

The introduction of new vaccines into developing countries II. Vaccine financing

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Abstract

The development of new vaccines for important childhood diseases presents an unparalleled opportunity for disease control but also a significant problem for developing countries: how to pay for them. To help address this problem, the William H. Gates Foundation has established a Global Fund for Children's Vaccine. In this paper, we discuss the allocation of this and other similar funds, which we call Global Funds. We propose that allocation of the Global Funds to individual countries be guided in part by a Vaccine Procurement Baseline (VPB). The VPB would set a minimum of 0.01% of gross national product (GNP) as an amount each developing country would devote to its own vaccine procurement. When this amount is not sufficient to procure the vaccines needed by a developing country, the Global Funds would meet the shortfall. The amount required of donors to maintain the Global Funds would be about \$403 million per year for both existing EPI vaccines as well as for a hypothetical group of five new vaccines costing \$0.50 per dose and requiring three doses per child. Including program costs, poor developing countries currently spend about 0.13% of GNP on EPI immunizations. In contrast, the United States, as one example donor country, spends about 0.035% of GNP for childhood immunization including several new vaccines. This paper analyzes the Global Funds requirements for hepatitis B and *Haemophilus influenzae* type b (Hib) vaccines. After a ramp-up period, needier countries would eventually require about \$62 million for hepatitis B and \$282 million for Hib at current prices. Various additional criteria could be used to qualify countries for participation in the Global Funds. © 2000 Elsevier Science Ltd. All rights reserved.

1. Introduction and background

1.1. The inequity of vaccine availability

The world is in the midst of one of the greatest health revolutions in history. A large number of new vaccines are being introduced and more will be developed in the coming years. These vaccines could greatly reduce the estimated 17 million deaths caused by infectious diseases each year worldwide [1].

Globally, vaccines are in wide use against six diseases: tuberculosis, polio, diphtheria, tetanus, pertussis,

and measles. The vast majority of children, no matter where they live and whether rich or poor, have access to these vaccines. These are the Expanded Program for Immunization (EPI) vaccines. The establishment of a supply and delivery system for these vaccines to over 100 million babies each year is one of the greatest of all health achievements.

There are several other vaccines, however, whose use is largely restricted to developed countries. These are vaccines against mumps, rubella, hepatitis B, *Haemophilus influenzae* type b (Hib) and other invasive diseases, and varicella (chickenpox). While the burden of disease caused by mumps and varicella may be relatively small, the disease burdens of rubella, hepatitis B, and Hib are often significant. There are many barriers and considerations that influence the pace of introduc-

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tion of vaccines into developing countries [2–4]¹, but cost is certainly one of the most important [5,6]. The current cost of each of these vaccines is ten times or more than the costs of the EPI vaccines (mostly <\$0.25 per dose). These higher costs deter their introduction into developing countries. For example, the addition of hepatitis B vaccine to the national immunization program of the Dominican Republic increased the vaccine procurement budget of \$658,190 by an additional \$590,040. The addition of Hib vaccine would require a further increase of \$2,880,000 [7] or a greater than four-fold increase at current prices.

1.2. *The inequity of resource allocation*

A useful perspective can be obtained by looking at what developed countries spend for childhood immunization services. In a recent paper, Weniger et al. [8] estimate in a pilot model that costs in the United States total about \$500 to vaccinate each child against diphtheria, tetanus, pertussis, hepatitis B and Hib (polio, mumps, measles, rubella and varicella are excluded from the model). Adding the costs for polio and measles increases the cost to \$670. Given the annual US birth cohort of 3.9 million children, the total allocation each year is approx. \$2.6 billion assuming full coverage. These numbers do not include local, state, and Federal spending for salaries and projects to administer, monitor, and assess the immunization programs [9].

The US GNP in 1998 was about \$7.5 trillion. Using the \$670 per child figure, the US allocates about 0.035% of GNP to immunize its 3.9 million newborns each year. The UK allocates about 0.0163% of GNP to all immunization services including adults but excluding surveillance costs [10]. The similar figure in Canada is about 0.0175% [11]. In contrast, we calculate that developing countries with a per capita GNP less than \$3000 allocate roughly 0.13% of GNP to immunization services.

Thus, developing countries carry a relatively much greater burden in providing immunization services.

1.3. *The need for Global Funds*

Global Funds for procurement of children's vaccines are needed for three reasons. First, they are needed to address a responsibility to achieve equity between developed and developing countries. Developed country children can receive new vaccines as they

become available. Most developing country children are not receiving these new vaccines. A system-wide change is required to seek equity [12].

