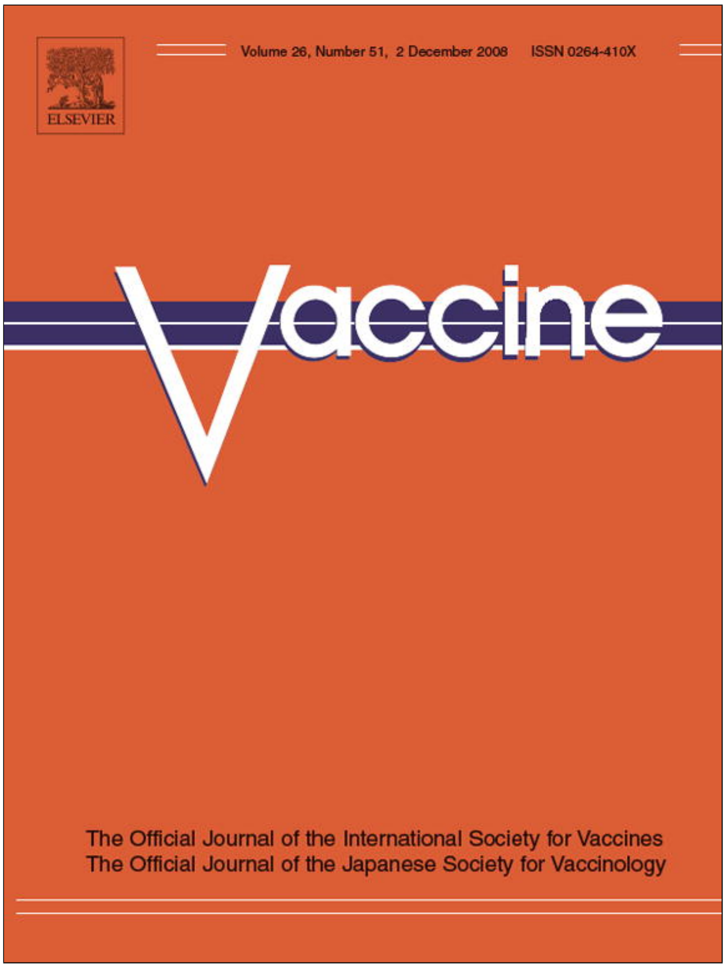
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Review

Introducing new vaccines in the poorest countries: What did we learn from the GAVI experience with financial sustainability?☆

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A B S T R A C T

This paper reviews the experience of the Global Alliance for Vaccines and Immunization (GAVI) in introducing hepatitis B and *Haemophilus influenzae* type b vaccines in the poorest countries, and explores how financing for immunization has changed since GAVI Fund resources were made available during its first wave of support between 2000 and 2006. The analysis of Financial Sustainability Plans in 50 countries allowed for some of the original funding assumptions of the GAVI approach to be tested against the realities in a wide set of countries, and to highlight implications for future immunization efforts. While the initial GAVI experience with financial sustainability has proved successful through the development of plans, and many countries have been able to both introduce new vaccines and mobilize additional financing for immunization, for future GAVI supported vaccine introduction, some country co-financing of these will be needed upfront for the approach to be more sustainable.

Contents

☆ This paper is the second in a series of three papers describing the work of the Financing Task Force in the first five years of the GAVI Alliance. The first document focuses on the Financing Task Force as a model for interagency coordination, and the third one looks at national strategies for achieving financial sustainability in the poorest countries funded by GAVI. A larger document on which these papers are based will be available at the WHO Immunization Financing web site (www.who.int/immunization_financing).

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1. Introduction [1,2]

When the Global Alliance for Vaccines and Immunization (GAVI) was created in early 2000, the architects sought to strengthen routine immunization systems and accelerate the availability of new life saving vaccines in 75 countries with annual per capita gross national incomes of less than $1,000. A particular set of assumptions underpinned the strategy of introduction in the poorest countries. For this to happen, GAVI needed to ensure that new vaccines were scaled up in ways that enable affordable prices to be set. Through the creation of a global purchasing pool that guaranteed countries free vaccines for five years, it was expected that the higher levels of effective demand would stimulate greater competition, economies of scale in production, and consequently lower prices. It was also assumed that during the five years countries would be able to take on the financial responsibility for purchasing new vaccines [3]. The vaccines prioritized by GAVI during its first wave of support (2001–2006) were those against hepatitis B (HepB) and *Haemophilus influenzae* type b (Hib) in combination with diphtheria, tetanus and pertussis vaccine (DTP).[8] These existing, but largely unavailable vaccines to poor countries, were safe, cost-effective, and known to have significant health benefits [4].

From the start of the GAVI Alliance, international partner agencies were concerned about ensuring the financial sustainability of immunization programs once the GAVI time-limited support ended. The essence of the GAVI financing strategy relied on a transition in funding away from continuing inputs by the GAVI Fund. The concerns about financial sustainability were addressed systematically by requiring that all countries receiving support indicate in their application proposals, in general terms, (a) how they expected to finance immunization services broadly, and new vaccines specifically, after the initial commitments drew to an end, and (b) commit to preparing a detailed Financial Sustainability Plan (FSP) mid-way through the funding period [5]. The FSP was to describe in detail how countries would transition from GAVI Fund resources to other sources of funding, and in line with GAVI's operating definition of financial sustainability [6].[9]

While the first paper in this series captures the experience of the GAVI Financing Task Force (FTF) and its work on financial sustainability [1], this paper analyses financial sustainability through the immunization expenditure and financing data collected in country FSPs. Such an analysis allows for testing the original assumptions of the GAVI approach of financing against the realities in a wide set of countries. These assumption include, in particular: (i) that five years would be sufficient for eligible countries to plan the transition away from GAVI Fund support to national and other sources of funding; (ii) that the GAVI push to rejuvenate global immunization efforts would catalyse additional resources by governments and donors agencies and not displace existing financial investments in immunization; thus ensuring financial sustainability of expanded schedules with new vaccines after GAVI [7]; and (iii) that stimulating a demand for vaccines in 75 of the poorest countries would help to create a competitive marketplace for vaccines and provide opportunities for manufacturers to realize scale economies in production, resulting in more affordable prices after the five-year term.

