IMMUNIZATION FINANCING TOOLKIT

A Resource for Policy-Makers and Program Managers



The World Bank
December 2010

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Acknowledgements

The **Immunization Financing Toolkit** was prepared by Logan Brenzel (World Bank) and Andrew Jones (Adeni Consulting), on behalf of the GAVI Alliance Immunization Financing and Sustainability Task Team. Editing of the document was provided by Gabrielle Hezekiah.

The authors are grateful to the numerous individuals who provided helpful comments and input on earlier versions of this document, especially: Claudio Politi, WHO; Lidija Kamara, WHO; Miloud Kaddar WHO; Claudia Castillo, PAHO; Santiago Cornejo, GAVI Secretariat; Dragoslav Popovic, UNICEF; Katinka Rosenbom, UNICEF; Robert Steinglass, John Snow, Inc.; and Violaine Mitchell, Bill & Melinda Gates Foundation.

We appreciate the feedback received from Chris Atim, Ajay Tandon, and Anthony Measham of the World Bank on the draft document. We are especially grateful for the feedback received from country EPI program managers and WHO regional staff.

The cover photo was provided by UNICEF: Image UNI43689: © UNICEF/NYHQ2006-0087/Noorani. A girl is vaccinated against measles with an auto-disable syringe in the village of Gumdandi near the southern port city of Chittagong. In February 2006 in Bangladesh, the Government launched the second phase of its national measles immunization campaign. Despite great strides made in the past decade, measles coverage stands at only 71 per cent nationwide and nearly 20,000 children under age five die annually from the disease. The campaign targeted some 35 million children and involved more than 50,000 skilled vaccinators and 750,000 volunteers, making it the largest public health undertaking in the nation's history. UNICEF and the World Health Organization joined the government and numerous other partners of the Expanded Programme on Immunization (EPI) to support the immunization drive.

Preparation of this document was supported by the GAVI Trust Fund to the World Bank. The views expressed in this document reflect those of the authors and not necessarily those of the GAVI Alliance or the World Bank. The many contributors may not endorse every point, and they bear no responsibility for any errors that remain.

Immunization Financing Toolkit: Introduction

The purpose of this Toolkit

Financing is a critical component of a sustainable immunization program. The **Immunization Financing Toolkit** is a series of short briefs on different options for financing national immunization programs and vaccines. It is intended to serve as a resource for program managers and decision-makers in ministries of health, planning, and finance. The Toolkit brings together the most up-to-date knowledge on the characteristics of various types of financing mechanisms as well as information on how the mechanisms are being implemented in practice, their potential benefits, and their limitations. Where possible, case studies on specific financing options are included. The field of immunization financing continues to evolve and the Toolkit will therefore be web-based and easily downloaded from the internet. As a web-based tool, the Toolkit contains links to other relevant websites for further understanding. The Toolkit is also available on a CD Rom.

This version of the Toolkit is an update of the <u>Immunization Financing Options</u> produced by the Global Alliance for Vaccines and Immunization (GAVI Alliance) in 2001. Health sector funding and management have evolved over the last decade, making the previous document out-of-date. New and innovative financing mechanisms to support immunization and the health sector have been developed and the types and costs of vaccines have changed. In addition, policy-makers and development partners have become much more knowledgeable about health financing.

What are the topics covered in the briefing sheets?

This Toolkit is designed to address questions that program managers and policy-makers might face, including:

- What are the available options for financing immunization services and new vaccines?
- What are the characteristics of each financing option? How predictable or reliable are these options and how technically feasible and equitable might they be?
- Some mechanisms might be effective financing strategies for other parts of the health sector, but are they effective for immunization?

All of these issues – and others – need to be considered by ministries of health, planning, and finance as they determine how best to finance their immunization programs. Some financing options will be more relevant in particular contexts than in others. Readers are encouraged to weigh the pros and cons of alternatives and assess them relative to their specific country context.

The Toolkit contains the following briefs:

- Brief 1: The Importance of Immunization Financing
- Brief 2: Immunization Resource Needs, Planning, and Budgeting
- Brief 3: Use of Tax-Based Financing for Immunization
- Brief 4: Risk-Pooling Mechanisms
- Brief 5: User Fees for Immunization
- Brief 6: National Trust Funds
- Brief 7: Other Country-Level Innovative Financing Mechanisms
- Brief 8: Development Project Assistance
- Brief 9: Development Loans for Immunization
- Brief 10: Budget Support
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- Brief 12: The Vaccine Market Pooled Procurement
- Brief 13: The Vaccine Market UNICEF Vaccine Independence Initiative (VII)
- Brief 14: The Vaccine Market Tiered Market Pricing
- Brief 15: The Vaccine Market Vaccine Production and the Market
- Brief 16: Innovative Financing The International Facility for Immunization (IFFIm)
- Brief 17: Innovative Financing Advance Market Commitments (AMCs)
- Brief 18: Innovative Financing Airline Ticket Tax
- Brief 19: Innovative Financing Results-Based Financing
- Brief 20: Health Systems Strengthening and Immunization
- Brief 21: Working with Parliamentarians
- Brief 22: Comparison of Immunization Financing Options

The briefs are followed by Appendix: Estimating Cold Chain Requirements, and a List of Abbreviations.

How to use this Toolkit

This Toolkit can be read in its entirety or separated by topic. Although the topics are grouped thematically, the briefs do not need to be read in sequence. (We do, however, recommend that readers pay attention to Brief 2: Immunization Resource Needs, Planning, and Budgeting since this document provides an overview of the characteristics we have selected for assessing the various immunization financing options.) Where there is overlap between the briefs – or where there is information in one brief that can serve to clarify the information provided in another – we have pointed the reader to the appropriate place in the relevant text. There are also several lists of documents that might be useful for further reading.

Brief 1: The Importance of Immunization Financing

Each year a new cohort of children is born with the potential risk of exposure to vaccine-preventable diseases. The World Health Organization (WHO) and UNICEF estimates that nearly 24 million children remain unimmunized, leading to many deaths that could otherwise have been prevented. Continued financing of routine vaccination programs is critical to reducing childhood death and disease. Many countries struggle to find the necessary resources for their national immunization programs (NIP) which account for approximately 5% of government health expenditures in low-income countries. Ensuring adequate and predictable financing for programs is important for several reasons:

- 1. The cost of vaccines is higher: New vaccines such as pentavalent, pneumococcal, rotavirus, and Human Papilloma Virus (HPV) vaccines are significantly more expensive than traditional EPI vaccines, such as oral polio and measles that cost pennies a dose. While unit prices are expected to decrease over time (as production efficiencies are found, emerging manufacturers enter the market, and demand for new vaccines grows), they will probably never be as low as traditional vaccines.
- 2. Scaling up programs is more costly at higher coverage levels: As coverage rates rise, children who remain unimmunized are often the hardest to reach. These children may have limited access to health facilities, live in geographically isolated areas, and have caretakers who are less convinced of the benefits of vaccination. National programs may focus more on accelerated strategies to reach these children. The result is that the average cost per child rises as countries focus on these unreached children, driving up costs to the immunization system.

How has immunization financing changed?

In the past few years, the scope and cost of national immunization programs have grown significantly. New vaccines are driving the total cost of national immunization programs up, and account for the largest share of total costs. A comprehensive review of immunization financing in 50 of the poorest countries finds that, in 2010, immunization spending increased from US\$6 per infant to US\$15 per infant, on average, because of new vaccines. The rate of increase and level of expenditure vary by income of the country and region. Campaigns are often a significant portion of immunization costs, particularly in countries where the health system is relatively weak. The encouraging news is that, in addition to increased external financing for immunization, national governments are also investing more in their national programs. However, despite the rise in total financing for immunization, a large financing gap still looms, and sustainability will be a challenge to programs. Policy- makers will need to look at the full menu of options presented here and elsewhere to support the immunization system.

 $^{^{\}rm 1}$ Okwo-Bele, J.M. WHO/HQ. "Global Immunization Overview." Paper presented at Global Immunization Meeting, Geneva, 1-3 February, 2010.

The GAVI Alliance ² was created in 2000 as a partnership between the WHO, UNICEF, the World Bank, donor governments, developing country governments, private industry, private foundations, the financial community, technical agencies, and non-governmental organizations (NGOs). The GAVI Alliance provides significant financial support to 72 of the world's poorest countries for the introduction of new and underused vaccines, as well as support for strengthening national immunization programs and health systems. ³ Since 2000, it is estimated that the GAVI Alliance has immunized over 300 million more children and prevented nearly 4 million deaths from hepatitis, Hib, and pertussis with support of over US\$3.7 billion to eligible countries.

In addition, innovative financing mechanisms for supporting both immunization and the health sector have been developed since 2000. One such mechanism, the International Finance Facility for Immunisation (IFFIm), leverages capital markets to frontload donor funds for immunization. There are others, such as Advanced Market Commitments (AMCs), which are designed to address market failures in the production and manufacture of new vaccines for low-income countries. AMCs are a pull-funding mechanism designed to speed access to a specific vaccine that is not widely available at an affordable price for low-income countries. These two mechanisms together have brought an additional US\$4 billion to immunization and health systems for low-income countries.

How has health sector spending changed?

Financing for health services from domestic sources has increased substantially in low-income countries, from approximately \$8 billion to \$18 billion per year in 2006. While domestic (government) financing for health is much higher than development assistance, health sector aid also has increased significantly – more than four-fold – from approximately US\$5 billion in 1990 to more than US\$21 billion in 2009.⁴ The increase in development funding for health follows the adoption of the Millennium Development Goals (MDGs), and is driven in large part by financing for HIV/AIDS, malaria, and tuberculosis prevention, treatment, and control. Despite the rise in donor assistance, a large funding gap still exists and international commitments for development assistance have still not been met. Many countries are off-track to reach the MDGs and recent research suggests that health spending in low-income countries needs to more than double from current levels of about US\$31 billion to between US\$67 and US\$76 billion per year by 2015.⁵

The global financial crisis that began in the fall of 2008 strained the resources of donor governments, and may limit aid budgets – or at least make further increases in aid budgets difficult. Moreover, many of the poorest countries have been affected by the crisis through challenges in accessing credit and declining purchases of their exported goods.

² Formerly the Global Alliance for Vaccines and Immunization (GAVI).

³ Recent revisions to GAVI's eligibility criteria mean that 58 countries will be eligible for support as of 2011.

⁴ Development Co-operation Directorate. "Aid for Better Health: What are we Learning about What Works and What we Still Have to Do? An Interim Report from the Task Team on Health as a Tracer Sector." DCD/DAC/EFF(2009)14, p. 55.

⁵ See Working Group 1 Report, "Constraints to Scaling up and Costs." Task Force on Innovative International Financing for Health Systems (International Health Partnerships (IHP+)).

Brief 2: Immunization Resource Needs, Planning, and Budgeting

Immunization financing cannot be considered in isolation from overall health sector financing, planning, and budgeting. The manner in which health services are financed will influence the effectiveness and outcomes of the health system. Health financing is concerned with how financial resources are generated, allocated, and used in health systems. Health financing systems have three important functions: to raise sufficient funds for health; to pool these funds to spread the financial risks associated with paying for care; and to use the available funds to purchase and provide the desired health services.

There are many ways to classify the different types of health and immunization financing options. In this Toolkit, we focus on how funding for immunization programs and new vaccines is generated, organized, and used. Funding can come from domestic sources or external agencies. In addition, funding may come from private sources or public resources, such as tax payments. In many cases, a financing mechanism may rely on a mix of funding sources. Funding can be channelled through national budgetary processes, pooled into managed funds, or used to establish innovative financing mechanisms.

<u>Health financing systems</u> focus on revenue collection, pooling, and purchasing. Mechanisms available to countries include health insurance, contracting for services between ministries of health and NGOs, performance-based agreements between health workers and their facilities, or purchasing of vaccines through revolving funds or Advanced Market Commitments (AMCs).

What needs to be financed?

Each government needs to determine the amount of financing needed to support the resource requirements of its national immunization program (routine) and of Supplementary Immunization Activities (SIAs). Immunization program resource requirements include the cost of health personnel, including management and supervision; vaccines; safe injection and other supplies; training, cold chain equipment and maintenance; recording and reporting tools; social and community mobilization; transportation and vehicles; and, cold stores and facilities.

In late 2005, as part of the implementation of the Global Immunization Vision and Strategy (GIVS), the WHO and UNICEF, together with GAVI Alliance partners, established guidelines for developing a comprehensive Multi-Year Plan (cMYP) to support countries in improving their immunization planning. This cMYP simplified and harmonized various immunization planning activities at national level to reduce duplication of efforts and transaction costs, and increase alignment with national systems. The cMYP process has streamlined the immunization planning process at national level into a single, comprehensive and costed plan. The cMYP Costing and Financing Tool estimates the current and past costs and financing of immunization programs, and makes projections of future resource requirements and financing in order to evaluate corresponding financing gaps.

The resource requirements and financing gaps reflected in the cMYP should be more fully integrated into national health planning and budgeting frameworks such as the annual or multi-year health budget and, ultimately, Medium-Term Expenditure Frameworks (MTEFs) which are three-year rolling planning and budgeting processes. Too often the cMYP is viewed as a stand-alone and separate exercise, and the cost estimates contained therein are not integrated within national budgets. The resource requirements of the national immunization program are therefore not fully represented in health sector budget discussions. As a result, national programs are underfunded relative to their requirements.

Since immunization programs are vying for government resources alongside many other priority health programs, there is interest to know how the total resource envelope for health may be increased. Fiscal space is the availability of budgetary room that allows a government to provide resources for a specific purpose without endangering the sustainability of a government's financial position. There are five ways for a government to increase the fiscal space available to the health sector, and to national immunization programs more specifically:

- More resources are allocated to the health sector, leading to greater allocations for specific programs such as immunization
- Within the health sector, resources are allocated from least to more costeffective services, such as immunization
- The immunization program is run more efficiently and can do more with the same level of resources
- There is new financing from sources not previously tapped, such as new taxes or lotteries
- There is new donor funding (grants or debt relief)

Expanding fiscal space for immunization Sources of financing Examples Uses of financing Reduced Government financing freed up from outside of health sector spendina Maintaining and expending Hospital Government financing freed up traditional EPI immunization efficiency from other health interventions efforts Program financing freed up from Reduced efficiency gains in immunization Paying for the incremental costs of wastage programs new vaccine adoption New, fresh government financing earmarked taxe from new revenue sources or from increased revenues GAVI, IFFImm, New donor financing, from grants or loans loans or grants

Figure 2.1 Expanding fiscal space for immunization

Source: Brenzel, L. Presentation to the Global Immunization Meeting, 2005.

How can different immunization financing options be assessed?

Financing arrangements can be complex. They can also differ greatly in their effect on the efficiency and equitability of service delivery and resource mobilization. Understanding the various characteristics of alternative financing options can help program managers and policy- makers select the best set of options tailored to their specific country context and priorities.

Countries will have different goals for their immunization program, and mechanisms for financing the program can contribute to achieving these goals. While the type of financing mechanism does not directly determine how well an immunization program performs, it can have a substantial effect on performance. For example, user fees may reduce utilization of services and project grants may increase the transaction costs and reduce policy ownership by the national government. The optimal package of financing mechanisms will be specific to each country and national program.

In this Toolkit, the range of immunization financing options is assessed relative to a core set of questions:

- Is the financing option predictable?
- Is it additional to current government financing?
- Is the option equitable?
- Is it efficient?
- Is it feasible?
- Is it sustainable?
- Does it promote self-sufficiency?
- Does it foster greater accountability?

These characteristics are outlined in Table 2.1.

Further Reading

Brenzel, L., N. Halsey, M. Miller, L. Wolfson, and J. Fox-Rushby, "Chapter 20: Vaccine Preventable Diseases." In *Disease Control Priorities in Developing Countries*, edited by Jamison et al.. Washington, D.C.: World Bank, 2006.

Lydon, P., R. Levine, M. Makinen, M., L. Brenzel, V. Mitchell, J. Milstein, L. Kamara, and S. Landry, 2008. "Introducing Vaccines in the Poorest Countries: What did we Learn from the GAVI Experience with Financial Sustainability?" *Vaccine* (26): 6706-6716. http://www.who.int/immunization_financing/analysis/JVAC_8566_LydonP.pdf

World Health Organization. cMYP Financing Tool: http://www.who.int/immunization-financing/tools/cmyp/en/index.html

Table 2.1 Characteristics of financing options for national immunization programs

Characteristic	Description
Predictable	The extent to which financing sources provide a steady stream of resources. Having predictable sources of financing will enhance overall planning and budgeting for the national immunization program and improve its effectiveness. Predictable funding sources will be those that a national program can count on, in terms of volume and timeliness.
Additional to government financing	The extent to which a particular financing source provides resources that are above and beyond the existing government financing levels, and so increases the overall funding envelope. Sources that do not necessarily add resources to the funding envelope may be highly fungible.
Equitable	The extent to which financing sources will have an impact on equity of resource allocation (by socio-economic, geographic, and gender, among other criteria). A financing source that enhances equity would ensure that the poor are not disproportionately burdened by the financing requirement, nor denied access because of their inability to pay. This is particularly relevant for domestic sources of revenue.
Efficient	The extent to which the financing source creates additional transaction costs, such as additional reporting or auditing requirements, as a requirement to obtain financing. Efficiency refers to attaining the same level of outcome for less cost. Efficiency can also be related to how flexible the use of funding is. Greater earmarking may reduce efficiency. Financing might also be designed (i.e., through specific incentives) to stimulate efficient provision of immunization services.
Feasible	The extent to which the option is technically complex, requiring development and coordination among a variety of systems and institutions, and skilled personnel for implementation.
Sustainable	The extent to which a financing source provides long-term support. Some financing sources generate funds on an on-going basis, and others are much more time-limited.
Promotes self- sufficiency	The extent to which the financing source allows a country to become less reliant on external funding sources. Funding from domestic sources is by definition the most self-sufficient source. Self-sufficiency can be related to whether the financing source supports improved capacity to procure vaccines and inputs.
Fosters greater accountability	The extent to which a financing option fosters open, transparent, accurate, and shareable information regarding the source, allocation, and use of resources for immunization services. Accountability is related to governance of the health sector.

