

IMMUNIZATION FINANCING

A RESOURCE GUIDE FOR
ADVOCATES, POLICYMAKERS,
AND PROGRAM MANAGERS

RESULTS FOR DEVELOPMENT

2017

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Results for Development (R4D) is a global nonprofit organization working with partners in more than 55 countries to find new ways to help people escape poverty and reach their full potential. We apply fresh thinking and rigor to emerging and stubborn development challenges—particularly within the fields of health, education, and governance—and we pioneer and advance creative, high-impact solutions. We do this by conducting analysis and generating evidence that helps to inform and influence decision-makers; building platforms and networks that connect people and ideas; by providing direct support to local change agents; and combining these approaches to deliver meaningful and lasting results.

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Preface

THIS RESOURCE GUIDE collects 26 brief documents on topics related to the cost and financing of national immunization programs in low- and middle-income countries. Some of the briefs explore possible financing sources. Others examine the components and drivers of immunization costs, planning and decision-making processes related to immunization programs and budgets, and the relationship between immunization and broader health system financing. The resource guide concludes with a set of country case studies that illustrate particular approaches or important challenges.

This volume is intended for immunization advocates, program managers, decision-makers, and planners in ministries of health and finance. The information is relevant to countries that are eligible for support from Gavi, the Vaccine Alliance, as well as to countries that are transitioning out of Gavi support and middle-income countries that have never received Gavi support.

The briefs can be read in sequential order or individually. Each begins with a summary of key

points. Some of the briefs are more technical than others, due to their subject matter, but they are all meant to convey practical information to readers who do not have specific technical expertise. Many of the briefs recommend other resources that offer more in-depth information.

The following table outlines the contents of the resource guide and the main questions addressed by each brief. It is followed by a list of key terms used in this document.

TOPICS AND MAIN QUESTIONS

PART I: IMMUNIZATION FUNDAMENTALS		
BRIEF 1	Why Immunization and Immunization Financing Matter	What is the value of immunization? Why is it important for governments to finance it? What new financing needs should countries plan for?
BRIEF 2	Universal Health Coverage and Immunization Financing	How does immunization fit into the movement toward universal health coverage? What challenges do changes in health financing pose for immunization?
BRIEF 3	Components of Immunization Costs	What are the key components of immunization costs, and how do they vary across delivery platforms? Which costs are typically shared with other health services, and which are specific to immunization?
BRIEF 4	Vaccine Decision-Making	What should countries consider in deciding whether to introduce a new vaccine? What kinds of institutions and processes can strengthen vaccine decision-making?

PART II: SOURCES OF FINANCING

BRIEF 5	Domestic Public Funding Sources	What are the main sources of domestic public financing? Why is domestic public revenue likely to remain the primary source of immunization financing, especially as countries transition away from development assistance?
BRIEF 6	Earmarking to Finance Immunization	What is earmarked funding? What are the pros and cons of earmarking for immunization?
BRIEF 7	Domestic Trust Funds	What are trust funds for immunization? How have they worked in practice?
BRIEF 8	Household Out-of-Pocket Payments	Why are out-of-pocket payments so strongly discouraged for immunization services? What kinds of informal fees persist in some countries today?
BRIEF 9	Gavi Financing for Immunization	Which countries are eligible for funding from Gavi? What kinds of support does Gavi provide? What is the process of transitioning from Gavi support?
BRIEF 10	Development Assistance for Immunization	How can development assistance for immunization be put to best use, bearing in mind the need for alignment with government priorities, efficiency, predictability, and sustainability?

PART III: STRATEGIC PURCHASING AND PROCUREMENT

BRIEF 11	Vaccine Procurement Overview	What vaccine procurement options do countries have, and what are the pros and cons of each? What are the main factors that determine the prices that countries pay for vaccines?
BRIEF 12	Pooled Procurement	What is pooled procurement? What options do countries have for participating in pooled procurement arrangements?
BRIEF 13	UNICEF's Vaccine Independence Initiative	Why did UNICEF establish a vaccine financing credit line? What countries might benefit from it? What are the requirements for participating?
BRIEF 14	How Provider Payment Approaches Affect Immunization Services	What are the pros and cons of the various approaches to paying providers for immunization services? What kinds of incentives do they create?

PART IV: STRATEGIES FOR POLICY CHANGE

BRIEF 15	Building Parliamentary Support for Immunization Financing	How can immunization advocates engage with national parliaments, including through parliamentary leaders, standing and ad hoc committees, and secretariat staff?
BRIEF 16	Immunization Financing Legislation and Regulation	How can immunization legislation create a legal commitment to immunization and support sustainable immunization financing? What are the common elements of immunization legislation and regulation?
BRIEF 17	Immunization Planning and the Budget Cycle	What are the main elements of the budget cycle, and what are the implications for immunization financing? When are the best times for advocates to engage in the budget process?
BRIEF 18	Key Questions for Immunization Advocates	What questions on immunization financing might immunization advocates raise with policymakers?

PART V: COUNTRY CASE STUDIES

BRIEF 19	Armenia: Strong Government Support for Immunization	What lessons can be drawn from Armenia’s high-performing immunization program, which has benefited from close collaboration between the Ministry of Health, Ministry of Finance, and the Standing Committee on Health Care, Maternity, and Childhood in Parliament?
BRIEF 20	Azerbaijan: Dramatic Savings from a Change in Procurement	What has been the impact of Azerbaijan’s switch from direct procurement to using UNICEF Supply Division? How did the country evaluate the pros and cons? What implementation challenges did it face?
BRIEF 21	Bhutan: A National Trust Fund for Immunization	What factors have contributed to the success of the Bhutan Health Trust Fund, one of the longest-running funds dedicated to essential medicines, including vaccines?
BRIEF 22	Costa Rica: Lottery Contributions for Immunization in a Mixed Financing System	Lotteries are among the innovative mechanisms that countries may consider for immunization financing. What role has the national lottery played in financing vaccines in Costa Rica?
BRIEF 23	Ghana: Mixed Financing for Immunization and Shifting Responsibility	What can other countries learn about immunization financing from Ghana’s experience with its National Health Insurance Scheme, which includes complex health financing and service delivery systems?
BRIEF 24	Indonesia: The Challenge of Protecting Immunization in the Transition to Universal Health Coverage	How have health financing reforms, decentralization, and the expansion of social health insurance affected the immunization program in Indonesia?
BRIEF 25	Kenya: Decentralization and Immunization Financing	Decentralization can pose challenges to immunization if roles and responsibilities for key functions are not clear. How have Kenya’s recent decentralization efforts affected immunization financing?
BRIEF 26	Sri Lanka: Sound Decision-Making Processes for Immunization	Sri Lanka’s national immunization technical advisory group (NITAG) is seen as a model of immunization decision-making. How does it work?

KEY TERMS

capital cost

The cost of assets (such as buildings and equipment) that have a working life of one year or longer and usually exceed some threshold cost. In immunization, this could include cold chain equipment, national and regional medical stores, and vehicles.

capitation payment

A fixed payment to a health care provider to deliver an agreed-upon package of services to each enrolled person over a fixed period of time.

co-financing

In the context of Gavi, contributions from both Gavi and Gavi-supported countries toward the cost of vaccines. Country contributions are not paid to Gavi; rather, the required co-financing amount is converted, using the full price that Gavi pays, into the number of vaccine doses the country is responsible for financing directly.

cold chain

A temperature-controlled supply chain. Vaccines must be kept in a narrow temperature range from the point of manufacture to the point of use.

comprehensive multi-year plan (cMYP) for immunization

A tool that countries use to estimate costs and financing for immunization and identify financing gaps.

conditional cash transfer program

A program that provides cash payments to poor households that meet certain behavioral requirements, such as bringing children in for immunizations and other health care.

earmarking

Setting aside some or all revenue from a tax or group of taxes for a designated purpose.

fiscal space

Room in a government's budget that allows the government to allocate resources for a desired purpose without jeopardizing the sustainability of its financial position or the stability of the economy.

general revenue

Money that a government raises through personal income taxes, taxes on corporate income and profits, value-added and sales taxes, duties and import taxes, property and inheritance taxes, payroll taxes, and/or taxes on profits from the sale of natural resources. These sources are typically pooled into a consolidated fund and appropriated toward payment of public expenses through regular budgeting and planning cycles.

Global Vaccine Action Plan (GVAP)

A strategic framework that lays out ambitious global immunization goals, proposed objectives, and actions for the period 2011–2020. It was endorsed by all 194 member states of the World Health Assembly in May 2012.

grant

A sum of money or a product that is provided by one entity to another without expectation of repayment.

immunization financing sustainability

The ability of a country to mobilize and efficiently use domestic and supplementary external resources on a reliable basis to achieve current and future immunization targets.

loan

Money lent from one entity to another that carries the requirement of future repayment.

out-of-pocket payment for health

Direct expenditure by households for health care.

pooling	The accumulation and redistribution of prepaid health revenues on behalf of a population for eventual transfer to providers in exchange for covered services.	transition process	The process during which a country moves, over a number of years, from eligibility for external assistance to ineligibility, usually based on per capita income or other criteria. Also known as the <i>graduation process</i> .
public financial management (PFM) system	The system by which financial resources are planned, allocated, and controlled to enable and influence delivery of public service goals. PFM includes all phases of the budget cycle, including budget preparation, internal controls and auditing, procurement, monitoring and reporting, and external auditing.	trust fund	A mechanism that governments can use to ring-fence, or protect, funding for specific purposes. Trust funds may receive funds from multiple streams of revenue and may be legally incorporated with policies and tax regulations that vary by country; a governing board oversees the strategy, business plan, management, and operations.
recurrent cost	A resource that is consumed within one year or has a working life of less than one year and must be regularly replaced. Also called <i>operating cost</i> .	universal health coverage (UHC)	Ensured access to essential health services for an entire population without risk of financial hardship or impoverishment.
results-based financing	Financial incentives that are linked to specific actions by providers or patients for improving health or health services.	user fee	A charge paid by users of goods or services at the point of use. User fees can be official (formal) or unofficial (informal).
shared cost	The cost of a resource that is shared by and can be allocated to multiple health services.	WHO pre-qualified vaccine	A vaccine from a particular manufacturer whose quality has met standards defined by the World Health Organization for use by United Nations agencies.
social health insurance	A health financing model in which coverage is mandatory for the entire population or a subset of the population, entitlement to covered services is linked to a contribution made by an individual or on the individual's behalf that is not related to health risk, and coverage is provided by a government or government-regulated body or bodies.	WHO/UNICEF DTP3 coverage estimate	A country-specific estimate, for a specific year, of the percentage of children in a country who have received the third dose of vaccine containing diphtheria-tetanus-pertussis (DTP3), as reviewed and published by WHO and UNICEF.

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Introduction

IMMUNIZATION IS ONE of the best uses governments can make of limited public funds for health. Yet 1.5 million children under age 5 die from vaccine-preventable diseases every year and 19 million remain underimmunized.* This introduction notes some important developments in the global immunization environment that set the context for this resource guide and highlights some important themes in the document as a whole.

TRENDS

Several important trends have emerged or accelerated since the previous edition of this resource guide (titled *Immunization Financing Toolkit*) was published in 2010:

- **Countries and the international community have made powerful new commitments to immunization and immunization financing.** Most importantly, the Global Vaccine Action Plan (GVAP) was endorsed in 2012 by all 194 member states at the World Health Assembly. This resource guide can help advance GVAP's Strategic Objective 5, which calls for immunization programs to have "sustainable access to predictable funding." In addition, at the Ministerial Conference on Immunization in Africa in 2016, African countries committed to increasing domestic financing for both vaccines and immunization service delivery.
- **Gavi, the Vaccine Alliance, the most important external source of funding for immunization programs in developing countries, revised its policies for eligibility and transition (formerly graduation) in 2009 and again in 2015.** As a result, many countries whose economies have

grown are in the process of phasing out Gavi support and preparing to assume full responsibility for financing their immunization programs.

- **The menu of new vaccines available to low- and middle-income countries has continued to expand.** Since 2010, Gavi has added human papillomavirus (HPV), Japanese encephalitis, inactivated polio, and rubella vaccines to its portfolio, and a dengue vaccine has been licensed in some countries. These vaccines are powerful life-saving tools, but they also bring new financing challenges; many are substantially more expensive than the traditional vaccines that most countries have long paid for using their own resources. Non-Gavi-eligible countries must pay the full cost of new vaccines from the start, while Gavi-eligible and transitioning countries that receive Gavi support must plan for assuming these costs over the long term.
- **Interest in new or unconventional financing sources for immunization, and for health more broadly, has grown.** These financing sources range from trust funds and endowment funds to new taxes and national lotteries. Many policymakers and other stakeholders have no experience with these mechanisms.

These trends are happening in the context of historic commitments by countries at all income levels to achieve universal health coverage (UHC)—access to necessary health care for all, regardless of the ability to pay and without financial hardship. This global commitment is embodied in a United Nations resolution and the 2030 Agenda for Sustainable Development, a global plan that includes a target to achieve UHC by 2030, along with access to

* These 19 million children have not received all three doses of DTP3-containing vaccine.

safe, effective, quality, and affordable essential medicines and vaccines for all. Although countries are moving toward UHC on different paths, the process often requires broad changes in the way health services, including immunization, are financed and accessed. The implications of UHC-related reforms for immunization financing are an important theme of this edition of the resource guide.

ASSESSING IMMUNIZATION FINANCING OPTIONS

This resource guide assesses financing mechanisms and financing sources for immunization using six main criteria: additional resources raised, cost, predictability, sustainability, flexibility, and equity. Not all of these criteria are relevant to every financing mechanism, however, and other considerations may be important in certain contexts. For example, particular financing mechanisms may promote transparency and accountability to a greater degree than others, and some new mechanisms may be useful in drawing attention to and building popular support for immunization.

In most cases, how a mechanism rates on a particular criterion depends on how it is implemented and on the country context. For this reason, the briefs in this resource guide focus less on definitive judgments about particular financing options and more on the conditions that affect whether a mechanism can be effective. For example, the predictability of financing from an earmarked tax depends on factors such as the nature of the tax, how consumption of the taxed good or service changes with economic conditions, and how easily the tax can be evaded.

Financing mechanisms can, of course, be assessed from different perspectives. The resource guide's primary focus is on the needs of immunization programs, but it also views these needs within the broader context of health financing and notes when these perspectives may come into conflict. Policymakers must balance immunization against other health priorities, and they must balance spending on commodities (such as vaccines) against spending on other aspects of the basic service delivery platform on which all programs depend. Ultimately, advocating for larger health budgets is as important as advocating for immunization within health budgets.

MAJOR THEMES

Each brief in this resource guide can be read separately, but several themes emerge from the volume as a whole.

Immunization is a public responsibility. Immunization is in the public interest because its benefits extend beyond those who receive vaccines to the population as a whole, through the control of infectious diseases.

Governments therefore have primary responsibility for overseeing and financing immunization programs, with assistance from international donors in the case of the poorest countries. Moreover, immunization should be free because even small costs to households can be a barrier to access. Thus, while the private sector may have important roles to play (for example, in vaccine manufacturing or service delivery) in some countries, governments retain overall responsibility for ensuring that vaccines in

Ultimately, advocating for larger health budgets is as important as advocating for immunization within health budgets.

the national program are available and free to those who need them.

Immunization financing should be considered in the context of the movement toward UHC.

Access to immunization—and investments in robust immunization services that can serve as a platform for delivering other vital health services—is central to the goal of achieving UHC. At the same time, immunization planning and budgeting must fit within each country’s health financing architecture as it evolves to meet the UHC goal. In the long run, immunization services will benefit from efforts to strengthen the capacity of health systems to deliver a full package of critical services. But the ongoing transformation of health systems can also pose risks to immunization programs. Countries must ensure that funding for the various components of immunization does not fall through the cracks as health financing systems evolve. Changes made to health financing and delivery as part of the move toward UHC can reduce access to immunization if the new UHC architecture covers less of the population than existing immunization programs do. Decentralization processes happening in parallel in many countries also pose challenges for immunization financing, and countries must think carefully about which essential functions and financing responsibilities should lie with which levels of government and plan to build needed capacity accordingly.

Regular health-sector budgets are likely to remain the main source of funds for immunization, although new sources of financing for immunization can play a complementary role. A wide variety of alternative financing mechanisms for immunization have been proposed, including trust funds, lotteries, and earmarked taxes, but

few have been implemented. Briefs in this resource guide offer general assessments of several innovative funding sources, but countries should carry out their own assessments in light of their own circumstances.

General government revenues, supplemented where relevant by social insurance contributions and donor financing, will remain the financial backbone of most countries’ health and immunization programs. These traditional public financing systems are typically the most equitable and sustainable, and they are managed through existing public financial management systems.

Regular health-sector budgets are likely to remain the main source of funds for immunization.

Pursuit of secondary funding sources should not distract governments and advocates from ensuring adequate and sustainable allocations from the general health budget both for immunization and for the broader health service delivery platform on which it depends.

The various components of immunization programs have different financing needs.

The activities that make up immunization programs have different characteristics, which in turn have implications for financing. For example, vaccine procurement typically involves long lead times, requires assured and timely disbursement of funds, and is best carried out centrally to maximize economies of scale and predictability for suppliers. Vaccine delivery, on the other hand, is typically integrated with the delivery of other services in clinics and communities, so most costs are shared. Supply chains involve responsibilities at different levels of the health system. The characteristics and financing needs of these functions must be taken into account in weighing alternative approaches to immunization financing.

Raising resources for immunization is important, but how funds are spent can also make a big difference. By using funds more efficiently, countries can do more with limited immunization resources. In many cases, the greatest opportunities for gains may come from improved procurement of vaccines because vaccine purchases account for a large share of immunization expenditure and the prices paid by countries in similar circumstances can vary considerably. Improvements in the way health services, including vaccine delivery, are purchased can also increase the quality and reach of those services by creating a better balance of incentives. Strengthening processes and institutions for immunization decision-making, including by making greater use of economic analysis, can also help

ensure that funds for immunization yield the greatest possible health and economic benefits. Finally, improvements in public financial management are critical to efficient and predictable financing of all health programs.

Gavi-eligible as well as transitioning countries must plan for life after Gavi. In the past 15 years, external financing through Gavi has given many countries an unprecedented opportunity to introduce important new vaccines and strengthen delivery systems and supply chains. However, countries must prepare to eventually assume full responsibility for financing their own growing immunization programs.

SOURCES AND FURTHER READING

Addis Declaration on Immunization. Ministerial Conference on Immunization in Africa. Addis Ababa, Ethiopia; 2016 Feb 7. Available from: <http://immunizationinafrica2016.org/ministerial-declaration-english>

Brenzel L, Jones A. Immunization financing toolkit: a resource for policy-makers and program managers. World Bank and the GAVI Alliance; 2010. Archived at: <https://perma.cc/2L2T-Z38V>

GAVI Financing Task Force. Immunization financing options: a resource for policymakers. Archived at: <https://perma.cc/C4D2-YV3H>

World Health Organization. Global Vaccine Action Plan 2011–2020. Available from: http://www.who.int/immunization/global_vaccine_action_plan/en/

PART I

IMMUNIZATION FUNDAMENTALS

Why Immunization and Immunization Financing Matter

KEY POINTS

- * Vaccines can save millions of lives and bring many other benefits, including healthier children, increased school attendance, and increased productivity. Immunization services are also a cornerstone of primary health care and can serve as a foundation for other vital health services.
- * Immunization is an exceptionally good value, returning many dollars in economic benefits for every dollar spent.
- * Immunization must be sustained indefinitely and is therefore a long-term investment that requires stable, long-term financing.
- * Governments have an opportunity to introduce a number of vaccines of great public health importance, but many face financing challenges. Gavi-supported countries must plan to fully fund their programs from domestic sources after Gavi support ends, and countries that are not Gavi-eligible must contend with uncertain vaccine prices.

VACCINES ARE AMONG the most powerful public health tools ever developed. Immunization made possible the complete eradication of smallpox—perhaps the greatest public health triumph in history—and has played a central role in the dramatic reduction in child deaths over recent decades. Immunization now saves an estimated 2 million lives every year; with higher coverage, it could save up to twice as many.

The scope of immunization continues to grow as new vaccines are developed against persistent and emerging diseases. The first malaria vaccine was approved by regulators in 2015, a dengue vaccine has been licensed in several countries, and a vaccine against Ebola showed promise in a trial during the recent epidemic in West Africa. Vaccines against other diseases, including Zika, are under development.

Immunization services are a cornerstone of primary health care and, with their already broad reach, can serve as a foundation for other vital services.

THE VALUE OF IMMUNIZATION

Immunization ranks among the most cost-effective health interventions, delivering a high ratio of health benefits—lives saved and illness prevented—to cost, especially where

disease burden is high. This means immunization is one of the best uses of limited public funds for health. When the benefits of vaccines are translated into economic terms—

A recent analysis found that every dollar spent on expanding access to a portfolio of vaccines in low- and middle-income countries between 2011 and 2020 would return \$16 in economic benefits.

by adding up savings in treatment costs, productivity lost to illness and caretaking, and years of earnings lost to premature death and disability—it becomes clear that immunization is an exceptionally good investment. A recent analysis found that every dollar spent on expanding access to a portfolio of vaccines in low- and middle-income countries between 2011 and 2020 would return \$16 in economic benefits.

This kind of analysis may well underestimate the value of immunization because it does not account for herd immunity (the protection that high levels of immunization in a population can provide even to unvaccinated people) or the long-term development dividend from healthier children and increased school attendance.

An underappreciated virtue of immunization is that its benefits reach the poor to a greater extent than most other health interventions. Poor people bear a disproportionate burden of the diseases addressed by immunization. And although in most countries the poorest children are immunized at lower rates than better-off children, the disparity is typically much less pronounced than for other health interventions in developing countries—and girls are immunized at the same rates as boys in almost all countries. Given the heightened focus on equity, including in the 2015–2030 UN Sustainable Development Goals, this provides yet another argument for investment in immunization.

Not all vaccines are appropriate in all settings, of course, and in deciding whether to introduce a new vaccine governments must consider factors including local disease burden, vaccine safety and effectiveness, and the costs of the vaccine and its delivery. Moreover, they must weigh the potential benefits of the vaccine against those of other uses of scarce resources. (See Brief 4.)

THE NEED FOR LONG-TERM FINANCING

Although the benefits of vaccines—and their cost-effectiveness—are well established, immunization programs demand considerable resources and

governments must plan carefully to ensure adequate and sustainable financing for these programs. Two features of immunization make long-term planning of immunization financing particularly important. First, immunization is, to a greater extent than almost any other health service, a public responsibility. In most countries, immunization is offered free of charge to all children through government health services or with public funding and oversight. Even where private providers play an important role, the ultimate responsibility for ensuring access to vaccines of public health importance remains with the government. Not only is access to immunization, along with other basic health services, broadly seen as a right, but the control of infectious diseases and the population-level protection that high rates of immunization provide are a classic example of a “public good” whose social benefit exceeds the value that individuals or households can be expected to place on it. Ensuring the provision of immunization services is thus a natural responsibility of governments.

Second, except in exceptional cases where a disease can be completely eradicated, immunization must be continued indefinitely, even when the diseases that vaccines prevent have greatly diminished (and faded from public consciousness). This is because these diseases would in most cases return rapidly if immunization were stopped, just as malaria has often rebounded when control measures have been eased and just as falling rates of measles immunization have led to outbreaks in many countries. Immunization is therefore a long-term commitment, and when governments introduce a new vaccine, they must consider how it will be paid for over the long term.

Why Immunization and Immunization Financing Matter

Immunization programs have, in fact, proven remarkably sustainable: while some health programs are neglected when donors or governments lose interest or other priorities take precedence, vaccines are almost never discontinued once they are introduced at the national level.

Strong immunization program performance depends not only on adequate financing of immunization-specific activities at the national level, including vaccine procurement and supply chains, but also on financing of the primary care facilities and staff that deliver routine immunization as part of a broader program of health services.

OPPORTUNITIES AND CHALLENGES

In planning the financing of immunization programs, governments face both big opportunities and important challenges. On the one hand, the portfolio of available vaccines continues to expand. As of mid-2016, Gavi supported 10 vaccines, up from just three when Gavi was founded in 2000. These include new vaccines, such as a meningitis A vaccine developed for Africa and a new vaccine against Japanese encephalitis, as well as vaccines that have been widely adopted in many high-income countries but were too expensive for the poorest countries without Gavi assistance, such as those against pneumococcus, rotavirus, and human papillomavirus (HPV). Middle-income countries that are not eligible for Gavi support are also adopting many of these vaccines.

On the other hand, Gavi-eligible countries, especially those that have introduced many vaccines, must plan to assume responsibility for financing these programs. This is most urgent for countries that have

entered the accelerated phase of transition, when they must rapidly scale up domestic financing for vaccines as Gavi support is withdrawn. But countries whose per capita income has not yet exceeded Gavi's eligibility threshold must also plan to pay for a growing share of vaccine costs in the form of co-financing. (See Brief 9.) Gavi-supported countries must ensure that secure financing will be available not only to purchase vaccines but also to deliver them and to sustain and extend coverage.

Middle-income countries that are not eligible for Gavi support face a more complicated immunization financing environment. Although prices for some important vaccines have fallen for some non-Gavi countries, the prices that these countries pay vary considerably, making planning more difficult, and cost remains an important obstacle for many countries. In some cases, these countries also face the withdrawal of donor funding for other health priorities, and all countries must find predictable sources of funding for immunization in an unpredictable global economic environment. The share of health resources devoted to immunization remains small in most countries, however, and with sufficient political will it should be possible to find the necessary funding to sustain and expand this vital public health service.

SOURCES AND FURTHER READING

Bloom DE, Canning D, Weston M. The value of vaccination. *World Econ.* 2005 Jul;6(3):15.

Levine OS, Bloom DE, Cherian T, de Quadros C, Sow S, Wecker J, Duclos P, Greenwood B. The future of immunisation policy, implementation, and financing. *Lancet.* 2011 Aug 5;378(9789):439-48.

Ozawa S, Clark S, Portnoy A, Grewal S, Brenzel L, Walker DG. Return on investment from childhood immunization in low- and middle-income countries, 2011–20. *Health Aff.* 2016 Feb 1;35(2):199-207.

International Vaccine Access Center [forthcoming]. Value of Immunization Compendium of Evidence (VOICE) tool. Available from: <http://view-hub.org/>

Universal Health Coverage and Immunization Financing

KEY POINTS

- * Ensuring access to immunization services is central to the global movement toward universal health coverage (UHC).
- * Immunization financing should be considered in the context of broader government health financing policies and approaches to achieving UHC.
- * As health financing and service delivery arrangements become more complex, countries face the challenge of defining institutional responsibilities for specific immunization program functions and ensuring that financial incentives in the system do not disadvantage immunization services.

THE GLOBAL MOVEMENT toward universal health coverage (UHC) has gained momentum, with the World Health Assembly and the UN General Assembly calling on countries to “urgently and significantly scale up efforts to accelerate the transition toward universal access to affordable and quality health care services.” Achieving this goal remains a major challenge, however, with an estimated 400 million people still lacking access to essential health services—including prenatal care, skilled birth attendance, childhood immunization, antiretroviral therapy, tuberculosis treatment, and access to clean water and safe sanitation.

UHC means ensuring that everyone has access to quality health services without financial hardship or the risk of being forced into poverty. As one of the most cost-effective life-saving health interventions, immunization figures prominently in UHC. In practical terms, this means immunization is typically among the health services that a government commits to making accessible and affordable by including it in the country’s essential services package or the national health insurance system’s benefits package.

UHC requires adequate financial resources to pay for necessary health interventions, including supplies and services. The way a country generates funding

for UHC, redistributes those funds to achieve equity, and purchases services from health care providers forms the overall health financing architecture within which immunization is funded. This brief provides an overview of the main approaches to UHC and their implications for immunization financing.

SOURCES OF REVENUE FOR UHC

Universal health coverage is costly. Ensuring adequate financial resources for UHC requires sufficient budgetary room, or fiscal space, to expand or maintain coverage without jeopardizing the sustainability of the government’s finances. Economic growth creates fiscal space naturally through increased tax revenues. But economic growth alone is usually not enough to bring about sufficient increases in government health spending; governments must also make health a priority in their budgets. Countries can also create fiscal space for UHC by broadening the tax base and improving tax administration, introducing dedicated revenue sources for the health sector such as social health insurance contributions, improving efficiency, obtaining grants, and temporarily borrowing. Within health budgets, immunization programs require adequate allocations for purchasing vaccines, injection supplies, and cold chain equipment; managing and transporting vaccines; and delivering immunization services.

EQUITY IN HEALTH COVERAGE

Health needs vary across a country's population, so providing UHC and financial protection for the entire population requires significant redistribution and cross-subsidization—from rich to poor and from healthier people (such as the young) to those with greater health needs (such as the elderly). Perhaps the most important equity issue related to immunization in many settings is adequate funding for—and attention to—extending services to hard-to-reach areas and populations to ensure at least 90% coverage overall and 80% in every district (Global Vaccine Action Plan goals for DTP3-containing vaccine by 2015 and for all vaccines in the national schedule, unless otherwise recommended, by 2020).

VALUE FOR MONEY

All countries face resource constraints in achieving or maintaining UHC, so getting the most from available funding is critical. One important way to improve value for money is through *strategic purchasing*—strategies that help countries pay lower prices for health commodities (such as drugs and vaccines) and create incentives for health providers to improve the quality and coverage of their services and to do so in the most efficient way. (See Briefs 11, 12, and 14.)

