Vaccination legislation in Latin America and the Caribbean

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Abstract Governments have the authority and responsibility to ensure vaccination for all citizens. The development of vaccination legislation in Latin America and the Caribbean (LAC) parallels the emergence of sustainable, relatively autonomous, and effective national immunization programs. We reviewed vaccination legislation and related legal documents from LAC countries (excluding Canada, Puerto Rico, the United States, and the US Virgin Islands), and described and assessed vaccination legislation provisions. Twenty-seven of the 44 countries and territories in the Region have proposed or enacted vaccination legislation. Provisions vary substantially, but legal frameworks generally protect the sustainability of the immunization program, the individual’s right to immunization, and the state’s responsibility to provide it as a public good. Of the legislation from countries and territories included in the analysis, 44 per cent protects a budget line for vaccines, 96 per cent mandates immunization, 63 per cent declares immunization a public good, and 78 per cent explicitly defines the national vaccine schedule. We looked for associations between vaccination legislation in LAC and national immunization program performance and financing, and conclude with lessons for governments seeking to craft or enhance vaccination legislation.


Keywords: public health law; immunization; vaccination law; vaccination policy; vaccine financing
Introduction

Immunization is one of the most successful public health interventions of the past century. Governments have a responsibility to ensure that the citizens are immunized and their chief means of doing so is public health legislation.\textsuperscript{1,2} Vaccination laws (free-standing laws devoted solely to immunization) and vaccination legislation (broader legal framework pertaining to immunization, encompassing one or more legal documents of any type) are two examples. Developing and updating legal support for vaccination becomes increasingly important as new, costlier vaccines come into use, and the economic value of immunized societies increases.\textsuperscript{3} The development of legal underpinnings for vaccination in Latin America and the Caribbean (LAC) parallels the emergence of sustainable, relatively autonomous, and effective national immunization programs.\textsuperscript{4–5} An expert panel recently estimated that immunizations have added as much as 15 years to life expectancy in Latin America.\textsuperscript{6} Over the past three decades, the majority of countries and some territories in the Region have sought to establish a legal basis for their national immunization programs.

Since the inception of the Expanded Program of Immunization in the Americas, in 1977, the Pan American Health Organization (PAHO) and its Revolving Fund for pooled vaccine procurement have promoted country ownership of national immunization programs.\textsuperscript{7} Throughout the 1980s, as governments assumed greater responsibility for vaccine purchasing and program financing, regional and national actors in the legislative sphere developed legal frameworks to protect immunization program budgets amid competing priorities. During this time, PAHO began collaborating with the Latin American Parliament (Parlamento Latino) to draft a model vaccination law that was shared with the legislative bodies throughout the Region.\textsuperscript{8}

Continued work led to the enactment of several national vaccination laws in the early 1990s and the Latin American Parliament promulgated a model vaccination law and a supporting resolution in 2009.\textsuperscript{8} With greater country ownership and effective procurement mechanisms such as the Revolving Fund, national immunization programs became increasingly institutionalized in regional and national public health agendas. Vaccine-preventable diseases steadily receded.\textsuperscript{4,6}

In May 2012, the World Health Assembly approved a new Decade of Vaccines action plan. The Global Vaccine Action Plan (2010–2020) calls
on all the 194 WHO Member Countries to develop robust vaccination laws. Specifically, the plan calls on member states to ensure legislation or legal framework in all countries, including provisions for a budget line for immunization, and for monitoring and reporting. Legal frameworks for immunization programs developed in LAC may serve as an example for other countries worldwide seeking to garner political support for their immunization programs and establish a legal basis for these health services.

Legislation varies substantially by country in LAC; some countries’ parliaments enacted freestanding vaccination laws, others situated vaccination legislation within more comprehensive legal frameworks. To date, 27 of 44 governments (61 per cent) in LAC have enacted or proposed legal provisions of one of the two types to guide immunization financing, policy, and practice. Of the Region’s population, 92.3 per cent resides in a country or territory with such legal provisions, as the countries lacking legal protection for their immunization programs tend to be smaller. We present a descriptive analysis of the two types of vaccination legal provisions in LAC, review development of vaccination legislation, and identify associations between legislation, improvements in national immunization program performance, and increasing public investment. To aid governments elsewhere wishing to create analogous legal frameworks and enact vaccination legislation, we highlight lessons learned and best practices.