Brief 3: Use of Tax-Based Financing for Immunization

What is tax-based financing?

National and sub-national governments raise revenues through a variety of taxes, including taxes on personal and business income, payroll taxes, excise duties on locally manufactured products and services, property taxes, sales and value-added taxes, inheritance taxes, sin taxes, customs and import duties, and other types of duties. The amount collected will depend upon the structure of the economy as well as the efficacy of tax collection and enforcement.

Taxes can be characterized along a continuum between regressive and progressive tax. A regressive tax is one in which lower-income individuals pay a greater share of their income, while a progressive tax is one in which higher-income individuals pay a greater proportion of their income. Taxes that are raised in a progressive manner are considered to be equity-enhancing.

Funds derived from government revenues, as well as resources raised via government borrowing and grants, are allocated to line ministries through a formal, annual budgetary process. Government recurrent and investment budgets are prepared annually by ministry and by economic classification or line item. Ministry of health budgets (and those of other sectors) are usually based on historical spending patterns. In the ideal case, health budget planning should be a 'bottom up' process from the primary facility to district, province or region, and national levels based on actual resource needs for achieving specific health goals. The health sector in most low- and middle-income countries tends to be underfunded relative to needs.

Government revenues usually are disbursed to line ministries on the basis of monthly requests for resources by line item. Final budget approval may come several months into the fiscal year and ministries will be allocated previous years' monthly amounts until final budget approval. The potential lack of predictability of disbursement from the treasury to line ministries is challenging to manage.

General revenues at sub-national level

Since the 1990s, there has been a trend towards <u>decentralization in the health sector</u> (as well as other sectors), with a shift of management and service delivery responsibilities from national to local authorities. The purpose of decentralization is to bring resources and resource allocation closer to the population to enhance health and development outcomes. In decentralized contexts, local governments raise and allocate revenues for health through local taxation.

Uses of government revenues (national and sub-national) for immunization

As a country's income increases, government revenues play an increasing role in <u>financing health care</u>. Government budgets also account for the <u>largest source</u> of immunization program financing in most countries. Government budgets support the salaries and wages of health workers, operating costs of service delivery, and procurement of vaccines, supplies, and equipment.

Across countries, there is tremendous variation in the proportion of total immunization program funding coming from the sub-national level, depending upon the extent of political and fiscal decentralization. In different countries, it may be the case that states, provinces, departments and/or municipalities, and districts have primary or sole responsibility for funding immunization services.

In highly decentralized contexts, the role of the central immunization program may be limited to policy-making, and perhaps disease surveillance and national reporting. The central level no longer has control over the amount of resources allocated to the immunization program, particularly at the local levels, though the central level can create guidelines. Procurement for vaccines, supplies, and equipment may become a sub-national function. In addition, funding for salaries and operating costs of the immunization program may be the responsibility of the sub-national level.

In less decentralized contexts, the central level may still finance critical inputs such as vaccines, supplies, cold chain equipment, and surveillance activities. Operating costs of facilities and salaries may be supported through block transfers from central government to complement local government inputs. Finally, in fragile states, central authorities may still retain full control and financial responsibility for immunization and other priority programs.

Unless immunization is explicitly protected within a decentralized system, either through earmarking of inter-fiscal transfers or development of performance-agreements with subnational authorities, <u>immunization service delivery may be negatively affected</u>. Local priorities for use of tax-generated resources at sub-national level may not focus on immunization or be in line with global or national level priorities. Inputs required for quality immunization service delivery may not be fully financed as a result of these differences. Local leaders are interested to fund projects and programs that increase their visibility and enhance their ability to be re-elected. Because immunization has been successful, and communities see fewer and fewer cases of measles and polio, the felt need to allocate resources to immunization programs may not be as great as was previously the case. In these settings, it is of critical importance that immunization policy-makers effectively advocate for, and provide evidence of, the importance of immunization programs in order to secure adequate financing.

One factor that appears to have contributed to increased government financing is the presence of budget line items for vaccines and immunization. A recent evaluation finds that nearly 160 countries report the existence of a vaccine line item in their national health budget. Nearly 85% of African countries report that their governments have specific budget line items for vaccines and/or immunization. Specific budget line items for immunization may create additional incentives for governments to ensure continued financing. Budget

line items also signal long-term political commitment to immunization and may help to protect budget allocations during economic downturns and budget negotiations. Budget line items also facilitate resource tracking and greater accountability for expenditures. In 2006, both globally and in low-income countries, the share of government financing for vaccines and routine immunization services was higher in those countries that reported a budget line item than for countries without line items. This finding suggests that budget line items can contribute to overall financing and sustainability of immunization.

Why should immunization services be financed from government revenues?

There are strong economic rationales for governments to invest in immunization. Vaccines have been shown to be a 'best buy' for health resources. Immunization is a low-cost and effective way of preventing child deaths and disability, compared with other priority health interventions. Traditional EPI vaccines such as measles and polio are one of the most cost-effective interventions, with investments of US\$2 to US\$20 per year of healthy life gained.⁶ New vaccines are still considered to be cost-effective, although these estimates are higher owing to their higher unit price per dose (US\$15 to US\$500 per year of healthy life gained).

Immunization is also considered to provide public good benefits, since immunizing part of the population reduces the likelihood that unimmunized people will become infected. As immunization coverage approaches 80% to 90%, the immunized population protects the unimmunized population through the mechanism of 'herd immunity'. The public good aspect of immunization makes this type of program ideally suited for public (government) financing, rather than financing from private or individual (household) sources. ⁷ In the case of private financing, individuals may choose not to be vaccinated because they believe they will be protected through the 'herd immunity' effect. According to Musgrove⁸, private financing will likely lead to under-consumption of immunization, potentially leading to greater transmission of disease. Therefore, sustained financing of immunization programs from government revenues is the ideal situation.

Immunization may also have important spill-over effects for overall development. As parents observe that immunization protects their children and, in fact, eliminates some childhood diseases, they will continue to demand it. Providing high quality immunization tends to ensure high quality of other basic health services. As satisfied users accumulate, the community will be more likely to trust in other services that the government provides.⁹

⁶ Traditional immunizations include measles, diphtheria, tetanus, pertussis, oral polio, and BCG.

⁷ Under the <u>Convention on the Rights of the Child (CRC)</u>, governments are accountable to provide vaccines to children.

⁸ Musgrove, P. "Public and Private Roles in Health: Theory and Financing Patterns." Health, Nutrition, and Population (HNP) Discussion Paper. Washington, D.C.: World Bank, July 1996. http://siteresources.worldbank.org/HEALTHNUTRITIONANDPOPULATION/Resources/281627-1095698140167/Musgrove-PublicPrivate-whole.pdf

⁹ Gilson, L. "Trust and the Development of Health Care as a Social Institution." *Social Science and Medicine* 56 (2003): 1453-1468.

Table 3.1 Assessment of the value of general revenues for immunization financing

Characteristic	Assessment
Predictable	Owing to budget shortages and government procedures, government revenues may be predictable for planning purposes, but not as predictable in terms of receipt of funds.
Additional to government financing	N/A
Equitable	Depends upon how taxes are raised at national and sub-national levels, and whether financial transfers from central to sub-national level are calculated on the basis of poverty and development indicators.
Efficient	Budget allocation to cost-effective services, such as immunization, improves allocative efficiency; under-funding of the health sector from taxes may result in technical inefficiencies in program delivery.
Feasible	Most governments have national and sub-national collection, budgetary, disbursement, financial management, audit, and reporting systems in place for tax financing. Strengthening of these systems will improve collection and utilization rates.
Sustainable	Increasing government responsibility for financing of immunization programs increases the likelihood for sustainability. Also related to overall growth and health of the economy.
Promotes self- sufficiency	Yes.
Fosters greater accountability	As the quality of the management and procurement procedures of government expenditure improves, so too does the level of accountability.

Further Reading

Gottret, P. and G. Schieber. "Health Financing Revisited: A Practitioner's Guide." Washington, D.C.: The World Bank, 2008.

http://siteresources.worldbank.org/INTHSD/Resources/topics/Health-Financing/HFRFull.pdf

World Health Organization. "Tax-Based Financing for Health Systems: Options and Experiences." Discussion Paper No. 4, 2004.

http://www.who.int/health_financing/mechanisms/en/index1.html

Brief 4: Risk-Pooling Mechanisms

What is risk pooling?

Risk pooling is also known as health insurance, which is a group of persons contributing to a common pool, usually held by a third party. These funds are used to pay for all or part of the cost of providing a defined set of health services for members of the pool. In low- and middle-income countries, there are relatively high-out-of-pocket expenditures for health care services. Families may go-into-debt and sell-critical assets in order to finance health services. Risk pooling is the collection and management of financial resources so that large, unpredictable individual financial risks become predictable and are distributed among all members of the pool. Risk pooling can provide financial protection to households in the face of high health care costs.

What are the different types of risk-pooling mechanisms available?

There are several different types of <u>risk-pooling mechanisms</u> that can be used to support and finance immunization services.

National insurance systems: Funding comes from general revenues and medical coverage is provided to the entire population for a fixed set of services (benefits package). Services are delivered through a network of public (and NGO) providers.

Social health insurance systems: Funding comes from mandatory, earmarked payroll contributions from individuals and employers. Coverage is provided to contributors, usually in a phased manner. Services are provided based on a defined benefits package that can include immunization services. Additional subsidies may come from external assistance or earmarked taxes.

Mutuelles or community-based health insurance schemes: These are generally non-profit prepayment plans for health care that are managed at the community level. Funding comes from prepayment into a pooled fund, supplemented by government or donor resources. Coverage is provided to community members, and services are provided by NGOs or public facilities. Benefits are based on community preferences and they may include preventive health care services, such as immunization.

Private health insurance: Funding of insurance premiums comes from individuals who purchase coverage (out-of-pocket) on a voluntary basis. Coverage is limited to contributors and benefits are pre-defined, and may include immunization. Service provision may be through a network of private providers.

The role of risk-pooling mechanisms for immunization

In the 58th session of the <u>World Health Assembly (May 2005)</u> of the WHO, member states endorsed Resolution WHA58.33. The resolution urges countries to strive towards sustainable health financing and achieving universal coverage through applying a mix of prepayment, social health insurance, and tax-financed services.

Risk-pooling mechanisms provide protection against high cost, low probability events. Immunization services are generally low cost and predictable, and are therefore not an obvious choice for financing through risk-pooling mechanisms. In addition, immunization services tend to be delivered through vertical programs supported by donors and government. For these reasons, immunization is usually not included in defined benefits packages provided to health insurance scheme enrolees. For instance, the Ghana National Health Insurance Scheme specifically excludes immunization.

There are a few examples in Latin America and Europe where insurance mechanisms support immunization. For instance, in Bulgaria, vaccines are procured directly by the Ministry of Health and distributed to practitioners, who are compensated through contracts with the National Health Insurance Fund. The <u>Costa Rican Social Security Administration</u>, which raises funding from payroll contributions and tax revenue (Ministry of Health), is required to provide adequate resources for delivery of the National Immunization Plan.

Case Study: Mutuelles in Mali

In West Africa, mutual health organizations (MHOs), or mutuelles, are voluntary organizations that provide health insurance services to enrolees. MHOs are owned, designed and managed by the communities they serve. Households pay an enrolment fee and regular premiums into a pooled fund to cover their use of a defined benefits package and the MHO reimburses providers out of the pooled fund for services. MHOs generally are not-for-profit organizations that are based on notions of mutual aid and solidarity. MHOs can provide additional sources of revenue mobilization and financial protection for households, increase financial access to care, and promote equity.

The experience of MHOs so far reveals that there is an increasing demand for these types of financial protection mechanisms: MHOs include individuals and households from a wide range of socioeconomic backgrounds; members tend to have lower out-of-pocket expenditures; and members tend to use health services more when needed.

In 1997, the Government of Mali recognized the potential of MHOs in its 10-year health and social sector development plan. In these schemes, households pay a one-time membership enrolment fee, and monthly premiums or an annual premium (related to the number of beneficiaries). On joining, members commit to making use of preventive services such as childhood immunization. A recent study found that membership in MHOs improved utilization of priority preventive and curative health services. The total household payment was between US\$29 and US\$54 per year, or 2% and 8% of household income. Geographic barriers related to use of preventive services, such as immunization, appear to have been overcome by the scheme.

Operationalizing health insurance

Although health insurance schemes offer many benefits such as risk pooling and covering the cost of catastrophic illness, they are complex to develop and implement. They require a range of systems, such as: financial processes and management; contract management; enrolment and member services; utilization and quality management; claims management; information systems (to track use of services by beneficiaries and their associated costs); accreditation and quality assurance mechanisms (to monitor services offered by providers); and marketing and communications. Some of the dimensions of a health insurance scheme are listed below:

Beneficiaries may be enrolled on a voluntary or mandatory basis. Schemes may target vulnerable population groups. There is usually some form of identification card for each beneficiary.

Benefits packages generally include out-patient and in-patient care, surgical procedures, consultations, and diagnostic services. There are excluded benefits in most schemes and, in some cases, vertically provided programs such as immunization may be excluded.

Sources of funding may be consumption taxes and social security, as well as direct government subsidies, payroll taxes, donor support, and other funding. In addition, patients may be required to pay a deductible and/or a co-payment at the time of service.

Payment of providers is usually done on a reimbursement basis. The level of reimbursement is usually pre-determined and may be adjusted for severity of illness, such as a diagnostic-related group. Providers submit claims for reimbursement.

Selection of providers can be made on the basis of accreditation (formal or informal).

Governance and management may be through a national health insurance authority, including a governing board. The ministry of health is usually the responsible ministry. In some systems, governance and management are decentralized to district level as well.

Because health insurance reimburses providers on the basis of services rendered, there is an incentive for providers to offer lower cost, perhaps lower quality, services or to only serve a healthier population (adverse selection). In addition, once a patient is covered under a health insurance scheme, there is the incentive for them to consume more health care than is otherwise needed (moral hazard) because services are not linked to price. Health insurance schemes need to be developed in such a way as to mitigate these two behavioral incentives, for example through requiring nominal co-payments at the time of service, instituting a waiting period before beneficiaries can use services, and reimbursing providers based on a contractual arrangement of population coverage.

The performance of a particular type of risk-pooling mechanism against our criteria will depend upon the number of persons covered, the source of financing for the risk pool, administrative requirements, and the types of benefits.

Table 4.1 Assessment of the value of different types of risk-pooling mechanisms for immunization financing

Characteristic	Assessment
Predictable	If immunization is included in the benefits package of risk-pooling mechanisms, financing of services will generally be predictable and reliable. National health insurance relies on budgetary approval and may be subject to variation in national policies.
Additional to government financing	Social health insurance, community-based health insurance, and voluntary health insurance are additional sources of financing to national governments (general revenues).
Equitable	National health insurance would be the most equitable form of risk pooling in that everyone is covered and enrolment is not based on ability-to-pay. Access to quality health care providers may be a challenge for lower-income patients. Social health insurance is based on payroll tax, and would generally not cover workers in the informal sector or the medically indigent population. Community-based health insurance targets the lowest level of the health system, but there is some evidence that the very poorest may be excluded from the scheme.
Efficient	National and social health insurance schemes are thought to be efficient in the sense that administrative structures are already in place. However, establishing risk-pooling mechanisms, including setting up new institutions, may be costly.
Feasible	Health insurance schemes are complex to develop and implement, and require management capacity and skill in ministries of health and at district levels.
Sustainable	Sustainability will depend upon the size of the risk pool, the health conditions to be managed within the pool, and the revenues collected to finance the cost of service provision.
Promotes self- sufficiency	These schemes promote greater self-sufficiency in financing to the extent that they are financed by national sources.
Fosters greater accountability	Insurance mechanisms are heavily information-dependent and require tracking of contributions, services provided, and providers, all of which would enhance accountability. Community-based schemes are managed at the community level and would foster greater accountability at that level. To the extent that service provision is contracted out to providers on the basis of the quantity and quality of care provided, this can improve accountability within the system.

Further Reading

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Brief 5: User Fees for Immunization

What are user fees?

User fees are charges faced by users of health care services in public and private health care facilities. These include consultation fees, charges for drugs and lab tests, and informal payments to providers. User fees are generally applied at the point-of-service and may be retained at facility level to improve services. User fees can act as signals to patients, causing them to use certain health services over others. For instance, lower fees at primary health care level compared to hospitals may encourage greater use of priority public health services.

What is the evidence around user fees?

Many countries struggle to find adequate resources to fund the health system. In some cases, cost-recovery through user fees is employed to supplement available resources, particularly for lower-level health care facilities in the system.

Studies have shown that user fees generate modest amounts of additional financing for the health sector: an average of about 5% of total health system expenditure minus administrative costs. User fees also are associated with lower utilization of health services, and result in the poorest not seeking appropriate care when needed. A review of studies undertaken between 1999 and 2005 on user fees in Africa and Asia suggests a negative overall trend in terms of the impact of user fees on access.

Importantly, out-of-pocket health expenditures can cause <u>significant health shocks</u>, driving households into poverty. In some cases, this comes through the imposition of informal user fees that are not part of the health system sanctioned by the government. Nonetheless, the potential impact is important – households can be pushed into poverty through health expenses. In Vietnam and Bangladesh, more than 15% of households have health expenses that exceed 25% of non-food spending. While immunization is a modest part of the health system, user fees for immunization can add to an already significant burden on the poorest households, and families may simply choose not to immunize children rather than face the additional cost.

