial contributions, if not to the fund, then as co-financing for related activities.
- A legal framework that permits the establishment of trust funds that are tax exempt. This includes a network of skilled and respected experts in banking, accounting, legal and financial practices. This may restrict the home base of the fund to a country with a well-developed legal and financial infrastructure.
- "A critical mass of people with a common vision." This may be the "global coalition" including representatives of the governments, agencies, foundations, civil society groups, corporations and individuals who would design, contribute to, manage, disburse, use, monitor, evaluate, and receive payments from such a fund.
- "Mechanisms to involve a broad set of stakeholders during the design process, and willingness of stakeholders to use these mechanisms." The current set of meetings on the development of innovative financing mechanisms confirms that this condition is being met.
- "Availability of one or more mentors -...twinning with another, more experienced trust fund – who can provide both moral and technical support to the fund during the start-up and program implementation phases."
- "Realistic prospects for attracting a level of capital adequate for the fund to support a significant program while keeping administrative costs to a reasonable percentage." Most trust funds reviewed by the GEF secretariat have operating costs equivalent to or lower than 20-25% of revenue, which includes day to day costs of doing business. This does not imply a huge amount of capital and it seems very likely that a Global Fund for New Vaccines could easily meet this requirement.
- "An effective demand for the fund's product." The key point here is that effective demand is linked with absorption capacity. Effective demand is the demand for financing by groups that can absorb it effectively. This is a very important issue that needs to be researched and documented before a Global Fund for New Vaccines is established and before calculations can be carried out on capitalisation requirements.

2.3 "Notorious" problems that could befall a trust fund

In 1988, Gow and Morss put together a list of the "notorious nine" causes of project failure (reviewed in Carvalho and White, 1996). Drawing from that list, particular problems that may apply to a Global Fund for New Vaccines include the following:

- Different agendas;
- Institutional realities;
- Technical assistance; and
- Political, environmental and economic constraints.

3. Equity

3.1 Working definition

Equity in health care means that: "Health care resources are allocated according to need, health services are received according to need, and payment for health services is made according to ability to pay" (Braveman, 1996). True equity means that special attention must be paid to gaps in level of service between genders, between geographic areas, between racial groups, between age groups and between socio-economic classes within a country.

3.2 Goals consistent with equity

Characteristics of equity as a goal are that it is consistent with goals of speed, transparency, capacity building, and potentially globalism. In some cases, coverage can serve as a proxy for access as an indicator, but the goal of coverage is not always consistent with the goal of equity.

3.3 Potential trade-offs

Considerations of equity most often involve trade-offs with goals of efficiency, coverage, feasibility, sustainability, and focus/simplicity. However, equity is consistent with efficiency when the practice of efficiency greatly reduces or eliminates the need for rationing. In this discussion, it is assumed that rationing of resources will be required.

3.3.1 Access

Table 1: Access summary

Goal: Access	Everyone has access to the vaccination-related health resources and health care services they need.
Consistent goals	Speed, transparency, sustainability (capacity building), and globalism.
Goals requiring trade-offs	Efficiency, coverage, feasibility, sustainability (financial), and focus/simplicity.
Arguments for	Meets ethical goals of equity, solidarity, and social justice. A human right. Can be effective when other sectors' required contributions are taken into account.
Arguments against	Low feasibility. Low effectiveness. Does not promote financial sustainability. High cost.

a) Arguments for access

In the World Health Declaration, all member states affirm that they are committed to the ethical concepts of equity, solidarity and social justice. This declaration was reaffirmed in May, 1996 by the World Health Assembly in its resolution WHA48.16 in which it called for … "developing a new holistic health policy based on the concepts of equity and solidarity,"…(WHO, 1998). Other international human rights instruments that address the equity issue include the 1966 International Covenant on Economic, Social and Cultural Rights; the 1979 Convention on the Elimination of All Forms of Discrimination Against Women; and the 1989 Convention on the Rights of the Child. Equity is ethical. All people have a right to vaccination. Access to vaccination for all is fair (Braveman, 1996). However, there is a strong tendency in health systems to allocate more resources to those who already have more (Braveman, 1996).

By definition, people without access to vaccination are underserviced and are among the world's neediest groups. Therefore, the demands of equity are that these people be the first priority in any further investments in vaccination. This means that according to the principle of equity, investment should be made into giving vaccine access to people who are currently underserviced before extending the services of those who already have acccess.

b) Arguments against access: feasibility and efficiency

It can be argued that given the current level of effort and investment in vaccination, those people who do not currently have access to vaccination are cut off by nearly insurmountable physical, political or institutional barriers, and these people cannot feasibly be given access in the foreseable future. Any additional expenditure focused on those groups at this point will be wasted.

Or, if there do exist unserviced groups which could be given access to new vaccines, reaching them would be very expensive. In fact, due to actual resource constraints, providing access to those groups might have the effect of depriving a greater number of others at a similar level of need. Therefore, for reasons of feasibility and efficiency, further efforts to achieve equity are not to be pursued for the introduction of new vaccines. New vaccines should be introduced only where feasibility and efficiency have been proven through experience with vaccines such as DTP that are available at low or no cost.

4. Impact

Maximizing positive impact has different meanings depending on what value you place on different impact goals. Effectiveness, coverage and speed are all aspects of impact that are in themselves distinct goals. Coverage and speed are considered together as they make similar demands on systems.

Where resources are scarce, the goal of coverage is consistent with speed, transparency, and globalism. Where resources are more abundant, coverage can also be consistent with equity, feasibility, solidarity, and sustainability. However, in most cases it is likely that trade-offs will have to be made between coverage and equity, effectiveness, feasibility, sustainability, solidarity, capacity building, and focus/simplicity.

The goal of speed is consistent with equity, effectiveness, coverage, solidarity, focus/simplicity, and globalism. Trade-offs will have to be made between speed and feasibility, transparency, sustainability, and capacity building, although speed is consistent with the development of infrastructure for vaccine delivery.

4.1 Effectiveness

Working definition: Maximizing reduction of burden of disease per dollar.

Consistent goals: The goal of effectiveness is consistent with goals of feasibility, speed, transparency, financial sustainability, focus/simplicity, and globalism.

Trade-offs: Trade-offs may be necessary with equity, coverage, and sustainability in terms of capacity building.

Table 2: Effectiveness summary

Goal: Effectiveness	Vaccination resources are used so that the total reduction in burden of new vaccine-preventable disease per dollar is maximised.
Consistent goals	Feasibility, speed, transparency, financial sustainability, focus/simplicity, and globalism.
Goals requiring trade-offs	Equity, coverage, and sustainabilty in terms of capacity building.
Arguments for	Reduces need for rationing. Elegant. Appeals to financiers.
Arguments against	Difficult to measure. Introduces bias against those in greatest need. In so far as it ignores equity, it is contrary to goals of international declarations on health and children's rights.

4.1.1 Arguments for effectiveness

The main argument in favour of effectiveness is that it may reduce the need for rationing by stretching the available resources. On the other hand, rationing on the basis of effectiveness is subject to many problems.

Cost effectiveness in terms of burden of disease averted per dollar is a very useful measure, and its elegance and power are very appealing. It has been proposed as one tool for use in determining a basic package of health services by the World Bank as detailed in the 1993 World Development Report "Investing in Health".