Second, the process of globalization demands a global solution to the problem of unequal access to vaccines. Vaccines are an international public commodity (a public good) that no individual government or corporation is likely to produce, in sufficient quantity and affordable prices, on its own. Responsibility for health is national but the determinants of health and the means for governments to fulfill that responsibility are increasingly global [13].

The third reason has to do with the economics of the vaccine industry. For vaccines, the greater the demand or competition, the lower the price. Industry cites the high cost of product development and capital investment for production facilities as rationales for high vaccine prices. In fact, vaccine prices are determined by demand and competition [14].

In a recent paper, Mahoney and Maynard described the key components of vaccine introduction [15], of which the most difficult is the mobilization of sufficient resources for their introduction. Following calls to establish a fund for vaccine procurement [16], the William H. Gates Foundation established a Global Fund for Children's Vaccines (GFCV). This GFCV is \$750 million provided in the form of a challenge grant to be used over a 5-year period beginning in 2000 [17].

1.4. *Review of international public sector vaccine procurement*

1.4.1. *UNICEF and bilateral donors*

Since the launch of the WHO EPI in 1974, various mechanisms have been found to help assure a continuing and generally adequate supply of EPI vaccines. In the early 1990s, the first "cracks" in this informal system began to appear. The Executive Board of the United Nations Children's Fund (UNICEF), a major purchaser, raised concerns about the steadily mounting cost of vaccine procurement and encouraged UNICEF staff to find ways to restrict further growth of these costs. The donor nations who sat on the Executive Board were concerned about a recurring large expenditure with no end in sight.

1.4.2. *The PAHO revolving fund*

The Pan American Health Organization (PAHO) has been successfully operating a revolving fund for vaccine procurement. In a recent review [18], Freeman notes that the revolving fund "is a tool within a broad program of technical assistance, not just a procurement mechanism". She lists three criteria that countries must meet to participate in the program:

- Allocation of a national budget item with a specific

¹ Developing countries are defined according to the World Bank classification of Low and Middle Income Countries. For 1998, the maximum per capita income for a Middle Income Country was \$9636.

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 authority to develop and implement the program.

Freeman concludes,

The Revolving Fund, then, plays an important role in the Americas region for planning, evaluating strengths and weaknesses and emphasizing sustainability before expansion... Similarly, the PAHO's program of technical assistance and the consolidated purchases through the Fund are intended to encourage and accelerate systematic uptake of vaccines where cost-effectiveness can be demonstrated, whatever the price of a vaccine may be.

The PAHO Revolving Fund has proven to be a powerful tool for ensuring availability of vaccines.

1.4.3. Development of the Global Targeting Strategy

The Children's Vaccine Initiative (CVI) was founded by WHO, UNICEF, the World Bank, the United Nations Development Program (UNDP), and the Rockefeller Foundation [19]. Among its many important accomplishments was the development of a Global Targeting Strategy [20,21]. This strategy provides a basis to assess which developing countries should be self-sufficient in supplying themselves with the EPI vaccines. Self-sufficiency is defined as a country obtaining all its vaccines with its own resources, not including external donor funds. Thus, a country could obtain the vaccines by direct procurement, local production, and by private sector activities such as import and sales.

The Global Targeting Strategy puts countries into four categories or Bands according to their population, per capita GNP, and "relative wealth or sheer size". Band A countries are the smallest and poorest countries for which financial assistance may be needed. Band B countries are somewhat larger or more well-to-do. They may need some interim financial assistance and technical assistance in procurement, but these countries should eventually be self-sufficient. Band C countries should immediately become self-sufficient. Band D countries should not receive any further support. The drawing of the lines to demarcate these Bands was done arbitrarily. The Strategy's measure of success — the Self-sufficiency Index — is the percent

of EPI vaccines that a country obtains with its own resources.

This strategy is attractive to industry because it means UNICEF will not provide free vaccine to countries that might be able to buy from the companies directly at negotiated market prices. The strategy is attractive to donors and international agencies because it provides a simple means to set priorities for allocating aid for EPI vaccines, and it reduces the overall demand for vaccine donations.

From the developing country's point of view, the Strategy has some disadvantages. Those countries in Bands B, and C may find themselves paying more for vaccines than they did obtaining the same vaccines through UNICEF. Second, the Self-sufficiency Index penalizes countries that attempt to introduce new vaccines. Consider a country that is self-sufficient in supply of EPI vaccines. If this country adds hepatitis B to its EPI but receives the vaccine on donation, it could drop from 100% self-sufficient to only 30%. Another drawback of the strategy is that it does not account for the substantial expenditures that developing countries make on program costs.

