PAN AMERICAN HEALTH ORGANIZATION
WORLD HEALTH ORGANIZATION

146th SESSION OF THE EXECUTIVE COMMITTEE

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Provisional Agenda Item 4.11

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ORIGINAL: SPANISH

STRENGTHENING IMMUNIZATION PROGRAMS

Concept Paper

Introduction

1. In 1977, the Directing Council of the Pan American Health Organization (PAHO), through Resolution CD25.R27 created the Expanded Program on Immunization (EPI), to reduce morbidity and mortality from vaccine-preventable diseases to levels that no longer constitute a public health problem.

2. Thirty-two years after its creation, the Expanded Program on Immunization continues to make a fundamental contribution to reducing infant morbidity and mortality in the Americas, and is an example of organization, commitment, solidarity, equity, and quality.

Background

3. The issue of immunization has been taken up at various meetings of the Governing Bodies of the Organization, always for the purpose of drawing attention to new challenges and addressing them. In recent years a number of documents have been discussed and approved, among them the "Regional Strategy for Sustaining National Immunization Programs in the Americas" (Resolution CD47.R10 (2006)); "PAHO Procurement Mechanisms for Strategic Supplies, including Vaccines" (Information Document CD48/INF/8 (2008)) of the 48th Directing Council, and "The Pan American Health Organization Revolving Fund for Vaccine Procurement" (Document CD49/21 (2009)) of the 49th Directing Council.

4. Although there have been major advances in the field of immunization in the Americas, there is a need for the adoption of strategies to sustain those achievements, tackle the unfinished agenda, and take on new challenges such as the introduction of new vaccines.

5. When the EPI was created, the majority of the Member States did not have regular immunization programs, which meant there were no national immunization authorities, skilled human resources, necessary infrastructure, or budgets for these activities.

6. With the full commitment of their ministers of health, and in collaboration with PAHO and its partners, the Member States proceeded to develop all the components of the EPI at the national level and put a basic immunization program in place that included vaccines against polio (OPV), diphtheria, tetanus, and whooping cough (DPT), measles, and serious forms of tuberculosis (BCG).

7. As the EPI evolved and was consolidated at the national level, new vaccines were also developed. The hepatitis B vaccine was introduced in 1990 and the pentavalent vaccine (DPT-Hib-HepB) was added to the *Haemophilus influenza* type b (Hib) vaccination series in 1995. The Region of the Americas was the first region that introduced with greater speed the use of this vaccine in regular immunization programs.

8. Moreover, at the recommendation of PAHO's Technical Advisory Group on Immunization, the yellow fever vaccine was added to the regular vaccination program in countries with enzootic areas. Introduction of the seasonal influenza vaccine began to be accelerated in 2004.

9. As part of its mandate, PAHO provides technical assistance to countries. Among other things, this has facilitated the development of strong national teams, specific budget lines for the programs, national vaccination laws, information systems, national immunization committees, interagency cooperation committees, and strong participation by civil society.

10. The firm commitment of the Member States promoted the EPI as a public good and established vaccination programs as the responsibility of the public services. Thanks to this strong political commitment, it is estimated that over 95% of the current budget for procuring vaccines and operating National Programs in Latin America and the Caribbean comes from national funds.

11. At the same time, PAHO brought together a group of experts in the field at the regional level, and teams of epidemiologists were formed to serve as immunization focal points in most countries of the Region, creating a laboratory network and an

epidemiological surveillance system for vaccine-preventable diseases. Moreover, a extensive network of partners was created, in which international research institutions, civil society organizations, and donor country governments participated.

Situation Analysis

12. The EPI is fundamental both to strengthening health and primary care services and taking an integrated approach to family and community health.

13. The EPI is the most socially accepted health program, which reflects the commitment and shared responsibility of countries, health workers, international and regional organizations, and various social actors.

14. Coverage in the Region is among the highest in the world. In 2008, coverage was reported at 97% for BCG, 93% for OPV3, 93% for DPT-Hib3 in children under 1 year of age, and 94% for mumps/measles/rubella (MMR) in children 1 year of age.