Waivers and exemption policies for the poorest households can help to maintain use of services. However, evidence suggests that waiver programs are challenging to implement and often exclude many of the neediest. Further, waiver programs introduce additional administrative requirements that might be more costly than the resources gained through the user fees.

Despite these concerns, fees have the *potential* to improve access to better quality services if the extra revenue from fees is re-invested into the health system. Studies have linked user fees in the <u>Bamako Initiative</u> in West Africa with improved drug availability and greater accountability of providers. In some cases, user fees simply formalize an already existing informal fee system. This is also important to bear in mind – informal fees can result in drops in utilization, and a poorly resourced health and immunization system may cause providers to seek funds from patients.

User fees and immunization services

Because curative services can provide a tangible benefit to patients, these types of services are better suited for user charges. A visit to the doctor or the purchase of a drug can result in an immediate, positive health outcome. However, since vaccination protects a child against an infection that may never occur – or may occur only months or years in the future – there is no discernible immediate benefit, and paying for vaccination does not appear to be a good expenditure decision. Many of the poorest households would simply choose to save the money until their child becomes sick, rather than pay for a vaccine up front.

Policies of various agencies on user fees

The 5th Board Meeting of the GAVI Alliance recommended that "in the absence of compelling country or regional data unequivocally documenting their value, user fees should not be levied in publicly financed national immunization services." Several organizations, such as The Commission for Africa, Department for International Development (DFID). UNICEF, and Save the Children – UK, do not support user fees. The WHO emphasizes the need for a broader reliance on pre-payment in order to ensure universal coverage. The World Bank has indicated its willingness to help countries remove user fees if this will also address long-term financial sustainability, benefit the poorest and provide high quality services. The Bank has also indicated that countries should use insurance and pre-payment mechanisms to protect the poorest against catastrophic expenditure. Much work has been done to examine how risk-pooling mechanisms can reduce indebtedness and the decline in utilization associated with out-of-pocket expenditures by households. More recently, the global consensus on MDG5 endorsed the removal of financial barriers to access (user fees) as a goal, encouraging free services at the point of use.

Removing user fees within the context of sustainable and accountable financing arrangements, such as social health insurance, has greater potential to ensure that services are provided to target groups. Insurance schemes not only bring additional resources to the health sector, but also are useful for identifying target groups at the community level. For instance, Ghana implemented exemptions from user fees for pregnant women, children, the aged, and the poor; and Rwanda exempts the poorest from user fees.

Table 5.1 Assessment of the value of user fees for immunization financing

Characteristic	Assessment
Predictable	Revenue generated from user fees tends to be a small proportion of overall service delivery cost. It also tends to be dependent upon the level of fees and the population's relative ability to pay, which can vary significantly, seasonally and from year to year.
Additional to government financing	This stream of revenue comes from the population directly and should be additional to government financing.
Equitable	User fees place a significant burden on the poorest citizens and have a negative effect on utilization of services.
Efficient	Collection and management of user fees will add administrative costs; waivers and exemption systems for the poorest also require additional administrative capacity.
Feasible	User fee systems require financial management and other information systems. User fees should be removed within a context of other sustainable and accountable health financing mechanisms.
Sustainable	Can be a sustainable source of financing, depending upon the level of fees and the ability of the population to pay. However, user fees generate 15% or less of needed resources.
Promotes self- sufficiency	User fees are domestically generated, and can therefore reduce the dependence of a government on external donor financing.
Fosters greater accountability	The act of paying for services means that a population is more likely to demand appropriate provision of services. User fees make payment explicit and this usually eliminates under the table payments.

Further Reading

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Brief 6: National Trust Funds

What is a national trust fund?

National trust funds are a pool of funds set aside for a particular purpose with specific rules about how the proceeds can be used. Trust funds pool resources from one or more sources of funding. For instance, domestic taxes, donor funds, and private sector contributions can be combined within a specific legal arrangement that specifies how the initial capital of the fund and/or interest is used over time. The amount and sources of the financing will determine its use. Possible uses include: a straight income stream (money used on a regular basis such as quarterly or annually to fund the immunization program); short-term credit support (to cover shortfalls in other funding sources); or loan guarantees (where the money in the trust fund is used to guarantee loans to support immunization).

What would the policies around a trust fund look like?

A trust fund is usually legally incorporated and has a funding base, statutes, and articles of constitution that specify its purpose, beneficiaries, and governance processes. The policies around trust funds can vary significantly depending upon the context. The governance and structure are usually set up in a memorandum of understanding (MOU) which lays out the responsibilities, rights, and obligations of the founding partners and contributors, the goals of the fund, reporting, and oversight.

The establishment of the governing board and the selection of members are critical first steps. The governing board oversees the strategy, business plan, management, and operations. The trustees or directors who oversee reporting, controls, planning, and evaluation activities should be appropriately selected to provide policy and financial management. The management of the funds themselves (asset management and investment) is usually handled by professional investment managers to ensure the appropriate rate of return at the levels of risk that are consistent with the charter and the recommendations of board members. Lastly, appropriate technical expertise in the use of the funds (those with an understanding of health and immunization) needs to be included in the board.

What are the key benefits of trust funds for immunization financing?

Trust funds have the potential to be innovative financing instruments for immunization because they can protect resources over the long term. In cases where the interest, rather than the principal, is used, the idea is particularly attractive. Using interest proceeds, a trust fund can provide a predictable and reliable source of immunization financing, since a balanced set of investments can generate a steady return, as the principal remains untouched.

In the case where vaccine costs are rising significantly over time, the fund size (capital) will need to be increased over time. If international organizations such as the World Bank or a United Nations (UN) agency hold the trust fund, they are not subject to taxation. However, national governments can create the appropriate legal precedents to exempt the trust fund from taxation, as Bhutan has done.

Nonetheless, tying up funds to generate a trust fund needs to be weighed against the alternative uses of the funds. Creating a trust fund makes particular sense when there is a sudden availability of new resources that cannot be spent rapidly (debt relief is an example). Making the determination to create a trust fund to generate a resource stream requires that a number of issues be taken into account: how well the resource requirements can be estimated over time; whether the risks associated with the investment policy are reasonable; and whether reserves can be built up to buttress the fund's operational purchasing power against the effects of inflation and currency fluctuations. Lastly, trust funds require administrative resources. Countries with limited management and operational capacity can pool multiple donor contributions into a trust fund and reduce the need for individual rules for each donor.

Case Study: The Health Trust Fund in Bhutan

In the late 1990s, the Government of Bhutan (RGOB) noted that the cost of vaccines and drugs accounted for almost 50% of all expenditures in the national health sector, leaving uncertainties in the future, given the volatility of much donor funding. In 1998, the RGOB established the Health Trust Fund with the goal of eliminating funding uncertainties and generating sufficient income to meet the cost of critical components of the health services in Bhutan. The Health Trust Fund is an innovative and viable model to provide a sustainable – and stable – form of financing for purchasing items such as vaccines that are extremely sensitive to fluctuations in financing. The Health Trust Fund is used to ensure several key components of a functioning health system.

- Provision of primary health care items such as vaccines, essential drugs, needles, syringes, cold chain equipment, and other related drugs and equipment in uninterrupted supply.
- Financing of training, and strengthening of programme management and human resource development.
- Development and implementation of management plans for drugs and vaccines, and strengthening of the monitoring capacity with regard to pharmaceuticals.

The Health Trust Fund in Bhutan is an important tool in ensuring the timely availability of critical vaccines, essential drugs, and needles and syringes. These components together form the backbone of primary health care services. Providing these components through a trust fund allows the RGOB to re-direct the national health budget to other key areas, such as supporting the health system, developing human resources, and strengthening monitoring and surveillance systems.

The Government agreed to finance half of the needed US\$24 million, with the rest coming from a <u>combination of different private and public donors</u>. Economic growth in Bhutan is anticipated to raise overall income levels (and, correspondingly, the capacity of the Government to spend on the health sector) over the next 15-20 years, at which point the RGOB and its Fund partners will review the impact of the Fund and determine the best way forward.

The Bhutan Health Trust Fund was legally incorporated in April 2000 with a secretariat consisting of the Executive Director, one Program Officer, two Office Secretaries and one Messenger. In addition, a Board of seven members governs the overall direction of the Fund. The Board includes members from the Ministry of Health (including the Minister), the aid and debt management department, and the monetary authority of Bhutan. The Fund enjoys tax free status within the country and invests both within and outside Bhutan, under the governance of its Board. The Fund became operational in 2003/04, after building capital through a series of contributions, primarily from external donors and the RGOB, with some support from private donors within Bhutan.

Table 6.1 Assessment of the value of trust funds for immunization financing

Characteristic	Assessment
Predictable	This type of financing provides a clear, long-term stream of resources. If it is based on interest earned off the principal, rather than the principal
	itself, it is highly predictable.
Additional to	This depends upon the source of the trust fund monies. If the principal of
government financing	the trust fund is used, and comes from a dedicated tax or charge, this will
	represent a reallocation of resources rather than a new source. If the trust
	fund is used to generate interest earnings, these can be new monies, and therefore additional.
Equitable	This depends upon how these funds are administered and spent.
Efficient	Trust funds require resources for administration. Depending upon the
	design, separate governance and accounting structures may be required
	and this incurs transaction costs.
Feasible	Requires fund raising and establishment of a fund mechanism, with
	governing and oversight bodies, as well as fund management to generate
	returns on investments.
Sustainable	If set up to use interest earnings, trust funds are a highly sustainable form
	of financing.
Promotes self-	This type of financing encourages capacity building in the country and the
sufficiency	financing can even grow over time, depending upon the size of the initial
	capital investment.
Fosters greater	The creation of a trust fund as a separate entity, with governance and
accountability	accounting rules, provides significant accountability.

Brief 7: Other Country-Level Innovative Financing Mechanisms

There is a range of innovative financing mechanisms that can use existing revenue channels to support immunization. A number of countries have experimented with this, including Mexico (oil revenues) and Costa Rica (lotteries). Tajikistan, Vietnam, and Haiti are raising resources for immunization through tax levies on luxury goods and on products harmful to health, such as alcohol and tobacco.

The idea of using sin taxes on products that are deemed to have a harmful impact on health is not new. Tobacco taxes have long been a policy tool of governments to reduce smoking, while at the same time supporting public health efforts to combat their spread. The same is true for alcohol. Specifically earmarking these types of taxes for immunization can be an effective way to raise new resources. In addition, earmarked taxes are generally acceptable to the public because they are designed for a clear priority goal that will benefit the population. In addition, an earmarked tax may be perceived as more transparent and accountable and less subject to waste.

The concept of sin taxes is expanding, particularly in high-income countries where taxes are being leveraged against fatty foods, sodas, and other items that have a deleterious impact on health status. These types of taxes can have the twin benefit of reducing a health-damaging behavior while providing additional resources for health programming. However, some governments oppose earmarked taxes on principle, as they limit government flexibility. Depending upon how they are set up or legislated, earmarked taxes may not allow a government the power to allocate resources as needed in emergencies, when dropouts in donor funding occur, or when there are changes in country context. As a single instance, an earmarked tax for immunization is relatively simple but, when multiplied across several efforts, it can significantly limit a government's ability to effectively plan and budget.

Innovative Financing of Immunization: Lottery Funds in Costa Rica

Costa Rica's National Immunization Act of August 2001 regulates the selection, procurement, and availability of vaccines throughout Costa Rica, with the aim of enabling the State to protect public health. The Act establishes the National Immunization Fund. Monies are to be used to support health promotion, education, and research activities in the field of immunization and vaccine-preventable diseases, and to purchase and acquire equipment to enhance the operation of the immunization program. In 2009, close to US\$19.3 million was spent, and the figure for 2010 will be higher because of the introduction of 23-valent pneumococcal vaccine.

The sources of funding for the National Immunization Fund include earmarked allocations of general revenues from the Ministry of Health and the Costa Rican Social Security Administration (CCSS). Both agencies are required to include an adequate budget to acquire vaccines and defray immunization program costs. In addition, the National Immunization Fund is financed from surpluses held in the Costa Rican Social Security Administration (2%). Most of the resources in the National Immunization Fund come from the CCSS.

In the last five years, proceeds from the November drawing of the National Lottery (overseen by the San José Social Protection Board) have been earmarked for the National Immunization Fund. Since 2009, these resources have been used to purchase vaccines to pursue the 'Cocoon Strategy'

(cessation of vertical transmission of pertussis) and to fund unplanned expenditures. Lottery resources have provided a small portion of the immunization budget.

The National Commission on Immunization and Epidemiology is a fully deconcentrated agency attached to the Ministry of Health. The National Immunization Act sets out the membership and terms of reference of this commission, that includes defining the vaccination schedule, overseeing the quality of vaccines, the supply and cold chain, and administering the National Immunization Fund. The Commission has representatives from the Ministry of Health, the National Pediatric Association, and the National Children's Hospital.

Table 7.1 Assessment of other innovative financing mechanisms for immunization financing

Characteristic	Assessment
Predictable	Depends upon the consumption levels of the population. As tobacco use or lottery purchases declines, the total revenues generated will decline.
Additional to government	Yes.
financing	
Equitable	Earmarked taxes tend to be regressive as they are based on consumption of alcohol, tobacco, and lottery tickets which makes up a disproportionately larger share of total income for the poorest in the population.
Efficient	If mechanisms are created specifically for immunization financing, there may be additional administrative costs, but resources would be allocated and targeted in an efficient manner.
Feasible	Generally, yes, as tax collection is a routine function of government.
Sustainable	Depends upon how much of the national immunization program is financed by these schemes.
Promotes self-sufficiency	These schemes promote greater self-sufficiency in financing to the extent that they are financed by national sources.
Fosters greater	Earmarked taxes may be perceived as more transparent, more
accountability	accountable, and less subject to waste and diversion.

Brief 8: Development Project Assistance

What is development project assistance?

Project assistance is a set of resources (money, technical assistance, and/or goods in-kind) that are usually transferred from higher-income countries (donor countries) to low- and middle-income countries (recipient countries). Unlike a loan, there is no expectation that the value of project assistance will be repaid. The amount and type of project assistance offered are based on donor aid policies and the needs within developing countries.

Project assistance derives from bilateral aid (often from development agencies) or multilateral channels such as UN agencies or the European Union. The World Bank and regional development banks (such as the African Development Bank (AfDB)) also offer grant financing. The World Bank offers grant financing through the International Development Association (IDA) which is responsible for lending to the poorest countries through highly concessional terms. JICA and USAID are two agencies that routinely use project assistance to support different components of the national immunization program.

Project assistance and immunization services

Project assistance is provided through a negotiated agreement between the financier and the recipient government for a specified time period. In some cases, project assistance supports third party technical assistance (through a private agency or non-governmental organization) to carry out work on behalf of the government. In other situations, project assistance may be a combination of grant, commodity support, and technical assistance to the recipient government. Project assistance for immunization can fund essential vaccines, cold chain equipment, technical assistance, recurrent/operating costs, monitoring and evaluation, and other inputs. Project assistance is generally not used to support health worker salaries, although the practice of 'topping up' low government salaries or hiring temporary workers might be part of the grant agreement.

Assessing the value of project assistance

Project assistance is aimed directly at immunization services – and it is therefore usually straightforward to see returns on investment for a particular program or project activity. Project assistance may also be the preferred mechanism for donors in post-conflict, fragile states or settings where country systems need strengthening in order to deliver services. In such cases, technical assistance is provided to build capacity and systems at national level.

On the other hand, project assistance is usually off-budget, and is not captured as part of a national government's annual budgeting and planning process. This limits the ability of the national government to plan and budget effectively for the program and the sector. In general, project assistance requires specific reporting processes which are parallel to usual government procedures. Separate program, administrative, accounting, and auditing reports may be required for each donor, thereby increasing the transaction costs for

countries in managing this support. If the amount of funding is small relative to other types of support, the administrative burden may not be worthwhile.

In addition, grant funding may reflect donor priorities, rather than those of the national government. At times the two can overlap, but when they do not, the difference can distort program budgeting and activities. Furthermore, political forces can cause a significant degree of volatility in donor funding. Donor priorities may change through policy reviews or a change in political leadership. Unfortunately, the need for program assistance and its availability are rarely coordinated. Many policy-makers believe that multi-year commitments tied to broader-based goals can improve this. Sometimes, a targeted grant can be processed relatively quickly compared to a larger, more complex source such as budget support, which can take time to negotiate and fine-tune. Project assistance can, in some cases, serve as a mechanism to cover a gap – particularly when there is a shortfall in government resources.

Case Study: IMMUNIZATIONbasics Project in India

Project grants often come from bilateral agencies in the form of programs that support technical assistance or other efforts that can allow the national government to reach its immunization goals. IMMUNIZATIONbasics was a 5-year project (2004-2009) supported by USAID that aimed to improve the ability of governments and collaborating organizations to deliver and maintain the coverage of quality immunization services.

IMMUNIZATIONbasics provided technical support to ministries of health, USAID missions, bureaus and projects, international and national NGOs, and other international partners. In India, IMMUNIZATIONbasics carried out a <u>series of projects</u> that included developing micro-planning tools and routine immunization job aids that could help train workers across India. In addition, <u>one project</u> created a program that helped health workers to establish goals, monitor performance, recognize good practices, and identify and correct problems. The project grant produced a manual for program managers implementing supportive supervision as well as several Excel tools and checklists.

