

LESSONS LEARNED FROM THE INTRODUCTION OF THE PNEUMOCOCCAL CONJUGATE VACCINE (PCV) IN LATIN AMERICA AND THE CARIBBEAN



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I. INTRODUCTION

The introduction of pneumococcal conjugate vaccines (PCV) into national immunization programs is a health strategy that contributes to controlling invasive diseases caused by pneumococcus with proven efficacy. [1]

According to WHO estimates, every year pneumococcal disease causes approximately 1.6 million deaths throughout the world, of which approximately 716,000 correspond to children under five. [2] For the Region of the Americas, it has been estimated that between 9,200 and 15,500 children under five could die annually due to this disease. [3, 4]

Starting in 2003, Latin American and Caribbean (LAC) countries began to introduce PCV into their national vaccination schedules. [5] Barbados introduced PCV in 2003, followed by Costa Rica in 2007. Mexico, Uruguay, French Guyana in 2008; Peru, Barbados, Cayman Islands in 2009; Aruba, Brazil, Ecuador, El Salvador, Panama, Nicaragua in 2010; Honduras, Guyana, Chile, Colombia, Curacao in 2011; and Argentina, Bahamas, Guatemala, Paraguay and, Trinidad and Tobago in 2012 (Figure 1).

All of these countries learned important lessons, but their experiences had not been systematized so that other countries could evaluate the methodological, logistical, economic/financial and operating needs of the process, and ensure long-term sustainability of the introduction of this new vaccine into immunization programs. [5]

The purpose of this document is to systematize and disseminate the lessons learned identified in order to support countries in the region that have not yet introduced PCV and to share experiences with other countries in the region and throughout the world that are beginning this process.

II. METHODOLOGY

On March 20 and 21, 2012, an international workshop organized by PAHO was held in Buenos Aires to identify lessons learned with the introduction of PCV in LAC countries. Representatives of Argentina, Aruba, Barbados, Bermuda, Bolivia, Brazil, Chile, Colombia, Costa Rica, Cuba, Ecuador, El Salvador, Guatemala, Honduras, Mexico, Nicaragua, Panama, Paraguay, Peru, Saint Martin, Uruguay and Venezuela participated in this workshop, during which different countries with diverse scenarios for introduction of PCV made presentations on the process.

Participants were grouped in 5 roundtables according to the topics selected by the technical team for new vaccines from the PAHO Comprehensive Family Immunization Project: 1) decision making, 2) determination of the vaccination schedule, 3) calculation of the number of doses, 4) interchangeability of vaccines and 5) experience of Caribbean countries.

A methodological guide was developed for the workshop, which had three phases. In the first phase, identification of lessons learned, each roundtable made an evaluation of the experience of introducing PCV, in which the participants in each group individually identified problems that had arisen during the process, strengths and weaknesses of the immunization program in dealing with problems, actions taken and potential lessons learned. Then members of the roundtable shared their results and reached a consensus on the lessons identified by the roundtable as a whole. In the second phase, each roundtable prepared their support for and prioritization of the lessons learned. For this purpose, they prepared a description of the

original assumption or initial situation prior to introduction of PCV to which the lesson learned alluded; the reason why the lesson learned is important; the country(ies) in which this lesson learned has been put into practice; and the priority of the lesson, considering whether it was indispensable, important or desirable. The output of each working group was a prioritized list of lessons learned with a brief rationale based on analysis of the problem situations which gave rise to them.

In the third phase, each group's results were presented at a plenary meeting, in which the contributions of all of the groups were received and the lessons learned were consolidated.

The purpose of this document is to systematize and disseminate the lessons learned identified in the workshop, in order to support countries in the region that have not introduced PCV yet and to share experiences with other countries in the region and other parts of the world that are beginning this process.

III. LESSONS LEARNED

DECISION MAKING FOR INTRODUCTION OF PCV

Lesson learned 1: Produce and identify relevant objective evidence of the impact of vaccination on the disease in the country. Ideally, this evidence should be supported by national data.