2. Methods

In fulfilling its role, the FTF recognized from the onset, the importance of developing a comprehensive database on immunization expenditures and financing in GAVI countries. Such a database would yield insights about donor and government financing patterns for immunization, and strategies for long-term financial sustainability. With support from the FTF, a database development team with representatives from many GAVI partner institutions was established to work through methodologies, data standardization, consolidation and analysis [8,9].

The findings presented in this paper are based on the data from the immunization financing database using a subset of 50 of the 75 GAVI countries for which the information reported in their FSP was deemed of sufficiently high quality and comparability.[10] More specifically, the data provided using the FSP costing, financing and gap analysis tool developed by the database team, were extracted into the immunization financing database available from a WHO website [10,11].[11]

[8] Hepatitis vaccine alone is referred to as the monovalent presentation; in combination with DTP it is called tetravalent vaccine, and in combination with DTP and Hib, the pentavalent vaccine.

[9] The FSP is a document that assesses the key financing challenges facing the national immunization program, and describes the government's approach to mobilizing and effectively using financial resources to support medium and long-term program objectives. It is prepared by the national government (including managers of the national immunization program, and officials of the Ministries of Health and Finance), in collaboration with other members of the Inter-Agency Coordinating Committee (ICC) and other relevant donor groups. It was expected to be a key instrument for governments to use in planning for the financial health of the immunization program—and in advocating among the Ministry of Health, Ministry of Finance and development partners to support planned and agreed program expansion and improvement. In June 2001, the GAVI Board accepted the following definition of financial sustainability: "*Although self-sufficiency is the ultimate goal, in the nearer term sustainable financing is the ability of a country to mobilize and efficiently use domestic and supplementary external resources on a reliable basis to achieve current and future target levels of immunization performance in terms of access, utilization, quality, safety and equity*".

[10] The 50 countries are: Afghanistan, Albania, Armenia, Azerbaijan, Benin, Bhutan, Bosnia and Herzegovina, Burkina Faso, Burundi, Cambodia, Cameroon, Comoros, Côte d'Ivoire, Democratic People's Republic of Korea, Democratic Republic of the Congo, Eritrea, Ethiopia, Gambia, Georgia, Ghana, Guinea, Guyana, Haiti, Kenya, Kyrgyzstan, Lao People's Democratic Republic, Lesotho, Madagascar, Malawi, Mali, Mauritania, Mozambique, Myanmar, Nepal, Niger, Republic of Moldova, Rwanda, Senegal, Sierra Leone, Sri Lanka, Sudan, Tajikistan, Uganda, Ukraine, United Republic of Tanzania, Uzbekistan, Viet Nam, Yemen, Zambia, Zimbabwe.

[11] www.who.int/immunization_financing. The data extracted may be different from those contained in the original FSP documents submitted to GAVI due to a

The data are presented over three time periods: a baseline year before GAVI support began, a year with GAVI support, and a future projected period between 2005 and 2010. These three periods reflect the trends before, during, and after the initial wave of GAVI financing (2000–2006). The baseline corresponds to a year for which data on expenditures and financing were available before any GAVI Fund support was awarded to a country. The GAVI year corresponds to one of the first few years after GAVI Fund support was approved, disbursed and received in a country (with at least one full year of implementation of new vaccines). For the most part, the baseline years were 2001 or 2002. The year with GAVI support was either 2003 or 2004, depending on when a country developed its FSP. For these two retrospective periods, inflationary adjustments were made to bring all expenditure and financing data to the same comparable reference year [12].

Given that the first wave of GAVI funding was provided for five years, the prospective period 2005–2010 captures the phasing out of awards and the extent to which the transition from GAVI to national and partner financing is occurring. As the FSP methodology required countries to make 10-year projections of future expenditures and financing, the 2005–2010 period was chosen as a cross-section of prospective years that was common to all 50 countries. Given uncertainties about future available financing for immunization, the analysis considered both committed (secured) and non-committed (probable) future funds projected by countries in their FSP. Although accounting for both types of financing depicts a more optimistic perspective, it was considered to be a more realistic portrayal of future financing than including only secured financial flows.[12]

The measures of central tendency favoured in this report are population weighted averages for the three chosen periods expressed in US dollars. Moreover, the indicators of choice in the analysis are immunization expenditures and financing per infant using the number of children under the one-year of age as the common denominator [13]. Such indicators should be interpreted as based on infants in the birth cohort, rather than infants fully immunized. In other words, vaccination coverage is not factored into the indicator.

Most of the findings are presented by grouping countries according to income groups and by the WHO regional classification of countries.[13] Unless otherwise specified, all figures correspond to routine immunization program-specific expenditures or financing. Shared health systems expenditures and financing, and those for immunization campaigns have been excluded to permit cross-country, and cross-temporal comparisons. Because of this, the analysis does not represent the full cost of immunization service delivery, rather those that are specific to routine immunization service delivery, such as training of immunization staff, cold chain equipment and maintenance, transport by immunization personnel, and so forth.

The findings in this paper will be presented around three pertinent dimensions: expenditures on immunization, immunization financing and health sector financing. Expenditures focus on how much is being spent on immunization; the composition of this spending and the sources of variability; as well as future trends of scaling up to reach program objectives, including with HepB and Hib vaccines. The financing dimension reviews past and future trends in immunization financing; the sources of financing and how they have changed with new investments through GAVI; and the financing gaps related to reaching immunization goals and targets. Finally, immunization expenditures are compared with overall government health expenditures on health to understand how immunization resources fit within the broader health financing context.