15. Among other things, the coverage levels attained have kept the Region free of poliomyelitis cases caused by the wild poliovirus since 1991, indigenous measles cases since 2002, and endemic rubella cases for more than a year. In March 2010, the Region of the Americas concluded Phase I of laboratory containment of the wild poliovirus, which is a prerequisite for declaring the global eradication of poliomyelitis. Phase I consists of identifying the laboratories in the Hemisphere that still store the wild virus.

16. However, when coverage is analyzed at the national, subnational, and, especially, municipal levels, it is clear that major challenges persist. According to information provided by the Member States for the WHO-UNICEF (*Joint Reporting Form on Immunization*) for 2008, 44% of municipios in Latin America and the Caribbean report coverage below 95% (with DPT3 vaccine as the tracer). An estimated 55% of children under 1 year of age live in these municipios.

17. The impact of the EPI on the health of the Region's population has been significant. It is estimated that from 1990 to 2002, one-third of the deaths prevented in children were attributable to immunization. Through the regular immunization program, it is estimated that 174,000 deaths in children are prevented annually in Latin America and the Caribbean, and that the use of the "new vaccines" (rotavirus, pneumococcus, and human papillomavirus) will also prevent thousands of cases and deaths in various age groups. These results represent EPI's progress toward the achievement of the Millennium Development Goals (MDG).

18. An essential element for the development and success of the EPI has been PAHO's Revolving Fund for Vaccine Procurement, which was also created in 1977 by resolution of the 25th Directing Council (CD25.R27). The Revolving Fund is the cooperation mechanism that gives Member States timely and sufficient access to quality vaccines at the lowest prices. Based on the principles of equity, solidarity, Pan-Americanism, and transparency, the Revolving Fund has permitted the timely availability of vaccines and is fundamental to introducing the new vaccines.

19. The majority of the Member States currently participate in the Revolving Fund. Through the Fund, 27 antigens with 39 different WHO-prequalified presentations are offered by 13 producers. In 2009, without taking into account the A (H1N1) flu vaccine, a total of 156 million doses were procured through the Revolving Fund for a total cost of US$302 million.[1] This represents a little more than four times the total cost of the doses procured in 2000 ($69 million).

20. As part of the Revolving Fund's activities, PAHO has provided technical support for countries to ensure the quality of the vaccines and syringes used in national programs. To this end, work is aimed at boosting the capacity of national regulatory authorities, as well as training the laboratory network in the quality control of syringes and supplies for immunization programs.

21. The Regional Plan for Quality Control and Safety of Syringes was created in 2005 to support the process of procuring syringes through the Revolving Fund for national immunization programs. The purpose of the plan is to assure the quality, efficacy, and safety of syringes, strengthening procurement and quality control mechanisms through (a) the use of laboratory tests to confirm conformity and compliance with ISO standards for products procured through bidding and the monitoring of products received by countries; and (b) institutional capacity building in the National Regulatory Authority to conduct quality-control tests.

22. PAHO's Expanded Program on Immunization has been working with the countries on the three components of the "Cold Chain": proper storage, distribution, and transport of vaccines. This is to ensure that vaccines retain their immunologic properties and to prevent interruption of immunization services due to lack of vaccines. With the introduction of new vaccines, the cold chain has been strengthened at all levels, as has the training of health personnel in this area.

23. Information, a fundamental aspect of decision-making, has been one of the building blocks for the success of the program, as it has permitted documentation of

[1] Unless otherwise indicated, all monetary figures in this document are expressed in U.S. dollars.

vaccination coverage, epidemiological surveillance data, and the monitoring of indicators. However, even more work is needed on data quality.

24. The laboratory network for the diagnosis of vaccine-preventable diseases helps make timely information available for decision-making as well as for verification of processes for the control and elimination of these diseases. There are over 148 laboratories in the Region that perform measles/rubella diagnosis and 11 laboratories that diagnose poliomyelitis. With the integration of new vaccines into the regular immunization programs of the Member States, the capacity of laboratories to diagnosis rotavirus, pneumococcus, and human papillomavirus (HPV) has been strengthened.