4.1.2 Arguments against effectiveness: equity and uncertainty

Effectiveness is often very difficult to measure. Units of effectiveness are typically expressed in terms of burden of disease averted per dollar. Burden of disease is itself an exceedingly complex concept and often defies measurement. In the developing country context, data to support measures of burden of disease is often lacking or unrealiable. In addition, because of the multi-factorial nature of the burden of disease, it is not always clear what proportion of the burden as indicated by statistics is due to vaccine preventable disorders.

Even given accurate burden of disease data, it is difficult to predict the impact of increased investment in vaccines and related capacity. Cost effectiveness data calculated on current expenditure and savings in burden of disease cannot always be extrapolated to predict future reductions in burden of disease following additional investment because a) unanticipated additional infrastructure and institutional capacity may be necessary to increase access beyond currently serviced areas and population size and b) current access may extend to all of the readily accessible population, making further gains in access orders of magnitude more difficult, or logistically close to impossible in the case of regions in active warfare.

A further problem with effectiveness as a goal is that it tends to result in policies that are biased against the neediest, poorest, most isolated people because it typically costs more to reach these people per unit of burden of disease saved. Effectiveness might also work to slow the introduction of more expensive technologies that may be safer, easier to use, easier to transport and store and thus more likely to reach the neediest populations. This goal would not distinguish between prevention of diseases that affect a large number of people to a minor degree, and than those that affect a smaller number of people, but with a greater toll of pain and suffering, or loss of life for affected individuals.

4.2 Coverage and speed

Working definition: Meeting the goals of coverage and speed means that as many people as possible are provided with the full set of vaccinations they need, as quickly as possible.

Consistent goals: Coverage and speed are consistent with globalism. Where resources are not constrained, coverage and speed are consistent with access.

Trade-offs: Trade-offs include effectiveness, sustainability (capacity building and financial), feasibility, transparency, and focus/simplicity. In the context of resource constraints, a trade-off would include access.

Table 3: Coverage and speed summary

Goal: Coverage	As many people as possible are given the vaccinations they need, as quickly as possible.
Consistent goals	Globalism. Access, if there are no resource constraints.
Goals requiring trade-offs	Effectiveness, sustainability (financial and capacity building), feasibility, transparency, and focus/simplicity.
Arguments for	Meets EPI goals. Politically expedient. Easy to measure.
Arguments against	Bias against remote/isolated groups. Does not provide incentive for sustainability.

4.2.1 Arguments for coverage and speed

The policy of the Expanded Programme on Immunization (EPI) is stated principally in terms of coverage and burden of disease: reduction of measles incidence, elimination of neonatal tetanus, eradication of polio and the achievement of 90% immunization coverage for all vaccines (Immunization Policy, WHO/GPV/GEN/95.03). Coverage is the most widely reported statistic in EPI work. It is perhaps the best tool available for the evaluation of the effectiveness of vaccination campaigns in the short term, and it is easily understood by the public, by potential fund capitalisers, and by other key stakeholders.

Where pain and suffering are involved, and when children are losing the chance for education due to illness, speed is an ethical imperative. Because burden of disease is often discounted over time, fast delivery increases efficiency by maximising the reduction in burden of disease per dollar. Speed is good financial management because every moment that supplies sit on shelves or trained personnel are idle is investment income lost. Fast delivery increases confidence in the system on the part of consumers, client countries and fund capitalisers.

Lesson learned on slow procurement

According to a World Bank report (Carvalho and White, 1996), procurement is a major cause of slow implementation. “Causes are deficient standards in the preparation of bidding documents, lack of experience among responsible project personnel, disagreement over proposed procedures, and inadequate attention to procurement issues during appraisal. In Africa, inexperience is the main problem. In the Middle East and North Africa, disagreement on procedures is the principal difficulty. Solutions include training both provider and recipient staff in procurement procedures, creating procurement units or designating procurement staff in international agency resident offices, and assisting governments in revising procurement procedures. The issue is usually country level, not project level.”

4.2.2 Arguments against coverage and speed

The most compelling argument against coverage as a goal is that it does not take into account health outcomes. Health outcomes may fall short of expectations even with high coverage if quality of care is low, if vaccine quality is low, and if risk of disease in the covered population is low.

Like effectiveness, coverage is easiest to achieve where there is good infrastructure. This leads to an immediate bias against the remotest groups, which are also more likely to be poorer and to have lower health status due to the difficulty of accessing social services and markets. Therefore, setting coverage as a goal can also be unfair and unethical if it increases disparities in access to health services.

In addition, as for effectiveness, it is often difficult to determine coverage accurately. Organisations and agencies often have incentives to either over- or under-report coverage, whether to meet targets, or to claim eligibility for assistance. Therefore, setting coverage as a goal or as eligibility criteria may in itself contribute to uncertainty in reported coverage data.

The difference between coverage as a goal and effectiveness as a goal is that coverage can be achieved even without significant reduction in burden of disease. The most efficient way to increase coverage is to vaccinate first all the highly accessible people who have the ability to pay for vaccination. However, these people are often not the most seriously affected by vaccine-preventable disease. Therefore, maximising coverage may not maximise progress towards reducing burden of disease nor will it directly address concerns of equity or provide vaccines to the neediest people.

Speed as a goal may raise the cost per dose above financially feasible levels by increasing requirements for technical assistance, transport and so on. The demands of transparency may slow down processes and introduce bureaucratic requirements that reduce speed. Sustainability and independence may also require more time in order to make sure national authorities have a chance to master new processes and develop the internal systems necessary for good management of new financial mechanisms, accounting practices, new vaccines or expanded programmes. For the same reasons, speed may run counter to efforts at capacity building, although speed is consistent with development of infrastructure.

5. Feasibility

In this chapter, feasibility criteria are examined as a constraint and the related characteristic of transparency is also discussed at length due to its particular importance in trust fund management. Note that project failure points and success criteria as well as experiences gained in trust fund establishment and management are discussed at length in "Chapter 2: Lessons learned", above.

5.1 Feasibility

Feasibility would seem to be an indispensable characteristic of any project. However, the issue here is that feasibility is often determined through subjective criteria. Many projects, from sailing around the world to flying to the moon, have been labeled "impossible". The essential consideration is to make sure the project has no obvious "fatal flaws" while avoiding the mistake of thinking too small, and discarding a valuable plan because of imagined barriers. The question is how strict the feasibility criteria should be.

Working definition: The absence of a "fatal flaw". This entails adequate capitalisation, acceptance by key stakeholders, effective demand, technically and financially sound implementation, limited complexity, transparent systems, and good management.

Consistent goals: Goals consistent with feasibility are effectiveness, focus/simplicity, moderate levels of transparency, moderate requirements for independence/ sustainability, and globalism. The essential element of feasibility is that these goals not be taken to their extreme limits, that trade-offs be made between them, and that compromises are accepted when called for.

Trade-offs: Trade offs include access, coverage, speed, high levels of transparency, and absolute requirements for independence/sustainability. It is even possible to say that the absence of trade-offs between other goals is inconsistent with feasibility.

Table 4: Feasibility summary

Goal	The absence of a "fatal flaw". This entails adequate capitalisation, acceptance by key stakeholders, effective demand, technically and financially sound implementation, limited complexity, transparent systems, and good management.
Consistent goals	Effectiveness, focus/simplicity, moderate levels of transparency, moderate requirements for independence/sustainability, and globalism.
Trade-offs	Access, coverage, speed, high levels of transparency, and absolute requirements for independence/sustainability.
Arguments for	Essential for recruiting support and developing a common vision. Encourages trade-offs and compromises to reach a common vision.
Arguments against	Estimates of financial feasibility as a constraint may underestimate long term capitalization achievable, artificially limiting impact. Difficulty in determining what is feasible.