NATIONAL HEALTH FINANCING AND IMMUNIZATION

How a country finances UHC, and the health financing and service delivery arrangements it puts in place, can affect the priority given to immunization and how access to immunization services is ensured. Low- and middle-income countries are increasingly moving toward mixed health financing models, which combine national budgets with public health insurance schemes and, to a lesser degree, private financing through voluntary insurance.* In many countries, private health providers play a growing role in health service provision and are increasingly contracted through public financing arrangements.

COMMON HEALTH FINANCING ARRANGEMENTS

Most low- and middle-income countries use one of the following health financing and service delivery arrangements in some form:

- Primarily general tax financing and public service provision
- Mixed public financing and mixed public and private service provision
- Primarily public health insurance financing and mixed public and private service provision

The following sections highlight the main features of each arrangement and key issues that can arise for immunization financing.

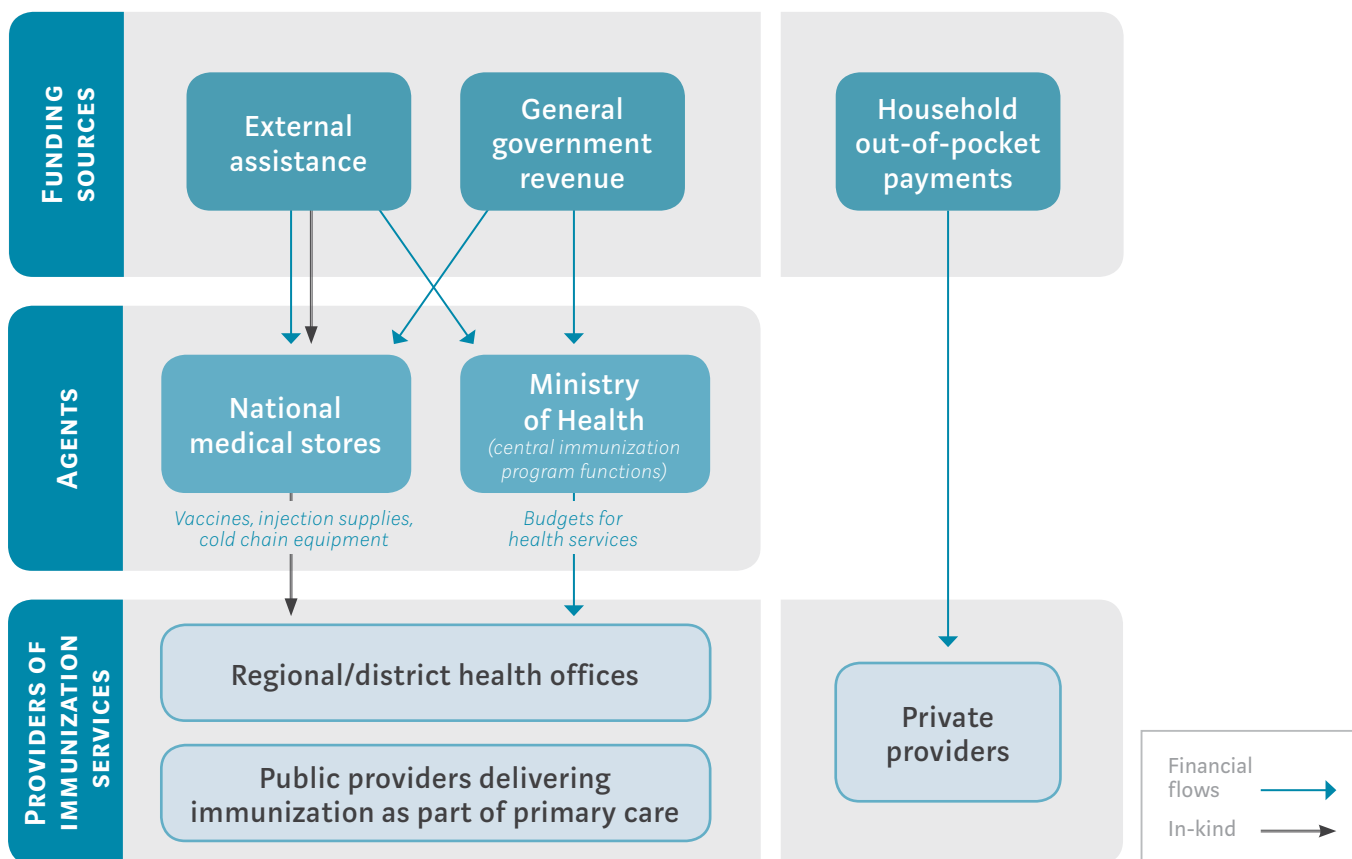
PRIMARILY GENERAL TAX FINANCING AND PUBLIC SERVICE PROVISION

Many low-income countries, and some middle- and high-income countries, have health systems that are financed through the government budget and run by the ministry of health, with services delivered through a network of public providers. These systems, also known as *national health services*, typically provide centralized financial allocations to the health sector; the funds are then distributed downward to subnational levels. In more decentralized systems, local governments also contribute funding to the health sector and exercise greater control over resource allocation and decision-making. In this arrangement, depicted in the figure on the next page, immunization financing comes almost entirely from general government revenues or donor contributions, with services delivered by public providers mainly at primary health care facilities.

* Experience has shown that private voluntary insurance cannot be the basis for achieving UHC, although it may have a limited role, such as for supplemental insurance (Kutzin 2012).

Universal Health Coverage and Immunization Financing

PRIMARILY GENERAL TAX FINANCING AND PUBLIC SERVICE PROVISION



Some health systems that rely on tax-based financing and public service provision, such as Malaysia and Sri Lanka, perform well in general and achieve high immunization coverage rates. But many other countries that use the national health service model have difficulty securing adequate funds in the yearly budget process. These systems are often characterized by chronic underfunding and staffing shortages. A parallel, and typically poorly regulated, private sector often emerges to meet the demand for health services; together with the chronic underfunding of public facilities, this often leads to high out-of-pocket payments for patients and weak financial protection.

In systems that rely primarily on tax-based financing and public service provision, immunization financing may benefit from coherent policies and transparent budget allocations at the national level. But potential challenges include general underfunding of the health sector, staffing shortages in rural and remote areas, unclear division of responsibilities for immunization financing between national and subnational levels of government in more decentralized systems, and weak incentives at the health provider level. The high levels of out-of-pocket payments and reliance on private providers that often emerge for many health services can also affect access to immunization, although there is limited evidence of this globally. (See Brief 8.)

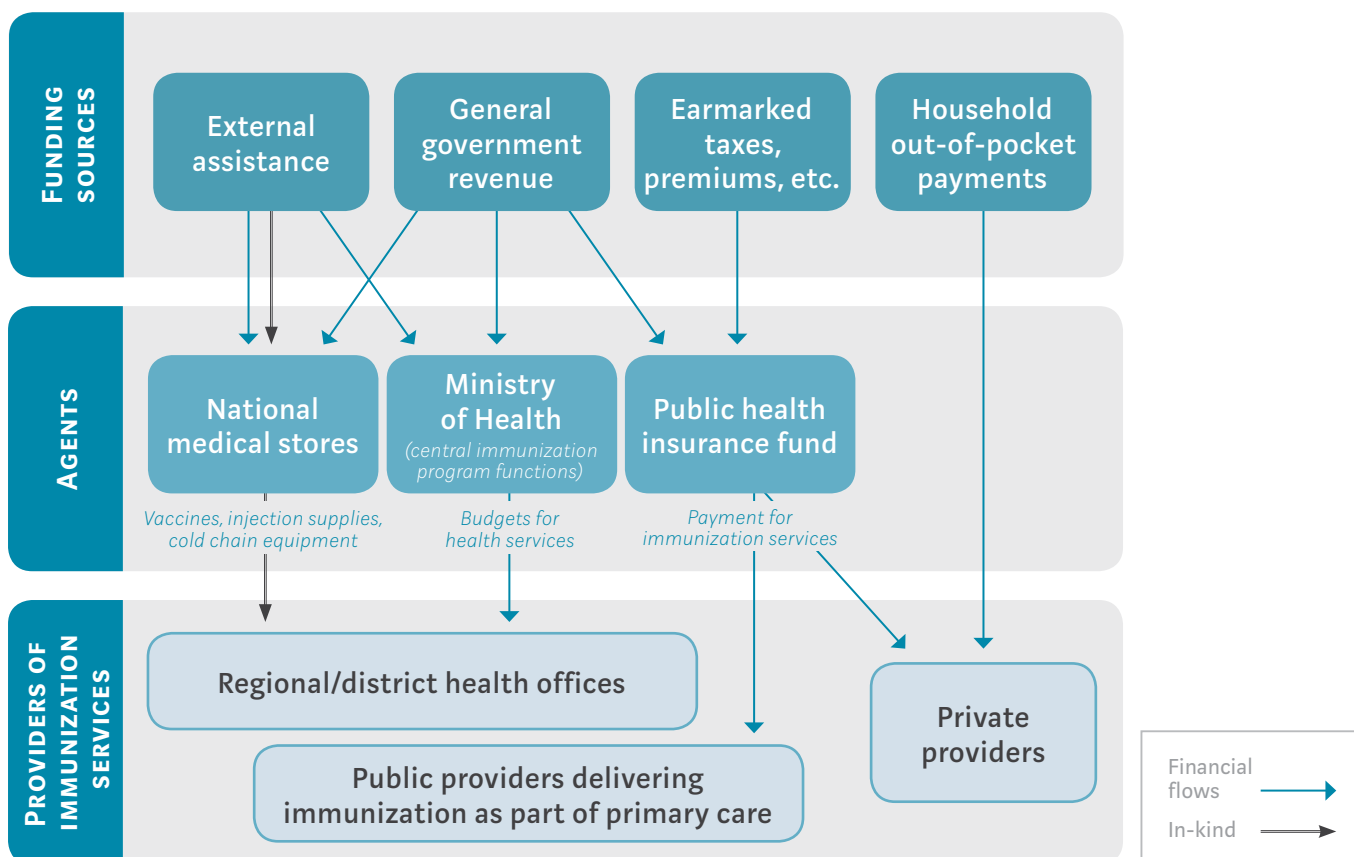
Brief 2

MIXED PUBLIC FINANCING AND MIXED PUBLIC AND PRIVATE SERVICE PROVISION

Some countries—including Ghana, Indonesia, Peru, and Vietnam—have introduced public insurance systems to inject additional resources into the health system and provide financial protection against out-of-pocket fees. (See the figure below.) These systems have also introduced new arrangements between the purchasers of services and the providers (although public providers still typically receive ministry of health allocations). These new purchasing arrangements can provide an opportunity to introduce new payment systems, including results-based financing, and other strategic purchasing approaches. These systems have increased financial protection for consumers in many cases, and funds that flow through insurance systems can often be used more flexibly than traditional budget funds.

In some countries, immunization coverage has increased as the national health insurance system has grown. But expansion of an insurance program, particularly one that focuses on curative services, can crowd out resources for immunization and other preventive services. Challenges arise in extending insurance coverage to informal-sector workers and achieving equity, particularly when the country has multiple insurance programs. Health promotion and preventive services, including immunization, typically continue to be funded through the ministry of health budget, as in Ghana and Vietnam. In Indonesia, immunization is included in the benefits package of the national health insurance system. Either way, countries should ensure that immunization financing and service delivery responsibilities are clear, and that people understand where immunization services can be obtained and how they are covered

MIXED PUBLIC FINANCING AND MIXED PUBLIC AND PRIVATE SERVICE PROVISION



Universal Health Coverage and Immunization Financing

so immunization is not neglected by the financing system and service providers. Cold chain supply and maintenance can be particularly vulnerable in mixed systems with multiple institutional actors and unclear lines of responsibility.

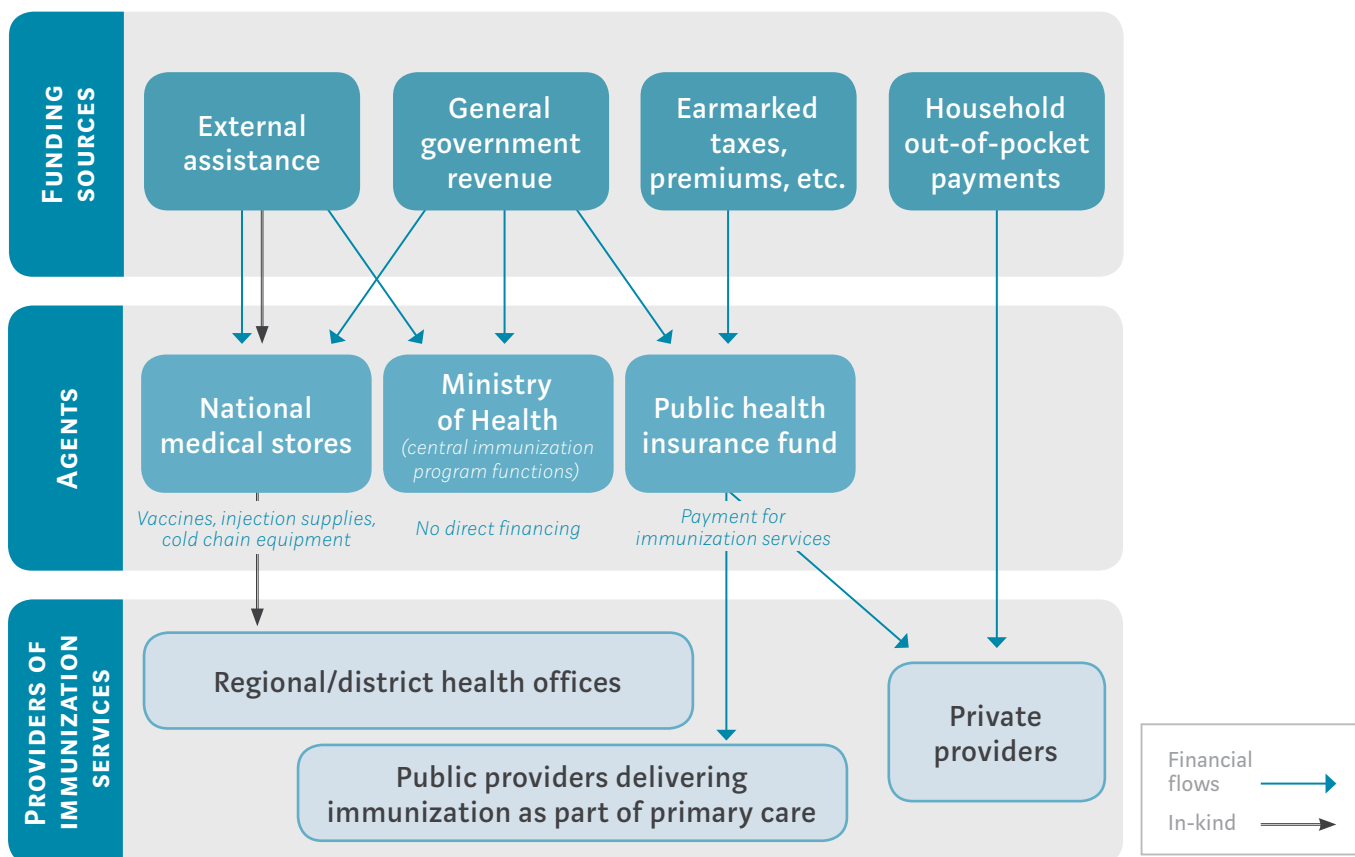
PRIMARILY PUBLIC HEALTH INSURANCE FINANCING AND MIXED PUBLIC AND PRIVATE SERVICE PROVISION

Some countries finance nearly all health services through a social health insurance system funded primarily by an earmarked payroll tax (as in Estonia and Moldova), or with mainly general tax funding through a public purchasing agency (as in Thailand). These approaches are termed "primarily public insurance financing and mixed public and private service provision" in this brief. In these systems,

immunization services are included in the benefits package and providers are paid to deliver those services. Vaccine procurement and other national functions are typically carried out by the ministry of health using budget funding, although in Thailand the purchasing agency is responsible for procuring vaccines and distributing them to health providers. The Ministry of Health typically no longer funds service provision. (See the figure below.)

Social health insurance systems often clearly delineate functions within the health system, such as regulation, financing, and service provision. This creates opportunities to use strategic purchasing and payment systems to create incentives for health care providers that are more comprehensive than in a mixed budget/insurance system. But this approach comes with the risk that responsibilities for particular

PRIMARILY PUBLIC HEALTH INSURANCE FINANCING AND MIXED PUBLIC AND PRIVATE SERVICE PROVISION



immunization functions may be unclear and payment incentives may disadvantage immunization services. Some social health insurance schemes tie specific financial incentives to immunization coverage to ensure that immunization services are not neglected. For example, Estonia's social health insurance system combines capitation payment for primary health care with a pay-for-performance program and additional financial incentives for achieving immunization coverage targets.

Social health insurance systems that clearly specify responsibilities for immunization functions across the ministry of health and the health insurance agency tend to achieve high immunization coverage rates. In Moldova, for example, the Ministry of Health has overall stewardship of the National Immunization Program, but the responsibilities of all cooperating agencies, including the National Health Insurance Fund as the payer of services, are clearly outlined in its comprehensive multi-year plan for immunization. This has resulted in a well-functioning program and high immunization coverage rates.

SOURCES AND FURTHER READING

Gottret P, Schieber G. Health financing revisited: a practitioner's guide. Washington D.C.: World Bank Group; 2006. Available from: <http://siteresources.worldbank.org/INTHSD/Resources/topics/Health-Financing/HFRFull.pdf>

Kutzin J. Anything goes on the path to universal health coverage? No. Bull World Health Organ. 2012 Nov;90(11):867-8.

Maeda A, Araujo E, Cashin C, Harris J, Ikegami N, Reich MR. Universal health coverage for inclusive and sustainable development: a synthesis of 11 country case studies. Washington D.C.: World Bank Group; 2014. Available from: <http://www.worldbank.org/en/topic/health/publication/universal-health-coverage-for-inclusive-sustainable-development>

World Health Organization. The world health report: health systems financing: the path to universal coverage. Geneva: World Health Organization; 2010. Available from: <http://www.who.int/whr/2010/en/>

Components of Immunization Costs

KEY POINTS

- * Immunization costs include vaccines, labor, supplies, transportation, operations and maintenance, cold chain equipment, and capital investments in buildings and technology. Labor and vaccines are the major cost components.
- * Delivery costs (non-vaccine costs) account for nearly half of immunization costs.
- * In health facilities and at the administrative level, immunization costs are typically shared across multiple health services and activities; adequately budgeted and staffed primary health services are thus essential to delivering comprehensive immunization services.
- * Recent studies on immunization costs have found significant variation in total facility and unit costs within and between countries.
- * High-volume health facilities tend to have lower immunization costs per child than facilities in rural areas. This should be taken into consideration in budgeting and resource allocation.
- * New vaccine introduction requires one-time startup costs—such as for training, printing of materials, and adjustments to the cold chain—that must be adequately budgeted for.

COUNTRIES NEED TO understand the key components of immunization costs in order to effectively budget for, finance, implement, and maintain a comprehensive immunization program. Immunization costs can be difficult to disentangle because they occur at different levels of the health system—from the centralized coordinating agency to the point of service delivery—and include several major components that may be financed differently. These include procurement of vaccines and injection supplies, supply chain and logistics, and immunization at the point of use.

At the health provider or facility level, where service delivery is integrated and health staff provide a range of services, inputs related to immunization delivery are shared. (See Brief 2.) The health worker who vaccinates children in a health clinic may also provide other services, possibly during the same visit. Although these inputs and costs may be difficult to disaggregate by health service, ensuring that financing is adequate to cover all shared costs at the facility level is essential for immunization service delivery.

This brief draws on the recent six-country Expanded Program on Immunization Costing and Financing of Routine Immunization (EPIC) studies. The first studies, conducted in 2012 and 2013, used a common approach to estimate routine immunization costs in Benin, Ghana, Honduras, Moldova, Uganda, and Zambia. (The data and associated materials, including data documentation, data collection instruments, and presentations of analytical results, can be found at www.immunizationcosting.org.*)

MAJOR COST COMPONENTS OF IMMUNIZATION SERVICES

The costs of immunization programs fall into two major categories:

- **Vaccines and injection supplies.** Total costs include delivery to the country, fees associated with clearing customs, import taxes, and procurement fees, if relevant.

* Other sources of data on immunization costs include estimates contained in country-specific comprehensive multi-year immunization plans, estimates used in cost-effectiveness studies, and earlier primary data collection efforts.

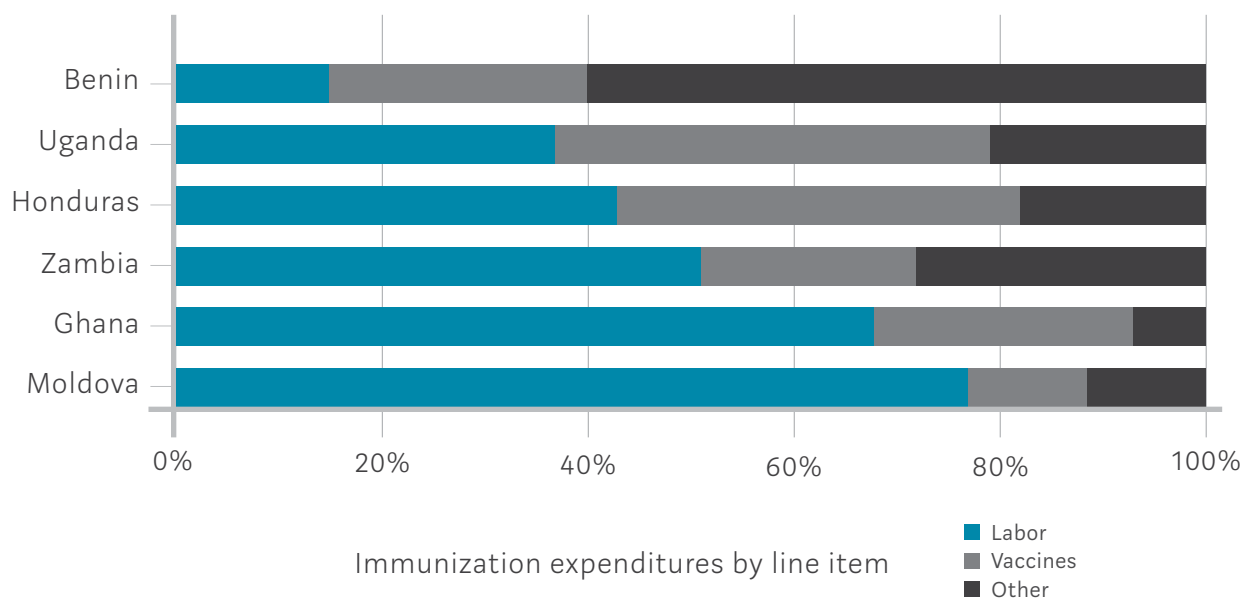
- Immunization delivery.** These costs are extensive and include the cost of health worker time to administer vaccines and costs related to training, planning, management and supervision, social mobilization, surveillance, and monitoring and evaluation. They also include supply chain and logistics costs, including for cold chain equipment and overheads, vehicles, transportation, and personnel time involved in the storage and delivery of vaccines to point-of-care settings. The supply chain has both recurrent and capital costs. Recurrent costs include transportation fuel, use of refrigeration units, salaries, and the maintenance of cold chain equipment (which is frequently underbudgeted in immunization planning). Capital expenditures include the purchase of new trucks, motorcycles, and refrigeration units.

COSTLIEST INPUTS AND ACTIVITIES

The EPIC study identified labor as the largest cost in routine immunization, accounting for an average of 49% of all costs across the six countries, ranging from a low of 15% in Benin to 77% in Moldova in 2011. (See the figure below.) The share of a country's immunization labor costs tends to correlate with its level of economic development, with more developed countries having higher health worker salaries and therefore higher proportional costs for labor than in less developed countries.

Vaccines and injection supplies are the second-largest cost category, accounting for an average of 27% of total immunization costs. Since vaccines

ROUTINE IMMUNIZATION EXPENDITURES IN SIX COUNTRIES (2011)



Note: "Other" includes supplies, maintenance, utilities, transportation, per diem, printing, taxes, vehicles, cold chain equipment, other equipment, vehicles, and unallocated.

Source: Brenzel et al., *Health Affairs* (2016)

Components of Immunization Costs

are such a large share of total costs, efficient procurement and careful choice of presentation (the number of doses and total volume per vial) are critical to determining the cost of services. (See Briefs 4, 11, and 12.)

Administration and management costs above the facility level account for about 15% of total routine immunization costs.

COST PER FULLY IMMUNIZED CHILD

The EPIC study found that the cost per fully immunized child was about US\$60 in Ghana, US\$132 in Honduras, and US\$332 in Moldova in 2011. These figures are much higher than those found in detailed cost studies covering the previous 10 to 20 years, when countries had many fewer vaccines in their schedules. For example, the estimated cost per fully immunized child (for routine vaccinations only) in Ghana was about US\$10 in 2001. The EPIC study found that in Honduras, 20% of the cost per fully immunized child was for the two most recent vaccine introductions, for rotavirus and pneumococcus.

HOW FACILITY VOLUME AFFECTS COSTS

The EPIC study showed wide variations in total and unit costs for immunization, with higher-volume facilities typically having lower unit costs (per dose given or per child vaccinated) because the fixed costs are spread over a greater number of outputs. Rural facilities tend to have lower volume because they serve sparsely populated areas, and they thus have markedly higher costs per dose compared to urban and peri-urban facilities. In Honduras, for example, the facility-level delivery cost per dose (excluding vaccine costs) ranged from about US\$1.6 in hospitals to US\$7.7 at rural vaccination posts. The study noted that achieving high immunization coverage in more rural areas of Honduras could cost more per dose than in highly populated areas.

HOW THE DELIVERY PLATFORM AFFECTS DELIVERY COSTS FOR NEW VACCINES

Evidence on how the delivery platform affects incremental delivery costs for new and underused vaccines is limited. However, it shows that school-based delivery strategies are more costly for human papillomavirus (HPV) vaccination than health-facility-based delivery (although the former may be needed in places where it is the more effective strategy).

STARTUP COSTS FOR NEW VACCINE INTRODUCTION

New vaccine introduction involves costs for procuring the vaccine and associated injection supplies as well as incremental delivery costs. It also involves costs for an array of important one-time startup activities that might include training of health workers, social mobilization, microplanning, and printing of new vaccine cards and training materials.

New vaccines may require additional investment in cold chain storage. However, certain combination vaccines (such as pentavalent or hexavalent vaccines) may replace several previously separate vaccines, thereby reducing demand for cold chain space and injection supplies.

GAPS IN COST DATA

Detailed costing studies have shown large variations in immunization delivery costs across countries, although substantial data gaps exist when it comes to delivery costs in Central Asia, South Asia, and Europe. Also, fewer studies have been conducted on immunization costs in low-income countries than in middle-income countries. Many countries have added vaccines to their immunization schedules in recent years, so older cost studies might be outdated or handle shared costs in an inconsistent way.

The most recent cost studies cover routine immunization. Less information is available on the cost of supplementary immunization activities, which aim to reach large populations that might have been missed by routine immunization services

and often immunize children whatever their vaccination history. More evaluation is needed on the costs of various delivery platforms, the costs of achieving higher coverage and greater equity, and the costs of better-quality services.

SOURCES AND FURTHER READING

Brenzel L, Schütte C, Gogvadze K, Valdez W, Le Gargasson J, Guthrie T. EPIC studies: governments finance, on average, more than 50 percent of immunization expenses, 2010–11. *Health Affairs*. 2016 Feb;35(2):259-65.

Brenzel L, Young D, Walker DG. Costs and financing of routine immunization: approach and selected findings of a multi-country study (EPIC). *Vaccine*. 2015 May 7;33:A13-20.

EPIC [Internet]. EPIC immunization costing studies. Available from: www.immunizationcosting.org

Janusz CB, Castañeda-Orjuela C, Aguilera IB, Garcia AG, Mendoza L, Díaz IY, Resch SC. Examining the cost of delivering routine immunization in Honduras. *Vaccine*. 2015 May 7;33:A53-9.

Le Gargasson JB, Nyonator FK, Adibo M, Gessner BD, Colombini A. Costs of routine immunization and the introduction of new and underutilized vaccines in Ghana. *Vaccine*. 2015 May 7;33:A40-6.

Levin A, England S, Jorissen J, Garshong B, Teprey J. Case study on the costs and financing of immunization services in Ghana. Bethesda (MD): Abt Associates; 2001. Archived at: <https://perma.cc/7BGP-Z5LS>

Schütte C, Chansa C, Marinda E, Guthrie TA, Banda S, Nombewu Z, Motlogelwa K, Lervik M, Brenzel L, Kinghorn A. Cost analysis of routine immunisation in Zambia. *Vaccine*. 2015 May 7;33:A47-52.

Vaccine Decision-Making

KEY POINTS

- * Decisions on introducing new vaccines have long-term implications for immunization costs as well as logistics systems and service delivery. The choice of vaccine presentation also affects cost and ease of delivery.
- * In making these decisions, policymakers should consider disease burden; vaccine safety and efficacy; cost, cost-effectiveness, and affordability; operational feasibility and delivery requirements; and public perceptions and demand.
- * Independent technical committees, often called national immunization technical advisory groups (NITAGs), can help ensure that decisions on new vaccine introduction are transparent, credible, and grounded in evidence.
- * A variety of tools and assistance are available to help countries with decisions on new vaccines and to strengthen decision-making processes. PAHO's ProVac Initiative is an impressive model of decision support.

