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## Evidence-based decision-making for vaccine introductions: Overview of the ProVac International Working Group's experience

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### Abstract

**Introduction**—Pan American Health Organization's (PAHO) ProVac Initiative aims to strengthen countries' technical capacity to make evidence-based immunization policy. With financial support from the Bill and Melinda Gates Foundation, PAHO established the ProVac International Working Group (IWG), a platform created for two years to transfer the ProVac Initiative's tools and methods to support decisions in non-PAHO regions.

**Methods**—In 2011, WHO Regional Offices and partner agencies established the IWG to transfer the ProVac framework for new vaccine decision support, including tools and trainings to other regions of the world. During the two year period, PAHO served as the coordinating secretariat and partner agencies played implementing or advisory roles.

**Results**—Fifty nine national professionals from 17 countries received training on the use of economic evaluations to aid vaccine policy making through regional workshops. The IWG provided direct technical support to nine countries to develop cost-effectiveness analyses to inform decisions. All nine countries introduced the new vaccine evaluated or their NITAGs have made a recommendation to the Ministry of Health to introduce the new vaccine.

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#### Contributors

This was a group effort led by the ProVac IWG Secretariat at the PAHO, with considerable contributions from IWG's partners: AMP, LSHTM, PATH, Sabin Vaccine Institute, the CDC, and WHO headquarters. This work was guided and overseen by Dr. Jon K Andrus, Deputy Director of PAHO and principal investigator of the ProVac Initiative.

#### Disclaimer

The findings and conclusions in this article are those of the authors and do not necessarily represent the views of the Centers for Disease Control and Prevention.

#### Conflict of interest statement

The authors have no conflicts of interest to declare.

**Discussion**—Developing countries around the world are increasingly interested in weighing the potential health impact due to new vaccine introduction against the investments required. During the two years, the ProVac approach proved valuable and timely to aid the national decision making processes, even despite the different challenges and idiosyncrasies encountered in each region. The results of this work suggest that: (1) there is great need and demand for technical support and for capacity building around economic evaluations; and (2) the ProVac method of supporting country-owned analyses is as effective in other regions as it has been in the PAHO region.

**Conclusion**—Decision support for new vaccine introduction in low- and middle-income countries is critical to guiding the efficient use of resources and prioritizing high impact vaccination programs.

### Keywords

Immunization program; Economic evaluations; Cost-effectiveness analysis; Evidence-based policy; Immunization policy

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## 1. Introduction

According to a study on the global burden of childhood pneumonia and diarrhea, estimates of annual childhood mortality due to rotavirus-associated diarrhea are 192,000 globally, and another 411,000 children younger than 5 die each year from pneumococcal disease [1]. Additionally, 266,000 women died prematurely in 2012 from cervical cancer caused by human papillomavirus (HPV) [2]. Vaccines to prevent these priority diseases offer opportunities to make substantial gains in health, oftentimes at a relatively lower cost than other preventive strategies. However, the relative value of many new vaccines may depend on variables that vary greatly between and within countries; consequently, policy decisions to introduce new vaccines require an evidence base that reflects national conditions.

Using the Pan American Health Organization (PAHO) ProVac Initiative's framework for promoting evidence-based decision-making, the International Working Group (IWG) was created in 2011 to help strengthen national capacity for evidence-based decisions regarding the introduction of new vaccines in developing countries in regions other than Latin America and the Caribbean (LAC). This article is an introductory overview of the work conducted by the IWG. More details about this work will be covered in other publications within this special Vaccine supplement.

## 2. Background

In 2004, PAHO created the ProVac Initiative. Since then, the ProVac Initiative has trained high-level technical staff from ministries of health from over 25 countries in the Latin America and Caribbean (LAC) region on the use of economic evaluations in the decision-making process for introducing new and underutilized vaccines to prevent rotavirus diarrhea, pneumococcal disease, and human papilloma virus (HPV) infection. ProVac has also supported 21 country-owned cost-effectiveness analyses on rotavirus, pneumococcal conjugate, and HPV vaccines to inform national decision-making processes in LAC.