Priority: Indispensable

Description: Adequate epidemiological and economic evidence is a fundamental element of scientific support for the political decision to introduce the vaccine. The most important national sources of information are:

- Epidemiological surveillance of invasive diseases for *S. pneumoniae*. Surveillance provides fundamental information for calculation of disease burden, for measurement of the impact of vaccination and for rational use of antibiotics. Currently, there is a PAHO regional guide available, as well as national surveillance guidelines and systems in each country that has introduced the vaccine.
- National burden of disease studies for S. pneumoniae which, to the extent possible, are specific for the most prevalent serotypes. This type of studies makes it possible to measure the health status of the population with regard to pneumococcal disease, taking into account any loss of health due to the disease that has an impact on people's welfare, including death as well as disability. There are regional and national studies that can serve as guidance for interested countries."
- Economic studies such as cost effectiveness, cost benefit and cost-utility. The cost of new vaccines – among them PCV – in comparison with other vaccines included in the national vaccination schedules of countries in the region is very important. Therefore,

ⁱ PAHO practical guide on the introduction of new vaccines: http://www.paho.org/spanish/ad/fch/im/GuiaPractica NuevasVacunas.pdf

[&]quot;Valenzuela MT, O'Loughlin R, De La Hoz F, Gomez AND, Constenla D, Sinha A, Valencia JE, Flannery B, De Quadros CA. The burden of pneumococcal disease among Latin American and Caribbean children: Review of the evidence. Rev Salud Panam Publica. 2009;25(3):270–9. Available at: http://www.scielosp.org/pdf/rpsp/v25n3/a11v25n3.pdf.

- the use of economic analyses when planning the introduction of a new vaccine becomes increasingly important to weigh the costs related to the investment to be made in vaccination with sufficient technical criteria. iii, iv
- Studies and evaluations of health technology. These studies, in addition to including
 epidemiological and economic evaluations, are enhanced with analysis of other
 aspects such as the biotechnological, organizational, legal and bioethical aspects.

It is always important to review worldwide and regional evidence or recommendations, as well as those of countries with similar characteristics, especially if reliable national information is not available. VII, VIII, IX

Lesson learned 2: Design a planning document for the introduction of PCV to ensure sustainable introduction of the vaccine and measurement of the impact of vaccination.

Priority: Indispensable

Description:

The planning document for introduction of PCV should consider evaluating the sustainability of vaccination through identification of the human, material and financial resources necessary, existing and lacking, as well as the source of national financing to cover the gaps identified.

Ideally, this planning should include different possible scenarios according to the population selected, the schedule to be used and expected coverage. In addition, it should specify the strategies and techniques to be used to measure the impact of the new vaccine introduced.

PAHO has prepared a practical guide to aid countries in the introduction and implementation of new vaccines.ⁱ

Lesson learned 3: Foster and advocate the introduction of PCV in order to have a political environment that facilitates the availability of resources to make introduction of the vaccine

iii PROVAC [Internet]. Washington DC: Pan American Health Organization [Quoted July 26, 2012]. Available at: http://new.paho.org/provac/index.php.

iv ACIP Ad Hoc WG on Economic Analyses. Guidance for Heath Economic Studies. Advisory Committee on Immunization Practices (ACIP). Centers for Disease Control and Prevention. Available at: http://www.cdc.gov/vaccines/recs/acip/downloads/economics-studies-guidance.pdf.

^v La Torre G, de Waure C, Chiaradia G, Mannocci A, Specchia ML, Nicolotti N, Ricciardi W. The future of best investing in vaccines: the Health Technology Assessment approach. Vaccine. 2008 Mar 20;26(13):1609-10. Epub 2008 Feb 1.

vi La Torre G, de Waure C, Chiaradia G, Mannocci A, Capri S, Ricciardi W. The Health Technology Assessment of bivalent HPV vaccine Cervarix in Italy. Vaccine. 2010 Apr 26;28(19):3379-84. Epub 2010 Mar 1.

vii Strategic Advisory Group of Experts on Immunization [Internet]. Geneva: WHO [Quoted July 26, 2012]. Available at: http://www.who.int/immunization/sage/es/index.html.

wiii WHO vaccine position papers [Internet]. Geneva: WHO [Quoted July 26, 2012]. Available at: http://www.who.int/immunization/documents/positionpapers intro/en/index.html.