3. Limitations

Important limitations need to be acknowledged upfront. First, the data used capture and reflect the assumptions and limitations of the national sustainability plans. This relates to both the limitations of the FSP guidelines and tools themselves, and to the quality of the data reported which varied from country to country.[14]

Second, the analysis and findings draw from the highest quality and comparable data from 50 of the 75 GAVI countries as reported in their FSP. The interpretation of the findings in this analysis should therefore be made with some understanding of the composition of the sample. While all 50 countries rank among the poorest countries with per capita gross national incomes of $1,000 or less, the sample average is in the neighbourhood of $400. In terms of regional representation, African countries are most predominant reflecting the GAVI eligibility bias.[15] Although the purpose of the analysis is not to make generalizations, the sample of 50 countries used and findings are mostly representative of the situation in African countries with incomes of $1 a day or less.

Third, given the difficulties in tracking the exact sources of financing, countries were asked to report only the source of financing closest to the end of the financing flows. Therefore, transfers of bilateral donor agency resources to multilateral agencies, or to a health fund or the national treasuries (through pooled funding) are not attributed to the donor countries. This is of particular, and growing, significance in countries receiving bilateral aid through sector-wide approach (SWAp) programs and national budget support. Likewise some bilateral agencies provide significant funding for immunization by contributing directly to GAVI.[16] In this case, the end source of financing is attributed to the GAVI Fund and not the bilateral agency. In addition, because of the focus on program-specific costs, the often significant contributions of the national government to the shared health systems costs that are critical to a well-functioning immunization program are not taken into account. If considered, these shared expenditures would represent at least 20% of total expenditures on routine immunization (both specific and shared) [14].

process of data harmonization, cleaning, and updating according to methodologies developed by an immunization financing database team.

[12] It is known that some countries would not consider any funding as secured even if these were committed. Instead they would consider secured funding as probable monies that the immunization program should expect to be available. For this reason, it is reasonable to expect that the most realistic funding scenario for immunization is one that includes both secure and probable monies.

[13] Using WHO's nomenclature of regions as follows: AFR (for Africa), AMR (for the Americas), EMR (for Eastern Mediterranean), EUR (for Europe), SEAR (for South East Asia) and WPR (for the West Pacific); www.who.int/about/en/. The income groups chosen were the following: $1 a day or less countries were those that had per capita gross national income levels of $365 or less (24 countries). The $2 a day countries were those that have per capita gross national income levels greater that $365 but less that $730 (17 countries). The $3 a day countries are those that have per capita gross national income levels greater that $730 but less than the GAVI eligible threshold of $1,000 (9 countries).

[14] The best available data were selected for this analysis. Further information on data quality is available on the immunization financing website: www.who.int/immunization_financing.

[15] The number of countries in the sample by region is as follows: 27 in AFR, 2 in AMR, 3 in EMR, 10 in EUR, 5 in SEAR and 3 in WPR. The relative proportion of infants in the sample by region is the following: 64% in AFR, 1% in AMR, 11% in EMR, 6% in EUR, 10% in SEAR and 8% in WPR.

[16] In the first phase of GAVI (2000–2006) about $1.2 billion were available in the GAVI Fund. This includes $750 million initial grant from the Bill and Melinda Gates Foundation. The remaining funds were topped up by bilateral agencies.

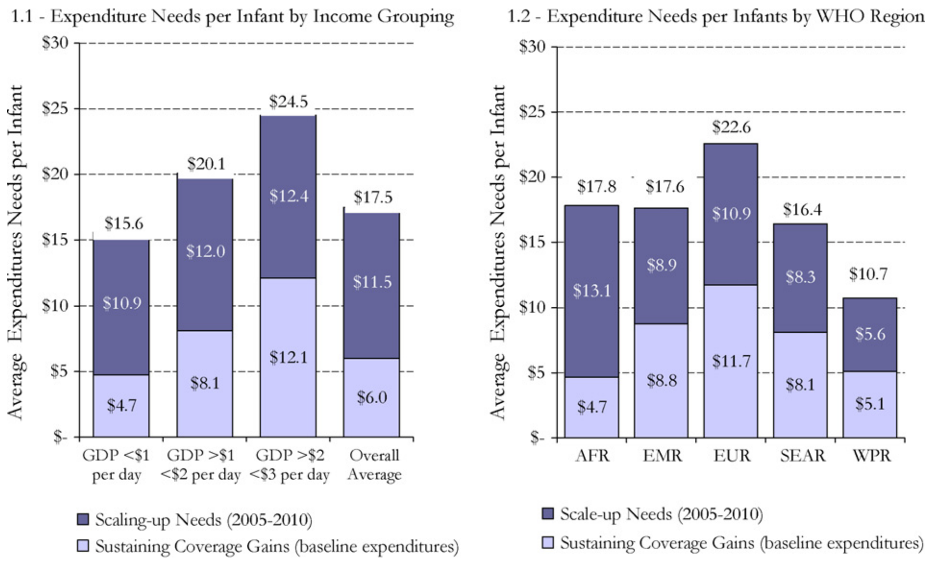

Fig. 1. Immunization expenditures per infant across income groups and regions to sustain current immunization gains and scale up during 2005–2010.

Fourth, because of uncertainties relating to future needs and funding availability, information on past expenditures and financing is likely to be more reliable than projections about future trends. In some instances, future projections of resource requirements may be over-estimated due to uncertainties around the future price of vaccines as these were based on holding vaccine prices constant. Likewise, these same projections could suffer from being under-estimated in countries where there have been changes in country priorities for vaccine introduction beyond HepB and Hib vaccines. Today the context for new vaccine introduction has changed considerably with the availability of pneumococcal conjugate and rotavirus vaccines and these two vaccines were not accounted for at the time of the FSP development.

Finally, the analysis is unable to account for the impact of financial sustainability strategies that countries have outlined in their FSPs, and how these might change the future financing landscape and funding gaps. The analysis of financial sustainability strategies is reviewed in the third paper of the series [2].

