Systematic documentation of new vaccine introduction in selected countries of the Latin American Region

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\textbf{A B S T R A C T}

\textbf{Background:} Countries in Latin America were among the first developing countries to introduce new vaccines, particularly rotavirus (RV) and pneumococcal conjugate vaccines (PCVs), into their national immunization schedules. Experiences and lessons learned from these countries are valuable to donors, immunization partners, and policy makers in other countries wishing to make informed decisions on vaccine introduction.

\textbf{Objectives:} In order to enhance knowledge and promote understanding of the process of new vaccine introduction in the Latin American Region, with particular focus on RV and PCV, we conducted a systematic qualitative assessment. We evaluated the decision-making process, documented the structure in place, and reviewed key factors pertaining to new vaccine introduction. These include country morbidity and mortality data available prior to vaccine introduction, funding sources and mechanisms for vaccine introduction, challenges of implementation, and assessment of vaccine impact.

\textbf{Methods:} From March 2010 to April 2011, we evaluated a subset of countries that had introduced RV and/or PCV in the past five years through interviews with key informants at the country level and through a systematic review of published data, grey literature, official technical documents, and country-specific health indicators. Countries evaluated were Bolivia, Brazil, Nicaragua, Peru, and Venezuela.

\textbf{Results:} In all countries, the potential of new vaccines to reduce mortality, as established by Millennium Development Goal 4, was an important consideration leading to vaccine introduction. Several factors—the availability of funds, the existence of sufficient evidence for vaccine introduction, and the feasibility of sustainable financing—were identified as crucial components of the decision-making process in the countries evaluated.

\textbf{Conclusions:} The decision making process regarding new vaccine introduction in the countries evaluated does not follow a systematic approach. Nonetheless, existing evidence on efficacy, potential impact, and cost-effectiveness of vaccine introduction, even if not local data, was important in the decision making process for vaccine introduction.

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1. Introduction

One hallmark of the twenty-first century is the development and availability of new vaccines. In January 2006, two new human oral vaccines against rotavirus (RV) were licensed and made available [1,2]. The World Health Organization’s (WHO) Strategic Advisory Group of Experts (SAGE) has recommended RV introduction in all National Expanded Programs on Immunization (EPI) where diarrheal deaths account for more than 10% of mortality among children aged less than 5 years (<5 y). In 2000, a heptavalent pneumococcal conjugate vaccine (PCV7) was licensed, with 10-valent (PCV10) and 13-valent (PCV13) PCVs made available in 2009 and 2010. SAGE has also recommended the introduction of PCVs, especially in countries with high child mortality [3,4].

Countries in the Latin American and the Caribbean (LAC) Region were among the first developing countries to introduce RV and PCV into their EPIs. In 2006, LAC Ministries of Health passed a resolution at the Pan American Organization (PAHO) calling upon Member States to mobilize additional resources to introduce new vaccines, while requiring PAHO to support countries in obtaining the evidence necessary to make informed decisions on vaccine introduction. Both RV and PCV were considered priority new vaccines for the Region [5].

As of June 2012, 15 countries and one territory in LAC had introduced RV and 21 countries and five territories had introduced PCV into their immunization schedules [6].

These vaccines are important for achieving Millennium Development Goal 4 (MDG4), which aims for a two-thirds reduction in mortality for children <5 y by 2015 [7]. Thus, countries must make informed decisions regarding the introduction of new vaccines [8].

2. Objectives

We conducted an evaluation of the process of new vaccine introduction in the Latin American (LA) Region focusing on RV and PCV. Our objectives were to enhance the understanding of the process of new vaccine introduction and to share lessons learned with other countries considering the introduction of new vaccines. Below, we provide a summary of lessons learned and offer recommendations for donors, immunization partners, and policy makers in countries wishing to make informed decisions on vaccine introduction.

3. Methods

We conducted an observational qualitative study, based on a systematic assessment of the process of new vaccine introduction in five countries (Bolivia, Brazil, Nicaragua, Peru, and Venezuela).

Criteria for making decisions on new vaccine introduction include political, technical, and programmatic aspects associated with the introduction (Fig. 1) [9,10]. The following criteria were assessed: EPI structure, morbidity and mortality data available
prior to vaccine introduction, introduction process, funding, challenges of implementation, and impact assessment.