Most important, from our point of view, it has proved difficult to apply the Global Targeting Strategy to the introduction and procurement of new vaccines [22,23]. The Strategy deals only with the costs of EPI vaccines.

1.5. Programmatic costs

The cost per fully immunized child in most developing countries is approx. \$15 [24]. As the cost of vaccine is only about \$1.50², the non-vaccine costs of EPI are about \$13.50 per fully immunized child. These costs are largely for staff salaries, facilities, training, and other miscellaneous expenses. The introduction of new vaccines will increase program costs somewhat. But because most of the investment is already made in systems to deliver several vaccines, the increased programmatic costs for new vaccines are likely to be substantially less than the increased procurement costs. For example, Shepard et al. estimate that the increased programmatic costs of introducing hepatitis B vaccine is about \$0.30 per fully immunized child [25]. The important point is that increased program costs will likely be a small fraction of the increased vaccine procurement costs. Furthermore, whereas today's cost of vaccines is a small component of total immunization costs, future vaccines may cost in total as much as or even more than the rest of immunization program costs. Thus planning for the procurement of these vaccines is an issue of the highest importance.

The cold chain is a capital intensive component of immunization programs. In many countries, the cold chain is aging and needs replacement. These costs will

² Including wastage, we assume that the average cost per fully immunized child with EPI vaccines is \$1.50. This number is derived using current UNICEF vaccine prices.

vary from country to country. They will have to be measured for each country and met as appropriate.

1.6. Global Fund for Children's Vaccines

The GFCV will begin operations in 2000. It will operate with oversight from the Global Alliance for Vaccines and Immunization (GAVI). GAVI is a new entity bringing the major agencies and industry together in a working partnership. The initial criteria for allocation of the GFCV are stated to be countries with per capita GNP <\$1000 and populations of less than 150 million people [26].

2. A proposal for allocating Global Funds: Vaccine Procurement Baseline (VPB)

We propose that Global Funds be allocated by applying a VPB of 0.01% of gross national product (GNP) representing an amount that each developing country should devote to its own vaccine procurement. When the VPB amount is not sufficient to procure the vaccines needed by a developing country, the shortfall would be met by the Global Funds. Global Funds should be used to purchase only vaccines made by facilities that have been approved by WHO. The Global Funds should be financed by the wealthier countries, foundations, individuals, corporations, and others. This VPB methodology has the ability to analyze vaccine financing on a global, regional, and national basis. It can be used as a tool for decision making at each of these levels.

The adoption of the 0.01% GNP goal would represent a system-wide change. Its adoption would be a major step in implementing the understanding that infectious disease control is a global responsibility in which all must share. Global Funds therefore provide an opportunity not only to buy needed vaccines, but also to realign health policies and priorities to control more effectively preventable morbidity and mortality.

The Global Targeting Strategy proposes that

³ It is assumed that the vaccines are purchased at UNICEF prices. Not all countries buy through UNICEF, but from a replacement-value point of view, it is reasonable to assume the countries pay UNICEF prices.

⁴ New vaccines such as Hib and rotavirus are priced much higher than \$0.50 per dose. We use \$0.50 per dose for all new vaccines for two reasons. First, it is likely that as new vaccines are purchased in very large quantities, the prices will drop substantially. Also, a uniform price for all new vaccines makes it easier to present the findings of this paper.

⁵ To simplify the calculations in this illustration, we assume that all countries introduce the same vaccines. However, the burdens of disease vary among countries, and therefore countries will often introduce only a subset of the new vaccines.

countries that do not manufacture their own vaccines and that have per capita GNP >\$500 (Band A) should eventually be self-sufficient in financing the supply of EPI vaccines. An analysis of GNP, population, and crude birth rate in countries with approx. \$500 GNP per capita indicates that they would have to allocate on average about 0.01% GNP to the purchase of EPI vaccines to be fully self-sufficient³. This is the rationale for the amount we propose as the VPB. The VPB would be the basic parameter guiding the allocation of the Global Funds.

According to UNICEF data, 26 countries with per capita GNP <\$500 that obtained some vaccines with their own resources in 1998, allocated, on average, 0.007% of GNP to vaccines. Thus achieving the 0.01% GNP target of the VPB should not represent an insuperable challenge for these countries.