25. Vaccination Week in the Americas has managed to ensure that the EPI receives high political priority, social commitment, high public visibility, and considerable public attention in the media, with activities that foster the participation of governments, civil society organizations, volunteers, academic institutions, international organizations, etc. Since its inception in 2003, this initiative has helped position vaccination as a regional public good. Through the initiative, the countries have succeeded in vaccinating nearly 300 million people across all age groups, especially vulnerable and hard-to-reach populations. In this way it has become a tool for generating equity and equality by reducing gaps in access to health and especially, by maintaining the commitment of all stakeholders to these preventive activities. This year marked the eighth Vaccination Week in the Americas, whose theme was "Reaching Everyone." Following the example of this successful experience in the Americas, Europe launched a similar program five years ago, and the Eastern Mediterranean Region did so this year. This means that, in the last week of April 2010, 122 countries in three WHO regions simultaneously held International Vaccination Week. This initiative is expected to keep expanding to include other regions in the world until it becomes World Vaccination Week.

26. One example of the response capacity developed with the EPI, from a technical and organizational standpoint, has been the response to the pandemic influenza A(H1N1) virus and the planning to introduce the corresponding preventive vaccine. National immunization plans have been buttressed with the development of national response plans, training for human resources, the production of manuals and guidelines, preparation of the study on events supposedly attributable to vaccination or immunization (ESAVI), and the administration of this vaccine.

27. Access to the influenza A(H1N1) vaccine in the Member States of the Region came through the direct procurement by the countries of approximately 290 million doses from producers (Argentina, Brazil [partial], Canada, Mexico, United States, and Suriname [partial]); the donation of approximately 11 million doses through WHO (Bolivia, Chile, Cuba, El Salvador, Guatemala, Guyana, Haiti, Honduras, Nicaragua, Paraguay, [partial], and Suriname); and procurement through the Revolving Fund, which

enabled 23 countries to acquire the vaccine, thus fully meeting the demand in the Member States. As of 14 May, over 400 million doses had been administered worldwide, 83 million in Latin America and the Caribbean , with 151 million distributed in Canada and the United States.

28. The availability of new vaccines that help reduce mortality and morbidity from rotavirus, pneumococcus, and HPV offers a great opportunity to achieve the MDGs, but these vaccines should only be introduced when the countries can do so sustainability.

29. The introduction of new vaccines into the regular immunization programs should be the decision of each country, based on existing scientific evidence as well as technical and programmatic criteria. Social aspects and a political commitment to guarantee the financial sustainability of these vaccines should also be considered. To this end, PAHO provides technical support for strengthening infrastructure, logistics and management, skilled human resources, the cold chain, information systems, epidemiological surveillance, the laboratory network, oversight, and impact assessment.

30. One important element in the introduction of new vaccines is to ensure the financial sustainability of national immunization programs. Based on the current cost of vaccines procured through the Revolving Fund, it can be estimated that adding the rotavirus vaccine to the vaccination series would require the doubling of a country's budget for vaccine procurement; adding the pneumococcus vaccine would require a sevenfold increase in the budget.

31. Given the significant financial impact that the introduction of new vaccines represents for the Member States, PAHO has developed the ProVac Initiative, whose mission is to boost national capacity for evidence-based decision-making through, among other things, cost-effectiveness studies and guidelines on how to conduct impact monitoring studies.

32. One element that is essential for the long-term financial sustainability of the immunization program and the introduction of new vaccines is the existence of laws or regulations that include a budget line for EPI operations and vaccine procurement. To date, 17 countries in the Region have vaccine legislation or regulations (Argentina, Bolivia, Chile, Colombia, Dominican Republic, Ecuador, El Salvador, French Guiana, Guatemala, Guyana, Honduras, Nicaragua, Paraguay, Peru, Suriname, Uruguay, and Venezuela).

33. As of 2009, seven countries in the Region had added the pneumococcus vaccine to their regular immunization programs (Barbados, Canada, Costa Rica, Mexico, Peru, the United States, and Uruguay) and 12 had added the rotavirus vaccine (Bolivia, Brazil, Colombia, Ecuador, El Salvador, Honduras, Mexico, Nicaragua, Panama, Peru, the

United States, and Venezuela). In 2010, 14 countries will universally use the pneumococcus vaccine (adding Aruba, Brazil, Chile, Ecuador, El Salvador, Panama, and Trinidad and Tobago) and 16 will use the rotavirus vaccine (adding Costa Rica, Guatemala, Guyana, and Paraguay).

34. As part of these actions to introduce new vaccines, PAHO provides technical cooperation in epidemiological surveillance of these diseases and identification of the circulating serotypes and strains. To date, 14 countries of the Region have implemented sentinel surveillance systems and four more are in the process of implementing one this year.