Methods

We extracted data from the PAHO Comprehensive Family Immunization Project (FCH/IM) vaccination legislation database. Launched in 2005, the database contains laws, decrees, and other legal documents pertaining to vaccines and vaccination in humans collected from PAHO surveys of its Member States. In September 2010, PAHO updated the database after requesting the Member States to submit new legal documents or amendments since the original request in 2005. This study focuses on the policy and programmatic implications of vaccination legislation in low- and middle-income countries. Thus, we excluded legislation from Canada, Puerto Rico, the United States, and the US Virgin Islands. Thirty-six countries and eight territories were eligible for the inclusion in the study. Sixteen countries and territories contributed new or updated legal documents. In addition, we determined that the legislation previously collected from 11 countries and territories remained
In total, we were able to include legislation from 27 governments in this study. Documents in the database include freestanding vaccination laws, broader public health legislation, including vaccination provisions, and the same content in other regulatory documents, legislative proposals, and ministerial or executive decrees. Two members of the research team (CBJ and SPT) conducted a content analysis of the documents. To begin, we considered for coding 11 key legal provisions that PAHO identified in 2006. After reviewing the updated database, we decided to retain only six of the legal provisions used in the 2006 study, and add three new provisions identified in the course of our analysis – resulting in nine. For each we constructed a clear definition and then divided the provisions into three global categories: declarative, operational, and financial. See details below (Table 1). We also excluded in-depth analysis pertaining to the legal aspects of vaccine development, licensure, and quality control as beyond the scope of this study (although six countries in the Americas do produce some of their own vaccines: Brazil, Cuba, Mexico, Argentina, Venezuela, and Colombia). We made one exception by analyzing provisions specifying which national health authority is responsible for authorizing and registering new vaccine and product

Table 1: Classification and definitions of vaccine legislation provisions

<table>
<thead>
<tr>
<th>Declarative criteria</th>
<th>Financial criteria</th>
<th>Operational criteria</th>
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<tbody>
<tr>
<td>Free vaccination</td>
<td>Budget line</td>
<td>Regulatory oversight</td>
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<td>Compulsory vaccination</td>
<td>Tax exemptions</td>
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<td>Supply mechanism</td>
<td>Enforceability</td>
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<td>Existence of NITAG</td>
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</table>

Free and universal provision of vaccines by the government for all citizens; vaccination as a free public good, guaranteed by the state. 

Mandatory vaccination of all citizens

Required line item in national budget for vaccine purchase and immunization program

Guaranteed tax exemptions for the importation of vaccines, vaccine-related supplies, and cold chain materials

Identification of specific procurements mechanism (for example, Revolving Fund) to guarantee a safe, efficient and reliable supply of vaccines and vaccine-related supplies

Established regulations on vaccination program to ensure safe, efficacious vaccines are administered

Required definition of a national immunization schedule

Established sanctions for failing to comply with provisions of law (fines, restrictions on school entry, etc.)

Legally chartered National Immunization Technical Advisory Group
licensure. We coded the documents using these nine provisions. For the purpose of our analysis, the denominator for all percentages is the number of countries and territories included in the analysis (n = 27).

Finally, to explore associations between vaccination legislation and program outcomes, we abstracted information from the WHO-UNICEF Joint Reporting Form (JRF) on government immunization program financing and performance, including routine vaccination coverage rates. The JRF is a standardized reporting system for countries to submit data on immunization program performance and vaccine-preventable diseases.

**Results**

Twenty-four countries and three territories in LAC provided 77 vaccine-related legal documents to PAHO (Table 2). Of these, 20 were free-standing vaccination laws and 13 were laws that supplemented or updated existing public health legislation. Two were executive or legislative decrees, one a vaccination law proposal, one an education law mandating immunization for children entering school, five were public health acts containing provisions on vaccination, and 34 were ministerial directives.

Although most of the countries and territories submitted one to three documents, a few, including Brazil and Uruguay, submitted as many as 10. The average number of documents submitted was 3.1 and half of the countries submitted only one. Larger countries tended to submit greater numbers and more types of documents (ministerial decrees, executive decrees, and parliamentary laws).