Through Immunizationbasics, PATH developed and implemented a model for supportive supervision in the state of Andhra Pradesh, which consisted of teams of trained supervisors visiting all health facilities in a district and a few randomly selected outreach immunization sessions, in a defined time period (2-3 days), and collecting specific programmatic information through structured checklists. It also involved instruction in correct practices through on-site demonstration and training of staff. Information was entered into an electronic spreadsheet that generates graphical reports. The findings can be shared with managers at different levels for corrective action. The reports allowed ranking of health facilities in terms of overall performance and the status of individual indicators.

Vaccine donations

Vaccine donations are sometimes offered to countries by vaccine manufacturers and donor governments. While the acceptance of a free health product may seem straightforward, there are some considerations that governments should bear in mind when making a decision. The <u>GAVI Alliance has adopted a policy of not accepting vaccine donations</u>, except when countries are experiencing emergency situations, and for countries where GAVI would have funded procurement of the new vaccine. Perhaps most obviously, a donation of vaccines from a manufacturer provides short-term financial savings, depending on the length of the donation. In addition, it can relieve short-term supply constraints. Finally, it

can add to the evidence base by supporting demonstration products or trials in specific areas of the countries and providing information on the effectiveness of the vaccine in the local context.

On the other hand, donations can distort the market by increasing uptake of one manufacturer's product over another, even though this product potentially could be more expensive or less effective. Moreover, it could have significant sustainability issues, since a vaccine that is provided free for the short-term is unlikely to be affordable for the country in the long-term. This means that a country is either likely to have to drop the vaccine, with significant consequences, or seek external funding. If a national government already has external financing ready, or can use the time of the donated vaccine to line up the appropriate financing, then a donation may enable a country to introduce the vaccine earlier than originally planned.

Table 8.1 Assessment of the value of project assistance for immunization financing

Characteristic	Assessment
Predictable	Provides clarity of funding for the length of the project, although this is often short-term in nature; can be a volatile source of funds because of shifting donor priorities.
Additional to government financing	Project grants are often off-budget, separating financing from the government. They are therefore above and beyond existing government financing.
Equitable	This will differ depending upon the grant design.
Efficient	Project grants usually require detailed reporting to each donor, creating additional transaction costs for governments.
Feasible	Depends upon the reporting requirements of each donor organization, and the conditionalities that might be associated with project assistance.
Sustainable	Project grants come to an end upon completion of the project (often less than 5 years) and are therefore not a sustainable resource.
Promotes self- sufficiency	With external funds provided for immunization (often off-budget, as noted), governments may shift resources away from immunization to other sectors. Grants are often short-term as well, limiting the flexibility of the government and the ability to build capacity over time.
Fosters greater accountability	Project grants include significant monitoring and oversight, promoting accountability to donors. However, much donor assistance remains 'off-budget' and is invisible to governments and parliaments. This prevents more holistic planning, budgeting, and management of the health sector.

Further reading:

Vaccine Donations WHO-UNICEF Joint Statement August 7, 2010 (WHO/IVB/10.09) http://whqlibdoc.who.int/hq/2010/WHO IVB 10.09 eng.pdf

Brief 9: Development Loans for immunization

What is a development loan?

A development loan is money borrowed by a government from a regional development bank or from the <u>World Bank</u>. The government guarantees the loan and is responsible for repaying it in full, with the interest rate varying according to the country's economic situation. Loans may also be referred to as debt financing. No-interest loans are referred to as soft loans or credits. Loans usually are negotiated by the lending agency with the ministry of finance, and used to support financing of a sector ministry, such as the ministry of health. There are several types of loans:

Loans offered at market or near-market interest rates: These include loans such as those from the <u>International Bank for Reconstruction and Development (IBRD)</u> of the World Bank, the <u>African Development Bank (AfDB)</u>, the <u>Asian Development Bank (ADB)</u>, and the <u>Inter-American Development Bank (IADB)</u>. IBRD loans are typically taken by middle-income countries. The repayment period is between 15 and 20 years with a 5-year grace period.

Highly concessionary loans: These are loans with a below-commercial market interest rate charge, repayment periods of up to 40 years, and an administrative fee. The <u>International Development Association (IDA)</u> of the World Bank provides these interest-free loans (soft loans or credits). IDA loans are specifically targeted to countries with per capita income less than US\$885, with exceptions for small-island states. Of the world's poorest countries (GNI less than US\$1,135 per capita), 79 are currently eligible for IDA loans.

Development loans typically require some level of matching counterpart funding to demonstrate commitment of governments to the project or program being financed.

When might it be appropriate to use development loans for immunization?

All loans must be repaid. Since loans are debt financing, loans make sense when a government is not already heavily indebted, and when there is little danger of a substantial currency devaluation that would make repayment difficult. Loans make sense from an economic point of view when the value of the immediate and long-term benefits to be generated is greater than the sum of the loan, fees, and interest paid over time.

There are clear cases when financing immunization through loans makes sense. For instance, when a normally strong economy is hit with a financial crisis and is temporarily short of funds to support the national program, a short-term loan to cover this period can be a useful strategy. This was the case for Argentina in the 1990s. Loans may also make sense in order to cover the high costs of short-term investments likely to provide big pay-offs in the long-term, such as taking loans for polio eradication as was the case for Pakistan, India, and Nigeria.

However, for economies that are struggling on a continued basis to make ends meet, debt financing to meet recurrent costs is not usually the best alternative. Where additional financing is needed, the decision to take a loan should be based on an evaluation of several factors, such as: costs and benefits associated with maintaining or increasing coverage or introducing new vaccines; availability of other, lower-cost financing options; strength and growth of the national economy; and capacity of the national economy to support the debt load when the repayment comes due.

What is the experience of using development loans for immunization?

The World Bank and regional banks are able to provide loan financing in support of immunization. Generally, loans for immunization are part of a broader set of activities that are financed through a health sector loan. While difficult to tease out of overall lending for maternal and child health, the most conservative estimate is that, since 2000, the World Bank has provided over US\$500 million in loans in support of national immunization programs and campaigns for polio eradication.

Table 9.1 Assessment of the value of development loans for immunization financing

Characteristic	Assessment
Predictable	Development loans provide access to resources over a relatively long period of time with a high degree of certainty. Development loans can provide needed access to foreign exchange.
Additional to government financing	Yes, but development loans also require government counterpart funding of activities and programs.
Equitable	Depends upon the extent to which the development loan will be used to finance activities and programs to improve the plight of the poor and to reduce poverty.
Efficient	Due to the interest rate, loan financing is more expensive than grant financing. Accessing funds through loans requires a government to meet conditions for readiness, use particular mechanisms and procedures for procurement, and produce quarterly financial and program reports. Increased transaction costs are envisioned.
Feasible	Large loan programs may require establishment of a separate project unit or team within the MOH to manage implementation, reporting, and fiduciary aspects of the loan.
Sustainable	If a country is not laden with unsupportable debt repayments, loans may be part of a package of sources for sustainable financing.
Promotes self- sufficiency	Loan financing may imply greater government financial and political commitment to the immunization program because of the counterpart funding requirement. Repayment of the loan implies a long-term commitment.
Fosters greater accountability	Funds from development loans are channelled through governments and their use would be based on the current public expenditure management system. However, if disbursement of loans to a country is tied to performance indicators or triggers, then this increases accountability and use of funds.

Brief 10: Budget support

What is budget support?

General budget support is donor funding that goes directly to the national treasury and is allocated to sector budgets along the lines of national priorities and processes. This type of support has become a more prominent form of development assistance since the late 1990s, and is part of an overall movement towards aid effectiveness. In this approach, poverty reduction support papers (PRSPs) are used as the basis for prioritizing government and partner development investments. The PRSPs are often the basis for sectoral budget allocations.

Funds provided through general budget support are disbursed through the recipient government's own financial management system and are not earmarked for specific uses. However, they are accompanied by agreements and conditions for disbursement that focus on the policy environment and government development strategy. Rather than monitoring the narrow use of aid funds, government and its partners work together to monitor implementation of the national strategy.

What is sectoral budget support?

Sectoral budget support is donor assistance paid directly into the account of the ministry in question and then allocated according to sectoral priorities. In the case of health, donor assistance is paid directly into the account of the ministry of health and then allocated to sectoral priorities according to the national health sector strategic plan (NHSSP). Disbursement of sectoral budget support may be made upon achievement of targets or conditionalities such as policy, output, or outcome. Monitoring of sectoral budget support is done jointly by government and development partners. In the health sector, budget support is related to improving harmonization and alignment of priorities and funding, as well as mutual accountability, as outlined in the Paris Declaration and the Accra Agenda for Action. The design of sectoral budget support is related to a general sector policy document - Medium Term Expenditure Framework (MTEF) — a sector coordination mechanism for policy dialogue, joint planning, monitoring, and evaluation.

What is a sector-wide approach?

Many countries are moving towards a <u>sector-wide approach</u> (SWAp) in the health sector. SWAps are coordination mechanisms for planning, budgeting, and monitoring progress towards achievement of sectoral objectives as expressed in the national health sector strategic plan. SWAps are not financing mechanisms, but coordination mechanisms for mobilizing and allocating resources to sectoral priorities. SWAps work differently in different countries but there are typical characteristics: 1) all significant government and donor funding for the sector supports a single sector policy and expenditure program; 2) government leads the process and its implementation; 3) common approaches are adopted across the sector by all funding parties (government and donors); and 4) there is progress towards relying on government procedures to <u>disburse and account for donor funds</u>.

It is common for countries with SWAp mechanisms to also have a pooling mechanism for government and donor resources. Pooling with government funding implies that government systems will be used for transferring and monitoring resources, financial reporting, and audit. A <u>Joint Financing Arrangement</u> (JFA) sets out the terms and conditions for pooling of resources, including eligible expenditures out of the pool, financial reporting and audit arrangements, planning and budgeting processes, and annual review procedures. The ideal is for all stakeholders to support one national health strategy through on-budget resources, using a common monitoring framework.

Relationship of immunization financing to budget support

Increasingly, the global health community is moving away from direct project assistance for health and towards sectoral or general budget support. This is in response to the perceived failings of classical project support. Projects often suffer from slow and delayed implementation, high transaction costs, and limited sustainability. They also tend to undermine government structures and processes. Projects are designed to respond to the preferences of donors rather than national priorities. This undermines ownership and the setting of national priorities, and compromises the sustainability of project results. (See Brief 8: Development Project Assistance.)

In the case of sectoral and general budget support, immunization resources fall less and less under the purview of national immunization program managers (as is the case with project assistance) and increasingly under the control of the ministry of health or the national treasury. It is therefore important to ensure that program needs are adequately prioritized within the national strategic plan and budget. This has been a challenge for national programs as they introduce new vaccines, particularly since they are outside of the national planning and budgeting framework (i.e., they are off-budget). Efforts need to be made to ensure the evidence base for the introduction of new vaccines, to facilitate adequate policy dialogue on priority setting, and to roll these resource requirements into annual or multiyear budgets to the extent possible. Greater advocacy between ministries, parliamentarians, and donor agencies may help in this regard.

Evidence on the effectiveness of budget support

Budget support has contributed to greater policy alignment and harmonization of development aid. General budget support has been linked to increases in pro-poor development expenditures, and reduced earmarking of government budgets. General budget support has also been an effective instrument in strengthening public financial management and improving transparency and accountability. By increasing needed expenditures, budget support has helped to expand service delivery. An additional expected benefit of budget support is reduced transactions costs. There is no specific evidence on the effectiveness of budget support for immunization programs.

Recent reviews of the <u>effectiveness of SWAp</u> mechanisms in improving health outcomes have found both strengths and areas for improvement. Sector programming is becoming better integrated within the budget planning process and there is improved diagnosis of barriers to service utilization. There is also evidence of closer links between policy and implementation. However, SWAp mechanisms explicitly require ministry of health

leadership and, in some contexts, limited capacity coupled with high turnover of leadership and weak relationships with the ministry of finance has made this difficult.

SWAp coordination has led to better planning and budgeting of the sector but vertical health initiatives still operate outside of these mechanisms to a large extent and this could potentially undermine gains. There is also a lack of information on the health impact of SWAp mechanisms. Broad participation in SWAp mechanisms has been limited in some cases, particularly in civil society. Weaknesses in monitoring systems persist and some donors are unable or unwilling to provide funding through government systems. In addition, budget support may increase the leverage of donors over national health policy since they participate more actively in planning, budgeting, and monitoring of the national health strategic plan.

Case Study: Development Policy Lending in Senegal

Development policy lending (DPL) aims to help a borrowing country achieve sustainable reductions in poverty through a series of program and policy actions that promote growth and enhance the incomes of poor people. DPL lending at the World Bank is a quick-disbursing financing mechanism in the form of loans, credits, and grants to cover specific expenditures. Development policy operations (DPOs) are provided in the form of unearmarked loans, credits, or grants that are consistent with the country's economic and sectoral policies. These operations generally support strengthened financial management, improved investment climate, improved service delivery (health and education), employment creation, and other priority areas of investment. Funding is in the form of general budget support directed to the national treasury.

With DPOs, countries access financing by meeting certain triggers or targets based on a predetermined time frame. Immunization coverage – either DTP3 or measles coverage rates – is often included as one of the triggers for disbursement of funds. In this sense, the strength of immunization programs will have wider benefits for the society and economy as a whole.

Development policy lending in Senegal (through a series of Poverty Reduction Strategy Credits (PRSCs)) supported a number of key policy and institutional actions in the area of health services. The series supported the Government in improving access to, and use of, basic health services by strengthening outreach activities, implementing improved infant and child health care management, extending services for maternal care (increased attended birth and development of obstetrical emergency care), and making additional progress in the prevention of infectious diseases. The authorities continued their efforts to improve the monitoring of health sector performance, both collecting data and measuring the quality of health services throughout the country (producing statistical reports for 2003 and 2004). These actions contributed to positive results: an increase in DTP3 immunization coverage, improvements in the attended birth rate, and a reduction in the share of underweight children.

 $\begin{tabular}{ll} Table 10.1 Assessment of the value of budget support for health and immunization financing \\ \end{tabular}$

Characteristic	Assessment			
Predictable	Budget support can increase predictability of financing through multi- party planning and budgeting of health sector priorities. If budget support is conditional on achievement of targets, there is some risk that disbursements will be less than commitment levels.			
Additional to government financing	Yes.			
Equitable	Depends upon the extent to which budget support will be allocated towards activities and programs to improve the plight of the poor and to reduce poverty.			
Efficient	Budget support is expected to reduce the transaction costs of dealing with the financial and programmatic reporting and audit requirements of each individual donor separately. The initial costs of establishing coordination mechanisms may be high in terms of time and effort, but these should decrease over time.			
Feasible	SWAp mechanisms require significant investment in time and coordination – both in the initial stages and for continued maintenance.			
Sustainable	Budget support is thought to be a sustainable mechanism as it creates a sense of ownership of the national plan and of financing of the health sector.			
Promotes self- sufficiency	Budget support from development partners is usually matched with government financing of the sector (and of the program) and would contribute to self-sufficiency.			
Fosters greater accountability	Given that planning, budgeting, and monitoring of use of budget support are integral to sector coordination, this will contribute to greater accountability.			

Brief 11: Debt Relief

What is debt relief?

<u>Debt relief</u> is a process by which the debtor country is relieved of the burden of repaying the principal and/or interest on past loans. Debt relief may take the form of cancellation, rescheduling, refinancing, or reorganization of debt. The eligibility, degree of conditionality attached, and implementation procedures vary based on the specific initiative.

What types of institutions provide debt relief?

There are two international institutions – the IMF and the World Bank – that provide debt relief. There are also various bilateral debt relief initiatives. These initiatives are designed, to different degrees, to reduce or eliminate the debt of the poorest countries and so provide national governments with more resources to finance services for their populations. The result is that governments are freed from paying debts that often consume significant portions of already strained budgets, providing an opportunity to increase spending on a variety of sectors, including health.

The HIPC Initiative

The IMF and World Bank jointly launched the Heavily Indebted Poor Countries (HIPC) Initiative in 1996 in IDA countries. The aim of the initiative was to reduce the debt of qualifying countries to sustainable levels (although this did not extend to full debt relief). Countries were required to draft and implement a poverty reduction strategic plan (PRSP) and use the funds made available by debt relief to increase spending on poverty reduction and activities that helped meet the MDGs (such as reducing child mortality through immunization).

The total committed debt relief to all potentially eligible countries (currently 40) amounts to US\$73.9 billion in end-2008 net present value terms (NPV), of which 53% relates to the 26 countries at completion point. Eligibility for the HIPC Initiative was based on the levels of income and external debt prevailing at the end of 2004.

The Multilateral Debt Relief Initiative

The <u>Multilateral Debt Relief Initiative (MDRI)</u> was initiated by the G8 countries¹⁰ in June 2005 and complements the HIPC Initiative in order to help countries advance towards the MDGs. Countries eligible for the MDRI receive 100% debt relief on eligible debt owed to the IDA, IMF and <u>African Development Fund (AfDF</u>). In early 2007, the Inter-American Development Bank (IADB) also decided to provide similar debt relief to the 5 HIPCs in the Western Hemisphere. Importantly, only countries that have graduated from the HIPC Initiative process (i.e., HIPCs at completion point) will

¹⁰ The Group of Eight (G8) Industrialized Nations is made up of France, Germany, Italy, Japan, the United Kingdom, the United States of America, Canada, and Russia.

benefit from the MDRI. The total committed debt relief from the 4 multilateral creditors amounts to US\$28.5 billion (in end-2008 NPV terms), of which 86% relates to the 26 post-completion point countries that have already qualified.

Bilateral debt relief initiatives

Many creditors such as Japan, Switzerland, France, and Spain have offered up to 100% debt relief on remaining official development assistance (ODA) debt. Bilateral debt relief initiatives are usually based upon the same conditions as the HIPC initiative. Bilateral creditors often provide their debt relief as general budget support or specific targeted sector support.