NEW VACCINES HAVE the potential to greatly reduce disease and mortality, but adding a vaccine to a national immunization program has consequences for budgets, logistics systems, service delivery, and, in some cases, public perceptions of and support for immunization. Moreover, decisions about new vaccines have long-term implications because unless a vaccine is later replaced by an improved one, it will likely remain in the national schedule indefinitely.

This brief outlines factors that countries should weigh in deciding whether to introduce a new vaccine, with special emphasis on issues related to cost and financing. It also explores relevant decision-making tools, institutions, and processes. (For more detailed guidance, see the World Health Organization's comprehensive guide to vaccine decision-making, which is listed at the end of this brief.)

Among the most important considerations in adoption decisions are:

- Disease burden and public health importance
- Vaccine effectiveness and safety

- Delivery requirements and operational feasibility
- Cost
- Cost-effectiveness
- Affordability
- Acceptability and public demand

DISEASE BURDEN AND PUBLIC HEALTH IMPORTANCE

As the starting point in considering a new vaccine, countries must weigh the importance of the disease the vaccine is intended to prevent. Questions include:

- What is the disease burden relative to other health problems to which resources might be directed?
- If the burden is currently low, what is the risk of an epidemic or major resurgence?
- How effective are other approaches to combating the disease?
- Is control of the disease central to the national health strategy and international commitments?

VACCINE EFFECTIVENESS AND SAFETY

Countries must evaluate the extent to which the new vaccine will contribute to control of the disease. Some vaccines, such as the yellow fever vaccine, can prevent virtually all disease if high coverage is achieved, while others may offer only partial protection. The duration of the protection afforded by a vaccine can also be an important consideration.

Vaccine safety is also of paramount importance. In general, vaccines that have been approved after rigorous testing and stringent regulatory review and have been recommended by WHO have proven to be safe wherever they have been used.

DELIVERY REQUIREMENTS AND OPERATIONAL FEASIBILITY

Countries must evaluate whether the vaccine can be delivered effectively to the target population. Delivery can be relatively straightforward if the vaccine can be provided during existing immunization contacts—for example, if its schedule coincides with that of another vaccine already in the national program. The challenges are greater if the vaccine must be provided to a different age group or to a hard-to-reach special population. The most prominent example is the human papillomavirus (HPV) vaccine, which is currently recommended for girls age 9 to 13 and is being delivered through schools in some countries.

COST

In estimating the cost of a new vaccine, program managers must consider not only the cost of the vaccine itself but also the additional cost of logistics and delivery systems, which can depend on vaccine presentation and packaging. Introducing a vaccine also involves startup costs, including the cost of training health workers, expanding the cold chain and logistics system, and, in some cases, catch-up campaigns.

How a country procures a vaccine also affects costs. (See Briefs 11 and 12.) UNICEF and the Pan American Health Organization (PAHO), which procure vaccines on behalf of many countries, make public the prices they pay. In general, the costs of newer vaccines can be expected to fall as new manufacturers enter the market and competition increases, but the extent and timing of price declines are difficult to predict.

COST-EFFECTIVENESS

Information on disease burden, vaccine efficacy, and cost can be combined to estimate the cost-effectiveness of a new vaccine, which can be useful in weighing the value of introducing the vaccine against other possible uses of limited resources. While cost-effectiveness analysis can be a powerful tool, it requires considerable data as well as technical expertise. PAHO's ProVac Initiative has worked with many countries in the Americas and, more recently, with countries in other regions to build local capacity to carry out vaccine cost-effectiveness analyses. (See the upcoming sidebar.)

AFFORDABILITY

In principle, countries should introduce any vaccine that promises to alleviate substantial disease burden and that represents good value for money. In practice, however, affordability is the limiting factor for many countries, which must find space in their budgets for the costs of new vaccines and their delivery. There is no absolute standard of affordability because budgetary room, or fiscal space, depends on how quickly immunization and health budgets are growing, other potential funding sources, and the feasibility of reallocating funds from other uses or making efficiency gains.

Ministries of health must also balance new vaccine introduction against other immunization program objectives, such as expanding coverage of existing vaccines or making coverage more equitable.

PAHO'S PROVAC INITIATIVE

The ProVac Initiative, created by PAHO in 2004, supports countries in the Americas in making evidence-based decisions on new vaccine introduction, with an emphasis on economic assessment. Nearly all countries in the largely middle-income region must pay the full cost of vaccines in their national programs, so rigorous economic analysis is particularly important in their adoption decisions. Founded on the premise that countries should develop their own capacity to make vaccine decisions based on national data, the initiative offers data, tools, training, and other support.

At the heart of ProVac's approach are user-friendly cost-effectiveness models. The TRIVAC model supports evaluation of the health impact, cost, and cost-effectiveness of Hib, rotavirus, and pneumococcal conjugate vaccines, while CERVIVAC does the same for HPV vaccines. A new model that will incorporate additional vaccines is being developed and tested. ProVac trains national technical staff in the use of these tools and works to enhance the use of evidence in policymaking, including through national immunization technical advisory groups (NITAGs). It has also established a network of regional academic "centers of excellence" to gather regional data and develop methodological guides. As of 2015, ProVac had supported 24 economic analyses in 16 countries in the Americas; many of these analyses contributed to decisions to introduce vaccines into national programs.

To meet demand for decision-making support outside of the Americas, PAHO established the ProVac International Working Group (IWG) in 2011 in collaboration with the U.S. Centers for Disease Control and Prevention, the Sabin Institute, WHO, PATH, and Agence de Médecine Préventive to transfer ProVac tools and approaches to other regions. During this two-year initiative, the ProVac IWG trained national staff from 17 countries and supported cost-effectiveness analyses in nine countries. Discussions are underway on ways to continue this work, which could be particularly valuable to countries that no longer receive Gavi support.

ACCEPTABILITY AND PUBLIC DEMAND

Vaccine introduction decisions do not rest only on technical and cost considerations. A new vaccine must also be acceptable to the target population. Beyond this, policymakers tend to respond to popular demand. Fear of seasonal meningitis epidemics in the Sahel region of Africa helped spur the development and rapid introduction of a new meningitis A vaccine, and concern over growing dengue epidemics will undoubtedly influence decisions on dengue vaccines. In contrast, some vaccines that address important public health concerns, including rotavirus vaccines, have not inspired comparable public demand.

Professional advocacy—sometimes supported by vaccine manufacturers—can draw attention to the potential benefits of a vaccine, but it can also distort public priorities and create a perception of inappropriate influence. These risks highlight the importance of a transparent and evidence-based process for making introduction decisions.

WHO RECOMMENDATIONS

Although each country must consider the relevant factors in its local context, WHO recommendations can provide useful guidance. WHO produces—and regularly updates—recommendations on the use of particular vaccines and publishes them in the form of position papers. These papers synthesize the best available information on vaccine safety and efficacy and are endorsed by the Strategic Advisory Group of Experts (SAGE), a group of outside advisors to WHO on immunization.

DECISION-MAKING INSTITUTIONS AND PROCESSES

Decisions on vaccine introduction inevitably encompass political and other considerations, but these decisions should ideally rest on a foundation

of evidence and analysis. WHO recommends that countries establish independent technical committees to advise policymakers on new vaccine adoptions and other immunization policy decisions. These bodies, known generically as national immunization technical advisory groups (NITAGs), should have the capacity to assess evidence on disease burden, vaccine safety and efficacy, vaccine service delivery, and other scientific and technical topics important to immunization decisions. According to WHO, which offers guidance on the creation and strengthening of NITAGs, 82 countries had committees that met a set of basic criteria regarding composition and functionality as of 2016.

Ideally, NITAGs should be able to evaluate economic as well as epidemiological and biomedical evidence on vaccines, but these committees often lack the necessary expertise. A 2010 survey found that only about one-fourth of NITAGs included health economists.

Sri Lanka is an example of country with a strong advisory body, the Advisory Committee on Communicable Diseases, whose mandate extends beyond immunization to other aspects of infectious disease control. (See Brief 26.)

VACCINE DESIGN, FORMULATION, AND PRESENTATION

Once a country has decided to introduce a new vaccine, such as a rotavirus or pneumococcal conjugate vaccine, it must choose the particular product to use. Vaccines can differ in their basic design as well as in their formulation, presentation, and packaging.

VACCINE DESIGN

Vaccines against a particular disease often vary in aspects of their design that have potential implications for efficacy and other important

Vaccine Decision-Making

characteristics. For example, the two currently available pneumococcal conjugate vaccines include different bacterial serotypes, or strains. Vaccines can also make use of different adjuvants (ingredients that boost immune response).

VACCINE FORMULATION AND PRESENTATION

Vaccine formulation and presentation should not affect efficacy, but they can have implications for delivery and cost. One aspect of formulation is whether the vaccine (or, more precisely, the antigen) is available as a standalone product or in combination with other vaccines. For example, the Hib and hepatitis B antigens are now usually provided in combination vaccines that also include diphtheria, tetanus, and pertussis. Another aspect of formulation is whether the vaccine is provided as a liquid or as a freeze-dried powder that must be reconstituted before use.

Strictly speaking, presentation differences include the number of doses and total volume per vial, but the term *presentation* is sometimes used to encompass differences in formulation and even vaccine design within a vaccine class. In choosing a particular vaccine presentation, program managers must consider not only the purchase price of a product but also ease of delivery, training needs, cold chain requirements, and wastage rates. These non-price considerations also have cost implications, and it is useful to compare the total cost per dose delivered (or per immunized child, if products differ in the number of doses required) of different products.

Another important consideration is whether the supply of a particular vaccine is secure. Some vaccine presentations are available from only one manufacturer, while others have several suppliers. Interruptions in vaccine supply can lead to stock-outs and to children missing immunizations; switching to other presentations can be disruptive and costly.

SUPPORT FOR IMMUNIZATION DECISION-MAKING

WHO, Gavi, and other agencies offer support for various aspects of immunization decision-making:

- Gavi offers support through partner agencies for establishing and strengthening NITAGs. For example, the SIVAC Initiative, implemented by the International Vaccine Institute and Agence de Médecine Préventive, has worked with 29 countries in Africa and Asia. WHO and its regional offices promote and support this work in many non-Gavi middle-income countries. It has also established an online NITAG resource center.
- The WHO-CHOICE program offers a range of tools to help countries assess the cost, impact, and cost-effectiveness of health technologies, including vaccines.
- The most comprehensive initiative to help countries make evidence-based decisions on immunization matters, including new vaccine introduction, is PAHO's ProVac Initiative. It was created to help countries in the Americas but has provided technical assistance to countries in other regions through the ProVac International Working Group.
- PATH developed the Vaccine Presentation Assessment Tool to model the logistical and financial impact of introducing a new vaccine or vaccine presentation.

SOURCES AND FURTHER READING

Andrus JK, Toscano CM, Lewis M, Oliveira L, Roper AM, Dávila M, Fitzsimmons JW. A model for enhancing evidence-based capacity to make informed policy decisions on the introduction of new vaccines in the Americas: PAHO's ProVac Initiative. *Public Health Rep.* 2007 Nov-Dec;122(6):811-16.

International Vaccine Access Center [forthcoming]. Value of immunization compendium of evidence (VoICE) tool. Available from: <http://view-hub.org/>

NITAG Resource Center [Internet]. NRC: About. Available from: <http://www.nitag-resource.org/about>

World Health Organization [Internet]. Immunization, vaccines and biologicals. Vaccine position papers. Available from: <http://www.who.int/immunization/documents/positionpapers/en/>

World Health Organization. Principles and considerations for adding a vaccine to a national immunization programme: from decision to implementation and monitoring. World Health Organization; 2014. Available from: http://www.who.int/immunization/programmes_systems/policies_strategies/vaccine_intro_resources/nvi_guidelines/en/

PART II

SOURCES OF FINANCING

Domestic Public Funding Sources

KEY POINTS

- * As countries transition from donor funding, domestic public financing sources such as general revenue have the greatest potential to be governed by existing budgetary controls, integrated into health financing architecture, and recognized as the financial foundation of universal health coverage, with immunization financing as an integral component.
- * Mechanisms such as health earmarks or trust funds, where they exist, are likely to play only a supporting role in immunization financing. They do not guarantee additive funding and can add complexity.
- * Well-timed budget advocacy can help ensure that general revenue is allocated to health priorities. In countries where public financing or the financial management systems through which funds flow is irregular, help from sources such as the Vaccine Independence Initiative can ease financing challenges.

A COUNTRY'S PUBLIC finance system provides the financial backbone for realizing national health commitments. Worldwide, governments use general revenue and additional, complementary public sources to finance the move toward universal health coverage (UHC) and the immunization services that are important for reaching UHC goals. As some countries take on a greater role in financing their immunization programs and transition away from Gavi and other donor support (see Brief 9), domestic public funding sources will play an increasingly important role in bridging the gap (see Brief 2).

An analysis of comprehensive multi-year plans (cMYPs) for immunization in 40 Gavi countries between 2008 and 2011 found that government spending from all sources covered an estimated 67% of total routine immunization costs and 76% of shared service delivery costs in the baseline year. More recent analyses based on modified System of Health Accounts data in six low- and lower-middle-income countries confirmed that, on average, governments financed more than 50% of immunization costs, with most of the financing channeled through government agencies and spent at the primary health care level.

This brief explores the role of domestic public funding sources in financing immunization programs. (External revenue sources for immunization are explored in Briefs 9 and 10.)

DOMESTIC FUNDING FOR HEALTH

Domestic funding for health can come from public or private sources. Public sources include general revenue raised through broad-based taxes at the national or subnational levels and public insurance contributions. These may be complemented by "on-budget" external resources that flow through government accounting systems. Private sources commonly include private (voluntary) health insurance premiums and formal or informal user fees paid at the point of service. (See Brief 8.) Domestic

public revenue sources for health programs that flow through government systems are more easily pooled and redistributed to achieve equity and financial protection.

As some countries take on a greater role in financing their immunization programs and transition away from Gavi and other direct support, domestic public funding sources will play an increasingly important role in bridging the gap.

GENERAL REVENUE

General revenue includes the money that governments raise through taxes on personal income, taxes on corporate income and profits, value-added and sales taxes, duties and import taxes, property and inheritance taxes, payroll taxes, and/or taxes on profits from the sale of natural resources. These sources are typically pooled in a consolidated fund and appropriated to pay public expenses through regular budgeting and planning cycles. (See Brief 17.) Because these resources are combined in a single fund, general revenue usually offers a better opportunity for redistribution and efficient allocation than other domestic resources that are not pooled in this way.

The amount of general revenue collected depends on the breadth of the country's tax base and the efficacy of tax collection and enforcement—both factors outside the health sector's control. However, the amount of general revenue allocated to health is determined in part by the budget process and how the government sets priorities during budget formulation.

The share of general revenue channeled into the various components of a national immunization program depends on budget allocation and structure, how much goes to the health sector as a whole, and how, within that pool of funding, allocations to immunization are made. Most low- and middle-income countries aim to make allocations to vaccine purchases transparent through a dedicated budget line. An evaluation based on data from 2000 to 2006 found that by 2006, 166 countries reported a vaccine line item in their national health budget. By 2006, 98% of African countries reported that their government had a specific budget line item for vaccines. However, the existence of a line item or

strategic plan for immunization is not a guarantee that immunization services will be funded, protected, or managed accountably.

SOCIAL INSURANCE CONTRIBUTIONS

Some countries rely on earmarked payroll taxes or other mechanisms to generate revenue for the health system. It is important that social insurance contributions be allocated effectively, efficiently, and equitably toward health priorities, including immunization. In some countries, the social health insurance system focuses on curative care, which can shift priority away from immunization. (See Brief 2.) If a country has any sort of non-universal contribution mechanism—such as an "opt-in" scheme that includes immunization in its benefits package—it must ensure that immunization is financed for those who remain uncovered.

OTHER DOMESTIC REVENUE SOURCES

Budgetary constraints in the health sector have led to discussions about alternative ways to generate domestic revenue for immunization programs—a policy avenue that is often outside of the direct decision-making power of the ministry of health. These mechanisms include domestic trust funds (which can still contain a mix of public and external funds) and other earmarks, including lotteries. (See Briefs 6 and 7.) Few countries have established trust funds and earmarks for immunization financing, and countries should carefully consider the pros and cons of these mechanisms before adopting them. For instance, earmarking may not actually provide more money over the long run if it results in cuts to other parts of the health budget. Trust funds can be burdensome to create and manage and, once in place, might only partially fund immunization priorities.

Domestic Public Funding Sources

ECONOMIC GROWTH AND NEW FISCAL SOURCES FOR HEALTH

As economies grow, governments can capture a greater share of increased economic output as revenue, as shown in the figure below. Reliance on out-of-pocket payments by patients generally decreases as the national income level rises and, in turn, as overall access to publicly financed services expands.

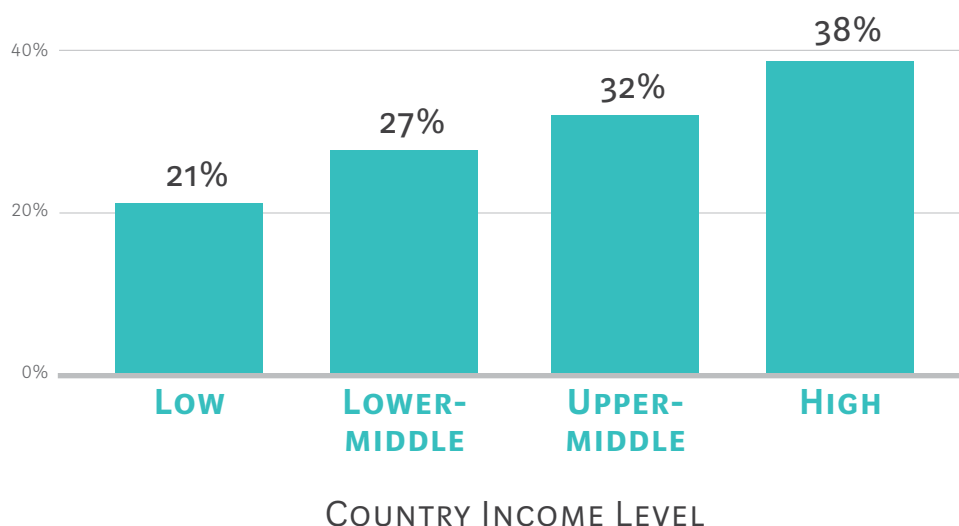
Even as their economies mature, most low- and middle-income countries will continue to face constrained resources for health. First, economic growth can act as a signal for donors to pull out funding, which leaves countries to take on more of the financial burden of supporting health. Second, it takes time for countries to broaden and strengthen their tax systems. Third, government budget

allocation processes are poorly linked to policy and planning in many countries, so even if health is a stated priority, budget allocations may not reflect this. Finally, fiscal space for health may be further constrained by inefficiencies, limited ability of the system to absorb and spend funds, corruption, and diversion or misuse of funds.

IMPLICATIONS FOR IMMUNIZATION FINANCING

Even when domestic public resources or the systems through which they flow are constrained, they still offer the best option in terms of being governed by existing general budgetary controls, integrated into the health financing architecture, and used flexibly to meet immunization program needs. Domestic public sources, particularly general revenue, are often more predictable, equitable, efficient, and sustainable than

GOVERNMENT REVENUE AS A PERCENTAGE OF GDP



Source: Adapted from IMF, World Economic Outlook (October 2015)

other revenue sources. Well-timed and coordinated budget advocacy can play an important role in improving the level, prioritization, and stability of general revenue flows to health, including immunization. (See Brief 17.)

Countries with irregular timing of funding flows can consider options such as negotiating release of time-sensitive funding early in the fiscal year, as Armenia has done for vaccine procurement (see Brief 19); using the Vaccine Independence Initiative (VII) as a way to bridge intermediate gaps (see Brief 13); and tapping commercial lines of credit or guarantees to provide more liquidity for the purchase of time-sensitive essential commodities.

SOURCES AND FURTHER READING

Brenzel L. What have we learned on costs and financing of routine immunization from the comprehensive multi-year plans in GAVI eligible countries? *Vaccine*. 2015 May 7;33:A93-8.

Hsiao WC, Heller PS. What macroeconomists should know about health care policy. Washington D.C.: International Monetary Fund; 2007.

Lydon P, Beyai PL, Chaudri I, Cakmak N, Satoulou A, Dumolard L. Government financing for health and specific national budget lines: the case of vaccines in immunization. *Vaccine*. 2008; 26(51):6727-34.

Tanzi V, Zee HH. Tax policy for developing countries. International Monetary Fund; 2001.

Welham B, Hedger E, Krause P. Linkages between public sector revenues and expenditures in developing countries. Overseas Development Institute; 2015. Available from: www.odi.org/sites/odi.org.uk/files/odi-assets/publications-opinion-files/9675.pdf

Earmarking to Finance Immunization

KEY POINTS

- * Earmarking—setting aside some or all revenue from a tax or group of taxes for a designated purpose—is a domestic financing option considered by some countries for health, particularly as they transition away from donor support.
- * Some immunization advocates are attracted to earmarking as a source of guaranteed funding, but finance authorities typically oppose it because earmarking can undermine their ability to allocate the budget most effectively.
- * Earmarking can safeguard particular funding streams for immunization. But this protection can be undermined by reductions in other parts of the health budget. Such offsets can jeopardize health services that are essential for vaccine delivery.
- * As funding requirements for vaccines and injection supplies increase, funding sources should be structured to support, and not limit, these changing requirements.
- * A more holistic approach to protecting and increasing general funding for the health sector and ensuring immunization services is likely to yield better results than advocating for earmarks.

EARMARKING—SETTING ASIDE some or all revenue from a tax or group of taxes for a designated purpose—has become part of the global conversation on domestic financing for health, particularly as countries transition away from donor-supported global health programs. Earmarking has the appeal of potentially bypassing the annual budget negotiation process and protecting a revenue stream for health coverage or a specific health priority, such as immunization. However, earmarking introduces rigidity into the budget process and can lead to inefficiency and reduced funding for other, possibly higher-priority, spending areas. Many countries use earmarking to fund national health priorities, but earmarking for immunization specifically is not common. Even in countries that have legislated earmarking for immunization, earmarks have been challenging to implement.

Global experience suggests that earmarking for health can be effective if health services are a high national priority, the purpose is broadly defined (such as for national health coverage), and there is some flexibility to reallocate from earmarked funds if other urgent priorities emerge. But the effectiveness of an earmark can diminish over time, with the budget rigidity it creates leading to inefficiencies.

PROS AND CONS OF EARMARKING FOR IMMUNIZATION

The most important argument for earmarking is that it can “ring-fence,” or protect, resources for a government priority, especially in times of government cutbacks. In addition, it can make tax increases more politically acceptable by tying them to popular programs or services.

On the other hand, earmarked revenues may also shrink during economic downturns, and earmarking ultimately limits the government’s ability to adapt to economic fluctuations. Earmarking might also create the perception that immunization is “taken care of,” leading to budget shifts away from the immunization program, and in this way impose a funding ceiling rather than set a funding floor. Funding mechanisms should be structured to allow for growing requirements for immunization. As vaccine financing requirements grow, earmarking for immunization could lead to cuts in other parts of the health budget, possibly jeopardizing the health services that support vaccine delivery. Finally, earmarking can increase fragmentation and hinder coordination of resource allocation across the health sector overall.

TYPES OF EARMARKING FOR IMMUNIZATION

At least nine countries (Bhutan, Bolivia, Cameroon, Costa Rica, Mongolia, Nepal, Nigeria, Senegal, and Uganda) have or have had legislation or governance structures in place to allow earmarking for immunization, but earmarked funds are actually flowing in only three of them (Bhutan, Bolivia, and Costa Rica). In these three countries, the earmarks are used to fund vaccines and injection supplies. Several other countries (including Ghana and the Philippines) have broader earmarks for health.

GENERAL BUDGET EARMARKS FOR IMMUNIZATION

Some countries, including Georgia, Indonesia, Mongolia, and Sri Lanka, legally mandate that the government is responsible for financing immunization. Others go a step further and mandate the percentage of total health funds that must be spent on immunization programs. In Bolivia, a certain percentage of funding is directed by law to vaccine procurement, syringes, and immunization program operating expenses through Cajas de Salud (Health Funds).

TAXES ON GOODS AND SERVICES

No countries currently earmark tax revenue on specific goods and services for immunization, although some countries fund immunization through broader earmarks for health. The Philippines raised taxes on alcohol and tobacco in 2012, with 85% of the additional revenue raised earmarked for the Department of Health to expand health coverage for the poor. The Department of Health further allocates this earmarked revenue to programs, including immunization. Ghana has no specific earmark for immunization, but the Ministry of Health used a portion of the earmarked value-added tax revenues that fund the National Health Insurance Scheme to fund vaccine purchases to meet the country's Gavi co-financing commitment in 2016. (See Brief 23.)

LOTTERY REVENUES

Costa Rica uses earmarked lottery earnings to fund immunization. Funds from one "draw" of the national lottery every November are dedicated to vaccines, after the lottery winnings and operating costs are deducted. Lottery-funded contributions to immunization are relatively small, however, at about 1% of total national funding for vaccine purchasing. (See Brief 22.)

DOMESTIC TRUST FUNDS

Trust funds are another mechanism that governments can use to ring-fence, or protect, funding for specific purposes. Trust funds may receive funds from multiple revenue sources. They can support accumulation of reserves by drawing down only a portion of gains from interest rather than drawing down capital. Bhutan has one of the longest-running domestic trust funds dedicated to essential medicines, including vaccines. Several other countries have established organizational structures or legislative processes around immunization trust funds, including Cameroon, Nepal, Nigeria, Senegal, and Uganda, but as of 2016 funds had not begun to flow. (See Briefs 7 and 21.)

SOURCES AND FURTHER READING

Bird R, Das-Gupta A. Public finance in developing countries. In: Medhora R, editor. International development: ideas, experience, and prospects. Oxford: Oxford University Press; 2014. p. 259-76.

Joint Learning Network [Internet]. Earmarking for health. WHO and R4D working paper. Available from: <http://www.jointlearningnetwork.org/earmarking>

Domestic Trust Funds

KEY POINTS

- * Domestic trust funds have attracted interest as a way to fund immunization programs, but few countries have implemented them.
- * In theory, trust funds can help protect or manage sources of immunization funding, generate additional revenue through interest earned on investments, and promote donor confidence.
- * The limited experience to date has shown that trust funds for immunization and for other health priorities can be costly and complicated to establish, fund, and manage.

DOMESTIC TRUST FUNDS have attracted interest as a way to fund immunization programs, but few countries have implemented them. A trust fund is one of several financial tools that governments can use to ring-fence, or protect, funding for specific purposes. However, there is often confusion about which of these tools policymakers are pursuing and what differentiates them. The figure on the next page shows these mechanisms (from left to right in order of increasing complexity).

An *account* is governed by regular accounting principles. A *fund* may be subject to other rules or regulations once it leaves the government general accounting system. An *endowment fund* is dedicated funding left in trust by a donor in the interest of the donor or an institution. A *trust fund* is established for a particular purpose but can have multiple revenue streams and purposes.

A trust fund may be structured to simply provide income, to cover shortfalls through short-term credit, or to provide guarantees against loans to support program implementation. Trust funds can be used to finance a mix of health activities (which might include immunization) or be restricted to a single type of activity (such as immunization).

HOW TRUST FUNDS WORK

Legal terms specify how the trust fund's initial capital or interest can be used over time. Trust funds also have the potential to accumulate reserves by tapping into only a portion of gains from interest.

Trust funds are usually legally incorporated according to policies and tax regulations that vary by country. A governing board generally oversees the strategy, business plan, management, and operations. Sometimes an immunization trust fund is established simultaneously with immunization legislation so the trust fund is legally embedded. In some circumstances, trustees or a board of directors manage reporting and financial controls and are liable for the fund's use, while asset managers seek to ensure the right rate of return and level of risk. Some countries institute a more limited administrative structure, perhaps with an individual fund manager sitting in an existing ministry or

Domestic trust funds have attracted interest as a way to fund immunization programs, but few countries have implemented them.

PROTECTED FUNDS FOR IMMUNIZATION

	ACCOUNT	FUND	ENDOWMENT FUND	TRUST FUND
PURPOSE	Maintain a separate funding stream for accountability against stated expenditure purpose	Can be used to fund "off-budget" activities such as social health insurance	Manage funds or gifts in the interest of a donor or an institution	Maintain dedicated revenue for a particular sector, population, program, or service
GOVERNANCE	Governed by regular accounting structures and rules	Can be governed by a board and/or an institution/NGO or MOF/MOH	Can be governed by a board and/or an institution/NGO; may spend down only income earned	Can have management structure similar to endowment or a leaner structure; can be governed by a board and/or an institution/NGO
DISBURSEMENTS	Separate bank account with limited access	Separate consolidated line from regular budget	Technical decisions managed by a board; principal managed by a fund/asset manager	Might have rules for drawing down capital; can exist in country or offshore, managed by an NGO or financial manager
REVENUE	Domestic public revenue, including general revenue	Domestic public revenue, including general revenue	Likely contains funds from a single donor or entity	Funded by domestic public revenue, donors, philanthropy, or other; requires seed capital (principal); may require matching funds
	LESS COMPLEX		MORE COMPLEX	

agency. In this case, other measures are needed to ensure transparent financial reporting and decision-making.

Trust funds can be *passive funds* (in which assets are regularly deposited and used at approximately the same rate at which they are deposited) or *working funds* (in which assets are invested and only the proceeds are spent). In a working fund, balanced

investments chosen to provide steady returns may enable the trust fund to act as a stable and reliable source of funding by primarily using gains from interest rather than drawing on the principal. If a trust fund is intended to fully fund a specific area where costs are expected to grow over time (such as an expanding immunization program), it might be necessary to add to the trust fund's capital.

