PAHO’s Regional Immunization Vision and Strategy 2007-2015

MISSION STATEMENT

To protect all people in the Americas against vaccine-preventable diseases.
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## GLOSSARY OF TERMS

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<td>ACTO</td>
<td>Amazonian Cooperation Treaty Organization</td>
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<td>AFP</td>
<td>acute flaccid paralysis</td>
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<td>AMR RCC</td>
<td>American Regional Commission for Certification of Poliovirus</td>
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<td></td>
<td>Laboratory Containment and Verification of Polio-free Status</td>
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<td>CAN</td>
<td>Caribbean Community</td>
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<td>CARICOM</td>
<td>Centers for Disease Control and Prevention</td>
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<td>COMISCA</td>
<td>Council of Ministers of Health of Central America</td>
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<td>CRS</td>
<td>congenital rubella syndrome</td>
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<td>EPI</td>
<td>Expanded Program on Immunization</td>
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<td>GIVS</td>
<td>Global Immunization Vision and Strategy</td>
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<td>HIV</td>
<td>human immunodeficiency virus</td>
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<td>HPV</td>
<td>human papillomavirus</td>
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<td>ICC</td>
<td>Interagency Coordinating Committee</td>
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<td>ISIS</td>
<td>Integrated Surveillance Information System for Vaccine-preventable Diseases</td>
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<td>MERCOSUR</td>
<td>Common Market of the Southern Cone</td>
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<td>MDGs</td>
<td>Millennium Development Goals</td>
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<td>NGO</td>
<td>non-governmental organization</td>
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<td>NIP</td>
<td>national immunization program</td>
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<td>NNT</td>
<td>neonatal tetanus</td>
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<td>OPV</td>
<td>oral polio vaccine</td>
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<td>ORAS/CONHU</td>
<td>Andean Health Organization</td>
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<td>Pro-Vac</td>
<td>Initiative to Promote the Implementation of Economic Analyses for Vaccine Introduction in Countries of Latin America and the Caribbean</td>
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<td>QA</td>
<td>quality assurance</td>
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<td>REMSA</td>
<td>Meeting of Ministers of Health of Andean Area</td>
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<td>RESSCAD</td>
<td>Health sector meeting of Central America and Dominican Republic</td>
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<td>RIVS</td>
<td>Regional Immunization Vision and Strategy</td>
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<td>RV</td>
<td>rotavirus</td>
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<td>TAG</td>
<td>Technical Advisory Group on Vaccine-preventable Diseases</td>
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<td>VPD</td>
<td>vaccine-preventable disease</td>
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<td>VWA</td>
<td>Vaccination Week in the Americas</td>
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DIRECTOR’S PREFACE

The countries of the Americas, with support from the Pan American Health Organization (PAHO), have made extraordinary progress in providing children with an umbrella of protection against basic, vaccine-preventable diseases. Sustained high national immunization coverage levels, the eradication of polio, the interruption of endemic measles virus transmission, and the more recent progress towards rubella and congenital rubella syndrome elimination, are hemispheric benchmarks of this progress.

In our Region, immunization has been responsible for almost one-quarter of the reduction in mortality in children aged under 5 years between 1990 and 2002, contributing significantly to progress towards the Millennium Development Goals (MDGs) and the target of the World Health Organization’s Global Immunization Vision and Strategy (GIVS). These outcomes have been achieved through dedicated country efforts and decades of innovation. Immunization, already regarded as a “best buy” public health intervention, is now believed to have even more far-reaching economic impact, in better education outcomes and more years of productive life.

In this context, the PAHO Regional Immunization Vision and Strategy (RIVS) offers national immunization programs continued technical support for challenges that will confront countries in the years to come. I am delighted to see that the vision tackles the critical issues surrounding protecting our achievements, completing the unfinished agenda, and meeting future challenges. As our organization faces those challenges, PAHO renews its commitment to support countries in technical and management areas.
GUIDING PRINCIPLES FOR TECHNICAL COOPERATION

PAHO assists countries in reducing inequities by supporting efforts to target underserved communities with low immunization coverage. Improving coverage in all municipalities will protect the progress made in eliminating measles in the Americas, facilitate the acceleration of rubella elimination, and strengthen health system capacity to improve routine services and to introduce vaccines currently available for children in economically developed countries but not in less-developed ones. Reducing inequities in health will continue to be a top priority in PAHO’s future technical cooperation with its Member States because they remain steadfastly committed to achieving Health for All. They also recognize the benefits of immunization and its potential impact on achieving the new MDGs, particularly those concerning the reduction of maternal and child mortality.

In addition, PAHO promotes the culture of prevention that has been expanding since the eradication of polio and the elimination of measles and neonatal tetanus (NNT), while also galvanizing political commitment and providing excellence in technical cooperation, all of which leads to a strengthened public health infrastructure.