Twenty-six governments have enacted some type of legal framework for immunization and one has drafted a vaccination law proposal yet to be enacted. Twenty governments have laws exclusively for vaccination and six have education or public health acts containing provisions on vaccination. Prior to 1980, only six countries in the Region had passed vaccination-related laws (Figure 1). The number of countries with such laws or broader legislation encompassing vaccination began increasing in the early 1980s, held constant in the following decade, and rose sharply in 1995. Twelve countries passed some sort of vaccination-related laws from 1995 to 2012. In 2012, Paraguay substantially updated its legal framework and El Salvador became the most recent country to pass a vaccination law. Guatemala has a vaccination law proposal pending in its legislature. Other countries, including Bolivia,
Table 2: Types of vaccine-related legal documents (n=77) per country as of Sept. 2010, PAHO vaccine legislation

<table>
<thead>
<tr>
<th>Countries</th>
<th>Law proposal</th>
<th>Free-standing vaccine law</th>
<th>Supplementary vaccine laws</th>
<th>Public health act</th>
<th>Education act</th>
<th>Ministerial directives</th>
<th>Executive or legislative decree</th>
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Colombia, and Honduras, are working to improve their laws or introduce new legislation in response to recent fiscal and programmatic developments and the availability of new vaccines.

All the countries and territories included in the analysis have proposed or enacted legislation that contains at least one declarative provision. Fifteen countries and territories have laws or proposals containing at least one financial provision. All the countries and territories have laws or proposals with at least one operational provision. Among the nine provisions, countries most frequently included compulsory vaccination (Figure 2).

Figure 1: Number of countries enacting vaccine legislation, from 1980 to present (n = 25). British Virgin Islands (BVI) was not included because of the undeterminable date of original legislation. Database includes legislation dated 2004 with reference to the earlier law. Guatemala was not included. At the date of analysis, the country was working towards presenting a law proposal to their legislatures.

Figure 2: Distribution of study countries (n = 27) by vaccine legislation.
Declarative provisions

Twenty-six countries and territories (96 per cent) have passed or are proposing laws mandating immunization; these vary in content and specificity. Some require all citizens and visitors to be vaccinated; others require that parents, as a prerequisite for school enrollment, ensure that their children have completed vaccination according to the schedule for their age. The most comprehensive laws identify the vaccines included in the national schedule and/or the government agency responsible for determining vaccine schedules.

Vaccination-related legal provisions in 17 countries and territories (63 per cent) declare immunization to be a public good provided free of charge by the State. Some provisions invoke the national constitution, which defines health as a right for all people and declare immunization to be a right for all citizens. To illustrate, in Panama this provision states:

The right to be protected against the diseases included in the National Immunization Schedule is hereby recognized for every individual, but particularly for children, adolescents in custody centers, child and adolescent workers, pregnant women, disabled individuals, senior citizens… (Article 8, Law 48, 2007)\textsuperscript{11}

Financial provisions

Four countries have embraced all the three financial provisions assessed. Six countries (22 per cent) guarantee tax exemptions for the importation of vaccines, vaccine-related supplies, and cold chain equipment, while seven countries (26 per cent) mention a procurement mechanism for vaccine purchases. Five countries (Bolivia, Costa Rica, El Salvador, Honduras, and Panama) stipulate that vaccines be purchased through bulk procurement mechanisms of international organizations, namely the PAHO Revolving Fund for Vaccine Procurement.

The 39 LAC countries that procure vaccines through the PAHO Revolving Fund, are required to earmark funds in the national budget for these purchases.\textsuperscript{4} However, only 12 countries and territories (44 per cent) require that funds in the national budget be reserved for vaccination. Many countries without a legally protected budget line for vaccine purchases are smaller Caribbean nations. Most large Latin American countries prescribe a national budget line for vaccine purchases. These
countries include the Region’s largest vaccine importers: Bolivia, Brazil, Costa Rica, El Salvador, Ecuador, Guatemala, Honduras, Nicaragua, Panama, Paraguay, Peru, and Venezuela.

Operational provisions

Eight countries and territories (30 per cent) include provisions to ensure regulatory oversight of vaccines. These typically specify which national health authority is responsible for authorizing and registering new vaccine and product licenses in the country. El Salvador’s law also stipulates that any new vaccine must be pre-qualified for safety and efficacy by the World Health Organization (WHO).

