



XVIII
Meeting of the
Technical Advisory Group
on **Vaccine-preventable Diseases**

Immunization:
Prioritizing Vulnerable Populations

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Immunization: Prioritizing Vulnerable Populations

The XVIII Meeting of the Technical Advisory Group (TAG) on Vaccine-preventable Diseases of the Pan American Health Organization (PAHO) was held from 24-26 August 2009 in San José, Costa Rica. The TAG recognized the substantial progress achieved by Member States since the last meeting in 2006, and the high quality presentations and abstracts at this meeting. The meeting focused on the challenges imposed by the current influenza A(H1N1) pandemic and the next steps to document and verify the elimination of measles, rubella and congenital rubella syndrome in the Americas, while strengthening routine immunization.

Dr. Ciro de Quadros, TAG President, opened the meeting by highlighting the progress achieved by the Americas. At the same time, he recognized the major challenges the Region must still face. Dr. Socorro Gross-Galiano, Assistant Director, PAHO, remarked on the technical strengths of the Expanded Program on Immunization (EPI) and the political support of Member States, who consider immunization as a public good. Dr. Daisy Mafubelu, Assistant Director, Family and Community Health, World Health Organization (WHO), reiterated WHO's commitment to the strengthening of EPI in all WHO Regions. Dr. María Luisa Ávila, Minister of Health, Costa Rica, declared her country's commitment to advancing the EPI in the Region.

Several partners, such as the Centers for Disease Control and Prevention (CDC) of the United States, the Canadian Public Health Association (CPHA), the Global Alliance for Vaccines and Immunization (GAVI), UNICEF, the United States Agency for International Development (USAID), Rotary International, and Sabin Vaccine Institute, reaffirmed their support to PAHO's immunization program and national programs during an Interagency Coordination Committee Meeting.

Gina Tambini, Manager, Family and Community Health, PAHO, reviewed the progress regarding the 2006 TAG recommendations and reiterated PAHO's commitment for implementing immunization activities within the framework of the Health Agenda for the Americas. Referring to the theme of the meeting, *Immunization: Prioritizing Vulnerable Populations*, she remarked that the Regional social and economic conditions must be taken into consideration and primary health care strengthened.

A special event took place during the meeting to celebrate the launching of the books *Images that inspire* and the *Compendium of Measles Articles* and the *Compendium of Rubella and Congenital Rubella Syndrome Articles*. The publications were presented by María Elena Carballo, Minister of Culture, Costa Rica, and Dr. de Quadros, respectively. Dr. Oscar Arias, President of Costa Rica, also attended the event. Dr. Arias highlighted the progress accomplished by the Region and remarked that if health activities need technical expertise they also need political support and commitment from all countries. He emphasized that thanks to the EPI, the PAHO Revolving Fund for Vaccine Procurement, and TAG, the Americas have made considerable progress, within the framework of the right to health and that those three components are essential for the advancement of populations in this Region.

The countries of the Hemisphere, with technical cooperation from PAHO, have made extraordinary advances in public health, providing children with protection against basic vaccine-preventable diseases. The EPI, created in 1977 by resolution of the PAHO Directing Council, laid the foundation for the creation of a program that was technically, financially, and socially sound. National infrastructure and human resource capabilities were extensively buttressed, and the

Revolving Fund for the procurement of vaccines, syringes, and supplies was created. During its 30-year existence, the Fund has been among the most successful of the technical cooperation mechanisms that have permitted equitable access to affordable, quality vaccines in sufficient quantities.

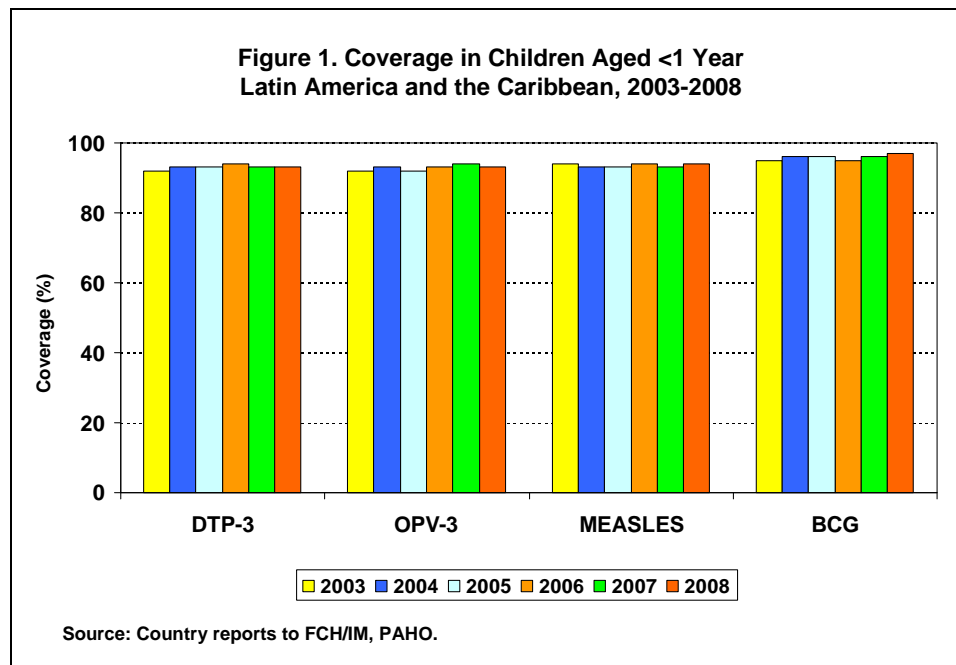
In the Americas, immunization has been responsible for nearly one-quarter of the reduction in mortality in children aged under 5 years between 1990 and 2002, making a significant contribution to the achievement of the Millennium Development Goals (MDGs) and the goal of the WHO's Global Immunization Vision and Strategy (GIVS).

