

Investing in Vaccines for the Developing World

Vaccines are one of the most effective, affordable, and beneficial tools in public health. The World Health Organization (WHO) estimates that global immunization campaigns save more than 2.5 million lives every year and protect millions more from disease and disability. In addition to being relatively inexpensive, vaccines are remarkably cost-effective; the human and economic costs of infectious disease far outweigh the costs of immunization. Even the more expensive vaccines on the market today are considered an extremely good value for the money. However, due to the cost of developing, manufacturing, and distributing these newer vaccines, many developing countries do not have access to them.

EXPANDING ACCESS TO VACCINES: COSTS AND CHALLENGES

Like any medical product, vaccines undergo a long-term, rigorously regulated development process. A recent report to the WHO estimates that developing a vaccine costs over US\$500 million and can take 15 years or more. Unlike many medical products, vaccines present a special challenge to those who attempt to develop them. Because bacteria and viruses are biological organisms, they can be harder to work with and less predictable than the chemicals and molecules used for medicines. They have to be tested in many more people before they are licensed, and they are harder to manufacture on a commercial scale in a consistent way.

Each vaccine presents different challenges. For example, a vaccine against hepatitis B requires a very different research, development, and manufacturing process than that against polio. Some vaccines take longer to develop than others, and some clinical trials are more expensive than others. The manufacturing process for each vaccine is different, resulting in a wide variety of systems for designing and testing efficiency and consistency. Most potential vaccine candidates do not make it through all the stages of this process successfully, requiring researchers to cover the costs of testing dozens of candidates in the effort to develop a single vaccine.



PATH/Siri Wood

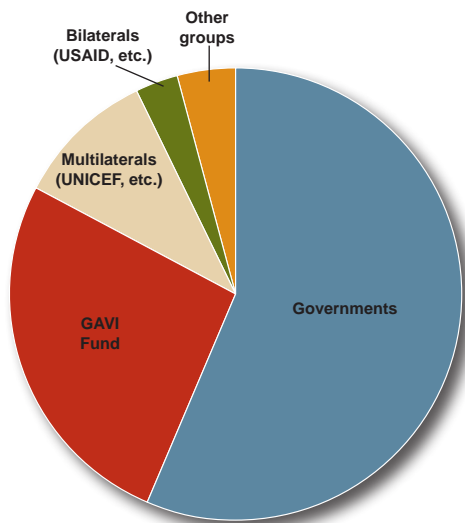
Vaccines for the developing world can involve additional hurdles. Infectious pathogens can vary according to region, so a vaccine that works well in the United States may not be as effective in Ghana. Therefore, clinical trials must also be conducted in the developing world. Planning and executing a comprehensive clinical trial can be especially difficult in resource-poor settings where infrastructure is lacking. Nevertheless, a number of successful clinical trials have been conducted in developing countries in recent years, yielding critical scientific data and enhanced research capacity in the participating communities.

Once developed, there are additional costs associated with the transport of vaccines to communities in resource-poor settings. Vaccines tend to be much more temperature-sensitive than other medical products and can spoil rapidly in the heat. Reliable refrigeration can be difficult in areas that have no electricity or underdeveloped transportation systems. In addition to these logistical difficulties, personnel with adequate training must be available to distribute and administer vaccines safely, and public health workers must conduct effective community outreach to help people appreciate the value of vaccination.

PAYING FOR VACCINES

Following World War II, routine vaccination campaigns became common in the developed world, with governments footing the majority of the bill. Such public health expenditures were not possible for developing nations, so vaccine coverage rates hovered at 10 to 20 percent in most countries until the 1980s. In 1984, the United Nations Children’s Fund (UNICEF), the WHO, and the World Bank set immunization as a top priority and launched an expanded immunization program to provide vaccines against six diseases: polio, measles, pertussis, tetanus, diphtheria, and tuberculosis. By 1996, UNICEF was supplying over 1 billion doses of vaccine to developing countries, half of them against polio.

