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ANALYSIS & COMMENTARY
Challenges To Building Capacity For Evidence-Based New Vaccine Policy In Developing Countries

ABSTRACT There are many challenges to ensuring that people in developing countries have equitable access to new vaccines. Two of the most important are having the capacity to make evidence-based new vaccine policy decisions in developing countries, and then when appropriate actually distributing those new vaccines to those who will most benefit from them. Based on our review of the Pan American Health Organization’s ProVac Initiative in the Americas, we found that when national governments in developing countries develop the expertise to make the best technical decisions about immunization programs; take responsibility for helping to pay for and distribute vaccines; and are supported by strong partnerships with international organizations, they succeed in saving more lives more quickly.

The experience of national immunization programs demonstrates that immunization is one of the “best buys” in public health. Rapid deployment and use of traditional vaccines against childhood diseases has arguably been the single most important health intervention contributing to the reduction of child mortality in developing countries and to increased life expectancy.

Vaccines and immunization provide a basis for further demonstrating that better health will produce sizable economic returns for developing countries. Healthier children grow up to be healthier, more productive adults, capable of holding and creating jobs and families and thereby contributing to growing economies and a vibrant society.

Clearly, “traditional” vaccines used in developing countries to prevent such diseases as polio, measles, rubella, diphtheria, tetanus, and pertussis have a tremendous value that has motivated countries, over many years, to develop the capacity to deliver these vaccines. In the Americas, the most obvious evidence of successful national immunization programs is the eradication of polio, measles, and rubella.

This article describes how new vaccine decision challenges have been addressed in the Americas. Specific issues addressed include the quality of national immunization technical advisory groups; the quantity and quality of country-specific epidemiological and economic evidence to inform the policy-making process; the financial sustainability of immunization programs; and immunization management capacity with respect to the introduction of new vaccines.

New Vaccines, New Challenges
New vaccines provide additional opportunities to improve public health and generate positive economic returns. However, if these new vaccines are to be delivered, the capacity of immunization programs must expand.

Several new vaccines have been developed and approved in the past few years, including those for infections and related mortality due to rotavirus, pneumococcal invasive disease, human papillomavirus infection, and seasonal influenza. Compared to “traditional” vaccines that cost pennies per dose, these new vaccines being...
Reducing Preventable Child Deaths In The Americas

In Latin America and the Caribbean, vaccines will play an especially important role in achieving the goal of reducing child mortality. They could even contribute to at least one-third of the remaining target of the Millennium Development Goal in this region.8

To take advantage of the life-saving potential of new vaccines, leaders in developing countries must accelerate their policy making to justify better decisions on whether or not to introduce a new vaccine and then, when appropriate, must implement the policy decision as rapidly as possible to save more lives.9

The experience of introducing the hepatitis B vaccine in developing countries is an example that must be avoided. It took more than two decades for developing countries to receive the benefit of this vaccine after it was introduced in industrialized countries.10 Factors that contributed to this delay included insufficient financial resources to cover the much higher vaccine price; the lack of expanded refrigerator capacity to adequately store the vaccine; a shortage of the necessary human resources to administer the program; and a lack of systems to monitor and evaluate introduction.

More than twenty years of such preventable mortality is clearly not acceptable. A far more desirable outcome would be to reduce—from twenty years to just a few years—the time it takes to provide a vaccine that is widely available in industrialized countries to those in developing nations.

Developing The Vaccine Leaders Of Tomorrow

Looking to the future, efforts to enhance national capacity to make evidence-based decisions should help ensure the sustainability of national immunization programs as new and more expensive vaccines become available. Decisions not grounded in evidence risk the choice of inappropriate vaccines that will overwhelm national budgets and vaccine delivery systems. Such decisions cannot be obviously sustained or justified.

Enhancing national capacity means training the current public health work leadership in decision science to ensure that their decision to support a particular vaccine’s introduction is grounded in the best available evidence and adequately justified.

Such leaders must be knowledgeable in all aspects of the technical, operational, and societal factors related to a particular vaccine’s introduction. Examples of technical factors include

introduced into the national immunization programs of developing countries come at higher cost, have less efficacy for the disease outcomes they are trying to prevent, and are often aimed at populations much older than young children.