However, the Region still faces substantial epidemiological, demographic, and social challenges. New vaccines and new ways of organizing and delivering services have provided hope for addressing those challenges. PAHO, through the Regional Immunization Vision and Strategy (RIVS), has developed a road map to offer all the Region's inhabitants the opportunity to receive the vaccines capable of protecting them against the greatest possible number of diseases, using an integrated approach in the context of family and community health, and also based on PAHO's principles of equity, quality, universal access, solidarity, and Pan Americanism.

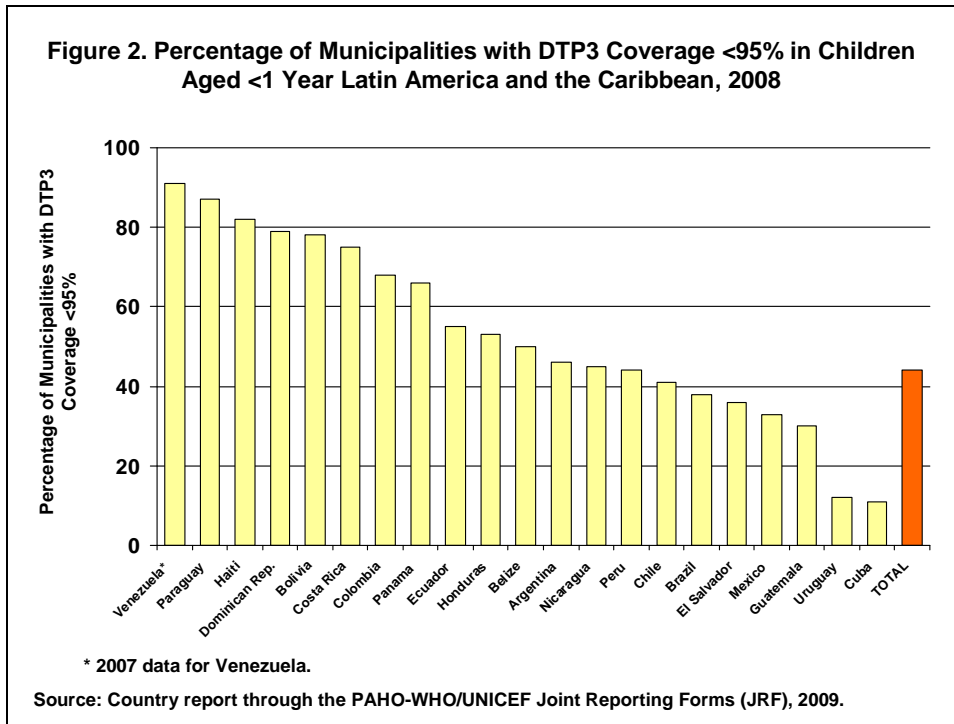
TAG fully endorses the RIVS and the road map.

Routine Immunization

Routine coverage for BCG, DTP-3, and polio-3 in children aged <1 year and measles-containing vaccines in children aged 1 year remains over 90% at the Regional level (Figure 1). Also, all countries in the Region include measles-rubella containing vaccines in their routine immunization schedules. All countries but Haiti are using *Haemophilus influenzae* type b (Hib) and hepatitis B vaccines for infants, and 35 countries and territories were using the seasonal influenza vaccine targeting various groups by 2008.



While the reported coverage at national level is high throughout the Region, heterogeneity in coverage exists at municipal level, with a significant proportion of municipalities reporting coverage <95% (Figure 2).



Given that equity is a key principle of PAHO’s technical cooperation, national immunization programs, with PAHO support, should continue to focus on reaching every family in these low-performing municipalities.

Recommendation:

- TAG reaffirms the recommendation that all countries should achieve $\geq 95\%$ vaccination coverage with all antigens in every municipality.

Pandemic Influenza

Epidemiological Situation

Beginning in mid-March 2009, surveillance systems in Mexico began to report a sharp increase in cases of acute respiratory disease, characterized by cases of influenza, accompanied by severe pneumonia. This increase began when cases of seasonal influenza typically started to wane. The number of cases continued to increase during the first weeks of April when a new influenza A strain (H1N1) was identified. During the same time period, the United States and Canada also began to report confirmed cases of influenza A(H1N1).

Given the emergence of the new influenza strain and its subsequent global spread, WHO moved through the pandemic phases, declaring pandemic phase six on 11 June 2009. As of 6 August 2009, a total of 174,913 cases of influenza A(H1N1) had been recorded, including 1,411 deaths, in 166 countries and territories, the West Bank, and Gaza Strip. Previously healthy young adults have been a particularly affected population group. The majority of influenza A(H1N1) cases have presented with mild symptoms, including cough, fever, sore throat, malaise, and headache; gastrointestinal symptoms have also been observed. Severe illness has been characterized by pneumonia and respiratory insufficiency, whereas bacterial co-infection has been infrequent. Risk factors for severe illness are emerging and appear to include pregnancy, heart disease, diabetes, asthma, pulmonary emphysema, immunodeficiency, and obesity.

Status of Vaccine

Current WHO estimates calculate the optimal global production capacity of a novel monovalent influenza A(H1N1) vaccine at 94 million doses per week, assuming vaccine yield is equal to seasonal influenza and that dose-sparing techniques are employed. Using this baseline, WHO estimates that 2.4 billion doses of influenza A(H1N1) vaccine could be available in 6 months and 4.9 billion doses available after 1 year of production. However, due to multiple pre-existing advanced purchase agreements, large quantities of these vaccines have already been committed, severely limiting supply to the majority of countries in the Americas.

A number of uncertainties exist, including the number of vaccine doses that will be necessary to achieve a sufficient immune response, whether simultaneous administration of the influenza A(H1N1) vaccine and the seasonal influenza vaccine will be possible, and whether or not adjuvant technology will be employed. Adjuvants represent a key dose-sparing strategy but experience with their use is limited in the Americas. Manufacturers' decisions regarding the final presentation and packaging of the vaccine are also not yet known. Many of the uncertainties will be resolved with the results of vaccine safety testing and clinical trials. PAHO's Revolving Fund will be a key procurement mechanism during this process to promote equity and access to available doses.