Implementing the ProVac Initiative in the Americas has yielded a number of valuable lessons and tools for supporting countries in making evidence-based decisions around the introduction of new vaccines. Specifically, multidisciplinary country study teams that collect data and do analysis have used TRIVAC (the integrated childhood vaccination cost-effectiveness model for rotavirus, pneumococcal conjugate, and *Haemophilus influenzae* type b [Hib] vaccines) to ensure that immunization policymakers in LAC recognize study results and weigh their outcomes in decisions about whether to introduce a new vaccine [3].

Over the years, PAHO has received requests from technical cooperation organizations and countries outside of the LAC region to implement ProVac tools and methods. Under the umbrella of the ProVac IWG, PAHO worked closely with organizations involved with global immunization activities – Agence de Médecine Préventive (AMP), United States’ Centers for Disease Control and Prevention (CDC), Program for Appropriate Technology in Health (PATH), the Sabin Vaccine Institute, and WHO headquarters, regional and country offices – to leverage lessons learned in the Americas for use in other regions.

It was decided to form the ProVac IWG to serve as the mechanism to bring together the above organizations because IWG would:

- Provide a unique platform to channel requests for technical assistance from developing countries around economic analysis for new vaccines and for adjustments/updates to existing ProVac tools and methodologies.
- Improve coordination among relevant parties supporting evidence-based decisions about introducing vaccines in developing countries—which in turn clarifies roles, responsibilities, and collaborations that help to avoid overlap and maximizes efforts.
- Increase the flexibility of the ProVac tools and methods, helping to ensure their appropriate use in different epidemiological and geographical contexts.
- Generate and encourage the publication of evidence to promote greater consistency between regions, both in the use of standardized methods and tools, and in the country-led evidence-based approach, too.

### 3. Methods

In 2011, WHO regional offices and partner agencies met at PAHO headquarters to establish the ProVac IWG, as a platform to transfer ProVac’s framework and experience (including its tools, methods, and training exercises that support making evidence-based decisions about introducing new vaccines) in selected countries in Africa, the Eastern Mediterranean and Europe—regions where IWG partners have strong existing networks. In 2012, IWG received support from the Bill and Melinda Gates Foundation for two years, during which the technical cooperation focused on low- and middle-income countries. These are regions where the burden of rotavirus, pneumococcal and cervical cancer is greatest and where countries are challenged by limited capacity to build evidence bases to support the decision-making process for introduction of new vaccines. The work focused on support to countries facing decisions about introduction of pneumococcal conjugate vaccine and/or rotavirus vaccine using the TRIVAC impact and cost-effectiveness model.

During the two years, PAHO served as coordinating secretariat, and partner agencies played implementing or advisory roles. AMP provided direct technical support to selected countries in the Eastern Mediterranean (EMR) and Europe (EUR); PATH did the same in Africa (AFR). Both partner agencies received training from PAHO as well as subsequent support from the WHO headquarters and regional offices. Sabin Vaccine Institute supported AMP's and PATH's capacity-building activities at country level with their expertise in effectively communicating evidence for informed decision-making; the CDC provided advisory support on epidemiological data quality. The IWG leveraged existing country relationships and subject matter expertise to support the rollout of this framework in nine countries. The countries were selected according to the following criteria: (1) interest from the ministry of health or an official request to conduct an economic evaluation, (2) a pending decision regarding a new vaccine introduction, and (3) a partner presence in the country.

The ProVac IWG had three main objectives: (1) transferring tools, methods, and lessons learned in the Americas to other regions to support national decisions about new vaccine introduction, (2) building national capacity for using economic analyses in low- and middle-income countries around the world, and (3) providing direct technical support collecting data and conducting economic analyses to inform immunization policy in low- and middle-income countries. Details and follow-up on the objectives are elaborated below.