Laws mandate a national immunization schedule in 21 countries and territories (78 per cent), and in all but one also establish sanctions to help enforce the law. Some countries delegate to a branch of the Ministry of Health, or to a National Immunization Technical Advisory Group (NITAG), the responsibility for determining which vaccines should be included in the national schedule and required for all citizens. Laws in six countries and territories (22 per cent) charter, or formally establish NITAGs.

Many laws name the pathogen-specific vaccines included in the schedule. Countries commonly incorporate newer vaccines into the schedules through ministerial decrees, which are published long after the original laws. Sanctions for non-compliance with the recommended vaccination schedule range from moderate fines to restrictions on school enrollment for children without proof of vaccination. Ten countries and territories have employed the stronger school enrollment sanction, which has long been the policy in the United States. One of the Region’s earliest examples is an executive decree from Honduras:

The presentation of an updated vaccination card will be a mandatory requirement to enter kindergarten, primary school, and orphanages…

Laws in two countries, Costa Rica and Panama, contained all nine provisions considered in the analysis. Four countries’ legislation contained at least seven provisions and the legislation in nine countries contained six.
Discussion

Using standardized qualitative methods we analyzed vaccine-related legal provisions of all sorts from 27 of 44 LAC countries and territories. Our results offer insights about legal mechanisms that may be useful to build and sustain strong national immunization programs. The scope and focus of legal support for vaccination has changed over time; as countries have increased their investments in immunization programs, legal frameworks supporting the Expanded Program on Immunization have become broader in scope, and more comprehensive. They vary substantially across the three categories: financial, declarative, and operational (Figure 3), emphasizing financial and declarative aspects over operational aspects. One possible explanation for this difference may be that countries participating in the Revolving Fund, where safety and efficacy of vaccines is guaranteed through the WHO pre-qualification process, have had less need to include regulatory provisions in their legislation.

There is little documented about the state of vaccination legislation in other WHO regions. As part of its Sustainable Immunization Financing Program, the Sabin Vaccine Institute is now working with 18 African and Asian countries to analyze existing laws and draft new ones. At this writing, eight countries are preparing or have already submitted new vaccine legislation to their parliaments. In the workshops, government and parliamentary counterparts come together to conceptualize and conduct peer reviews of their draft laws. Latin American and Caribbean laws are important resources in this process.14

Figure 3: Number of countries meeting the declarative, financial and operational legal criteria, from 1980 to present ($n = 27$).
Most vaccination legal frameworks in the Region mandate compulsory vaccination, free of charge to the recipient and his or her family and include a budget line for vaccine purchases. Too few countries and territories, however, incorporate most or all nine provisions that are the focus of this analysis. In recent years, many countries have improved or expanded their legal framework for vaccination by updating earlier laws that included only a few essential declarative provisions.

The content and specificity of the legal provisions vary greatly. Of the 26 countries and territories that enacted some vaccination relevant provisions, six place immunization within broader national health program legislation. These broader laws generally incorporate fewer of the vaccine-specific provisions. While laws exclusively for immunization appear to benefit immunization programs, country-specific circumstances matter. For smaller countries or territories, such as those in the Caribbean, it may be impractical to establish freestanding vaccine laws; a more appropriate solution may be to include vaccine-related provisions in the public health law.

Best practices

The analysis allows us to conclude that certain legal provisions are particularly effective as tools for protecting and extending immunization programs.

Sustainable financing

Foremost are provisions to ensure sustainable financing. Between 1996 and 2008, the number of pieces of vaccination legislation passed (including eight freestanding laws) and national immunization expenditures in the Region rose sharply (Figure 4). In the same period, the percentage of vaccine expenditures supported by national governments increased by 8 per cent, from 91 per cent to 99 per cent. This study suggests an association between increased national investment in routine immunization programs and increasingly comprehensive legal frameworks. For example, legislation often guarantees a budget line for vaccines and earmarks funds by creating a national vaccine fund (Costa Rica) or requires that a given percentage of the national health budget be reserved for vaccination (Bolivia). This increasing emphasis on financing requires greater cooperation among State actors, particularly legislatures.
and ministries of health, finance, and justice. The most specific laws identify the roles and responsibilities of all actors, making explicit budget contributions to program and specific timelines to transfer funds.