Debt relief and immunization programs

Debt relief does not always translate into a direct increase in spending, since money from debt relief may be used for other purposes such as to reduce taxes or pay down domestic debt. The size of this funding mechanism varies significantly, depending upon the level of debt a country holds and the terms of the agreement. Given the variation in public expenditure management systems, many countries receiving debt relief set up specific mechanisms or institutions (such as trust funds) to manage the savings. (See Brief 6: National Trust Funds.) These can include institutional funds and virtual poverty funds which ring-fence debt relief funding. The alternative is a comprehensive expenditure tracking mechanism which provides debt relief resources through traditional budgetary processes.

Debt relief has been centered on a Poverty Reduction Strategy Paper (PRSP) that includes many sectors, including health. In order to ensure allocation of debt relief to the health sector, officials will need to be engaged in the process and to actively advocate how investment in immunization can contribute to poverty reduction.

In theory, debt relief is designed to be additional. That is to say, funds provided by a donor for debt relief should be in addition to existing forms of aid, rather than replacing this funding. Determining whether this is the case is quite challenging. The WHO has carried out work on debt relief and immunization in ten case study countries with data sheets available on each country.

What are the key benefits of using debt relief as a tool to support immunization?

Debt relief can be a new, and potentially significant, source of funds for the immunization system. It can significantly reduce countries' long-term debt service, allowing them to transition to sustainable indebtedness, thereby improving their credit rating and encouraging greater foreign investment. Lastly, it can strengthen development efforts through an increased allocation of funds to the social sectors.

Debt Relief in Cameroon

Cameroon currently benefits from <u>debt relief</u> under the Heavily Indebted Poor Countries (HIPC) Initiative, the Multilateral Debt Relief Initiative (MDRI), and additional bilateral debt relief initiatives. The Government committed to allocate resources made available from debt relief to priority expenditures in the fight against poverty as outlined in the Poverty Reduction Strategy Paper (PRSP). Cameroon will receive a total of US\$4917 million from HIPC, in nominal terms, between now and 2020. In addition, it received US\$1297 million from MDRI, in nominal terms, up-front. Finally, it also received debt relief from bilateral creditors such as France. The health sector received an increase in debt relief monies from about US\$9 million in 2001/02 to US\$40 million in 2007. A proportion of these funds has gone to the immunization sector, totalling US\$14 million between 2001 and 2006.

In order to manage the HIPC Initiative savings, Cameroon set up a special framework consisting of the following elements:

- A special treasury account at the Bank of Central African States (BEAC) to deposit the savings from HIPC relief
- A special code for HIPC funds in the budget which makes them easily distinguishable from other budget lines
- An independent institution for HIPC allocation and tracking, the 'Comité Consultatif et de Suivi de la Gestion des Ressources PPTE' (CCS/PPTE), consisting of representatives from the ministries, development partners and civil society
- Specific tracking and monitoring of projects financed through HIPC funds via dissemination of regular technical and financial audits

The preparation of a solid, comprehensive multiyear plan (cMYP) for immunization, including a detailed costing of activities and statement about future secure and probable financing sources, was instrumental in convincing the Ministry of Finance and the HIPC Committee of the need for additional funding and its efficient use. The latest cMYP (2007-2011) anticipates annual contributions from the HIPC account between US\$3.5 million and US\$7.3 million. In addition, the EPI is benefiting from significant allocations resulting from the French bilateral debt relief program C2D. Together, these two sources of debt relief cover 30% of total immunization-program-specific financing needs over the 5-year period.

Potential policy implications for health officials

The presence of an institutional fund mechanism to manage savings from the HIPC Initiative/MDRI allows health officials to target advocacy efforts specifically at these resources. The following strategies proved to be helpful in accessing the funds:

- Ensure that health priorities are adequately identified in strategic national documents such as PRSPs
- Be well informed about the annual amount of debt relief savings in the budget and the procedures in place to allocate these resources
- Submit coherent health projects which are well harmonized with the national health sector strategic plan and budget
- Ensure participation of key health officials on specific committees and in institutions in charge of the management and tracking of debt relief funds
- Carefully monitor the trend of debt relief allocations

What are the problems associated with using debt relief?

The most significant challenge is securing the use of debt relief funds for immunization. Both within and beyond the health sector, many essential investments compete for the funds, and effective advocacy with ministries of finance is critical. Health and immunization officials must strive to ensure that the money provided through debt relief is additional to ordinary foreign assistance and also to ordinary government budget allocations. In addition, debt relief has a mixed impact on health sector spending because governments do not necessarily prioritize health in their poverty reducing activities.

Table 11.1 Assessment of the value of debt relief for immunization financing

Characteristic	Assessment
Predictable	Debt relief provides clear long-term estimates of the money saved that
	would otherwise have been spent on financing debt payments.
Additional to	This increases the overall size of government revenues and is therefore
government financing	additional. However, at the sector level, the government may decide to re-
	allocate funds to other sectors to compensate for debt relief funds,
	negating the impact.
Equitable	If debt relief funds are used as intended – for investments that alleviate
	poverty – they can improve conditions for the poorest.
Efficient	Debt relief usually has low transaction costs although directing the
	monies to a special fund can incur some costs.
Feasible	Requires prioritization of health and immunization as part of poverty
	reduction, and compliance with triggers and conditions on the part of
	government.
Sustainable	Debt relief can be a sustainable resource because it increases the overall
	size of resources rather than re-allocating amongst different priorities.
Promotes self-	Can support country capacity because it provides additional resources
sufficiency	without reliance on donors.
Fosters greater	The structure established by the government to use debt relief will
accountability	influence accountability, with specific poverty-focused funds being more
	transparent.

Brief 12: The Vaccine Market - Pooled Procurement

Pooled procurement combines several buyers into a single entity that purchases vaccines on behalf of those buyers. For example, several countries within a region could combine as a single buying bloc, combining their resources and total request for doses. The countries together could purchase a greater number of doses than each could individually and, because of larger volumes in a pooled procurement, there is generally a lower price per dose. Furthermore, taken as a whole, the group of countries represents a greater proportion of a given manufacturer's business than a single country, increasing negotiating leverage.

There are several examples of pooled procurement in the purchase of vaccines. The oldest is UNICEF Supply Division, which procures on behalf of lower and lower-middle income countries through a public tender system. Since 1977, the Pan American Health Organization (PAHO) has operated a regional pooled procurement system, working with Latin American and Caribbean (LAC) countries. The Revolving Fund is critical for several small island states and territories in the Caribbean. The Gulf Cooperation Council has been working with six countries in the Middle East since 1978 to buy a range of goods, including vaccines. The Eastern Mediterranean Region of WHO (EMRO) is beginning an effort to coordinate vaccine procurement more broadly, and the WHO African Region (AFRO) and European Region (EURO) have also explored the idea.

How does pooled procurement work?

Pooled procurement can cover a range of different activities. When combining their resources, as described above, countries can use an external provider as procurement agent or set up the structure themselves. However, traditionally, the concept of pooled procurement has been linked to associated activities such as currency exchange, technical assistance, financial support, and forecasting expertise. In general, a request for proposals (RFP) is developed which specifies the specific type of vaccine, time period, and number of doses to be delivered. Manufacturers are requested to submit an offer meeting these requirements. In some cases, a range of dose and price combinations will be provided. Manufacturers traditionally give lower prices as volumes increase. Manufacturers usually make significant up-front costs and, as these are spread over larger numbers of doses, prices will fall. In addition, price reductions are related to market uncertainties and whether suppliers are dealing with multiple antigens or a simpler vaccine.

What are some examples of pooled procurement mechanisms?

• <u>UNICEF</u>: UNICEF procures vaccines for between 80 and 100 countries annually. The majority of its vaccine purchases are made through donor funding, although a small number of countries pay in full for their vaccine purchases through national budgets. Those countries that pay for their own procurement use UNICEF as a procurement agent, gaining access to its skills and expertise, along with its market leverage. Countries are requested to pay UNICEF an administrative fee of between 3% and 6% to cover operating costs. UNICEF buys approximately 40% of the global volume of vaccine doses, although this represents only 5% of the market revenues,

given the relatively low cost of vaccines procured. Vaccines procured by UNICEF must be <u>prequalified</u> by the WHO. UNICEF usually purchases vaccines on a multi-year tender, considering length of contract and type of procurement arrangement for each vaccine, to optimize the process.

• PAHO Revolving Fund: Forty Latin American and Caribbean countries and territories procure vaccines through the PAHO Revolving Fund (RF) created in 1977. Member States have designated a 3.5% recapitalization fee in addition to the price of the vaccine. This recapitalization builds a funding pool that provides a line of credit to of allow countries to place orders in a timely manner and to pay suppliers (with national currency when needed) 60 days after delivery of vaccine. In 2009, the RF purchased US\$304.7 million of vaccines. The Revolving Fund generally buys vaccines on an annual tender. The existence of the Revolving Fund has been cited as a critical component in the success of immunization across LAC, as PAHO countries have consistently introduced new vaccines earlier and more widely than is the case in other developing countries. The RF is an attempt to promote competitive conditions and lower prices through earlier entry of new suppliers.

The objectives and methods of PAHO's Revolving Fund and <u>UNICEF's Supply Division</u> are broadly similar, with some exceptions.

- UNICEF procures mainly for lower-income countries globally whereas the Revolving Fund procures primarily for middle-income countries in LAC.
- The Revolving Fund is financed almost entirely from national budgets, whereas UNICEF is primarily donor-funded.
- UNICEF may procure using multi-year tenders (though not always), while PAHO purchases annually.

What are the benefits of pooled procurement?

Pooled procurement has a price-reducing effect. For instance, Hepatitis B was introduced in the 1980s, but <u>recent evidence</u> suggests that prices have fallen more dramatically since the creation of the GAVI Alliance and the PAHO Revolving Fund, as the pooling of vaccines has increased. Pooled procurement has additional benefits.

- Strengthens the negotiating position of countries when operating as a single bloc
- Reduces the need for specialized skills required for national vaccine procurement (such as forecasting demand, defining vaccine specifications and requirements, and preparing appropriate bid documents) that may not be available in all countries but may be easier to build through a combined entity
- Allows for greater stability in vaccine supply through pooled resources and purchasing
- Results in lower unit prices, generating cost savings for countries

Pooling vaccine procurement does present some challenges.

- Capacity is not always built up within countries for purchasing of vaccines and this
 can create long-term dependence on an external body for expertise. Countries
 typically do have some capacity for forecasting, budgeting and planning which are
 critical activities in the overall procurement process.
- Reporting and record-keeping may need to be maintained according to procedures determined externally rather than using national processes.
- National procurement legislation is required and this must be aligned across participating countries.
- The range of products procured through the pooled mechanism may be limited and not completely tailored to country needs.
- The buying power of pooled procurement can shift market balances and result in a shrinking supplier base overall.

Table 12.1 Assessment of the value of pooled procurement for immunization financing

Characteristic	Assessment			
Predictable	If the structure is set up with a working capital to bridge shortfall, this			
	type of instrument can smooth over potential interruptions and allow for a stable flow of funds.			
Additional to	Depends upon the structure of the financing flow.			
government financing				
Equitable	Provides low-income or small countries with access to quality and			
	affordable vaccines that otherwise would be very difficult to obtain.			
Efficient	By combining resources, cost savings can be achieved through efficiencies			
	in procurement operations and a lower vaccine cost.			
Feasible	Requires initial capitalization of a fund and fund management. Als			
	requires national procurement legislation.			
Sustainable	If properly constructed, it can be used over the long-term.			
Promotes self-	Depends upon the structure of the system; those that rely on donor funds			
sufficiency	for vaccine purchase do not promote self-sufficiency.			
Fosters greater	Accountability may be increased as information is shared among			
accountability	countries using standard reporting formats and procedures.			

Brief 13: UNICEF - Vaccine Independence Initiative (VII)

The <u>Vaccine Independence Initiative (VII)</u> was established by UNICEF and WHO in 1991 to support lower-middle income countries working to become self-reliant in vaccine procurement. The VII offered four advantages: participation in a pooled procurement mechanism (through UNICEF); benefitting from economies of scale; payment after delivery instead of in advance; and payment in local currency (as permitted by the UNICEF Treasurer). In the current vaccine market dynamics, access to a pooled procurement system supporting a vaccine security strategy is of high value. Participation in the VII provides such assurances through UNICEF vaccine procurement.

The VII started as a revolving fund with a donation held in a 'Funds in Trust' account that serves as the guarantee, or capital fund. Today, the VII capital totals US\$9 million. The current approval period for the VII will expire in 2015.

How does the VII work?

The VII capital fund allows pre-delivery financing for member countries wishing to buy vaccines through UNICEF. The goal of the fund is to help member governments become independent in vaccine funding and procurement without disruption to the vaccine supply. The VII can provide this service by rotating the capital quickly and often enough to finance the countries' routine needs while they reimburse UNICEF.

The UNICEF Programme Division/Health Section invites member countries to enter into a VII Procurement Service (PS) agreement. The VII agreement allows countries to make payment after the vaccine is delivered and, if necessary, with local currency.

While VII offers its members financial incentives, UNICEF absorbs the risk of non-payment (default) and holds onto currency that may lose its value due to fluctuations in the market exchange. To offset these risks, the VII capital fund provides a guarantee to countries against any loss in value of their resources.

Which countries are the intended targets of the VII?

The diversity among developing countries means that they face a wide range of different needs and challenges. At one end of the spectrum are the least-developed countries that cannot finance their own vaccines and require donor support. At the other end, are more independent, industrialized countries that can procure, produce and finance their vaccine needs independently. Countries between these two poles were originally targeted by the VII, though today only a small number of countries in this category (such as the small island states) participate.

Member countries often face specific vaccine financing and management challenges, such as:

Accessing necessary hard currency from scarce foreign currency sources

- Working with ministries of finance or planning that do not recognize immunization as a priority
- Working within government regulations that often require receipt of goods before payment
- Vaccine forecasting which is often under- or over-estimated
- Managing shortages due to poor planning

The VII offers 4 types of services to address these challenges: preplanning support to define vaccine needs; access to a dependable, affordable vaccine procurement system; providing alternative financing terms; and handling inter-ministry relations to ensure cooperation and facilitate the transaction process.

In the short term, the VII provides member countries with a smooth and reliable means of vaccine procurement while they learn to manage and assume the responsibilities associated with the process and develop their own budgeting and planning capacity. In the long term, the VII enables and encourages countries to become independent with respect to vaccine financing, procurement, and management.

Country Experiences with the VII: Pacific Island Countries (PICs)

UNICEF provides assistance to 21 Pacific Island Countries (PICs), and manages a pooled vaccine procurement for 14 of those. These countries are highly diverse in development and population size and face several logistics constraints. There is a very limited and expensive airfreight service, which often results in a doubling of the landed cost of the vaccines after shipping. (Due to the population size, some shipments are only a handful of vials.)

Pooling procurement through VII includes vaccine needs/supply planning, purchase, and stock management in Suva for all countries. It also includes managing an offsite cold store facility and arranging freight forwarding to final destinations. This is a complex undertaking currently managed by UNICEF Suva with a locally contracted cold storage facility.

The key benefit of VII to participant countries is the ability to make payment after delivery. Most of the PIC members will not agree to pay a supplier in advance.

 $\begin{tabular}{ll} Table 13.1 Assessment of the value of the Vaccine Independence Initiative (VII) for immunization financing \\ \end{tabular}$

Characteristic	Assessment			
Predictable	Countries receive information on 'annual funds ceilings' in advance and			
	before signing the MOU for the current year.			
Additional to	Because local currency is substituted for hard currency, there is no			
government financing	additionality with this financing mechanism.			
Equitable	Candidate countries that are not benefiting from other partnerships are			
	prioritized.			
Efficient	There is room for improvement. Higher annual turnaround of available			
	funding is desired.			
Feasible	Relies upon existing mechanisms for procurement through UNICEF and			
	this is a complex undertaking.			
Sustainable	Yes, as long as it is recapitalized. However, the VII is meant to be a short-			
	term mechanism to help countries during a transition period towards			
	greater self-sufficiency in vaccine procurement.			
Promotes self-	The mechanism assists countries to procure using local currency, and			
sufficiency	encourages countries to become more self-sufficient in vaccine			
	procurement.			
Fosters greater	Potentially improves stock management and procurement.			
accountability				

Further Reading

Chang-Blanc, D., R. Matthews, and S. Schmitt. "Assessment Report on Vaccine Procurement and Supply in the Pacific Island Countries (PIC)". UNICEF/WHO. May 2010.

Brief 14: The Vaccine Market - Tiered Vaccine Pricing

What is tiered pricing?

Tiered pricing is a form of price differentiation: charging different prices, in different markets, for the same product. Generally, manufacturers charge higher vaccine prices in wealthier countries, while keeping prices lower for countries that cannot afford the price on the open market. In this manner, manufacturers can use the revenues generated in industrialized country markets to support the research and development costs that are required to bring new products to market.

How does tiered pricing work?

The costs of vaccines can vary enormously. Costs are linked to production as well as to research and development. (See Brief 15: The Vaccine Market – Vaccine Production and the Market.) The cost of production is linked to volume. The production cost of a particular vaccine is a flat cost, therefore the higher the number of doses produced, the lower the cost. In the case of the traditional EPI vaccines, the technology is relatively simple and the required investment in research and development is not high. In the case of the newer vaccines, there is considerable new investment and the capitalization required is high. The costs of research and development are built into the price of the vaccine and lower-income countries are necessarily able to afford the open-market price. Tiered pricing allows for price differentiation based on ability to pay.