Reducing inequities in health services has long been a driving force in PAHO’s approach to providing technical cooperation in immunization to PAHO Member States. The PAHO Revolving Fund for Vaccine Procurement strives to do exactly that on behalf of all the countries of the Americas. The Fund provides countries with a reimbursement mechanism for the purchase of vaccines, syringes, needles, and cold chain equipment at affordable prices. Since the Fund was established in 1979, PAHO has allowed countries to participate in the benefits of the Revolving Fund if they meet the requirements of (1) allocating a national budget line item for the cost of vaccines and syringes; (2) formulating a comprehensive and realistic national plan of action that covers multiple years of operations and is consistent with PAHO policy; and (3) appointing a national program manager who has the authority to develop and implement the national plan of action. Therefore, in addition to facilitating equitable prices through bulk purchase, the Fund also helps to ensure that countries develop sustainable programs, ultimately benefiting underserved populations that most need immunization services.

SITUATIONAL ANALYSIS

National immunization programs (NIPs) in the Americas have reached approximately 90% vaccination coverage for all of the childhood vaccines, and they strive to achieve greater than or equal to 95% coverage in all municipalities. This is one of the best ways to ensure equitable access to existing vaccines and ultimately provide
new life-saving vaccines that address important public health priorities to the people who need them most. Over the five years since its inception, the yearly Vaccination Week in the Americas (VWA) has reached over 200 million people, of which more than 64 million were children aged under 5 years. Despite the success of polio eradication (Figure 1) and measles elimination (Figure 2), pockets of unvaccinated susceptible persons still persist, leading to outbreaks of diseases like diphtheria and pertussis (Figure 3), which carry high case-fatality rates.

**Figure 1. Polio Eradication**

Source: Immunization Unit, PAHO.

**Figure 2. Measles Elimination**

Source: Immunization Unit, PAHO.

Note: 81 confirmed cases in 2005
In 2005, approximately 28% of the municipalities in the Region had not achieved measles vaccination coverage of greater than or equal to 80%, and one out of every three children in the Americas live in these poor performing districts. This is of concern, because 95% population immunity is required to maintain interruption of indigenous measles transmission and prevent large outbreaks after importation. Therefore, efforts must be focused on interventions in these high-risk municipalities. This is a particular concern in the five priority countries—Bolivia, Guyana, Haiti, Honduras, and Nicaragua—where the percentage of municipalities with measles vaccination coverage less than 95% ranges from 45% (Honduras, 2005) to 80% (Haiti, 2005).

The work of PAHO is guided by the principles of access and equity, disease control, and development of public health infrastructure. One of the EPI milestones was polio eradication from the Americas in 1991 and the dramatic reduction of NNT, both diseases associated with high case-fatality rates: 8% to 10% for polio and 50% for NNT. By 2002, the last case of endemic measles was reported in the Region. In 2003, PAHO's 44th Directing Council adopted a resolution to eliminate rubella and congenital rubella syndrome (CRS) by 2010 and urged Member States to prepare national plans of action in support of that objective (Figure 4). By the end of 2006, five countries remained to conduct the rubella mass vaccination campaigns necessary to achieve the target. Surveillance will need to be strengthened to ensure that endemic transmission has been interrupted. While only 18 countries/territories in the Americas were reporting on CRS in 1998, by 2003 the entire Region was conducting CRS surveillance. A high of 41 cases were reported in 2001, and by 2006 only 5 cases were reported.
Rubella and CRS elimination is another example of PAHO using disease elimination strategies to spearhead the reduction in health inequities. Equally important, PAHO promotes access to existing immunization services, while introducing new and underutilized vaccines in an affordable, sustainable fashion. Mortality from vaccine-preventable diseases is not distributed evenly in the Region, and not all countries have shared equally in the advances made at the Regional level. The number of NNT cases decreased 94% in the Region during 1986-2005. Since the case-fatality rate is 50% to 70%, this has represented an important reduction in infant mortality in the Region. However, this decrease was not shared by Haiti, which in the last four years has reported approximately 50% of all NNT cases in the Region.

Pneumococcal disease kills more children than HIV, malaria, and tuberculosis combined. Yet the vaccine, at greater than US $50 per dose for a three-dose schedule, does not allow countries to vaccinate children who need this vaccine most. Rotavirus (RV) kills approximately 16,000 children and causes more than 77,000 hospitalizations per year in the Region. In order to achieve the MDGs of child mortality reduction, pneumococcus and RV vaccines will need to be introduced in many countries. Cervical cancer is a significant, preventable, global health problem, which has been estimated to cause nearly half a million new cases and more than 230,000 deaths annually. Eighty-three percent of this disease burden is borne by women in developing countries. Every year, more than 72,000 new cases and over 32,000 deaths occur among women residing in Latin America and the Caribbean. In 2006, human papillomavirus (HPV) vaccines against cervical cancer became commercially available, offering for the first time a primary preventive tool and the unique opportunity for comprehensive cervical cancer control through the dual application of vaccination and screening. This approach is possible thanks to the collaboration between immunization programs and cervical cancer

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**Figure 4. Impact of Rubella Elimination Strategies, The Americas, 1990–2007**

- **Strengthening of Measles Elimination**
- **Accelerated Rubella Control**
- **Strengthening of Febrile Rash Illness Surveillance**

Source: Country Reports.  
* Includes rubella cases reported to PAHO as of Epidemiological Week 19/2007.  
** Provisional data.
prevention and control programs. The Caribbean has some of the highest cervical cancer rates in the world and, with the availability of new vaccines against the causative agent, new opportunities to promote maternal and women’s health must be seized.