Using traditional egg-based production technology, manufacturers are producing the following pandemic influenza A(H1N1) vaccine formulations: inactivated non-adjuvanted vaccines, inactivated adjuvanted vaccines, and live attenuated vaccines. Concerns exist about the safety and the immunogenicity of these formulations, especially with the use of adjuvanted vaccines for pregnant women. Europe has been using inactivated adjuvanted vaccines for at least two years. To date, their experience suggests no risk to pregnant women being vaccinated with adjuvanted

vaccines. However, no controlled studies have been performed. SAGE¹ recommends that inactivated nonadjuvanted vaccines similar to most seasonal influenza vaccines be considered the preferred option given the extensive safety data on their use in pregnant women. However, if such a product is not available, pregnant women should be vaccinated with another pandemic influenza vaccine available at that time, for example, an adjuvanted inactivated influenza vaccine or a live attenuated influenza vaccine.

PAHO's Regional Plan for Pandemic Vaccination

As part of PAHO's technical cooperation activities with Member States in response to the influenza A(H1N1) pandemic, a Regional Vaccination Plan for Pandemic Vaccination was developed and distributed to Member States in May 2009. Ensuring equitable access to vaccine, the two main objectives of this plan are to (a) strengthen seasonal influenza vaccination in the Region and (b) assist Member States in their preparation for the introduction of influenza A(H1N1) pandemic vaccine.

As of December 2008, 35 Member States and territories administered the seasonal vaccine in the public sector, vaccinating a variety of risk groups, compared to 13 in 2004. Most countries purchase vaccine through PAHO's Revolving Fund. While there is no evidence that seasonal influenza vaccines confer cross protection against influenza A(H1N1), strengthening vaccination with the seasonal vaccine is essential to reduce the seasonal disease burden and to prevent the co-circulation of both seasonal and influenza A(H1N1) strains.

As of 21 August, the majority of country and territories had estimated the need to vaccinate approximately 200 million people. As more information becomes available concerning dose requirements and finalized target groups, this consolidation will need to be revised. Because intense public demand for influenza A(H1N1) vaccine is expected to be coupled with initial vaccine shortages, messages will have to be elaborated carefully to clearly communicate national target groups, in essence suppressing the public turnout for vaccination. This presents a unique communication situation in the Region that will need to be handled carefully.

Considering that influenza A(H1N1) vaccine supply will be limited, countries will need to prioritize risk groups. On 7 July 2009, WHO's Strategic Advisory Group of Experts in Immunization (SAGE) recommended that countries should consider three objectives (and associated population groups) when deciding upon vaccination priorities: protecting essential health infrastructure (vaccinating health care workers), reducing morbidity and mortality (vaccinating individuals with chronic disease), and reducing virus transmission (vaccinating school children). After considering the current context, SAGE recommended the following population groups (edited to reflect age ranges more commonly managed in the Region):

- Health care workers
- Pregnant women
- Population older than 6 months of age with chronic disease
- Healthy young adults aged 19-49 years
- School children aged 5-18 years
- Children aged 6 months to 4 years
- Healthy adults older than 50 years.

¹ SAGE: Strategic Advisory Group of Experts (WHO).

As with all new vaccines, the detection of events supposedly attributable to vaccine or immunization (ESAVIs) will be essential. The main objectives of ESAVI surveillance are:

- Detection of triggers and known events from previous use of pandemic vaccines and events possibly associated with adjuvants.
- Rapid, transparent, and efficient communication of investigation results to the public and parents.

Neurological ESAVIs are one specific concern. Guillain–Barré Syndrome (GBS) is a rare condition with an annual incidence of 10–20 cases per one million adult population and has been associated with many respiratory and gastrointestinal illnesses. During the swine influenza vaccination campaigns of 1976 in the United States, the increase in the GBS cases above the background rate was approximately one case per 100,000 persons vaccinated. Through the surveillance of acute flaccid paralysis (AFP) from 2000-2008 in the Americas, approximately 10,500 GBS cases were diagnosed, resulting in an average incidence of 0.82/100,000 aged less than 15 years.

Protocols to evaluate the impact of influenza A(H1N1) vaccine in the Region of the Americas will be developed and implemented through the ProVac initiative, once the vaccine is introduced.

Recommendations:

Considering the current dynamic epidemiological situation of the influenza A(H1N1) virus and the current SAGE recommendations concerning the use of an influenza A(H1N1) vaccine, TAG makes the following recommendations, which may need to be updated based upon evolving information.

- The national objectives for vaccination against pandemic influenza should be to reduce morbidity and mortality and keep health services functioning. Therefore, priority groups for vaccination should be health care workers, pregnant women, and persons aged >6 months with chronic diseases (heart disease, diabetes, respiratory conditions, immunodeficiency, obesity). Depending on the epidemiological situation, availability of resources, and EPI capacity, TAG suggests the following additional risk groups to be prioritized: children aged 6 months to 4 years, healthy children aged 5-18 years, and healthy adults aged 19-49 years.
- Due to the annual high morbidity and mortality caused by seasonal influenza viruses, vaccination with the seasonal vaccine should be continued. Technical recommendations regarding the simultaneous administration of both influenza vaccines should be followed, when applicable. Continued epidemiological monitoring of the circulating influenza strains should be continued to inform decisions regarding the future composition of influenza vaccines.
- Countries should conduct retrospective studies to calculate baseline rates of GBS in different populations so that potential changes in the incidence of GBS associated with influenza A(H1N1) virus circulation, and potentially with influenza A(H1N1) vaccines can be detected.
- Countries should monitor the following events during the introduction of the vaccine: (1) serious events (require hospitalization, life-threatening, cause disability, fatal), (2) new events, (3) rumors, (4) events that occur in groups of people, and (5) programmatic errors.
- Countries should prepare social communication strategies to:
 - Maintain public trust by informing in a clear and transparent fashion;