5.1.1 Arguments for feasibility

A sound analysis of financial, political and technical feasibility can serve to rally support for a concept, reduce wastage of time and resources in the pursuit of flawed options, facilitate consensus-building and break down artificial barriers to innovative or new directions.

One example of analysis of feasibility criteria is a study of economic and policy considerations for vaccination in Thailand (Cooper & Lybrand *et al.*, 1997). They took a close look at the pressures on vaccination programmes due to increased costs, as well as on socio-economic factors like willingness to pay, the increase in private health services, the spread of health insurance, and the political shift from curative towards preventive medicine. The key point here is that the study looked at macro level influences on the system in the context of the whole health sector, and did not arbitrarily rule out any option for vaccine financing, including user fees, insurance, managed care, and so on.

5.1.2 Arguments against financial feasibility as a constraint

It is very difficult to predict the supply of capital for a Global Fund for New Vaccines. This is in part because there are untapped sources of capital for health trust funds, and in part because capitalisation may depend very much on proof of concept during a fund's early years. There is a danger of artificially limiting the scope of a fund due to misperception of feasibility limits or of dismissing unconventional but valid sources of capital.

5.2. Transparency

Working definition: Verifiable, responsible fund management according to agreed procedures, supported by appropriate documentation. Transparency is perhaps not so much an end goal for a finance facility as an aspect of feasibility. However, because transparency is so important in determining progress towards all other goals, it is discussed at length here.

Consistent goals: Goals consistent with transparency are access, effectiveness, feasibility (when transparency demands are not excessive), sustainability (financial and capacity building), and globalism.

Trade-offs: The main trade-off is simplicity. If the demand for transparency is very high, then effectiveness and feasibility are also trade-offs.

Table 5: Transparency summary

Goal	Verifiable, responsible fund management according to agreed procedures, supported by appropriate documentation.
Consistent goals	Access, effectiveness, feasibility (when transparency not excessive), sustainability (financial and capacity building), globalism.
Trade-offs	Focus/simplicity. If demand for transparency is high, feasibility and effectiveness.
Arguments for	Transparency is essential for good management that learns from experience, to adjust practices to maximize impact, to assure financiers that resources are being used responsibly, to protect clients and to prevent fraud, corruption and misallocation of funds.
Arguments against	High demands for transparency can lead to excessive bureaucracy and the need for administrative procedures that divert resources and limit flexibility, effectiveness and responsiveness.

5.2.1 Arguments for transparency

Transparency is essential to maintain the confidence of financiers, and other partners in financing vaccination. In the absence of transparency, the task of effective management is nearly impossible, and potential clients may be put off by opaque procedures and the lack of clarity on process. Transparency is needed in order to improve the quantification of costs, efficient project management, and effective use of resources. It is also a means of preventing abuse of fund resources.

5.2.2 Arguments against high demands for transparency

Although it is clear that affairs must be managed responsibly, experience in conservation trust funds (GEF Secretariat, 1998) shows that there has been too much pressure on a limited human resource pool to meet excessive administrative demands for transparency. These demands are generally financier-driven and have the effect of greatly increasing bureaucracy while decreasing flexibility and speed of response.

The Global Fund for Women is an example of a quick-response fund that responds to applications received in any form. It has very limited bureaucracy and loose criteria. It works well, but awards are small. Information on the fund and its mechanism of operations is available from its web site (www.igc.apc.org/gfw/gfw.html). The Grameen Bank of Bangladesh is another example of an easily accessible, highly successful system of limited bureaucracy. It was founded to counteract the demands for collateral, written reporting for transparency, etc., of the formal banking sector (see www.grameen.com). However, again the amounts disbursed per client are small. The key issue is to strike a balance between the demands for transparency from financiers and the drag of bureaucracy on fund operations.

6. Sustainability

Sustainability has two main aspects in this context: capacity building and financial sustainability. Both are elements of independence at the country level. However, financial sustainability at a global level is possible even where some individual countries do not have the ability to pay for new vaccines.

6.1 Independence

Working definition: Independence is long-term, sustainable, financial, technical and logistical self-reliance in the satisfaction of needs for high quality vaccines and related health products and services.

Consistent goals: If the development of independence is made the priority goal of a vaccination programme, then effectiveness and transparency are the only other goals that are consistent.

Trade-offs: Independence as a priority will reduce the access of those with little or no ability to pay. Therefore, access is a trade-off. Similarly, coverage and speed are trade offs. In addition, demands for speed can bias programmes against capacity building. Independence at country level is often not feasible in the foreseeable future. Further, capacity building is a complex process, therefore, focus/simplicity would have to be compromised if the development of country capacity were the priority. Globalism implies mutual cooperation, whether in financing or in purchasing, and this implies some loss of autonomy at the country level.

Table 6: Independence summary

Goal: Independence	Long-term, sustainable, financial, technical and logistical self-reliance in the satisfaction of needs for high quality vaccines and related health products and services.
Consistent goals	Efficiency and transparency.
Trade-offs	Access, coverage and speed, feasibility, focus/simplicity and globalism.
Arguments for	Reduction of dependency fosters autonomy and socio-economic development. Lessens reliance on financiers and other international partners.
Arguments against	May bias fund against those with little or no ability to pay now and in near future. May have negative impact on quality. Increases complexity and capital demands if extensive capacity building is to be financed through the fund. Could reduce leverage of fund on supply side if purchases are made autonomously.

6.1.1 Arguments for independence

As indicated in the plan of the February 1999 meeting of the Children's Vaccine Initiative, overall financial aid in real terms has been declining. It is becoming harder to find funds to cover recurrent costs, and there is reduced financial assistance for immunization. According to the CVI (February 1999 meeting plan), sustainability in financing capacity consists of but is not limited to:

- "The accurate estimation of costs associated with vaccination efforts.
- The prediction of future needs including programme expansion.
- The ability to mobilize appropriate national financing for immunization.
- The creation of financing mechanisms which are relatively 'robust' (can continue to meet specified needs despite variances in the political and economic situations).
- Smooth transitions where shifts in financing sources and/or mechanisms are required so as to avoid gaps.
- Efficiency in the use of financing."

Sustainability and country commitment make sense for a number of reasons:

- Governments have committed themselves to take responsibility for the health of their people in the World Health Declaration and in other agreements such as the Declaration of the Rights of the Child.
- Dependency on international partners for financing can result in unreliable supply and stockouts.
- Dependency runs counter to socio-economic development.
- Health policy should recognise the power of preventive health measures by making them a priority for investment within the health sector.
- Macroeconomic policy should recognise the important contribution of human capital to development and should make social needs such as vaccination a priority in public spending. Some countries have committed themselves to spending 20% of their budgets on social issues through the UN's 20/20 initiative.

Independence is also desirable to ensure that external financial is not taking the place of government funding but complementing it.

6.1.2 Arguments against independence as a constraint on fund access

Independence and self-reliance are irrefutable development goals. However, there are problems with using independence in vaccine finance as a goal in isolation. Furthermore, there are strong arguments for the development of buyers groups in the purchasing of vaccines and related products, even under conditions of financial independence. This implies a trade-off between autonomy and solidarity in procurement.

