Commentary

Perspectives on the development and use of economic evidence for immunization decision-making in a developing country

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Honduras first established the Expanded Program on Immunization (EPI) nearly 40 years ago and it rapidly became a priority disease prevention program. In the early years of the program, five vaccines were offered in the basic national schedule (Bacillus Calmette-Guérin [BCG], polio, diphtheria–pertussis–tetanus [DPT], measles and tetanus toxoid). Beginning in 1997, the Secretary of Health initiated an accelerated vaccine introduction process, transitioning from the traditional EPI vaccine schedule to an expanded schedule including new and underutilized vaccines. Today, the national immunization program in Honduras includes a schedule of fifteen vaccines.

1. Evidence generation and decision-making on new vaccines

During the period of 1979 to 2003, decisions on the introduction of vaccines followed recommendations from the Pan American Health Organization (PAHO) and the World Health Organization (WHO), taking into consideration data on the local epidemiological profile and burden of disease. In parallel to the decision-making process, Honduras’ Secretariat of Health (SoH) prepared financial sustainability plans in the context of the EPI’s five-year strategic plan and annual work plans to identify resource needs and potential financing sources. At the time, these instruments were sufficient for decision-making and national priority setting regarding the adoption of additional vaccines.

With the arrival of new, more expensive vaccines, Honduras sought to formalize the decision-making process with a more systematic technical consultation at the national level. To this end, the National Advisory Committee on Immunization (NACI) was created in 1999 [1]. This Committee has played an important role in the introduction of new vaccines. Importantly, it provides recommendations to the SoH as inputs for political discussions about the sustainability and feasibility of adoption of these vaccines that often are many times more expensive than the traditional childhood vaccines. To date, Honduras has introduced new vaccines such as the rotavirus vaccine (RV) and the pneumococcal conjugate vaccine (PCV).

For each of these new vaccine introduction decisions, the NACI and SoH have considered a number of evidence inputs to guide the decision-making process. Since 2004, the NACI and SoH systematically consider technical, political and programmatic aspects regarding new vaccine introduction in Honduras. Of these, the most relevant are political priority; burden of disease; availability of safe, high-quality and effective vaccines; as well as the economic and financial sustainability analyses of vaccine introduction to the national schedule. In the case of the rotavirus vaccine, the private sector had developed an economic evaluation in 2006 that was considered by the health authorities. In following years, Honduras sought to generate evidence from within the SoH to inform decisions and therefore the EPI requested technical cooperation from PAHO’s ProVac Initiative to develop cost-effectiveness studies on new vaccines. Evaluations of the PCV and HPV vaccines were conducted in 2009 and 2013, respectively. Support from the ProVac Initiative has been crucial for the development of locally derived evidence providing a credible input into decision making for the Honduran SoH. The evidence on cost-effectiveness of PCV vaccine was used in the 2011 decision-making process. The study on HPV in 2013, concluding that vaccine introduction would represent a highly cost-effective intervention to prevent cervical cancer in Honduras, is currently being used in the national decision making process [2,3].

2. Opportunities and challenges to ensure the sustainable introduction of new vaccines

The Honduran government has a high-level commitment to guarantee free, universal vaccination for its entire population throughout the life cycle, as reflected in its legislation and state management processes. Since the creation of the EPI, the SoH has financed the purchase of vaccines and safe injection supplies, ensuring sustainable supply at the national level. This budget line has been supported since 1998 with the establishment of the “Act to Purchase Vaccines through the PAHO Revolving Fund” [4]. Today, the purchase of vaccines continues to be a protected budget line by the Finance Secretariat (FS) and the SoH.

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Honduras has been eligible for support from Gavi, the Vaccine Alliance, since 2000 due to its status as a low-income country based on the GNI per capita. The country first received financial support in 2003, as well as significant subsidies for introducing the rotavirus vaccine in 2008 and the pneumococcal vaccine in 2010. The window of opportunity from Gavi for new vaccine support has accelerated the country’s ability to incorporate new vaccines into the national schedule. The World Bank recently reclassified Honduras as a lower middle income country [5]. Because of this reclassification, in 2012, the country began a gradual process of graduation from Gavi support. As a result, in 2016, the Government of Honduras will assume 100% of the costs associated with new vaccine introduction and no will longer qualify for other windows of opportunity from Gavi. The country has secured gradual incremental government co-financing for both vaccines (RV and PCV) as of 2012. Ongoing advocacy from SoH with the FS and the existing legal framework have been critical in this process.

However, the country currently faces challenges related to the cost of vaccine procurement and operational activities for the introduction of new vaccines. To meet the challenge of securing sufficient financing to fund operational activities, the legislative authorities passed the “Vaccine Act of the Republic of Honduras” in January 2014 [6]. It is expected that the law will ensure the sustainability of traditional, new and underutilized vaccines. This law went into effect on 26 March 2014 and its regulation is in process, helping to ensure implementation. The EPI conducted a study in 2013 to determine the costs of immunization in the country and to map the available funding sources [7,8]. These data will contribute to developing strategic plans and resource mobilization activities with the aim of achieving 100% of domestic financing for essential EPI needs.

Recently, SoH authorities announced a decision to introduce HPV in the national schedule to target adolescent girls. Introduction plans are underway. Despite the announcement of the technical decision, analyses regarding budget impact and available fiscal face for expansion of the existing routine program are still a key criterion for implementing the vaccine because of the current fiscal crisis facing the country, which is a clear challenge to sustainability. The FS is actively involved in identifying financing sources to support the introduction of HPV. National experience demonstrates that the accelerated introduction of new and underutilized vaccines requires the availability of many different kinds of evidence (e.g. cost-effectiveness, disease burden) as well as different instruments (e.g. vaccine legislation) to ensure its sustainability. It also requires a clear vision of how to address challenges brought on by a fiscal crisis and ways to ensure the sustainability of the entire program.

Going forward, advocacy at the highest political level will be required in order to expand the fiscal space for immunizations. Leadership across the health sector is needed to identify and allocate resources effectively from disparate revenue sources within the health system. Civil society could play a key participatory role in this dialogue, in the context of prioritizing investment for high-impact health interventions such as immunization towards universal health access and coverage strategies.

3. Conclusion

The financial sustainability of new vaccine introduction remains a challenge in the face of a fiscal crisis, where new vaccines have to compete with other health system priorities, even if the vaccine being considered for introduction is expected to contribute to the reduction of the morbidity and mortality of a public health problem. The introduction of new and underutilized vaccines in a developing country as based on the experience of Honduras requires wide-reaching analyses of technical, political and programmatic aspects for decision-making. The economic criterion is essential for decision-making given the high costs of new vaccines. Evidence generation through studies of cost-effectiveness and financial analyses that contribute to introduction sustainability are also required.

Conflict of interest

None declared.

References