Yet, the global landscape continues to change. Until recently, vaccines used in developing countries were



Vaccine Program Financing, by Percentage
Source: Bill & Melinda Gates Foundation, WHO, 2012

the same as those used in industrialized nations. Overproduction in wealthier countries of the “traditional” vaccines—DPT (for diphtheria, pertussis, and tetanus), polio, measles, and BCG (which protects against some forms of childhood tuberculosis)—kept supply plentiful and prices low. But starting in the 1990s, wealthier nations began using newer, more sophisticated, and more expensive vaccines, and many manufacturers stopped producing the less profitable ones used mostly in developing countries. At the same time, vaccine shortages also occurred as a result of spikes in demand due to successful campaigns against polio, maternal and neonatal tetanus, and measles.

These gaps in the international market provided a major opportunity to manufacturers in the developing world, many of whom were already producing vaccines for use in their own countries. Over the last decade, these manufacturers have become a vital component

in ensuring the global supply of traditional childhood vaccines. In fact, the majority of traditional vaccines supplied to UNICEF for its immunization program are now manufactured in the developing world.

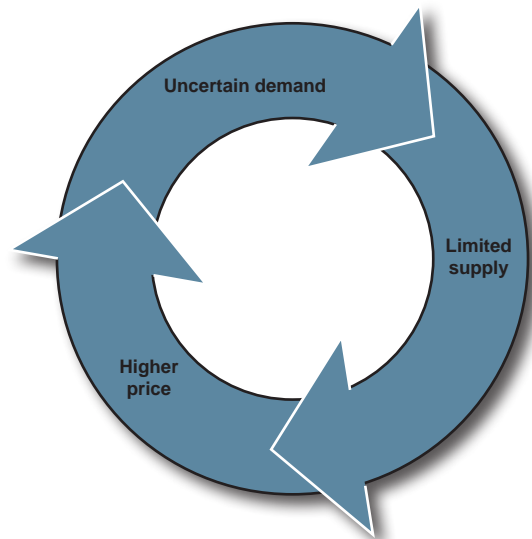
NEW GLOBAL COMMITMENTS

Gavi, the Vaccine Alliance was launched in 2000 to strengthen immunization services and introduce new and underused vaccines to the developing world. Governments in industrialized and developing countries, UNICEF, the WHO, the World Bank, the Bill & Melinda Gates Foundation, nongovernmental organizations, vaccine manufacturers, and public health and research institutions work together as partners in the Alliance.

Though governments currently finance an average of 56 percent of their own vaccine costs, they also rely heavily on contributions from UNICEF, the GAVI Fund, and a host of other donors.

It is estimated that immunization programs save the lives of 2.5 million children each year. Despite this success, approximately 8.8 million children under the age of five die each year, of which approximately 1.5 million die from vaccine-preventable illnesses.