Work to introduce new vaccines will be integrated with diarrhea control, women, and maternal health programs whenever possible. The transition from child to family immunization programs will catalyze the process as well. Seasonal influenza vaccination has dramatically increased in the last three years. By 2006, a total of 28 countries introduced seasonal influenza vaccination in high-risk populations compared to 13 countries by 2004. Seasonal influenza vaccination is cost-effective and will help create demand in the Region to increase the likelihood that a pandemic vaccine is available for all. Yellow fever vaccination in enzootic countries will remain a priority. Lessons learned from influenza and yellow fever control will be integrated with disaster and pandemic preparedness as well. Introduction of new vaccines will require strategies to ensure solid program operation, strengthened epidemiological surveillance, and introduction sustainability, such as vaccine legislation, enhanced mechanisms for creating fiscal space, and efficient management of PAHO’s Revolving Fund.

PAHO promotes the strengthening of national capacity to introduce new vaccines based on the best available information. However, in 2006 a few countries decided to introduce RV vaccine before fully assessing the logistical capacity to absorb the new vaccine, in particular cold chain and training issues. PAHO will continue to advocate that PAHO’s framework and technical guides for vaccine introduction be strictly adhered to, as endorsed by PAHO’s 47th Directing Council in September 2006 through Resolution CD47.R10. Fundamental to this process is that the vaccines be pre-qualified by WHO so that quality and safety is assured, supported by competent national regulatory authorities.

High quality surveillance will allow adequate preparedness to be in place for pandemics and vaccine-preventable actions related to threats of national and international concern. Surveillance systems for vaccine-preventable diseases need urgent upgrading, with emphasis on capacity development. Other challenges relate to ensuring the quality of vaccines, which need to be guaranteed by competent national regulatory authorities.

The Americas remain free of indigenous circulation of wild poliovirus, and acute flaccid paralysis (AFP) surveillance continues at acceptable levels 14 years after eradication. Since the certification of eradication, the laboratory network has tested around 1,400 samples from AFP cases annually without isolating the wild virus.

Because the global program for polio eradication is facing enormous challenges in reaching its target, polio will be given special space here. Twelve years have passed since the Americas were certified free of indigenous circulation of wild poliovirus, and 15 years since the last case of wild virus was isolated in the Hemisphere. Certification was issued by the International Commission for the Certification of Poliomyelitis Eradication after reviewing the evidence that each country had submitted on its eradication activities and the status of AFP surveillance.
Laboratory containment of wild poliovirus and evidence that there is no circulation of the wild poliovirus in the world for at least the past three years are the conditions set by the Global Commission for the Certification of the Eradication of Poliomyelitis for certifying that all the Regions of the World Health Organization have eradicated poliomyelitis. In June 2000, PAHO’s Executive Committee adopted Resolution CE126.R4 recommending that the Directing Council urge Member States to “initiate activities related to the containment of any laboratory material that may harbor specimens of wild poliovirus, to ensure that global certification of eradication is eventually accomplished.” According to the March 2004 report presented by the National Committees for the Containment of Wild Poliovirus, which was examined by the Regional Commission, 39 of the 47 countries of the Hemisphere had submitted reports. Eight countries reported that they had completed their inventory, and the rest reported substantial progress had been made in drawing up the list of laboratories and completing the inventory.

The Regional Certification Commission of the Americas (AMR RCC) has been formed, and all the countries in the Hemisphere have National Committees for the Certification of Laboratory Containment of Wild Poliovirus. The AMR RCC has asked countries to broaden the terms of reference of National Committees to include not only containment activities, but also activities guaranteeing the countries’ status as free of the circulation of wild poliovirus. From an analysis of the reports presented in Antigua, Guatemala in 2005, it was concluded that Bolivia, Canada, Costa Rica, El Salvador, Guatemala, Honduras, and the USA had completed phase I. The rest of the countries should complete phase I in 2006. Work to complete phase II will be initiated in 2007.

**GOALS**

The goals of the Immunization Unit are in alignment with the MDGs, and will be to:

- Further reduce child and infant mortality;
- Improve maternal and women’s health in general;
- Promote high quality surveillance;
- Achieve effective program management; and
- Promote partnerships.

**STRATEGIC AREAS OF WORK**

The strategic areas of work are to (1) Protect the achievements; (2) Complete the unfinished agenda, and (3) Meet future challenges.