To highlight the diversity of experiences in the LA Region, we selected five countries that had introduced RV and/or PCV as case studies. Countries were chosen based on select variables (Table 1). All countries agreed to participate in the assessment providing official government authorization.

Demographic and socioeconomic indicators of countries assessed are presented in Table 2.

The study was conducted from March 2010 to February 2011. We first reviewed published data, gray literature, and official country-specific health indicators (Table 3). We then conducted interviews with key informants at the country level, using standardized piloted questionnaires (online annex).

In each country, we conducted an average of 10 interviews addressing select issues (Table 4).

Two investigators reviewed and summarized all data. Findings were compiled for each country, aggregated for the Region, and

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<th>Vaccine introduced, year</th>
<th>Variable considered for country selection</th>
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Fig. 1. Decision-making criteria for new vaccine introduction.
discussed among a group of economists, immunization experts, epidemiologists, and national EPI managers.

4. Results

The main issues identified are summarized in Table 5.

4.1. Bolivia

4.1.1. EPI structure

Established in 1979, the EPI in Bolivia is funded by the government treasury, with additional support from international and non-governmental organizations (NGOs), and bilateral cooperation agencies. A vaccine law ensuring specific EPI budgetary funding line from the national treasury was recently issued.

4.1.2. Disease burden data pre-introduction

Acute diarrheal disease in children <5y is a notifiable disease and the main cause of death and hospitalization in this age group. In 2004, the WHO estimated that diarrhea caused 4% of the total 18,117 deaths in children <5y in Bolivia [11].

Bolivia was among the first countries in the Region to initiate sentinel surveillance for diarrheal disease in 2005. The country estimated rotavirus disease burden based on data from acute diarrheal disease and rotavirus sentinel surveillance systems, and on estimates of rotavirus in non-hospitalized diarrhea cases from the international literature.

Prior to RV introduction, cost-of-illness [12,13] and cost-effectiveness studies [14] were conducted. The country used local data to make the case for vaccine introduction. The process was transparent and technical. Discussions began in 2003 and reached high political levels after 2006.

4.1.3. Vaccine introduction

Making national authorities aware of new vaccine introduction was a crucial process that involved various partners, including officials from academia, the Immunization Interagency Coordinating Committee (ICC), and the Bolivian National Immunization Technical Advisory Group (NITAG).

RV was introduced in August 2008. Several challenges were encountered. Staff turnover at all EPI levels consumed resources and posed operational and training difficulties. Vaccine
distribution was difficult in hard-to-reach areas. In October 2008, vaccine delivery was interrupted for three months, resulting in shortages in many parts of the country.

4.1.4. Financing and purchase

GAVI provided financial support for RV introduction for the period 2008–2011 [15]. Bolivia’s government co-financed the vaccine, providing the highest level of co-financing among GAVI countries to date.

4.1.5. Implementation challenges

Second dose of RV (RV2) vaccine coverage (40%) was lower than expected in 2008. Possible causes include vaccine stock-out and age restrictions for RV administration [16].

4.1.6. Vaccine impact evaluation

A case-control study is being conducted to assess the effectiveness of RV. Trends in the incidence of severe rotavirus and all-cause gastroenteritis among children are also being evaluated. These studies will help Bolivia estimate the impact of vaccination against rotavirus.

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<td>2 EPI coordinator at time of new vaccine introduction</td>
<td>Decision-making process, data used to generate evidence, key institutions and staff involved in the process, planning and introduction of the vaccine, critical assessment of the introduction process</td>
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<td>3 Expert investigator involved in studies and projects on surveillance, disease burden, or cost effectiveness of new vaccines</td>
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<td>4 Coordinator of the department overseeing EPI in the MoH, at time of new vaccine introduction</td>
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* Expanded Immunization Program.  
  * Pan American Health Organization.  
### 4.2. Nicaragua

#### 4.2.1. EPI structure

The Nicaraguan EPI was created in 1980. Nicaragua has neither a national vaccine law nor a specific budget line for vaccine purchases. In addition to funding from the National Treasury, the country receives significant support from international agencies.

#### 4.2.2. Disease burden data pre-introduction

Acute diarrhea in children <5 y is a notifiable disease, being the main cause of morbidity and one of the main causes of mortality in this age group. The WHO estimated the rotavirus disease burden for 2004 to be 220 child deaths, with a mortality rate of 30 deaths per 100,000 children <5 y [17]. Rotavirus sentinel surveillance began after RV introduction in October 2006.