The key problem with making independence or a commitment to independence in financing vaccines a criteria for fund access is that it does not imply a sector approach to health finance planning. It also fails to address the reality that some countries may not realistically expect to be able to pay the full costs of vaccination in the foreseeable future. In order to make sure that countries move forwards towards self-reliance while contributing towards an integrated effort at rational sector planning (which is possible, even in the poorest countries) means-testing for subsidised vaccine purchases should be coupled with technical assistance for health sector planning.

In some cases, a long term (10 year) projection of financial needs and resources together with lobbying and advocacy for support may result in a plan that involves continued long term support for vaccine subsidies from a Global Fund for New Vaccines. The prospect of such long term reliance on the fund, in the context of a sector plan, should not be used to disqualify potential fund clients, if there is clearly a justifiable need. On the other hand, sector planning should emphasize the cost-effective nature of vaccination and provide arguments for its support in country budgets. This is a key opportunity to provide health ministries with rational arguments for increased spending on preventive health measures.

7. Scope

7.1 Focus/simplicity

Working definition: Resources are concentrated on limited goals and systems are simplified in order to minimize potential failure points and maximise the chances of achieving the chosen goals.

Consistent goals: A simple, focussed fund is likely to be more feasible than a more comprehensive initiative. Streamlined processes should prove faster, and more effective. Although the goals of simplicity and focus do not promote independence, they are compatible with it.

Trade-offs: Globalism implies a level of complexity that is incompatible with this goal. Focussing on a specific set of vaccines will involve compromise on increasing coverage and access to those not financed by the fund. However, there could be some positive spill-over effects.

Table 7: Focus/simplicity summary

Goal	Resources are concentrated on limited goals and systems are simplified in order to minimize potential failure points and maximise the chances of achieving the chosen goals.
Consistent goals	Feasibility, speed, effectiveness, independence.
Trade-offs	Globalism, access, coverage.
Arguments for	Critical success factor, ethically defensible. This system enhances feasibility by approaching larger goals one discrete but achievable step at a time.
Arguments against	Opportunity costs of restricting investment.

7.1.1 Arguments for focus and simplicity

According to a 1992 World Bank task force (Carvalho and White, 1996), project downfall is linked with complexity. The fewer the objectives, components and sponsors, the more likely the project is to succeed. These arguments point to focus and simplicity as key success factors.

7.1.2 Argument for a new vaccine focus

Arbitrary distinctions between groups, such as geographical, may not be ethically defensible, but as Outka is quoted in Childress (Soundings, 62, (Fall 1979) 258-269 in Bioethics), it is more just to discriminate by category of illness, for example, rather than between rich-ill and poor-ill. According to ethical theory, diseases that are the cause of greater burden of disease in terms of pain, suffering and age of onset, as well as cost, should be given priority in decision-making.

The theory behind this is that resource allocation would then follow the same values as individuals express in their desire to avoid pain and suffering. Therefore, the ethical arguments support focussed allocation of funds according to category of illness, with priority to those that cause the greatest burden of disease. These arguments support a fund focussed on the provision of specific vaccines.

7.1.3 Arguments against a new vaccine focus

The principal arguments against a focus on new vaccines are the opportunity costs. That is, the potential benefits lost that could have accrued through spending fund revenues on capacity building such as training or cold chain expansion, or on increasing coverage for the standard EPI six vaccines, for example.

Alternatives include different potential niches for a fund for new vaccines. These niches could be geographical, socio-economic, epidemiological, technical or logistical. For example, the fund could focus on just one or two vaccines, on a region, on countries with certain socio-economic characteristics or epidemiological profiles. The niche could be determined in the design process, as a consequence of the preferences of the stakeholders, or as a result of lessons learned and experience after the fund is established.

7.2 Globalism

Working definition: A worldwide system of finance, technical assistance, procurement, and supply is coordinated to profit from economies of scale in manufacturing, demand forecasting, market intelligence, bulk purchasing and access to foreign exchange. The system functions to assure financiers of responsible use of resources and to leverage co-financing and improved vaccination systems through advocacy and other innovative mechanisms. Long term impacts include market transformation in the form of increased demand for vaccines, and thus the creation of incentives for the development of new vaccines and related technologies.

Consistent goals: In broad terms, a global fund should be compatible with goals of effectiveness, through economies of scale and bulk purchasing, and coverage of new vaccines.

Trade-offs: Trade-offs that would be made for a truly global system including a Global Fund for New Vaccines are focus/simplicity, independence (autonomy in purchasing), feasibility (large capitalisation), coverage of standard six EPI vaccines (through opportunity costs), transparency, and speed.

Table 8: Globalism summary

Goal	A worldwide system of finance, technical assistance, procurement, and supply is coordinated to profit from economies of scale in manufacturing, demand forecasting, market intelligence, bulk purchasing and access to foreign exchange.
Consistent goals	Access, effectiveness, and coverage.
Trade-offs	Focus/simplicity, independence (autonomy in purchasing), feasibility (large capitalisation), transparency, and speed.
Arguments for	Leveraged co-financing, purchasing, and improved vaccination systems through advocacy and other innovative mechanisms. Market transformation in the form of increased demand for vaccines, and thus the creation of incentives for the development of new vaccines and related technologies.
Arguments against	Complexity leading to potential failure, loss of country level autonomy, and difficulties in achieving adequate capitalisation.

7.2.1 Arguments for a global fund

A global vaccine fund is a unique opportunity to influence policies at the local, national, regional, and global levels in industry, in government and among financiers. These policies include co-financing, pricing, production, research and development, advertising, resource allocation, and assurance of quality.

7.2.2 Arguments against a global fund

One of the principal benefits of country level funds is that there is a sense of "resource security" for in-country managers. This allows them to focus on broader issues of vaccination improvement and expansion, beyond just trying to meet immediate staffing and operating costs. In other sectors, this has had the effect of greater staff continuity at the country level (GEF Secretariat, 1998). This benefit would be lost in a global fund unless long-term planning and commitments between clients and the fund were a feature of the financing mechanism.

A global fund would tend to be complex and is likely to involve a greater number of stakeholders. This could result in a higher failure rate, more potential for bureaucratic bottlenecks, and difficulties in achieving adequate capitalisation.

The main alternative to a globally administered fund is to use the revenue from a global fund to seed country level or regional funds. This model is being used by the Global Environment Facility (GEF Secretariat, 1998). It may be possible to devise global criteria for these seeded funds. For example, the seeded funds may be required to make demands on their clients for disbursement that could include submission of national plans to WHO, and countries using these seeded funds could commit themselves to using a global procurement system.

Goals of independence and sustainability could be met by requiring country level matching of Global Fund for New Vaccines seed capital, at a ratio appropriate to the level of economic development of the particular country or sub-region. This might have positive indirect impacts such as freeing vaccination staff time from meeting

basic budgetary needs towards working towards expanding and improving vaccination, as well as decreasing staff turnover due to better working conditions and secure financing of salaries and operating costs at country level.

The country level plans could be used by the global procurement system to forecast demand, and this information could be passed on to suppliers. The purchasing power of the global procurement system, together with a dedicated market intelligence unit, should ensure a lower price for high quality vaccines. The main drawback of this system is that the lack of advocacy pressure the funds would have unless they were independent of Ministries of Health, which is unlikely. However, this might be overcome by a tiered seeding of country level funds. In other words, seed funds might be disbursed by tranche with succeeding tranche payments coming when agreed achievements are reached on the government side.