Considering differences in data availability, data quality, and new vaccine policy questions that exist between WHO regions, the ProVac IWG collaborated to adapt the tools used in the Americas for use to support national-level decision-making about the introduction of new vaccines in developing countries in the WHO Regions of AFR, EMR and EUR. This included revising input parameters of the model (as needed) and translating the ProVac tools and methods to French and Russian. A number of improvements to TRIVAC were also made as a result of direct feedback from countries involved in the IWG. These include: (1) greater clarity in the way inputs were organized—e.g., dose-specific vaccine efficacy and assumptions about vaccine timeliness (on-time, delayed) and age restrictions (age-restricted or unrestricted); (2) improved popup explanations and workshop materials designed to suit a wider geographical audience; (3) improved graphical output; (4) greater flexibility to customize the type of diseases considered by the country team—e.g., pneumonia admissions, X-ray-confirmed pneumonia, or clinical pneumonia, etc.; (5) development of features to help users calculate a plausible case fatality ratio and understand how it was derived—i.e., combining a top-down (proportional mortality) estimate of deaths with a bottom-up (incidence-based) estimate of cases; (6) increased scope of the OLIVES on-line data repository—e.g., incorporating evidence from outside the Americas on vaccine type coverage, waning vaccine protection etc.; and (7) the addition of two new language options for users of the model—i.e., Russian and French.

National capacity to perform economic analyses to inform new vaccine introduction is considered limited in most developing countries. To address this challenge and ensure that the IWG's tools helped a greater number of public health decision-makers, IWG partners organized regional workshops to provide training on basic concepts of health economics and disease epidemiology, and on the use of ProVac tools for economic analyses. Regional workshops provided national public health professionals with a broad understanding of how

to collect and critically assess data, conduct analyses, interpret results, and contextualize findings in light of other relevant criteria for deciding on whether to introduce a new vaccine.

ProVac IWG partner-led regional workshops used PAHO's TRIVAC model as a practical training tool. TRIVAC is an Excel-based, cohort model that provides users with a friendly, stepwise template to collect data for each model parameter [3]. It evaluates the incremental program costs, health benefits gained, and disease-associated costs averted from introducing vaccines that prevent Hib, rotavirus, and pneumococcal infection.

Although the regional workshops were the primary method for training national people on using ProVac tools, the ProVac Centers of Excellence also developed training materials on health economics and evidence-based decision-making in the Latin American region [4]. The training materials, which explained the key concepts required for understanding the tools and how to use them, were provided to country teams and discussed in regional workshops.

The ProVac Initiative promotes capacity-building as an overarching principle to ensure long-term sustainable impact. As stated above, the IWG supported this concept by helping to form multidisciplinary country teams to use ProVac tools, carry out data collection, conduct analysis, and communicate study results to policymakers. The majority of these study teams were appointed by the Ministry of Health; they included participation from WHO regional and/or country immunization staff, Expanded Programme on Immunization (EPI) managers, and relevant experts from ministries of health and academic centers (health economists, epidemiologists, pediatricians, public health and immunization experts). In each country, a ministry of health focal point or a national consultant was also identified to coordinate the study activities. These teams served as technical working groups to support deliberations on the introduction of new vaccines by National Immunization Technical Advisory Groups (NITAGs), where these exist. IWG partners provided ongoing technical support throughout the study, with in-country visits to initiate and support the study and a final visit to review databases, address any methodological challenges, and assist in interpreting the results for decision-making purposes.

CDC partners led technical reviews and provided recommendations regarding epidemiological data on rotavirus and pneumococcal disease. After data collection, multidisciplinary country teams critically assessed the data and conducted the analyses. With support from the whole ProVac IWG, AMP led studies in EMR and in EUR. Similarly, PATH led studies in AFR, complementing work previously conducted in other African countries. The current supplement showcases a more detailed description of AMP's experience, as well as country-led publications from the three regions studied [5–12].