- Ensure that individuals and their families are using mitigating interventions for prevention;
 - Ensure that the public fully understands the recommendations and the reasons for vaccination of priority groups; and
 - Understand the general benefits and risks of events associated with vaccination when they occur.
- PAHO and WHO should continue to strengthen and prioritize the global regulatory network and national regulatory bodies that comply with WHO policy.
 - In unique emergency situations, TAG endorses the SAGE recommendation which allows for countries to buy unlicensed vaccine. In these situations TAG also recommends that national regulatory authorities fast track their licensing procedures.
 - In order to ensure comparability, countries should follow PAHO/WHO guidelines to strengthen and standardize surveillance systems.
 - Ministries of Health should continue strengthening national influenza centers and influenza laboratories by allocating more resources.
 - Countries should conduct retrospective hospital-based studies to more accurately determine morbidity and mortality of influenza A(H1N1).
 - To promote dose-sparing and ensure equitable access to the limited pandemic vaccine supply, adjuvanted vaccine should be used whenever possible.
 - Industrialized countries in the Region of the Americas with abundant pandemic vaccine access are encouraged to contribute vaccine supplies to countries with considerable less access. To do this, they should consider limiting their vaccine interventions to priority groups, as seconded by SAGE and TAG.
 - Recognizing that Brazil and Mexico are embarking on influenza vaccine production, TAG encourages PAHO to develop a Regional strategic plan that will ultimately lead to Regional vaccine self-sufficiency.
 - PAHO should revitalize the supply chain alliance that in the past successfully identified unused oversupply of vaccine in some countries that could be used in other resource-poor countries.
 - To assure equitable access to an influenza A(H1N1) vaccine, countries should use the PAHO Revolving Fund for Vaccine Procurement to buy vaccine.

Rubella, Congenital Rubella Syndrome, and Measles

Rubella and Congenital Rubella Syndrome

Through the implementation of PAHO's recommended elimination strategies by the countries of the Region between 1998-2008, nearly 440 million people-children, adolescents, and adults-have been vaccinated mainly with the measles-rubella (MR) containing vaccine during *catch-up* (140 million), *follow-up* (50 million) and *speed-up* campaigns (250 million), or the vaccination of adolescent and adult men and women to rapidly interrupt virus circulation. As a result, routine vaccination has also been strengthened.

The Region of the Americas has made extraordinary progress in rubella and CRS elimination, with an estimated 112,500 CRS cases prevented in Latin American and the Caribbean over a fifteen-year period. Endemic virus circulation has been limited to only one country (Argentina). The last confirmed indigenous rubella case was reported in epidemiological week 4 of 2009. Canada and the United States have reported 3 and 4 import-associated rubella cases (genotype 2B in the United States), respectively. In 2008-2009, the Americas reported a total of 39 CRS cases in Argentina (n=3), Brazil (n=33), Chile (n=2) and the United States (n=1).²

Despite limited molecular epidemiology information, the wild-type rubella virus genotype 1C has been identified as endemic in the Americas since it has frequently been found in the Region, without having been identified in other regions of the world. The last occurrence of 1C virus transmission was identified in 2005 in Chile and Peru. In 2006, the genotype 2B was introduced in the Region through an importation to Brazil that spread to Chile and Argentina. Genotype 2B is now considered endemic in the Americas.

Taking into account the seasonal pattern of rubella and the fact that CRS cases can excrete virus for up to 12 months, it is essential that countries that reported the last rubella and CRS cases intensify surveillance and monitor virus excretion from CRS cases until two viral negative cultures are obtained to verify the interruption of endemic virus circulation in the continent.

Measles

In November 2002, D9 virus transmission was interrupted. The last measles case associated with that outbreak occurred in Carabobo, Venezuela. Since 2003, imported and import-associated measles cases have been reported in historically low numbers in the Americas: 119 in 2003, 108 in 2004, 85 in 2005, 237 in 2006, 167 in 2007, 207 in 2008,³ and 81 in 2009.³ In the period 2008-2009, 199 secondary cases resulted from a total of 69 importations, while for 24 cases the source was unknown.⁴ Measles cases reported in the Americas have been isolated and/or sporadic and outbreaks have resulted in a limited number of cases secondary to importation, with outbreak size ranging from 1 to 52 secondary cases in Canada and the United States, respectively, and from 1 to 2 secondary cases in Latin America and the Caribbean. Sixty percent of measles importations to the Americas for the same period have come from Europe; these outbreaks occurred in Argentina, Canada, Chile, Ecuador, Jamaica, Peru, and the United States.

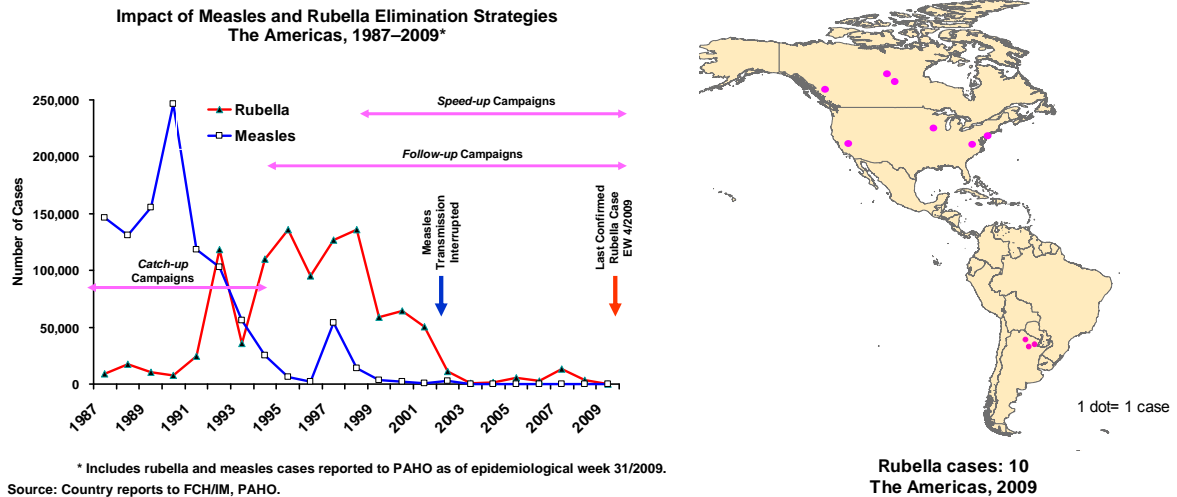
² Data until epidemiological week 31/2009.