4. Results

4.1. Immunization expenditures are on the rise

Since 2000, expenditures for routine immunization in the poorest countries have risen and are projected to increase in the future. Baseline expenditures in the 50 countries before GAVI averaged $6.0 per infant in the birth cohort. These increased to $9.2 in the year with GAVI Fund support, and are projected to reach an average of $17.5 per infant during the 2005–2010 period in order to both scale up with HepB and Hib containing vaccines, and increase immunization coverage (Fig. 1.1). In other words, expenditures to scale up immunization during 2005–2010 need to increase beyond baseline investments in immunization specific items by at least a factor of three. While the majority of the scale up needs are attributable to the new vaccines, a portion is required to increase immunization coverage from 66% in the baseline year to 71% in the year with GAVI to projected targets averaging 88% during 2005–010.

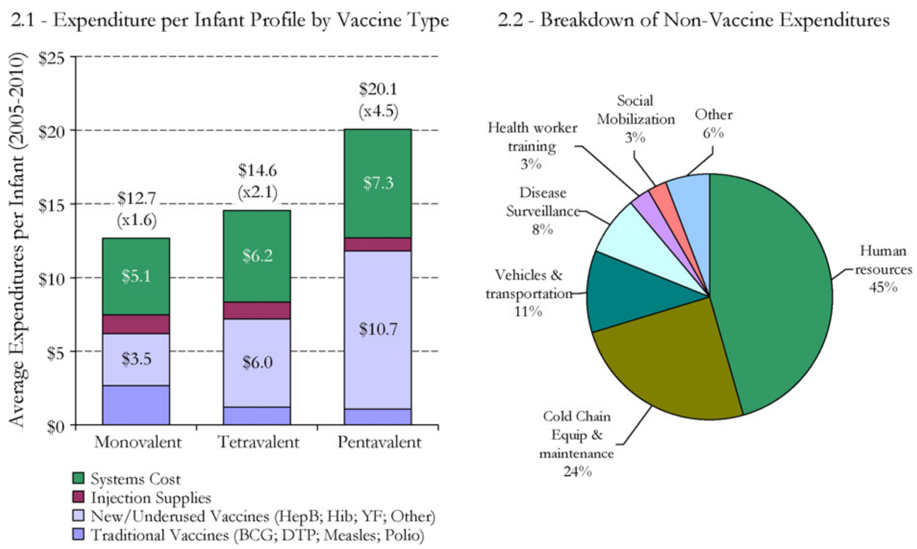

Fig. 2. Immunization expenditures profile and systems cost profile.

By grouping the 50 countries into those with gross national incomes levels per capita of less than $1, $2 and $3 a day, Fig. 1.1 highlights that immunization expenditures to sustain and scale-up immunization are positively related to the level of income. Conversely the amount of resources needed to scale-up between 2005 and 2010 as a percent of baseline expenditures tends to drop by country income.

Countries with less than a dollar a day spent on average $4.7 per infant to reach 62% coverage in the baseline year. On the other hand, $3 a day countries spend more than twice as much as $1 day countries to achieve average immunization coverage rates above 80%. It is hardly surprising that the needs to scale up immunization systems between 2005 and 2010 are greater in $1 a day countries than in $3 a day countries as the former require a tripling of baseline investments whereas the latter require a doubling. Most of the scale up needs in $1 a day countries are attributable to the planned introduction of HepB and Hib combination vaccines and the need to scale up coverage. In the $3 a day countries, the scale up is mainly attributable to the introduction of HepB vaccines and sustaining high coverage levels.

In addition to variations linked to income levels, important regional differences feature in Fig. 1.2. The baseline expenditures in Africa (AFR) and in the West Pacific region (WPR) tend to be lower than in other regions, particularly in the European region (EUR). This is explained by differences in immunization coverage in the countries of the sample representing these regions—spending more implies reaching more children with vaccination. Important variability across regions is also due to differences in wage bills, human resource constraints and levels of integration of immunization in the health system. In WPR and AFR labour costs are lower than in other regions [14].

Regional differences are further evidenced when looking at expenditures required to scale-up. By 2010 in the Africa region, immunization expenditures will represent four times more investments per infant than those of the baseline year (Fig. 1.2). This is explained by lower baseline levels of coverage as compared to other regions (and thus the greater scaling up targets), and the preference in Africa, more than in other regions, to introduce the most expensive pentavalent vaccine (DTP-HepB-Hib). Indeed, at the time of the FSP development, European countries represented in the sample were not planning to expand immunization schedules beyond HepB, or combination products with HepB (DTP-HepB). Most are $3 a day countries.

4.2. Vaccines are becoming the largest expenditure driver

The composition of expenditures gives some insight about which inputs drive the increasing cost of immunization. The introduction of HepB and Hib vaccines account for the majority of the increase. Combined with related injection equipment, vaccines have become the single largest cost driver of routine delivery systems. This is a substantial departure from the past when human resources constituted the bulk of immunization expenditures. The importance of vaccines and related injection supplies are expected to increase in the future to account for at least 50% of planned expenditures between 2005 and 2010 [14].

The changing cost profile for immunization is most evident when countries are grouped according to new vaccines introduced and vaccine presentation. Fig. 2.1 shows that the average cost per infant in countries that expanded their immunization schedules beyond the traditional vaccines to include HepB in a monovalent form is approximately $13.0. This contrasts to the $20.0 per infant in countries that introduced the pentavalent vaccines. The relative share of new vaccines in the total can range from $4.0 per infant in countries with monovalent HepB vaccine, to $11.0 per infant in the group of countries that introduced the pentavalent presentation that includes both Hep B and Hib.

Expenditures per infant have doubled in countries that introduced tetravalent HepB vaccine. These can be expected to increase by a factor of three to four if pentavalent vaccine is added to national immunization schedules. Such a changing expenditure profile for immunization will have implications in terms of the need for mobilizing greater annual funding to guarantee the provision of all vaccines and injection materials to countries in the future.

The cost implications of introducing new vaccines go well beyond the cost of the vaccines alone. Overall, systems expenditures have a tendency to rise in the immediate years following introduction of new vaccines by an average of 22% [14]. These are important non-vaccine inputs needed for vaccine delivery (also known as systems costs). It is difficult to reach any firm conclusion about these trends without knowing what increases would have occurred in the absence of HepB and Hib introduction. What is clear is that the performance-based immunization services strengthening (ISS) funding from GAVI was used to pay for systems costs, along with the $100,000 new vaccine introduction cash grants [15,16].[17] On average, spending of ISS funds accounted for 11% of overall non-vaccine expenditures, and in some countries represented more than 30% [14].