In most cases, the evidence is only as good as the methods used to communicate. The Sabin Vaccine Institute led an effort to develop a communication and advocacy strategy to be applied in study countries to ensure that the evidence generated through ProVac studies reaches stakeholders and decision-makers. The institute developed a practical guide and several templates to help multidisciplinary national teams to package their evidence into

concise and practical materials so that the evidence relevant to the decision process could be effectively communicated to a range of stakeholders. The strategy involved these steps:

- Analyze the country's existing decision-making process for introducing new vaccines.
- Identify stakeholders and their roles in the decision process.
- Identify relevant evidence that should be used to properly inform the decision.
- Address common questions about cost-effectiveness and its role in the decision-making on new vaccine introduction.
- Create concise and effective technical presentations based on data from the economic analysis performed.
- Construct key messages and provide supporting evidence to accompany the results of the economic analyses.
- Draft policy briefs that include the national economic analysis and other relevant criteria for decision-making.
- Draft technical reports, including more detailed information about the economic evaluation that was conducted.

#### 4. Results

Economic analyses represent one component of a broader policy framework for evidence-based decisions regarding the introduction of new vaccines. PAHO's ProVac introduction policy framework [13], which considers technical, programmatic, and social criteria, has helped guide countries to use economic analyses in the context of other relevant decision criteria to ensure that a comprehensive policy analysis is conducted to ground decisions in evidence. The ProVac IWG promoted the use of the same framework.

ProVac IWG held both an initial and final meeting during the 2-year period. The initial meeting served as a platform for the IWG partners to agree on specific activities and for PAHO to train implementing partners on the TRIVAC model and ProVac methods; the final meeting was to evaluate the IWG's outcomes. This allowed the incorporation of improvements in the TRIVAC model to accommodate the needs of countries outside the LAC region. Those improvements included adding two new language options (French and Russian), a designated area for manual calculations, and updated default data.

A total of 59 national professionals from 17 countries received training through IWG's regional workshops. Each partner had existing regional ties in one or more of these regions and the workshops complemented their ongoing regional work.

AMP led regional workshops on the use of economic analyses to inform decisions around the introduction of pneumococcal conjugate vaccines in EUR and EMR in 2012 and 2013 respectively; WHO headquarters, regional, and country offices provided support. Similarly, PATH led a workshop on conducting cost-effectiveness analyses of new vaccine introductions, focused on the rotavirus vaccine in AFR in 2013. This workshop in AFR



complemented two previous workshops PATH had organized on the use of economic analyses in 2011 (funded by other sources). The regional workshops targeted EPI managers, national health economists, and other relevant ministry of health professionals working in the area of vaccine-preventable diseases. During the workshops, country teams that were conducting their own cost-effectiveness studies within the ProVac IWG shared their experiences; this helped achieve the ProVac objective of capacity-building.

The IWG provided direct technical support to nine countries<sup>1</sup> to develop cost-effectiveness analyses and inform decisions on pneumococcal conjugate or rotavirus vaccines [see Table 1]. Seven of those nine countries had received training as part of the above-mentioned regional workshops. After considering the cost-effectiveness results obtained and taking into account other criteria considered relevant, countries either made the decision whether or not to introduce the new vaccine that had been evaluated, or the countries' NITAGs or equivalent advisory bodies used the new evidence and made recommendations to their respective ministries of health [see Table 2 for country-specific information.]

Where data gaps or weaknesses were identified from national sources, the national team presented recommendations to their authorities to strengthen surveillance and health information systems (HIS).

The resources needed for supporting EUR consisted of the partner's staff time and travel costs, workshop participants' travel and per diems, and translation of materials into French and Russian. In EMR and AFR, in addition to all these expenses, a small amount of funds was also required to convene internal working group meetings within each of the countries, to cover coffee breaks, and as a financial incentive for nationals to attend the meeting (which was not necessary in EUR). Lessons learned in the EUR and EMR regions include (1) the need for a well-balanced multidisciplinary team in the country to carry out the cost-effectiveness analysis (CEA), including all relevant specialties and institutions, (2) the importance of involving all stakeholders from the start of the study so that study results are accepted by all parties, and (3) the necessity of providing a regional approach which encourages peer-to-peer interactions between countries that builds esprit de corps among investigators and embraces intellectual development.

Partners working in the AFR region faced different challenges including a more complex country selection process. They also learned that having a country office where the study is being conducted and holding regional workshops before beginning country analyses are critical elements for success of the work. A specific lesson learned from AFR was the importance of beginning these studies well in advance of policymaking timelines that are advanced by the Global Alliance for Vaccines and Immunization (Gavi).