Research on pediatric diarrheal diseases has been conducted in Nicaragua since 1983 with studies on various disease aspects [18,19], including vaccine clinical trials [11,20]. Taking into account local morbidity data and published studies in LA [21], Nicaragua’s MoH estimated the prevalence of rotavirus among children and the potential impact of RV on rotavirus economic burden [22].

During an outbreak of acute diarrhea (February–April 2005), a total of 47,470 cases and 52 deaths were reported. Rotavirus was identified in 42% of children hospitalized with diarrhea [23].

#### 4.2.3. Vaccine introduction

The Decision making process for RV introduction was initiated in high political levels and later discussed at the EPI. In 2006, the MoH was offered a three-year donation of RV from one of the vaccine manufacturers. This donation, local disease burden estimates, and the outbreak of rotavirus were the principal considerations of the country’s decision-making process.

Based on this evidence, Nicaragua’s NITAG and the National Committee for Health Research and Ethics (CONIS) recommended RV introduction [24]. Many organizations provided technical support in the process, including the Pediatric Society, The American University, NicaSalud, the Japan International Cooperation Agency (JICA); PATH; UNICEF; and PAHO.

#### 4.2.4. Financing and purchase

To ensure financial sustainability after the donation period (2006–2009), the MoH requested GAVI support for RV vaccine for 2009–2015 [25]. In 2015, the country will assume full funding of rotavirus vaccines.

#### 4.2.5. Implementation challenges

Challenges encountered during RV introduction include insufficient capacity of the regulatory agency to perform lot-by-lot quality control, difficulties vaccinating populations in hard-to-reach areas, and lack of resources for training and social mobilization activities.

Vaccine coverage for RV third dose (RV3) was 79% in 2007 and increased to 98% in 2010.

The country implemented rotavirus sentinel surveillance in October 2006.

#### 4.2.6. Vaccine impact evaluation

Several studies have evaluated the vaccine’s impact and effectiveness [26,27]. Results indicated 58% effectiveness of three doses against severe rotavirus disease [26]. In addition, assessments using

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#### Table 5


<table>
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<tr>
<th>Issues</th>
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<th>Nicaragua</th>
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<td>Major factor for initiating technical discussions and for driving decision on which vaccine should be introduced</td>
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<td>– Major factor for initiating technical discussion</td>
<td>Major factor for technical discussion and for driving decision regarding which vaccine to be introduced</td>
<td>– Major factor for initiating technical discussion</td>
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<tr>
<td>NITAGs(^a) role</td>
<td>Important</td>
<td>Minimal</td>
<td>Non-existent</td>
<td>Important</td>
<td>Non-existent</td>
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<td>ICC(^b) and international cooperation</td>
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<tr>
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<td>Significant</td>
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<tr>
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<td>Political transit of EPI(^d) staff</td>
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<td>Significant</td>
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\(^a\) Pan American Health Organization.  
\(^b\) World Health Organization.  
\(^c\) National Immunization Technical Advisory Group.  
\(^d\) Immunization Interagency Coordinating Committee.  
\(^e\) Expanded Immunization Program.  
\(^f\) Disability adjusted life-years.
secondary hospitalization data in the country demonstrated RV initial impact [28].

4.3. Brazil

4.3.1. EPI structure

Brazil’s EPI was established in 1973. In 1975, the country passed a vaccine law requiring federal health institutions to purchase and distribute vaccines. EPI funding is provided in full by the Government treasury. New vaccine sustainability has been strengthened by a new vaccine budget law passed in 2010, which prevents Congress from rejecting vaccination budget lines prepared by the MoH and approved by Ministry of Planning and Budget.

4.3.2. Disease burden data pre-introduction

Research groups had generated some evidence in selected hospitals in the country [29], but limited data on rotavirus specific disease burden was available when the country decided to introduce RV. Although acute diarrhea is a notifiable disease in the country, rotavirus sentinel surveillance was not established.

In 2005, a large rotavirus outbreak of occurred in Brazil’s Amazon region [30], which substantially stimulated discussion regarding RV introduction.