Fig. 1.1 highlight the importance of systems costs which are critical for the routine immunization systems ability to deliver vaccines to children. Depending on the new vaccine being introduced, the systems cost requirements tend to be greater. Fig. 2.2 presents the overall expenditure profile of the 50 countries when looking at the breakdown of non-vaccine expenditures into more detailed components. Some 80% of systems costs are related to service delivery including immunization specific human resources (45%), cold chain equipment and maintenance (24%) and vehicles and transportation expenditures (11%).

4.3. Other important sources of variability in expenditures

The variability in immunization expenditures per infant is largely influenced by differences in the vaccines provided, level of economic development, and coverage. Another important source of variability is linked to differences in delivery strategies. Many of the 50 countries rely on supplemental immunization activities to reach more children and respond to epidemiological needs or eradication initiatives. Mass campaigns, national immunization days, mop-up activities and outbreak responses are becoming an integral part of national immunization programs. The amounts being spent to support these are important, and in a particular year, can sometimes exceed the expenditures on routine delivery systems (Table 1).

Overall, an additional $3–5 per infant in the figures we are discussing can be attributed to supplemental immunization activities beyond routine immunization services. The reliance on campaign activities for polio, measles, neonatal tetanus and yellow fever prevention is greatest in countries that are economically fragile and whose immunization programs are weaker performers. In Africa, an additional $5.2 per infant was spent on campaigns in the baseline year above and beyond the $4.7 spent on routine immunization services (Table 1). Given weaker systems, important resources for immunization in Africa have been tied up in supplemental

[17] In supporting HepB and Hib vaccine introduction in countries, GAVI provided a one time vaccine introduction grant of $100,000 to support vaccine introduction activities. To support immunization services strengthening, the ISS window of support provided performance based cash of $20.0 per child fully immunized above the number in a baseline year, then $20.0 per fully immunized child above the highest previous number, once the baseline is surpassed. (www.gavialliance.org).

Table 1
Expenditures on immunization campaigns.

	Coverage DTP3	Expenditures on campaigns per infant (US$)[a]		
	Baseline year	Baseline year	Year with GAVI	2005–2010[b]
Overall	66%	$4.7 (44%)	$3.8 (29%)	$3.1 (15%)
WHO African region	62%	$5.2 (53%)	$4.0 (33%)	$2.6 (13%)
By income group				
<$1 per day	62%	$5.4 (53%)	$4.5 (37%)	$3.1 (16%)
>$1 and <$2 per day	72%	$3.4 (30%)	$2.7 (20%)	$3.4 (14%)
>$2 and <$3 per day	90%	$2.9 (20%)	$2.3 (12%)	$2.1 (8%)

[a] The figures in percent refer to campaign spending as a share of total immunization spending (both routine immunization and campaigns).
[b] The figures for the years 2005–2010 refer to the average projected needs for that period.

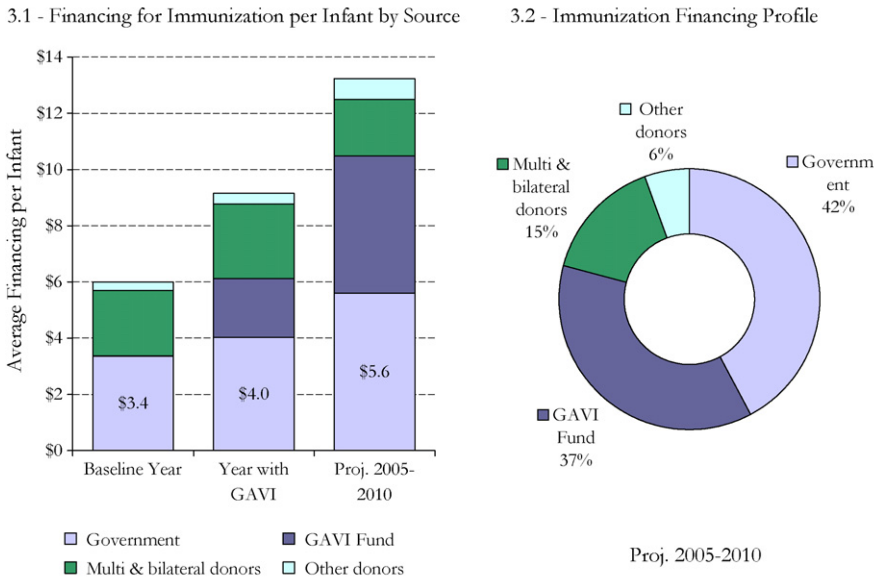

Fig. 3. Immunization financing trends and profile (routine).

immunization activities where over 50% of total expenditures on immunization are for campaign activities.

4.4. *Immunization financing is also on the rise*

Since 2000 the trend in immunization financing is one characterized by increases in both national and external financing for routine immunization. National government financing has risen from $3.4 to $4.0 per infant between the baseline and the year with GAVI; and is projected to increase to an average of $5.6 per infant over the 2005–2010 period. Likewise, financing per infant from multilateral, bilateral and other sources increased between the baseline year and the year with GAVI funding from $2.6 to $3.0 per infant (Fig. 3.1). The trend from these sources is less certain in the future, particularly as bilateral donor agencies are unable to make multiyear commitments. As such, bilateral donor contributions may not be included in the financing projections despite the fact that key bilateral donors have a historical track record in supporting immunization programs. The overall financing from multilateral, bilateral and other external donor sources is projected to average $2.7 per infant over the 2005–2010 period. In essence, funding from these sources is projected to maintain at their baseline levels.[18]

The most important change in immunization financing are the contributions from the GAVI Alliance. On average, GAVI Fund commitments during the first wave of support represent an average of $4.9 per infant per year over the 2005–2010 period.