## 5. Discussion

Many of the countries supported through the ProVac IWG are moving away from donor-funded immunization programs. As such, they have an increasing interest in weighing value against the financial cost of adopting the new vaccine. The ProVac approach to conducting

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<sup>1</sup>The nine countries were: Albania, Azerbaijan, Croatia, Egypt, Georgia, Iran, Kenya, Senegal, and Uganda.

country-owned economic evaluations can be a valuable and timely aid to this national decision-making process, although the unique challenges encountered in each region require further consideration. For Gavi-eligible countries, conducting a country-level CEA is not a current prerequisite for funding and so the dynamics and motivations vary. A cost concern with regard to a new vaccine's affordability is more pertinent. Despite this, we consider the process of generating and collecting data required for a cost-effectiveness study relevant to Gavi-eligible countries: It promotes a culture for evidence-based decision-making while also helping the government evaluate the long-term strategic planning and sustainability of the new vaccine being considered for introduction.

Similar to ProVac's experience in the Americas, one of the key problems we faced in these countries was lack of national-level data on important information such as disease burden and serotype distribution. This often led to using regional data or international estimates for these parameters. One lesson learned is that countries prefer national data, but this requires they anticipate this and that they have surveillance systems in place well before the analysis is conducted, or that they perform focused studies that provide reliable, quality national data. When this has not happened, the question of what constitutes a good surrogate often arises. Examples include regional estimates and data from bordering countries. The variable national technical expertise on subject matter and on how to set up these studies is another lesson to highlight, and indicates the need for regional WHO offices and other partners help them build such capacity.

Sustainability or "nationalization" of the process is yet to be documented in these regions. The Americas has had several experiences of countries performing further studies with significantly less support from the ProVac team [14], but this is yet to happen in the IWG regions where the ProVac support is more recent.

As will be further reinforced in the specific related publications in this supplement, the experience suggested that (1) there is great need and demand for technical support and for capacity-building to conduct economic evaluations at the national level in the regions where the work took place, and (2) the ProVac method of supporting country-owned analyses through extensive training, direct support, and promotion of country ownership of process and results could become as effective in other regions as it has been in the PAHO region if it is properly adapted to the regional context. This collaboration is one of several experiences where regions with more advanced immunization programs transfer successful initiatives to other regions. More international and regional funding mechanisms for cross-regional sharing are needed to maximize the impact of existing initiatives and prevent having each region "reinvent the wheel."

The leveraging of expertise of the partner agencies proved useful. The PAHO ProVac team, which includes the modeling team at the London School of Hygiene and Tropical Medicine (LSHTM) and a core team of international consultants, provided its years of experience developing tools and trainings specifically for country teams and supporting country-led economic analysis, and provided a coordinating role for the group. PATH offered a strong health economics expert team, and also had disease epidemiology experts available to provide support. AMP provided effective training techniques. CDC provided important



subject matter expertise on epidemiological and surveillance data. WHO headquarters and regional offices provided convening power and global immunization policy expertise. The Sabin Vaccine Institute offered useful and practical tools for communicating results to national authorities.

This experience demonstrated again the critical importance of establishing national multidisciplinary teams for the country to gain ownership over the process and its results. User-friendly, scientifically robust decision-support tools are needed in resource-constrained and/or data-sparse settings and the ProVac tools are an option for filling this gap. The IWG work also confirmed that having a focal point from within the ministry of health or other national institution who is assigned to lead and coordinate the study, rather than hiring an external consultant, is likely more sustainable in the long term and more effective in national-capacity development. However, this could prove challenging, given the more limited time that ministries of health and sometimes even WHO regional or country office staff have to provide support—especially in high-risk regions overwhelmed with emergency or dire health situations as well as with international technical cooperation activities such as in AFR. In the future, it will be necessary to find a more systematized way to deal with country demand for technical cooperation and to prioritize the countries. Finally, as shown in Table 2, technical support to strengthen capacity on economic evaluations of vaccines can be resource-intensive. Combining innovative ways of interacting with local technicians and decision-makers through distance learning with high-quality, easy-to-use tools is necessary for a sustainable approach going forward.