4.3.3. Vaccine introduction

The decision making process for RV introduction was initiated in 2005 in high political levels stimulated by a potential technology transfer agreement, and later brought for discussion at the EPI. After the decision had been made, discussion took place at a NITAG’s special meeting in 2005.

The decision making process for new health technology policy decisions, including new vaccines, was further structured in Brazil as of 2008, with the establishment of a secretariat charged for decision making for the public health care system considering all evidence and information available [31].

4.3.4. Vaccine production and technology transfer

Over the past 20 years, Brazil has developed a strong infrastructure for local vaccine manufacturing. As part of the National Program for Sufficiency for Vaccine and Biologicals established by the MoH in 1985, the country has made investments to improve quality and enhance the capacity for internal supply [32]. Today, Brazil is an important potential source of vaccines for the developing world [33].

4.3.5. Financing and purchase

When RVs were made available in early 2006, the MoH initiated discussions on a technology transfer agreement with vaccine manufacturers and Biomanguinhos/Fiocruz, a national public vaccine producer.

Shortly thereafter, in March 2006, the country introduced RV. In 2007, an agreement was established, with an expected timeline of 5 years for full technology transfer.

4.3.6. Implementation challenges

Challenges encountered during implementation include insufficient cold chain capacity, limited training received by healthcare staff, and lack of time to prepare for vaccine introduction.

RV3 coverage in Brazil reached 77% in 2007 and 81% in 2010. Rotavirus sentinel surveillance system began in 2007.

4.3.7. Vaccine impact evaluation

Several studies have assessed rotavirus vaccine effectiveness [34–37], a few by the vaccine manufacturer [38,39], and one by the MoH with support from PAHO and the Centers for Disease Control and Prevention (CDC) [40].

Time series analysis of diarrhea hospitalization using secondary data from the National Hospitalization Information System demonstrated significant reductions in morbidity and mortality following RV introduction [37,40].

4.4. Peru

4.4.1. EPI structure

The Peruvian EPI was created in 1979. In June 1993, the country enacted a vaccine law assuring government funding for most immunization activities.

4.4.2. Disease burden data pre-introduction

Rotavirus is the most common cause of severe diarrhea in Peruvian children. The WHO estimated the 2004 rotavirus disease burden to be 691 child deaths, with a mortality rate of 23 deaths per 100,000 children <5 y [41].

Before introduction, Peru lacked national estimates of pneumococcal disease burden, but, given regional data, the country acknowledged the cause for concern [42].

In 2008, the MoH commissioned a study that demonstrated that pneumonia was the second leading cause of loss of healthy life years [43]. At the time of RV and PCV introduction, sentinel surveillance of rotavirus and pneumococcal disease had not been established.

4.4.3. Vaccine introduction

In 2006, Peru’s EPI began discussing the introduction of new vaccines. In 2008, with support from the Comité Consultivo (committee resembling NITAG), the Minister of Health decided to include rotavirus, pneumococcal, and influenza vaccines in the country’s EPI.

International partners reported having had limited participation in the decision-making process. Research groups generated substantial evidence on RV development, epidemiology, economic burden and cost-effectiveness. However, few studies on pneumococcal disease were generated in Peru. Therefore, the country considered regional evidence, specifically a study assessing the cost-effectiveness of PCV, in deciding to introduce PCV [44]. RV and PCV were introduced in 2009.

4.4.4. Financing and purchase

Health funding in Peru has increased significantly from 2000–2007, with immunization funding increasing from 6.5% of the MoH budget in 2000 to 44% in 2006 [45]. Since 2008, Peru has purchased RV and PCV through PAHO’s Revolving Fund.

4.4.5. Implementation challenges

Challenges identified during vaccine introduction include lack of a specific social mobilization plan for RV and PCV introduction, insufficient staff training prior to vaccine introduction, limited cold chain capacity, and introduction of PCV at three and five months of age rather than at two and four months as recommended.

RV3 coverage was 41% in 2009 and increased to 75% in 2010. PCV3 coverage was 8.8% in 2009 and increased to 83.2% in 2010. Possible reasons for lower-than-expected coverage include the age restriction for RV and PCV vaccine schedule used in Peru, which, in turn, may have led to missed vaccination opportunities [16]. Additionally, issues with vaccine distribution and vaccine registration presented challenges to the introduction of the vaccines.