Technical Advisory Group on Vaccine-Preventable Diseases [Internet]. Washington, D.C.: Pan American Health Organization [Quoted July 26, 2012]. Available at: http://new.paho.org/hq/index.php?option=com_content&task=view&id=1862&Itemid=1674&Iang=es.

sustainable.

Priority: Indispensable

Description:

Political advocacy raises awareness among political decision makers regarding relevant information in order to facilitate decision-making for the introduction of PCV. For this purpose, the importance of pneumococcal disease should be emphasized to decision makers, drawing attention to the impact it has on the population's health, primarily in children under 5 years of age, which is a vulnerable population. In addition, the vaccine should be perceived as a safe and effective measure, in addition to representing savings for the government and the population.^{i,x,xi,xii}

Lesson learned 4: Monitoring and integrated analysis of information should be performed by every component of the immunization program in planning for introduction of the vaccine.

Priority: Important

Description:

The process of introducing a new vaccine requires epidemiological, economic and organizational components. The epidemiological component performs an analysis of the efficacy and effectiveness of the vaccine and the burden of disease. The economic component analyzes the economic impact of the vaccine by means of cost effectiveness and cost benefit analysis. The organizational component evaluates the capacity of the immunization program to deal with the new challenge. This information should be analyzed periodically to evaluate the impact of vaccination. All of this requires joint participation of all of the program components, including the technical area, epidemiology, laboratory, logistics and the national regulatory area, among others, to perform a comprehensive analysis of the information needed for making decisions during the introduction of PCV.

Lesson learned 5: The existence of a legal framework on vaccines facilitates their introduction and ensures the sustainability of PCV in the immunization program.

Priority: Important

Description: The enactment of a law on vaccines that includes procedures for the introduction of new vaccines facilitates the decision-making process for their introduction by helping those

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^{*} Pan American Health Organization. *Curso de gerencia para el manejo efectivo del Programa Ampliado de Inmunización (PAI). Módulo V: Programación de las actividades de inmunización (Management course for the effective management of the Expanded Programme on Immunization (EPI). Module V: Scheduling of immunization activities).* Washington, D.C.: PAHO©, 2006. Available at: http://www.paho.org/english/ad/fch/im/isis/epi_mod/spanish/docs/modulo5.pdf.

xi PATH. Advocacy for immunization. Available at: http://www.path.org/vaccineresources/files/GAVI-AdvocacyHandbook.pdf.

wii World Health Organization. Euro. Setting the immunization agenda. Available at: http://www.euro.who.int/ data/assets/pdf file/0008/98981/setting immunization agenda.pdf.

involved to foresee the legal mechanisms and requirements necessary to achieve this objective. xiii,xiv

Lesson learned 6: The purchase of vaccines through the PAHO Revolving Fund lends feasibility and sustainability to the introduction of PCV.

Priority: Important

Description: The purchase of vaccines through the PAHO Revolving Fund makes it possible to obtain high-quality vaccines produced by laboratories certified by WHO, at a lower price, which is crucial to the financial sustainability of the introduction process and to producing a beneficial impact on the health of the target population.^{xv}

Lesson learned 7: National immunization advisory committees, committees on immunization practices or however whatever they are called in each country, should be technically sound and independent.

Priority: Important

Description: The presence of a group of national experts that are independent of the vaccination program, have no conflicts of interest and can make technical recommendations on the introduction of new vaccines can facilitate decision making for the introduction of PCV. This will lead to greater acceptance of the introduction of the vaccine among other decision makers. VII, IX, XVI

2. SELECTION OF THE VACCINATION SCHEDULE.

Lesson learned 1: Coordination with the national regulatory authority beforehand is necessary to ensure that the registration of the vaccine and the vaccination schedule are in line with the recommendations of other supranational committees.