35. Although new vaccines represent an opportunity to expand the benefits of the EPI, it is important to consider the challenges that they pose, such as their high cost, the limited number of producers, the new actors in the field of immunization, and the various public-private cooperation mechanisms in the international area.

36. Vaccine production in the Latin American and Caribbean countries is limited. Given the high cost of the new vaccines and the emergency created by influenza A(H1N1), the Member States have noted the need to bolster regional productive capacity to help cover regional vaccine requirements and guarantee the quality of these biologicals.

Proposals

37. The existence of diseases in other regions of the world that have already been eliminated in the Region of the Americas, the ease with which people move across all countries, and the persistence of vaccination coverage of less than 95% in many municipalities of the Region are cause for concern about continuing to give the EPI the highest political, social, and public health priority.

38. It is advisable for the Member States to support the EPI as a public good, which will make it possible to sustain the achievements to date and face the new challenges ahead.

39. Based on previous resolutions of the Directing Council and on the provisions in the Health Agenda for the Americas, the Member States are requested to support the Regional Strategy for immunization and its vision, maintaining the goal set in 1977 when the EPI was established, of reducing morbidity and mortality from vaccine-preventable diseases to levels that no longer constitute a public health problem. To this end, achievement of the following objectives is necessary:

a) Sustain the achievements: a Region free of polio, measles, rubella, and congenital rubella syndrome, with control of diphtheria, whooping cough, and Hib.

b) Complete the unfinished agenda: elimination of neonatal tetanus; epidemiological control of hepatitis B, seasonal influenza, and yellow fever; ensure that all municipalities have coverage above 95% (using DPT3 as the tracer), and complete the transition from an immunization approach geared to children to one focused on comprehensive family immunization.

c) Tackle new challenges: introduce new vaccines that contribute to the achievement of the MDGs; improve national decision-making capacity; promote the financial sustainability of the EPI, and strengthen vaccination and immunization services within the framework of systems and services based on primary health care.

40. We call for maintaining the PAHO Revolving Fund for Vaccine Procurement as a basic element to guarantee timely access to quality vaccines while at the same time preserving the principles of equity, solidarity, Pan-Americanism, and the lowest possible prices, and strengthening its operations to make it more efficient.

41. PAHO should continue to provide technical assistance to the Member States for evidence-based decision-making through the ProVac Network of Centers of Excellence, comprised of academic centers with recognized experience in economic evaluation and decision analysis.

42. It is necessary to strengthen the operational capacity of national immunization programs within the framework of primary health care through strategies that promote activities in municipios with low coverage, as well as action to help disadvantaged and hard-to-reach populations.

Action by the Executive Committee

43. The Executive Committee is requested to review the progress and challenges of the Expanded Program on Immunization in the Americas and reiterate its commitment to the Regional Strategy for immunization and its vision in order to preserve the achievements to date and tackle the new challenges that lie ahead. Moreover, please consider approval of the proposed resolution in Annex B.

Annexes

PAN AMERICAN HEALTH ORGANIZATION

Pan American Sanitary Bureau, Regional Office of the

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Annex A

ANALYTICAL FORM TO LINK AGENDA ITEM WITH ORGANIZATIONAL MANDATES

1. Agenda item: 4.11. Strengthening Immunization Programs

2. Responsible unit: Comprehensive Family Immunization Project FCH/IM

3. Preparing officer: Cuauhtemoc Ruiz Matus

4. List of collaborating centers and national institutions linked to this Agenda item:

- Ministries of Health (all Latin American and Caribbean countries)
- World Health Organization
- UNICEF
- United States Department of Health and Human Services
- Public Health Agency of Canada
- Caribbean Epidemiology Centre
- Latin American Center for Perinatology and Human Development
- Regional Technical Advisory Group on Vaccine-preventable Disease
- American Red Cross
- Bill and Melinda Gates Foundation
- Centers for Disease Control and Prevention
- Canadian International Development Agency
- GAVI Alliance
- Inter-American Development Bank
- Spanish Agency for International Cooperation for Development
- International Federation of Red Cross and Red Crescent Societies
- Japanese International Cooperation Agency
- March of Dimes
- Sabin Vaccine Institute
- United Nations Children's Fund
- United States Agency for International Development
- Church of Jesus Christ of Latter-day Saints