While national government funding is expected to account for 42% of overall funding between 2005 and 2010, GAVI Fund resources will represent the second largest source of financing for routine immunization (37%). Almost 80% of all funding for routine immunization will rely on these two sources of funding up to 2010 (Fig. 3.2).

In the absence of GAVI awards, immunization financing from all other sources has increased between the baseline and the year with GAVI. The rise in immunization financing is confirmed over the 2005–2010 period. Based on analysis of overall and average trends in the 50 countries, there is no clear indication that GAVI funding has displaced existing financial flows for immunization; rather GAVI funding added to growing funding from both national and other external sources.

However, country specific information shows important variations, however. Of the 50 countries, five saw a drop in their overall funding even with the infusion of additional GAVI resources. If GAVI support is excluded, 17 countries saw a drop in routine immuniza-

[18] The trends are quite different for multilateral agencies if funding for campaigns is included. By including campaign funding, financing from multilaterals would represent 30% of overall immunization financing and average approximately $4.0 per infant. Multilateral funding for campaigns often exceeds flows for routine immunization. Although substantial funding for immunization is tied up in supplemental immunization activities, campaigns as a strategy to deliver vaccines continue to play a significant role in reaching the objectives and targets of immunization programs.

Fig. 4. Future needs, financing and gaps—2005–2010.

tion financing. It is difficult to ascertain whether this trend is simply cyclical, or indicative of a real downward movement in financing. Funding for vaccines and capital equipment can explain upward and downward movements depending on stock levels for vaccines and the need to invest in new equipment (e.g. cold chain). Yet, in five countries, there were explicit mentions in the FSP document that GAVI Fund resources had displaced or resulted in a reduction in financing for immunization by other sources [14]. In other countries it is difficult to conclude that these specific country trends would have occurred whether or not GAVI resources had been made available.

4.5. *Funding gaps are looming*

Increasing resource requirements to meet program objectives are accompanied by the challenge of mobilizing the additional required financing. By combining the information from both the expenditure and financing dimensions of the analysis, the situation can be assessed in terms of how the transition away from GAVI Fund support to other sources of funding is taking place according to the GAVI approach to financing.

Earlier findings showed that both expenditures and financing were on the rise and that GAVI resources are making an important contribution to meeting the increasing needs for routine immunization. Yet, despite positive trends, expected future funds will not be enough to match the needs to sustain the gains nor scale up immunization to complete the HepB and Hib agenda as envisioned by GAVI. The growth rates in financing are far outpaced by the growth rates in future resource requirements. Of the $17.5 per infant needed annually during 2005–2010, there are average funding gaps of $4.3 per infant per year if both committed and non-committed funds are considered. In this optimistic funding scenario, some 25% of the expenditure needs remain largely unmet to reach objectives of the program.

The size of the gaps reflects the different capacities and opportunities available to countries to mobilize the needed resources for their program in the short-term and medium-term. Fig. 4.1 suggests that the willingness of national governments to finance immunization increases with income levels. In countries with incomes less than a dollar a day, the average government financing is projected to average $3.0 per infant whereas national governments in countries with incomes of $3.0 a day project that they will finance $14.9 per infant. It is not surprising to see that the funding gaps between 2005 and 2010 are greater in $1.0 a day countries, almost three times more than in $3.0 a day countries. At the same time, the reliance of GAVI Fund support tends to decline with economic development. In less that $1 a day countries, the GAVI Fund is the single largest source of financing, above the national government contribution for routine immunization. Regionally, the largest gaps are found in Africa where the shortfalls exceed $5.0 per infant per year to reach program objectives. This region is heavily dependant on GAVI Fund resources.

4.6. *Unfavourable movement in vaccine prices*

One of the objectives of the GAVI approach to financing was to generate a market impact on vaccines to make them more affordable to the poorest countries. From the beginning, leveraging GAVI's significant resources of over $1.2 billion on the vaccine market was central to this approach and would facilitate countries' ability to get on a path of financial sustainability during the initial phase of GAVI support. However, with the exception of HepB vaccine in the monovalent formulation, the price of other GAVI supported HepB and Hib combination products showed a pattern of rising prices per dose between 2001 and 2006. The price per dose of pentavalent vaccine rose from $3.2 to $3.6 during this period—over a 10% increase [17].Many factors explain this trend including the declining value of the US dollar. During the initial phase of GAVI, the market for tetravalent and pentavalent vaccines was fragile, both in terms of supply from manufacturers and demand from countries. The supplier base for GAVI supported vaccines was limited between 2000 and 2006. In the case of both pentavalent and tetravalent vaccines, there was only one supplier from the outset and this supplier was unable to meet the full demand from countries. Thus the effective uptake from countries was slower than anticipated. The presence of multiple suppliers and strong demand is critical for the approach to work. GAVI's initial expectations of rapid price declines within the first five years were too optimistic (Fig. 5).