Success would depend on the choice of trustees for the coutry level fund, together with siting the fund in a context of legal and financial security. Ideally, trustees would be senior policy makers and technical experts who are prepared to act in the interests of the fund goals, rather than purely as representatives of the agencies they represent. The principle advantage of this system is the leverage that it offers in terms of raising matching funds at country level, and the benefits of ownership by the country that will result. The advantages of a country level health trust fund are well described in a brochure produced to promote the Bhutan Trust Fund (Government of Bhutan, 1998) and by Becher *et al.* (1999).

8. Existing and proposed funds and mechanisms

In this section, existing funds and mechanisms are described and analysed with respect to the goals and parameters that have been introduced in this discussion. These funds and mechanisms include the PAHO Revolving Fund, the Vaccine Independence Initiative, a proposed global fund for new vaccines (Levine, Batson and Sakai, 1999) and the preparedness fund for the finance of meningitis vaccine under the International Coordinating Group on Vaccine Provision for Epidemic Meningitis control (ICG).

8.1 ICG: A mechanism for epidemic meningitis control

One example of a transparent mechanism for the allocation of vaccines and financial resources is the International Coordinating Group (ICG) on Vaccine Provision for Epidemic Meningitis Control (ICG, 1997a,b,c, 1998). This group was formed in January 1997 in response to a need for a rational, fair and transparent vaccination resource allocation system to deal with recurrent epidemics of meningitis, initially in Africa. (Note that in December 1997 there was a decision to extend the ICG to any country in need, not just African countries.) It was not feasible to provide universal coverage of meningitis vaccine, but the populations to be vaccinated (those in epidemic areas) could not be accurately predicted from one year to the next. In addition, when the group was established, there was limited meningitis vaccine supply due to a global shortage. Therefore, there was a need to ration this resource and coordinate procurement according to a system which would ensure that as much vaccine as possible would be available to countries in greatest need. It was also important that this system be acceptable to the stakeholders.

It was initially decided that the ICG would comprise international organisations, NGOs, development agencies, technical agencies, manufacturers of meningitis vaccine and auto-destruct syringes, and any countries affected by epidemics or at risk. WHO funded the participation of representatives of three countries which had managed the epidemic at country level. The functions of the group were to make vaccine and syringe demand forecasts with a lead time of one to two years; to establish criteria for emergency supplies distribution; and to maintain and distribute an emergency supply of vaccine and injection material (ICG 1997a, p.7).

An executive subgroup was formed to expedite decision-making. It consisted of one member each of the four leading agencies in epidemic interventions which launched the appeal, namely IFRC, MSF, UNICEF and WHO. The WHO representative on the subgroup delivered the consensus position of the inter-divisional task force in WHO Headquarters, and the concerned WHO Regional Offices, particularly those of Africa and the Eastern Mediteranean. The sub-group had a mandate to respond within 48 hours of a vaccine request with either a recommendation to supply vaccine or an on-site assessment.

The strategy was a global initiative, but country level commitment was crucial. All 15 countries in the meningitis belt had national focal points, strengthened surveillance systems, and set up national and sub-regional stocks of vaccines (to be maintained with the manufacturer to avoid expiry). Some countries set aside funds to deal with epidemics and WHO offices had a budget line for emergency epidemics. A fund for $2.3 million for vaccines and auto-destruct syringes was proposed, with a plan for it to be developed into a revolving fund (ICG 1997a, p.7). The mechanism for the revolving fund was that WHO should aim to have a stock of 5-10 million doses of vaccine and auto-destruct syringes for emergency use. This stock was to be purchased after deposit of appropriate funds, then it was to be replenished as distribution under ICG and reimbursement of supplies occurred. Thus a "revolving" supply would be managed by WHO for response to special epidemic requests.

An appeal was to be prepared to set up the fund. It was envisaged that the fund would function initially as an emergency fund to be depleted according to priority needs, with no reimbursement. The fund would then be modified and established on a revolving basis to provide a sustainable mechanism for progressive self-sufficiency in meningitis vaccine procurement. The appeal was launched and raised more than US$16 million, of which nearly a quarter was sourced through WHO. Funds from the appeal were used for the 1997 emergency response. Surplus funds as well as re-imbursed funds were used as the basis of the preparedness fund, which is managed by WHO, the technical secretariat to the ICG.

Criteria were developed for the format of requests and for distribution of vaccine. The requests were to be directed to the relevant WHO regional office. Essential information in the request included the size of the population involved, the age distribution of cases, the geographical limits of the epidemic, and previous vaccination history. The requests were to be forwarded to the technical secretariat of the ICG, which included the WHO "focal point" person. The "focal point" would seek a consensus decision first in WHO and then in the executive sub-group. A positive decision to release vaccine, injection material or oily chloramphenicol from ICG stock would be made only if the 4 agencies (IFRC, MSF, UNICEF and the WHO) were in favour.

Vaccine release was based on the following criteria (ICG 1997a, p.4):

- Existence of a plan for use of the vaccine, submitted to ICG with the request;
- Exclusion of requests for vaccine for routine immunization;
- Development of a monitoring system for vaccine use and regular reporting on use to the ICG;
- Bundling of orders for vaccines with those for auto-destruct syringes, needles and safety boxes for disposal;
- Assurance of the availability of proper storage conditions for the vaccines; and
- Indication of the exact amount of vaccine already available in stock.

Indicators that the request was of a lower priority were:

- Access to vaccine already in stock;
- Delay in relaying surveillance data, leading to delayed immunization interventions which would be ineffective;
- Indication of a need for assistance in administering the vaccine (in which case such assistance should be assured when the vaccine is released).

Monitoring was carried out using simple tally sheets of doses administered by age group, provided at weekly intervals. Data on attack rates and number of cases in areas conducting epidemic response were to be submitted to the ICG.

The results were very good and questions were raised about applying the system to other vaccines. Criteria were proposed for candidate vaccines as follows (ICG 1997b):

- The vaccine should be appropriate for use in an epidemic situation;
- There should be supply problems as a constraint on epidemic response;
- Establishing and managing a reserve stock should be feasible;
- The ICG mechanism should have a positive impact and there should be resources available for the mechanism to function for the proposed vaccine.

Yellow fever was considered as a candidate vaccine, but rejected.

An evaluation of the ICG mechanism was carried out. The findings were as follows (ICG 1997c):

- All urgent vaccine needs were met;
- Rational use was made of available vaccine;
- The best price for the vaccine was obtained;
- Vaccine wastage was avoided;
- Safe injections were assured;
- Better planning at country level was carried out;
- A preparedness fund for 1998 was set up; and
- Better surveillance and preparation for epidemics in countries at risk were initiated.

However, by mid-1997, there were still country level agencies that were not aware of ICG. It was also found that the criteria for distribution of vaccines were restrictive and rigidly applied because of expected shortages of vaccine. There was also a need for improved local coordination and for monitoring of procurement outside the ICG.

An adaptive management structure was adopted, and the terms of reference of the ICG were changed as the group gained experience in managing the system.

