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CONCEPTUAL ARTICLES

Performing Country-led Economic Evaluations to Inform Immunization Policy: ProVac Experiences in Latin America and the Caribbean

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ABSTRACT

New vaccines have been demonstrated to be effective in reducing morbidity and mortality, particularly in children, but come at increased costs to societies, governments, and their national immunization programs compared with other traditional childhood vaccines. Rational allocation of available resources requires systematic collection of the evidence base to decide whether to introduce a new vaccine, an important component of which is cost-effectiveness analysis. In this article, we develop in-depth case studies to examine the country experience of conducting cost-effectiveness analysis with the support of Pan American Health Organization ProVac Initiative and the implications of its process for decision making on new vaccine introduction in Latin America and the Caribbean. Key lessons regarding how cost-effectiveness analysis may be effectively used to inform evidence-based immunization policy are highlighted, drawing from the experience of Nicaragua and Paraguay. Based on the lessons identified, the vision going forward will focus on promoting the sustainability of multi-disciplinary country teams while continuing to prioritize capacity development as an overarching guiding principle for preparing countries to face future new vaccine policy decisions.

Keywords: cost-effectiveness analysis, economic evaluations, evidence–based policy, national immunization programs.

Introduction

New vaccines hold the extraordinary potential of saving lives and preventing disability but come at increased costs to governments and their national immunization programs. Considering the large investment new vaccines represent for many programs, the decision to introduce a new vaccine into a universal immunization schedule is a highly complex task [1,2]. Efficient allocation of available resources requires systematic review of the local evidence base to decide whether to invest public funds in a new vaccine. One component of the evidence base is economic analysis, including, among others, cost-effectiveness analysis [3]. Increasingly, national immunization programs in low- and middle-income countries are seeking ways to estimate the economic and financial burden as well as potential health gains of new vaccine introduction to ensure financial sustainability and efficient resource allocation in the long term [4]. As low- and middle-income countries assume greater financial responsibility for their national immunization program budgets, questions around financial sustainability and competition of resources among different health priorities become more relevant [5].

Ensuring sustainable vaccine introductions as well as efficient and equitable allocation of resources for health means that national public health decision makers must invest the time to collect the evidence base necessary to inform the decision-making process [1]. The Pan American Health Organization (PAHO), the regional office of the World Health Organization (WHO) for the Americas, provides technical assistance to

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Authors' contributions: J.K.A. is the Deputy Director of PAHO and Principal Investigator of ProVac. He conceived and designed the initiative. B.J. is the Project Manager of the initiative, and C.B.J. is a technical officer for the initiative. J.K.A., B.J., C.B.J., and C.T. execute and coordinate the initiative's operations. A.D.C., B.M.B., S.R., and A.S. serve as technical consultants. A.D.C. developed the TRIVAC model. C.B.J., B.J., A.S., and A.D.C. drafted the manuscript. B.M.B., S.R., and C.T. made substantial contributions to the manuscript. J.K.A. revised the intellectual content of the manuscript. All authors participated in drafting and reviewing the article and approved the final manuscript.

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countries in Latin America and the Caribbean (LAC) to facilitate and promote this process. Specifically, PAHO's ProVac Initiative has extended support to countries to build local evidence bases to inform decisions regarding the introduction of new vaccines [6]. The rationale and structure of the ProVac Initiative have been previously described [1,2,6]. In this article, we develop in-depth case studies to describe the country experience of conducting cost-effectiveness analyses (CEA) and developing local evidence bases to inform decision-making processes in LAC countries. The case studies reveal several lessons regarding the use of CEA to inform evidence-based immunization policy.

Supporting Country-Led Economic Analyses: ProVac's Approach to Strengthening Evidence-Based Immunization Policy

With support from the Bill and Melinda Gates Foundation, PAHO's ProVac Initiative was established to strengthen national capacity to perform economic analyses on new vaccines and to use the evidence to guide the decision-making process. While the ProVac Initiative promotes the development of a comprehensive evidence base to inform the decision on whether to introduce a new vaccine or not, drawing from technical, operational, and social criteria, its primary focus to date has been to respond to country requests to strengthen their capacity to conduct and to use economic analyses as one component of the evidence required for the introduction of new vaccines in the region [1,2,6].