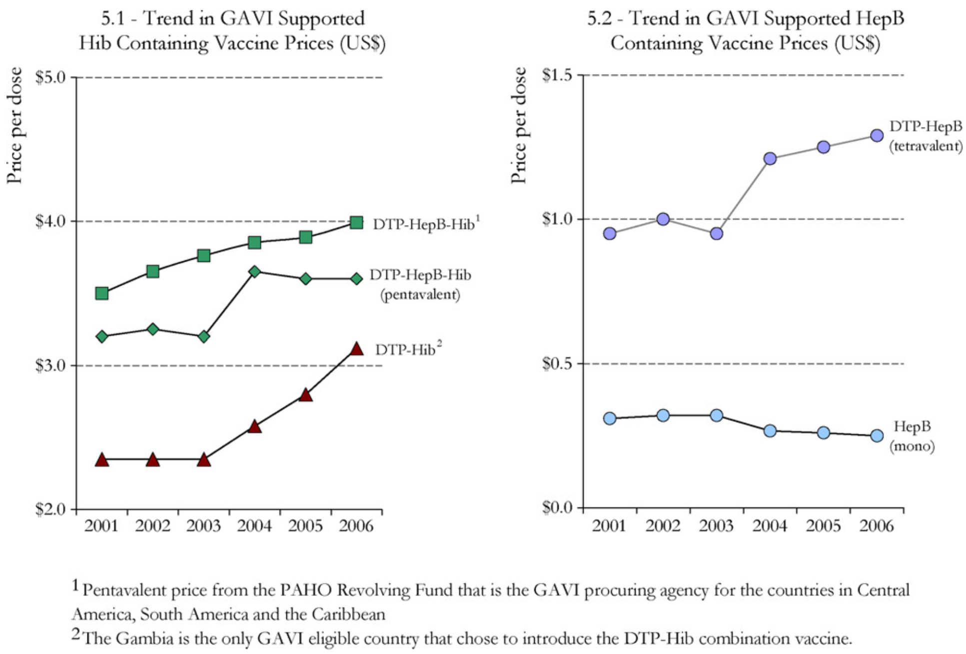

Fig. 5. Trend in the price per dose of GAVI supported vaccines—2001–2006. [21] (1) Pentavalent price from the PAHO revolving fund that is the GAVI procuring agency for the countries in Central America, South America and the Caribbean. (2) The Gambia is the only GAVI eligible country that chose to introduce the DTP-Hib combination vaccine.

Experience is now showing that prices do decline but that this process requires more time. The price of HepB containing tetravalent vaccine is declining substantially as new manufacturers, particularly emerging suppliers enter the market [18]. Similarly the future evolution of pentavalent prices is showing promising trends. Recent market intelligence highlights that as multiple new products become available and obtain WHO pre-qualification status, the price per dose of pentavalent will begin to mature, and the market will become healthier in terms of competition [18].

4.7. Financial sustainability is far from assured

Moving towards financial sustainability is invariably linked to future macroeconomic trends and how these will affect the availability of overall resources and financing for the health sector, and the priority that is placed on immunization services compared to other health priorities.[19] This in turn needs to be balanced against the overall budgetary impact of scaling up immunization to reach coverage targets and expanding vaccination schedules with HepB and Hib vaccine.

Analysis of immunization expenditures compared to national health financing shows that routine immunization represents on average, 2.4% of government health expenditures in the baseline year (Table 2). During 2005–2010, immunization is expected to average 3.7% of annual projected government health expenditures. There are some important ranges in theses estimates. In eight countries, routine immunization exceeds 10.0% and in two, the share is greater than 20.0% of government health expenditures.

The findings suggest that the pressure on health budgets drops with income levels as immunization accounts for a decreasing share of government health expenditures. In countries with less than a $1 a day, immunization expenditures will average 9.0% of overall government health expenditures during 2005–2010 (Table 2). This contrasts with $3 a day countries where the average for the same period is less that 1%. Regionally, the largest pressure on health budgets will be found in Africa where the scaling up of immunization during 2005–2010 will represent, on average 8.6% of government health expenditures.

Much of this variability is linked to the vaccines awarded by the GAVI Alliance that are being included in vaccination schedules. As highlighted earlier, the introduction of HepB and Hib vaccines account for the majority of the increase in expenditures for routine immunization. Stratifying the analysis by GAVI-awarded vaccine gives a sense of the relative challenge of financial sustainability of different vaccination schedules.

During 2005–2010 when we can expect a full introduction of these GAVI supported new vaccines, the analysis showed that for countries introducing monovalent HepB, a 1.1% allocation of the government health budgets would be sufficient to cover the entire needs. This compares to an average of 6.0% and 9.2% in the group of countries that introduced combination tetravalent and pentavalent vaccines, respectively. If we take as a benchmark the 3.7% average future immunization requirements in estimated health budgets, the figures presented suggest that the pressure on health budgets will be significant in countries that choose to introduce combination vaccines with Hib (Table 2).

5. Discussion

From the beginning, the architects of the Alliance knew that helping the poorest countries introduce new vaccines and strengthen their immunization systems through multiyear funding commitments would be accompanied by enormous challenges. They recognized that without addressing the long-term financing consequences, countries would continue to depend on global funding and would be unable to finance improvements once GAVI funding came to an end. The ultimate fear was that countries would end up worse off after the GAVI time-limited support, if financial sustainability was not addressed from the start [19].

The extent of the challenges of introducing HepB and Hib combination vaccines into more fragile routine delivery systems became

[19] Immunization is still considered the “best buys” for the health sector. The price tag, even with new vaccines, is relatively small if one considers the long-term health benefits and poverty-reducing effects that vaccinations confer.

Table 2
Expenditures on routine immunization in government health expenditures.

	Countries	Immunization expenditures % government health expenditures[a]		
	Number	Baseline year	Year with GAVI	2005–2010
Overall	50	2.4%	2.7%	3.7%
Range (min–max)	50	(<1–24%)	(<1–31%)	(1–35%)
WHO African region	27	3.6%	4.4%	8.6%
By income group				
<$1 per day	29	5.0%	7.2%	9.0%
>$1 and <$2 per day	16	2.2%	2.7%	3.4%
>$2 and <$3 per day	5	0.5%	0.8%	0.9%
By GAVI vaccine				
HepB (mono)	20	1.5%	1.6%	1.1%
DTP-HepB	8	3.4%	2.4%	6.0%
DTP-HepB + Hib	19	3.1%	7.4%	9.2%

[a] Note that government health expenditures, also known as public sector spending, combines government resources and external assistance for health. The estimates of future health budgets were made by taking the latest available figures on government health expenditures as a share of gross domestic product (GDP) and applying these to forecasted GDP figures up to 2010. The data on national health accounts were available from www.who.int/nha/country for 2006. The World Bank development indicators (WDI) were the source of GDP figures (www.publications.worldbank.org/WDI/). Forecasted GDP growth rates up to 2010 were taken from the IMF World Economic Outlook (WEO) and from the Economist Intelligence Unit (EIU—www.eiu.com).

evident from the early analyses of the first rounds of country FSPs [20,21]. These challenges were confirmed in this analysis, which allowed for some of the original funding assumptions of the GAVI approach to be tested against the realities in a wide set of countries, and to highlight implications for future immunization efforts.