**Procurement**

Specification of a reliable and efficient procurement method for vaccine purchases appears to be another best practice. Bulk procurement methods, such as PAHO’s Revolving Fund, guarantee a timely and continuous supply of safe and effective vaccines at the lowest market price. Historically, the Revolving Fund has played a critical role in helping national programs decrease their dependence on external partner funding. Procurement through the Revolving Fund also reduces risks of private gain at public expense by promoting transparent and competitive processes. Accordingly, some countries in the Region have found it advantageous to designate in law the PAHO Revolving Fund as their sole or primary purchasing mechanism. This practice benefits countries region wide and helps ensure the Fund’s long-term sustainability.

**Specifying target groups**

Provisions mandating immunization for targeted risk groups may be effective tools for ensuring greater compliance and achieving high coverage. Laws in many LAC countries and territories require children to be vaccinated prior to school entry and some sanction parents or

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**Figure 4:** Number of countries with free-standing vaccine laws and EPI financing source from 1989 to 2008 \( (n=19) \). Only countries with freestanding vaccine legislation through 2008 have been included.
households for failing to comply. The most explicit laws identify target age groups and specific sanctions.

No charge for vaccination – a public good
In most countries and territories mandating immunization, laws establish vaccination as a free public good provided by the state. From the mid-1980s to 2009, vaccine coverage increased almost 25 per cent among the countries that have passed vaccination legislation, from 67.6 to 91.9 per cent.\textsuperscript{15} By recognizing vaccination as a public good, legal frameworks have the potential to substantially raise coverage levels, reduce health inequities, and improve health outcomes.

Several other best practices warrant mention: tax exemptions for vaccine imports; priority for vaccinating vulnerable and hard-to-reach populations; delegation of an advisory role to NITAGs; and inclusion of new vaccines in national immunization schedules.

The legislative process of passing a vaccine law
What appears common to the successful passage of a vaccination law – and of a successful national immunization program – is cooperation among parliamentarians and government officials. These laws require cooperation and thus unite, multiple disciplines, opposing political parties, and several levels of national authority. The process for proposing, drafting, and passing vaccine legislation varies.

Legal protection and promotion of immunization has been an iterative process in LAC. During the 1980s and 1990s, countries with vaccination-specific laws or broader legislation incorporating vaccination provisions witnessed substantial benefits of polio and other disease eradication campaigns and became convinced of the importance of legal tools to protect program gains and ensure future success.\textsuperscript{10} Expanding policy commitments to reduce childhood mortality and promote population health led politicians to advocate and ultimately legislate for more resources for national immunization programs.\textsuperscript{17} In this sense, the broadening scope of the Region’s vaccination legal frameworks could be seen as both the cause and the effect of successful national immunization programs. It is clear from other studies that public health law has played a role in strengthening and sustaining immunization programs.\textsuperscript{17,18}
Study limitations

The research team assumes that all freestanding vaccination laws and public health legislation including vaccination related provisions of the LAC Region were included in the analysis, but we may have overlooked some legal and regulatory documents at lower administrative jurisdictions. In addition, we captured some legislation pertaining to the licensure and registration of vaccines, but did not look for all such provisions since regulatory aspects were not the primary purpose of our study. In addition, some Dutch, English, and French territories may fall under legislation enacted in their parent countries and therefore we did not capture this legislation. We did not examine causal links between the passage of vaccine legislation, vaccine prices, financial sustainability, and program performance. Many factors contribute to the sustainability of the Region’s immunization programs. Vaccine legislation in the LAC dates back to 1953 (Suriname); however, data on program performance and sustainability, proxy indicators such as coverage, disease burden, and program financing, have not been collected consistently or systematically. We included only data successfully collected in a systematic manner over the past several years, beginning with the implementation of the WHO-UNICEF JRF.