³ Preliminary data.

⁴ Data until epidemiological week 31/2009.

It is estimated that the PAHO elimination strategies will prevent a total of 3.3 million measles cases and 16,000 deaths in the period 2000-2020 (Figure 3).

Figure 3. Impact of Measles and Rubella Elimination Strategies, The Americas, 1987-2009*



Process for Documenting and Verifying Measles and Rubella Elimination

Following the interruption of indigenous measles virus circulation in 2002 in the Americas and in light of the achievements in the implementation of immunization strategies and the accelerated reduction in the number of rubella cases, Resolution CSP27.R2 was adopted during the 27th Pan American Sanitary Conference in October 2007. The resolution authorized the formation of an international Expert Committee and urged PAHO Member States to establish national commissions to document and verify elimination in each country of the Region. This decision marked the beginning of the process for the documentation and verification of the interruption of endemic measles and rubella transmission in the Americas.

Recommendations:

TAG congratulates Member States and their health workers for the tremendous efforts made toward achieving and maintaining measles, rubella, and CRS elimination and for the rapid response to importations to the Americas. TAG also urges other regions to eliminate measles and rubella as a step towards eradication.

In addition to the following recommendations, TAG encourages countries to continue to adhere to previous TAG recommendations regarding measles, rubella, and CRS surveillance, vaccination strategies, and laboratory issues.

Immunization Strategies

- Countries should routinely maintain high, homogenous coverage (>95%) by municipality through the administration of the 1st routine dose, monitor the accumulation of susceptibles, and continue the implementation of high quality nationwide *follow-up* campaigns to ensure the vaccination of the entire cohort as a second opportunity to give the first dose to those children that were missed by the routine program.
- In accordance with previous TAG recommendations, any resident of the Americas traveling to areas with reported measles or rubella cases should be immune to measles and rubella and provide proof of vaccination before departure.
- Only where coverage $\geq 95\%$ with each of the two routine MMR doses is guaranteed for all municipalities can the *follow-up* campaigns be waived and, before introduction of routine MMR2, countries should determine a suitable age for administration of this dose, define an accurate denominator, implement a nominal registry, monitor coverage, and track defaulters.

Surveillance

- Countries should achieve an adequate level of preparedness by developing national plans for preparation and rapid response to an importation and potential outbreaks.
- Countries should actively involve the private sector in measles, rubella, and CRS surveillance to support the rapid detection of importations and response to outbreaks and to strengthen immunization activities.
- Countries should guarantee the full integration of measles and rubella surveillance systems and ensure the completion and continuous monitoring of the recommended standardized measles/rubella surveillance indicators to attain high-quality surveillance, emphasizing high-risk and “silent” areas.
- Countries that have reported the last rubella and CRS cases should implement activities, such as active case searches and monitoring of virus excretion of identified CRS cases, in order to document and verify the interruption of endemic virus transmission.
- TAG reiterates the previous recommendation to increase sensitivity and quality of the CRS surveillance system by strengthening sentinel site reporting.

Laboratory

Documentation that elimination of measles and rubella has been achieved requires that each national laboratory produces the highest quality surveillance data possible. The final report and recommendations of the Measles/Rubella Laboratory Network Meeting are endorsed by TAG.

- Laboratories must be fully certified according to the current WHO and PAHO LabNet standards.
- Countries should establish priorities for obtaining viral samples with emphasis on, for example, border areas, industrial areas, areas with frequent foreign travel, and contacts with a high likelihood of exposure.
- Laboratory and epidemiologic teams from each country should use the specific PAHO laboratory testing guidelines for classification of sporadic measles and rubella cases according to their needs.
- Measles, rubella, and CRS cases should be classified only after the laboratory and epidemiologic teams have reviewed all laboratory results and epidemiologic data.

- Laboratories should attempt to establish a genetic baseline of rubella and measles viruses through characterization of endemic cases or archival samples (serum, oral fluid, nasopharyngeal swab, and tissue), starting with the year 2000.
- Laboratories/countries should establish the means to support CRS case confirmation and monitoring of virus shedding by CRS cases.

Regional Plan of Action for Documenting and Verifying Elimination

TAG endorses the regional plan of action for the documentation and verification of measles, rubella, and CRS elimination in the Region of the Americas. The plan of action provides an opportunity to place immunization programs as a high-ranking priority on the political agenda of countries and strengthen vaccination activities and surveillance systems.

- In accordance with PAHO Resolution CSP27.R2, countries should establish a national commission and develop a plan of action for the documentation and verification of measles, rubella, and CRS elimination, which includes a realistic timetable for goal completion.
- Countries should complete the analysis and evaluation of the following key components of the documentation process as described in the regional plan of action:
 - Analysis of coverage with the measles-rubella vaccine in population cohorts aged <40 years.
 - Epidemiology of measles, rubella, and CRS and the impact of vaccination strategies.
 - Quality and efficiency of integrated measles, rubella, and CRS surveillance.
 - Analysis of virologic epidemiology and verification of the absence of endemic measles and rubella virus strains (through viral detection) in all countries of the Americas.
 - Sustainability of national immunization programs to maintain measles and rubella elimination.
- Countries should prepare and implement a national plan of action for the verification of measles, rubella, and CRS elimination, with technical cooperation from PAHO and the international Expert Committee.