When new vaccines emerge, developing countries face a series of difficult decisions about introduction, implementation, and capacity to administer the vaccines. Many developing countries’ national immunization programs lack the necessary capacity to take on a new vaccine.

For example, in some countries, the addition of pneumococcal vaccine might triple the country’s budget for vaccine purchase. The decision to introduce such a life-saving vaccine requires additional analytic and decision-making skills that are not always present in developing countries.

A decision to add the pneumococcal vaccine to a developing country’s immunization arsenal also requires that country to have adequate scientific information to determine where pneumococcal disease ranks as a national priority. But many countries have insufficient scientific information, including disease surveillance, to adequately determine where a disease ranks among other national priorities.

If the data are not available locally, then what other information is needed? The economic analysis of a vaccine, alone, requires a sophisticated set of skills that most national immunization managers currently do not have.

Tight national budgets that have arisen in response to the current global economic crisis have made it even more difficult for national vaccine programs to expand. Adding to this tension, developing countries are under increased pressure to bring new vaccines into their national immunization programs as a result of the Millennium Development Goals, outlined in the United Nations Millennium Declaration.7

Essentially, all governments of the world have committed to achieving the eight Millennium Development Goals by 2015. The goals range from reducing extreme poverty to stopping the spread of HIV/AIDS and providing universal primary education. One goal calls for a two-thirds reduction in mortality of children age five or younger compared to levels in 1990.

In 1990 the estimated child mortality rate per 1,000 live births in Latin America and the Caribbean was 54; by 2000 it was 36.4 Based on these data and the Millennium Development Goal, the mortality rate among the region’s children age five or younger should be 18 by 2015. To achieve that goal, developing countries will need to focus on preventing pneumonia and diarrhea—the leading killers of children age five and younger in those countries.
knowledge of the disease in question and where it ranks as a national public health priority. Other technical factors deal with the vaccine’s characteristics, such as its degree of efficacy, the schedule of administration, the duration of immunity, the likelihood of side effects and other factors. Operational factors include knowledge of the national capacity to store the vaccine, manage supplies, and distribute the vaccine. If there are gaps in such capacities, what will it take to overcome them? Societal factors include the economics inherent in buying and distributing the vaccine, the public perception of risk, and the political commitment to support the new vaccine introduction.

In this article we refer to all of these factors—technical, operational, and societal—as the decision package, the body of evidence we think is needed to make an informed decision. However, having adequate evidence will not be enough. Expertise to interpret the evidence must be present.

To that end, countries should also have scientific oversight committees to steward the decision-making process. Many countries currently do not have such committees, or if they have them, the committees function poorly. National responsibility for the program and its oversight are fundamental to overcoming the barriers of new vaccine introduction.

Weighing The Benefits Of New Vaccines

Even as developing countries attempt to overcome barriers to the introduction of new vaccines, the benefits that could result will vary from country to country, largely based on the burden of disease, local costs, and other vaccine priorities.

For example, the burden of rotavirus diarrhea is well established as a substantial killer of children in Central America. However, policy makers in Chile decided not to introduce rotavirus vaccine because, in their view, the overall disease burden of rotavirus-caused diarrhea was not a national priority. Other public health challenges, such as tackling the burden of cervical cancer among women, were given higher priority.

Vaccines And National Security

Enhancing national immunization programs will also provide additional benefit for maintaining national and regional security. A well-functioning, well-managed vaccination program will help countries face the continued risk of importations of vaccine-preventable diseases such as yellow fever, polio, measles, and rubella.

The yellow fever outbreak in urban Paraguay in April 2008 threatened national security because of civil disturbances resulting from public concerns about lack of a vaccine. This was the region’s first such outbreak in more than forty years. When the disease erupted, there was insufficient vaccine supply in the country to control the disease, which had a potential case fatality ratio of greater than 30 percent (meaning that more than 30 percent of those with the condition might die). The shortage of vaccine led to a public outcry. Fortunately, two million doses were provided by the World Health Organization’s global stockpile, and the rest of the required vaccine needed was donated by neighboring countries.