COUNTRY EXPERIENCES WITH IMMUNIZATION TRUST FUNDS

Trust funds are under discussion in many countries, but as of early 2016 only one fund with explicit immunization financing components was fully functioning: the Bhutan Health Trust Fund (BHTF). (See Brief 21.) According to analysis from Gavi, the BHTF is playing an increasingly important role in vaccine financing, although the government of Bhutan will remain the major funding source for immunization and will continue to cover non-vaccine immunization delivery costs. The BHTF has raised significant resources for vaccines and can serve as a model for other countries with similar national contexts. Factors contributing to the trust fund's successful establishment include a small population, political champions, a supportive monarchy, flexible funding to meet emerging priorities, and good governance and accountability structures that can adapt to meet changing needs.

Some countries have embarked on the lengthy legislative and operational processes required to establish a trust fund, including Cameroon, Nepal, Nigeria, Senegal, and Uganda. Others countries at even more preliminary stages of exploring trust funds include Cambodia, Kenya, Mali, the Republic of the Congo, and Sierra Leone. Given the time required for legislation to be passed, funds to be raised, and political commitment to be fostered, it is too early to draw any lessons from the experiences of these countries.

A number of countries are exploring trust funds for health programs other than immunization, such as HIV/AIDS, but little evidence is available from these experiences. Only Zimbabwe operates a functioning national HIV trust fund; HIV trust funds are still under discussion in Kenya, Tanzania, and Uganda. The Zimbabwe National AIDS Trust Fund was set up in 1999 and provides 50% of national spending for antiretroviral therapies, accounting for about 10% of Ministry of Health spending on HIV/AIDS. The fund

raised US\$2.6 billion between 2000 and 2006 and another US\$26 million in 2011. The funding source is a 3% AIDS levy charged on incomes and profits in the formal sector. Revenue depends significantly on the economic climate of the formal sector, and challenges have arisen related to accountability and financial flows, with reports of local governments diverting some funds. While the fund is integrated into the tax system, administrative costs are high. Although reported to be unpopular, the fund does have a broad and growing revenue base. One important lesson from the Zimbabwe experience is that high inflation from 2005 to 2007 wiped out attempts to maintain the fund's value, demonstrating that such a fund is not necessarily insulated against macroeconomic shifts.

IMPLICATIONS FOR IMMUNIZATION FINANCING

One of the main arguments in favor of trust funds is that they can be a source of investment income, providing a way to both ring-fence revenue streams and generate additional income in the process. They can also potentially introduce more flexibility into public financial management by enabling funding to be directed quickly toward important priorities. If a trust fund is dedicated to specific immunization-related priority populations, programs, and services, it could help improve tracking of immunization resources, strengthen donor confidence, and harmonize revenue sources from different initiatives into one controlled fund.

On the other hand, trust funds can be costly and challenging to manage, and much has yet to be learned about governance and managerial structures in relation to immunization funding. Trust funds could use up more political capital than is justified by the payout, while not necessarily meeting all of the funding needs for immunization. Also, ring-fencing funds for immunization could reduce funding to other parts of the health budget (see Brief 6) or

create funding allocation challenges. Additional challenges can include lack of accountability and transparency in the distribution of funds, depending on the management structures in place. Finally, trust funds require significant time and expense to set up. Several countries have already spent years trying to establish trust funds, with variable results.

SOURCES AND FURTHER READING

Bhutan Health Trust Fund [Internet].

Archived at: <https://perma.cc/W5YV-QQVW>

Kumar A, Bhawalkar M. HIV/AIDS trust funds: what do we know? Background paper for Montreux Collaborative Agenda on Fiscal Space, PFM, and HF; Montreux, Switzerland; 2016 April 7.

Sabin Vaccine Institute [Internet]. Trust funds. Available from: <http://www.sabin.org/search/content/Trust%20funds>

Household Out-of-Pocket Payments

KEY POINTS

- * User fees for immunization services create a barrier to access, especially for poor people, thus jeopardizing the public health goal of achieving high rates of coverage.
- * Officially sanctioned user payments for immunization are now uncommon, but informal charges still occur in some countries. For example, households may be forced to buy injection supplies, such as syringes, out of pocket when a public facility runs out.
- * Best practices include centralized procurement of injection supplies and ensuring that vaccines are bundled with injection devices in the supply chain.

USER FEES FOR immunization are out-of-pocket payments made by households for immunization services. They are sometimes referred to as copayments or cost-sharing requirements. These fees can be formally sanctioned by the health system or occur informally, “off the books.” One example of informal out-of-pocket payments is when a public facility runs out of injection supplies and parents are forced to purchase syringes elsewhere in order for their children to be immunized.

In striving to achieve high immunization coverage, some governments have included user fees as a source of additional revenue. However, experts widely view user fees as an obstacle to immunization, especially for the poorest households. (The exception is when wealthier households choose to opt out of publicly financed services and pay private providers out of pocket.)

CONCERNS ABOUT USER FEES

Evidence suggests that the benefits of revenue from user fees are outweighed by the potential negative impact on immunization coverage because parents might be discouraged from vaccinating their children. Some low- and middle-income countries have not only eliminated user fees for immunization but

have instituted conditional cash transfers to low-income families as an incentive to seek a package of maternal and child health services, including immunization. (See the sidebar on the next page.)

FORMAL USER FEES

Most governments have phased out formal user fees for immunization over the past 20 years. When such fees were more common, they typically took the form of a fee per vaccine or a fee to obtain an immunization card. An email survey by the Pan American Health Organization (PAHO) and UNICEF offices in the late 1990s found that 12 of 78 countries had fees for immunization in public facilities, most of them in Sub-Saharan Africa. Cost recovery was fairly low—less than 5% of total immunization costs.

The phasing out of formal user fees has yielded positive results. For example, hepatitis B is a leading cause of illness and death in China, with infection often occurring in early childhood. The hepatitis B vaccine was first recommended for Chinese infants in 1992, but because local health departments charged high fees for the vaccine, coverage was low. In 2002, the vaccine was added to the National Immunization Programme and, with Gavi funding, the government began supporting free hepatitis B vaccination in

CONDITIONAL CASH TRANSFERS

Conditional cash transfers for health care are the opposite of user fees. Instead of having to contribute to the cost of health services, families receive a cash payment when they use such services.

Conditional cash transfer programs are intended to encourage the use of health services, reduce poverty through cash rewards, improve health, and help break the intergenerational cycle of poverty. Countries including Brazil and Mexico offer conditional cash transfers for low-income families to encourage the use of maternal and child health services, including immunization. Evaluations have shown that these programs can increase use of health services, but evidence on immunization coverage is inconclusive, perhaps in part because immunization coverage rates were already fairly high in the program areas. There is some indication that when conditional cash transfers are weakened or made more complicated, immunization coverage may drop.

China's poorest counties and provinces. In 2005, a government regulation abolished all charges and user fees for all nationally recommended vaccines. Coverage of the three-dose hepatitis B vaccine increased from 60% in 2000 to 84% in 2005 and reached 99% by 2015, according to World Health Organization / UNICEF estimates.

INFORMAL USER FEES

Informal fees persist in some countries. Because they are not officially sanctioned, they are harder to track. Some countries have decentralized responsibility for procuring injection supplies, which has contributed to stock-outs at the facility level. Parents are forced to buy injection supplies elsewhere and bring them to the facility in order to have their children vaccinated. This creates a barrier to access. The cost of injection supplies from local pharmacies is also much higher than the cost to the government through bulk purchasing. WHO and UNICEF recommend that governments centralize purchasing of injection supplies and also bundle vaccines with their required injection devices in the supply chain. When advocates or governments probe whether user fees for immunization occur in publicly financed facilities, they should look into informal as well as formal fees.

SOURCES AND FURTHER READING

Centers for Disease Control and Prevention. Progress in hepatitis B prevention through universal infant vaccination – China, 1997-2006. *Morb Mortal Wkly Rep.* 2007 May 11;56(18):441.

DeRoek D, Levin A. Review of financing of immunization programs in developing and transitional countries. Bethesda (MD): Partnerships for Health Reform Project, Abt Associates. 1998 Dec. Archived at: <https://perma.cc/Y7HL-LZDL>

Glassman A, Duran D, Fleisher L, Singer D, Sturke R, Angeles G, Charles J, Emrey B, Gleason J, Mwebesa W, Saldana K. Impact of conditional cash transfers on maternal and newborn health. *J Health Popul Nutr.* 2013 Dec;31(4 Suppl 2):S48.

Gavi Financing for Immunization

KEY POINTS

- * Gavi is the world's largest channel of external financing for immunization.
- * Gavi supports a menu of 10 vaccines and contributes to global stockpiles of meningitis, oral cholera, and yellow fever vaccines. It also provides support for procurement of cold chain equipment, health systems strengthening grants, vaccine introduction grants, and operational support for campaigns.
- * Gavi works to help countries achieve financial sustainability in their immunization programs. Countries that receive Gavi vaccine support are required to make contributions that increase over time.

GAVI, THE VACCINE ALLIANCE, was founded in 2000 by a partnership of major donors, international agencies, and leaders of the vaccine industry to accelerate the adoption of new and underused vaccines in the world's poorest countries and to improve immunization coverage. Its creation was spurred by concerns over stagnating immunization coverage and the financial barriers to introducing new lifesaving vaccines in the poorest countries.

Gavi is a funding entity that has become the largest channel of external financing for immunization. By the end of 2015, it had disbursed US\$8.7 billion to support country immunization programs. It provides both commodities (vaccines, injection supplies, and equipment) and grants to support the introduction of vaccines, the operational costs of campaigns, and health system strengthening. It works with public and private partners, including the World Health Organization and UNICEF, to support countries in improving the performance of immunization programs.

Gavi also works to shape vaccine markets in order to make vaccines more affordable and their supply more secure. In concert with UNICEF Supply Division, which handles most procurement for Gavi-supported

countries, and the Bill & Melinda Gates Foundation, it works to establish healthy markets and better support countries' vaccine needs. Gavi pays relatively favorable prices for the vaccines in its portfolio.

GAVI ELIGIBILITY

When Gavi was created in 2000, 75 countries with gross national income (GNI) per capita below US\$1,000 were eligible to receive assistance. In late 2009, Gavi reset the eligibility threshold at US\$1,500. It also provided for the eligibility threshold to be adjusted for inflation and for country eligibility to be based on the World Bank's release each July of GNI per capita figures for the previous year. The Gavi Board made further revisions to the eligibility and transition policy in 2015, changing the eligibility indicator from the country's most recent GNI per capita to a three-year average to smooth out year-to-year variations and make it easier for countries to project when they will exceed the eligibility threshold. In 2017, the eligibility threshold stood at US\$1,580.

Once countries cross that threshold, they enter a five-year "accelerated transition" phase, during which Gavi support is phased out and the national contribution to vaccine financing grows rapidly

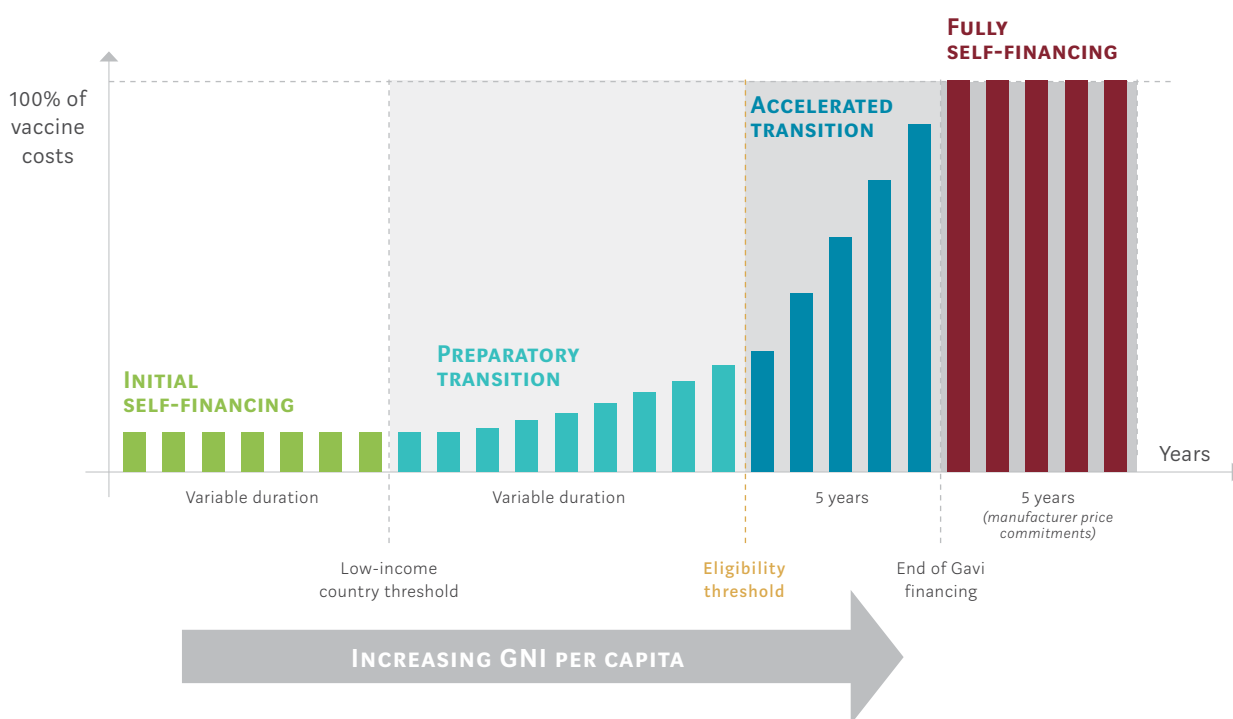
(as detailed later in this brief). After the first year of this transition, called the “grace year,” the country cannot apply for new vaccine support. As of 2017, 32 countries are in the initial self-financing phase, 15 are in the preparatory transition phase, and 17 are in the accelerated transition phase. The Gavi transition model is depicted in the figure below.

HOW GAVI SUPPORT WORKS

Gavi supports a portfolio of vaccines (and associated injection safety devices) that includes human papillomavirus (HPV), inactivated polio vaccine (IPV), Japanese encephalitis, measles, measles-rubella, meningitis A, pentavalent, pneumococcal, rotavirus, and yellow fever. Countries can apply for vaccine support for campaigns or, more commonly,

for introducing new vaccines into the routine immunization program. Gavi provides financial support for the procurement of vaccines and injection safety devices. (It provides funding to UNICEF to procure these commodities rather than providing funds for their purchase directly to countries.) Gavi also provides support through its Health Systems and Immunization Strengthening (HSIS) support framework, which includes health systems strengthening grants, grants to fund one-time startup costs for new vaccine introduction, and grants to help fund operational costs for immunization campaigns. HSIS grants are intended to strengthen immunization systems and, in particular, to improve coverage and equity, which is a major objective of Gavi’s 2016–2020 strategy. In 2016, Gavi began offering support for cold chain equipment upgrades.

THE GAVI MODEL: COUNTRY CONTRIBUTIONS TO VACCINE COSTS (2016)



Gavi Financing for Immunization

Gavi makes long-term commitments to continue supporting the routine use of the vaccines until a country transitions out of Gavi support. Gavi periodically adds new vaccines to its portfolio (primarily based on its Vaccine Investment Strategy, which is developed every five years). New additions to Gavi's vaccine portfolio and changes to Gavi policies are announced and explained on the Gavi website so countries can stay up to date on the available opportunities.

CO-FINANCING

The Gavi model helps prepare countries for full self-financing once Gavi support ends. Through its co-financing policy, Gavi requires countries to pay for and procure (usually through UNICEF) a share of the vaccines that they have introduced with Gavi support. Co-financing requirements as of 2016 are depicted in the figure on the previous page. Countries are responsible not only for co-financing vaccines but also for covering the ongoing incremental supply chain, logistics, and service delivery costs associated with new vaccines, although sometimes other donors help cover these costs.

Co-financing obligations increase as countries grow economically. When they are in the World Bank's low-income country category (referred to as the initial self-financing category), they procure a small share (equivalent to US\$0.20 per dose) of the vaccines that Gavi is supporting. This modest obligation is intended primarily to promote country ownership rather than financial sustainability of the immunization program. After a country crosses the threshold to lower-middle income status (referred to as the preparatory transition category), its co-financing obligation is tied to the prices of the vaccines it has adopted and increases by 15% per year. Once it exceeds the eligibility threshold, its co-financing obligation increases by 15% for one more year (the grace year) and then ramps up steeply over the next four years (when it is in the accelerated transition category).

Ideally, by the time Gavi support ends, the country is prepared to fully self-finance vaccine costs. Another challenge for countries as they transition from Gavi support is that they might have to pay higher prices. To ease this concern, several manufacturers have made commitments to continue providing countries with access to the same price that Gavi pays, or to maintain the prices countries are currently paying for certain vaccines for set periods of time after they have transitioned out of Gavi's financial support. Information about manufacturers' commitments is offered at www.gavi.org/library/gavi-documents/supply-procurement/.

PREPARING FOR TRANSITION

Although in principle co-financing helps prepare countries for eventual transition from Gavi support, some countries, particularly those that have introduced many vaccines with Gavi support, face a fiscal challenge as that support ends. Thus governments must consider the long-term cost implications of new vaccines when making introduction decisions. Other briefs in this resource guide can help governments weigh financial and other considerations in their introduction decisions, make the case for immunization with decision-makers, calculate budget requirements, minimize costs through strategic purchasing, identify appropriate sources of financing, and ensure sustainable and adequate immunization financing as they reform health-sector financing more broadly.

New additions to Gavi's vaccine portfolio and changes to Gavi policies are announced and explained on the Gavi website so countries can stay up to date on the available opportunities.

FURTHER READING

See the UNICEF Supply Division website for information on prices for vaccines supplied by UNICEF for Gavi (http://www.unicef.org/supply/index_gavi.html).

See the Gavi website for information on Gavi support (<http://www.gavi.org/support/>) and on Gavi policies (<http://www.gavi.org/about/governance/programme-policies/>).

Development Assistance for Immunization

KEY POINTS

- * Development assistance can play an important role in immunization financing. It should ideally be predictable, well-coordinated with government efforts, aligned with government priorities, and accompanied by a plan for sustaining activities once the assistance ends.
- * Development assistance for health that is used to strengthen health systems can generate important benefits for immunization because routine immunization services depend on strong health systems for delivery.
- * The poorest countries with slow economic growth are likely to need development assistance for health and immunization for many years. Countries with fragile economies or those in conflict also have extra needs.
- * Most development assistance for immunization comes in the form of grants, but loans and credits can play a role too.

FOR LOW-INCOME countries and many lower-middle-income countries, development assistance is an important addition to highly constrained public budgets for health and for immunization. The Institute for Health Metrics and Evaluation, in its Financing Global Health 2015 report, defines development assistance for health as “financial and in-kind contributions provided by global health channels to improve health in developing countries.” Within health, funds for immunization are those that can be explicitly identified as supporting immunization.

This brief explores development assistance for immunization in the context of development assistance for health more broadly. Depending on its purpose, development assistance for health can be highly relevant for immunization because routine immunization services require strong health systems for delivery. For example, development assistance that is used to strengthen the reach and quality of primary health services in underserved areas can help advance immunization coverage goals.

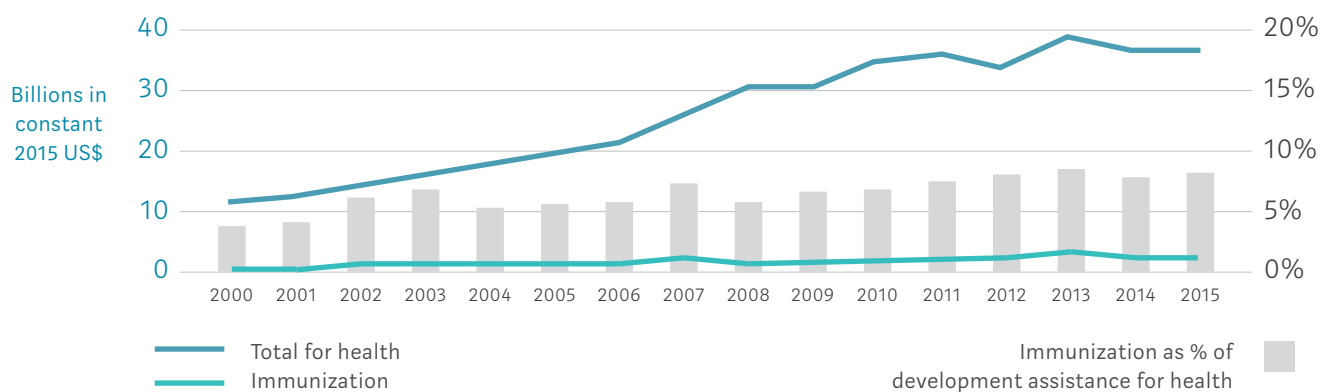
GROWTH IN DEVELOPMENT ASSISTANCE FOR HEALTH AND IMMUNIZATION

The figure on the next page plots total development assistance for health from 2000 to 2015 in constant 2015 U.S. dollars. Development assistance for health increased from about US\$11.7 billion in 2000 to US\$36.4 billion in 2015. (Figures for 2014 and 2015 are preliminary.) During this same period, assistance for immunization rose from about US\$400 million to US\$2.9 billion per year. As a percentage of total health assistance, assistance for immunization rose from 4% in 2000 to 8% in 2015.

A significant share of development assistance for immunization flows through the Global Polio Eradication Initiative (GPEI). About US\$900 million was disbursed in both 2013 and in 2014 for this program, and requirements for 2013 to 2019 will total US\$7 billion, or about US\$1 billion per year, according to GPEI annual reports.

Development assistance for health can be highly relevant for immunization because routine immunization services require strong health systems for delivery.

DEVELOPMENT ASSISTANCE FOR HEALTH AND FOR IMMUNIZATION WITHIN HEALTH (2000 TO 2015)



Source: Institute for Health Metrics and Evaluation

CHANNELS OF DEVELOPMENT ASSISTANCE FOR HEALTH AND IMMUNIZATION

Development assistance can be categorized by source of funding or channel of funding. Channels of assistance are agencies and organizations that direct their own funds or funds from other sources. From a country perspective, channels are of greatest interest because countries receive financing from channels.

For health generally, the five largest channels of assistance from 2000 to 2015 were nongovernmental organizations collectively (21.8%), the United States (18.7%), the Global Fund to Fight AIDS, Tuberculosis and Malaria (8.1%), the World Bank’s International Development Association (IDA) and International Bank for Reconstruction and Development (IBRD) (7.9%), and the World Health Organization (7.0%).

For immunization, the five largest channels during the same period were Gavi (37.9%), the Bill & Melinda Gates Foundation (14.9%), WHO (13.3%), U.S.-based nongovernmental organizations (9.4%), and the U.K.’s

Department for International Development (5.7%). Gavi funding has risen steadily since the alliance was created in 2000. By 2015, Gavi funding accounted for about 50% of all assistance for immunization. (See Brief 9.) Many small and medium development assistance channels also play important roles in health and immunization.

FORMS OF ASSISTANCE FOR IMMUNIZATION

Most immunization support is in the form of grants; loans and credits also play a role.

Grants. Grants are transfers of resources—which can include money, technical assistance, and commodities or equipment—without expectation of repayment. For example, Gavi support comes in the form of vaccines, injection safety devices, cold chain equipment, and grants to strengthen health systems and immunization programs. (See Brief 9.) USAID has provided project grants for a host of immunization-related purposes, including cold chain equipment upgrades, learning materials and

Development Assistance for Immunization

training, Gavi proposal development, Expanded Program on Immunization (EPI) reviews, vaccine post-introduction evaluations, and capacity building in many areas. Japan International Cooperation Agency (JICA) provides assistance for immunization primarily through technical cooperation projects, grant aid, and loans.

Vaccine donations (except for those procured through UNICEF Supply Division with donor financing) can have adverse effects on national immunization programs. Sometimes they do not meet the needs of immunization programs, are unsustainable after the donation ends, incur costs that were not budgeted for, or have quality (such as expiry) issues. UNICEF and WHO have a joint statement that outlines five key requirements for vaccine donations in order to avoid adverse effects. Cold chain equipment donations can also have negative effects if they are not aligned with the needs of the national program. UNICEF guidelines on such donations can be helpful.

Loans and credits. The World Bank and regional development banks provide loans, credits, and (less frequently) grants. Loans and credits are funds borrowed by country governments that must be repaid; the terms can vary, with credits carrying highly concessional (subsidized) rates. Development loans and credits are negotiated with the country's ministry of finance, and the government guarantees repayment. Other channels, such as JICA, also provide loans.

The World Bank maintains a list of country eligibility requirements for its various forms of assistance: IBRD-only loans (at or near market rates), IDA-only credits (at highly concessional rates), and blends of both. Eligibility for IDA credits is updated annually. Eligibility depends on a country's GNI per capita (with a threshold of US\$1,215 in 2016) as well as other factors such as small island status and creditworthiness. As countries grow economically and surpass the IDA threshold, they gradually phase out of IDA support and IBRD support phases in.

In 2016, 78 countries were eligible to receive IDA resources either in full or blended with IBRD support. Regional development banks take fairly similar approaches.

Buy-downs of loans and credits. In some instances, the terms of loans and credits are softened upon achievement of certain goals, most commonly for polio. Since global eradication of polio is a global "public good," it makes sense that the burden should not fall on individual countries involved in the final push for global polio eradication. The World Bank has provided a series of IDA credits to Nigeria for polio eradication, with the Gates Foundation, Rotary Foundation, and U.S. Centers for Disease Control, via the UN Foundation, pledging additional funds to convert some of these credits to full grants if polio campaign targets are achieved. Similarly, JICA has provided loans to Nigeria and Pakistan to support polio eradication, and the Gates Foundation agreed to repay the loans to JICA—a "loan conversion" or "buy-down"—if the projects are successfully completed.

As economic growth leads countries to transition from concessional financing (IDA) to loans (IBRD), some governments become more reluctant to borrow for health and immunization projects. Although loans and credits must be repaid (except in cases such as loan conversion), they can be sound investments if the benefits of the supported project outweigh the costs. The government must have the capacity to repay the loan or credit, however, and the loan or credit makes sense only if cheaper financing is not available. Loans and credits for recurrent costs can pose particular concerns because countries must assume not only the recurrent costs after the assistance ends, but also repay the loans or credits. Many middle-income countries do not have as much access to development assistance grants as the poorest countries. Loans can be an especially important source of financing for these countries for investment purposes.

WORLD BANK ASSISTANCE

The World Bank has four main types of instruments relevant to health and immunization:

- **Investment project financing** to support specific physical and social infrastructure
- **Development policy financing** to support a program of policy and institutional actions, such as to address bottlenecks in service delivery, with non-earmarked general budget financing
- **Program-for-results financing**, which links disbursements to defined program results
- **Trust funds and grants** to help scale up activities (especially pilot innovations) or support activities in fragile and conflict situations

The World Bank, along with partners, launched the Global Financing Facility (GFF) in 2015 as a platform to support improvements in reproductive, maternal, newborn, child, and adolescent health (RMNCAH). The GFF Trust Fund links grant funds to IDA or IBRD projects to finance country investment cases (prioritized investments) that focus on “best-buy” RMNCAH interventions (which include immunization) as well as broader health system issues. GFF investments are likely to be an important source of financing for health and immunization services over the next few years. Investment cases are intended to guide financing from GFF partners and national governments for a period of three to five years. As of 2016, 62 low- and lower-middle-income countries were eligible for grants from the GFF Trust Fund.

ASSESSING DEVELOPMENT ASSISTANCE

Development assistance is complicated to assess because it comes in many forms, with varying requirements and lending terms. But six main criteria apply: additional resources raised, cost, predictability, sustainability, flexibility, and equity.

How much funding a country might raise from development assistance depends on its country characteristics (such as GNI per capita, disease

burden, region, and other factors) and its relationships with donors. The poorest countries generally have the most access to development assistance, but there are important exceptions.

Assistance from multiple sources can bring important benefits but also be complex to assess and manage. Project grants, loans, and credits vary in size, and they can offer significant additional resources or be more limited in scope. What development assistance adds to government budgets depends on how those budgets might be shifted or cut in response to development assistance flows. Loans and credits that require repayment need approval from the ministry of finance or treasury, and the ministry might reduce general budget allocations to health and/or immunization as a result of the perceived availability of development assistance for the health sector.

There are also costs associated with applying for, getting approval for, and using development assistance. Some of the transaction costs can be confusing and burdensome for countries.

In terms of predictability, some grants and loans/credits have a short time horizon and are for specific activities, while others may come with multi-year commitments. The predictability of payment for results-based financing depends, of course, on the likelihood that the results will be achieved. This type of assistance is intended to increase focus on results, improve government accountability, and encourage innovation. Some of the assistance is approved on a year-to-year basis, with no assurance of continuation, which makes planning difficult.

Development assistance is complicated to assess because it comes in many forms, with varying requirements and lending terms. But six main criteria apply: additional resources raised, cost, predictability, sustainability, flexibility, and equity.

Development Assistance for Immunization

Development assistance is time-bound, so governments must carefully consider the sustainability of activities funded by that assistance. The activities may have recurrent operating costs and maintenance costs that will have to be financed by public budgets once the assistance ends.