In 2009, Peru began reporting rotavirus diarrhea and bacterial pneumonia and meningitis.
4.4.6. Vaccine impact evaluation

To our knowledge, few studies assessing the impact of vaccine introduction have been conducted. Recently, Peru requested PAHO’s support in evaluating the impact of PCV introduction in the country.

4.5. Venezuela

4.5.1. EPI structure

Established in 1997, the Venezuelan EPI receives regular budget funds from the government and has benefited from extrabudgetary funding since September 2005. The country also possesses a vaccine law that declares immunization a public good but does not provide information on vaccine funding.

4.5.2. Disease burden data pre-introduction

Diarrhea is the third leading cause of child death in Venezuela, representing 7% of child deaths <1 y, and the main cause of death and hospitalization in children <5 y. The WHO estimated the disease burden for Venezuela in 2004 to be 428 child deaths due to rotavirus, with a mortality rate of 15 deaths per 100,000 children <5 y [46].

Research groups have produced studies on RV development, efficacy, and safety and on the disease’s epidemiology, genotype distribution, and economic burden. In Venezuela, acute diarrhea is a notifiable disease. Rotavirus sentinel surveillance began in 2004.

4.5.3. Vaccine introduction

Substantial local evidence was available when the decision to introduce RV was made. Following technical discussions, the decision was made at the vice-minister level.

International partners were not involved in the decision-making process. There is no functioning ICC, nor a technical advisory committee or NITAG equivalent in Venezuela. RV was introduced into the EPI in April 2006.

4.5.4. Financing and purchase

Though MOH and immunization budgets increased significantly from 2000–2009, there was a sharp reduction in immunization expenditures in 2009–2010. Since 2006, Venezuela has purchased RV through PAHO’s Revolving Fund.

4.5.5. Implementation challenges

Challenges during vaccine introduction include limitations in cold chain capacity and limited communication and social mobilization activities.

Very low RV2 coverages have been reported: 26% in 2006, 19% in 2007, 47% in 2008, 54% in 2009, and 48% in 2010. Potential reasons include missed vaccination opportunities, age restrictions for the second dose of the vaccine, lack of routine supervision activities, an inadequate information system, and population estimates used for vaccine coverage estimation [16].

4.5.6. Vaccine impact evaluation

To our knowledge, few studies assessing the impact of vaccine introduction have been conducted.

5. Discussion

The decision making process regarding new vaccine introduction in the countries evaluated does not follow a systematic approach. In most countries, the process was initiated as a political decision, later supported by technical aspects. Nonetheless, existing evidence on efficacy, potential impact, and cost-effectiveness of vaccine introduction, even if not local data, was important in the decision making process for vaccine introduction in all countries.

Reaching MDG4 and society’s perception of vaccines as a public good were also important motivators in governmental decisions to introduce new vaccines. The availability of vaccines and funds for vaccine introduction either through donation, co-funding by GAVI, or national funds for vaccine purchase was essential in the process. In countries funding the EPI program, vaccine laws have proven essential for supporting the decision-making process on vaccine introduction and sustainability.

Although few countries possessed surveillance and local disease burden data prior to new vaccine introduction, all countries studied implemented surveillance during or following vaccine introduction and are planning to conduct impact assessments.

Limited evidence is available in the literature on the process of new vaccine introduction. The issues identified in this study are being addressed by PAHO through the ProVac Initiative, which has been working in the LAC Region since 2004 to strengthen the decision making process for new vaccine introduction [47].

6. Conclusion

Despite the fact that the countries assessed do not represent the Region as a whole, the results are useful for each respective country, and lessons learned valuable for other countries and Regions.

Political commitment is crucial in the decision making process, but coordination with technical sectors for evidence based decision making is of utmost importance.

Mechanisms for sharing the scientific evidence with decision makers need to be enhanced.

Countries should capitalize on NITAG’s role in providing technical support during the decision-making process and on the participation of other technical agencies and institutions supporting immunization.

Lastly, prior to vaccine introduction countries must conduct cold-chain assessments at all levels and more accurately forecast vaccine demand and financial needs in order to avoid lack of resources during the implementation period.

Conflict of interest

None of the authors has reported a conflict of interest.

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Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at http://dx.doi.org/10.1016/j.vaccine.2013.05.032.

References