In terms of access, effectiveness, coverage and speed, feasibility, transparency, independence, focus/simplicity and globalism, the following table (Table 9) summarises the ICG fund's characteristics:

Table 9: ICG summary

Goal	ICG fund characteristics
1. Equity: Access	Excellent provision of affordable access to the neediest people in limited focus area, justifiably chosen: High
2.1 Impact: Effectiveness	Highly effective in terms of reduction of burden of disease and focused allocation of limited supplies: High
2.2 Impact: Coverage and speed	Extremely limited coverage (epidemic response only, few countries, and only one vaccine), but very quick response: Low coverage, high speed
3.1 Feasibility	Proven approach: High
3.2 Feasibility: Transparency	Transparent allocation and administrative system: High
4. Sustainability: Independence	Encouragement of financial independence through evolution of revolving fund. Relationship with capacity building and technical assistance, though not funded directly: High
5.1 Scope: Focus/simplicity	Highly focused on one vaccine for use in the African meningitis belt, therefore relatively simple in procedures and management: High
5.2 Scope: Globalism	Initially restricted to African meningitis belt: initially Low (although a 1997 decision expands eligibility to any country in need)

8.2 The Vaccine Independence Initiative

The Vaccine Independence Initiative (VII) is a programme launched in 1991 by WHO and UNICEF for sustainable supply of vaccines (de Roeck and Levin, 1998). The objective of the initiative is to increase the self-reliance of middle-income countries with functional EPI systems to finance their immunization programmes. Functional systems were defined as those with at least 50% coverage of the standard six EPI vaccines. The intent of this system is to facilitate the transfer of vaccine finance from external partners to government budgets in the context of decreasing external support. In addition, the UNICEF procurement system is intended to facilitate access to quality vaccines at the best available price through the use of approved suppliers and bulk purchasing.

The VII was financed by UNICEF and several bilateral agencies. Later, in 1996, the European Union, UNICEF and several bilateral partners contributed to a parallel initiative in Africa (UNICEF, 1998). Since pledges began in 1992, over $8 million has been raised. Basically, the initiative gives countries a line of credit for procurement through the UNICEF system. They can then pay for vaccines and related supplies after receipt and in local currency. Essentially this is a revolving fund mechanism, with a specific budget and credit limit for each participating country. Countries have 45 to 60 days to reimburse the fund for the vaccines they have received.

Foreign exchange is provided through UNICEF's country programme budgets in countries where those budgets are large enough to absorb the local currency. (UNICEF country programmes are spending local currency in-country, but are financed by UNICEF in hard currency, thereby providing a source of foreign exchange.) In order to have access to the VII facility, countries must have a specific national budget provisions (not necessarily a budget line) for vaccines and related consumable equipment. They also need to have an annual national plan for vaccine needs. Technical assistance can be made available for the preparation of this plan (de Roeck and Levin, 1998).

The VII has faced many logistical issues arising from bureaucratic processes at UNICEF and at the various involved governments and associated ministries, and the complexity of payment with local currencies. Stock-outs, when they have occurred, have often been caused by slow procurement procedures ("security barriers"), rather than problems in payment (UNICEF, 1998). This seems to be an example of demands for transparency being too rigid, and the procurement system being too complex, so hampering effectiveness. Countries without substantial UNICEF country programmes have to pay for vaccines with hard currency. Furthermore poorer countries unable to maintain a budget for vaccines have had to drop out of the programme, at least temporarily (de Roeck and Levin, 1998).

The VII is on a learning curve. Steps are being taken to improve and streamline the procurement procedures. This includes a systematic analysis of bottlenecks and suggestions for getting rid of them in a workshop format with the participation of key stakeholders. In principle, the VII will accept any mechanism that results in Ministries of Health becoming self-reliant in the supply of quality vaccines. This has resulted in modifications such as a "vaccine stabilisation fund" that enables Ghana to respond to outbreaks of disease and unexpected shortfalls of vaccines. The VII is aiming to be flexible and is open to innovation, including greater decentralisation of management and simplification of procedures. This reflects a service-orientation: seeing purchasing countries as clients for a financial and procurement service rather than as aid beneficiaries.

Since 1996, VII has involved at least 20 countries including 12 Pacific Island nations. Eight of the original target countries and some of the countries which joined VII later have achieved independence or near-independence in vaccine finance.

The European Union parallel programme, which involves access to VII, includes eight Sahelian countries, all of which set up budget lines for vaccines. Of these eight, six have increased their national budget line for vaccines over the first two years of the initiative. The amount of increase over the two year period ranged from 6% to 314%. One of the countries can now satisfy its basic vaccine requirements through its own budget.

The increased commitment to vaccine finance represents the efforts of health ministers and EPI directors in advocating for vaccination at the highest political levels. This has increased dialogue between policy-makers and technical experts and a better understanding of needs at country level.

Table 10: VII aummary

Goal	VII characteristics
1. Equity: Access	VII aims to prevent stock-outs due to disruptions in cash flow. This should increase access: Medium
2.1 Impact: Effectiveness	Bureaucratic issues seem to be impeding effectiveness, but these are being addressed: Medium
2.2 Impact: Coverage and speed	VII aims to maintain or increase coverage in the context of reduced financing from external partners, but response rate is slow, and there are currently few participants: Low
3.1 Feasibility	VII is working at eliminating bottlenecks and improving performance: Medium
3.2 Feasibility: Transparency	There seems to be a high degree of transparency, perhaps to the extent that procedures are unduly bureaucratic: High
4. Sustainability: Independence	Budget lines for vaccines have increased substantially in VII partners: High
5.1 Scope:	Focus/simplicityThe procurement process is extremely complex and difficult: Low
5.2 Scope: Globalism	The VII concept uses global mechanisms such as the UNICEF procurement process: High

8.3 Proposal for a "new" vaccines fund

Levine, Batson and Sakai (1999) have outlined a possible formula for a global fund that would finance new vaccines. Their proposal involves raising capital for an endowment fund of approximately $1 billion, to provide revenues of roughly $63 million per year. It is calculated that this could provide Hep B and Hib to a set of poorer, smaller countries currently unable to access these vaccines, with some targeting based on epidemiological evidence of need and absorption capacity. Some of the fund revenues might be used to cover infrastructure costs, based on the recommendations of a technical committee. It is assumed that coverage would be equivalent to current coverage for the EPI standard six vaccines. Financing would not be 100% grant, but would require governments to contract to take progressively more and more responsibility for vaccine finance. Perhaps countries would have to show that they are increasing their own vaccine budget in order to gain access to the fund.

A plan for oversight and monitoring calls for a technical committee to review requests, reporting of vaccine purchases, number of doses administered, and other expenditures, and tracking of vaccines provided to avoid illegal resale. The proposal also details mechanisms for procurement.

Table 11: "New" vaccines fund proposal summary

Goal	New vaccines fund proposal characteristics
1. Equity: Access	The focus on the neediest countries that can absorb vaccine is meant to improve access: High
2.1 Impact: Effectiveness	It is unclear whether new vaccines can be introduced as outlined and funds dispersed in an effective manner: ??
2.2 Impact: Coverage and speed	Coverage would be greatly improved by this plan. Speed of response is unknown: High
3.1 Feasibility	The plan involves raising over one billion dollars of capital: Low
3.2 Feasibility: Transparency	There is a clear system proposed for choosing vaccines, target countries, and so on: High
4. Sustainability: Independence	There is a proposal to include movement towards financial independence as an eligibility criterion, but there is some question about whether to invest in absorption capacity with this fund: Medium
5.1 Scope: Focus/simplicity	There appear to be a number of features to this fund, such as eligibility criteria, advocacy for a vaccine budget line, possible investment in infrastructure, and a global procurement strategy which make this a complex proposal: Low
5.2 Scope: Globalism	This proposal is aimed at the neediest countries, wherever they are on the globe: High

8.4 The PAHO Revolving Fund

The essential feature of the PAHO Revolving Fund is that it is part of a system for vaccination expansion and improvement in the Americas (Freeman, 1999). The way the PAHO system works for new vaccines is that a strong and well respected technical advisory committee takes on the task of evaluating absorption capacity and burden of disease in candidate countries. In addition, countries have to make commitments in terms of financial and logistical sustainability of country vaccination programmes. This means creating a line item for vaccines in the national health budget.