3. Results of applying the VPB

3.1. Illustrative application

To illustrate how Global Funds would be allocated applying the VPB, it is assumed that there are five new vaccines each requiring three doses at a cost of \$0.50 per dose⁴. Wastage is set at 10%⁵.

In 1998, there were about 115 million births in developing countries. Thus the annual procurement "bill" for the EPI vaccines at 100 percent coverage is the equivalent of about \$173 million. Adding the five new vaccines would increase the per child costs to \$9.83, the total bill to \$1.13 billion, and the cost

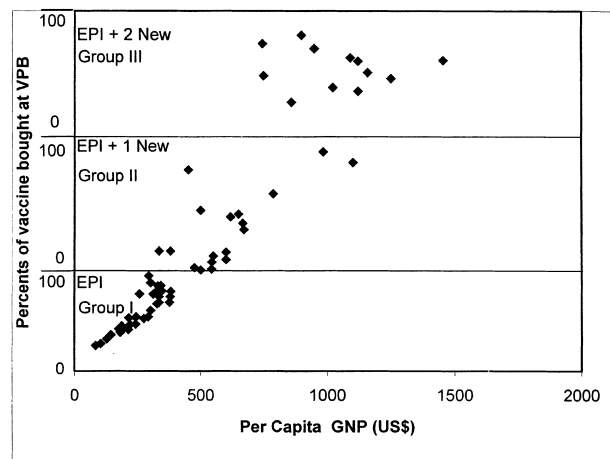


Fig. 1. Percents of increasing amounts of vaccines able to be purchased when countries allocate 0.01% of GNP for vaccine procurement. Group I countries are not able to procure 100% of EPI vaccines. Group II can buy EPI vaccines but cannot fully buy one additional vaccine. Group III can buy EPI vaccines and one new but cannot fully buy a second new vaccine.

Table 1
Summary of results applying VPB for five new vaccines at \$0.50 per dose

| Group ^a | Countries (<i>n</i>) | Average per capita GNP (US\$) | Total required | Developing country contribution \$ and % | Global funds contribution |
|--------------------|------------------------|-------------------------------|----------------|--|---------------------------|
| | | | US\$ millions | | |
| I | 38 | \$300 | \$324.3 | \$24.5 (8%) | \$299.8 |
| II | 10 | 676 | 27.1 | 6.4 (24%) | 20.7 |
| III | 13 | 1027 | 118.4 | 51.8 (44%) | 66.6 |
| IV | 11 | 1504 | 32.8 | 18.5 (56%) | 14.3 |
| V | 7 | 1547 | 20.1 | 18.9 (94%) | 1.2 |
| VI | 31 | 3986 | 608.0 | 608.0 (100%) | 0.0 |
| Totals | 110 | | \$1130.7 | \$724.8 (64.1%) | \$402.6 |

^a Group I — able to pay for a portion of the EPI vaccines and none of the new. Group II — able to pay for all the EPI vaccines and a portion of one additional new vaccine. Group III — able to pay for all the EPI vaccines, one new vaccine and a portion of a second new vaccine. Group IV — able to pay for all EPI, two new and a portion of a third new. Group V — able to pay for all EPI, three new and a portion of a fourth and perhaps fifth. Group VI — fully self-sufficient.

of the immunization program to about 0.20% of GNP. If the new vaccines cost \$1 per dose, the per child costs rise to \$18.16 and the bill is \$2.09 billion or a twelve-fold increase over the EPI bill. Some have suggested that the new vaccines such as Hib will not fall to prices as low as \$1 per dose for developing countries. This would make these procurement “bills” even larger.

We apply the VPB concept to the introduction of the five new vaccines at \$0.50 per dose. The results are presented in Fig. 1.

Six Groups are identified of which three are demarcated by the horizontal lines in Fig. 1.

- Group I — able to pay for a portion of the EPI vaccines and none of the new; these are the neediest countries
- Group II — able to pay for all the EPI vaccines and a portion of one additional new vaccine
- Group III — able to pay for all the EPI vaccines, one new vaccine and a portion of a second new vaccine
- Group IV — able to pay for all EPI, two new and a portion of a third new vaccine
- Group V — able to pay for all EPI, three new and a portion of a fourth and perhaps fifth
- Group VI — self-sufficient.