In the most common form of tiered pricing, low-income countries are able to purchase vaccines through the bulk procurement facility offered by UNICEF (See Brief 12: The Vaccine Market – Pooled Procurement.) For example, it is estimated that the price of the EPI vaccines in low-income countries through bulk procurement can be less than 10% of the price in wealthy countries. In the case of the EPI vaccines, there is a market in both high-income and low-income countries and manufacturers are able to recuperate the costs of production both through volume and the ability to charge higher prices in the wealthy countries. GAVI-eligible countries are able to introduce new vaccines at lower-than-market prices.

What are the challenges involved in tiered pricing?

There is an inherent tension between vaccine manufacturers' accountability to their shareholders and profit-making, and the global public good benefits of immunizing populations in low-income countries. Because of this, the actual price of vaccines that should be set in different markets is unclear.

In general, the price of vaccines is high when a new product is introduced. New vaccines are often based on new production techniques that are complex and expensive. In addition, there is often only a single supplier, which limits supply and gives the manufacturer power to set the price. Over time, the cost of production may drop, new manufacturers may come on stream and the volume of supply may increase, thus lowering prices.

Historically, low-income countries have adopted newer vaccines at lower prices. This limits the market for the manufacturer and means that low-income countries do not have early access to the most recently developed vaccines. Tiered pricing may help alleviate the problem of access by allowing manufacturers to charge different prices in different markets. In addition, donor subsidies may bring the price down further for the poorest countries.

Pooled procurement is another strategy that low-income countries can use to bring down the price of their new vaccines. (See Brief 12: The Vaccine Market: Pooled Procurement.) Pooled procurement has been an effective tool, alongside tiered pricing, to increase the access of low-income countries to newer vaccines. Consolidating orders has increased the leverage of these countries by sending clear demand signals to suppliers.

Other challenges in tiered pricing include: re-importation; and the role of middle-income countries. In order for tiered pricing to work properly, the manufacturer will want to guard against having low-income country products sold in high-income countries (known as re-importation). Among the current issues under debate is how much middle-income countries should contribute to the cost of developing new vaccines.

Brief 15: The Vaccine Market - Vaccine Production and the Market

What does the vaccine manufacturing landscape look like?

The global vaccine market is expected to increase by more than 100%, from US\$24 billion in 2009 to US\$56 billion in 2016.¹¹ Multinational vaccine companies historically have conducted much of the innovation, research, and development in the field of vaccine production. They have used significant revenues, global size, and deeper expertise to fund the development of new technologies for vaccine development – an expensive and relatively time-consuming process. Biotechnology companies have also had a role in vaccine development – particularly in the early stages during discovery, though these firms lack the capacity to bring a vaccine to market.

Local manufacturers in low- and middle-income countries, primarily in Latin America and Asia, have supplied traditional EPI vaccines to countries for many years. These suppliers produce vaccines using relatively simple technology and are able to do so without significant research and capital investment.

In recent years, a few local manufacturers have begun to export their products to other low-income countries and international agencies, such as PAHO and UNICEF. As many of them remain state-owned, they are obligated to supply domestic needs first and can export only the remainder of their supply. Well-known examples of state-owned vaccine producers are Brazil's BioManguinhos (the biologics arm of Fiocruz) and Butantan, Indonesia's Biofarma, Mexico's Birmex, and Cuba's Finlay Institute. While initially focusing on production of existing vaccines, many manufacturers are considering greater research and development investments as they look to develop new vaccines. In order for local manufacturers to supply their products internationally through regional and international organizations, they must become prequalified with the WHO.

In addition to state-owned firms, a number of private manufacturers, particularly in India, have expanded and now supply a significant proportion of traditional EPI vaccines purchased by UNICEF for distribution worldwide.

How is vaccine cost linked to price?

There are two broad types of vaccine costs: manufacturing costs; and research and development costs. Often, the focus is on the cost of production, with an assumption that the cost of the vaccine should be close to the cost of production. However, this ignores the research and development costs.

For many of the newest vaccines, manufacturers will invest many years and several hundreds of millions of dollars. For vaccines that have both an industrialized country and

 $^{^{11}\,}http://center for vaccine ethics and policy. word press. com/2010/01/17/global-vaccines-revenues-projected-to-more-than-double-by-2016/$

developing country market, research and development costs are often borne through higher priced sales to wealthier countries, in line with tiered pricing. (See Brief 14: The Vaccine Market – Tiered Vaccine Pricing.) In addition, research costs are often subsidized by governments and other organizations through subsidies, rebates, and tax exemptions to local firms.

In addition, manufacturers often price vaccines without a link to the cost of production, focusing instead on what the market will bear and setting prices in line with the avoided costs of treatment. This is particularly the case in wealthy countries. For example, a pneumococcal vaccine can prevent substantial expenses from treatment of pneumonia and this is often considered by manufacturers in developing a pricing strategy. The cost of producing a given vaccine is closely guarded by manufacturers and, in the case of new vaccines, the cost is rarely known by the public sector. Moreover, early in the production of a new vaccine, when there is often only one manufacturer, the public sector has limited leverage. Thus, vaccine prices often begin at very high levels.

Vaccine manufacturing has significant economies of scale, meaning that producing a bigger volume reduces the price per dose. For example, even if a manufacturing plant is producing at only 20% of its capacity, it still has to pay the operating costs of the plant and those costs are divided over fewer doses, therefore driving up the cost per dose.

The costs of producing a vaccine can therefore vary enormously. For instance, a polio vaccine that is developed from a relatively simple technology, has a high global demand, and is produced by multiple suppliers will have a much lower unit price per dose than a multivalent conjugate vaccine, like pneumococcal, that requires a complex manufacturing technology, and is produced globally in smaller quantities. However, it is worth noting that over time, costs generally drop as efficiencies are found in production, and as manufacturing plants increasingly operate at full capacity.

Types of costs relevant for national immunization programs

Variable costs have a steady unit cost and could include such items as vials. Every dose of vaccine increases cost. A larger volume means a higher total cost.

Semi-fixed costs have a consistent batch (generally a size of several thousand doses) cost regardless of dose number. So, if a manufacturer is able to produce a bigger batch size, the cost per dose will drop.

Fixed costs are the biggest proportion of production costs. These costs are independent of volume and so, as the number of doses produced goes up, unit costs go down. In general, this means that a larger scale of production is cheaper.

Most vaccine production costs are either fixed (60%) or semi-fixed (25%) with the remainder (15%) being variable.

What does this mean for newer vaccines?

High fixed costs and increasingly complex production techniques make it difficult for new manufacturers to enter the market. In addition, these new vaccines are simply more complex, making it possible that they may never reach the low prices at which traditional vaccines are set in developing countries. To date, new vaccines have come to the market at a high price, reflecting the complexity of the technology and the limited supply (often there is a single supplier initially). Then over time, the technology becomes cheaper and efficiencies are found in production that maximize yield and lower costs. Additional manufacturers enter the market, driving up supply level and increasing competition to lower costs.

With newer vaccines this may be a slower process. A case in point is DTP combination vaccines. Initially, GAVI expected prices of this vaccine to drop quickly. But producing the pentavalent (DTP-HepB-Hib) vaccine used widely by GAVI required conjugation technology for which many emerging manufacturers lacked expertise. For several years, only a single manufacturer produced the vaccine. While a second manufacturer entered the market in 2006, real price reductions did not emerge until additional manufacturers entered the market. Now – after almost ten years – the price of pentavalent is beginning to drop.

There are a series of steps that can be taken to ameliorate this situation. First of all, manufacturers who are first to market with new vaccines can be encouraged to define transparent pricing criteria for various markets from the outset. International organizations are advocating for this approach with manufacturers. In addition, efforts can be taken to support emerging manufacturers through technology transfer and advice on intellectual property and regulatory issues. Organizations such as PATH and other product development partnerships are making efforts to partner with manufacturers to increase supply and reduce prices. In some cases, support to manufacturers from public sector organizations comes with specific requirements regarding a price ceiling for the product that is eventually developed.

Further Reading

Oxfam International and MSF. "Giving Developing Countries the Best Shot: An Overview of Vaccine Access and R&D." April 2010.

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"Supply and Procurement Report for GAVI Board." GAVI Alliance, 2002. http://www.gavialliance.org/resources/Supply Background.doc

16th GAVI Board. "Global Vaccine Supply: The Changing Role of Suppliers." Meeting held in Paris, 2005. http://www.gavialliance.org/resources/16brd 08. Supplier study.pdf

Brief 16: Innovative Financing – The International Finance Facility for Immunisation (IFFIm)

Since the adoption of the Millennium Development Goals (MDGs) in 2000, the global community has recognized the need for additional resources to achieve these goals. Donor financing for the health sector has increased significantly. However, the cost of vaccines has increased and scaling up programs is more costly at higher coverage levels. New sources of development financing needed to be tapped to allow for greater predictability of financial support for recipient countries and more flexibility for donors.

The health sector has been a testing ground for a number of new innovative financing mechanisms. Immunization, in particular, was the focus of two of the new tools: the International Finance Facility for Immunisation (IFFIm), which borrowed against donor funds in the capital markets; and the Advanced Market Commitment (AMC), which sought to accelerate the development of new vaccines for developing countries. (See Brief 17: Innovative Financing – Advance Market Commitments (AMCs).)

What is the IFFIm?

The International Finance Facility for Immunisation (IFFIm) is one of the funding sources for the GAVI Alliance. The IFFIm is supported by the World Bank in fiduciary matters and by GAVI on programmatic issues. <u>Currently, the governments</u> of the UK, France, Italy, Spain, Norway, Sweden, The Netherlands, and South Africa have pledged resources that will generate approximately US\$3.2 billion over the period 2006-2015. Each donor has made a multi-year commitment (most are 20 years) that is flexible in terms of its shape. Some donors pay the same every year, while others pay lower amounts in the early years and higher amounts in the later years. The IFFIm then bundles all of these commitments – which are legally binding – together. The chance of default (non-payment) by the donors is considered very low-risk and the bonds are therefore rated as very safe investments.

The IFFIm then issues bonds in the capital markets. When these bonds are purchased, the investor provides money up front in exchange for a stream of payments over the next 20 years (the length of donor commitments), plus a borrowing cost. This borrowing cost can be very low because of the low risk of default noted above. This is important because it minimizes the costs of the mechanism. The bond issuances are done periodically – when funds are needed – to generate money for GAVI programs. Over the period of the IFFIm, the bonds will be issued within 10 years and paid back to investors over 20 years. GAVI therefore gains the benefit of front-loading its funds in a flexible manner, without being constrained by individual donor budgeting limitations, in exchange for paying a modest borrowing cost.

Some critics point out that the borrowing cost could be avoided entirely if donors were willing to be more flexible with their financing and simply front-load it at the outset. Others are also concerned that when the bond issuances are finished and the front-loading of cash

to GAVI has been completed, resources will suddenly drop, since donors will still be committed to making payments to the bondholders for an additional 10 years.

Key benefits of the IFFIm

- **Front-loading:** Long-term donor resources can be provided up front through the issuance of bonds allowing more children to be immunized in the near term, in exchange for a small borrowing cost
- **Predictability:** The predictability of IFFIm funding is expected to yield a number of specific benefits:

Improved planning and budgeting in country: Predictability enables GAVI to make longer term commitments to national governments, enabling these governments to make longer-term budgeting and planning decisions.

Leveraging the market: The predictable funding of the IFFIm provides strengthened negotiating power and the ability to negotiate longer-term arrangements with suppliers. This increases the potential for lowering prices and obtaining more vaccines for the same envelope of funds.

Brief 17: Innovative Financing – Advance Market Commitments (AMCs)

Advance Market Commitments (AMCs) are a mechanism designed to accelerate the development of priority new vaccines and their availability to developing countries. The process of developing a new vaccine entails significant scientific challenges. The process can take up to 20 years and requires a series of large investments in research, product development and production. The risks and costs of each of these investments are normally recouped through sales once the vaccine is on the market. (See Brief 15: The Vaccine Market – Vaccine Production and the Market.) However, industry has no assurance of recouping investments to serve developing country markets because the markets are perceived by private industry to be small and risky. The result is that children and adults in poor countries often do not have access to new vaccines for 10-15 years after initial licensure in rich countries. Further, the development of vaccines targeted for diseases prevalent in Africa may be either untouched or on a much slower track than vaccines for more profitable markets.

An AMC for vaccines is a financial commitment to subsidize the future purchase of a currently unavailable vaccine (up to a pre-agreed price) – if an appropriate vaccine is developed and if it is demanded by developing country governments. By guaranteeing that the funds will be available to purchase vaccines once they are developed and produced, the AMC mimics a secure vaccine market and takes away the risk that countries will not be able to afford a high priority vaccine that they would like to introduce into their national program. A pilot AMC for pneumococcal vaccine was launched by GAVI in 2009. This pilot project is designed to accelerate the availability of pneumococcal vaccines in developing countries by stimulating the building of additional manufacturing capacity. The Governments of the UK, Italy, Canada, Norway, and Russia and the Bill & Melinda Gates Foundation have provided US\$1.5 billion to this pilot AMC.

Some of the criticisms of the AMC regard its cost relative to alternative models. The Meningitis Vaccine Program (MVP) has been cited as a potentially more efficient example, since this worked with a single supplier to develop a cheap vaccine. Proponents argue that donors could have worked with a single supplier to set up a binding agreement, resulting in lower vaccine prices. While a binding agreement with a single supplier may well have lowered the vaccine price, it would have limited vaccine choice by countries and required significant, binding financial commitments from GAVI up front. Other criticisms have focused on the fact that pneumococcal vaccine was in too late a stage to effectively test the mechanism, which is more appropriate for products that are in earlier research phases (such as malaria or tuberculosis). While this is true to a certain extent – the AMC is expected to have an impact on expanding manufacturing capacity to fit the global need, and to induce manufacture of vaccine presentations relevant for low-income countries as well – the AMC may also provide some stimulus to local manufacturers.

Key benefits of AMCs

- Address a current market failure: By establishing a secure market, AMCs create
 incentives for investment in specific vaccines for poor countries. In this way, AMCs
 will mobilize additional private resources to fight poverty and global diseases even
 before donors disburse any money.
- **Stimulate competition:** AMCs are open to all firms. Therefore, they can be designed not only to accelerate the development of new and effective vaccines, but also to develop second and possibly even third generation products that improve on the first and ensure a competitive market.
- **Encourage lower vaccine prices:** AMCs can also provide incentives for firms to invest in more efficient, large volume production facilities, thus allowing firms to incur lower costs per dose. These lower costs can then be passed on through the provision of vaccines at lower prices in the long term.
- Complement a range of interventions: AMCs are particularly effective when combined with push interventions such as the public and philanthropic funding of research through academia, public-private partnerships, and other bodies. This is because of the network effects of the increased number of scientific researchers working on the target diseases, as well as the enhanced probability that scientific research will swiftly translate into the production of effective and safe vaccines.

Brief 18: Innovative Financing - Airline Ticket Tax

Since 2004, a group of countries led by France has considered implementing an additional tax, called the airline solidarity contribution, to existing airline taxes in order to generate resources for global health. The additional airline tax is not a global tax in the strict sense of having a single agreed-upon tax and a global authority that has the power to levy it and allocate proceeds. Rather, it is a domestic tax that participating countries have agreed to coordinate and allocate to support UNITAID, an International Drug Purchase Facility for AIDS, tuberculosis, and malaria. To date, UNITAID has not supported vaccines, although the current malaria vaccine in late stage development may provide such an opportunity.

UNITAID is supported mainly (70%) through the airline ticket tax, though a total of 29 countries support UNITAID. It is particularly unique in that it has support from both traditional donor countries and developing countries themselves. Chile, Côte d'Ivoire, France, Republic of Korea, Madagascar, Mauritius, and Niger apply the airline tax to passengers. Norway allocates part of its tax on carbon dioxide emissions from fuel to UNITAID. Additional countries aiming to introduce an airline ticket levy include Benin, Burkina Faso, Cameroon, Central African Republic, Gabon, Guinea, Kenya, Liberia, Mali, Morocco, Namibia, Senegal, São Tomé and Principe, and Togo.

The airline solidarity contribution is an innovative attempt to gain the benefits of a global tax (MassiveGood). An airline tax can be introduced using pre-existing airport tax systems, with relatively low implementation costs and possibly limited negative effects on the industry. The tax can be largely 'exported', for example, if developing countries tax only international first- and business-class passengers. Globally, air traffic has grown historically at a rate of about 8% a year, so it can become a consistent and growing source of revenue for global health. UNITAID has also worked with the Clinton Health Access Initiative to negotiate lower prices for HIV/AIDS drugs.

Key benefits of the airline tax

- **Broad participation:** By gaining participation from both traditional donors and developing countries, the tax expands the concept of development assistance.
- **Sustainable financing:** Unlike budget allocations that are typically only a few years in length, and can be stopped when the donor country has budgetary constraints or the government changes, the airline tax is a dedicated and sustainable source of funds.
- Leveraging the market: Barring massive changes in air travel, the ticket tax provides a predictable source of funding for development that can enable UNITAID to negotiate better prices for drugs and diagnostics.

Brief 19: Innovative Financing - Results-Based Financing

Results-based financing (RBF) for health is a cash payment or non-monetary transfer that is made to a provider, manager, or consumer as an incentive to deliver or use priority health care services. Payment is made <u>conditional on measureable actions being undertaken</u>. RBF is an umbrella term that includes: pay-for-performance contracts with health care providers; output-based aid; and conditional cash transfers and other demand-side schemes. Payment can be made to a national or sub- national government, NGO, manager, health care provider, payer, or consumer of health services.

The international community is increasingly focused on achieving the health MDGs within the next five years, and RBF is gaining increasing attention as a strategy to scale-up provision of essential child and maternal health services. RBF schemes tie financing to the attainment of specific results or targets. It therefore offers a way to make service providers more accountable and also provides funding agencies with a clear method to determine the impact of their financing. RBF represents a shift from a 'business as usual' approach of funding inputs of health services such as medical equipment and supplies, pharmaceuticals and vaccines, training, vehicles, and buildings. With RBF, the funds are provided as an incentive to produce results.