In terms of flexibility, budget support is the most flexible and grants tied to specific inputs are the least flexible. Governments must assess whether the package of development assistance they receive is

furthering their goals and whether different types of assistance would improve efficiency and impose fewer restrictions or constraints on health budgets and planning.

Some assistance is intended to improve equity in health outcomes or specifically in immunization coverage. As mentioned earlier, donors are increasingly linking disbursements to desired results, which may have an equity component.

SOURCES AND FURTHER READING

Institute for Health Metrics and Evaluation. Financing global health 2015: development assistance steady on the path to new global goals. Seattle (WA): Institute for Health Metrics and Evaluation; 2016.

WHO-UNICEF Joint Statement on Vaccine Donations, August 7, 2010. Available from:
http://www.who.int/immunization/hpv/plan/who_unicef_joint_statement_on_vaccine_donations_who_unicef_2011.pdf

PART III

STRATEGIC PURCHASING AND PROCUREMENT

Vaccine Procurement Overview

KEY POINTS

- * Vaccine procurement is a vital function of immunization programs, with important implications for total program cost as well as reliable supply of appropriate products.
- * Countries can procure vaccines directly from manufacturers or through UNICEF or the PAHO Revolving Fund (for countries in the Americas). Most Gavi countries procure vaccines through UNICEF or the Revolving Fund. In most cases, countries can obtain lower prices through UNICEF or PAHO than by procuring directly. In some cases, policy and regulatory changes may be necessary before they can use these options.
- * Vaccine prices are affected by the volume of the order, the certainty of demand and of payment, and the duration of the supply contract, as well as by product characteristics and market competitiveness. Countries can influence some determinants of vaccine prices, but others are beyond their control.
- * Markets for many older vaccines are fairly competitive; middle-income countries can usually obtain these vaccines at prices similar to those paid by Gavi, at least when they procure through UNICEF or PAHO. Some newer vaccines are produced by only one or two multinational suppliers; these firms typically charge higher prices to countries with higher average incomes.

PROCUREMENT IS THE process of acquiring goods or services; it involves defining requirements and understanding markets and potential suppliers, as well as contracting and payment. This brief focuses on vaccine procurement, which accounts for a large share of immunization expenditure.

Vaccine procurement for national immunization programs should be guided by the same basic principles that should govern all public-sector procurement, including openness, fairness, and integrity. It should be based on clear criteria and follow well-defined procedures, consistent with each country's laws and regulations. According to the World Health Organization, the objective of vaccine procurement is "to receive products of assured quality at affordable prices in a timely manner, making it possible to optimize immunization programme performance."

Vaccine procurement differs in important respects from procurement of other health commodities. First, since vaccines are given to healthy children, safety and product quality must be an exceptionally

high priority in procurement decisions. Second, most vaccines have relatively few suppliers, which limits procurement options and in some cases gives suppliers considerable leverage. Third, lead times are typically long, from 8 to 24 months, so procurement decisions must be made well in advance to avoid stock-outs. Ensuring continuity of supply and sustainable prices can also be more important than for other commodities, given the importance of long-term financial planning and the disruption associated with product switches.

Assessing vaccine products also requires specialized expertise. For example, few governments have the resources to verify that suppliers based in other countries have met appropriate manufacturing standards. For this reason, the WHO system of vaccine prequalification, which assesses the acceptability of vaccines for purchase by UN agencies, fills an important need, and many countries require that vaccines procured for their national programs be prequalified. All of the vaccines recommended by WHO for routine immunization have suppliers with prequalified vaccines.

VACCINE PROCUREMENT OPTIONS

Governments have two broad options for procuring vaccines. They can procure directly from manufacturers, using their own processes—this is known as *self-procurement* or *direct procurement*. Alternatively, they can use an external procurement agent; the two most widely used options are UNICEF Supply Division and the Pan American Health Organization (PAHO) Revolving Fund. Countries that have domestic vaccine producers can choose to procure from those suppliers. (See the sidebar below.)

The vaccines financed by Gavi for national programs are generally procured through UNICEF or, for some countries in the Americas, the Revolving Fund. Most Gavi countries also use UNICEF to procure their co-financed share of Gavi vaccines, as well as vaccines that Gavi does not financially support, such as the BCG vaccine against tuberculosis. Some countries in the Americas use the Revolving Fund, while others procure these self-funded vaccines directly.

The Revolving Fund and UNICEF (in its procurement for Gavi countries) consolidate, or pool, demand from participating countries. The resulting large volumes,

DOMESTIC VACCINE MANUFACTURING

A few middle-income countries have well-developed vaccine industries that are capable of supplying a range of important vaccines at competitive prices. India, in particular, has several firms that export prequalified vaccines, which together account for a large share of vaccines used by low- and middle-income countries. Serum Institute of India now produces more vaccine doses than any other manufacturer in the world. Other countries have manufacturers that carry out certain phases of vaccine production.

Some countries procure only from domestic manufacturers as a matter of policy. Indonesia, for example, uses only vaccines produced by Biofarma, a state-owned manufacturer, in its public immunization program. India and China have relied on both state-owned and private-sector domestic producers for their national immunization programs, while Brazil procures from two state-owned vaccine manufacturers when an appropriate product is available.

Historically, countries have made several arguments for sustaining or encouraging national vaccine production. Domestic production is often seen as a way to ensure stable supply, since a national manufacturer can be required to give priority to the national immunization program. Supply security is certainly an important consideration, although relying on a domestic firm does not protect against supply disruption caused by a production failure. Locally produced vaccines are sometimes assumed to be cheaper than vaccines from foreign suppliers, but this is not always the case; established low-cost manufacturers such as those in India have important competitive advantages that domestic producers in other countries cannot easily match. Some countries support domestic production for reasons of industrial policy.

In considering procurement from domestic sources (and investing in establishing or expanding domestic production capacity), countries may have to balance procurement criteria such as quality, timely delivery, and price against other considerations, including industrial policy and perceived vaccine security.

Vaccine Procurement Overview

along with secure financing, provide substantial bargaining power and have historically resulted in lower prices than countries have been able to obtain on their own. (See Brief 12.)

After countries transition from Gavi support, they can continue to procure through UNICEF or self-procure. Gavi is working with UNICEF and vaccine manufacturers to ensure that countries that choose to use UNICEF and are able to meet UNICEF's requirements will not face sudden price increases. Several suppliers have committed to offering these countries continued access to prices similar to those Gavi pays for selected vaccines under specific circumstances and for a specified period.

Middle-income countries that have never been eligible for Gavi support can also procure vaccines through UNICEF (or, in the Americas, through the Revolving Fund). These countries are not included in the Gavi pool, however, and do not necessarily have access to the same prices paid by Gavi. UNICEF procures vaccines on behalf of 80 to 100 countries, while 41 countries use the Revolving Fund.

In practice, many countries take a mixed approach, using UNICEF or the Revolving Fund for some vaccines and procuring others directly.

CHOOSING A PROCUREMENT OPTION

In considering whether to self-procure or make use of UNICEF or the Revolving Fund, governments should consider several factors:

- **Legal restrictions.** Some countries have laws or regulations that restrict the use of external agents for procurement or forbid prepayment, which UNICEF requires.
- **Price.** UNICEF and the Revolving Fund can often obtain lower prices than countries can get for the same products on their own. Both UNICEF and the Revolving Fund charge a small percentage of the order value for procurement services.
- **Assured supply.** Some countries have had difficulty generating responses to tenders. Although UNICEF also struggles to ensure sufficient supply of

some vaccines, it is generally in a better position than individual countries to generate bids from manufacturers and manage supply challenges.

- **Control over payment terms.** UNICEF's prepayment requirement is an obstacle for some countries, although UNICEF offers short-term financing through its Vaccine Independence Initiative. (See Brief 13.)
- **Product choice.** Countries procuring directly have complete control over product specifications (although they will find more suppliers for some choices than others). UNICEF tries to accommodate country preferences but generally procures only prequalified vaccines. The range of products available through PAHO is somewhat more limited because this pooled procurement mechanism works best when product preferences are harmonized.
- **Development of procurement capacity.** In some countries, procurement is viewed as a government function that should not be "outsourced" except in exceptional circumstances. For these countries, the use of an external agent is a temporary expedient and the goal is to build national procurement capacity as quickly as possible.
- **Domestic production.** Countries that use only domestically produced vaccines or want to favor local producers typically self-procure.

STEPS IN THE PROCUREMENT PROCESS

Procurement begins with defining and quantifying needs. How many doses of which vaccines, with which characteristics, will the national immunization program need, and when will it need them? Good demand forecasting is critical to avoiding stock-outs and waste and getting the best possible prices from suppliers. Once vaccine needs are clearly defined, the program can identify potential suppliers.

Before approaching suppliers, the entity responsible for procurement should define a procurement strategy and process, with clear specifications and criteria for evaluating bids, consistent with national law and regulations. It can then solicit offers,

evaluate bids, and choose one or more suppliers. Finally, it can arrange for contracts to be signed and vaccines to be delivered.

WHO offers guidance on vaccine procurement on its website and has produced a comprehensive manual on public-sector vaccine procurement. WHO and UNICEF also offer technical assistance on vaccine procurement, and UNICEF has an online platform for facilitating peer-to-peer exchange called the Vaccine Procurement Practitioners Network.

VACCINE MARKETS AND PRICE DETERMINANTS

Markets for different vaccines vary considerably, with implications for vaccine prices and supply. Three important newer vaccines—human papillomavirus (HPV), pneumococcal conjugate, and rotavirus—are currently produced by only two firms, which therefore have considerable control over prices. For these vaccines, multinational firms have moved toward systems of “tiered pricing” in which prices vary by country income level. Under these pricing regimes, non-Gavi-eligible middle-income countries are charged more than Gavi countries but less than high-income countries.

Some older vaccines, including those against yellow fever and measles, also have few suppliers. Nonetheless, these vaccines, which are supplied primarily by manufacturers in middle-income countries, are available through UNICEF at a uniform price, regardless of country income. Notably, these vaccines, unlike those for which tiered pricing is imposed, do not have important markets in high-income countries. (High-income countries use the measles-mumps-rubella vaccine instead of the measles vaccine.)

Finally, some vaccines have enough suppliers to ensure that markets are competitive and individual manufacturers have less influence over prices. In these markets, prices are driven to a substantial degree by manufacturing costs, and middle-income countries with efficient and transparent procurement can generally obtain prices similar to those paid

by Gavi. The market for pentavalent vaccines, for example, has become highly competitive, with eight prequalified suppliers as of 2016, and non-Gavi countries procuring through UNICEF can expect to pay roughly the same prices as Gavi countries.

Vaccine prices are influenced by a number of factors besides the cost of manufacturing and the country income tier. In general, larger volumes, longer-term contracts, greater certainty of demand, and timely payment bring lower prices. For vaccines that have large markets in high-income countries, the availability of manufacturing capacity in excess of what is needed to supply demand in these markets can also affect prices, especially for middle-income countries. UNICEF makes public the prices that it pays for the vaccines it procures for Gavi, and it plans to do the same for its procurement on behalf of non-Gavi countries. The Revolving Fund publishes weighted average prices. Until recently, however, little information has been available on prices and contract terms obtained by self-procuring countries. A new WHO initiative, the Vaccine Product, Price and Procurement (V3P) Project, seeks to fill this gap by collecting and disseminating information on vaccine prices and other aspects of procurement, with a focus on middle-income countries.

SOURCES AND FURTHER READING

UNICEF. Product menu for vaccines supplied by UNICEF for Gavi, the Vaccine Alliance. Available from: www.unicef.org/supply/files/product_menu_2016.pdf

UNICEF's Vaccine Procurement Practitioners Network: www.vppnetwork.org

World Health Organization [Internet]. Immunization, vaccines and biologicals. Procurement mechanisms and systems. Available from: www.who.int/immunization/programmes_systems/procurement/mechanisms_systems/en/

World Health Organization [Internet]. Immunization, vaccines and biologicals. Vaccine product, price and procurement (V3P). Available from: www.who.int/immunization/programmes_systems/procurement/en/

World Health Organization [Internet]. WHO prequalified vaccines. Available from: extranet.who.int/gavi/PQ_Web/

World Health Organization. Procurement of vaccine for public-sector programmes. Geneva: World Health Organization; 2003.

Pooled Procurement

KEY POINTS

- * Countries can cooperate on vaccine procurement in several ways, ranging from information sharing to pooling of demand, joint tendering, and joint contracting with suppliers. Pooled procurement is usually done through an external agent.
- * Pooled procurement can help participating countries bargain for lower prices and can ensure more secure supplies by offering suppliers larger and more predictable orders. Gains from pooled procurement are typically greatest for small countries and can vary by vaccine.
- * UNICEF Supply Division and PAHO's Revolving Fund do pooled procurement on a large scale. The Revolving Fund procures a broad range of vaccines on behalf of countries in the Americas, while UNICEF procures on behalf of Gavi as well as many middle-income countries.
- * For pooled procurement to work well, participating countries need to have reliable demand forecasts and secure, long-term financing; they must also work to harmonize regulatory requirements and product preferences. Regional cooperation in procurement outside the Americas has proven challenging, but efforts continue.

THE POOLING OF demand for vaccines by multiple countries—acting in concert or through an external procurement agent—can bring a number of benefits, including lower prices. The best-known pooled procurement schemes are those of UNICEF Supply Division and the Pan American Health Organization (PAHO) Revolving Fund. This brief examines different types of pooled procurement, outlines some of their potential benefits and drawbacks, and summarizes the experiences of UNICEF and PAHO. It also discusses challenges involved in setting up and reaping the benefits of pooled procurement and reviews the status of some efforts to expand its use.

TYPES OF POOLED PROCUREMENT

In the most fully developed form of pooled procurement, projected demand from participating countries (along with funding or commitments of funding) is aggregated by a procurement agent and presented in a single tender to suppliers, who can then bid to supply all or part of the total demand. The procurement agent then chooses suppliers, contracts and pays them, and ensures that each country receives the amount of each vaccine it requested.

In practice, the process can be more complicated because the products and terms offered by suppliers can differ and countries can have differing preferences. The agent might have to make choices if the offered supply is inadequate to meet all of the demand or if not all country preferences can be met. In awarding contracts, the agent might also want to take into account longer-term considerations, such as ensuring supply security and keeping markets competitive.

The World Health Organization distinguishes four levels of pooled procurement, which range from information sharing to the type of joint tendering and contracting described above.

PROS AND CONS OF POOLED PROCUREMENT

Pooled procurement can offer substantial benefits to countries as well as suppliers. In some circumstances, it can help participating countries obtain lower prices by allowing suppliers to manufacture on a larger scale, which usually means lower costs, and by giving participating countries greater bargaining power. The benefits are greatest for small countries that buy in small volumes and

have little bargaining power on their own, but larger countries can benefit too. Countries that participate in procurement pools managed by UNICEF and PAHO also benefit from these agencies' procurement expertise and technical assistance.

For suppliers, a big advantage of pooled procurement is dealing with a single agent rather than many individual countries. This is particularly important for developing-country suppliers, which often do not have many country offices or experience in dealing with governments in many regions. Multinational firms, with their broader reach and greater marketing resources, may prefer to deal with countries directly in some cases. In addition, UNICEF and PAHO, whose rules require them to have cash in hand before purchasing, offer suppliers certainty of payment.

Countries that participate in pooled procurement may have to cede some flexibility. In some cases, they may have to accept a more limited set of product options; pooling is more effective when product preferences can be harmonized. Participating countries must also meet the payment requirements of the particular pooling scheme. Finally, not all vaccines that a country requires may be available through a pooled procurement mechanism.

Some countries may see procurement through UNICEF or PAHO as a temporary measure, with self-procurement as the long-term goal, despite the advantages of pooling. Participation in the Revolving Fund and the use of UNICEF's procurement services have been quite stable, however.

UNICEF SUPPLY DIVISION

UNICEF Supply Division has procured the bulk of Gavi-funded vaccines since the creation of Gavi in 2000. This procurement is pooled: UNICEF aggregates projected demand for each Gavi-supported vaccine and issues periodic tenders. Most Gavi countries also procure their co-financed doses of Gavi vaccines through UNICEF, and these doses are included in the aggregated demand presented to suppliers.

In addition to its procurement for Gavi and Gavi-supported countries, UNICEF also procures vaccines for some non-Gavi-eligible middle-income countries. For traditional vaccines and vaccines with relatively competitive markets (such as pentavalent), for which suppliers do not generally try to apply tiered pricing, UNICEF can pool demand and make flexible use of long-term framework agreements to accommodate country demand. (Tiered pricing is discussed in Brief 11.)

In the case of three more expensive, newer vaccines—human papillomavirus (HPV), pneumococcal conjugate, and rotavirus—which are supplied by only two multinational firms each, tiered pricing is more of an obstacle to pooling. In 2012, UNICEF conducted a tender intended to gain some of the benefits of pooled procurement for middle-income countries while acknowledging the constraints imposed by the firms. This initiative was not as successful as UNICEF had hoped, primarily because relatively few firms submitted bids. Manufacturers cited uncertainty in country demand forecasts and concerns over making

Countries that participate in pooled procurement may have to cede some flexibility.

Pooled Procurement

prices for middle-income countries public as reasons for not participating. UNICEF plans to further explore the potential of pooled procurement for middle-income countries while continuing to procure vaccines for interested countries on an individual basis.

PAHO REVOLVING FUND

PAHO established the Revolving Fund in 1979 to help countries in the Americas obtain stable and affordable supplies of vaccines for their national programs. The Revolving Fund consolidates demand from participating countries and issues annual tenders. Unlike UNICEF, which requires that countries pay in advance, PAHO pays manufacturers from a fund established for this purpose; countries are expected to repay the fund within 60 days. The Revolving Fund is thus both a pooled procurement mechanism and a short-term financing facility like UNICEF's Vaccine Independence Initiative. (See Brief 13.) More than 40 countries and territories participate in the fund.

Historically, the Revolving Fund has been able to translate large volumes, assured payment, and bargaining power into low prices and secure supplies of most vaccines. Although participating countries—many of which are classified as upper-middle-income—pay somewhat more than Gavi countries do for a few newer vaccines, Revolving Fund prices are still far lower than those paid by high-income countries.

OTHER POOLED PROCUREMENT INITIATIVES

Regions outside the Americas have attempted to develop pooled procurement mechanisms. In particular, WHO's Eastern Mediterranean Region, which includes many non-Gavi-eligible middle-income countries, has been working toward this goal

for several years. On a smaller scale, seven countries in the Persian Gulf region, working through the Gulf Cooperation Council, issue joint tenders for some vaccines. Countries then contract with manufacturers individually.

These efforts have revealed some challenges with implementing pooled vaccine procurement. To reap the benefits of aggregating demand, participating countries must harmonize their product preferences and regulatory

requirements as much as possible, improve their demand forecasts (including introduction dates for new vaccines), and secure long-term financing. The willingness of suppliers to offer low prices will depend on all of these factors.

Historically, the Revolving Fund has been able to translate large volumes, assured payment, and bargaining power into low prices and secure supplies of most vaccines.

CONCLUSIONS

In principle, pooled procurement can bring important benefits, including more secure and affordable supply, as the examples of UNICEF and the Revolving Fund have demonstrated. Establishing pooled procurement mechanisms in other regions has proven challenging. But countries that want to do so can take important steps toward this goal by improving cooperation, including by sharing information, while working with UNICEF to address some of the challenges that hindered its recent pooled procurement initiative for middle-income countries.

SOURCES AND FURTHER READING

Pan American Health Organization. PAHO Revolving Fund. Archived at: <https://perma.cc/QR8D-M65C>

UNICEF [Internet]. Vaccine procurement services. Available from: http://www.unicef.org/supply/index_54052.html

UNICEF's Vaccine Independence Initiative

KEY POINTS

- * **The Vaccine Independence Initiative (VII) is a successful revolving fund managed by UNICEF. It provides country subscribers with flexible financing that enables steady vaccine supplies.**
- * **The VII provides credit to countries for vaccine purchase through UNICEF, with repayment due 30 days after delivery of vaccines.**
- * **Vaccines arrive several months sooner than would otherwise be expected using the fund's credit line.**
- * **More than 20 countries in Africa, the Pacific Islands, and Southeast Asia have used the fund to prefinance vaccines, injection supplies, and cold chain equipment.**
- * **In addition to applying to VII, governments that have challenges with late budget releases might also consider approaching commercial banks about commercial financing instruments for critical vaccine purchases.**

A STEADY SUPPLY of vaccines and injection supplies is critical to carrying out an effective immunization program. But procurement regulations and irregular timing of budget releases—particularly during a country's transition from donor funding to domestic funding of vaccine supplies—can cause difficulties in maintaining adequate vaccine supplies. UNICEF Supply Division requires prepayment before initiating procurement on a country's behalf. Countries may experience stock-outs of critical vaccines as a result of delays in transfers of funds to UNICEF Supply Division. To bridge this gap, UNICEF's Vaccine Independence Initiative (VII) provides more flexible financing terms for countries that need them, allowing a country to pay after delivery. Nearly 30 low- and middle-income countries have taken advantage of VII credit lines to help improve the stability of their vaccine supplies.

In 2015, the UNICEF Executive Board renewed the VII through 2020 and permitted the capital base to expand from US\$10 million to US\$100 million (if enough funding is contributed by donors). The Executive Board also approved the use of VII capital to prefinance non-vaccine commodities, such as antimalarial bed nets and nutrition products.

HOW THE VII WORKS

The VII, established in 1991, uses a capital fund to allow UNICEF Supply Division to initiate procurement on behalf of countries. Country recipients have 30 days to repay the VII once the vaccines are received and invoiced. Every participating country has a cap on the amount it can owe the VII at any one time. This helps manage the financial risk to the VII and encourages countries to reimburse the VII promptly so they can take advantage of VII credit in the future. The VII is essentially a country-specific revolving fund. It is similar in many ways to the PAHO Revolving Fund (described in Brief 12), but it serves countries in regions outside the Americas and is distinct in that the line of credit is country-specific. The VII mechanism enables vaccines to arrive several months earlier than would otherwise be possible, helping to minimize stock-outs and ensure continuous supplies. Repayment can be in the local currency if UNICEF's country program can absorb that currency in its operations.

The VII provides other important benefits. Delays in transfers of financing from countries to UNICEF Supply Division can result in postponed orders and reduce the predictability and stability of the market. Stable financing gives suppliers greater confidence that payment will be timely and helps UNICEF Supply Division procure vaccines at affordable prices.

Using the fund as leverage, UNICEF works with countries' health and finance ministries to forecast vaccine needs, determine immunization funding requirements, and budget appropriately.

The VII's funds are limited, however, and UNICEF'S ultimate goal is for countries to "graduate" from using these credit lines to meeting standard advance payment terms (using UNICEF Supply Division's procurement services) and eventually self-procurement.

WHICH COUNTRIES ARE ELIGIBLE

Any country that has a Programme Cooperation Agreement or Basic Cooperation Agreement with UNICEF can apply to the VII. Governments must also have:

- Sufficient budgetary resources to purchase the vaccines and injection supplies and/or cold chain equipment
- A VII memorandum of understanding approved and signed by UNICEF and the ministry of health
- A letter of guarantee signed by the ministry of finance for the value of the country cap (which is renewed annually while the country is a VII subscriber)

Before allowing a country to subscribe to the VII, UNICEF Supply Division works with the country to assess the status and causes of vaccine stock-outs, historical funding patterns for the national vaccine program, relevant budgeting processes, the likelihood of default, and other factors. The application to the VII is ultimately assessed by UNICEF'S comptroller and the director of Supply Division, who have discretion to approve or reject it.

WHICH COUNTRIES SUBSCRIBE

The VII has been used by both Gavi and non-Gavi countries. From 2012 to 2015, Cape Verde, Chad, Kenya, Niger, Nigeria, and the Pacific Island countries were all subscribers. Several countries have graduated from the VII, including Morocco and the

Philippines. As of mid-2016, discussions were ongoing with other potential subscribers.

Some Gavi-eligible countries, such as Kenya, have used the VII to purchase traditional vaccines and to meet Gavi co-financing procurement requirements. As Gavi-eligible countries transition to full self-financing, the VII mechanism could remain useful in providing financial flexibility.

Countries most likely to benefit from the VII include:

- Countries outside of Latin America (which have no access to the PAHO Revolving Fund)
- Countries that do not intend to self-procure
- Countries that are likely to have cash-flow timing challenges

Middle-income countries that were never Gavi-eligible can benefit from the VII if they are struggling with cash-flow timing for vaccine procurement and cannot find other appropriate solutions. In addition to subscribing to the VII, countries can explore commercial bank financing for lines of credit or guarantees to provide more liquidity when the timing of government budget releases is an issue.

As of February 2016, the VII had helped finance BCG, hepatitis B, OPV, IPV, DT, TT, Td, measles, MR, MMR, PCV, rotavirus, HPV, yellow fever, meningococcal, and cholera vaccines; DTP-containing vaccines; Hib-containing vaccines; and injection supplies. The fund has also prefinanced cold chain equipment.

Countries interested in exploring the VII's services can contact UNICEF for more information.

FURTHER READING

For archived information on UNICEF'S Vaccine Independence Initiative: <https://perma.cc/FV2R-TEZS>. See the UNICEF website for current information (www.unicef.org).

How Provider Payment Approaches Affect Immunization Services

KEY POINTS

- * The methods used to pay health care providers to deliver immunization services affect the incentives providers have to make immunization a priority.
- * The most common provider payment methods are line-item or global budgets, fee-for-service payments, and capitation payments. Each method has strengths and weaknesses, so they are often combined or used with performance-based incentives. Some countries are experimenting with tying performance incentives to immunization coverage targets.
- * Performance-based payment for immunization has the potential to increase coverage, but results have been inconclusive in low- and middle-income countries. Sustainability is a concern when these programs are donor-supported.
- * The right mix of payment methods depends on the country context, so good monitoring systems are needed to track the effects of incentives on immunization.

FRONTLINE PROVIDERS SUCH as primary health care clinics are the critical final link in the chain of immunization service delivery. The way health care providers are paid to deliver immunization services affects the financing and staffing of service delivery as well as how actively providers work to ensure that the target population receives them. Purchasers, such as ministries of health or public insurance agencies, use a range of payment mechanisms to transfer funds to health provider institutions to deliver covered services. These payment mechanisms create economic signals, or incentives, that influence provider behavior—the volume of services they deliver, how they deliver them, and the mix of inputs they use. In the case of immunization programs, strategically designed payment mechanisms should create incentives for providers to achieve coverage targets and deliver high-quality services efficiently. On the other hand, poorly designed provider payment mechanisms with chronically low payment rates can put immunization services at a disadvantage compared to more highly paid curative services and contribute to underprovision of services and missed opportunities to expand coverage.

COMMONLY USED PAYMENT METHODS

Many countries still fund health service delivery through input-based line-item budgets—giving health facilities specific budgets for staff, utilities, equipment, and so on. Line-item budgeting is often rigid and can create numerous inefficiencies and inequities in health service delivery. These budgets are often historically based and not aligned with the health needs of different populations. They often have a bias toward urban areas and tertiary facilities that leaves primary health care, and particularly preventive services such as immunization, underfunded. It is often difficult to move expenditures across line items to meet service delivery needs. Finally, line-item budgeting does not allow for efficiency and quality incentives to providers.

In the case of immunization programs, strategically designed payment mechanisms should create incentives for providers to achieve coverage targets and deliver high-quality services efficiently.

For these reasons, many countries are moving toward more strategic provider payment approaches that are based on outputs rather than inputs and that reward providers for productivity, quality, and efficiency. One payment type is fee-for-service, which pays providers by the individual service, such as each immunization delivered. Capitation (per capita) payment gives providers a fixed payment per enrolled person for a defined package of services for a fixed period of time. Immunization services are typically included in the defined package.

There is no gold standard or perfect payment method. Each method has strengths and weaknesses, and each can create adverse incentives and unintended consequences. Capitation payment can be more equitable and create incentives for providers to focus on prevention and keep the enrolled population healthy. But it can also lead providers to underprovide services once they have received their fixed payment, resulting in poor quality of care or excessive referrals. Fee-for-service payment, on the other hand, can increase access and use of priority services but also lead to cost escalation.

Many countries combine payment methods to create a *blended payment system*, or *mixed model*. For example, a capitation payment system for primary care can include a small amount of fee-for-service payment for priority preventive interventions (such as immunization) to counteract the potential incentive to underprovide services. In Romania, as part of a reform program to strengthen primary care and prevention, primary care providers received 60% of their revenue from capitation payments and 40% from fee-for-service for priority services including immunization.

Any payment method can also be combined with specific performance-based rewards or penalties; this is known as *pay-for-performance (P4P)* or *results-based financing (RBF)*.

Performance incentives can be tied to immunization coverage targets. In Estonia's social health insurance system, capitation payment for primary care is combined with a pay-for-performance program that provides additional financial incentives for achieving immunization coverage targets.

PAY-FOR-PERFORMANCE

P4P mechanisms are used in health systems in all regions of the world by countries at all income levels. The aim is to create financial incentives that encourage better quality of care and coverage of high-priority services such as immunization. In many low-income countries with largely public service provision and health personnel who are salaried civil servants, P4P is often introduced to address low productivity and inadequate coverage of priority services, including immunization. For example, P4P programs in Afghanistan, Burundi, and Rwanda pay providers a per-service bonus on top of their line-item budgets, adjusted by a quality score, for delivering a set of priority services that includes childhood immunization.

Many countries are moving toward more strategic provider payment approaches that are based on outputs rather than inputs and that reward providers for productivity, quality, and efficiency.