Priority: Indispensable

Description:

National regulatory authorities are the agencies responsible for ensuring access to, as well as rational use of, pharmaceutical products that are safe and effective. In the selection of a

xiv El Salvador. Ley de Vacunas (Vaccination Law). Available at:

http://www.asamblea.gob.sv/eparlamento/indice-legislativo/buscador-de-documentos-legislativos/ley-de-vacunas.

http://new.paho.org/hq/index.php?option=com_content&task=view&id=1864&Itemid=2234&lang=es.

xvi Advisory Committee on Immunization Practices [Internet]. Atlanta, Georgia: Centers for Disease

Control and Prevention [Quoted July 26, 2012]. Available at: http://www.cdc.gov/vaccines/recs/ACIP/.

xiii Costa Rica. *Reglamento de la Ley Nacional de Vacunación (Regulation of the National Vaccination Law)*. Available at: http://www.hacienda.go.cr/centro/datos/Decreto/Decreto%2032722-S-Reglamento%20Ley%20Nacional%20Vacunaci%C3%B3n-La%20Gaceta%20213-4%20NOV-2005.pdf.

xv Revolving Fund [Internet]. Washington, D.C.: Pan American Health Organization [Quoted July 26, 2012]. Available at:

vaccination schedule for a new vaccine, it is necessary to ensure that the vaccine is registered with the regulatory authority, as must be the indications on its use, both in terms of the vaccination schedule and the target population selected for intervention.

Lesson learned 2: In Caribbean countries, special innovative agreements should be fostered between the public and private sectors to facilitate adherence to the schedule selected.

Priority: Indispensable

Description:

In Caribbean countries, immunization activities are largely carried out by the private sector, due to which specific spaces for coordination between the public and private sectors is essential for adherence to the vaccination schedule, as well as achievement of the overall goals of the program.

Lesson learned 3: Having epidemiological data on the distribution of the disease makes it possible to identify the vaccination schedule for PCV which is best suited to the country's needs.

Priority: Important

Description:

Epidemiological evidence obtained through epidemiological surveillance and national burden of disease studies make it possible to more precisely identify target groups for vaccination and the type of vaccine to be used, as well as the ideal age to begin vaccination to obtain the greatest impact from PCV in the country. II, xvii

Lesson learned 4: Timely access to recommendations from international reference sources facilitates selection of the best vaccination schedule for PCV.

Priority: Important

Description:

There are a number of vaccination schedules for PCV. The existence of recommendations by a group of internationally renowned external consultants with ample knowledge of immunization and vaccine-preventable diseases in the region facilitates the selection of a vaccination schedule, especially in situations in which there is limited national, regional or

xvii Dagna Constenla, Elizabeth Gomez, Fernando Pio de la Hoz, Rosalyn O'Loughlin, Anushua Sinha, Juan AND. Valencia, and Maria Teresa Valenzuela. The Burden of Pneumococcal Disease and Cost-Effectiveness of a Pneumococcal Vaccine in Latin America and the Caribbean: a review of the evidence and a preliminary economic analysis. Sabin Vaccine Institute, Pan American Health Organization, GAVI PneumoADIP, CDC. Available at:

http://www.sabin.org/files/attachment/The%20Burden%20of%20Pneumococcal%20Disease%20and%20Cost-

 $\underline{Effectiveness\%20of\%20a\%20Pneumococcal\%20Vaccine\%20in\%20Latin\%20America\%20and\%20the\%20Caribbean.pdf.$

worldwide evidence, such as when the introduction of PCV began in LAC. This should include the possibility of the PAHO Technical Advisory Group on Vaccine-preventable Diseases holding emergency meetings in situations in which countries need to make decisions quickly. ix

Lesson learned 5: When a PCV is introduced into the national vaccination schedule, it is recommendable to take advantage of vaccination opportunities already established by each country's schedule.

Priority: Important

Description:

It is recommended that PCV be incorporated in the national vaccination schedule maintaining the vaccination ages already established for other vaccines in order to take advantage of the opportunity that the population's demand for vaccines already offered presents. Otherwise, vaccination at an age at which vaccination is not already customary may require a significant complementary effort to attain the expected coverage. Even so, it may become a source of lost vaccination opportunities. **viii*

Lesson learned 6: Establish standardized technical guidelines and disseminate them to different target audiences.