For each Group, Table 1 shows the total amount of funds required to purchase all vaccines and the contributions to that total needed from the countries and from donors. The table illustrates how the application of the VPB ameliorates the depth of the problem. Of a total bill of \$1.13 billion, the 31 totally self sufficient

countries (Group VI) would contribute \$608 million, partially self-sufficient countries numbering 79 (Groups I–V) would contribute \$120.1 million, leaving a balance of \$402.6 million. Overall developing countries would cover about 64 percent of the total cost. As economic development proceeds, the number of countries requiring assistance and the amount of assistance required will decline.

It is interesting to note that if the developing countries in Groups VI were to donate the amount in excess of the VPB needed to buy their vaccines, they could make a contribution to the poorer countries of about \$170 million, perhaps through regional co-operation mechanisms.

3.2. Hepatitis B⁶ and Hib vaccines

There are two licensed vaccines, in addition to the traditional EPI vaccines, available for introduction into developing countries. These are hepatitis B and *Haemophilus influenzae* b (Hib). About half of the world's developing countries have national hepatitis B immunization programs [27]. Several have introduced Hib vaccine [28]. The following analysis deals only with these two vaccines and assumes all countries will introduce them. This is a fair assumption for hepatitis B in light of the World Health Assembly Resolution calling for universal use of that vaccine. The assumption is less justified for Hib vaccine. Cost effectiveness studies have not been completed for all regions and there are some doubts as to whether Hib vaccine will be used everywhere. By assuming all countries use Hib vaccine, the calculations yield maxima. Global Funds will have a “ramp-up” period during which procurement would grow year-by-year, and it is during that period that a more accurate determination of Hib demand and need can be made. Epidemiologic and disease burden studies need to receive high priority during this period.

⁶ Even though it received first regulatory approval in 1981, hepatitis B vaccine is included in this analysis as a “new” vaccine because it will be new as a widely-used vaccine for many developing countries.

Table 2
Summary results of applying VPB methodology for Groups I–II

| | Group | | Totals |
|--|-------|-------|------------|
| | I | II | |
| Demographics | | | |
| No. of countries | 38 | 12 | 50 |
| Birth cohort (millions) | 33.00 | 26.94 | 59,925,000 |
| Average per capita GNP | \$300 | \$645 | \$383 |
| Vaccine Costs (US\$ millions) | | | |
| Total cost of EPI vaccines | 48.8 | 39.8 | 88.6 |
| Total cost of HBV vaccine | 55.0 | 44.9 | 99.9 |
| Total cost of Hib vaccine | 239.7 | 195.7 | 435.4 |
| Combined cost of EPI, HBV, and Hib | 343.5 | 280.4 | 624.0 |
| Developing Country Contributions (US\$ millions) | | | |
| Contributions by countries to total vaccine needs (VPB) | 31.3 | 43.0 | 74.3 |
| EPI shortfall after meeting VPB Goal (US\$ millions) | | | |
| Needed to cover EPI shortfall | 17.5 | 0 | 17.5 |
| Annual Contributions Required from the Global Funds (US\$ millions) | | | |
| Needed to cover HBV shortfall | 55.0 | 41.8 | 96.8 |
| Needed to cover Hib shortfall | 239.7 | 195.7 | 435.4 |
| Total needed from Global Funds | 294.7 | 237.5 | 532.2 |

The price of hepatitis B vaccine to UNICEF for developing countries has fallen to about \$0.50 per dose for both plasma-derived and recombinant DNA produced vaccines. PAHO reports on considerable success in introducing Hib vaccine in the Americas [29]. Vaccine has been procured through the PAHO revolving fund, and the price has fallen from the \$4.50 to \$8.50 per dose range before 1998 to \$2.18 for the liquid formulation and \$2.60 for the freeze-dried formulation since 1998.

For further analysis of VPB, it is assumed that hepatitis B costs \$0.50 per dose and Hib costs \$2.18 per dose⁷. Wastage is taken at 10% and coverage at 100%. This assumption on coverage is “conservative” because it will lead to the highest possible purchase costs for vaccines.

Only Groups I, II, and III need to be addressed as Groups IV–V–VI would be self-sufficient in supply of hepatitis B and Hib vaccines if they meet the VPB goal. The discussion that follows focuses on Groups I and II as they include the poorest countries. Group III will require assistance for Hib only, if they meet the VPB goal, and that need could eventually rise to about

\$276 million of which China would require about \$124 million at current prices. If China meets the VPB goal, it would be able to procure sufficient hepatitis B vaccine for universal coverage of new borns⁸.

UNICEF has published data showing the percent of EPI vaccines procured by some countries [30]. Our analysis takes account of these procurement activities. The results are summarized in Table 2 (note: by using actual vaccine prices, the number of countries in Group II increases to 12).