Implementation of a mass vaccination campaign stopped the transmission of yellow fever in Paraguay, saved lives, and provided national security. The public was assured that life-saving vaccines were available, and the initial outcry and public demonstrations were alleviated.

Accelerating The Policy Process

Historically, the vaccine decision-making process in countries of Latin America and the Caribbean has been driven by regional immunization priorities. This was certainly the case for the eradication of polio, measles, and rubella.

Each year, the region’s ministers of health convene a meeting of the Directing Council of the Pan American Health Organization (PAHO) in Washington, D.C. At this annual meeting, the ministers discuss regional priorities and make decisions about public health priorities for the Western Hemisphere. Indeed, it was as a result of such meetings that countries agreed to collectively eradicate polio, measles, and rubella from the Americas.

Although this process of setting regional priorities has been highly successful in eradicating certain diseases, until recently it has not been balanced by a comparable effort to make certain that individual nations also had the capacity to make decisions about and to deliver vaccines. Both the regional and national capacity for vaccine decision making need to be further strengthened in order to ensure that limited resources are used most appropriately.
A 2008 study by PAHO and the World Health Organization found that twelve of thirty-five countries in Latin America and the Caribbean did not have a national immunization technical advisory group, such as those found in the United States and Canada. These advisory groups provide the scientific oversight described above.

Arguably, most experts would agree that such groups are fundamental to sound public health practice. Although some smaller island nations have been successful without this approach, much larger countries with greater population diversity need individual national mechanisms.

**INSIDE IMMUNIZATION TECHNICAL ADVISORY GROUPS** All of the other seventeen countries participating in the PAHO/World Health Organization study were located outside the Caribbean group of countries. In these countries, where national immunization technical advisory groups reportedly function, each country’s ministry of health relies on the recommendations of advisory groups. The process is formalized, because ministers of health generally do not make decisions on the introduction of new vaccines without this consultative process. Obviously, such a formalized, institutional process should be considered sound public health practice.

Seventy-seven percent of these advisory groups had legislative mandates; that is, their actual existence was linked to legislation. This institutionalizes their function in the decision-making process. However, despite being required by law to meet and function, only 41 percent of these federal advisory groups were financially supported by their governments. This raises questions about sustainability of the advisory committees and their work.

Another concern is that 47 percent do not have the right mix of scientific expertise—that is, they may be lacking immunology, microbiology, or mathematical modeling expertise. Perhaps most concerning, none reported having economic expertise. Such expertise is absolutely fundamental for decisions about vaccines and immunization that are grounded in notions of sustainability. The economic expertise of health systems and cost-effectiveness must complement scientific expertise, to ensure that new vaccines can be introduced without wasting financial resources.

Other aspects of the composition of such advisory groups demonstrate the varying quality of their functioning across the region. For example, national immunization technical advisory group members report potential conflicts of interest to varying degrees in the Americas. This practice of reporting conflicts of interest should continue to be encouraged as a fundamental requisite to ensure transparency and scientific rigor in the recommendations and to prevent third parties with vested interests from influencing the process.

Although infrequent, inappropriate financial or other compensations from a few manufacturers to key government policy makers have occurred, leading to inappropriate product choice.

To compound this risk, certain vaccine manufacturers have an extensive network of representatives working not only throughout the Americas but throughout the world. These representatives frequently meet with other ministry of health officials to sell their products. The obvious policy risks for national immunization programs include the choice of an intervention that is not the most cost-effective, objectively evaluated, or in the interest of national health priorities.

**THE PROVAC INITIATIVE** PAHO’s ProVac Initiative, funded by the Bill & Melinda Gates Foundation, has as its prime mission the strengthening of the national capacity to make informed, evidence-based decisions on the introduction of new vaccines, taking into account the other critically important guiding principles, equity and access. A team at PAHO’s Washington, D.C., headquarters coordinates a plan of action to support countries with efforts to strengthen their national capacity. The team implements its country support through multiple training workshops; direct technical support for national-level decisions; and coordination of national expertise to visit US and Canadian advisory group meetings.