Priority: Important

Description:

A specific technical document prepared by the immunization program stating the national vaccination schedule for PCV, among other aspects, should be disseminated at every level of responsibility during vaccination with PCV, with special emphasis on technical personnel at the local level through training workshops. Dissemination of the vaccination schedule to other audiences such as opinion leaders and the general public through the media is also important.^x

3. CALCULATION OF THE NUMBER OF DOSES FOR THE YEAR OF INTRODUCTION

Lesson learned 1: The calculation of the number of vaccines needed should consider the vaccination schedule, 100% of the target cohorts, and the vaccination policy in the year the vaccine is introduced.

Priority: Indispensable

Description: The calculation of the number of doses must be made for each cohort, considering 100% of the population of each one. Among the considerations for its calculation, the vaccination schedule selected, as well as expected coverage and loss of vaccines should be included for each cohort. Coverage and loss should be adjusted to the levels found in the introduction of other vaccines from the program that are administered to the same cohorts and have similar presentations. If there is no historical information available, the judgment of

http://www.paho.org/english/ad/fch/im/isis/epi mod/spanish/2/conceptos oportunidades.asp.

xviii Pan American Health Organization. *Oportunidades perdidas de vacunación (Lost Vaccination Opportunities)*. Available at:

experts, such as the advisory committee on immunization, would be a good source of evidence for decision making. In addition, the experience of other countries in the region can serve as a reference.

Lesson learned 2: Cold chain capacity must be adapted to the vaccination schedule, to the number of doses planned for introduction of the vaccine and to future demand.

Priority: Indispensable

Description: Cold chain capacity at every level should respond to the needs generated by the introduction of PCV, especially with regard to the number of doses not only for the year it is introduced, but also considering future demand for the vaccine. x,xix

Lesson learned 3: Plan for availability of a stock of at least 25% of the annual requirement for the vaccine for the year it is introduced.

Priority: Important

Description: A stock of the vaccine requirement will make it possible to continue with vaccination in the event of any situation that may affect the timely supply of the vaccine to the country. This will allow vaccination activities to take place regularly during an additional quarter following the year of introduction while the national supply problem is being resolved.

Lesson learned 4: It must be decided whether to vaccinate only those who turn a certain age or all of those who are of the ages of the cohorts scheduled for vaccination.

Priority: Important

Description:

During the year of introduction of the vaccine, including individuals who are of a certain age, as opposed to only those who turn a certain age, in the target group for vaccination can almost double the number of doses required. Vaccinating those who turn a certain age represents an annual birth cohort, while those who are of the age may represent almost all or a considerable part of the birth cohort for the preceding year, depending on the age at which vaccination begins and the schedule used for each cohort.

Lesson learned 5: Ideally, the vaccine should be introduced at the beginning of the year.

Priority: Desirable

Description: This facilitates the calculation of goals and coverage, as well as monthly, quarterly, semi-annual or annual monitoring of the same. In addition, budgets are annual,

xix Pan American Health Organization. Curso de gerencia para el manejo efectivo del Programa Ampliado de Inmunización (PAI). Módulo III: Cadena de frío (Management course for the effective management of the Expanded Programme on Immunization (EPI). Module III: Cold chain). Washington, D.C.: PAHO©, 2006. Available at: http://www.paho.org/english/ad/fch/im/isis/epi_mod/spanish/docs/modulo3.pdf.

which facilitates the determination of the budget required to achieve the objective during the year the vaccine is introduced.

4. INTERCHANGEABILITY

Lesson learned 1: Evidence must be generated to support decisions on exchanging one vaccine presentation for another.

Priority: Indispensable

Description:

Exchanging one type of vaccine for another should be done based on available evidence that uses national data to compare the type of vaccine in use with the one to be introduced, in relation with efficacy, effectiveness, cost effectiveness and cost benefit. This type of hard evidence can be helpful in dealing with pressure from different parties, among which may be companies that want a certain type of vaccine to be included. In addition, using international recommendations for support can make a difference in a situation where little information is available. Ill, ill, iv, vii, ix

Lesson learned 2: The decision to change the type of vaccine used should be discussed and taken jointly by all of the components of the immunization program and the advisory committee.