Group II is dominated by India. India has a birth cohort of 23,625,000. If it meets the VPB goal, it will cover all its need for EPI vaccines and have a shortfall of \$38,540,312 for hepatitis B vaccine and \$171,675,000 for Hib vaccine. The table shows the demands on Global Funds after an initial 3–4 -year ramp up period. In the near-term, countries in Group I and Group II will need support on the order of \$96.8 million for hepatitis B vaccines and about \$435 million for Hib. (Recall that Group III will require about \$276 million for Hib.)

3.3. An initial group of priority countries

The first criterion of the PAHO revolving fund is that countries must have a vaccine budget line in their national budgets. Applying the VPB methodology, we compare the percents countries are actually procuring with the percents they would procure applying the VPB methodology. Several countries are doing very well. An analysis of procurement by Group I and II countries, using UNICEF data [31], identifies two categories. First are countries that match or exceed the VPB Goal. They may or may not be self-sufficient in

⁷ The use of this price for Hib should not be taken to mean that this is the likely price the vaccine will sell at when global use is achieved. It is very likely that as volumes rise and competition takes effect, the lowest price for this vaccine, i.e. the one available for the poor in developing countries, will fall to less than \$1 per dose. During the ramp-up period, the costs will be higher, and this period is the focus of this paper.

⁸ In China, hepatitis B vaccine is not part of EPI. Thus coverage is determined to a great extent by demand in urban areas. To improve coverage and to meet the VPB goal, China could subsidize the vaccine or provide it as a part of EPI.

EPI vaccines. Second are countries that make no or some contribution to procurement of EPI vaccines, are not self-sufficient and do not meet the VPB Goal. In implementing the VPB methodology, countries in the first category would be eligible for immediate assistance in introducing new vaccines, and most of the costs should be met by Global Funds. These countries are doing more than their share in obtaining the vaccines needed by their children.

The results of analyzing the needs of these countries, suggest one approach to setting priorities for assisting countries. Initially, assistance for introducing new vaccines could be limited to the 12 countries in Groups I and II (the most needy) who meet or exceed the VPB goal (Table 3). The initial need for hepatitis B is about \$21.2 million. The need for Hib vaccine is about \$92.7 million. These 12 countries could be priority targets of Global Funds in the first few years. Additional countries could be added either to meet special needs or as they achieve the VPB goal.

Of the \$62.2 million required for hepatitis B, about \$39.4 million would be allocated to meet India's needs and \$8.3 million for Pakistan. If the Global Funds begin with these 12 countries, they will be addressing about 62% of the children in the two Groups (~60 million).

India is an interesting case with respect to hepatitis B vaccine. It has two local producers, and it is not known what price these producers would offer vaccine at in large quantities. If these producers are to be eligible to supply through Global Funds, they should

meet WHO standards. Thus, Global Funds can be a mechanism to encourage the improvement of vaccine production in developing countries.

4. Discussion

4.1. Comparison of VPB with Global Targeting Strategy and initial GFCV criteria

The VPB methodology results in clustering countries into six Groups according to their ability to buy an expanding number of vaccines. This can be compared with the Bands of the Global Targeting Strategy. The Bands are arbitrary and therefore do not provide a transparent means for policy making. The Groups are not arbitrary and therefore provide one basis for transparent policy making.

The GFCV's initial screening criteria are that eligible countries will be those with per capita GNP <\$1000 and populations of less than 150 million. There are more than 55 countries that meet these criteria. These criteria eliminate, among developing countries, China, India, and Indonesia as possible recipients of Global Funds assistance. We do not believe it is justified to exclude these countries. Each has local production of hepatitis B vaccine. The Global Funds should be used to help these countries pay for sufficient locally-produced vaccine to meet national needs, assuming they meet the VPB requirement. Such in-