The evidence gathered from the 50 countries suggests that resource requirements for routine immunization will continue to increase in the future due to the higher prices of new vaccines and will be primarily driven by the current price of Hib. In many countries the changing expenditure profile of immunization has led to a doubling and tripling of program budgets from pre-introduction baseline levels. In the short-term, the increased costs of immunization programs are offset by GAVI's multi-year commitments. However, the long-term challenge will be the need for the mobilization of significantly greater funding for immunization programs on an annual basis.

As long as adequate funding can be secured in the future, reaching immunization goals and objectives should be achievable. The findings have shown that immunization financing is on the rise and that GAVI resources are making an important contribution to meeting the increasing needs to scale up with new vaccines. Despite this favourable context, it still remains an open question as to whether the GAVI approach to financing succeeded in fully catalysing investments in immunization by others, and is ensuring financially sustainability. The analysis showed limited signs that countries will transition to other sources of financing following the first wave of GAVI support. Even in the most optimistic future financing scenario, the share of the unfunded mandate reached an average $4.3 per infant. And until 2010, almost 80.0% of all funding for routine immunization relies on just two sources of financing: government budgetary allocations and the GAVI Fund. Expected future financing, even with GAVI support will not suffice to match the needs to sustain current immunization gains, and complete the HepB and Hib agenda as envisioned. However, it was never GAVI's intention to fully fund all the needs of routine immunization services. Financing of traditional vaccines, and the majority of the expenditures on service delivery currently unfunded, should continue to be the national governments responsibility supported by national and international partners of immunization.

The findings do not support the notion that GAVI displaced existing resources for immunization and do not demonstrate that GAVI funding has fully catalysed additional support from development partners at country level. Several factors have hindered countries ability to move towards financial sustainability. First, vaccine prices did not decline to affordable levels within the GAVI five-year time frame. Second, although there are signs of change, traditional immunization donors have been unable or unwilling to make multi-year commitments into the future. Finally, the FSPs presented mid-way through GAVI support provided insufficient time for national governments and donor partners to line up and implement a comprehensive strategy for transitioning from GAVI to other sources of financing.[20]

Closing the funding gaps for immunization and achieving financial sustainability will require several important actions in these countries, for instance: a larger public sector budget resulting from economic growth; greater government commitments to immunization within health budgets; greater donor multi-year commitments; a reduction in vaccine prices; and under any scenario, a major sustained effort by the GAVI Alliance to support countries to introduce new vaccines and to permit sufficient time and planning for a transition away from GAVI support enabling countries to become financially self-sustainable.

6. Conclusion

Unlike previous global immunization initiatives, such as UNICEF's Universal Childhood Immunization (UCI) in the late 1980s and early 1990s, GAVI chose to focus on financial sustainability from the outset. To date, GAVI remains the only global partnership to have tackled and made financial sustainability at country level a priority. Despite the challenges and limitations in GAVI's approach to financial sustainability outlined in this paper, many countries considered the FSP development process to be positive. For many countries, the FSP was the first opportunity to have a complete appreciation of the expenditures and financing of their immunization program and within the broader health system [7]. For others, the FSP development process marked the first time immunization program managers worked with their colleagues in the Ministry

[20] It is important to note that because of the difficulty of obtaining long-term commitments, it is expected that a gap of some size will always exist when projecting into the future.

of Finance. Importantly, it was only through the FSP process mid-way through vaccine introduction that the financial implications of the decision to introduce HepB and Hib vaccines were evident to both Ministries of Health and Finance. In some cases, countries that had introduced Hib-containing combination vaccines expressed considerable concern whether their limited health budgets would withstand the costs of the combination vaccine at current price levels once GAVI support ended.

Although a clear understanding of the costs of immunization and gaps in financing is crucial to mobilizing adequate and sustainable resources, decision-makers need to be reminded early on, of the value of vaccines as a crucial cost-effective investment in health. A specific GAVI country consultation process illustrated that decisions about new vaccine introduction were often made without detailed analyses of disease burden and cost-effectiveness [22], both of which are crucial for informed decision-making and for medium and long-term planning for sustainability after introduction. Attempts to resolve the issue were made subsequently through high level advocacy for political buy-in, and by ensuring that the FSP was integrated into the broader strategic planning processes of the health sector that influence the level of resources allocated for immunization.

Two key lessons for GAVI in moving forward will be to ensure that disease burden and cost-effectiveness inform national decision making about new vaccine introduction from the beginning and that financial sustainability considerations are an integral and fundamental part of the preparation and implementation of a program's multi-year plan of action [23]. For the next phase of support (2006–2015), GAVI needs to continue strengthening the work with countries on financial sustainability as part of the decision making process about new vaccine introduction and ensuring that countries commit from the onset to co-financing awarded vaccines. At the global level, GAVI should strengthen its monitoring systems for immunization financing at country level as this was seriously lacking during its first phase of support. Equally important will be the close monitoring of projected funding gaps that could compromise the ability of countries to sustain the delivery of new vaccines in the future, and reach routine immunization and coverage targets by 2015.

Leveraging GAVI's significant resources of $1.2 billion on the vaccine market was central to the approach to make them more affordable to the poorest countries. This was crucial for ensuring countries' ability to get on a path of financial sustainability during the initial phase of GAVI support. Now that GAVI has leveraged substantially more resources for its second wave of (around $4.0 billion), GAVI will need to continue capitalizing on its unique ability to engage in long-term planning to mitigate the demand risks for new vaccines through improved forecasting and ensure it can obtain the best possible prices on new vaccines.

In the meantime, infants in the poorest countries are being vaccinated and protected by life saving HepB and Hib vaccines. Immunization is still considered the "best buy" for the health sector and the price tag, even with HepB and Hib vaccines seems small if one considers the long-term health benefits and poverty-reducing effects that vaccinations confer.

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[21] The main procuring agency for GAVI is UNICEF Supply. The data is based on the weighted average prices for GAVI awarded vaccines available on http://www.unicef.org/supply/index_7991.html.

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