To implement these strategic areas of work, immunization programs must position themselves within a strategy of comprehensive care throughout the life of individuals and they must play a significant role in primary health care delivery.
Strategic Area of Work 1: Protect the Achievements

- Goal 1.1: Maintain the Region free of polio
  - Intermediate objective 1.1.1: By 2010, 90% of the countries of the American Region will maintain AFP surveillance, and comply with indicators required by the Global Certification Commission.
  - Intermediate objective 1.1.2: The American Region will continue to maintain the Oral Polio Vaccine (OPV) as the vaccine of choice for NIPs, as part of the regular schedule and also for national immunization days.
  - Intermediate objective 1.1.3: 90% of countries will achieve OPV3 coverage ≥95% in at least 65% of districts before 2008.
  - Intermediate objective 1.1.4: Countries will complete phase I of wild poliovirus laboratory containment by 2008.

- Goal 1.2: Maintain the Region free of endemic measles
  - Intermediate objective 1.2.1: By 2009, 80% of countries in the Region will have ensured protection through a measles/rubella supplementary immunization activity within the last five years.
  - Intermediate objective 1.2.2: By 2010, all countries in the Region will document the interruption of endemic transmission of the measles virus.
  - Intermediate objective 1.2.3: By 2015, 80% of countries will sustain the achievements of measles elimination activities by implementing follow-up campaigns every 3-4 years, ensuring coverage ≥95%, and continuing high-quality, integrated measles/rubella surveillance systems while maintaining standardized surveillance indicators ≥80%.

- Goal 1.3: Maintain achievements of diphtheria control
  - Intermediate objective 1.3.1: Countries will achieve DPT3 coverage ≥95% in at least 65% of municipalities before 2008.
  - Intermediate objective 1.3.2: Every diphtheria outbreak will be contained within three months after detection in the municipalities where the cases are reported.
  - Intermediate objective 1.3.3: Specific diphtheria antitoxin will continue to be available through the Revolving Fund for Latin American and Caribbean countries.

- Goal 1.4: Maintain achievements of pertussis control
  - Intermediate objective 1.4.1: Countries will achieve DPT3 coverage ≥95% in at least 65% of the municipalities before 2008.
- Intermediate objective 1.4.2: Every pertussis outbreak will be contained within six months after detection in the municipalities where the cases are reported.

- Goal 1.5: Maintain achievements of Hib control
  - Intermediate objective 1.5.1: By 2009, all countries will include universal Hib vaccination in infancy, with coverage similar to that of DPT.
  - Intermediate objective 1.5.2: By 2010, the Regional network SIREVA will record a 50% reduction in the number of Hib isolates from meningitis and pneumonia cases.

- Goal 1.6: Maintain achievements of hepatitis B control
  - Intermediate objective 1.6.1: By 2009, all countries will introduce universal hepatitis B vaccination in infancy, with coverage similar to that of DPT3/Pentavalent.
  - Intermediate objective 1.6.2: By 2009, 80% of countries with high prevalence, defined as HBsAG ≥8%, will vaccinate against hepatitis B at birth, with coverage similar to that of BCG.

Strategic Area of Work 2: The Unfinished Agenda

- Goal 2.1: Improve coverage and quality of services in poor performing districts.
  - Intermediate objective 2.1.1: By 2008, 90% of countries will have updated 5-year Plans of Action with associated yearly budgets and work plans.
  - Intermediate objective 2.1.2: 90% of countries will participate in VWA, aiming to increase public awareness about immunization and, consequently, coverage in high-risk, isolated, border, and indigenous populations.

- Goal 2.2: Eliminate rubella and CRS
  - Intermediate objective 2.2.1: By 2008, all countries will implemented effective interventions and/or high quality campaigns to achieve rubella and CRS elimination in the Americas.
  - Intermediate objective 2.2.2: By 2009, 80% of countries in the Region will have high quality integrated measles/rubella and CRS surveillance systems in place while maintaining standardized surveillance indicators ≥80%.
  - Intermediate objective 2.2.3: By 2010, all countries in the Region will document the interruption of endemic transmission of the rubella virus.
  - Intermediate objective 2.2.4: By 2015, 80% of the countries will sustain the achievements of rubella elimination activities by implementing follow-up
campaigns every 3-4 years ensuring coverage ≥95%, and continuing high-quality integrated measles/rubella and CRS surveillance maintaining standardized surveillance indicators ≥80%.

- **Goal 2.3: Eliminate maternal and neonatal tetanus (taking into account the Haiti challenge)**
  
  - Intermediate objective 2.3.1: Countries will maintain NNT incidence <1 case per 1,000 live births in every municipality.
  
  - Intermediate objective 2.3.2: Latin American and Caribbean countries will maintain adequate NNT surveillance and every NNT case will be subject to a panel review to determine how to prevent new cases.
  
  - Intermediate objective 2.3.3: Specific tetanus antitoxin will continue to be available for Latin American countries through the Revolving Fund.
  
  - Intermediate objective 2.3.4: By 2010, Haiti will routinely provide two doses of TT to women of childbearing age.
  