Table 3
Individual needs of priority countries for hepatitis B and Hib vaccines

| Country | Birth cohort (000 s) | Per capita GNP (US\$) | HBV shortfall (US\$ millions) | Hib shortfall (US\$ millions) |
|-----------------|----------------------|-----------------------|-------------------------------|-------------------------------|
| Group I | | | | |
| Africa | | | | |
| Burkina Faso | 495 | 218 | 0.83 | 3.60 |
| Chad | 294 | 143 | 0.49 | 2.14 |
| Mali | 490 | 240 | 1.07 | 4.63 |
| Nigeria | 4715 | 240 | 7.86 | 34.26 |
| Senegal | 360 | 544 | 0.60 | 3.21 |
| Asia | | | | |
| Nepal | 814 | 214 | 1.96 | 7.87 |
| Pakistan | 4958 | 475 | 8.26 | 44.29 |
| Latin America | | | | |
| Nicaragua | 165 | 340 | 0.28 | 1.47 |
| Group II | | | | |
| Africa | | | | |
| Ivory Coast | 518 | 671 | 0.86 | 3.76 |
| Zimbabwe | 341 | 618 | 0.39 | 2.87 |
| Asia | | | | |
| India | 23,625 | 379 | 39.38 | 171.68 |
| Latin America | | | | |
| Honduras | 210 | 667 | 0.26 | 1.79 |
| Groups I and II | | | | |
| Totals | 36,985 | 396 (average) | 62 | 282 |

clusion could serve as a lever to improving vaccine production in those countries, where needed.

4.2. Possible other criteria

There are a number of other criteria that might be applied such as the extent to which the program has succeeded in immunizing children — coverage. Coverage is measured in various ways such as the percent of children who receive the third shot of DTP. The problem with using this criterion is the difficulty in obtaining reliable coverage data and that there are no accepted standard methodologies for measuring coverage. An audited budget line for vaccine procurement would be an indirect and probably more reliable measure of vaccine distribution. Another criterion could be membership in the group of heavily indebted poor countries (HIPC). These countries have recently been offered debt forgiveness, if they use the funds that would have been used for debt repayment instead for health and social programs. The implementation of this plan is in its early stages. Of the priority countries identified in this paper, Honduras, Mali, Nicaragua, and Senegal are HIPC countries.

4.3. Feasibility of the VPB goal

Developing countries with per capita GNPs < \$500 allocated approx. 1.97% of GDP⁹ to health through the public sector and 2.36% through the private sector for an average allocation of 4.33% of GDP [32]¹⁰. Thus the suggested VPB of 0.01% GNP represents only about 0.2% of all health expenditures and 0.5% of public health expenditures, on average. By comparison, the World Bank estimates that “EPI plus” (EPI plus hepatitis B, yellow fever where appropriate, and iodine and vitamin A supplementation) will cost about 2% of the public health expenditures of developing countries [33].

⁹ For most developing countries, the difference between GNP and GDP does not significantly affect our calculations.

¹⁰ The contribution of the private sector to the provision of immunization services is increasing in many developing countries. To the extent that consumer purchase of vaccine through the private sector grows, the need for the government and/or donors to bear the cost of immunization services for such middle and upper class children is reduced. The vaccine procurement costs computed below, which omit private sector distribution, are therefore maximums because the private sector purchases will reduce the total requirement. Particularly in the poorest developing countries, the private sector is not a significant supplier of vaccine for children.

¹¹ We do not deny that in the absence of patents, the vaccines might not be developed at all. We are only noting that patent protection can lead to higher prices.

4.4. The VPB goal in the larger context of economic development and globalization

Sen has recently analyzed the connection between health and development [34]. He notes that there is a clear positive relationship between per capita income and life expectancy. This correlation seems to support a strategy of general economic development as a means to improve life expectancy. However, Sen points out that this correlation can be explained fully by controlling for two factors: the incomes of the poor, and public expenditure particularly in health care. Thus, countries can increase the life expectancy of their populations by focusing on two factors: raising the incomes of the poor, and increasing the quantity and quality of health care. In the absence of a general increase in incomes, life expectancy can still be increased by focusing on the quantity and quality of health care. This paper proposes the establishment of a baseline vaccine procurement goal for developing countries of a certain percent of GNP. There is a proposal for the amount developed countries should allocate for development assistance (0.7% of GNP), but, to our knowledge, none for amounts developing countries should allocate for development either in total or for any particular sector. We believe our proposal obtains its justification from the direct link between investment in health and life expectancy in the absence of general economic development, and from the processes of globalization.

The critical globalization factors are the consolidation of the international vaccine industry into a very small number of companies; the increasing centralization and importance of intellectual property rights for vaccines under the World Trade Organization; and the global transmission of infectious disease. The globalizing trends have both positive and negative ramifications for developing countries [35]. For access to new vaccines, the impact seems to have a number of negative features such as the higher prices of vaccines that are controlled by patents¹¹. The management of Global Funds must take these issues into account and not become an unwitting counterproductive partner. It should seek ways to ensure that its programs do not simply accelerate the dominance of the international vaccine market by a few multinational companies. Some aspects of globalization make it even more difficult for high technology companies in developing countries to compete in the international market place. India and Indonesia may be test cases where Global Funds could procure hepatitis B vaccine from local companies, provided the vaccine meets appropriate standards of production, and safety and efficacy.