When it can be demonstrated that countries can integrate new vaccines into their programmes without disrupting existing vaccination services, and where there is sufficient burden of disease to justify introduction of new vaccines, a country is a candidate for the use of the PAHO Revolving Fund to purchase these vaccines. They are then judged on the following criteria (Freeman, 1999):

- Allocation of a national budget item with a specific line item for the cost of vaccine and syringes;
- Formulation of a comprehensive and realistic national program plan of operations covering at least a 5 year period and conforming to the General Policies of the EPI in the Americas; and
- Appointment of a national program manager with the authority to develop and implement the program.

Countries that meet these criteria, often through PAHO technical assistance, can buy vaccines through the PAHO Revolving Fund purchasing system. This system works to win the lowest possible prices through bulk purchasing and a high level of market intelligence. Payment can be made in local currencies, within 60 days of invoice. A missed deadline results in suspension of purchasing priviledges, except in the case of crisis or disaster.

In some cases, a judgement is made that a country cannot afford to buy a certain vaccine or vaccines. In this case, if the country meets the other criteria, PAHO works with financiers and partner agencies to generate subsidies for these purchases.

The results are impressive. The fund has grown steadily in capitalisation over the 20 years of its operation from about $1 million in 1979 to its current purchasing power of approximately $145 million (Freeman, 1999). It provides lower priced vaccines and price stability to purchasers, while allowing them to pay in local currency. Through the national plans, it also gives suppliers a means of forecasting demand. It is capable of responding quickly to emergencies through rerouting of existing supplies.

On a global scale, the PAHO Revolving Fund is somewhat replicated by UNICEF and the Vaccine Independence Initiative. However, VII and UNICEF do not fulfill all the elements of the PAHO system as a whole.

PAHO Revolving Fund success factors can be summarised as follows:

- Iterative management, resulting in an evolution of policies and implementation of policies over a 20 year period;
- Institutional memory over the 20 years, so that experience is built on and lessons are learned;
- Intense market surveillance and intelligence;
- Ease of communication and sharing of information between partners, facilitated by the use of Spanish and Portuguese by many countries in the region;
- Excellent technical advisory committee that is trusted and respected as advisors by client countries and financiers. Client countries receive the advice they need to be well prepared to use vaccines and financiers know that resources will be used responsibly;
- Country eligibility for use of PAHO Revolving Fund is determined by a transparent process that fosters financial sustainability, good planning and management at country level; and
- Charisma, energy and discipline in the leadership, and long-term staffing continuity at PAHO, ensures benefits of long term relationships with suppliers and superior market intelligence.

Table 12: PAHO Revolving Fund summary

Goal	PAHO Revolving Fund characteristics
1. Equity: Access	Access to new vaccines remains low in the poorest countries, but standard vaccines have excellent coverage: Medium
2.1 Impact: Effectiveness	The PAHO system has managed to combine market intelligence with a bulk procurement process and technical assistance to provide lowest cost vaccines to those who can absorb them: High
2.2 Impact: Coverage and speed	Access to new vaccines remains low in the poorest countries, but that is not necessarily due to deficiencies in the approach: ???
3.1 Feasibility	The process is proven and has evolved over a period of 20 years of implementation: High
3.2 Feasibility: Transparency	High level of market intelligence and vigilence ensures excellent accountability: High
4. Sustainability: Independence	The revolving fund mechanism is engineered to encourage financial independence and the link with technical assistance promotes capacity building: High
5.1 Scope: Focus/simplicity	The revolving fund is part of a complex system of technical assistance, market intelligence, procurement and finance, and provides many vaccines to many countries: Low
5.2 Scope: Globalism	The fund is accessible to any eligible country in the Americas, but that is a relatively uniform group compared to some other regions: Medium

8.5 Comparison of existing and proposed funds

The ICG, VII, the proposal for a global fund for new vaccines, and the PAHO Revolving Fund vaccine finance initiatives all place emphasis on specific goals. By analysing what these funds have emphasized, it is possible to learn how a choice of goals impacts the way a financial mechanism ultimately functions and what it delivers. The following table (Table 13) compares these four funds in terms of the factors described above:

Table 13: Existing and proposed funds - summary

	ICG fund	Global Fund for New Vaccines	PAHO revolving fund	VII
1. Equity: Access	High	High	Medium	Medium
2.1 Impact: Effectiveness	High	???	High	Medium
2.2 Impact: Coverage and speed	Low cov./	High High speed	???	Low
3.1 Feasibility	High	Low	High	Medium
3.2 Feasibility: Transparency	High	High	High	High
4. Sustainability: Independence	High	Medium	High	High
5.1 Scope: Focus/simplicity	High	Low	Low	Low
5.2 Scope: Globalism	Initially Low	High	Medium	High

9. Opportunity costs

In assessing options for a Global Fund for New Vaccines, it is important also to consider the opportunity costs associated with the fund. It has been suggested that the capital raised for investment could generate a return of 8% if well managed (Batson, Levine and Sakai, 1999). If the return on directly investing this capital in vaccination immediately is greater than 8%, then it may not be efficient to construct a fund.

9.1 Potential indirect positive impacts of a Global Fund for New Vaccines

These benefits would accrue in addition to the 8% return on investment of the fund capital.

- Assurance of stability in financing for qualifying countries or population groups.
- Assurance of stability in demand for producers.
- Leverage in obtaining the best possible prices for vaccines, based on expanded and stable demand.
- Potential influence on policy decisions to invest further in vaccination, for example, through leveraging of matching funds at country or community level.
- Potential influence on countries to expand and improve vaccination.

9.2 Potential indirect positive impacts of investment in vaccination

These benefits would accrue in addition to the burden of disease averted:

- Better absorption capacity for other investments in human development, such as education (see "Health for All Renewal", WHO, 1997) for the "wave" of people vaccinated with the pulse of funds.
- Higher labour productivity.
- More choice for health administrators on how to use the funds. For example, they may choose to set up their own country-based fund or to invest in cold chain infrastructure with the one-time award of funds. This could allow for more appropriate spending with lower overhead costs than a Global Fund for New Vaccines.

9.3 Return on immediate investment in vaccination

For simplicity, an assumption being made here is that capital that may be available for a Global Fund for New Vaccines is capital that is already earmarked for vaccination. (If this were not true, then the indirect impacts of a Global Fund for New Vaccines would be even greater, through leveraging of additional financing.)

Immediate investment could be a proxy for development projects.

In the 1993 World Development Report, it is estimated that in poorer countries, it costs US$12-17 per DALY gained through vaccination in an "average" low-income country (pp. 73-74). (These data are now out of date, but can be used as approximations for the purpose of this argument.) These DALYs are calculated using a discount factor of 3%.