  - Intermediate objective 2.3.5: By 2010, Haiti will implement a surveillance system to detect, investigate, and report all NNT cases.

- **Goal 2.4: Complete transition from child to family immunization program**

  - Intermediate objective 2.4.1: By 2008, all countries will review their existing health structure, immunization program, and immunization information system and commence discussions with stakeholders on transitioning to the family immunization approach, as a necessary step towards formulating a plan of action.
  
  - Intermediate objective 2.4.2: By 2010, 50% of countries will develop a comprehensive plan of action for the successful transition from child to family immunization programs, based on lessons learned from countries that have vaccinated groups beyond childhood.
  
  - Intermediate objective 2.4.3: By 2015, all countries in the Region will have incorporated into their national immunization schedule appropriate vaccines for all family members throughout their life span as appropriate and according to the countries’ EPI situation, to ensure the attainment of the MDGs and within the principles of equity and universal access and the right to health for all people.

- **Goal 2.5: Improve coverage of underutilized vaccines such as influenza vaccine in all countries, yellow fever vaccine in enzootic countries, and pentavalent vaccine in Haiti**

  - Intermediate objective 2.5.1: By 2015, all countries with yellow fever enzootic areas will complete vaccination of all the population residing in enzootic areas, and areas where migration to those areas originate, while monitoring vaccination coverage, to be similar to that of MMR at 1 year of age.
- Intermediate objective 2.5.2: By 2015, all countries will establish an influenza vaccination policy for seasonal influenza vaccine for high-risk populations, while generating coverage data and strengthening surveillance system.
- Intermediate objective 2.5.3: By 2015, 80% of countries will provide seasonal influenza vaccination to children aged 6-23 months.

**Strategic Area of Work 3: Meet Future Challenges**

- Goal 3.1 Strengthening of operational capacity
  - Intermediate objective 3.1.1: By 2008 all countries in the Region will have a five-year plan of action.
  - Intermediate objective 3.1.2: By 2010, activities for the strengthening of management capacities, training of human resources, and strengthening of the cold chain, management of biologicals, and shipping will have been conducted.

- Goal 3.2: Strengthen infrastructure (surveillance, laboratory networks, ISIS)
  - Intermediate objective 3.2.1: Laboratory networks
    - Intermediate objective 3.2.1.1: By 2015, a well-functioning QA program will be implemented throughout the laboratory networks in support of the Region’s NIPs to promote a fully functional laboratory network united by common objectives, programming, supervision, and evaluation.
    - Intermediate objective 3.2.1.2: By the year 2015, the laboratory network for HPV and rotavirus will be established in the Region, with harmonized and standardized laboratory procedures for effective surveillance and vaccination impact monitoring through enhanced laboratory support.
    - Intermediate objective 3.2.1.3: By 2012, national health authorities from all countries in the Region will receive PAHO assistance to develop a plan of action to ensure that full support is provided to their measles/rubella laboratories, including financial, logistical, regulatory, and staffing support, as witnessed with polio laboratories.
    - Intermediate objective 3.2.1.4: By 2008, a standardized database to improve the timeliness of reports will be available to all laboratory networks in the Region.
  - Intermediate objective 3.2.2: ISIS
    - Intermediate objective 3.2.2.1: By 2010, 90% of the countries will report case-based data for AFP surveillance to the ISIS database.
    - Intermediate objective 3.2.2.2: By 2010, 80% of the countries will report case-based data for integrated measles/rubella surveillance to the ISIS database.
    - Intermediate objective 3.2.2.3: By 2012, 70% of the countries will report case-based data for suspect CRS cases to the ISIS database.
Intermediate objective 3.2.2.4: By 2015, ISIS database will integrate all VPD surveillance.

Goal 3.3: Strengthen national capacity to make evidence-based decisions (Pro-Vac)

- Intermediate objective 3.3.1: By 2008, 50% of countries will have initiated economic evaluation studies in each subregion for new and underutilized vaccines.
- Intermediate objective 3.3.2: By 2010, 50% of countries will have defined expert bodies for vaccine introduction decisions.
- Intermediate objective 3.3.3: By 2012, 80% of countries will have completed and disseminated comprehensive economic evaluations of new vaccine introductions. The experience and evidence will have been shared during a regional workshop.

Goal 3.4: Introduce new vaccines to reach MDGs and GIVS targets (currently available vaccines such as rotavirus, pneumococcus, and HPV, and other vaccines that will become available in the medium-term) and do so with optimal integration with other sectors.

- Intermediate objective 3.4.1: By 2010, relevant evidence will be available for each subregion in Latin America and the Caribbean to inform rational public health decision-making for the introduction of priority vaccines (rotavirus, pneumococcus, and HPV).
- Intermediate objective 3.4.2: By 2010, functional linkages and close intersectoral collaboration will be established with other health sector partners (cancer control, adolescent health, women’s health) to ensure that more children and families have access to the complete package of disease control (diarrhea, pneumococcus, and HPV prevention and control).
- Intermediate objective 3.4.3: By 2009, a new vaccine introduction plan will be developed by each country, based on each country’s epidemiological priorities and operational and financial capacities.