5. Link between Agenda item and Health Agenda for the Americas 2008-2017:

The Expanded Program on Immunization (EPI) is related to all Areas of Action in the Health Agenda for the Americas, with particular relevance to the following:

(a) Strengthening the National Health Authority: inter-sectoral collaboration, community participation, political commitment to health, health equality, resource mobilization;

(b) Harnessing Knowledge, Science, and Technology: systematic evaluation of programs, evidence based strategies, health information dissemination, strengthening of health surveillance;

(c) Strengthening Solidarity and Health Security: measures to address natural disasters, pandemics, and zoonoses, securing the health of border populations;

(d) Diminishing Health Inequities among and within countries: improvements in health of vulnerable

populations, promotion of continuity of care for women and specific actions to reduce maternal, neonatal, and child mortality in all groups of society;

(e) Reducing the Risk and Burden of Disease: actions to combat vaccine-preventable disease and related sequela;

(f) Increasing Social Protection and Access to Quality Health Services: promoting universal access to health services, promotion of primary health care strategies;

(g) Strengthening the Management and Development of People Working for Health: increased opportunities for health worker capacity building.

6. Link between Agenda item and Strategic Plan 2008-2012:

Strategic Objective 1: To reduce the health, social and economic burden of communicable diseases

7. Best practices in this area and examples from countries within the Region of the Americas:

- Role of EPI in strengthening health worker capacity, sustaining political and community commitment, and for reducing maternal and child mortality.
- Strategies for elimination and eradication of vaccine-preventable diseases, including improvements in surveillance and laboratory capacity.
- Evolution and sustainability of national immunization programs with capacity to support introduction of new vaccines.
- Role of the EPI Revolving Fund for the timely procurement of safe, quality vaccines.
- Increased national capacity for making evidence based decisions.
- Development of strategies/initiatives to reach vulnerable populations with quality health services.
- Lessons learned to support the transition from child to family immunization programs.
- Rapid response to pandemics and improved national capacity for addressing events supposedly attributable to vaccination and immunization.

8. Financial implications of Agenda this item:

The estimated program budget for the biennium 2010-2011 is $34,300,000, which is financed by PAHO Member States and strategic partners.

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146th SESSION OF THE EXECUTIVE COMMITTEE

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Annex B
ORIGINAL: SPANISH

PROPOSED RESOLUTION

STRENGTHENING IMMUNIZATION PROGRAMS

THE 146th SESSION OF THE EXECUTIVE COMMITTEE,

Having reviewed the Concept Paper *Strengthening Immunization Programs* (Document CE146/19), and considering the significant progress made by the countries in the field of immunization;

Considering that the protection of national and regional immunization programs is essential to sustaining the achievements of all the Member States and tackling the new challenges that lie ahead;

RESOLVES:

To recommend that the Directing Council adopt a resolution written in the following terms:

STRENGTHENING IMMUNIZATION PROGRAMS

THE 50th DIRECTING COUNCIL,

Having reviewed Concept Paper CD50/__, *Strengthening Immunization Programs*, as well as the significant progress made by the countries in the field of immunization;

Recognizing the effective efforts of the Member States and the Pan American Health Organization (PAHO) to harmonize vaccination policies and strategies, promoting the training of national teams in the effective management and implementation of national programs and including the adoption of the Revolving Fund for Vaccine Procurement as the cooperation mechanism that facilitates access to biologicals and other supplies by all Member States;

Recognizing that the Member States have determined that immunization is a public good that has made a significant contribution to the reduction of infant mortality, the eradication of polio, measles, rubella, and congenital rubella syndrome, and to the epidemiological control of other vaccine-preventable diseases in the Region;

Reiterating that the Revolving Fund has been a key factor in the Member States' timely and equitable access to vaccines and that, as part of technical cooperation, it has permitted the standardization of vaccination programs in the countries of the Americas, the achievement of high vaccination coverage, a timely response to outbreaks and other health emergencies, and the rapid introduction of "new vaccines" against rotavirus, pneumococcus, human papillomavirus, and, recently, the influenza A(H1N1) virus;

Recognizing that protecting national and regional immunization programs is essential to sustaining the achievements of all the Member States and that reducing vaccination levels in any country directly affects the others;

RESOLVES:

1. To urge the Member States to:

(a) endorse national immunization programs as a public good;

(b) support the Regional Strategy for immunization and its vision and meet the following objectives:

- sustain the achievements: a Region free of polio, measles, rubella, and congenital rubella syndrome, with control of diphtheria, whooping cough, and Hib.