4.5. Developing countries helping each other?

More economically advanced developing countries might be able to contribute to the Global Funds. To justify such redistribution, it will be necessary to understand the benefit that developing countries obtain from improved health in their neighbor countries. Studies of the economic impact of tuberculosis, HIV, malaria, cholera, and other disease transmission could help answer this question by providing a basis on which to show the economic benefits to one developing country helping other developing countries to control infectious diseases.

4.6. Guaranteed purchase proposals

From time to time there are calls for the establishment of special funds to guarantee the procurement of yet-to-be-developed vaccines such as against AIDS, malaria, and rotavirus [36–38]. These would be funds of several billion dollars that would be available to buy new vaccines as they become available. The basic concept is that there are certain vaccines that industry in the Western world will not readily develop because the vaccines are against diseases that occur predominantly in developing countries. The special funds would show industry that the world is serious about buying the vaccines, and industry would therefore invest to develop the vaccines. These proposals face difficulties. Will governments appropriate sizable amounts of money to be controlled by others for use at an unknown time for an unknown vaccine produced by unknown companies in unknown countries? If funds for malaria, rotavirus and AIDS are justified, what about for hepatitis B, *Streptococcus pneumoniae*, tuberculosis, shigella, etc., all of which cause about 1 million deaths or more each year? Assuming there are seven such funds (for the vaccines listed) and each has \$10 billion, as proposed for malaria, the total would be \$70 billion.

Furthermore, is it proper to set up funds that may guarantee procurement of a particular vaccine for only a few years? Finally, what if a fund is set up for one needed vaccine, e.g. malaria, but development is completed first on another vaccine, e.g. TB, — would the malaria funds be restricted and not available for procurement of the TB vaccine? It seems the Global Funds allocated with the VPB methodology is a much better approach. As representatives of industry have often pointed out, the best indication that the public sector will buy needed vaccines would be for it to buy hepatitis B which is in great need in the developing world and is now reasonably cheap. A transparent and functioning system, as proposed in this paper, to procure current and new vaccines that takes into account

each country's ability to pay will be the best guarantee to industry.

4.7. Limitations of this analysis

The analysis presented here has several limitations. A clearer picture would be obtained by analyzing the burden of disease for Hib vaccine in various countries as it may impact on the need for introducing the vaccine in each country. A more thorough analysis of the possible impact of production of hepatitis B and Hib vaccines in developing countries would be merited. The analysis assumes 100% coverage and 10% wastage. In practice, coverage is likely to be lower and wastage higher. The impact of different levels of each on vaccine procurement requirements should be analyzed.

5. Conclusions

This paper provides an analysis of the application of the VPB methodology for allocating Global Funds. Several conclusions are reached:

- The VPB methodology has the ability to analyze vaccine financing needs on a global, regional, and national basis, and we have shown the application of this methodology with real vaccines using actual costs.
- The immediate priority for Global Fund would be to provide about \$62.2 million per year for procurement of hepatitis B vaccine and \$282 million for Hib.
- One way to initiate the program, at least for the first few years, would be to extend assistance to countries that have met or exceeded the VPB goal. These countries are: Group I — Burkina Faso, Chad, Mali, Nepal, Nicaragua, Nigeria, Pakistan, and Senegal; and Group II — Ivory Coast, Honduras, India, and Zimbabwe.
- Global Funds provide an opportunity not only to buy needed vaccines, but also to realign health policies and priorities to control more effectively vaccine preventable morbidity and mortality. This opportunity should be seized.

The proposed strategy has certain benefits:

- It is transparent. Every country is included and every country is treated the same.
- It is fair and equitable. Every country contributes according to its ability.
- It is workable. It relies on a single criterion of great meaning — the annual allocation by the government of a fair amount of funds for vaccine procurement.
- It is sustainable. Countries will establish an annual

process of allocating funds specifically for vaccine procurement.

- It encourages improvement of local production and regulation/control, and it helps to “diversify” the vaccine market place by possibly bringing in developing country producers.
- The transparency and feasibility encourages donor contributions to the Global Funds giving high visibility to the donor be it an industrialized country or an advanced developing country.
- It stabilizes a sustainable international market for new vaccines thus encouraging development of additional vaccines that are needed most by the poor developing countries.

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