Poliomyelitis and Containment of Wild Poliovirus in Laboratories

The Western Hemisphere was certified as free of the circulation of the indigenous wild poliovirus in 1994 and the last case of poliomyelitis caused by a wild poliovirus was detected in Peru in 1991.

In 1998, resolution WHA41.28 of the World Health Assembly established the goal of global eradication of poliomyelitis. However, by the end of 2008 poliomyelitis was still circulating in 18 countries of Asia and Africa. It is a matter of concern that 12 of these countries have become reinfected since mid-2008, demonstrating that international spread of poliovirus is continuing, and that unless the Americas maintain a high level of immunity, they could be vulnerable to reintroduction of the virus.

In the American Region, the vaccine-derived outbreak of polio in 2000-2001 in the Dominican Republic and Haiti highlighted the risk of low OPV coverage in countries and municipalities, and the risk of failing to detect the circulation of poliovirus in a timely manner in a country or Region that has remained free of its circulation for a long time.

TAG supports the need to minimize the potential for reintroduction of wild polioviruses into communities through containment of poliovirus strains in the laboratories. Most countries of the Region of the Americas have concluded Phase 1 of the Plan of Action for Containment, corresponding to the conduction of a survey and the elaboration of a national inventory of laboratories that may have stored wild poliovirus or potential infectious material. TAG received a report on containment and notes the progress that has been made in containment activities in the Region and looks forward to the final report that the Regional Commission on Containment will send to the Global Commission.

Acute flaccid paralysis (AFP) surveillance remains in place in the American Region and the polio laboratory network continues to conduct timely analysis of specimens of AFP cases.

As long as global eradication and containment in the laboratories are not achieved, the risk of reintroduction of wild polio virus into the American Region remains a real threat.

Recommendations:

- While there is poliovirus circulating in the world and the danger of importations continues, TAG recommends that the vaccine of choice remain OPV as stated in previous TAG reports and as recommended by WHO. This recommendation will continue to be reviewed as the global situation evolves.
- To reduce the risk of importations and to prevent another outbreak caused by a Sabin-derived poliovirus, countries that do not achieve OPV coverage $\geq 95\%$ in every municipality should conduct annual OPV immunization campaigns for children aged <5 years, regardless of their vaccination status.
- Countries should maintain certification standards of AFP surveillance (compliance with surveillance indicators).

- To prevent reintroduction of wild poliovirus into their communities, all American countries should conclude phase I of wild poliovirus containment in the laboratories as requested by the Regional Commission on Containment.

Polio Laboratory Network

Considering that poliovirus is still endemic in other regions, the polio laboratory network in the Americas must continue to be fully functional, providing fast and quality results critical for monitoring and verifying virus circulation in the Region. Rapid detection and reporting of wild and vaccine-derived polioviruses are essential to facilitate early implementation of public health interventions to minimize virus spread.

In this context, a new test algorithm was designed to reduce the time for laboratory results and to increase the sensitivity of poliovirus detection. In the Americas the average time for completing laboratory procedures was 42 days. The new algorithm will allow for a 50% reduction of the overall laboratory target test time from the current 42 days to a maximum of 21 days. The current data management system and reporting of PESS⁵ results should be reviewed to include the new timeliness indicator for polio laboratory results.

Recommendations:

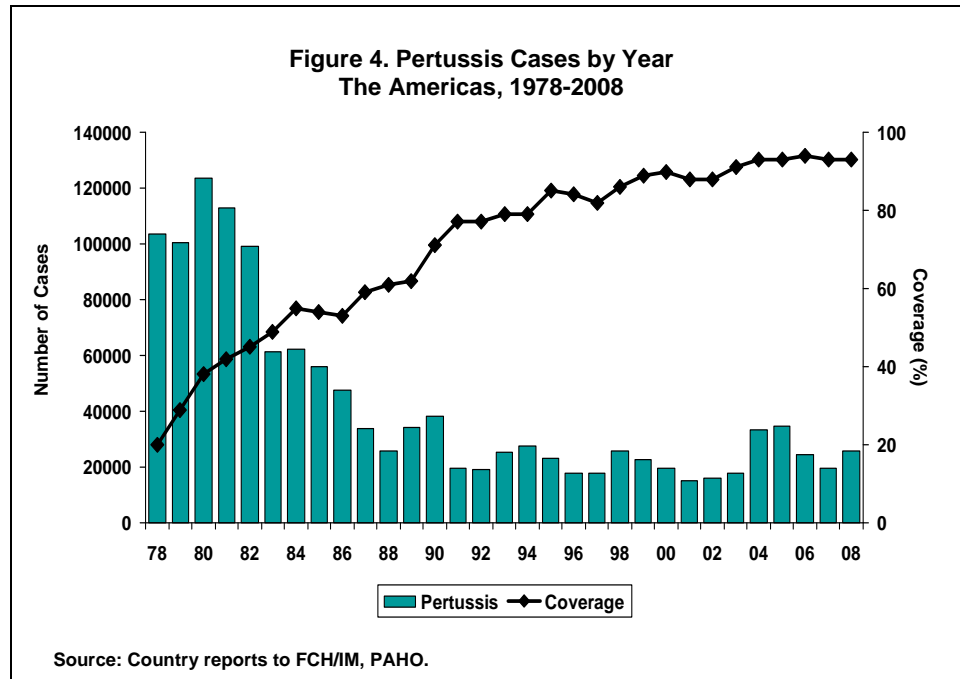
- The laboratory network should have implemented by October 2009 the new test algorithm for cell culture and intratypic differentiation (ITD) with current updates to provide faster results. Resource mobilization may be required for implementation in some settings.
- The data management systems (PESS or ISIS⁶) should accommodate the changes in reporting to reflect the new algorithm and the surveillance indicator for laboratory of up to 14 days for cell culture results and up to 21 days for polio and non-polio positive specimens.
- The network laboratories should ensure that all poliovirus isolates are appropriately screened for the presence of vaccine-derived poliovirus (VDPVs); detection should be conducted by screening with genetic ITD test followed by analysis of the complete sequence of the VP1 poliovirus protein.
- All network laboratories should continue to implement Quality Assurance processes, including preparation, use, and periodic update of Standard Operating Procedures and ensure compliance.