Goal 3.5: Promote sustainability of national immunization programs to introduce new vaccines. Demand measures will be pursued on fiscal space, other financial sustainability initiatives, and vaccine legislation. Supply initiatives will include several key actions to strengthen the Revolving Fund.

- Intermediate objective 3.5.1: By 2008, conduct studies on financial sustainability and fiscal space, to be disseminated in cooperation with key regional organizations. For vaccine legislation, complete ongoing studies and model law recommendations for regional utilization.
- Intermediate objective 3.5.2: By 2010, provide technical assistance on fiscal space, financial sustainability and vaccine legislation, in at least five countries,
based on previously studied policies and priorities, and country needs and requests, in collaboration with other PAHO units.

- Intermediate objective 3.5.3: By 2008, ensure vaccine supply by developing the Regional business plan for the Revolving Fund activities.

- Intermediate objective 3.5.4: By 2008, strengthen the Revolving Fund supply chain, including vaccine management and cold chain by establishing performance indicators.

- Intermediate objective 3.5.5: By 2012, mobilize an additional US $40 million for the Revolving Fund’s working capital, in cooperation with partners and key regional players.

- Goal 3.6: Promote technical excellence (country consultants, TAG, subregional meetings, Immunization Newsletter, country evaluations, information management)

  - Intermediate objective 3.6.1: By 2008, have quality indicators allowing comparison, both internal and external, of national EPI program progress.

  - Intermediate objective 3.6.2: By 2010, conduct two meetings of the TAG.

  - Intermediate objective 3.6.3: By 2012, print newly revised Field Guides.

  - Intermediate objective 3.6.4: Publish Immunization Newsletter every two months.
    - Intermediate objective 3.6.4.1: Continue publishing the Immunization Newsletter in Spanish, English, and French, and distributing it worldwide. The purpose of the Immunization Newsletter is to facilitate the exchange of ideas and information concerning immunization programs in the Region, in order to promote greater knowledge of the problems faced and possible solutions to those problems.
    - Intermediate objective 3.6.4.2: By 2009, having a search engine available on the Immunization Unit website to facilitate searching for Immunization Newsletter articles.

**IMPLICATIONS FOR PAHO/WHO TECHNICAL COOPERATION**

This strategic vision offers NIPs continued technical support for challenges that will confront countries in the years to come. It essential to strengthen existing mechanisms and develop new modalities of technical cooperation, such as:

- Extending cooperation among all sectors within countries, including participation of academic and scientific institutions and research centers;
- Strengthening the Revolving Fund, including work that would continue to promote the manufacturing of inexpensive, good quality vaccines and supplies by emerging market countries;
- Promoting cooperation with Reference and Collaborating Vaccine Centers;
- Continuing to promote inter-programmatic work modalities by creating feasible and efficient mechanisms to achieve common goals and objectives, such as task forces,
working groups, joint missions to priority countries, joint projects among different regional plans, develop regional and subregional initiatives within one or more regional plans, create virtual means networks, and promote the mobilization of resources for joint projects.

**External Functional Structure:**

- Groups of experts to advise on technical and scientific recommendations by consensus, such as TAG and ad-hoc scientific meetings;
- Commissions, opinion leaders, champions, responsible for mobilizing political support and visibility;
- As with the HPV partnership, interagency coalitions/networks to coordinate and promote dialogue among countries and different partners and stakeholders;
- Establishing new Regional networks or strengthening the existing national public health networks, such as economic centers of excellence, to enhance economic studies for vaccine introduction policy; and
- Considering the different modalities available for service delivery in countries and promote joint and efficient collaboration.

**PAHO’s Immunization Unit:**

- The primary function of the Immunization Unit is to support and provide technical expertise to countries to develop strong immunization programs.
- The RIVS utilizes the usual formal structures, but also incorporates other innovative approaches for technical cooperation, such as Pro-Vac and the HPV partnership. Within these new frameworks, the Immunization Unit should continue to coordinate the institutional response to countries’ needs, especially priority countries;
- Groups of regional consultants with knowledge and experience in public health related to the design, planning, implementation, follow-up, and evaluation of the Regional Immunization Plan, to provide direct and indirect support at the regional, subregional, country, and local levels;
- Inter-programmatic and interdisciplinary coordination mechanisms at the regional, subregional, country, and local levels; and
- Prompt administrative, legal, planning, resource allocation, execution, monitoring, and evaluation mechanisms.

**Subregional and Country Levels:**

To facilitate intersectoral participation, RIVS must respond to the many diverse needs of countries or subregional groups of countries sharing a common geopolitical and/or development agenda, or those linked by specific health issues. These include ACTO (Amazonian Cooperation Treaty Organization), CARICOM, CAN, COMISCA, ORAS/CONHU, REMSA, MERCOSUR, and others.
The RIVS should incorporate subregional initiatives based on the profiles and needs of the subregions, as well as identifying financial strengths in the subregions and other modalities relating to financing, sources, networks, and types of cooperation.