Virtually all countries in Latin America and the Caribbean have requested support from the initiative to increase the effectiveness of existing advisory groups or to help establish such groups. But there are other elements of national capacity that need to be enhanced, not just the recommendation body itself.
The Need For Strong Evidence In Vaccine Policy Making

The evidence to inform vaccine policy decisions in many countries in the Americas is often lacking or of insufficient quality to provide accurate estimates of the disease burden and related economics. National investigators physically present and working in the region’s developing countries are clearly best positioned to generate or collect the missing evidence.

For example, countries might not have collected actual cost evidence at the point of service, or the actual number of cold storage units required for vaccine storage in the country.

The challenges of surveillance to provide evidence on national disease burden have been previously described. Enhancing national decision-making capacity for new vaccines also aligns with efforts to enhance the regional capacity to promote “South-South” and “South-South-North” technical cooperation.

Here, the term South generally refers to all countries in Latin America and the Caribbean south of the United States. Technical cooperation refers to the support provided by countries that have the knowledge and experience to help less fortunate countries, with the aim to strengthen their national expertise and self-reliance in decision making.

ProVac Centers of Excellence

To these ends, in 2010, the ProVac initiative created a regional Network of ProVac Centers of Excellence. Before the creation of these centers, it was a major challenge to try to draw on the expertise of those in the South knowledgeable about vaccines because more formal processes and networks for bringing them together were insufficient. If these networks did exist, they were not well coordinated.

The tendency was always to fall back on Northern partners because of the obstacles and cost involved in bringing those from the South with expertise together. These partners—the United States and Canada—have the resources to maintain national vaccine expertise.

Pulling together centers of excellence in the South to conduct policy research strengthens both regional and national vaccine capacity. This network will provide technical support to ongoing activities of the ProVac initiative, particularly those aimed at strengthening vaccine capacity within each country, developing national economic analysis by making available tools and methodological guides to support economic analysis and evidence-based decision making.

The ProVac initiative network is undertaking several major projects in 2011. One project is the creation of a vaccination program cost tool, which will include a budget impact analysis component to estimate the financial burden of introducing a new vaccine. Another project is the creation of a new cost-effectiveness model that will evaluate the human papillomavirus vaccine and screening. The group is also developing methodological guides on generating and collecting data on disease burden, health services use, and cost of illness, using national sources whenever possible.

Ensuring the Quality of Evidence

Another challenge is whether the evidence used to make decisions best represents the national situation. For example, global estimates for disease burden are generally derived from modeling studies resulting from special studies conducted in a relatively few localities. It is rare for a country to know with any accuracy how many pneumococcal cases or deaths from pneumococcal invasive disease occur each year. Rather, national estimates come from similar modeling studies.

In other words, the estimates may be the “best guess.” Historically, most of the evidence used for national vaccine decision making did not come from national sources.

The Decision Package

The decision package is the framework of evidence that countries should use in making informed decisions for introducing new vaccines. It needs to account for the presence of sufficient political commitment to actually finance the vaccine introduction. None of the factors included in the decision package alone are adequate to provide sufficient evidence for an informed decision on introducing a new vaccine.

For example, it seems reasonable that a vaccine that addresses the greatest disease burden of a country should be considered a top priority for that country. But if the vaccine’s price per dose is highly prohibitive—consuming a substantial portion of the national budget or perhaps even risking the diversion of national resources from other priority public health interventions—then introducing that vaccine is
most likely not a priority, and certainly not until prices are more affordable. In such a situation, the benefit of this particular vaccine introduction will need to be weighed against other public interventions for preventing and controlling this particular disease.

A critical challenge has been to transform modeling tools or approaches from academic settings to practical settings to assist with decision making, using more local data, while still maintaining scientific rigor that would prevent erroneous results. The ProVac Initiative and its partners, with the help of some of the world’s leading experts, have developed modeling tools for practical cost-effectiveness studies for pneumococcal, rotavirus, and seasonal influenza vaccines. For example, ProVac’s cost-effectiveness tool being developed for human papillomavirus vaccine introduction is largely being done by Sue Goldie and her team at Harvard University.