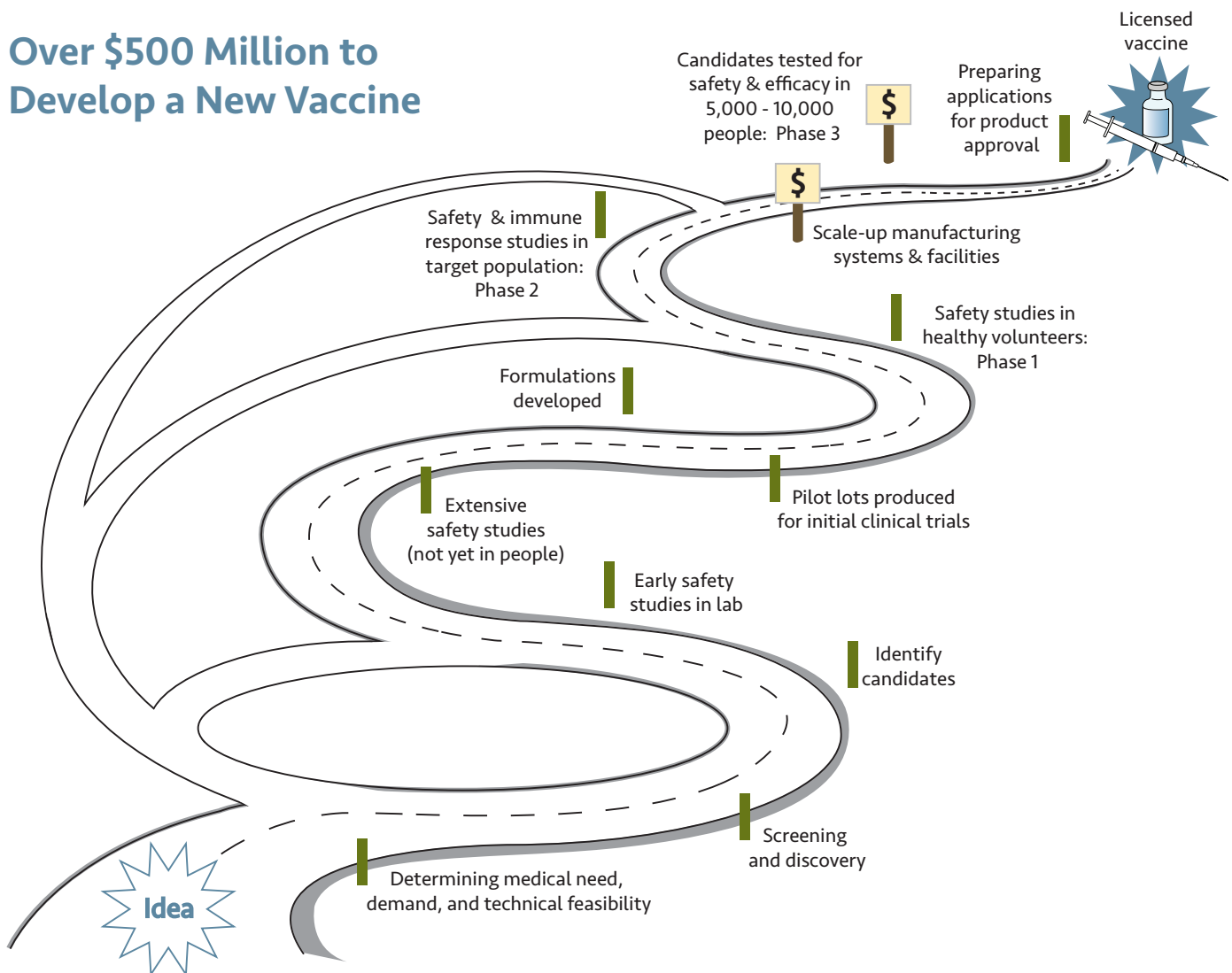
Many of the policy challenges confronting widespread vaccine availability stem from unpredictable and insufficient donor funding. This in turn contributes to unpredictable and insufficient demand by developing-country governments. The resulting instability of the vaccine market discourages manufacturers from investing in the additional production of vaccines, driving up the unit price of vaccines and contributing to shortages.



INNOVATIVE FUNDING SOLUTIONS

In order to bridge the gap that exists in the current rates of coverage, decision-makers in donor and recipient countries are seeking new ways to leverage resources for vaccines

Over \$500 Million to Develop a New Vaccine



and immunization strategies. Three innovative funding solutions are currently being piloted that may hold significant potential for improving global health.

International Finance Facility for Immunization (IFFIm)

IFFIm was launched in 2006 as a strategy for “frontloading” funds to purchase vaccines, by raising a large sum of money upfront through legally binding payment obligations from donors. IFFIm’s financial base consists of more than US\$6.3 billion in grant pledges from its sponsors (France, Italy, Norway, Spain, Sweden, the United Kingdom, South Africa, Australia, Brazil, and the Netherlands). Under these agreements, countries guarantee future payments, against which IFFIm issues bonds in the international capital markets. The money earned from the sale of these bonds is used to finance immunization programs, and bondholders will be repaid using the funds provided by donor countries. Put more simply, these grants are pledges of future aid that allow IFFIm to raise money from international markets for immediate use.

By investing the majority of resources upfront, this program will provide reliable, predictable funding for immunization programs and health systems strengthening for the next decade. An anticipated IFFIm investment of \$4 billion is expected to help prevent 5 million child deaths between 2006 and 2015, and more than 5 million future adult deaths through campaigns against measles, tetanus, and yellow fever. The fund has already disbursed at least \$2.3 billion to support vaccine purchase and delivery in 71 developing countries.