- complete the unfinished agenda: elimination of neonatal tetanus; epidemiological control of hepatitis B, seasonal influenza, and yellow fever; ensure that all municipios have coverage of over 95% (using DPT3 as the tracer); and complete the transition from an immunization approach geared to children to one focused on comprehensive family immunization.

- tackle new challenges: introduce new vaccines that contribute to the achievement of the MDGs; improve national decision-making capacity; promote the financial sustainability of the EPI; and strengthen vaccination and immunization services within the framework of systems and services based on primary health care.

(c) support the PAHO Revolving Fund for Vaccine Procurement as the strategic cooperation mechanism that enables the Member States to have timely and equitable access to the supplies of the immunization program.

2. To request that the Director to:

(a) continue providing technical support to the Member States to strengthen the operating capacity of national immunization programs within the framework of primary health care, using strategies that ensure action in municipios with low coverage as well as among disadvantaged and hard-to-reach populations;

(b) provide technical assistance to the Member States for evidence-based decision-making through the ProVac Network of Centers of Excellence; and

(c) strengthen and maintain the Revolving Fund as an active, efficient mechanism based on the principles and procedures that have yielded successful results over its 30 years of operation.

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Annex C

Report on the Financial and Administrative Implications for the Secretariat of the Proposed Resolution

1. Agenda item: 4.11. Strengthening Immunization Programs

2. Linkage to Program Budget 2008-2009:

(a) Area of work: Comprehensive Family Immunization Project (FCH/IM)

(b) Expected result:

Strategic Objective I: To reduce the health, social and economic burden of communicable diseases.

Three Regional Expected Results:

RER 1.1: Member States supported through technical operation to maximize equitable access of all people to vaccines of assured quality. Including new or underutilized immunization products and technologies; strengthen immunization services; and integrate other essential family and child health interventions with immunization.

RER 1.2: Member States supported through technical cooperation to maintain measles elimination and polio eradication; and achieve rubella, congenital rubella syndrome (CRS) and neonatal tetanus elimination.

RER 1.4: Member States supported through technical cooperation to enhance their capacity to carry out communicable disease surveillance and response, as part of a comprehensive surveillance and health information system. (RER indicator 1.4.2 corresponds to Immunization)

The total program budget for 2008-2009 was $32.3 million. Please find below a table of Implementation Rates for funds distributed at HQ level in 2008-2009.

RER	Budgeted	Obligated	Implementation Rate
RER 1.1	11,367,798.00	10,363,755.00	91.2%
RER 1.2	2,563,709	2,450,629	97.1%
RER 1.4	1,427,838	1,365,902	95.7%
TOTAL	**17,219,045**	**16,511,494**	**95.9%**

3. Financial implications

(a) **Total estimated cost for implementation over the lifecycle of the resolution (estimated to the nearest US$ 10,000, including staff and activities):** As stated below, our estimated budget for biennium 2010-2011 is $34,400,000. This estimate includes the entire FCH/IM project. Costs for future biennia should be similar or greater than that of biennium 2010-2011.

(b) **Estimated cost for the biennium 2010-2011 (estimated to the nearest US$ 10,000, including staff and activities):** The total estimated budget for biennium 2010-2011 is $34,400,000.

(b) **Of the estimated cost noted in (*b*), what can be subsumed under existing programmed activities?**

Operations: $22,704,000
Fixed-term personnel: $9,288,000
PSC (Grant overhead): $2,408,000

4. Administrative implications

(a) **Indicate the levels of the Organization at which the work will be undertaken:** The work will be undertaken at the regional- and country-levels.

(b) **Additional staffing requirements (indicate additional required staff full-time equivalents, noting necessary skills profile):** Additional staff requirements include an HPV advisor, the Immunization focal point post in Bolivia, and a New Vaccines Specialist (NUVI).

(c) **Time frames (indicate broad time frames for the implementation and evaluation):** The time frame for implementation is 2 years, with periodic evaluations taking place every six months.

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