⁵ Poliomyelitis Elimination Surveillance System.

⁶ Integrated Surveillance Information System.

Pertussis

Pertussis, or whooping cough, is one of the diseases that generally receives little attention in the global public health context and yet warrants study, given its potential for outbreaks when coverage with the diphtheria-tetanus-pertussis vaccine (DTP) is low. In the past 10 years, the total annual number of reported cases in the Americas has ranged from 20,000 to 30,000, and vaccination coverage with the third dose of DTP by one year of age has been over 85% (Figure 4). The proportion of Latin American districts (or municipalities) with DTP3 coverage in children aged <1 year is ~ 40%.



In October 2007, the Pan American Health Organization (PAHO) convened a meeting of experts to discuss the suggestion that TAG modify its current recommendations on pertussis surveillance and prevention. This group emphasized the need for a strengthened surveillance system with laboratory confirmation. The group also concluded the following:

- To prevent countries from making wrong policy decisions based on erroneous surveillance data, additional effort to enhance surveillance is essential in the Region.
- There is no reason for countries to change from vaccines containing whole cell pertussis (wP) to vaccines containing acellular pertussis (aP).

Pertussis surveillance is a significant challenge due to the difficult clinical and laboratory diagnoses, the lack of a clear case definition for newborns and adults, and the use of different case classification definitions in most countries.

TAG considers that the epidemiology of pertussis must be properly studied in Latin America to guide the decision-making process, and that PAHO must support countries in this initiative. In that respect, TAG welcomes the joint CDC/Sabin Vaccine Institute/PAHO project aimed at strengthening the surveillance system in 3 countries in the American Region as a way of creating evidence that can facilitate the decision-making process in pertussis control.

Recommendations:

- Countries must consider pertussis control as a priority and strengthen their surveillance system and control measures.
- Changes in immunization policies and control measures should only be justified with adequate documentation and analysis of the basic causes of outbreaks.
- Before shifting from the whole-cell vaccine (wP) to the acellular vaccine (aP), countries should take into consideration the impact of the change on the immunization schedule, delivery issues, and affordability.
- Since adding boosters to the primary three-dose schedule will extend the duration of the immunity, countries should apply a 4th DTP dose as part of the regular vaccination schedule. The coverage of the 4th DTP dose must be monitored and must become part of the reporting system.
- During outbreaks, immunization of newborns can begin at 6 weeks of age, especially if that age group is being affected. Death prevention in neonates will rest in community awareness and medical protocols. The importance of obtaining specimens for culture, especially in neonates, should be underscored.
- The current emphasis on PCR for pertussis diagnostics in the field makes obtaining a culture appear to be less important. However, since PCR can result in false positives, it should be stressed that obtaining specimens for culture is still essential for confirming the diagnosis, especially in neonates.

Yellow Fever

Yellow fever is a zoonosis found in extensive areas of subtropical and tropical Africa and the Americas. In the past 30 years, yellow fever virus activity in the Americas was confined to the enzootic area shared by Bolivia, Brazil, Colombia, Ecuador, French Guiana, Guyana, Panama, Peru, Suriname, Trinidad and Tobago, and Venezuela; however, since late 2007, the Region has witnessed intense circulation of the yellow fever virus, with extensive epizootics and outbreaks of human cases, expanding the enzootic area to Paraguay and northern Argentina.

From 1960 to 2008, a total of 6,696 confirmed yellow fever cases were reported to PAHO from 13 countries of the Region of the Americas. Since 2000, detailed surveillance data have been available. From 2000 to 2008, a total of 1,009 confirmed yellow fever cases were reported to PAHO, with a case-fatality rate of 51.5%. The greatest number of cases was reported by Peru (345), followed by Brazil (274), Colombia (202), Bolivia (85), Venezuela (63), Paraguay (28), Argentina (10), and Ecuador (2). Some 82.6% of the cases were male. Of the cases with a known occupation, 54.5% were agricultural workers and 4.6% ecotourists. Approximately 6.1% of the cases reported having been vaccinated against yellow fever, although the time between the vaccination and symptom onset is unknown. With the exception of the event that occurred in Asunción, Paraguay, in 2008, all cases reported since 2000 were jungle yellow fever.

In late 2007, Paraguay reported its first yellow fever case in 34 years, as part of a large epizootic wave which began in Brazil. The first case in Paraguay was reported from the north of the country; the disease subsequently spread southward, with 28 confirmed yellow fever cases, including a cluster of 9 cases of urban transmission of yellow fever detected in the metropolitan area of Asunción. Prior to this, the last confirmed outbreak of urban yellow fever in the Americas had been in Brazil in 1942. In Argentina, epizootics and monkey deaths were reported from the Misiones and Corrientes Provinces in January 2008. An outbreak of eight yellow fever cases in humans was reported from the Misiones Province in February. Prior to this outbreak, Argentina had not reported any human cases of yellow fever in 40 years.

Yellow Fever Vaccination

Yellow fever can be prevented with live attenuated yellow fever vaccine 17D. Over 500 million doses have been administered worldwide since its development in 1937. The yellow fever vaccine has been considered safe and effective.

Until 2008, 9 of the 13 countries with enzootic areas (Bolivia, Colombia, Ecuador, French Guiana, Guyana, Paraguay, Peru, Trinidad and Tobago, and Venezuela) had introduced the vaccine as part of their routine vaccination programs for children, attaining coverage of approximately 73%.

Mass vaccination activities vary from country to country, from reactive campaigns to control outbreaks to preventive campaigns conducted in stages, targeting the resident population in enzootic areas, border areas, and areas where migration originates. Peru vaccinated over 10 million people in the period 2004-2007; Brazil, 90 million over the past 10 years; and Bolivia conducted a national campaign, vaccinating approximately 5 million people in 2007. In response to the 2008 outbreaks, Brazil administered over 18 million doses; Argentina, 1.5 million; and Paraguay over 3.5 million. Concerning ESAVIs, in 2007, Peru reported a cluster of 5 cases of

viscerotropic disease, and in 2008, Brazil reported 6 cases, Argentina 1 case, and Paraguay 1 case.