**GUARDING AGAINST MISUSE OF DATA** Another challenge is to prevent the misuse of these tools. Poor-quality data used to populate vaccine decision-making models will surely lead to poor-quality results. There is a major concern from the key partners, experts, and staff working on the ProVac initiative that misinterpreted results will lead to the wrong decision.

Countries from around the world are now asking for copies of these tools, which is a very positive development, but the use of the tools needs to be supported with sound technical input and assistance.

To that end, PAHO has created a working group to manage the transfer of these tools and the expansion of their use in other regions of the world. Some of the benefits of expanding the ProVac initiative to other regions through a working group include the synergistic effect of the effort and resources of complementary projects and programs; expansion of the impact of the existing models, tools, and methodology; and increased capacity to improve the models and tools.

Expansion also can lead to the accelerated use of cost-effectiveness analysis worldwide as part of the evidence needed to make an informed decision on vaccine introduction and the generation and publication of evidence that is comparable between regions.

**Sustaining National Immunization Programs**

The developing countries of the Americas have been referred to as the “first introducers” of new and underused vaccines. Collectively, the countries of Latin America and the Caribbean were the first among the developing countries of the world to introduce measles-mumps-rubella vaccine (1996), diphtheria-pertussis-tetanus-hepatitis B-Haemophilus influenzae type B vaccine, known as pentavalent vaccine (1999), seasonal influenza vaccines (2005), and, most recently, rotavirus (2006) and pneumococcal (2006) vaccines.

With the exception of Haiti, all countries in the region have introduced measles-mumps-rubella and pentavalent vaccines. Additionally, thirty-five countries have introduced seasonal influenza vaccine. Rotavirus vaccine was introduced in Nicaragua in 2006—just one year after its introduction in the United States. To date, sixteen countries in the Americas have introduced rotavirus vaccine, and sixteen countries have introduced pneumococcal vaccine.

The long-term success of these and other introductions, and ultimately the achievement of the Millennium Development Goal on childhood mortality reduction, will rely on how well countries deal with the huge challenge of ensuring their financial and operational sustainability. One of the most effective mechanisms to ensure the sustainability of health interventions is for country self-financing to replace historically fragile external funding sources. The availability of external sources of funds is usually restricted to a particular period of time. National responsibility for paying the bill for vaccines relieves countries of the uncertainty that external financing may not be available when they need it.

**VACCINE LAWS PROMOTE IMMUNIZATION PROGRAM STABILITY** Vaccine laws in the Americas have been used to guarantee the sustainability of vaccination programs by requiring countries to purchase vaccines for public use by using funds from their own national budgets. In 2010 PAHO reassessed the vaccine laws in the region by evaluating whether factors such as tax exemptions for the importation of vaccines, creation of a national health or vaccine fund, and laws requiring the obligatory use of PAHO’s Revolving Fund correlated with beneficial health outcomes, such as improved rates of vaccination, effective resource management, and cost savings.

The Revolving Fund is a mechanism intended to assist with the bulk purchasing of vaccines. It is managed by PAHO on behalf of member countries.

Although the results of PAHO’s assessment of vaccine laws are preliminary, the findings suggest that legislation committing countries to the use of the Revolving Fund for vaccine purchase correlates with more equitable vaccination coverage: Fewer communities report low estimates of vaccination rates. This finding supports...
PAHO’s commitment to ensuring equity and access to health services.

**CONTINUED FOCUS ON EQUITY AND ACCESS** The fundamental goal of enhancing vaccine programs in the Americas is to ensure access to life-saving vaccines for the poorest of the poor. Although the region has generally high regional vaccination rates, that statistic hides important coverage differences within and between countries, and masks a trend of decreasing vaccination rates in some countries.

Within a country, vaccination is measured by municipality. The municipalities with lower rates tend to be located in hard-to-reach areas, in border regions, in areas primarily inhabited by indigenous groups, and among neglected settlements close to urban areas.