Priority: Indispensable

Description:

Once the decision has been made based on evidence and by means of consensus with the advisory committee, awareness should be raised among other institutional and social stakeholders that will influence political decision making on the change of vaccine. Awareness-raising and obtaining support from medical and professional associations, as well as that of social organizations involved in children's rights, can make them powerful allies in placing the change to a new type of vaccine on the political agenda. However, this will be very difficult without consensus between the components of the program and the advisory committee.

Lesson learned 3: The document on the scheduling of vaccine interchangeability should keep the transition period and vaccine loss to a minimum.

Priority: Indispensable

Description:

The change to the new vaccine should be done in the most orderly manner possible. It should specify delivery periods with at least a year of lead time. In addition, the transition period during which the cohorts vaccinated will have combined schedules should be as short as possible, taking into account that loss of the prior vaccine should be kept to a minimum.

Lesson learned 4: The information system should be enhanced in order to identify the cohorts

vaccinated by type of vaccine.

Priority: Indispensable

Description:

For appropriate monitoring of the introduction process, the information system should capture data by type of vaccine administered in order to calculate the number of doses administered for the new vaccine and the one being replaced. The capacity to discriminate between the types of vaccine administered should be reflected in every individual instrument for recording individual information (vaccination cards, daily records, computerized system), as well as consolidated data (forms where information is consolidated by levels). X,xxx

Lesson learned 5: For Caribbean countries, establishing channels of communication with the private sector in charge of vaccination is critical for the purchase and provision of vaccines. In addition, communication among countries in the area is important for coordinating a joint approach.

Priority: Indispensable

Description:

In Caribbean countries, the private sector carries out a significant part of the activities related to vaccination. For this reason, it is of vital importance to involve them in the process of changing the type of vaccine used, in order to achieve adequate vaccination coverage and have a successful exchange process. There are sound levels of coordination among Caribbean countries regarding immunization that should be considered when deciding on the inclusion of a new type of vaccine in their countries. xxi,xxii,xxiii

Lesson learned 6: Train the different levels of the immunization program extensively and effectively on the process of introducing a new type of vaccine.

Priority: Important

Description:

Every component of the immunization program should be trained by levels in relation with the process of changing to a new type of PCV. It should be ensured that training is provided at the operational level, as that is where the change will be executed and recorded, subsequently involving the greatest number of actors for the purpose of conducting effective advocacy.

IV. CONCLUSIONS

Pan American Health Organization. *Curso de gerencia para el manejo efectivo del Programa Ampliado de Inmunización* (PAI). *Módulo VI: Supervisión, monitoreo and evaluación (Management course for the effective management of the Expanded Programme on Immunization (EPI). Module VI: Supervision, monitoring and evaluation*). Washington, D.C.: PAHO©, 2006. Available at: http://www.paho.org/english/ad/fch/im/isis/epi_mod/spanish/docs/modulo6.pdf.

xxi Caribbean Epidemiology Centre. Available at: http://www.carec.org/.

xxiii Caribbean Health Research Council. http://www.chrc-caribbean.org/.

xxiii Caribbean Public Health Agency. Available at: http://www.carec.org/.

The lessons learned with the introduction of PCV are very similar to those learned during the introduction of the rotavirus vaccine in LAC discussed previously, where the three essential pillars were the technical, operation and financial sustainability aspects. The consensus reached emphasized the need to prepare vaccine introduction plans that encompass the different aspects mentioned in the lessons learned presented in this document.

LAC is very successful in terms of vaccination in general, due to which it has the opportunity to introduce vaccines quickly, based on successful experiences managing the immunization program. [6] In addition, the fact that LAC has been the first to introduce these vaccines into its national programs has presented a challenge to the countries due to the different scenarios in which they have been introduced, as well as the limited amount of information available on the matter.

This meeting contributed a wealth of material that will make it possible to support countries in the region and other parts of the world in the process of introducing PCV and other new vaccines.

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