How Provider Payment Approaches Affect Immunization Services

Despite the widespread use of P4P, there is limited evidence on its effects on health service delivery and population health outcomes, and the evidence that is available remains mixed. This is also true for P4P efforts aimed specifically at improving immunization coverage. Evaluations of P4P programs in Afghanistan, Burundi, Rwanda, and Tanzania show no significant effect on coverage of childhood immunization. P4P programs in low-income countries also tend to be donor-driven, which gives rise to concerns about sustainability.

P4P has been linked to increases in childhood immunization coverage in some higher-income countries, however. A study of 11 P4P programs in Organisation for Economic Co-operation and Development (OECD) countries found that P4P programs in Estonia and New Zealand resulted in modest increases in coverage rates for childhood immunization.

IMPLICATIONS FOR IMMUNIZATION

How providers are paid to deliver services affects the mix of services they deliver and how they deliver them. Payment systems must therefore be carefully designed and combined to ensure that immunization services are rewarded and not neglected by providers in favor of other, more highly paid, services. Singling out immunization for fee-for-service payment or providing bonuses for achieving immunization coverage targets may encourage providers to focus on immunization. But the evidence is inconclusive, particularly in lower-income countries, and P4P programs in particular may create sustainability concerns when they are donor-driven. The right mix of payment methods depends on many contextual factors in the country, so good monitoring systems to track the effect of incentives on immunization are essential.

The right mix of payment methods depends on many contextual factors in the country, so good monitoring systems to track the effect of incentives on immunization are essential.

SOURCES AND FURTHER READING

Cashin C, editor. Assessing health provider payment systems: a practical guide for countries working toward universal health coverage. Joint Learning Network for Universal Health Coverage; 2015.

Eichler R, Levine R, Performance-Based Incentives Working Group. Performance incentives for global health: potential and pitfalls. Washington D.C.: Center for Global Development; 2009.

Merilind E, Salupere R, Västra K, Kalda R. The influence of performance-based payment on childhood immunisation coverage. Health Policy. 2015 Jun 30;119(6):770-7.

PART IV

STRATEGIES FOR POLICY CHANGE

Building Parliamentary Support for Immunization Financing

KEY POINTS

- * Immunization advocates should engage key actors in parliaments, including parliamentary leaders, standing and ad hoc committees, and secretariat staff.
- * When engaging with policymakers, advocates should be prepared to discuss the performance of the country's immunization program, its challenges, and its present and anticipated resource needs.
- * Advocates can use the key points presented in each brief in this resource guide as primers for parliamentarians on critical issues related to immunization financing.

THE POLICIES AND practices discussed in this volume cannot be implemented without the support of governments. Although ministries of health and finance implement the relevant policies, national parliaments also play a crucial role. Legislative power is typically held by a parliament or other representative body. Parliaments also have the power to direct the flow of public funding to public projects, which are then implemented by the executive branch. Parliaments or congresses can enact legislation that mandates the introduction of new vaccines, approve and amend the budgets for immunization programs, establish financing mechanisms for immunization services, and oversee the implementation of new immunization-related policies.

This brief explores how immunization advocates can engage effectively with parliaments to build support for sustainable immunization financing.

HOW PARLIAMENTARY FUNCTIONS AFFECT IMMUNIZATION FINANCING

Parliaments have four main functions, each relevant to sustainable immunization financing:

- **Lawmaking/legislating.** Members of parliament introduce bills, propose amendments, and vote on legislation that affects all government functions. Immunization legislation is an example of this function. (See Brief 16.) Parliamentarians can also endorse resolutions and make declarations that express support for a particular issue; these can be important milestones toward future legislation.
- **Budgeting.** Parliaments approve the collection and allocation of national revenues by setting the country's annual budget. The executive branch typically proposes the budget, but parliament must approve it. The budget for the ministry of health includes, in most countries, a line item for vaccines.
- **Oversight.** The parliament oversees and monitors executive branch actions to ensure that public resources are used responsibly and consistently with legislative directives. In practice, it does this primarily through the annual budget process, which provides a regular check on the executive's power and involves review by multiple committees and members of parliament. Parliamentary committees can also hold hearings and call expert witnesses to provide testimony on the operations of government and matters of national policy. This can provide immunization advocates with an opportunity to press for sustainable immunization financing. The relationship between parliament and the executive branch can vary—some parliaments have significant capacity to check the powers of the executive, while others have less authority to direct and oversee executive action.

- **Representation.** Members of parliament serve as representatives of the people and, more specifically, of the constituents in their legislative districts. They can amplify the voices of constituents by advocating for their interests in the chambers of parliament and in parliamentary committees. Advocates for immunization can therefore influence parliament by mobilizing local constituencies.

STRATEGIC ENTRY POINTS FOR WORKING WITH PARLIAMENTS

Although parliamentary structures vary (for example, in the number of chambers and the makeup of committees), a number of discrete actors within the parliamentary process are most influential in determining immunization financing agendas. They include:

- **Parliamentary leaders.** The leaders of the majority and opposition parties and other senior members of parliament tend to set the legislative agenda, assign bills to particular committees, and rally support for legislative initiatives.
- **Committees.** Much of the work of parliament is conducted through standing (permanent) or ad hoc committees, whose members and leaders reflect the parliament's political configuration and generally set a committee's agenda. Support staff, including staff attached to members, committees, and nonpartisan secretariats, can play an important role behind the scenes and therefore merit engagement by advocates. In terms of immunization financing, committees can review legislation related to public immunization services, ensure consistency with existing national and international legal frameworks, and evaluate the government's performance in implementing new laws.
- **Specific committees.** Standing committees on finance and appropriations are a key target for issue advocates because they review all requests for government spending. Without the approval of these committees, a spending bill is unlikely to be adopted by parliament as a whole. Health committees, which consider immunization programs and budgets, are another obvious target of advocacy efforts. These might be organized as separate committees or subsumed under committees on social affairs or social welfare or grouped with women, youth, sports, or labor. These broad committees generally have subcommittees dedicated to health issues.
- **Secretariat staff.** Secretariat staff ensure that members of parliament have the information they need to make informed legislative decisions. They help arrange committee meetings and hearings and can be important sources of institutional memory. Advocates can ensure that secretariat staff are copied on all communications to committees and members of parliament. They can also maintain contacts with parliamentary library, research, and documentation staff to ensure access to relevant documents and information related to immunization programs and financing.
- **Influential members of parliament.** Particularly well-regarded, charismatic, or effective members of parliament can be influential without holding positions of seniority within the formal parliamentary structure. They often become champions for particular issues and collaborate with advocates to further their agenda.
- **New members of parliament.** With each election cycle, new members of parliament look for areas of legislative focus where they can have a lasting influence. If engaged early on issues of immunization and immunization financing, they can become active champions.

International unions of parliaments can be influential in shaping and determining regional agendas and policies. In 2009, for instance, the Latin American Parliament, a consultative assembly, generated a Model Vaccine Law, drawing on the experience of countries within the Pan American Health Organization (PAHO). The law provides a framework for PAHO region countries to ensure adequate and effective access to, and financing and operation of, national immunization services.

KEY MESSAGES TO PARLIAMENTS ON IMMUNIZATION FINANCING

Parliamentarians need timely, accurate, and targeted information in order to make informed legislative decisions. The key points presented in the briefs in this volume offer a succinct summary of the major issues, challenges, and opportunities related to immunization financing. Among the most important of these for parliamentarians to understand and act on are the following:

- Vaccines are among the most powerful and effective public health interventions ever developed.
- Immunization is good value, and one of the best uses governments can make of limited public resources for health. For every \$1 invested in immunization, countries can realize \$16 in returns for the broader economy.
- Governments must plan carefully to ensure adequate and sustainable financing for immunization programs. Failure to invest in immunization—or unstable immunization financing—increases the risk of disease outbreaks and endangers public health.
- Strong immunization program performance depends not only on funding for vaccine purchases but also on adequate financing of primarily local-level health workers and facilities, who deliver routine immunization as part of a broader program of health services.

Key questions parliamentarians may have about the country's immunization services include:

- How is my country's immunization program performing? (What are the coverage rates for vaccines in the national schedule, how equitable is coverage, and how do they compare to targets? What vaccines are in the national schedule compared to WHO's recommended schedule?)

- What does the future of the immunization program look like? (Will coverage change over time? Are new vaccines likely to be introduced?)
- Is the immunization program adequately funded? (Are vaccine budgets adequate? Are investments in the cold chain suitable?)
- As financing is only one part of the picture, what other bottlenecks are impeding program performance and how might they be addressed?

EFFORTS TO ENGAGE PARLIAMENTARIANS ON IMMUNIZATION FINANCING

Many organizations—including UNICEF, the World Bank, and the World Health Organization—have actively engaged with parliamentarians on issues of health and human development. The Sabin Vaccine Institute has been a leader in this effort through its Sustainable Immunization Financing (SIF) Program. The program has worked in 22 countries—12 in Africa, six in Asia, and four in Eastern Europe—to provide technical and legislative guidance on promoting and protecting immunization financing.

The SIF Program convenes national and subnational briefings for policymakers, parliamentarians, and other government officials and facilitates peer-to-peer exchanges, workshops, and meetings on best practices and progress in achieving sustainable immunization financing. As of mid-2016, the program had contributed to the launch of legislative initiatives in several SIF countries, all of which are transitioning or close to transitioning from Gavi support. In 2014, Nigeria became the first SIF country to pass new immunization financing legislation, thanks in large part to the efforts of parliamentarians in the health committees of the senate and house of representatives.

SOURCES AND FURTHER READING

Advocacy for Immunisation [Internet]. PATH, IVAC, and Gavi resources to assist in advocacy for immunization.

Available from: <http://advocacy.vaccineswork.org/>

Committee for the Future of Vaccination in Latin America (COFVAL). Framework act on vaccination for Latin America. 2009.

Archived at: <https://perma.cc/C2NR-YBMW>

Ozawa S, Clark S, Portnoy A, Grewal S, Brenzel L, Walker DG. Return on investment from childhood immunization in low- and middle-income countries, 2011–20. *Health Affairs*. 2016 Feb 1;35(2):199-207.

UNICEF. Guide to working with parliaments. New York: UNICEF; 2009. Archived at: <https://perma.cc/6KUR-B6PE>

World Health Organization. Immunization advocacy library. WHO Regional Office for Europe. Available from: <http://www.euro.who.int/en/health-topics/disease-prevention/vaccines-and-immunization/publications/immunization-advocacy-library>

Immunization Financing Legislation and Regulation

KEY POINTS

- * Immunization advocates consider legislation to be a powerful tool in support of sustainable immunization financing because it provides a legal commitment to immunization and an operational framework for immunization services.
- * Legislation can be effective only if it is enforced and implemented by the government.
- * Immunization legislation frequently includes three types of legal provisions: operational, declarative, and financial.

TO MANY IMMUNIZATION advocates, immunization legislation is a potentially powerful tool in support of sustainable immunization financing. Legislative action can provide a legal commitment to public funding of immunization, which can help secure adequate financing and promote accountability and transparency. The Global Vaccine Action Plan 2011–2020 recommends ensuring “legislation or legal framework in all countries, including provision for a budget line for immunization, and for monitoring and reporting” to support the strategic objective that all countries commit to immunization as a priority. Legislation can also provide a legal framework for the operation of immunization programs, including how vaccines are added to the national immunization schedule and who has regulatory oversight.

Explicit legislation can also help clarify legal frameworks for the procurement of vaccines and injection supplies. Some countries in Latin America, for example, have legislation that explicitly provides for procurement through the Pan American Health Organization (PAHO) Revolving Fund. Other countries have procurement regulations that restrict payment in advance of delivery, making it difficult for ministries to procure vaccines and injection supplies through UNICEF Supply Division.

Immunization legislation varies across countries. Some countries have separate immunization laws; others legislate immunization through provisions within general health acts or public health laws. Countries have also taken different approaches to the legislation

of immunization financing. In Vietnam, the Law on Prevention and Control of Infectious Diseases guarantees “funds for the use of vaccines and medical bio-

products,” while Bolivia’s Law on Vaccines mandates that a specific share of earmarked funds for health go toward vaccines and associated syringes and operational costs. Some laws, such as Georgia’s Public Health Law, require the financing of vaccines in the national immunization schedule; others, such as Panama’s Law 48, enshrine access to vaccines in the national immunization schedule as a legal right for all citizens.

Legislative action can provide a legal commitment to public funding of immunization, which can help secure adequate financing and promote accountability and transparency.

Legislation is only as strong as its enforcement and implementation, however. The adoption of an immunization law is not in itself a guarantee of sustainable financing. It might be only a milestone on the road to sustainable immunization financing.

This brief examines legal provisions in immunization legislation enacted by various countries and discusses recent efforts by the Sabin Vaccine Institute and by PAHO and the Latin American Parliament to promote sustainable immunization financing through legislative action.

COMMON PROVISIONS IN IMMUNIZATION LEGISLATION

Immunization legislation can include a variety of provisions. According to a 2013 study by Trumbo et al. that analyzed immunization legislation in 24 countries and three territories in the Latin America and Caribbean region, the most common provisions fall into three categories: declarative, operational, and financial.

Declarative provisions establish legal rights and duties relating to access to immunization. Some countries mandate universal access to immunization for all citizens; some adopt legislation recognizing immunization as a public good. Many countries establish clauses guaranteeing free and universal access to vaccines in the national immunization schedule. Legislation can also establish a legal duty to vaccinate and call for mandatory vaccination for adults and children (particularly in the context of school enrollment).

Operational provisions in immunization legislation provide a legal framework for public health authorities relating to

immunization. These provisions may establish regulatory oversight of immunization programs to ensure that vaccines are administered in accordance with legislative directive. They may require a legally chartered national immunization technical advisory group (NITAG). In countries with mandatory vaccination, operational provisions may set legal penalties for individuals who fail to comply.

Immunization legislation often includes an operational provision that governs the national immunization schedule. Such a provision usually defines the process by which vaccines are introduced and removed from the schedule, who is empowered to make the decision, what the decision-making criteria are, who has oversight over the decision-making process, and so on. These elements are critical for both routine vaccine delivery and the financial needs of national immunization programs.

Financial provisions establish the legal framework for immunization financing. They might establish explicit line items within the national budget for the procurement of vaccines and for other elements of the immunization program; identify the procurement mechanisms that must be used; and guarantee tax exemptions for the purchase and importation of immunization materials (including vaccines and cold chain equipment).

The adoption of an immunization law is not in itself a guarantee of sustainable financing.

Financial provisions might also establish the sources of immunization financing. Many countries have adopted legislation declaring that the government must pay for immunization, but immunization laws typically do not define the mechanism by which immunization should be financed.

EFFORTS TO SUPPORT IMMUNIZATION LEGISLATION

The Sabin Vaccine Institute's Sustainable Immunization Financing (SIF) Program has supported efforts by immunization advocates and policymakers in 22 countries to develop or update immunization legislation. The program convenes national and subnational briefings for policymakers, parliamentarians, and other government officials and facilitates peer-to-peer exchanges, workshops, and meetings on achieving sustainable immunization financing. To date, the program has guided three countries in passing laws that mandate public funding for immunization.

The SIF Program recently worked with immunization advocates to push for Nepal's Immunization Act, which became law in 2016. The law outlines a fiscal framework for the country's immunization program, including financing provisions. As of August 2016, six other SIF countries had adopted immunization legislation.

In 2010, the Latin American Parliament, in conjunction with PAHO, developed a model vaccination law that could serve as a framework and template for revisions to existing legislation in Latin American countries or as the basis for new legislation. The law includes declarative, operative, and financial provisions that can be tailored to suit particular countries.

Many countries have adopted legislation declaring that the government must pay for immunization, but immunization laws typically do not define the mechanism by which immunization should be financed.

SOURCES AND FURTHER READING

Committee for the Future of Vaccination in Latin America (COFVAL). Framework act on vaccination for Latin America. 2009. Archived at: <https://perma.cc/C2NR-YBMW>

Sabin Vaccine Institute [Internet]. Legislation. Available from: <http://www.sabin.org/programs/sif/legislation>

Trumbo SP, Janusz CB, Jauregui B, McQuestion M, Felix G, Ruiz-Mata C, Andrus JK, Quadros CD. Vaccination legislation in Latin America and the Caribbean. *J Public Health Policy*. 2013 Jan; 34(1):82-99.

World Health Organization. Global vaccine action plan 2011–2020. Available from: http://www.who.int/immunization/global_vaccine_action_plan/en/

Immunization Planning and the Budget Cycle

KEY POINTS

- * Domestic public funding is the most important source of immunization financing, and immunization planning and financing must be considered as a part of the broader budget process.
- * Understanding budget cycles and processes is crucial to finding opportunities and mitigating financial risks for immunization efforts.
- * Existing planning tools can help with estimating costs, identifying sources of financing and resource gaps, and formulating arguments in favor of immunization investments.
- * Standalone planning for immunization disconnected from the national budget can lead to fragmentation and budgeting problems and make it difficult to win support for immunization goals and build integrated processes.

IMMUNIZATION PLANNING AND budgeting should align with overall government public financial management rules as well as health sector objectives. This brief examines the phases of the budget cycle, issues that can result from misalignment of budget processes, and ways to link immunization planning to health and broader planning processes.

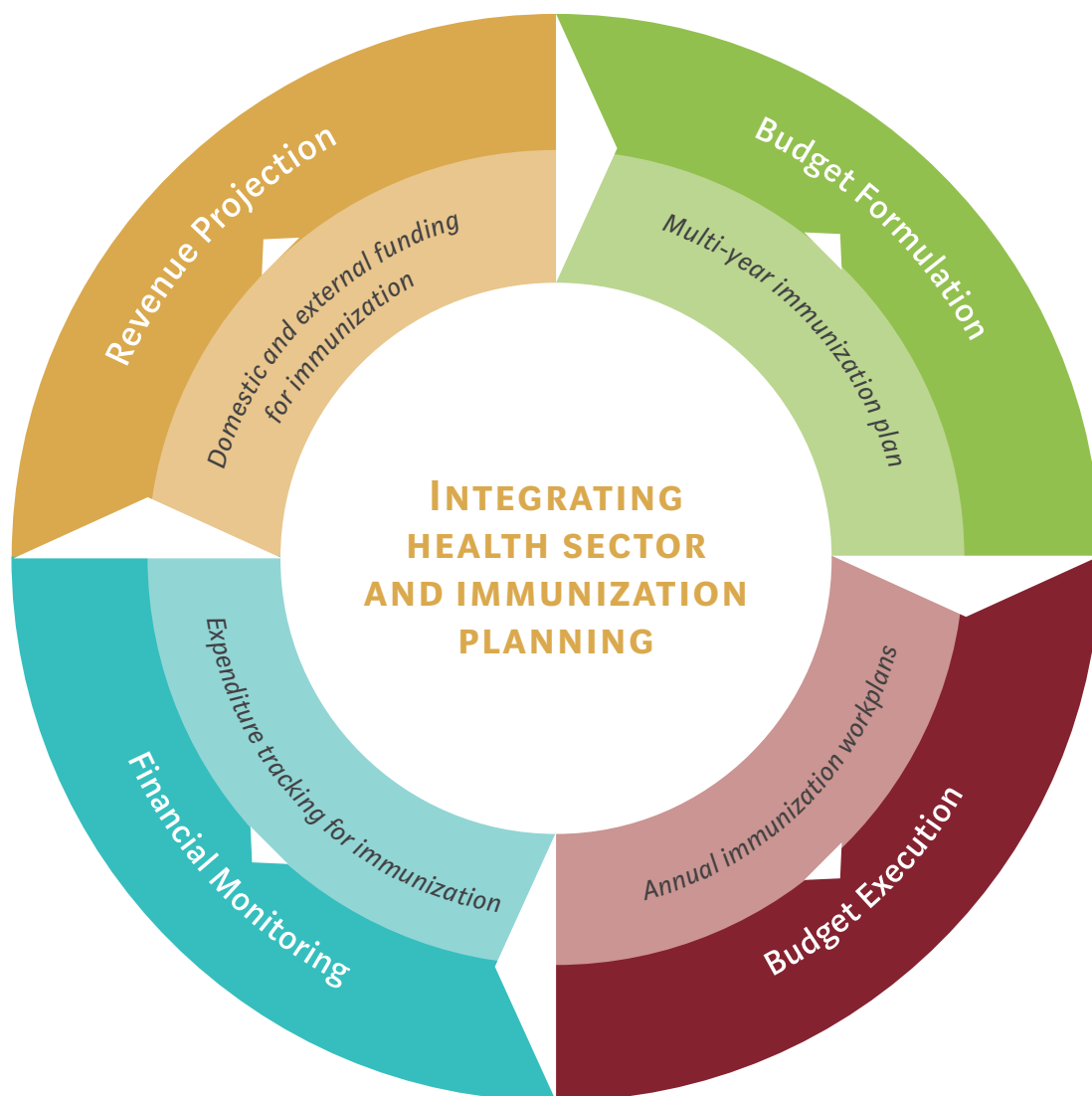
THE BUDGET CYCLE

Every government follows a budget cycle that includes phases for policy-based revenue projection, budget formulation, budget execution, and monitoring. In many countries, however, the budget planning tools and processes for the health sector in general and immunization programs in particular are not well integrated into this cycle. When budget processes are misaligned and funding is not available when and where needed, the consequences can be severe, hampering health sector and immunization-specific efforts that are essential to progress toward universal health coverage. (See Brief 2.) Understanding a country's budget cycle is important for effective immunization advocacy and planning, as shown in the figure on the next page.

REVENUE PROJECTION

The budget cycle starts with revenue projection. The ministry of finance determines what level of overall expenditure is feasible, given existing policy objectives, expected revenues, and the level of national deficit. The better a government is at projecting revenue across sources—for instance, across different streams of “on-budget” revenue—the more credible the budget will be and the more timely and complete budget execution (spending against needs) will be. Countries with high donor funding may have “off-budget” streams—for instance, those that go directly from a donor to an implementing partner and do not pass through government accounting systems—for immunization and other services. This can lead to budget fragmentation and lack of transparency and reduce the government's ability to identify where limited public funds can have the most impact. Getting a full estimate of potential on- and off-budget external funding for immunization, along with other health revenue streams, is critically important to getting a clear fiscal picture and determining realistic health spending levels.

OPPORTUNITIES TO INTEGRATE IMMUNIZATION PLANNING INTO THE BUDGET CYCLE



Adapted from WHO-UNICEF Guidelines for cMYP for Immunization (September 2013)

BUDGET FORMULATION

During the budget formulation phase, funds are negotiated (with line agencies), reviewed (by the cabinet or another body), approved (by the parliament or other body), and allocated across line agencies (by the ministry of finance or the treasury). In most countries, much of the work of parliament is conducted through permanent or ad hoc committees whose members and leaders reflect the parliament’s political configuration. (See Brief 15.) These

committees often drive the approval of spending on both broad and specific issues. For instance, standing committees on finance and appropriations review all requests for government spending and are therefore a key target for advocacy, including for immunization funds. Health committees, which consider immunization programs and budgets, are another target, as well as individual parliamentarians who advocate for particular issues both within and outside of committees.

Immunization Planning and the Budget Cycle

Budget negotiations often include a consultative phase in which subnational governments provide evidence-based indications of need across cost centers and administrative units. This phase, known as “bottom-up planning,” may or may not be well coordinated with the timing of the broader budget formulation and approval process. If it is, this phase can be an important entry point for advocates. If it is not, immunization advocates might push for better accountability or consultation mechanisms. Once the broad health budget is approved by the ministry of finance, the ministry of health determines spending priorities among programs and services within its budget allocation and in line with agreed-upon policy priorities, such as immunization.

The overall budget framework and national budget law partly dictate how ministries allocate funds. If the rules are rigid, they can constrain the ministry of health when it comes to pooling and redistribution

according to need, as well as to strategic purchasing of vaccines and services. For example, the budget might have a line item for vaccines that does not reflect actual levels of need, or a program budget might include particular outcome or output indicators for defined program areas that are misaligned with program goals. If the country has a multi-year, combined bottom-up and top-down planning process in place, such as a medium-term expenditure framework (MTEF), the ministry of health budget might be projected across a number of years, which can aid in planning. (See the sidebar below.) For instance, if the ministry of health budget grows over time, this might create fiscal space for immunization financing from domestic sources. (See Brief 5.) If the budget remains flat or declines, resources for a growing immunization program will have to come from efficiency gains, reallocations within the health budget, or new external financing.

MEDIUM-TERM EXPENDITURE FRAMEWORKS

Over the past 20 years, countries have adopted a more sophisticated approach to planning and budgeting: the medium-term expenditure framework (MTEF). The framework was developed in the early 1980s, and by 2008 it had been adopted by more than two-thirds of all countries, although it is not functioning perfectly in all cases. MTEFs help policymakers align government priorities with what they can afford by creating multi-year plans, typically covering three to five years.

MTEFs include macroeconomic and fiscal targets and projections of the resource envelope to help establish expenditure ceilings for sectors and agencies, which in turn guide bottom-up planning. The level of detail in an MTEF varies by country, but this approach enables transparent allocation of public resources against strategic priorities, creating an activity- and output-based orientation. Expenditure allocations can be set at the spending agency level or can be more comprehensive. Ghana’s MTEF, for example, includes immunization coverage as an output indicator.

MTEFs can also be combined with program-based budgeting, an annual monitoring and evaluation tool and budget framework that defines program areas, outcomes, and outputs as well as key performance indicators for programs within or across line ministries.

Without this kind of comprehensive, multi-year planning process, budgeting problems can occur. For example, a national health strategy or plan may function only as a laundry list of activities and may lack cost information that can help guide implementation. In addition, disease-specific plans that are not linked to the national strategy may proliferate in isolation across technical areas (including immunization). Compounding this issue, these separate plans may not be linked in any specific way to the budget formulation or costing process, which can impede coordination between the ministry of health and the ministry of finance. If cost data are not available, or if planning processes dictate, budgeting may be based only on historical estimates, making it more difficult for immunization advocates to win support for emerging goals and changing needs. Finally, if plans are not linked to annual budgeting, it will be nearly impossible to nurture integrated, longer-term planning processes, such as inclusion of immunization in the MTEF.

An understanding of immunization costs at the budgeting and planning phase can help advocates argue for continued support or expanded need as an integral part of health sector requests and to integrate immunization into the MTEF, program budgets, and other key planning processes. These include health sector strategic planning decisions that inform pooling and redistribution according to need, vaccine procurement, and strategic purchasing for services. The World Health Organization maintains country-by-country data on planning cycles, fiscal year dates, the years that recent national and subsector plans cover, and a document repository that can help with advocacy planning efforts.

One tool that can help with integrated health and fiscal planning is the comprehensive multi-year plan (cMYP). (See the sidebar below.) The WHO website also offers several other tools for forecasting vaccine requirements and determining the need for injection supplies, logistics, and cold chain equipment and

THE COMPREHENSIVE MULTI-YEAR PLAN (cMYP)

Launched in 2006 by WHO and UNICEF, the cMYP is an immunization-specific planning tool that encompasses immunization planning, costing, and financing. While the outputs are intended for use in budget submissions and national health plans, ministries of health often develop these plans separate from broader health-sector planning.

Creating a cMYP involves several phases: developing a situation analysis; determining specific activities, milestones, and strategies; identifying links to national, regional, and international goals; preparing activity timelines and monitoring and evaluation plans; estimating immunization-specific costs (such as for vaccines, injection supplies, and full-time staff); and identifying financing sources. Shared costs can also be estimated.

Effective cMYPs rely on government consultation and collaboration with civil society, partners, and the private sector. In practice, cMYPs vary in quality, but these plans and the process of preparing them have generally made a strong contribution to immunization planning. Each cMYP should be updated annually, and Gavi requires an updated cMYP from governments when a new vaccine or campaign is introduced. Applications for health system strengthening support require both a cMYP and a national health plan, and that support must align with the national planning and budget cycles. When accurate and up to date, cMYPs can be used to advance the budget process and promote dialogue between the ministry of health and the ministry of finance.

Immunization Planning and the Budget Cycle

supplies. It also maintains a database of cMYPs. The Pan American Health Organization (PAHO) offers an Immunization Toolkit with an Annual Plan of Action, which informed the guidelines for cMYPs. It also provides resources on vaccine forecasting, supply chain sizing, and logistics forecasting; a cold chain volume calculator; and a vaccine presentation assessment.

BUDGET EXECUTION

In the budget execution phase, public financial management systems should support efficient disbursement, receipt, and use of funds by cost centers to purchase immunization services and commodities (including vaccines and cold chain equipment and supplies) and fund costs related to service delivery. These funds are often spread across many levels of the system, but they should be allocated according to health needs and through line-item, input-oriented payment systems (payment according to materials needed to produce an output) or output-oriented payment systems (payment according to what is produced rather than used). (See Brief 14.)

In practice, many governments face challenges with transferring funds on time or in full, which hampers program execution. For instance, a baseline survey of immunization bottlenecks in the Republic of the Congo found that disbursement delays and commitment shortfalls from the state budget contributed to vaccine shortages around the country. Fund flow issues can occur at many points throughout the system, depending on how the system is organized and what entities are responsible for receiving and disbursing funds to progressively lower levels. For example, a program might be sufficiently funded at the national level but have difficulty getting funds to facilities due to poor systems, weak accounting, or corruption and leakage. Politics can also affect the flow of funds for health. For instance, if a district bank account holds funds that are meant for both health and non-health priorities, determining how to allocate the funds between these priorities can be a challenge. In addition, rigidities

in the public financial management system can prevent the use of strategic purchasing that promotes quality immunization service delivery or rational procurement. Finally, decentralized countries may face issues in managing budgets and coordinating procurement across levels. (See Brief 25.) To help address these issues, policymakers in the ministry of health should work to align annual immunization work plans with annual health sector and individual program work plans.