9.4 Comparison of returns on investment from a Global Fund for New Vaccines versus immediate investment in vaccination

In essence the comparison between rate of return on investment in a Global Fund for New Vaccines and rate of return on immediate investment in vaccination depends on the discount factor used in calculating DALYs. If a discount factor of 8% is used in calculating DALYs, then the return on investment is the same in each case. If the discount factor used in calculating DALYs is 3%, then it makes sense to invest money at 8% and spend it later. In fact in that case, it is most efficient to wait as long as possible before spending the money on vaccination in order to maximise gains.

The key differences seem to be that a one-time payment to countries (perhaps matched by government funds) could allow more focus and simplicity and respond better to client country demands for choice and autonomy. A Global Fund for New Vaccines would allow the global coalition more influence over supply issues and in fostering the sustainable expansion and improvement of vaccination according to WHO standards of technical excellence. A Global Fund for New Vaccines is likely to be a force for leveraging additional financing for vaccination, both from financiers and from client governments themselves, as has been found in the case of environment funds (GEF Secretariat, 1998). It is also probable that more funds would be available through a fund mechanism than through one-time payments.

10. Conclusions

Conclusions are a set of optional goals for a Global Fund for New Vaccines, working definitions of potential goals, lists of compatible goals, and lists of potential trade-offs, as illustrated in the quick reference table (Table 14) shown here. Recommendations are to pay special attention to lessons learned in innovative financing in other sectors, to continue to explore financing options, to build consensus among stakeholders on goals and trade-offs for a possible Global Fund for New Vaccines, and to move forward to the preparation of a proposal for such a fund.

Table 14: The five parameters summary

EQUITY	Access	Everyone has access to the vaccination-related health resources and health care services they need.
	Goals consistent with access	Speed, transparency, sustainability (capacity building), and globalism.
	Trade-offs with access	Efficiency, coverage, feasibility, sustainability (financial), and focus/simplicity.
IMPACT	Effectiveness	Vaccination resources are used so that the total reduction in burden of new vaccine-preventable disease per dollar is maximised.
	Goals consistent with effectiveness	Feasibility, speed, transparency, financial sustainability, focus simplicity, and globalism.
	Trade-offs with effectiveness	Equity, coverage, and sustainabilty in terms of capacity building.
	Coverage and speed	As many people as possible are given the vaccinations they need, as quickly as possible.
	Goals consistent with coverage and speed	Globalism, and access if there are no resource constraints.
	Trade-offs with coverage and speed	Effectiveness, sustainability (financial and capacity building), feasibility, transparency, and focus/simplicity.
FEASIBILITY	Feasibility	The absence of a “fatal flaw”. This entails adequate capitalisation, acceptance by key stakeholders, effective demand, technically and financially sound implementation, limited complexity, transparent systems, and good management.
	Goals consistent with feasibility	Effectiveness, focus/simplicity, moderate levels of transparency, moderate requirements for independence/sustainability, and globalism.

FEASIBILITY ***(continued)***	Trade-offs with feasibility	Access, coverage, speed, high levels of transparency, and absolute requirements for independence/sustainability.
	Transparency	Verifiable, responsible fund management according to agreed procedures, supported by appropriate documentation.
	Goals consistent with transparency	Access, effectiveness, feasibility (when transparency not excessive), sustainability (financial and capacity building), and globalism.
	Trade-offs with transparency	Focus/simplicity. If demand for transparency is high, feasibility and effectiveness.
SUSTAINABILITY	Independence	Long-term, sustainable, financial, technical and logistical self reliance in the satisfaction of needs for high quality vaccines and related health products and services.
	Goals consistent with independence	Efficiency and transparency.
	Trade-offs with independence	Access, coverage and speed, feasibility, focus/simplicity and globalism.
SCOPE	Focus/simplicity	Resources are concentrated on limited goals and systems are simplified in order to minimize potential failure points and maximise the chances of achieving the chosen goals.
	Goals consistent with focus/simplicity	Feasibility, speed, effectiveness, and independence.
	Trade-offs with focus/simplicity	Globalism, access, and coverage.
	Globalism	A worldwide system of finance, technical assistance, procurement, and supply is coordinated to profit from economies of scale in manufacturing, demand forecasting, market intelligence, bulk purchasing and access to foreign exchange.
	Goals consistent with globalism	Access, effectiveness, and coverage.
	Trade-offs with globalism	Focus/simplicity, independence (autonomy in purchasing), feasibility (large capitalisation), transparency, and speed.

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Annex 1: Sources of further information

New vaccines for Hib, pneumococcus, rubella, and rotavirus are discussed in CVI Forum, numbers 12 (1996),13 (1996), 14 (1997), and 15 (1998), respectively. Another source of information on new vaccines is the WHO Vaccine Supply and Quality web page (www.who.int/gpv-supqual.htm).

Vaccine finance is reviewed in "Vaccine Finance Mechanisms", a draft paper by Choi (unpublished draft, WHO, 1999). General background on sector-specific trust funds for development can be found in Becher, Jennings and Shorey, 1999, "Health Trust Funds for Sustainable Development", and at the Global Environment Facility Secretariat document entitled "GEF Evaluation of Experience with Conservation Trust Funds" (see web site www.gefweb.com). It should be noted that apart from housing the GEF, the World Bank has a specialised department devoted to the establishment and management of trust funds. An example of a country-specific health trust fund is to be found in Bhutan and a description of that fund is made in a brochure by the Bhutanese Government (Bhutan, 1998), and in papers by Becher *et al.* (1999) and Choi (1999).

Specific background on a Global Fund for New Vaccines and other financing mechanisms can be found in the report of a Children's Vaccine Initiative meeting at UNICEF, New York which resulted in a document entitled Framework for Immunization Financing (1999) as well as in the position paper by Levine, Batson and Sakai (1999) entitled "Strategies for Financing the Purchase of Vaccines and Strengthening the Infrastructure for Delivery of Immunizations in Economically Disadvantaged Countries". Relevant data and background materials can be found on the WHO Vaccine Supply and Quality web page (www.who.int/gpv-supqual.htm).

It is worth noting that there exists also the SimFin economic model developed by WHO Headquarters economists Guy Carrin and Jean Perrot for use in national health planning. This model uses national health system and national macroeconomic data to show what the financial impact are of health resource spending decisions relative to the supply of financing for the health sector. However, the results of a SimFin analysis are not expressed in terms of health outcomes. SimFin analysis results indicate whether budgetary possibilities and financial needs will meet, or what the gap is in monetary units between projected spending and anticipated budgetary constraints under different spending and resource scenarios. This can be used by countries in determining the potential impact of new sources of vaccine financing on their health sector planning decisions.

As interest in health service rationing has increased together with demands for transparency in the rationing of resources for health, work has been carried out on processes for priority setting, drawing on the disciplines of economics, political science, philosophy and epidemiology. A review of these processes can be found in European Health Care Reform, analysis of current strategies (Saltman, R. and J. Figueras, 1997), which is based on 30 background papers written by international scholars and practitioners, including experts from the World Bank and WHO.

A computer model for use in health systems planning and resource allocation at the district level has been developed by the Swiss Tropical Institute (Godelmann, 1995). Outputs are expressed in preventable deaths averted and health service coverage. It has been field tested in Pune and is currently being used as a simulation device in exercises for training in health planning in Tanzania and Thailand. With some modification, it may be useful in modeling the potential outcomes at district level of specific vaccine finance policies.

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Annex 2: Individuals contacted

The following individuals were contacted. The author gratefully acknowledges those who generously shared their knowledge and experience of vaccine finance, and provided references and data.

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