ProVac helps countries to establish multidisciplinary teams and then supports these multidisciplinary teams to gather evidence for economic analyses on new vaccines, conduct the analyses, contextualize results with other evidence criteria related to the introduction of new vaccines, and message results to relevant authorities, either ministries of health or National Immunization Technical Advisory Groups (NITAGs). Central to the ProVac approach has been ensuring that multidisciplinary national teams include collaborators from several government agencies and disciplines—health economists, immunization program managers and staff, clinicians from health care organizations, and experts in related disciplines from academia. ProVac promotes local stakeholder ownership over the data collection and analysis process to bolster national capacity to conduct future studies and to establish a strong, sustainable foundation for evidence-based immunization policy.

Efforts have resulted in a number of country-led economic analyses, including 17 CEAs to inform national decision making around the introduction of new vaccines. Nine studies have been performed on the pneumococcal conjugate vaccines in Argentina, Bolivia, Guatemala, Costa Rica, Ecuador, El Salvador, Paraguay, Peru, and Nicaragua, two studies on the rotavirus vaccines in Argentina and Guatemala, and six studies on human papillomavirus vaccine in Argentina, Bolivia, Ecuador, Jamaica, Paraguay, and Uruguay (Table 1). Case studies from Nicaragua and Paraguay illustrate how the locally derived quantitative results are critical for new vaccine policymaking at the national level, but also how the process renders many other important inputs for the decision-making process. Evaluating these case studies reveals key opportunities for the ProVac Initiative to continue bolstering national capacity around evidence-based immunization policymaking.

Table 1 – ProVac supported country-led economic evaluations conducted in LAC.

Country-led economic evaluations	Countries
Cost-effectiveness analysis of pneumococcal conjugate vaccines	Argentina, Bolivia, Costa Rica, Ecuador, El Salvador, Guatemala, Nicaragua, Paraguay, Peru
Cost-effectiveness analysis of rotavirus vaccines	Argentina, Guatemala
Cost-effectiveness analysis of HPV vaccines	Argentina, Bolivia, Ecuador, Jamaica, Paraguay, Uruguay
Costing of HPV delivery strategies	Barbados
Costing of EPI	Bolivia

EPI, Expanded Program for Immunization; HPV, human papillomavirus. LAC, Latin America and the Caribbean.

Case Studies on the Use of Decision Support Models for New Vaccine Policymaking

In the Americas, nearly 12% of all-cause mortality among children younger than 5 years is attributed to pneumonia. Of the estimated 284,248 all-cause deaths among children younger than 5 years in LAC countries that occurred in 2008, 4366 deaths were caused by meningitis and 33,798 deaths were caused by pneumonia [7]. Pneumococcal infection is an important pathogenic cause of these deaths and other serious diseases in children, including meningitis and sepsis. With the licensure of two efficacious vaccines to prevent pneumococcal infection in children, many countries in the Americas have sought to evaluate the cost-effectiveness of introducing either the 10-valent pneumococcal conjugate vaccine (PCV-10) or the 13-valent pneumococcal conjugate vaccine (PCV-13) as one component of the necessary evidence base to inform the decision-making process.

In collaboration with the London School of Hygiene and Tropical Medicine, PAHO's ProVac Initiative has developed an integrated childhood vaccination cost-effectiveness model (TRIVAC) for countries to use and to apply in their local decision-making process. A user-friendly, Excel-based cohort model, TRIVAC evaluates the costs, health benefits, and cost-effectiveness of introducing Hib, rotavirus, or pneumococcal conjugate vaccines. TRIVAC has preloaded data available from international sources for demography, vaccine coverage, disease burden, health service utilization, and costs, but national ProVac teams are encouraged to challenge and improve these estimates with local estimates where quality data are available. The model allows users to evaluate a series of possible scenarios favorable and unfavorable to the vaccine by varying parameters such as community herd immunity, vaccine serotype replacement, and waning protection. Because there may be a great deal of uncertainty around these parameters in the initial years of new vaccine introduction, ProVac generally encourages countries to consider these factors in alternative scenarios to the base-case scenario. By modeling these alternative scenarios, the TRIVAC model assesses the effect of such uncertain parameters on primary model outcomes. In addition, the TRIVAC model features options to conduct sensitivity analyses. Further description of TRIVAC model's methods are presented in the forthcoming article by Clark et al [8].

Experience from Nicaragua

In 2009, Nicaragua began weighing the option to introduce one of the two available WHO prequalified vaccines to prevent pneumococcal pneumonia and other invasive disease. Alongside plans to implement sentinel surveillance sites for bacterial pneumonia and meningitis, the Ministry of Health requested support to undertake special studies to inform the decision-making process. One such request was for support from PAHO's ProVac Initiative to evaluate the cost-effectiveness of introducing a pneumococcal conjugate vaccine into the routine vaccination schedule.

The Ministry of Health established a national team to perform the study, including participation from the national Expanded