Conclusion

This study produced the first comprehensive analysis of vaccination-relevant legal frameworks and specific provisions in the LAC. The findings demonstrate how expansion of these has accompanied improvements in immunization program performance and national immunization financing. Additional analysis is needed to understand the causal relationships more fully, specifically whether legislative activity is the cause or effect of increasing immunization program investments and performance. The emergence of vaccination laws and broader public health legislation may also reflect ongoing democratization trends in the Region. Their passage and implementation require cooperation of previously antagonistic political and institutional actors. Passage of vaccine legislation in Latin America that occurred during a period of tremendous growth in national programs, established legal precedents making immunization free and obligatory in most of the Region’s countries. Such an accomplishment, at minimum, helps to protect
future generations against the rollback of public immunization program support during economic downturns.

Acknowledgement

We gratefully acknowledge the contributions from ministry of health immunization program staff and immunization staff from PAHO country offices to this article. Several individuals from the Region tirelessly tracked down legal documents for the database, helped to specify research questions, and participated in telephone and in-person interviews in the early stages of the project. We are also grateful for the revisions and comments Carolina Danovaro (PAHO, FCH/IM) provided on early drafts. The ProVac Initiative is funded by the Bill and Melinda Gates Foundation, with additional in-kind support from the PanAmerican Health Organization.

About the Authors

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Cara B Janusz is a technical officer for the PAHO ProVac Initiative. In this capacity, she has provided technical assistance to several countries in LAC to conduct cost-effectiveness analyses on the introduction of new vaccines. In addition, she oversees capacity building activities for members of National Immunization Technical Advisory Groups in LAC. She holds a Masters of Public Health in program evaluation and Masters of Arts in Latin American economic and political policy from the George Washington University.

Barbara Jauregui is an Argentine MD MSc. She has dedicated her work to improving systems and processes to promote evidence-based decisions and equity in health. Under direct supervision of the Principal Investigator, Dr Jon Andrus, she is currently managing the ProVac Initiative in LAC countries, providing training and technical collaboration in the generation of cost-effectiveness analysis regarding new vaccine
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Michael McQuestion is the Director of the Sustainable Immunization Financing program at the Sabin Vaccine Institute. He holds a PhD in sociology from the University of Wisconsin and Master’s in Public Health from Tulane University. In addition to extensive teaching and research experience at the university level, he has been the Global Supervisor for the PolioPlus Program of the Rotary Foundation, Technical Officer for PAHO’s diarrheal diseases control program and a volunteer in the US Peace Corps.

Gabriela Felix is a technical officer for the PAHO ProVac Initiative. Currently, she is serving as the coordinator for ProVac International, a 2-year project to pilot the ProVac Initiative in countries in Europe, the Middle East and Africa. She holds a Masters of Law (LL.M) degree, with a focus on human rights.

Cuauhtémoc Ruiz-Matus, a Mexican physician, graduated from the National Polytechnic Institute School of Medicine, and specialized in epidemiology at the School of Public Health of Mexico. He is a graduate of the Public Entity Management Program of the National Public Administration Institute. Dr Ruiz Matus worked in Mexico’s Ministry of Health for 25 years. During the last 10 years, he served as Chief of Staff to the Undersecretary for Health Prevention and Promotion at the Ministry of Health. He is currently Senior Advisor of the Comprehensive Family Immunization Project at the Pan American Health Organization/World Health Organization (PAHO/WHO).

Jon Kim Andrus, a public health expert with 25 years of experience in vaccines, immunization, and primary care in developing countries, is the Deputy Director at the Pan American Health Organization. Earlier in his career, Dr Andrus worked on polio eradication in Latin America, South-East Asia and Africa. Among other posts, he served as a medical epidemiologist at the Global Immunization Division at the Centers for Disease Control and Prevention (CDC) in Atlanta. He holds degrees from Stanford University (BS) and the University of California at Davis School of Medicine (MD). He also spearheaded ProVac, an initiative to enhance countries’ capacities to use evidence in immunization decision
making. As Deputy Director of PAHO, he continues to serve as the initiative’s Principle Investigator.

Ciro de Quadros was Director of the Division of Vaccines and Immunization at the Pan American Health Organization. Before joining the Sabin Vaccine Institute as Executive Vice-President. He also served as the World Health Organization’s Chief Epidemiologist for the Smallpox Eradication Program in Ethiopia from 1970 to 1976. Dr de Quadros is a leader in the development of successful surveillance and containment strategies for the eradication of smallpox worldwide, and has directed successful polio and measles eradication efforts in the Americas. He completed his medical and public health studies in Brazil.

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