BUDGET MONITORING

Policymakers and advocates need to understand how money is being spent in order to ensure accountability, efficiency, and equity and to inform spending decisions. The ministry of health can help provide this information by tracking funding flows and linking funds to expenditures on services produced or inputs purchased (such as vaccines, cold chain supplies, and/or other commodities). The ministry of health must also use measures such as internal audits to ensure accountability and inform the next budget cycle. (See the figure shown earlier.)

Output-based mechanisms such as the MTEF and program-based budgeting can create incentives for the ministry of health to track immunization-related results as well as inputs purchased. This information is crucial to disentangling the causes and effects of underspending. For instance, underspending might be the positive result of system efficiencies that make existing funds go further, or it might result from poor financial management, limited capacity on the part of units that receive funds to spend those funds, late disbursement, or inadequate capacity to track and account for expenditures.

Monitoring can also be a challenge if responsibility for implementing programs is fragmented or if the program components themselves—such as immunization and maternal and child health—are not integrated. Tracking of immunization spending should be integrated into general accounting and accountability measures to provide a holistic view of expenditures.

SOURCES AND FURTHER READING

Allen R, Hemming R, Potter BH. International handbook on public financial management. New York: Palgrave Macmillan; 2016.

World Health Organization. WHO-UNICEF guidelines for comprehensive multi-year planning for immunization: update September 2013. Geneva: World Health Organization; 2014.

cMYP: http://www.who.int/immunization/documents/WHO_IVB_14.06/en/

cMYP database: http://www.who.int/immunization/programmes_systems/financing/countries/en/

EPI planning: <http://www.paho.org/immunization/toolkit/epi-planning.html>

MTEF: <https://openknowledge.worldbank.org/handle/10986/11971>

WHO country planning cycles: <http://www.nationalplanningcycles.org>

Key Questions for Immunization Advocates

KEY POINTS

- * Immunization advocates can benefit from knowing pertinent questions to ask about a country's immunization program.
- * The questions in this brief can also be useful in discussions with governments and donors.

THE FOLLOWING QUESTIONS can guide advocates in learning about a country's immunization program and associated program financing; challenges that the program faces; and options for addressing those challenges. These questions can also be used in discussions with governments and donors and to help hold them accountable.

OVERALL PRIORITY FOR IMMUNIZATION

- Is immunization clearly identified as a priority in the national health plan?
- What immunization targets has the government committed to, if any?
- Are immunization indicators used to monitor the success of health strategies and plans?
- Is immunization clearly identified as a priority at the subnational level?

PROGRAM PERFORMANCE

- How high is immunization coverage? Note that World Health Organization / UNICEF diphtheria-tetanus-pertussis (DTP3) coverage estimates are often used as a proxy measure for overall performance.
- How does coverage compare to that of peer countries?
- Is coverage stable, improving, or declining? If coverage is declining, why?

- How equitable is immunization coverage? How widely does it vary across geographic regions, income levels, and ethnic groups within the country? (DTP3 coverage by district and by income quintile are often used as indicators.)

VACCINES IN THE NATIONAL SCHEDULE

- What vaccines are in the national immunization schedule? How does this list compare to WHO's recommended schedule?
- Which of the newer vaccines—such as rotavirus, pneumococcal, and HPV—have been introduced?
- Which vaccines is the government planning to introduce next?
- Does the government have a financial plan for the vaccines it plans to introduce?
- Does the country have a national immunization technical advisory group (NITAG) to advise on vaccine introduction?

VACCINE FINANCING

- What are the sources of financing for vaccines and service delivery? What are the trends in financing?
- If any vaccines are currently financed by donors, how predictable is that support?
- If the country is Gavi-eligible or transitioning from Gavi, is the government meeting its annual co-financing commitments?

- What are the government's plans for covering these costs when donor support ends?
- Are other sources of financing for immunization sustainable?
- Does the government have a clear plan for financing immunization over the next five years?
- Does the national budget have a line for vaccines and injection supplies? What is funded from the national budget, and what is funded by donors?
- Are budgeted funds for vaccine procurement released in a timely manner? Does late disbursement impede procurement? If so, what options might be available to address this problem?
- Do health facilities have adequate funds for immunization services, including staff, transport, and outreach? If there are problems, are they worse in certain areas? What might be done to address funding gaps?
- What non-financial factors are affecting program performance, and how might they be addressed?
- Are any health reform initiatives planned or underway that might affect the immunization program? Have the responsibilities for various immunization functions in the reformed system been thought through? Is sufficient funding assured for both vaccine procurement and service delivery?

VACCINE PROCUREMENT

- How reliable are vaccine supplies? Have there been any stock-outs at the national or subnational level in the past two years?
- How are vaccines procured? Are all procured vaccines WHO-prequalified?
- If the government is procuring vaccines, is it getting good prices (for example, compared to prices obtained by UNICEF Supply Division)?
- Are vaccines delivered to health facilities with the appropriate injection supplies?

FURTHER READING

Country-reported immunization financing indicators:

http://www.who.int/immunization/programmes_systems/financing/data_indicators/en/

Country support from Gavi: <http://www.gavi.org/country/>

Immunization advocacy: <http://advocacy.vaccineswork.org/> and World Health Organization. Immunization advocacy library. WHO Regional Office for Europe. Available from: <http://www.euro.who.int/en/health-topics/disease-prevention/vaccines-and-immunization/publications/immunization-advocacy-library>

Immunization schedules by country: http://apps.who.int/immunization_monitoring/globalsummary/schedules

Vaccine prices paid by UNICEF: http://www.unicef.org/supply/index_57476.html

WHO vaccine price database:

http://www.who.int/immunization/programmes_systems/procurement/v3p/platform/module1/en/

WHO/UNICEF immunization coverage estimates:

http://www.who.int/immunization/monitoring_surveillance/routine/coverage/en/index4.html

WHO recommended immunization schedules: http://www.who.int/immunization/policy/immunization_tables/en/

PART V

COUNTRY
CASE STUDIES

Armenia: Strong Government Support for Immunization

KEY POINTS

- * Armenia's high-performing immunization program has benefited from close collaboration among the Ministry of Health, the Ministry of Finance, and the Standing Committee on Health Care, Maternity, and Childhood in Parliament.
- * The country has met 100% of its Gavi co-financing requirements and is on track to fully finance its immunization program starting in 2018.
- * The Ministry of Finance and Ministry of Health have a working agreement that calls for funds for vaccines and injection supplies to be released in full by April of each year to ensure smooth procurement through UNICEF Supply Division.
- * The two ministries have a working agreement that makes immunization a priority program and calls for the budget line for vaccines and injection supplies to be maintained even if other areas need to be cut.

ARMENIA HAS STRONG immunization coverage, indicated by its 94% coverage of diphtheria-tetanus-pertussis (DTP3) in 2015, according to World Health Organization / UNICEF estimates. Since 2001, the country has used external support to spur new vaccine introduction and as of 2016 had the full list of WHO-recommended childhood vaccines except human papillomavirus (HPV), which was under consideration. Armenia is approaching the final stages of transitioning from Gavi support and has already transitioned from support from other donors. It has met 100% of its co-financing requirements for Gavi.

Armenia's immunization program has benefited from strong political commitment from the Ministry of Health, the Ministry of Finance, and Parliament. The Ministry of Health shares immunization performance data, strategies, and policies with the Ministry of Finance. During the budget cycle, Armenia's immunization program staff work closely with budget and finance staff in the Ministry of Health to prepare the budget. The immunization program has a key champion in Parliament, the chair of the Standing Committee on Health Care, Maternity, and Childhood.

BUDGET PROCESSES AND VACCINE FUNDING

Budget processes in Armenia clearly delineate budgets for vaccines and injection supplies and donor support. The budget line called "National Immunization Program" is specifically for vaccines and injection supplies. Financing for other immunization activities is integrated throughout the health system. All external support for immunization is accounted for in the budget. For example, the value of Gavi-supported vaccines is estimated in local currency and appears in the budget. In the past, Gavi financial support (vaccine introduction grants and health system strengthening grants) appeared in the budget in the extrabudgetary account.

The Ministry of Finance and Ministry of Health have a working agreement that calls for National Immunization Program funds to be released in full by the Ministry of Finance no later than April of each year so they can be transferred to UNICEF for the timely procurement of vaccines. The ministries also have a working agreement that the budget line is a "priority program" that must be protected even if other areas are facing budget cuts.

THE ROLE OF EXTERNAL SUPPORT

In strengthening and expanding its immunization program, Armenia has benefited from external support—primarily from Gavi, the Millennium Armenian Children’s Vaccine Fund (MACVF), the Rostropovich Vishnevskaya Foundation, UNICEF, and WHO. Both the MACVF and the Rostropovich Vishnevskaya Foundation are U.S.-based organizations. Long-term sustainability has been a consideration in planning for the use and phase-out of external assistance.

From 2002 to 2009, the Rostropovich Vishnevskaya Foundation, the MACVF, and UNICEF contributed funding to immunize children against measles, mumps, and rubella. These organizations funded the required doses, and the Ministry of Health covered the non-vaccine delivery costs. In 2010, the government assumed 100% of the financing for the vaccines. The Rostropovich Vishnevskaya Foundation, UNICEF, WHO, Fighting Infectious Diseases in Emerging Countries (FIDEC) Armenia, and the MACVF provided the funding for a campaign in 2007 to vaccinate people age 6 to 27 against measles and rubella.

The government introduced the hepatitis B, rotavirus, pneumococcal, and inactivated polio vaccines with Gavi support. (The hepatitis B vaccine was later replaced by pentavalent, while the birth dose of hepatitis B was maintained.) It also received financial support from Gavi for health system strengthening and injection safety support. Armenia has met its annual co-financing obligations to Gavi by procuring some of the doses itself (through UNICEF), with Gavi financing the remaining share. The MACVF provided some of the funding for the co-financing requirements for pentavalent and rotavirus (about US\$15,000 per year), with the government providing the rest. This arrangement ended in 2015.

The immunization program procures all vaccines from UNICEF Supply Division, with the exception of tularemia vaccine. Armenia’s national immunization technical advisory group (NITAG) is currently reviewing the effectiveness of this vaccine.

CHALLENGES AHEAD

One of the continuing challenges is the lack of trust in vaccines among some segments of the population. The Ministry of Health monitors popular parent websites and promptly responds to questions and concerns about vaccine efficacy and safety.

Azerbaijan: Dramatic Savings from a Change in Procurement

KEY POINTS

- * After a careful and comprehensive review of pros and cons, Azerbaijan's government moved from direct procurement of vaccines to delegating procurement to UNICEF Supply Division in 2014.
- * The country's spending on vaccines fell from US\$3.3 million in 2013 to about US\$1.3 million in 2014. The money saved went toward cold chain equipment upgrades, immunization of health care workers against hepatitis B, and immunization of adolescents against measles-rubella in 2014.
- * Procurement from UNICEF Supply Division has ensured vaccine quality and steady supply.
- * Challenges in the switchover included reconciling prepayment of vaccines with national procurement regulations. This was achieved by ensuring that payment and receipt of vaccines would occur in the same fiscal year.

AZERBAIJAN HAS a high-performing immunization program, with diphtheria-tetanus-pertussis (DTP3) coverage reaching 96% in 2015, according to World Health Organization / UNICEF estimates. As of 2016, the country was well on its way to transitioning from Gavi support. As part of this process, it is scaling up its co-financing of Gavi-supported vaccines.

The government previously procured almost all vaccines directly. After carefully weighing this approach against the use of UNICEF Supply Division, it switched procurement of all vaccines to the UN agency in 2014. This brief reviews the factors behind the change and the impact on vaccine expenditures, supply, and quality. It also discusses how the government reconciled UNICEF Supply Division requirements for prepayment of vaccines with government procurement regulations. (See Briefs 11 and 12.)

PROCUREMENT CHALLENGES PRE-2014

Responsibility for vaccine procurement in Azerbaijan lies with the Ministry of Health's Innovation and Supply Center. Through 2013, procurement was done directly, but the Ministry of Health had concerns about pricing, quality, and compliance with cold chain requirements during delivery to Azerbaijan.

Health officials also viewed requirements for local registration of products, as well as Azerbaijan's relatively small market size, as hindrances to getting more vaccine manufacturers interested in supplying Azerbaijan. For all of these reasons, the government began considering a switch to UNICEF Supply Division for vaccine procurement as it began the process of transitioning from Gavi support.

CHALLENGES OF MOVING TO UNICEF SUPPLY DIVISION

In considering the switch, the government needed to determine whether it could harmonize its own procurement regulations with UNICEF's technical rules and processes governing payment and delivery of vaccines. UNICEF requires prepayment before delivery of vaccines to countries. The Ministry of Health determined that UNICEF's requirements would be consistent with government regulations as long as the prepayment and the delivery of vaccines to Azerbaijan occurred in the same fiscal year. To accomplish this and also ensure steady vaccine supplies, the Ministry of Health and UNICEF agreed to work together to forecast vaccine requirements at the end of each year for the following year. Once the actual budget is released by Azerbaijan's Ministry of Finance the following year, the government pays UNICEF and the vaccines are delivered in the same year.

BENEFITS OF MOVING TO UNICEF SUPPLY DIVISION

Since 2014, all vaccines in Azerbaijan's national schedule have been procured by the Ministry of Health through UNICEF Supply Division. Government officials report several advantages to date:

- **Better prices.** The price per dose has been considerably lower than with direct procurement.
- **Guaranteed quality.** All vaccines procured by UNICEF are prequalified by WHO, guaranteeing their quality. Previously, not all vaccines procured were WHO-prequalified.
- **Steady supply.** Health officials report no disruption in supply or stock-outs since the switch.
- **Transparency.** UNICEF Supply Division is seen by the government as a respected organization with clear procedures.
- **Cold chain compliance.** The government trusts UNICEF's requirements for cold chain compliance during delivery.
- **Flexibility.** UNICEF requires payment of a 10% buffer for market and exchange rate fluctuations. If these funds are not used, they can be reprogrammed or returned to the country. Azerbaijan's government requested that it reprogram those funds for other national needs, such as the purchase of vitamin A and additional doses of pneumococcal vaccine.

COST SAVINGS

Savings from the procurement switch were immediate and dramatic. In 2013, the last year before the switch, the country spent US\$3.3 million on vaccines. In 2014, it spent about US\$1.3 million. This US\$2 million in savings was reinvested in the immunization program and used to buy vaccines to immunize health workers against hepatitis B, immunize adolescents with the measles-rubella vaccine, and upgrade cold chain equipment.

Given all the positive outcomes to date, government officials have concluded that UNICEF Supply Division is the best procurement option for Azerbaijan's immunization program over at least the medium term.

Bhutan: A National Trust Fund for Immunization

KEY POINTS

- * The Bhutan Health Trust Fund (BHTF) is a flexible financial tool established by the government to protect income for particular health priorities. The BHTF is the world's longest-running national immunization financing trust fund.
- * The BHTF is committed to fully financing all vaccines once donor support phases out.
- * Factors contributing to the trust fund's success include a small population, political champions, a supportive monarchy, flexible funding to meet emerging priorities, and good governance and accountability structures that can adapt to meet changing needs.
- * The BHTF experience can provide lessons for other countries with similar national contexts.

A TRUST FUND is a mechanism that governments can use to ring-fence, or protect, funding for specific purposes. Trust funds may receive funds from multiple revenue streams, and they may be legally incorporated with policies and tax regulations that vary by country; a governing board may oversee the strategy, business plan, management, and operations. Trust funds may also have asset managers that seek to ensure the right rate of return, level of risk, and rate of capital depletion. Revenue sources can include domestic taxes, donor funds, and private contributions. (See Brief 7.)

The government of Bhutan has the world's longest-running national trust fund dedicated to health, including immunization. In 2000, the government established the Bhutan Health Trust Fund (BHTF) to "help sustain and achieve self-reliance in the primary health care sector by eliminating financing uncertainties through income generated out of capital investments." The fund plays an increasingly important role in financing essential medicines, vaccines, syringes and needles, and cold chain equipment for the country's population, which stood at 775,000 in 2015. This brief explores Bhutan's use of this innovative and evolving immunization financing model, which offers other countries interesting lessons about governance, balanced expenditure, and the role of political champions.

ESTABLISHING THE FUND

The concept for the BHTF was first discussed in 1997 as a means of ensuring sustainable financing of key elements of primary health care in Bhutan. Bhutan has had success with trust funds for other sectors and considers the BHTF a key mechanism to help ensure the constitutional right to access basic health services free of cost for the entire population. Political champions at the highest level of government played important roles in launching, publicizing, and capitalizing the fund.

The fourth king of Bhutan, His Majesty Druk Gyalpo, issued a royal charter that legally established the fund in 2000. To publicize the fund and encourage public donations, Bhutan's then prime minister, Sangay Ngedup, joined the first Move for Health Walk, which spanned more than 560 kilometers from the country's eastern border to the capital city. This has been an annual fundraising event for the fund since 2013. (See the photo on the next page.)

Trust funds may receive funds from multiple revenue streams, and they may be legally incorporated with policies and tax regulations that vary by country.



The Move for Health Walk in 2015. Prime Minister Tshering Tobgay, his wife, and the health minister are pictured in this photo.

In its first year, the Move for Health Walk raised about US\$1.6 million. In 2015, it raised about US\$300,000 from voluntary individual donors alone. While this amount translates to only US\$0.38 per capita, it is more than three times the country's vaccine expenditure for 2015. Since 2000, the government has matched each donation to the BHTF. The walk also generates public solidarity and provides a way for the government to spread key health messages. Each district coordinates and promotes its own annual walk.

The initial target capitalization of US\$24 million was achieved in 2010, but increases in expenditure on some of the core components of primary health care have led to BHTF revising the fund capitalization target to US\$45 million to help ensure the long-term sustainability of the fund. The prime minister, in his address on the annual Move for Health day in 2016, pledged to raise the additional capital over the next two years.

HOW THE FUND IS MANAGED

The 2000 royal charter defines the governance and regulation of the BHTF, including limits on capital depletion. The fund is currently administered by a board made up of representatives from the ministries of health and finance, the Gross National Happiness Commission, and the private sector. The board is fully responsible for the management of the BHTF and is supported by an advisory committee. The BHTF was delinked from the Ministry of Health as of July 2016 and functions as an autonomous government agency. The BHTF has a staff of eight people, following the approved organizational structure.

The fund is expected to be fully autonomous once the revised target capitalization of US\$45 million is achieved. The new management structure will enable the BHTF to recruit more staff, including people with dedicated marketing and investment management roles, although operational costs, which are currently paid by the government, will have to come from the BHTF's return on investments.

ROLE OF THE FUND IN IMMUNIZATION FINANCING

Along with a small population, Bhutan has a shrinking birth cohort—about 13,500 in 2015, according to UN population projections. Bhutan has slightly below replacement-level fertility. Its vaccine requirements are therefore smaller than those of larger low- and middle-income countries, many of which also have rapidly growing birth cohorts. These are relevant factors in considering the size of the fund and expenditures needed for immunization.

In terms of vaccine expenditures, the BHTF initially covered only Bhutan's Gavi co-financing requirement for pentavalent vaccine. It now covers the full cost of this vaccine because Bhutan has transitioned

Bhutan: A National Trust Fund for Immunization

out of Gavi support. Some other vaccines are not currently financed by the BHTF because donor assistance is available. For example, the Australian Cervical Cancer Foundation has extended funding for the human papillomavirus (HPV) vaccine in Bhutan to 2020, while the Japan Committee, Vaccines for the World's Children, has been covering the cost to Bhutan of traditional vaccines. Vaccines are procured through UNICEF Supply Division. The government is committed to fully financing all vaccines in its national schedule from the BHTF as donor support is phased out, along with associated injection supplies and cold chain equipment.

Beginning in the 2014–2015 fiscal year, the BHTF also began funding the cost of other essential drugs. As a result, vaccines now make up a small proportion of its spending. In 2015, the fund spent US\$87,000 on vaccines and US\$2.5 million on essential drugs; projections for 2016 spending are US\$89,000 on vaccines and US\$3.37 million on essential drugs. For 2016, this puts total spending on vaccines and essential drugs at about US\$4 per capita. In July 2016, the director of the BHTF and the health minister (who chairs the BHTF) signed an annual performance agreement for 2016–2017 pledging to finance 100% of the essential drugs and pentavalent vaccine for the country.

FUNDING SOURCES AND INVESTMENT STRATEGY

In 2015, the BHTF's total capital and reserves stood at US\$20.9 million—including US\$1.5 million of interest income—of which 6% was spent on vaccines. The fund's longstanding investment approach has been to invest a large portion of assets in short-term deposits, fixed deposits, savings deposits, bonds, and other vehicles. In 2013, the portfolio breakdown included 75% investment in fixed deposits and

19% investment in a government loan mechanism. In the same year, the fund had more than US\$1 million in interest income generated through these mechanisms, but it used a conservative 5% on vaccines. A 2013 review team found that interest income appeared to have been underused.

In October 2015, the Ministry of Finance began contributing about US\$2.1 million annually to the BHTF for the expansion to include essential drugs, which will be managed according to the fund's investment strategy. This new source of income, called the "health contribution," is collected through a 1% salary deduction from corporate private-sector employees and civil servants, with contributions from the informal private sector also being explored. If this contribution continues as planned, it could significantly change the scope of what can be funded from the BHTF and change the funding mix of the fund.



Launching the BHTF's expanded financing of essential drugs and vaccines in 2015.

THE BHTF AS A MODEL

The BHTF is well placed to continue financing essential drugs and move beyond financing only pentavalent vaccine costs as donor support phases out. But as other countries think through whether to establish their own trust funds, they should consider some important nuances and differences in country characteristics.

Bhutan is a stable monarchy and has a strong commitment to the health and well-being of the population. Political champions in Bhutan were essential to establishing the fund and maintaining support through nationwide activities such as the annual health walk. In addition, Bhutan has introduced few new vaccines and has a small population, which helps keep overall costs down.

The country also has other successful trust funds, all governed by clear rules, which provide a model for the BHTF. Robust and transparent governance will be a continued priority as the fund transitions to becoming an autonomous entity. Replicating the BHTF's success in other countries without this particular confluence of factors could be challenging, but the BHTF's experience does indicate that this financing model could be viable for smaller countries if pursued with a similar level of political will and support from the international donor community.

FURTHER READING

Bhutan Health Trust Fund [Internet]. Archived at:
<https://perma.cc/W5YV-QQVW>

Costa Rica: Lottery Contributions for Immunization in a Mixed Financing System

KEY POINTS

- * Costa Rica's immunization program is financed primarily by the national health insurance program, known as the *Caja*, which provides health services to about 90% of the population.
- * Financing for vaccines comes from three sources: the *Caja*, the Ministry of Health, and the national lottery. The *Caja* covers all immunization delivery costs.
- * The national lottery is an innovative financing source but accounts for only about 1% of the annual cost of vaccines.
- * New vaccine introduction is a challenge in Costa Rica due to financial pressures faced by both the *Caja* and the Ministry of Health. An added challenge is lack of clarity on the two institutions' respective roles in financing vaccines.

IMMUNIZATION SERVICES in Costa Rica are provided through the national health insurance program, *Caja Costarricense de Seguridad Social* (Costa Rican Department of Social Security), also known as the *Caja*. The *Caja* was established in 1943 with coverage initially for salaried workers. Coverage was gradually expanded, and now about 90% of the population is covered. In the 1990s, the *Caja* took over provision of health services from the Ministry of Health, and the ministry's role has since been one of norm-setting, regulation, strategic guidance, and coordinating health efforts across ministries.

This brief describes how the immunization program in Costa Rica is financed and some of the achievements and challenges. A unique feature of the program is that some funding for vaccines is generated by the national lottery. Given global interest in innovative financing mechanisms, the brief describes this source of financing in some detail.

2001 NATIONAL IMMUNIZATION LAW

Costa Rica's 2001 National Immunization Law guarantees free access to immunization for the entire population. The law also created the National Commission on Vaccination and Epidemiology, which is charged with establishing and periodically updating the national immunization schedule. The

commission is also charged with formulating overall policies and strategies for immunization, approving norms, approving manuals and educational materials related to immunization, overseeing the quality of vaccines, administering the national vaccine fund, coordinating vaccination campaigns, and overseeing surveillance. It is chaired by the minister of health or the minister's representative.

The 2001 law also established the National Vaccine Fund and stipulates that financing to support the immunization program should come from the Ministry of Health and from the *Caja*. The law requires both institutions to ensure sufficient amounts in their budgets to purchase vaccines and cover other costs of the program. It also stipulates that a portion of the funds raised from the national lottery go into the National Vaccine Fund, after deducting administrative and operating costs (and the lottery payout). The law further mandates that vaccines and related materials not be taxed.

HOW IMMUNIZATION FINANCING HAS EVOLVED

The *Caja* finances all immunization delivery costs. Financing of vaccines is shared by the *Caja*, the Ministry of Health, and the national lottery proceeds. The *Caja* is the largest contributor to vaccine



A lottery ticket in Costa Rica. (Tico Times, 2013)

purchases, accounting for 70–85% of the total over the past five years. The Ministry of Health is the second-largest contributor, at 15–30%, and national lottery funds are a distant third, at less than 1%.

Although the 2001 law established the National Vaccine Fund and called for pooled funding, in practice Caja funding for vaccines is kept separate from the National Vaccine Fund. The Ministry of Health and lottery funds are pooled and used by the ministry to purchase vaccines through the Pan American Health Organization (PAHO) Revolving Fund. (See Brief 12.) The Caja also purchases vaccines through the Revolving Fund. The funds from the lottery, held in November or December of each year, are made available for vaccine purchases by March or April of the following year.

The Caja's budget previously had separate lines for pharmaceuticals and for vaccines. Around 2013, vaccines were folded into the pharmaceuticals budget line. Initially, there was some concern that this might pose a risk to vaccine financing, but government representatives report that it has not been a problem to date. In fact, when the need arose for some unexpected purchases of influenza vaccine in 2015, the shared budget line offered more flexibility and the increased demand for influenza vaccine was

easily met. Safety boxes and injection supplies are financed through service provision budget lines that cover the purchase of injection supplies and handling of biohazard waste for all types of health services.

The 2001 law also specified that 2% of any Caja surpluses be earmarked for the National Vaccine Fund. The Caja has not had any surpluses to date and has in fact faced strong financial pressures.

THE NATIONAL LOTTERY

Costa Rica established a national lottery in 1885 with the goal of raising funds for the public hospital, San Juan de Dios. The country now has six different lottery games, all managed by Junta de Protección Social (the Social Protection Council). The tradition of using lottery proceeds for social welfare purposes continues, and the demands on these resources are numerous. Funds raised by the lottery are used for hospitals, retirement homes, HIV/AIDS programs, the Red Cross, cancer prevention, substance abuse programs, and more. As stipulated in the National Immunization Law, one lottery per year, held in November or December, is devoted to immunization. The Ministry of Health has made efforts to promote the immunization lottery and has raised about US\$100,000 to US\$200,000 each year for immunization. This innovative financing source plays a small role in total vaccine financing (at less than 1%), and prospects for expanding financing from this source, given all the competing demands on the lottery proceeds, are limited.

ONGOING CHALLENGES

New vaccine introduction is a challenge in Costa Rica due to financial pressures faced by both the Caja and the Ministry of Health. An added challenge is lack of clarity on the two institutions' respective roles in financing vaccines.

Ghana: Mixed Financing for Immunization and Shifting Responsibility

KEY POINTS

- * Mixed health financing and service delivery systems can provide opportunities for sustainable immunization financing, but financing responsibilities must be clearly delineated.
- * The growing role of the National Health Insurance Scheme (NHIS) in Ghana's overall health financing has created a potential additional source of sustainable financing for immunization.
- * The shift in responsibility for immunization financing from the Ministry of Health to the NHIS has not been made explicit, however, so cuts to the ministry budget could jeopardize immunization efforts and affect immunization coverage.

GHANA OFFERS AN example of the potential opportunities and challenges for immunization as health financing and service delivery systems become more complex. Ghana has a mixed financing and service delivery system that combines a public delivery network funded through the Ministry of Health, many private nonprofit and for-profit providers, and the National Health Insurance Scheme (NHIS), which contracts with both public and private providers.

Within this mixed system, the components of the immunization program (vaccines and injection supplies, vaccine supply chain and logistics, and service delivery) are largely funded through the Ministry of Health budget and delivered by public facilities at the district and subdistrict levels. Immunization services are not included in the NHIS benefits package. However, as the ministry's budget for goods and services has been cut in the face of macroeconomic and fiscal constraints, the share of financing through the NHIS has increased; a growing share of immunization service delivery is now implicitly covered by NHIS payments to providers. This offers opportunities for greater diversification and stability of financing for immunization, but it also creates a risk that immunization services will get crowded out as NHIS funding increasingly replaces the ministry budget and as curative services become more lucrative for both public and private providers.

GHANA'S IMMUNIZATION PROGRAM

Ghana has been a leader in adopting new vaccines, and it recently introduced several new and underused vaccines with Gavi support. The program has a legal mandate for the public health system to provide vaccines in the national schedule free of charge.

Ghana once had the highest immunization coverage in the West African region, with a World Health Organization / UNICEF diphtheria-tetanus-pertussis (DPT3) coverage estimate of 98% in 2014. In 2015, this figure fell to 88%.