In 2009 approximately one million infants—of an estimated 10.8 million birth cohort in Latin America and the Caribbean—were left unprotected against vaccine-preventable diseases. Municipalities are often referred to as the smallest geopolitical unit in a country. Municipalities are equivalent to US counties and are used to measure and identify communities of poor vaccination rates or performance.

Receipt of three doses of diphtheria-pertussis-tetanus vaccine among children younger than one year old was found to be less than 95 percent in more than 40 percent of the municipalities of Latin America and the Caribbean. Ninety-five percent is the target vaccination rate that PAHO encourages all countries to achieve.

When municipalities do not reach this level for three doses of this vaccine, they are referred to as poor performers. Accordingly, 40 percent of municipalities in the region are not performing up to accepted standards. Of those municipalities, 21 percent reported less than 80 percent receipt of the three vaccine doses, and 4 percent reported less than 50 percent receipt of the three doses.

These pockets of low vaccination in the region are at risk for the emergence of disease outbreaks. Such risk obviously applies for diphtheria and pertussis, as well as importations of polio, measles, and rubella viruses, all potentially leading to extensive outbreaks.

PAHO is assisting member countries in reducing these inequities by supporting efforts to specifically target underserved communities with low rates of immunization. This was a key strategy in the Americas over the past two decades for the eradication of rubella, measles, and polio.

Improving vaccination rates in all municipalities of the region will protect the progress made in eradicating these diseases, while strengthening health systems’ capacity to improve routine services and to introduce new and underused vaccines.

**MANAGEMENT AND SUPERVISION** Once it has been decided to embark on technically proven strategies, sound program management is essential for the efficient and effective implementation of the program’s plan of action. Each country in the Americas is required to have an updated national plan of action for immunization. This approach includes supervision and evaluation with accountability as key drivers for program implementation. For example, managers must conduct regular supervisory site visits to evaluate health workers’ performance.

Pockets of low vaccination, as illustrated above, need to be properly addressed. National plans of action must be in place and should have clear targets and indicators for monitoring progress, as well as for projecting costs for all activities, in order to identify program needs and gaps in resources.

PAHO has been promoting various plans of action since the commitment to polio eradication in the 1980s. The polio eradication efforts and subsequent creation of plans of action to ensure the program’s sustainability are partially responsible for the strength and level of political support of current immunization programs in the Americas.

Experience also demonstrates that technical and financial oversight in the form of expert review committees will enhance the coordination of necessary technical expertise provided by key international partners such as the US Centers for Disease Control and Prevention and others.

For instance, PAHO’s technical advisory group on immunization comprises the region’s leading experts on immunization, vaccinology, and delivery of health services. An interagency coordinating committee comprising representatives of the diverse groups and organizations that support the national immunization programs provides a forum for aid coordination that avoids competition and duplication of support.
Both of these groups and several other partners meet regularly to review progress in the control of vaccine-preventable diseases. They make recommendations that should improve access to vaccines in the region.

**Conclusion**

The review of our experience suggests that when national governments in developing countries are supported for evidence-based new vaccine policy, take responsibility for helping to pay for and distribute vaccines when appropriate, are supported by strong partnerships with a vision of technical cooperation grounded in a long-term vision for capacity and infrastructure development, they succeed in saving more lives more quickly.

We hope that this review will contribute to similar efforts in other parts of the world. We believe that the road map for developing countries to address challenges of new vaccine introduction must prioritize capacity and infrastructure development.

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**NOTES**

In this issue of Health Affairs, Jon Kim Andrus and coauthors explore the challenges developing countries face in ensuring access to needed vaccines, using the Pan American Health Organization’s (PAHO’s) ProVac initiative in the Americas as a backdrop.

The initiative, funded by the Bill & Melinda Gates Foundation, has as its prime mission the strengthening of national capacity to make informed, evidence-based decisions on the introduction of new vaccines. The authors consider in this paper not only obstacles to introducing a new vaccine, but also how to best implement it in order to meet the United Nations’ goal of reducing childhood under-five mortality rates by two-thirds between 1990 and 2015.

Among other findings, they conclude that enhancing national capacity to make evidence-based decisions should help ensure the success and sustainability of national immunization programs as new, more expensive vaccines become available.

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