## 6. Conclusion

A nationally based, evidence-driven decision process for new vaccine introduction in low- and middle-income countries is critical to guiding the efficient use of resources and prioritizing high-impact vaccination programs. It is the antithesis of the top-down approach. This experience demonstrated that the ProVac method for capacity-building – which includes using workshops to promote the socialization of general concepts and tools, providing direct support to countries after an official ministry of health request has been received, convening a multidisciplinary team, and fostering strong working relationships between NITAG, ministry authorities, and the team conducting the analysis – can be implemented successfully in countries outside of the LAC region.

The ProVac method provides an opportunity to get multiple national stakeholders to sit at the same table, which enhances the evidence-based decision-making process at country level. Several agencies are well-suited to provide this technical assistance and coordination at the global level will be required. ProVac IWG partners have expressed their interest in continuing to collaborate on this important work. Going forward, both PAHO and WHO may have an opportunity to coordinate the expanded reach of the ProVac toolkit and decision-support methods to additional regions and countries requiring real-time support.

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**Table 1**

Countries and people trained through workshops and through direct technical support.

	<b>EUR region</b>	<b>EMR region</b>	<b>AFR Region</b>
Countries trained through workshops	Albania Croatia Estonia Georgia	Egypt Islamic Republic of Iran Iraq Jordan Lebanon Tunisia	Botswana Kenya Nigeria Senegal South Africa Uganda
Number of national people trained through workshops	18	20	20
Countries that received direct technical support	Albania Azerbaijan Croatia Georgia	Egypt Iran	Kenya Senegal Uganda
Number of national people trained through direct technical support	52	28	11

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Table 2

Country studies' characteristics, results and policy implications.

Country	Gavi eligibility 2014?	Vaccine	Schedule	Vaccine price	% Reduction of deaths	Net costs**	DALYS averted	ICER	GDP per capita***	CEA result	Country decision	Justification for single product evaluation
Kenya	Eligible	RV1	2	\$0.20	46%	\$50,000,000	1312,920	\$38	\$942	Highly cost-effective	Introduction scheduled July 2014	RV1 has vial monitor
Senegal	Eligible	RV1	2	\$0.20	42%	\$17,570,000	190,280	\$92	\$1,040	Highly cost-effective	Introduction planned 2014	Country preference
Uganda	Eligible	RV1	2	\$0.20	40%	\$52,000,000	1509,030	\$34	\$572	Highly cost-effective	Introduction planned 2016	Country preference
Albania	Graduated	RV1	2	\$8.50	68%	\$1910,000	950	\$2,011	\$4,149	Highly cost-effective	Introduction planned for 2015	N/A (comparative analysis)
Georgia*	Graduating	PCV10	3 + 0	\$3.50	30%	\$2300,000	1,438	\$1,599	\$3,602	Highly cost-effective	Introduced in 2014	Global shortage of PCV13
Croatia	Not eligible	PCV10	3 + 0	\$ 30.00	58%	\$42,508,000	540	\$78,649	\$13,227	NOT cost-effective	Not introduced	N/A (comparative analysis)
Egypt	Not eligible	PCV13	3 + 0	\$35.00	58%	\$50,250,000	540	\$92,973	\$13,227	NOT cost-effective	No decision yet	Interested in PCV13 as it covers more serotypes circulating in Egypt
Iran	Not eligible	RV5	3	\$10.00	65%	\$219,640,000	76,591	\$2,868	\$4,763	Highly cost-effective	Decision to introduce; year of introduction pending	Pentavalent vaccine available for Iran. RV5 vaccine price negotiated

Note: Study results in this table reflect the government perspective.

\* In 2013, there was a global shortage of PCV13. Countries only had the option of evaluating PCV10 for immediate introduction.

\*\* All benefits and costs were discounted 3% in the base case. All figures shown here have been rounded up/down.

\*\*\* Of the year of the analysis.