The decline happened at the same time that the Ministry of Health's general budget was shrinking, with a drastic reduction in real terms in the non-salary budget between 2015 and 2016. Ghana will fully transition from Gavi support in 2022 and will be responsible for an increasing annual share of vaccine co-financing until then. The combination of general budget cuts and increasing financial obligations creates enormous vulnerability for the government in sustainably financing vaccines.

Ghana has been a leader in adopting new vaccines, and it recently introduced several new and underused vaccines with Gavi support.

Ghana was in default on its co-financing obligations to Gavi for 2014 and 2015. With high-level advocacy from the Ministry of Health and development partners, the Ministry of Finance was able to make the payment, but Ghana's co-financing obligation far exceeded the Ministry of Health's entire general non-salary budget. (See Brief 9 for an explanation of co-financing obligations.) This co-financing obligation will continue to grow.

In addition, the country relies almost completely on Gavi's health system strengthening support to maintain the vaccine cold chain, and there is not enough funding in the operational budget to provide preventive maintenance for cold chain equipment at the regional and district levels. Ghana's immunization financing challenges are occurring against the backdrop of a rapidly increasing role for the NHIS in financing health services, which is creating both opportunities and challenges for establishing a stable funding base and continued high priority for immunization supplies and services.

NHIS AND IMMUNIZATION FINANCING

Ghana's NHIS was established by the National Health Insurance Act (Act 650) of 2003. Ghana's value-added tax is 17.5%. Of that, 2.5 percentage points are earmarked for (dedicated to) the NHIS. Other sources of funding include an earmarked 2.5% of the total 17.5% social security contribution by formal-sector workers, as well as investment income and premiums paid by nonexempt individuals (such as self-employed and informal-sector workers). The revenue from the earmarks is entirely protected for health, with 90% going to the NHIS and the other 10% to the Ministry of Health for special programs as a supplement to the ministry's general budget. In 2016, the portion of the earmark allocated to the ministry was used to meet Gavi co-financing commitments.

About 40% of the country's population is currently enrolled with the NHIS. Although the benefits package is comprehensive, covering an estimated 95% of the burden of disease in Ghana, preventive

services—including immunization—are outside of the benefits package and are funded directly by the Ministry of Health. Immunization services are free to all Ghanaians, regardless of whether they have NHIS coverage. But public and private providers contracted to deliver services in the benefits package are paid additional fees for these services, whereas no additional payments are made for immunization and other preventive services outside of the benefits package.

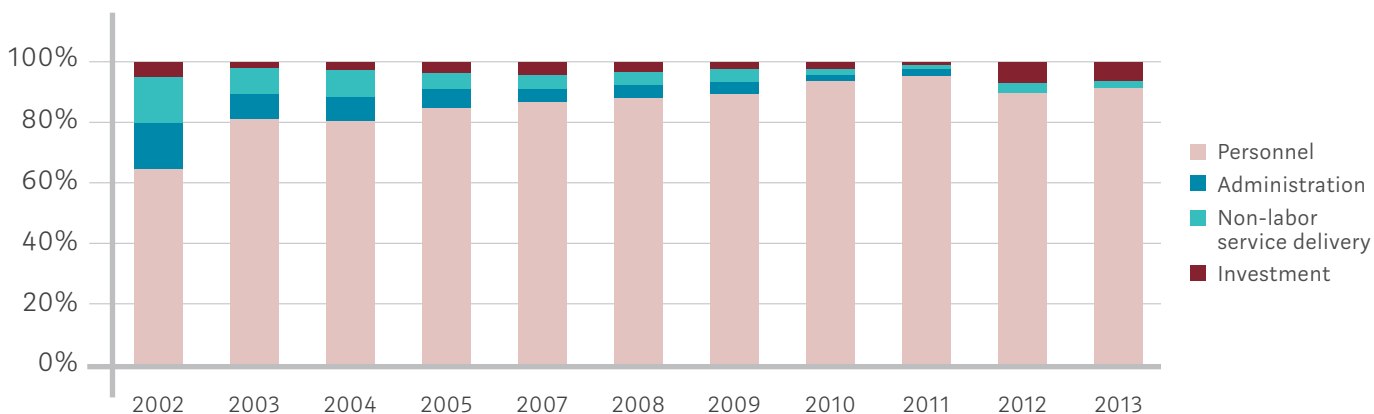
In parallel with the NHIS, the Ministry of Health continues to receive a budget that funds salaries for government health workers (through the Ghana Health Service), as well as capital investment and some goods and services costs for government health facilities, including immunization services. The Ministry of Health budget is now almost entirely consumed by salaries, with the NHIS funds covering more service delivery costs for government health providers by default. (See the figure on the next page.) The ministry's wage bill has been growing due to the expansion of the health labor force and the government's unification of the wage scale across all public institutions beginning in 2010. At the same time, Ghana has been struggling to recover from a macro-fiscal crisis compounded by falling commodity prices, which has required tighter fiscal policies and budget restraint.

SUSTAINABILITY OF IMMUNIZATION FINANCING

With the Ministry of Health budget shrinking, public health facilities increasingly rely on claims payments for services covered by the NHIS for their day-to-day operations as well as some immunization delivery costs, such as for fuel used in outreach efforts. As a result, curative services may be crowding out preventive services that are not financed by the NHIS, including immunization. On the other hand, the NHIS is helping to diversify the funding base for Ghana's immunization program, which could help ensure more stable funding in the future.

Ghana: Mixed Financing for Immunization and Shifting Responsibility

MINISTRY OF HEALTH BUDGET ELEMENTS IN GHANA (2002–2013)



Note: Data for 2006 are not available.

Source: Ghana Ministry of Health, Health Sector Programme of Work (2016)

Ghana is at a critical moment for the sustainability of its immunization program as it proceeds with the transition from Gavi and faces cuts in the Ministry of Health budget. At the same time, the ministry's vaccine bill is rapidly increasing, which may lead to trade-offs within the health sector budget and possibly for immunization financing as a whole. An implicit shift has already happened as the NHIS has taken on a greater share of financing for service delivery overall at the health facility level. Planning

and budgeting for Gavi co-financing commitments and other parts of the immunization program, particularly the cold chain, have been inadequate. As in all mixed health systems, more diversified funding sources and more flexible payment systems can potentially improve health service delivery. To realize these benefits, the responsibility for financing the country's immunization program must be made explicit and communicated to all stakeholders, particularly health providers and the population.

SOURCES AND FURTHER READING

Ghana Ministry of Health. Health sector programme of work. 2016.

Health Development Partners Group. Analysis of 2016 health budget [unpublished]. 2016 Jan.

Novignon J, Abankwah N, Cashin C, Bloom D. Earmarking revenues for the NHIS in Ghana: practical experience, results, and policy implications. Geneva: World Health Organization; 2016.

World Bank. Ghana immunization program assessment [unpublished]. 2016.

Indonesia: The Challenge of Protecting Immunization in the Transition to Universal Health Coverage

KEY POINTS

- * Indonesia's transition from Gavi support is happening during a time of rapid health system changes, including decentralization of the health delivery system and a transition to universal health coverage under a single national health insurance system.
- * Immunization is provided free to the population through the public health service delivery network regardless of health insurance coverage status. Nonetheless, inequities in access to immunization between insured and uninsured children may be emerging.
- * The high level of decentralization in Indonesia also poses challenges to sustaining and strengthening the national immunization program.
- * As JKN coverage expands, the key to financial and institutional sustainability of the immunization program will be better integration with the universal health coverage system, especially as the government introduces new vaccines over time.

INDONESIA WILL FULLY self-finance its immunization program starting in 2018, after Gavi support ends. Although external contributions to total health spending are low—at only 1% in 2013—the government has received significant support from Gavi to fund immunization. International partners also provide substantial technical assistance to Indonesia's immunization program. At the same time, Indonesia has instituted a series of major health reforms over the past decade that affect how resources are allocated to the immunization program.

Since 2001, responsibility for health service delivery has been fully decentralized to local governments. In 2014, the country's public health insurance schemes were consolidated into one national unified social health insurance program—Jaminan Kesehatan Nasional, or JKN. In 2016, its third year of implementation, JKN covered about 60% of the population; universal coverage is planned by 2019. At the same time, Indonesia has one of the lowest rates of public spending on health as a share of GDP (about 1% in 2014) and as a share of total government spending (about 6% in 2014).

In this period of transition from Gavi financing and rapid changes in the health financing system, Indonesia is faced with the challenge of ensuring adequate domestic financing for immunization, as well as governance, service delivery, and coordination of immunization program functions as JKN expands insurance coverage, all under tight financing constraints. The financial burden will continue to increase as the government introduces four additional vaccines to the national immunization schedule over the next three to four years. Indonesia also has the challenge of sustaining immunization program management and ensuring health provider capacity to deliver immunization services during the transition from Gavi support.

Indonesia has instituted a series of major health reforms over the past decade that affect how resources are allocated to the immunization program.

INDONESIA'S IMMUNIZATION PROGRAM

Indonesia's immunization schedule covers all traditional vaccines recommended by the World Health Organization except rubella. Of the newer vaccines in the recommended schedule, Indonesia has adopted only pentavalent vaccine. Despite increases in coverage rates in recent decades, large inequities exist and Indonesia does not compare favorably with peer countries with similar income levels when it comes to immunization. WHO/UNICEF coverage estimates for Indonesia in 2015 are 81% for diphtheria-tetanus-pertussis (DTP3), 77% for BCG (tuberculosis), and 69% for measles (first dose).

The central government is responsible for procuring vaccines, and district governments are responsible for service delivery. Operational costs, including the cold chain and immunization service delivery, are the responsibility of subnational governments. The Ministry of Health's National Immunization Program (NIP) oversees immunization and carries out forecasting and planning for vaccine procurement. The central government finances vaccines through a national budget line item, and regulations require that all government-procured vaccines be supplied by Biofarma, a state-owned enterprise. As with other health services, district governments are responsible for service delivery costs, including operational costs for primary health care facilities to provide immunizations. The NIP provides technical assistance, guidelines, monitoring and evaluation, quality control, training, and supplementary activities such as immunization campaigns. The NIP also uses a standardized tool for assessing supply-side readiness for immunization at the local government level.

Vaccines on the national immunization schedule are provided free of charge by the government to public and private providers, and a 2011 health facility census showed that more than 90% of all health

centers (*puskesmas*) reported availability of government-mandated vaccines. However, the census also showed availability issues at the public and private provider level in three provinces (Papua, West Papua, and Maluku), where more than 20% of *puskesmas* reported no supplies of measles, DPT, polio, and BCG vaccines. Vaccine availability is less reliable among private providers, with only about a quarter of private facilities, and less than 10% of those in eastern provinces, reporting availability of government-mandated vaccines.

Immunization is provided free to the population through the public health service delivery network regardless of health insurance coverage status.

IMMUNIZATION AND SOCIAL HEALTH INSURANCE

Immunization is provided free to the population through the public health service delivery network regardless of health insurance coverage status. Although most government financing for immunization comes from the government budget, some financing also comes from JKN. JKN currently covers routine immunizations for children under age 5 and tetanus immunization for pregnant women. At public health facilities contracted to provide services under JKN, individuals do not need to present their insurance card to obtain free immunizations. At contracted private facilities, a JKN card is required to receive free services; otherwise, people usually have to pay a service charge even though private providers also receive vaccines for free from the government. Overall, there is no evidence of significant out-of-pocket payments for immunization services.

Indonesia: The Challenge of Protecting Immunization in the Transition to Universal Health Coverage

Although immunization services are provided free of charge, household survey data show that differences in access to immunization between insured and uninsured children may be emerging. Children who had not received any doses of the DPT vaccine were more likely to be uninsured than were children who received three doses of the vaccine, according to household survey data. Individuals and providers are sometimes unclear on entitlements and funding sources for immunization services for insured versus uninsured individuals, which could affect access for the uninsured. A further challenge is that funds for immunization services are part of the capitation payment to primary care providers under JKN to deliver all covered primary health care services, including immunization, but confusion among local governments and providers sometimes results in capitation payments being used to finance only curative care.

DECENTRALIZATION

Although the central government procures and distributes vaccines, provincial and district governments manage the operations of public health facilities and services. Intergovernmental fiscal transfers from the national to subnational levels are not used to incentivize immunization coverage and there are no clear ways to influence allocation of resources for immunization at the subnational level. Expenditures on the immunization program at the subnational level are not reported back to the Ministry of Health or the Ministry of Finance, so they are difficult to monitor. Management capacity and commitment to immunization vary greatly across provinces and districts. Anecdotal evidence shows limited allocated operational budget for the immunization program at the local government level, which could potentially affect service delivery and coverage. With regard to the new vaccines that are

planned for inclusion in the national immunization schedule, strong advocacy at the local government level may be needed to ensure adequate operational budgets for service delivery.

PROTECTING IMMUNIZATION IN A TRANSITIONING HEALTH SYSTEM

Indonesia's health system is complex and undergoing rapid change. The transition to universal health coverage (UHC) under the JKN national health insurance system and the high level of decentralization pose challenges to sustaining and strengthening the national immunization program. Lack of clarity in the links to JKN is a challenge. The government has an ambitious plan to introduce four new vaccines in the next three to four years, so issues around financing and service readiness will become more urgent. Furthermore, there is no procedure for deciding when to include new vaccines in the JKN benefits package, and any new vaccines included in the routine immunization schedule are automatically covered by JKN without considering the financial implications.

As in all mixed health systems, the responsibility for financing the country's immunization program in Indonesia needs to be made explicit and communicated to all stakeholders. As JKN expands coverage, the key to financial and institutional sustainability of the immunization program will be better integration within the UHC system and explicit processes for matching service delivery readiness and financial capacity with immunization commitments.

SOURCES AND FURTHER READING

Tandon A. et al. Health financing system assessment: Indonesia. Jakarta: World Bank; 2016.

Kenya: Decentralization and Immunization Financing

KEY POINTS

- * Many countries are implementing decentralization—the shifting of functions from higher to lower levels of government—in health and other sectors. Decentralization can improve responsiveness to population needs, but it can also hinder the delivery of health services if roles and responsibilities are not clearly defined and the levels of government taking on new functions are not supported during the transition.
- * Decentralization can make subnational decision-makers such as local mayors good targets for immunization financing advocacy.
- * In some country contexts, it may be possible to pilot-test decentralization and related capacity-building efforts and then roll them out gradually.
- * Kenya experienced challenges with shifting fund management to subnational levels. For immunization, this resulted in some gaps in funding for vaccine and injection supplies and delivery, operational costs, and cold chain maintenance, resulting in a drop in immunization coverage.
- * A compelling argument can be made for keeping certain health functions, especially vaccine financing and procurement, at the national level.

DECENTRALIZATION—shifting responsibilities in health and other sectors from national to local authorities—has been a growing trend among countries around the world, particularly since the 1990s. Decentralization can involve varying degrees of fiscal, administrative, operational, and political power shifts. Examples include *devolution*, in which both decision-making and financial control shift, or *deconcentration*, in which only decision-making control is shifted to lower levels.

In many countries, decentralization is part of a broader political shift for purposes that might include increasing autonomy and control at lower administrative levels, pursuing political and economic liberalization, improving service delivery, bringing resources and resource allocation closer to the population, and improving health and development outcomes. This brief explores issues related to decentralization and immunization and draws insights and lessons from recent experiences in Kenya.

FEDERAL AND SUBNATIONAL FINANCING RESPONSIBILITIES FOR IMMUNIZATION

In highly decentralized countries, the national government's role in the immunization program usually involves policymaking, procurement, financing of vaccines and injection supplies, national storage, stock management (and some distribution), developing overall delivery strategies and multi-year plans, coordinating any external and donor financing, aggregating and reporting on nationalized coverage data and surveillance, setting skills standards, and coordinating training. Financing for salaries, supply chain, and operating costs associated with the immunization program might be a subnational responsibility, using funds raised and allocated to health through local taxation. Procurement almost always remains national—because of the specialized knowledge required, the need for pooled resources, and economies of scale generated.

In countries where both national and subnational governments raise revenues, decentralization reforms can affect the domestic sources of funding that flow to immunization and the health system generally. In some countries, facility operating costs and salaries can be funded through block transfers from the central government to augment local government contributions. Some countries give states, provinces, departments, and/or municipalities and districts primary or sole responsibility for funding immunization services.

Unless health, including immunization, is a priority within a decentralized system and the new structure includes performance agreements and clear guidelines developed with subnational authorities, immunization financing and service delivery can be weakened.

DECENTRALIZATION IN KENYA

Kenya's 2010 constitution recognized the population's right to health and affordable health services. In 2013, in line with these constitutional rights, the central government devolved authority for a number of fiscal and administrative functions—including health, agriculture, and water—to 47 counties. This involved a large number of administrative changes to the health sector and immunization, but the Ministry of Health retained responsibility for standards, policy, regulation, and national hospitals.

Under the new arrangement, counties receive central government resources through three main channels:

- "Equitable-share" block grants, which are based on a formula set by a dedicated central commission for revenue allocation across all sectors
- Conditional grants that are linked to specific priorities such as free maternity care or elimination of user fees
- An equalization fund that was designed to provide support to marginalized counties

The decentralization process in Kenya has affected immunization financing and immunization programs in both negative and positive ways.

Funding gaps and capacity issues have led to procurement delays and shortages of vaccines and supplies.

It took almost three years for Kenya to fully implement devolution, which affected the procurement of vaccines and injection supplies because funds for these purposes were transferred to lower levels. The Ministry of Health and other stakeholders worked with the parliamentary committee on health to address the resulting vaccine and supply shortages. Through this channel, they lobbied the Ministry of Finance to shift all vaccine procurement back to the national level because some county governments did not recognize the funding requirements, did not have forecasting expertise, or did not understand the procurement and distribution rules and processes. By July 2014, protected national funds were secured to meet some vaccine procurement needs; the bulk of funding for injection supplies remained at lower levels of the system. The Kenyan Medical Supplies Authority (KEMSA) also led reforms that moved medical supplies into a pooled procurement system through which counties could place orders directly with KEMSA using local budgets. While there is broad recognition at the national and county levels that vaccine procurement functions should be centralized, there are challenges to doing so: Kenya's constitution does not allow for reducing funds allocated to counties or shifting funds from the county to the national level, so the central government has had to raise additional funding for vaccine procurement. These challenges are likely to persist. Kenya defaulted on its co-financing commitment to Gavi in 2013 and 2014—an outgrowth of the complexities of decentralization as well as misalignment of the government fiscal year and Gavi's fiscal year. In 2015, Gavi aligned the co-financing obligation with the Kenyan government's fiscal year and Kenya fulfilled its Gavi co-financing obligations on time. This shows that the government and partners are moving toward rectifying funding flow issues.

Kenya: Decentralization and Immunization Financing

Commitment to immunization may not be equally strong in all counties. Under Kenya's new system, counties receive block grants and allocate funds as they see fit across sectors, including health. Health management teams in counties further allocate funds across the health sector. If county administrators do not see immunization or other health matters as a priority, such programs might not get funded and immunization advocates have to present their case to new decision-makers in the system. In some parts of Kenya, advocates have made significant efforts to reach local decision-makers (such as mayors and district health management teams); this has resulted in some counties allocating sufficient funds for immunization programs. In other counties, some aspects of immunization programs, such as outreach, are no longer properly funded. This is because facilities have less control over their own funding. Previously, some operational costs for immunization and certain other activities were financed using income generated, retained, and allocated by the facility; these funds are now consolidated in county bank accounts for use across sectors.

Capacity to manage services and financing varies by county. As counties move to control health under district health management teams, retaining the right level of competencies at the county level can also be a challenge. In Kenya, counties have varied capacity to procure quality vaccines at reasonable prices and from approved manufacturers, to operate and maintain the cold chain and logistics, and generally to manage the system. In early 2013, this translated to significant issues around the country with procurement of both injection supplies and cold chain components. For instance, injection supplies for the BCG vaccine became a challenge because supplies had previously been procured by the central health ministry and counties were not able to procure them locally. This led to some local health staff trying to substitute other supplies that did not permit accurate measurement of the smaller dosage for BCG and could have resulted in dangerous misadministration of the vaccine and compromised

the entire immunization program. BCG coverage began to decline. World Health Organization / UNICEF estimates showed a drop in BCG coverage in Kenya from 97% in 2012 to 92% in 2013. In 2014, KEMSA reverted to stocking BCG syringes to address this issue.

Accountability has likely improved in some counties. Alongside the many initial challenges as a result of decentralization, there were also some benefits. Decentralization gave some local decision-makers more autonomy to manage money and identify personnel issues such as salary payments to nonexistent people, or "ghost workers." Some Kenyan counties are reportedly spending more money on health, pharmaceuticals, and expanded primary health care networks.

Local champions for immunization had a positive impact in some counties. Decentralization may have led to increased community participation in planning. Despite initial challenges with building support for immunization funding, many counties now have immunization champions who can mobilize local political and community support.

LESSONS AND CONCLUSIONS

Decentralization can be part of a country's political evolution. But if roles and responsibilities are not carefully considered and clarified at the outset, the decentralization process can have a negative effect on health service delivery. The success of decentralization will likely depend in part on how far responsibilities devolve, and how quickly. A reform that shifts responsibilities without considering the full range of consequences at the lowest political level is likely to face significant challenges and result in potentially harmful consequences.

In some country contexts, it may be possible for decentralization and related capacity-building efforts to be pilot-tested first and then rolled out over time, using an incremental approach. In others, ongoing policy decisions can be supported through consensus building and targeted support. For instance, in South

Africa all nine provinces have significant power over financial decisions. Additions to the vaccine schedule are discussed in cross-governmental forums and then released as national policy with guidelines and related training. In Brazil, institutional and management reforms led by decentralized authorities have led to positive outcomes when the central government has provided the right level of incentives, guidance, and support.

These lessons aside, questions remain about what aspects of immunization financing and delivery should or should not be decentralized. The documents listed in the box below give a high-level overview of functions that should ideally be maintained at the central level during decentralization reforms and functions that can be distributed effectively to lower levels.

SOURCES AND FURTHER READING

Feilden R, Nielsen OF. Immunization and health reform: making reforms work for immunization. A reference guide. Geneva: World Health Organization, Department of Vaccines and Biologicals; 2001.

Ndegwa SN. Decentralization in Africa: a stocktaking survey. World Bank, Africa Region; 2002 Nov.

World Health Organization. Health sector reform (HSR): fact sheet for national managers. Geneva: World Health Organization, Department of Vaccines and Biologicals; 2003.

World Health Organization. Health sector reform (HSR): the impact of health sector development on immunization services. Geneva: World Health Organization, Department of Vaccines and Biologicals; 2003.

World Health Organization. Sub-national management of immunization services during health sector reform (HSR). Geneva: World Health Organization, Department of Vaccines and Biologicals; 2003.

Sri Lanka: Sound Decision-Making Processes for Immunization

KEY POINTS

- * Independent technical bodies can help strengthen vaccine decision-making. Sri Lanka's Advisory Committee on Communicable Diseases (ACCD) is an example of a well-functioning and influential body of this type.
- * The ACCD's mandate includes not just immunization but all policy decisions related to the control of infectious disease, and its decisions are binding on the public sector.
- * Committee members span a broad range of disciplines. In assessing the introduction of new vaccines into the national program, they consider disease burden, vaccine efficacy and safety, feasibility, cost, and cost-effectiveness. The ACCD does not recommend introduction unless funding is assured.
- * Sri Lanka has completed the transition from Gavi support and must find domestic resources for all new vaccines; this makes the rigorous ACCD decision-making process even more valuable.

DECISIONS ON IMMUNIZATION policy, especially on the introduction of new vaccines into national programs, have important implications for program financing as well as for population health. Even when a vaccine is broadly recommended by the World Health Organization, it may not be a high priority in a particular setting, given local epidemiology, health system strengths and weaknesses, and immunization program capacity. Moreover, even if a vaccine would bring clear benefits, it may not be cost-effective or affordable at the price available to a particular country. Decisions on vaccine introduction are highly technical and require a range of epidemiological, economic, programmatic, and vaccine expertise. (See Brief 4.)

WHO recommends that countries establish an independent technical body, sometimes called a national immunization technical advisory group (NITAG), to advise the government on vaccine introduction and other aspects of immunization policy. Although 82 countries had set up NITAGS as of 2016, these groups vary greatly in their capacity, functioning, and influence.

Sri Lanka's Advisory Committee on Communicable Diseases (ACCD) is an example of a long-established, well-functioning advisory committee, although its

mandate differs in some respects from that of other NITAGs. This brief summarizes the ACCD's functions and composition and highlights its role in important recent decisions concerning Sri Lanka's immunization program.

SRI LANKA'S IMMUNIZATION PROGRAM

Sri Lanka's government launched its Expanded Programme on Immunization—now called the National Immunization Programme (NIP)—in 1978.

The program rapidly achieved high coverage. The national immunization schedule now includes pentavalent vaccine, the measles-rubella-mumps combination, and

Japanese encephalitis, as well as the basic vaccines provided from the start of the program. Inactivated polio vaccine (IPV) was introduced in July 2015, and the typhoid vaccine is given to high-risk groups. The country was among the first in South Asia to introduce several of these vaccines. Immunization

Even when a vaccine is broadly recommended by the World Health Organization, it may not be a high priority in a particular setting.

coverage is exceptionally high, reaching 99% for the third dose of diphtheria-tetanus-pertussis (DTP3) as well as for both doses of measles, according to WHO/UNICEF estimates for 2015. The program has contributed, as part of a strong health system, to low rates of vaccine-preventable diseases, a child mortality rate of 10/1,000, and a life expectancy of 76 years.

ADVISORY COMMITTEE ON COMMUNICABLE DISEASES

The ACCD was established in the 1960s—before the launch of the Expanded Programme on Immunization—to review the status of communicable diseases in the country and make policy decisions related to their prevention and control. This mandate differs from that of NITAGs in most countries in two important respects. First, its scope includes all measures to control communicable disease, not just immunization. Second, its decisions are binding on the public sector—in this sense, it is more than an advisory body.

The ACCD meets quarterly and has 36 members, with a broad range of expertise in epidemiology, vaccinology, child health, health administration, and specific infectious diseases, among other disciplines. Most members are academics, physicians, or high-level government administrators. Its chair is the director general of health services; the chief of the Ministry of Health's epidemiology unit serves as the committee's secretary. Notably, as of 2016 it did not include members with economic expertise.

APPROACH TO VACCINE INTRODUCTION

In considering the introduction of a new vaccine into the NIP, the ACCD assesses evidence on disease burden, vaccine safety and effectiveness, feasibility, cost, and cost-effectiveness. When data on disease burden from the routine surveillance system are insufficient, the ACCD sometimes recommends that special studies be done. In some cases, it has requested additional studies of vaccine safety and immunogenicity in the Sri Lankan population.

As a matter of policy, the ACCD will not recommend introducing a new vaccine unless sustainable financing is in place. It also considers cost-effectiveness, and the NIP has commissioned cost-effectiveness studies of several vaccines in recent years.

When a new vaccine is under consideration, the ACCD typically establishes a working group to gather and analyze the necessary information. The next step is discussion at a National Immunization Summit—a stakeholders' forum attended by academic experts, representatives of professional associations, international organizations, and Ministry of Health officials. Although the ACCD is ultimately responsible for decisions on new vaccines, the immunization summits are important opportunities to seek broader input and build consensus.

The ACCD's decision-making on the human papillomavirus (HPV) and rotavirus vaccines illustrates the committee's approach.

Sri Lanka: Sound Decision-Making Processes for Immunization

HPV VACCINE

Cervical cancer is the second most common cancer among women in Sri Lanka, accounting for 10% of female cancers. The country's cervical cancer screening program currently reaches only 30–40% of women. Given the burden of cervical cancer and the high cost of treatment, a cost-effectiveness study carried out by a Ministry of Health expert concluded that introduction of the HPV vaccine would be cost-effective in Sri Lanka. Moreover, Sri Lanka has a well-established school-based immunization program to which the new vaccine could be added, making delivery less challenging than in many other developing countries.

In light of these analyses, in 2015 an expert group established by the director general of health services recommended nationwide introduction of the HPV vaccine for girls, along with efforts to expand coverage of cervical cancer screening to 80%. The ACCD endorsed this recommendation in 2016.

ROTAVIRUS VACCINE

The rotavirus vaccine has been discussed at the annual National Immunization Summit, but an ACCD working group has not been established. The primary reason for the relatively low priority currently accorded to this vaccine is low disease burden. An ongoing hospital study has found low mortality and morbidity from rotavirus infection in Sri Lanka, presumably because of widespread access to safe water and sanitation (84% and 86%, according to UNICEF) and broad access to treatment for severe diarrhea.

IMPLICATIONS OF GAVI TRANSITION

At the end of 2015, Sri Lanka became one of the first countries to complete the transition from Gavi support. Compared to countries that introduced more vaccines, Sri Lanka faced a smaller increase in domestic vaccine financing during this transition. Nevertheless, it will now have to find domestic resources to pay for any new vaccines it introduces. The rigorous decision-making process led by the ACCD—including the requirement that assured financing be in place—puts Sri Lanka in a strong position to face these new challenges.

At the end of 2015, Sri Lanka became one of the first countries to complete the transition from Gavi support.

SOURCES AND FURTHER READING

NITAG Resource Center [Internet]. NRC: About. Available from: <http://www.nitag-resource.org/about>

Wijesinghe PR, Palihawadana P, Peiris TS. Participatory decision-making through the Advisory Committee on Communicable Diseases: the Sri Lankan experience. *Vaccine*. 2010 Apr 19;28:A96-103.

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