Preface

Evidence base for new vaccine introduction in Latin America and the Caribbean

In the past few years, new and underutilized vaccines against diseases associated with high disease burden in developing countries such as Streptococcus pneumoniae, Haemophilus influenzae type b (Hib), Neisseria meningitidis, rotavirus and human papillomavirus (HPV) have become available. These vaccines should substantially contribute toward achieving the Millennium Development Goals by 2015 [1], and have been recommended for inclusion in national Immunization Programs [2–6]. However, these new vaccines are more complex and expensive, and the process of preparing for their introduction requires more time, better communication, and adequate planning for logistic and operational issues, compared to older vaccines. Therefore, national decision makers require a comprehensive evidence base to make informed decisions, including evidence about epidemiological and economic burden of disease as well as the cost-effectiveness and incremental costs to the immunization program.

Recognizing these challenges, Ministers of Health from countries in Latin America and the Caribbean (LAC) at the Pan American Health Organization’s (PAHO) Directing Council meeting in 2006 requested PAHO to “support country activities to integrate economic studies into the decision-making process for the introduction of new and underutilized vaccines.” In response to this request, the ProVac Initiative was launched, with financial support from the Bill & Melinda Gates Foundation. ProVac has been supporting countries in LAC since then to strengthen the decision making process, including the development of country-led cost-effectiveness analysis of new vaccines, and improving the operational procedures of National Immunization Technical Advisory Groups (NITAGs) [7,8].

To date, ProVac has supported 24 analyses in fourteen countries of the Region. National teams have led the process of obtaining and evaluating the best available evidence on disease burden, vaccine effectiveness, program cost, and disease costs, among others. These data are then used in models developed by the ProVac Initiative, which include TRIVAC, a cost-effectiveness model for H. influenzae type b (Hib), pneumococcal and rotavirus vaccines [9] and CostVac, an immunization program costing tool [10]. These models are useful tools for supporting the decision making process only when there is sufficient quantity and quality data to drive them. The ProVac Initiative’s first years of experience providing support to countries demonstrated a clear need for standardized methods to develop locally derived evidence to support real-time decisions concerning newer vaccines such as rotavirus and pneumococcal vaccine.

Central to ProVac’s activities, a regional network of academic institutions with expertise in supporting public health decision making in the LAC Region – the ProVac Network of Centers of Excellence (CoE) – was established in 2010. As Toscano et al. describes in this supplement, the ProVac Network of CoE was tasked with providing technical support to ongoing activities of the ProVac Initiative, including developing methodological guides for generating accurate estimates on several key factors that are relevant for an informed decision. The Network also worked with developing, reviewing, or adapting models and tools to support economic analysis and evidence-based decision making [11]. This Vaccine journal supplement highlights this work from the ProVac CoE in the LAC region, including commentaries and original research on evidence-based decision making, disease burden, economic burden, cost of illness, cost-effectiveness analysis methods, EPI program costing and impact post-introduction.

Two systematic reviews of cost of illness studies of rotavirus and pneumococcal diseases in the LAC Region bring to light that a variety of methods, perspectives, currencies and approaches have been used to estimate the economic cost of illness in the Region, leading to substantial diversity in the available data [12,13]. Considering the limited external validity of cost data, standardized methods to develop locally derived pneumococcal and rotavirus healthcare service utilization and cost of illness estimates to support decisions have been proposed [14,15].

This supplement also highlights how immunization and surveillance program costs are often underestimated [16]. As a key parameter not only for program management and planning but also for estimating accurate routine immunization program costs and incremental costs of introducing new vaccines, standardized tools and methods to improve costing of immunization programs (EPI) have been developed [10]. CostVac is an EPI costing tool which is to be made available to all countries in the LAC Region and the world to help standardize methods for estimating immunization program costs at all relevant administrative levels.

The Global Framework for Immunization Monitoring and Surveillance (GFIMS) recommends that ministries of health enhance national surveillance of vaccine preventable diseases (VPDs), integrating surveillance when possible. Hyde et al. discusses the critical issues in implementing integrated VPD surveillance system [17]. Considering the experience of Costa Rica, which in 2009 became the first country to implement such integrated surveillance, Toscano et al. have estimated the costs for implementing and maintaining such surveillance in the country level [18].

All these methods and data can support the national decision making processes on new vaccine introduction. Once a decision has been made, operational issues must be considered, and introduction needs to be carefully planned to ensure an efficient and sustainable immunization program. Evidence-based decision making on new vaccines happens on a continuum. Vaccine effectiveness and impact should be assessed after introduction, and a
decision regarding the new vaccine program continuation will take place [19,20]. Oliveira et al. highlights challenges and opportunities for rotavirus vaccine impact assessment post-introduction using surveillance data [19].

The pressing need for the approaches and methods described in this supplement are highlighted in a second study conducted by De Oliveira et al. [21]. These authors have conducted a qualitative assessment of new vaccine introduction in selected countries in the LAC region, demonstrating that the factors contributing to vaccine introduction in these selected countries generally are not well-grounded in a systematic approach. The authors reiterate a need to ground decisions in criteria including political, technical, programmatic and feasibility aspects [22].

Finally, comments from immunization experts globally will bring to the reader historical perspectives on new vaccines introduction in low- and middle-income countries [23], the importance of institutions for efficient spending in vaccines [24], key factors for sustainable vaccine introduction [25], challenges on estimating disease burden with available national data [26], and the experience of a developed country and early introducer of new vaccines, which can be valuable for developing countries in the Region [27]. The tools, training materials, methodological guides, and an online international vaccine economics and statistics data repository [8] described in this supplement are available to support countries to assess existing data and generate new evidence on new vaccine introduction. Additionally, this supplement shares valuable experience and information with national decision-makers, immunization technical experts, global partners and donors on methods to further strengthen the decision making process of new vaccine introduction in LAC and beyond.

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