At country level, NIPs should be supported by different groups, national networks, and partnerships, such as:

- Interagency Coordinating Committees (ICCs);
- Advisory committees including representatives of scientific associations, academia, NGOs, and other civil society groups including those representing indigenous communities and other minority groups;
- Inter-programmatic and inter-country coordination through horizontal cooperation;
- Bilateral and horizontal cooperation among and within countries;
- Centers of Reference;
- National and border epidemiological surveillance networks; and
- PAHO/WHO Representations.

**THE WAY FORWARD**

The major challenge countries will face will be to comprehend how to face new challenges while ensuring that achievements are sustained and the unfinished agenda is addressed. To that effect, PAHO must support countries as they strengthen their programs at operational level, develop management and human resources capacities, build up their cold chain, develop an efficient laboratory network and an epidemiological surveillance system allowing for timely and adequate decision-making, increase their supervisory capacity and mechanisms to evaluate program quality, and develop methods for financial and legal sustainability.

One this process is completed, or in parallel to it, it will become possible to introduce new, life-saving vaccines that will enable countries to achieve the MDGs in a way that ensures equity, access, and sustainability of these interventions. PAHO estimates the annual child mortality in Latin America and the Caribbean to be 16,000 deaths by rotavirus-caused diarrhea and 18,000 deaths caused by pneumococcal disease. In addition, 32,000 women die each year from cervical cancer caused by HPV, and between 30,000-50,000 children and adults die from influenza infection. The use of new or underutilized vaccines for these priority diseases presents opportunities to make substantial gains in health, thus bringing many countries closer to achieving the MDGs. The relative value of these vaccines depends on the burden of disease, vaccine cost, and the available resources for introducing the vaccines into NIPs. As burden of disease and resources available vary between countries and subregions, the decision to introduce these vaccines must be grounded in a greater body of evidence that reflects national conditions. In contrast, national policy-makers in some countries are making decisions for new vaccine introduction irrespective of the evidence available or necessary. Such actions risk undermining the long-term sustainability of programs.
The current decision-making process has been historically driven by Regional priorities in immunization. Examples include elimination initiatives such as polio, measles, and rubella, and the expansion of childhood routine vaccinations to add *Haemophilus influenzae* type b (Hib) and hepatitis type B (HB) vaccines into national immunization schedules. The financial and logistical burden of newer vaccines on already constrained programs will require future decisions to be grounded in more rigorous methodology. Given the urgency to press these new vaccines into use, swift action must be taken to strengthen national decision-making.

Two recent country experiences in 2006 highlight our concern that decisions are being made irrespective of the evidence available. One country introduced varicella-zoster virus vaccine, despite disease burden data and preliminary economic analyses to suggest that pneumococcal and rotavirus infections may be of greater public health significance. Another, much poorer, country decided to introduce rotavirus vaccine without addressing the system’s capacity for including such a vaccine.

To ensure that future decisions for new vaccine introductions achieve the greatest sustainable impact, three essential factors must be addressed:

1. **Decisions should be nationally based.** As alluded to above, the paradigm must be changed to expand from primarily Regional decisions to nationally based decisions. These decisions must be supported by national or subregional evidence. While the end-products will be distinctly national approaches for new vaccines, Regional technical cooperation will continue to play a critical role in supporting the generation of essential evidence and developing sustainable immunization policies.

2. **Evidence used to support decisions must be broad-based.** Regional immunization policy decisions have historically relied primarily on the burden of disease and vaccine efficacy; however, the higher cost of new vaccines will require a much broader evidence base, ranging from cost effectiveness and financial sustainability to health systems concerns.

3. **Infrastructure must be in place to support nationally based process.** In the transition to primarily country-based decisions, national decision-making bodies must have the necessary technical capacity to ensure decisions are reached through rigorous and informed deliberations, drawing on the expertise of national advisory boards. To that end, Ministries of Health of some countries will need substantial organizational support to establish or strengthen these advisory boards.

Achieving the greatest impact with new and underutilized vaccines will require national decisions grounded in local information, representing an expanded body of evidence, supported by the effective health infrastructure, such as advisory boards of national experts. RIVS will use PAHO’s experience to strengthen the national capacity to make evidence-based, informed public health policy decisions. Much of the vision and strategy in this area of work has already been developed by PAHO’s Pro-Vac Initiative and will be incorporated and budgeted into the work of RIVS.
Ideally, when countries make evidence-based, informed decisions they should be accounting for all the factors listed below.