Overall, the impact of RBF on health outcomes is mixed. Demand-side mechanisms, such as conditional cash transfers (CCTs) which link household payments to use of essential child health and education activities, have been associated with positive health outcomes. One study showed that the CCT was associated with increased immunization rates in Mexico and Nicaragua, particularly for households with less educated mothers and those situated furthest from health facilities.

The results of supply-side interventions are less clear, and in some cases have not shown improvement in health outcomes. In Rwanda, the RBF scheme was associated with positive health outcomes. Interventions such as performance-based payment for providers are harder to study because they often lack a fair comparison: what would have happened in the absence of the scheme? Implementation of supply-side mechanisms is dependent upon availability of quality health services, which may be a constraint in low-income countries. Weak institutional arrangements, management information, and monitoring and evaluation systems can make initiating an RBF scheme challenging. In addition, the cost of establishing an RBF scheme – and the long-term financial implications of the scheme – needs to be carefully considered.

Country experiences of results-based financing

Examples of RBF schemes include the pay-for-performance contracts between the <u>Haitian</u> government and NGOs providing health and family planning services. This scheme began as a pilot in 1999 with the support of USAID. The scheme covers approximately 2.7 million of the population. NGOs are contracted to provide a set of health and family planning services and, each year, pre-defined health and management targets are established against which performance is measured. NGOs lose funding if they do not achieve their performance targets, and receive a bonus payment if they achieve or exceed their targets.

<u>Plan Nacer</u> in Argentina began by providing basic health services to the poorest groups in the poorest provinces in the north of Argentina through a maternal and child health insurance program. Funding was provided by the MOH to provincial level health insurance agents on the basis of the agents achieving enrolment targets. In addition, health facilities were given financial incentives upon achievement of targets on 10 tracer conditions.

In <u>Rwanda</u>, a broad-based RBF scheme was put in place. This included providing financial payments to participating health facilities for incremental increases in the quantity of basic health services provided, such as immunization, prenatal care, and assisted deliveries. The overriding goal was to improve the utilization of health services by motivating providers to deliver services. Health facilities receive payments above routine budget levels based on achievement of pre-defined targets for both the quantity and quality of specific services achieved, such as institutional deliveries.

GAVI employs RBF through its <u>immunization services support (ISS)</u>, providing countries with a bonus payment per additional immunized child above their current coverage rates. This has been successful in raising coverage in GAVI countries. In addition, immunization coverage rates are usually one of the target indicators against which provider or consumer achievements are measured and payment is made.

Case Study: Results-Based Financing in Rwanda

Rwanda is one of the pioneers of results-based financing. RBF was adopted as a national policy as part of the 2005–09 National Health Strategic Plan and subsequently incorporated into the National Finance Law. The Government also allowed bonus payments to staff at both public and NGO health facilities and district hospitals. Under the scheme, district steering committees negotiate 3 types of performance contracts: those between the Ministry of Health and the 30 administrative districts; performance contracts between district steering committees and the health center management committees; and motivation contracts between the health center committees and individual health workers.

Sources of health center revenue are derived from government funding of health workers, user fees, *mutuelle* membership fees, donor contributions, and payments from the RBF scheme. (See Brief 4: Risk-Pooling Mechanisms, for a discussion of the *mutuelle* approach.) In the scheme, facilities are reimbursed for the quantity of services provided according to a standardized fee structure for a list of 14 services (including immunization services), adjusted by a quality score. Health centers can raise revenues by increasing the quantity and quality of these services delivered. Bonus payments to health centers are calculated as follows:

RBF earnings per facility = (fees x quantity of target services delivered) x (% quality score)

Quality is assessed quarterly by the district hospital team examining 14 services and 185 variables. Scores of less than 100% discount the negotiated payment proportionately. Validation of facility reports of achievements is done through district committees and transfers are made directly into facility bank accounts. The staff in facilities makes decisions about the use of the funds: directed towards improving the facility or salary bonuses. In addition to provider-based incentives, the Rwandan Government provides free institutional deliveries to women who participate in regular antenatal clinics.

During the period of the scheme, contraceptive prevalence increased from 7% to 28%, and assisted deliveries increased from 29% to 52%. HIV prevalence and malaria incidence declined. Between 2005 and 2007, under-5 mortality declined from 198 to 103 per 1000 live births, and immunization (DTP3) coverage increased from 83% to nearly 100%. An impact evaluation showed that the RBF was associated with improved health outcomes, such as weight for age and child height.

Lessons learned in results-based financing

The <u>development and implementation</u> of RBF schemes can be complex. As in the case of health insurance schemes, RBF schemes require detailed and interlocking systems and procedures: financial and health management information systems; verification mechanisms; payment mechanisms; contracting capacity; quality assurance; and fund management capacity, among others. Based on a review of RBF mechanisms supported by the World Bank world-wide, the following lessons have been learned:

Political commitment and country ownership at national and sub-national levels are essential to good design, effective implementation, and sustainability of RBF elements.

Involvement of all relevant stakeholders in the design of the RBF scheme helps to mitigate resistance and facilitate understanding of the mechanism.

A focused and gradual approach appears useful for layering reforms and facilitating the institutional changes required to create the right environment for RBF implementation. However, RBF mechanisms have been established quickly to fulfill needs in fragile states and post-conflict environments.

Adequate organizational structures and institutional capacity are key for RBF mechanisms to work well.

RBF projects need to focus on **improving quality of services provided**, in addition to increasing overall service provision and utilization.

Selection of performance indicators is critical. **Independent validation of achievement** of indicators linked to performance-based contracts is necessary to mitigate 'gaming' and perverse incentives to over-report results.

Adequate and appropriate monitoring and evaluation frameworks are critical for demonstrating results to stakeholders and for fostering sustainability.

 $\begin{tabular}{ll} Table 19.1 Assessment of the value of results-based financing (RBF) for immunization financing \\ \end{tabular}$

Characteristic	Assessment		
Predictable	The amount and timing of resources generated depends upon achievement, and verification of achievement, of results. RBF may be less of a predictable source of financing in an environment where achieving results is challenging.		
Additional to government financing	If the RBF is donor-supported, resources can be additional to government financing.		
Equitable	Unknown at present, as evidence is weak. Financial incentives may enhance targeting of previously underserved populations.		
Efficient	Because of the focus on results rather than paying for inputs, this mechanism might enhance the efficiency of service delivery. The cost and cost-effectiveness of these mechanisms both need to be evaluated.		
Feasible	RBF mechanisms can be highly complex undertakings which require: tracking of provision/use of the quantity and quality of services provided; verification of achievements; contracting with providers; and establishing funds flow and financial management mechanisms.		
Sustainable	Sustainability depends upon whether there are adequate resources to cover the cost of paying households for use of services, or paying providers for services rendered.		
Promotes self- sufficiency	Depends upon whether a country can afford the long-term cost of the financial incentive. Countries may feel pride in – and ownership of – their RBF mechanisms and this may enhance self-sufficiency.		
Fosters greater accountability	RBF mechanisms require verification of achievement of results and this may enhance accountability. However, there will be an incentive to over-state results which may lead to creative ways of 'gaming the system'.		

Further Reading

RBF for Health: www.rbfhealth.org.

Brief 20: Health Systems Strengthening and Immunization

What are health systems?

Success in achieving health results requires a well-organized, well-financed and well-functioning health system capable of responding to the needs of the population in an equitable manner. Traditionally, governments and donors have attempted to improve service delivery by investing in two principal areas: increasing the availability of critical inputs (such as infrastructure, equipment, vehicles, training, supplies, drugs, and vaccines); and building household knowledge on the use services (through information and education strategies designed to increase access, coverage, and quality of services).

Despite significant global and domestic investments, the poor often have unequal access to health services. In low- and middle-income countries, the quality of services is low, service delivery is inefficient, management capacity is weak, and households face impoverishment due to limited financial protection.

The WHO has identified <u>six building blocks</u> or elements of a health system: good, quality service delivery; a well-performing health workforce; a functioning health information system; availability of drugs, medicines, and supplies; good governance; and health systems financing. In addition to these building blocks, there are several <u>critical functions</u> undertaken within a health system that affect performance and these can be described by a framework of 'control knobs' in which financing, payment, organization, regulation, and behavior are incorporated.

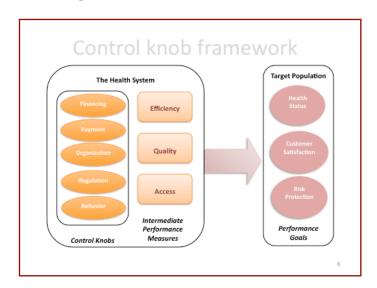


Figure 20.1 Control knob framework

Source: Adapted from Figure 2.2 in Roberts, Hsiao, Berman and Reich, "Getting Health Reform Right", 2008.

Investing in health systems to achieve immunization goals

Investment in critical inputs, together with careful planning and resource mobilization, has contributed to achieving immunization program goals. However, reaching and sustaining universal coverage requires good integration with the broader health system, and investments in those systems to support immunization outcomes. Health care workers need to be retained in rural areas and they need to receive appropriate support and incentives in order to do their job well. Appropriate supply chain management, warehousing, and distribution of vaccines and supplies need to function without interruption. Effective management and information systems are also integral to immunization service delivery.

Between 1995 and 2006, there was a substantial increase in public financing for health from domestic sources, in low income countries, from approximately \$8 billion to \$18 billion per year. Domestic (government) financing for health is much higher than development assistance, which topped \$5 billion in 2006. ¹² Nevertheless, there has been renewed interest in development support for health systems. In 2005, the GAVI Alliance Board opened a \$500 million window of cash support for health systems strengthening (HSS) , to help countries overcome institutional bottlenecks and barriers to service delivery. An additional US\$300 million was added to the HSS window in 2008. Since 2006, more than US\$568 million has been committed to GAVI-eligible countries for HSS.

The GAVI Alliance encouraged countries to use HSS funding to address bottlenecks in a number of areas:

- Health workforce mobilization and distribution
- Providing incentives to health personnel engaged in immunization and other health services at the district level and below
- Organization and management of health services at the district level and below (including financial management)
- Supply, distribution, and maintenance systems for drugs, equipment, and infrastructure for primary health care

The importance of better coordination of HSS investments

The total donor investment in health systems strengthening is difficult to quantify. The World Bank recently reported new lending of over US\$4 billion in 2010, but not all of this was in the area of HSS. Other UN agencies, and bilateral agencies such as USAID and DFID, support some aspect of health system strengthening, as do the Global Fund and GAVI. Estimates suggest that an additional US\$10 billion is needed each year to tackle health systems and the health MDGs.

¹² C. Lu, M.T. Schneider, P. Gubbins, K. Leach-Kemon, D. Jamison, and C.J.L. Murray. 2010. "Public Financing of Health in Developing Countries: A Cross-National Systematic Analysis." *The Lancet* 375: 1375–87.

In 2009, at the recommendation of the High Level Taskforce on Innovative International Financing for Health Systems (HLTF), the Health Systems Funding Platform was established. The task of the Platform is to use new and existing funds for health systems strengthening more effectively, and to leverage additional funding for HSS to help achieve better health results for MDGs 4, 5 and 6. The process will be led by countries and supported by their partners. The Platform supports three vital elements at country-level:

- One national health plan, including identification of necessary technical support needs
- One financial management and procurement arrangement, with shared audit
- One performance assessment framework, one shared annual report linked to a joint annual review and aligned with national cycles, and one monitoring and evaluation (M&E) system.

A key characteristic of the Health Systems Funding Platform is that donor funds, whether provided through bilateral or multilateral mechanisms at the country level, global health initiatives, or innovative financing mechanisms, will be allocated based on a single national results-based strategy to tackle MDG 4, 5 and 6 through HSS. Funds will be subjected to a common, annual monitoring and evaluation framework and a collective tracking system of donor and domestic financing that flows through the Health Systems Funding Platform. The principles underlying the Platform are those of the International Health Partnership (IHP+).

With these criteria firmly in place, the new Platform will improve harmonization, significantly reduce transaction costs for countries, and provide incentives for comprehensive HSS planning and implementation in support of greater progress towards achieving the health MDGs. With input from the WHO and other partners, GAVI, the Global Fund (GF), and the World Bank will coordinate their existing HSS resources towards this effort. An additional US\$1 billion has been pledged by Norad, AusAID and the United Kingdom through an expanded IFFIm. (See Brief 16: Innovative Financing – The International Finance Facility for Immunization (IFFIm).)

Further Reading

World Health Organization (Health Systems Topics): http://www.who.int/healthsystems/topics/en/index.html

World Bank Institute (Health Systems): http://wbi.worldbank.org/wbi/about/topics/health-systems

Roberts, M., W. Hsiao, P. Berman, and M. Reich. *Getting Health Reform Right: A Guide to Improving Performance and Equity.* Oxford: Oxford University Press, 2008.

Brief 21: Working with Parliamentarians

What do parliamentarians do?

Parliaments play three fundamental roles: oversight, representation, and legislation. All three are important for immunization financing. As overseers of government, parliaments scrutinize program and budget performance.

Oversight: In practice, most oversight activities center on examining and approving the government's proposed annual budget. Parliament approves all revenue collection and budgets put forward by the executive.

Representation: As representatives, members of parliament (MPs) look after the interests of their constituents. They frequently travel to their respective jurisdictions where they periodically stand for election. In most countries, ordinary citizens know little about their parliaments. Their expectations of government in general are low due to historical, cultural, and other factors.

Legislation: As legislators, MPs can introduce new bills or propose amendments to existing bills. Most bills, such as the annual budget, are introduced by government. No bill, however, can become law without parliament's approval. Parliaments sometimes adopt declarations and resolutions which may act as milestones to eventual laws. An example is the 2010 Kathmandu Resolution, in which the Parliament of Nepal expresses its support for the sustainable immunization goal.

How do parliaments work?

Parliaments do most of their work through committees. Parliamentary committees often 'shadow' particular ministries. For immunization and other essential health programs the key permanent committees are usually budget, finance, and health. Health is sometimes subsumed under social affairs or social welfare or grouped with women and youth, or labor.

A well-functioning committee will review and approve budgets and maintain contact with its highest-level executive branch counterparts, usually permanent secretaries. Committees receive at least quarterly performance reports from the particular ministries and programs they oversee, and will hear from outside experts on substantive issues. Committees may also conduct field investigations. There is a trend towards more active committee oversight of actual program implementation although this depends upon the resources available.

Key committees and individual MPs are supported by secretariat staff. Though not generally technically qualified, the secretariat is keenly aware of important issues and acts as the institution's memory. Key staffers schedule the MPs' workloads, ensure that they receive background documents and sometimes schedule witnesses for committee hearings. All updates and communications to MPs should be copied to their respective secretariat staff.

How and when to engage parliamentarians

Parliamentarians have a perpetual need to know – about policy, government performance, and conditions in their respective districts. Much of the information they receive comes from the government ministries they oversee. Other sources include public hearings, contacts with constituents, lobbyists and colleagues, and occasional international exchanges and fact-finding missions. All of these mechanisms can be used to inform them about immunization financing and other health issues.

Three metrics determine the best times to engage MPs: the budget cycle, parliament's own schedule, and the electoral calendar. Although parliaments are not always in session, committee leaders and parliamentary secretariats are usually accessible year round. Committees only meet when parliament is in session. At various times during a session, the committee chairperson reports on the committee's work to the full parliament. Parliamentary briefings should be timed with these dates in mind.

MPs exchange experiences, strengthen capacities and elaborate global policy statements through a growing array of international parliamentary institutions. Advocacy work with these inter-parliamentary institutions is essential. At its July 2010 summit, for instance, the Pan African Parliament (PAP) adopted a resolution in support of the African Union Campaign on Accelerated Reduction of Maternal Mortality in Africa (CARMMA). The PAP will work with national parliaments and other stakeholders towards implementation of policy and budget support for this initiative.

Every MP wishes to keep constituents informed about what government does for them, for example, how well it delivers immunization and other public health programs. As part of their oversight role, MPs should be invited to participate in immunization-related district-or community-level events in their jurisdictions. Efforts should be made to publicly praise any MP who champions immunization and other essential health programs.

Parliamentarians are busy people. As their elections approach they are even harder to reach, but their need for timely and accurate information increases. Whenever possible, important immunization-related events should be scheduled well before or after parliamentary elections. If this is not possible, a key MP should nevertheless be invited, particularly if the event is in that MP's jurisdiction.

Experience of working with parliamentarians for immunization financing

Over the past year, the Sabin Vaccine Institute's <u>Sustainable Immunization Financing Program</u> has organized 19 national briefings for parliamentarians in 11 pilot countries. The Program also arranges peer exchanges among the countries. In these activities, MPs are updated on national immunization program operations and financing. They learn about the economics of immunization and see what other countries are doing. The Program strives to strengthen links among three national institutions: ministry of health, ministry of finance, and parliament. Immunization is presented as an applied case study for health sector financing requiring inter-sectoral solutions.

These advocacy activities are already having an impact. In Sierra Leone, Nepal, Senegal, and DR Congo, MPs successfully argued for larger health budgets during 2010 budget hearings. Immunization budgets correspondingly increased. In DR Congo and Sierra Leone, MPs induced governments to release delayed GAVI co-payments totalling nearly US\$2 million. In Cameroon, as part of the country's recently launched decentralization program, MPs are working with sub-national elected officials (*maires*) to form regional immunization budgets. They have recommended the creation of a national immunization fund to be financed by federal and district revenues.