Advance Market Commitments (AMCs)

The first AMC was launched in February 2007 as a strategy to address two of the major policy challenges to vaccine introduction: a lack of affordable vaccines on the market and insufficient commercial incentives to develop vaccines for diseases concentrated in developing countries. Under the terms of an AMC, donors (currently Canada, Italy, Norway, the United Kingdom, Russia, and the Bill & Melinda Gates Foundation) make a legally binding guarantee that, if a future vaccine is developed against a

particular disease, they will purchase a predetermined amount at an agreed-upon price. The guarantee is linked to safety and efficacy standards that the vaccine must meet and is structured in a way to allow several firms to compete to develop and produce the best possible new product.

AMCs reduce risk to donor governments by eliminating the need to fund individual research and development projects that may never produce a vaccine. If no company produces a vaccine that meets the predetermined standards, governments (and thus their taxpayers) spend nothing. For the bio-pharmaceutical industry, AMCs create a guaranteed market, with a promise of returns that would not normally exist. For developing countries, AMCs provide funding to ensure that those vaccines will be affordable once they have been developed.

The pilot AMC to develop a vaccine against pneumococcus was launched in June 2009. Pneumococcus is a bacterium that is the leading vaccine-preventable killer of children in the developing world. It is estimated that the pneumococcal AMC could save more than 1.5 million childhood deaths by 2020.

UNITAID

UNITAID was launched in 2006 by the governments of Brazil, Chile, France, Norway, and the United Kingdom. By the end of 2008, UNITAID's membership grew to 29 countries. The Bill & Melinda Gates Foundation is also a member. Both the mission and the mechanism of UNITAID are simple: many of the participating governments levy a carefully structured tax on airline ticket purchases, the proceeds from which go to a fund that is housed under the auspices of the WHO and dedicated to the purchase of drugs to combat AIDS, TB, and malaria. Other governments choose to complement the tax with multi-year budgetary contributions. UNITAID's structure avoids creation of a new agency and is designed to have a minimal economic impact on the airline travel industry.

The initiative has raised close to \$2 billion in health funding. At present, this funding has supported projects in 94 countries worldwide. UNITAID is financing HIV/AIDS and related drugs for nearly half a million adults and children, and has delivered 196 million malaria treatments and 1.5 million tuberculosis treatments since 2006.

A SMART INVESTMENT IN THE FUTURE

As global health needs continue to evolve, advances in vaccines must evolve with them. Innovative new methods must be explored to ensure that these advances are available to those who need them most. To be successful, these methods require broad global support and strong evaluation. A global commitment to the goal of enhanced access to comprehensive vaccination is a crucial component in ensuring the future's global health.

PATH is working to close gaps in access to lifesaving vaccines. By strengthening health systems, expanding access to new vaccines, accelerating research and development, and creating innovative technology solutions, PATH is working to make safe and effective vaccines affordable and available to those most in need.

RESOURCES

WHO: <http://www.who.int/immunization/en/>

WHO: http://www.who.int/immunization_financing/data/country_donor/en/

WHO: <http://www.who.int/mediacentre/factsheets/fs378/en/>

UNICEF: <http://www.unicef.org/immunization/>

Gavi, the Vaccine Alliance: <http://www.gavi.org/funding/pneumococcal-amc/about/>

International Finance Facility for Immunization: <http://www.iff-immunisation.org/>

UNITAID: <http://www.unitaid.eu/index.php>

WHO: http://whqlibdoc.who.int/publications/2009/9789241563864_eng.pdf



www.path.org

PATH is the leader in global health innovation. An international nonprofit organization, we save lives and improve health, especially among women and children. We accelerate innovation across five platforms—vaccines, drugs, diagnostics, devices, and system and service innovations—that harness our entrepreneurial insight, scientific and public health expertise, and passion for health equity. By mobilizing partners around the world, we take innovation to scale, working alongside countries primarily in Africa and Asia to tackle their greatest health needs. Together, we deliver measurable results that disrupt the cycle of poor health. Learn more at www.path.org.

455 Massachusetts Ave NW,
Suite 1000
Washington, DC 20001