Technical Criteria:

- **Disease burden.** Pneumococcal disease kills more people than tuberculosis and malaria combined.
- **Characteristics of the vaccine.** There are several critical vaccine characteristics, including immunogenicity and efficacy, duration of immunity, type-specific composition in vaccines that have multiple possibilities (i.e., conjugated pneumococcal vaccine), safety and adverse event profile, dosage and route of administration, and thermostability.
- **Adverse events and post-marketing surveillance.** Most adverse events are mild but severe adverse events can be life-threatening and need to be rapidly identified and treated. Otherwise, public confidence in the program will be undermined with obvious future implications on effectiveness of program delivery and acceptance.
- **Cost-effectiveness and other economic evaluations.** If economic analyses demonstrate that an intervention is cost-saving, it is very easy for a policy-maker to make a decision, as was the case with rubella elimination. However, few newer public health interventions are truly cost-saving. Cost-effectiveness analysis allows for assessing the incremental costs needed to ensure health gains when compared to other strategies.

Programmatic & Operational Criteria:

- **Vaccine supply.** Maintaining long-term vaccine availability may have inherent impediments, such as technical difficulties in ensuring supply meets demand or a limited number of producers.
- **Logistical and operational issues.** Single-dose vaccines packaged in large boxes may rapidly consume cold chain capacity and impede the ability of programs to go to scale on delivery, thereby limiting access to its benefits.
- **Financing strategies.** Vaccines that are affordable are much more likely to be sustainable in the national program. More than 26 countries in the Region have vaccine laws, some of which requiring the nation to purchase introduced vaccines. Such laws also help sustain the program.
- **Partnerships.** Support from partners during the initial phases of new vaccine introduction has proven essential in some countries with poor or borderline economies. Such countries can then assume gradual responsibility for financing over time.

Social Criteria:

- **Perception of risk.** Although the incidence of some diseases is rare (e.g. meningococccemia), the perception by society of the disease consequences is vivid and could influence policy, particularly in a more affluent country.
• **Political will.** High-level political commitment has driven the introduction of some vaccines regardless of the evidence available.

• **Equity.** Many vaccine-preventable diseases disproportionately affect the poor and immunization is an opportunity to prevent disease in underserved populations. The introduction of some vaccines will contribute to the reduction of health inequities.

To reach the best overall decision, most experts agree that all the factors described above need to be critically assessed. However, over the last three years NIP managers in the Americas have indicated that they needed expanded support with some of these components, particularly cost-effectiveness and economic evaluations of interventions. To that end, with help from partners such as WHO and CDC, in July 2004 PAHO conducted a “Prevention Effectiveness Workshop” to brief national immunization managers and epidemiologists about the above framework and, more specifically, about methodologies for conducting cost-effectiveness studies and interpretation of their results. In 2006, this meeting was followed up with the “Pro-Vac Workshop on Economic Analysis to Support Decision-Making on Vaccine Introduction” supported by the Bill and Melinda Gates Foundation. All countries participated in a hands-on experience utilizing tools developed by PAHO and its partners for conducting cost-effectiveness analyses of the following priority vaccines: pneumococcus, rotavirus, human papillomavirus, and influenza.

In September 2006, Ministers of Health at PAHO’s annual Directing Council Meeting passed a resolution requesting PAHO to continue providing technical assistance for evidence-based decisions and for the development and use of economic analyses at the country level. Ministers expressed that the absence of suitable economic analyses represented a “weak link” in the development of immunization policy. Support was needed from applied epidemiologists and their economic colleagues. While the Pro-Vac initiative seeks to promote and strengthen economic analyses, the initiative will continue to promote critical assessments of all factors in the decision-making framework, as highlighted in the following section on objectives.

Over a five-year period, concluding in 2012, the Pro-Vac initiative should have accomplished the following objectives:

• **Strengthening infrastructure or process:** Countries have functional advisory boards of national experts for immunization and vaccine introduction.

• **Developing tools for the analyses:** Countries have methodologically sound and peer-reviewed frameworks and models for estimating disease burden, program costs, and cost-effectiveness available, and the necessary training materials and technical expertise for their use.

• **Strategizing subregional impact:** Subregional strategies should be defined so the minimum burden of research is able to provide comprehensive evidence for all countries. Countries should not feel obligated to do all analyses for all vaccines.
• **Collecting data and conducting analyses:** Countries are collecting the essential national or subregional data to allow for the estimation of disease burden, program costs, and cost-effectiveness analyses using standardized methods.

• **Making evidence-based decisions:** Countries are making decisions considering the different components of the framework for vaccine introduction decision-making.

• **Effectively planning for introduction:** Countries have comprehensive costed plans for new vaccines that incorporates budget impact analysis and financial plan for sustaining funds to support vaccine introduction and its long-term sustainability.

• **Promoting partnerships:** Countries have built durable partnerships with different actors at national, subregional, and international levels to provide ongoing support to countries long after project determination.

It is envisioned that RIVS, a long-term comprehensive plan grounded in the principles outlined above, will prove to be a useful way to serve the countries of Latin America and the Caribbean when addressing the challenges of new vaccine introduction. In this context, it will be important for countries to individually develop their own strategic plans or white papers that will pave the way for informed decisions and actions to sustain gains, complete the unfinished agenda, and meet future challenges.