Table 21.1 Assessment of the value of working with parliamentarians for immunization financing

Characteristic	Assessment
Predictable	Parliament must review and approve proposed government budgets annually. Committee membership may change year-to-year, necessitating regular briefings for key committees to ensure adequate and predictable funding.
Additional to government financing	Advocacy messages educate parliamentarians on the need for an adequate immunization budget. If the government share is less than 100% of need, additional government funding would be expected.
Equitable	Since resources are allocated through government processes, this would depend upon how well the resources are targeted to particular groups. Based on the information received through advocacy efforts, parliamentarians might improve equity by ensuring that services reach all areas of their constituencies.
Feasible	This approach is feasible but requires preparation of evidence for policy dialogue and advocacy.
Efficient	Lobbying efforts with parliamentarians can be time-consuming and they require effort. However, there could be big pay-offs. Since funding would come through usual government channels, efficiency of disbursement would be related to public expenditure management practices.
Sustainable	Financing from additional allocations approved by parliaments could be either a one-time event or a long-term commitment, depending upon the country and the context.
Promotes self- sufficiency	Working with parliamentarians to increase immunization financing can improve parliamentary capacity for budget review, oversight, and health legislation. Added parliamentary involvement lessens the need for external expertise.
Fosters greater accountability	As funding would be channelled through government systems, accountability would be the same as it is in the case of general tax resources. However, if parliamentarians are concerned about the results of these additional investments, there could be greater incentives for accountability and reporting.

Further Reading

Hudson, A. and C. Wren. "Parliamentary Strengthening in Developing Countries: Final Report for DFID." London: Overseas Development Institute, 2007.

http://www.odi.org.uk/pppg/politics and governance/publications/ah Parliamentary strengthening.pdf

Africa All Party Parliamentary Group. "Strengthening Parliaments in Africa: Improving Support." Unpublished Report, 2008.

 $\frac{http://siteresources.worldbank.org/EXTPARLIAMENTARIANS/Resources/Strengthening-Parliaments-in-Africa.pdf$

Brief 22: Comparison of Immunization Financing Options

Making decisions on the best strategies for immunization financing is not easy. This set of briefs has provided a short overview of the main types of financing mechanisms available to program managers and policy-makers. It is intended as a reference and tool. The mechanisms vary in their utility depending upon the context in which they are implemented and the decisions made around their use. In practice, national governments will want to employ several complementary strategies. A range of country conditions will affect decisions about financing mechanisms. Some of these are listed below.

The health sector context: How does immunization fit within other priorities for the health sector that the government has identified? How adequately are these other priorities funded? What is the balance between preventive and curative services? Will EPI investments help strengthen health systems? How strong is the health system? Are there significant barriers within the system that need to be resolved? Considering the answers to these questions will enable governments to properly consider the best types of mechanism for their program – and which criteria are most important to examine.

Financial management and accounting: Is the financial system transparent and accountable? Is it possible to track funding flows in a timely manner? Are systems reliable? Can immunization be used as a case study for improving financial management practices? These types of issues will be important in considering which types of tools will be most suitable.

Macroeconomic context: The national income level determines the eligibility for various funding mechanisms, such as IDA from the World Bank and the GAVI Alliance. The degree of indebtedness can affect the impact of debt relief as well as the feasibility of taking additional loans. The potential for economic growth affects the potential for the resource base through taxes to grow over time. In addition, the overall stability of the country is going to affect the balance of different funding mechanisms and the capacity for self-sufficiency over time.

Relationship with donors: The historical and current relationship with bilateral donors, regional and global development banks, and other multilateral organizations and NGOs will impact the potential for pursuing some of the different funding opportunities. Can government and parliament work together to sustainably finance immunization and other key health programs? If so, this will lessen donor dependency.

The purpose of this Toolkit is not to be proscriptive or to recommend which mechanisms are the most suitable. However, the table below can serve as a rough guide by summarizing the various options presented. The table uses 'Y' and 'N' to indicate how particular options stand up to the eight characteristics that we have been using throughout the briefs: predictable; additional to government funding; equitable, feasible; efficient; sustainable; promotes self-sufficiency,; and fosters greater accountability. A 'O' indicates a neutral score. A 'D' indicates that the outcome depends upon how the mechanism is structured or whether the existing system has the conditions necessary to meet the criteria once the mechanism is in place. A question mark '?' is used when the evidence is mixed and 'N/A' indicates that the question is not applicable.

Table 22.1 Comparison of immunization financing of	ptions
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Immunization Financing Option	Predictable	Additional to Government Funding	Equitable	Feasible	Efficient	Sustain- able	Promotes Self- sufficiency	Fosters Account- ability
General revenues (taxes)	D	N/A	D	Y	D	Y	Y	D
Risk Pooling	Y	Y	Y	N	D	D	D	Y
User Fees	D	Y	N	Y	N	D	?	Y
Trust Funds	Y	Y	D	N	N	Y	Y	Y
Other Innovative Financing Mechanisms	D	Y	D	Y	Y	D	Y	Y
Project Assistance	N	Y	D	Y	?	N	N	N
Development Loans	Y	Y	D	Y	N	Y	Y	Y
Budget Support	Y	Y	D	N	Y	Y	Y	Y
Debt Relief	Y	Y	D	N	Y	Y	Y	Y
Pooled procurement	Y	D	Y	Y	Y	D	Y	Y
Vaccine Independence Initiative	Y	N	Y	Y	0	Y	Y	Y
Results-based Financing	D	D	?	N	Y	?	Y	Y
Working with Parliamentarians	D	Y	D	Y	0	D	Y	D

This table suggests that the impact of an immunization financing option on equity depends upon how it is designed and how funds are allocated and channelled. Many of the financing options promote self-sufficiency and accountability. The extent to which a financing option is sustainable will depend upon how it is designed and implemented, and how it is situated within the mix of financing of the health sector. Most of the financial options considered were additional to current government funding (except for general revenues and the VII). There is a mixed picture on whether options contribute to efficiency: many options may add transaction or administrative costs, while at the same time being a more effective channel for immunization financing.

National immunization managers and policy-makers are encouraged to consider a range of immunization financing options and to identify the best mix of options for the national program. Identifying the best options will require making tradeoffs among the potential effects and characteristics of the options.

Further Reading

Kamaral, L., J. Milstein, M. Patyna, P. Lydon, A. Levin, and L. Brenzel. 2008. "Strategies for Financial Sustainability of Immunization Programs: A Review of the Strategies from 50 National Immunization Program Financial Sustainability Plans." *Vaccine* (26): 6717-6726.

GAVI Alliance. "Financial Sustainability for Immunisation in the Poorest Countries: Lessons from GAVI 2000-2006."

http://www.who.int/immunization_financing/analysis/fctc_report_web_simple_pages.pdf

Appendix: Additional Information: Estimating Cold Chain Requirements

Logistics is central to a well-functioning national immunization program (NIP). The key areas of logistics support include vaccine management and monitoring, cold chain management, and immunization safety. Logistics ensures that vaccines are available at the right time, in the correct amount, and in the correct condition. Timely availability requires timely demand forecasts, transport, and delivery. Estimating and delivering the correct amount involves proper demand forecasts and communication within the country. Ensuring that vaccines are received in the correct condition requires ensuring cold chain. Taken together, these elements can save programme costs and ensure efficient implementation without compromising the quality of service delivery. A poorly functioning logistics system can result in unnecessary vaccine wastage rates, stock-outs, or improper management of waste, thus driving up immunization program costs and potentially reducing the number of immunized children.

What does cold chain encompass?

The cold chain refers to the storage and transportation of vaccines at recommended temperatures from the manufacturing location to where they will be used. An effective cold chain ensures that vaccines will remain effective and usable when they are administered to children and their mothers. Cold chain includes staff to manage the vaccine distribution, equipment for vaccine storage and transport (i.e., fridges), maintenance of that equipment, and effective monitoring of the system.

Cold chain needs are changing with the introduction of new vaccines that often require large volumes of storage space. This factor is often overlooked or under-budgeted by national immunization programs, and could compromise the efficacy of new vaccines and lead to high wastage costs. Evaluating cold chain requirements may help governments determine which types of vaccines to introduce based on cost and affordability criteria.

A number of issues need to be taken into account when considering cold chain requirements for new vaccines. They include:

- Storage conditions (temperatures, Vaccine Vial Monitor (VVM))
- Presentation (prefilled device, single-/multi-dose vials)
- Packaging (particularly the volume of packaging)
- Cost per dose

Determining vaccine volumes

The <u>vaccine volume per child</u> is determined by the packed volume (bearing in mind that vaccines are stored in secondary packaging) multiplied by the number of doses, multiplied by a wastage factor. The package volumes and wastage rates can vary significantly, with larger volume vials generating higher wastage rates. On the other hand, with larger vial sizes, the cost of cold chain storage per dose drops dramatically.

Parameters Needed to Estimate Cold Chain Storage Requirements

The following information is useful in estimating cold chain requirements and comes from the UNICEF Supply Division.

Example calculation

A single-dose vial vaccine that requires three doses per child on the EPI schedule would total $40.64~\text{cm}^3$ per child $(12.9~\text{cm}^3~\text{x}~3~\text{doses}~\text{x}~1.05~\text{wastage})$.

Table A.1 Vaccine volume reference

Presentation	Maximum Packed Volumes
Pre-filled (PF) syringe	60.0 cm ³ /dose
Compact PF device	11.0 cm ³ /dose
Single-dose vial	12.9 cm ³ /dose
2-6 dose vial	6.0 cm ³ /dose
10-dose vial	3.0 cm ³ /dose
20-dose vial	2.5 cm ³ /dose
50-dose vial	1.5 cm ³ /dose

Table A.2 Vaccine wastage rates for cold chain requirement calculations

Vial Size	Presentation				
	Lyophilized Vaccines	Liquid Vaccines			
20 doses	50%	-			
10 doses	40%	25%			
2 doses	-	10%			
1 dose	-	5%			

Determining country readiness

The introduction of new vaccines is placing significant pressure on the cold chain. Analysis by UNICEF shows that the volume per child will triple to 180 cm³ with rotavirus, pneumococcal, and pentavalent vaccines added to the schedule. This is compared with only 60 cm³ before their introduction. Many countries currently face challenges in increasing the capacity of their existing cold chain in order to accommodate the pentavalent vaccine. The introduction of pneumococcal and rotavirus vaccines will require further significant investment in the cold chain, from central storage facilities to vaccine carriers used by health workers. Given the relatively high cost per dose of these new vaccines, there is a need to minimize vaccine wastage. The current WHO Open Vial Policy, which encourages opening vaccine vials even to immunize one child, may be associated with high vaccine wastage if vial sizes are large. Therefore, it is likely that new vaccines will be introduced in smaller vial

sizes (1- or 2-dose vials) to minimize wastage and associated costs. This will require investment in additional cold chain storage capacity. Recent analysis suggests that only 51% of countries analyzed had sufficient capacity for both rotavirus and pneumococcal vaccine introduction. Of the remaining countries, 34% could introduce 1 of the 2 vaccines, and 29% could not introduce either vaccine.

Estimating costs

There are a number of tools available to policy-makers and immunization managers seeking to determine the state of their cold chain. A <u>logistics and planning tool</u> has been developed by WHO to guide governments in understanding the issues around vaccine management, including cold chain. In addition, a specific tool to calculate vaccine volumes is available as an <u>Excel spreadsheet</u>. Fixing the current gap in cold chain can be achieved in one of two ways: through complementing existing facilities (lower cost) or rebuilding the stores (higher cost). The cost of rehabilitating the existing vaccine stores is a relatively modest US\$1.3 per child. In total, across the countries analyzed in WHO regions, the full investment required to rebuild (acquire new stores) is just under US\$100 million; the investment required to complement existing facilities is US\$19.2 million.

Case Study: Estimating Cold Chain Requirements for Pakistan

A recent study in Pakistan compared the relative cost-effectiveness of Hib, pneumococcal, and rotavirus vaccines and undertook an analysis of the fiscal implications of introducing these new vaccines. The assessment of the financial implications included an analysis of the cold chain requirements associated with each new vaccine, particularly the rotavirus vaccine which is much more bulky than others.

Across different scenarios, investments in cold chain development and maintenance were found to be highly efficient in Pakistan. For the pentavalent vaccine alone, an initial investment of about US\$300,000, followed by US\$50-100,000 per year, would reduce wastage from 10% to 5% and result in annual cost savings of around US\$2 million. With the introduction of additional new, more costly vaccines, savings from reduced wastage would be even greater. Whatever decisions are made about adding new vaccines to the program, the cold chain investments required would remain well under US\$1 million per year and, in most years, under US\$500,000. This is small in comparison with the commitments involved in vaccine purchase that during the co-financing period, are of the order of US\$10-20 million. The case for investment in cold chain infrastructure is, therefore, very clear.

As new fridges have been developed and prequalified for use in the cold chain, the emphasis has often been on small fridges that can be deployed to small health centers such as those that work on solar power or absorption. However, with the increasing volumes of new vaccines, this trend needs to be reversed: larger machines for cold chain need to be rolled out , in country, to support the transport and delivery of the new vaccines. In the longer term, more radical changes such as re-designing the supply chain, creating mobile

warehouses, or alternatives to cold storage will need to be considered. These are options currently being explored by Optimize, a joint WHO/PATH project. This project is looking at creating a more flexible and robust cold chain for the future, and is carrying out demonstration projects in several countries. Its efforts should provide information for countries considering how to modify their cold chain effectively for the future.

List of Abbreviations

ADB Asian Development Bank AfDB African Development Bank AfDF African Development Fund AFRO WHO African Region

AMC An Advanced Market Commitment provides a commitment to

purchase a vaccine at a certain price if it meets certain specifications and is demanded by developing countries.

AusAID Australian Agency for International Development

BEAC Bank of Central African States (Banque des Etats de l'Afrique

Centrale)

BCG Bacillus-Calmet Guerrin vaccine for tuberculosis

C2D French bilateral debt relief program operating within the HIPC

Initiative

CARE A leading humanitarian agency fighting global poverty

CARMMA Campaign on Accelerated Reduction of Maternal Mortality in

Africa

CCS/PPTE Comité Consultatif et de Suivi de la Gestion des Ressources

PPTE', an independent consultative committee for allocation and

tracking of the HIPC Initiative in Cameroon

CCSS Costa Rican Social Security Administration

cMYP Comprehensive Multi-Year Plan which sets out a 3-5 year budget

and plan for the immunization system

Co-payment Used by GAVI as part of its efforts towards financial

sustainability. Countries are requested to provide a small copayment of no more than US\$0.30 per dose currently, depending

on their income and the grouping into which they fall.

DFID United Kingdom Department for International Development

DPL Development Policy Lending
DPO Development Policy Operations

DTP3 Diphtheria-Tetanus-Pertussis vaccine (third dose)

EMRO WHO Eastern Mediterranean Region EPI Expanded Program on Immunization

EURO WHO European Region

FSP A country-level Financial Sustainability Plan that preceded the

cMYP and was used by GAVI as a mechanism for countries to set

out how they would support the costs of new vaccines.

Group of Eight Industrialized Nations – France, Germany, Italy,

Japan, the United Kingdom, the United States of America, Canada,

and Russia.

GAVI GAVI Alliance (formerly the Global Alliance for Vaccines and

Immunization)

GF Global Fund for HIV/AIDS, TB and Malaria
GIVS Global Immunization Vision and Strategy

GNI Gross National Income
GNP Gross National Product

Hib Haemophilus Influenza type b vaccine

HIPC Initiative The Heavily Indebted Poor Countries Initiative was launched

jointly by the World Bank and the IMF to provide debt relief

(although not complete relief) to eligible countries

HLTF High Level Task Force for International Innovative Financing HSS Health systems strengthening. A broad based support for

strengthening health systems to reduce challenges, where these present a bottleneck for delivering better immunization services.

IADB Inter-American Development Bank

IBRD International Bank for Reconstruction and Development

IDA International Development Association

IFFIm The International Financing Facility for Immunisation borrows in

the capital markets, based on long-term pledges from donors, in

order to frontload resources for immunization.

IHP+ International Health Partnership+
IMF International Monetary Fund

ISS Immunization Services Support. Provided as a payment, by GAVI,

of US\$20 per additional child immunized in order to support the

strengthening of the immunization system.

JFA Joint Financing Agreement or Joint Financing Arrangement

JICA Japan International Cooperation Agency

M&E Monitoring and Evaluation
MDG Millennium Development Goal

MDRI The Multilateral Debt Relief Initiative expanded the HIPC

program to cover the IDA, IMF and African Development Fund

(AfDF) and offer 100% debt relief to eligible countries

MHO Mutual Health Organizations, or 'mutuelles', in West Africa.

Voluntary organizations providing insurance to enrolees.

MOH Ministry of Health

MOU Memorandum of Understanding

MP Member of Parliament

NGO Non-Governmental Organizations
NHSSP National Health Sector Strategic Plan
NIP National Immunization Program

Norad Norwegian Agency for Development Cooperation

NPV Net Present Value

ODA Official Development Assistance
PAHO Pan American Health Organization

PAP Pan African Parliament

PATH Program for Appropriate Technology for Health

PF Pre-filled (syringes for vaccine doses)

PRSC Poverty Reduction Strategy Credit PRSP Poverty Reduction Strategy Paper

RBF Results-based financing provides development aid to countries

based on outcomes rather than inputs. Countries can therefore be paid based on the number of children immunized or number of

attended birth deliveries.

SIA Supplemental Immunization Activity

UN United Nations

UNICEF United Nations Fund for Children

USAID United States Agency for International Development

SWAp Sector Wide Approach

VF Vaccine Fund

VVM Vaccine vial monitor that is used to monitor the temperature of the

vaccine during transport and storage. The VVM changes colour if

it has been stored outside of its temperature range.

WHO World Health Organization