TAG acknowledges the progress countries have made in vaccinating populations in enzootic areas through the implementation of plans for yellow fever control and the inclusion of the yellow fever vaccine in the routine schedule in most countries. However, the recent yellow fever dynamic observed makes it necessary to reassess the risk areas, considering the changing ecological and environmental conditions that favor yellow fever transmission. This will permit better definition of the areas and populations to vaccinate.

Recommendations:

- Countries with enzootic areas should consider completing their plans for yellow fever control vaccinating all residents in these areas aged >1 year. Travelers to these enzootic areas should also be vaccinated.
- Countries should assess vaccination coverage through rapid monitoring or other methodologies to ensure that the entire population living in risk areas is vaccinated.
- The four remaining countries with enzootic areas that have not yet introduced the yellow fever vaccine in their routine program should target children aged one year in order to have protected cohorts in the long term. Vaccination coverage should be maintained at over 95% in routine vaccination programs for the first year of life.
- Epidemiological information and careful yellow fever risk assessment, considering ecological, environmental, and cultural factors that favor disease transmission, should guide vaccination activities. Therefore it is important that countries maintain and improve their epidemiological surveillance systems.
- Countries should ensure the quality and sensitivity of the epidemiological surveillance system for yellow fever, including surveillance of icterohaemorrhagic febrile illnesses, epizootics, vaccination coverage, and adverse events associated with yellow fever vaccination. In non-enzootic areas of these countries, the sensitivity of the surveillance system should be increased and outbreak control measures strengthened. It is recommended that countries have a national stock of vaccines.
- In light of outbreaks in Brazil, Paraguay, and Argentina in 2008, Regional and Global Emergency vaccine supplies were consumed in their entirety in January and February 2008. Given the limited availability of yellow fever vaccines, priority should be given to primary vaccination and re-vaccination should be avoided.
- Given the current risk of the reurbanization of yellow fever in the Region, a comprehensive approach should be adopted that highlights vector control of *Aedes aegypti* in urban centers bordering enzootic areas. Elimination of breeding sites should be undertaken and, insofar as possible, environmental conditions should be improved so that they don't foster mosquito reproduction.
- Countries should have a risk communication plan in order to avoid crisis situations due to yellow fever outbreaks and ESAVIs related to the vaccine.
- Countries should consider adequate screening mechanisms to identify vaccine contraindications and precautions before vaccination.

Rotavirus and Pneumococcus

Rotavirus

Rotavirus infection is the most common cause of diarrhea in children aged <5 years worldwide. It is responsible for some 600,000 deaths annually and approximately 40% of hospitalizations due to diarrhea in children in that age group. According to the available data, each year around 75,000 hospitalizations and nearly 15,000 deaths in the Region of the Americas are attributable to rotavirus. While the incidence of rotavirus infection in developed and developing countries is similar, 80% of deaths occur in developing countries.

Since 2004, the Regional Office has been working with Member States in the Region of the Americas to implement hospital sentinel surveillance of rotavirus diarrheal disease, using case definitions, laboratory diagnosis, and analyses of standardized data. Thirteen countries in the Region now have sentinel surveillance and systematically send reports to PAHO. In 2008, only Bolivia, Chile, Ecuador, El Salvador, Guatemala, Honduras, and Nicaragua reported their data. A total of 149,853 hospitalizations of children aged <5 years were reviewed in these countries; of these cases, 14% (20,863) had been admitted for diarrhea and of these, 57% (11,904) were classified as suspect rotavirus infection. Of the investigated cases with stool samples, 28% tested positive for rotavirus. Guyana, St. Vincent and the Grenadines, and Suriname have discontinued reporting data to PAHO since 2008. The data produced by this reporting network are currently being fed into a global database for the consolidation of information.

Two rotavirus vaccines are available on the market and prequalified by WHO. Since 2006, 14 countries and one territory have introduced this vaccine in their national vaccination schedule: in 2006, Brazil, El Salvador, Mexico, Panama, Nicaragua, the United States, and Venezuela; in 2007, Ecuador; in 2008, Bolivia; in 2009, Colombia, Guyana, Honduras, Peru, and the British territory of Cayman Islands. The countries of the Region of the Americas were the first to introduce this vaccine into their vaccination programs, and for the first time ever, a new vaccine is being introduced in developing and developed countries at the same time.

Many lessons were learned from the introduction of the rotavirus vaccine in the Region of the Americas: for example, the need for adequate evaluation of the cold chain and the logistics of the immunization program prior to introducing a new vaccine, the need for training at all levels, the importance of strengthening the network for ESAVI reporting and investigating, the importance of ensuring the sustainability of the EPI vaccine in the national budget, and the establishment of rotavirus diarrhea surveillance prior to the introduction of the vaccine and the subsequent maintenance of that surveillance as fundamental to decision-making.

Another lesson learned was the importance of having the countries conduct special studies on cost-effectiveness, effectiveness, and safety when introducing a new vaccine for which there is no precedent of use in developing countries. Efficacy studies for the rotavirus vaccine are being conducted in two countries in the Region (Nicaragua and El Salvador), along with a safety study in Brazil and Mexico. The studies are contributing new knowledge about the large-scale use of the vaccine in immunization programs.

An international network for the reporting and investigation of ESAVIs linked with the rotavirus vaccine (SANEVA) has been set up, whose main objective is to determine whether there is an association between the rotavirus vaccine and intussusception. To date, the available information

from this passive surveillance network has not revealed any association between the vaccine and intussusception.

Pneumococcus

Pneumococcal disease causes an estimated 1.3 million cases of acute otitis media, 327,000 cases of pneumonia, 1,229 cases of sepsis, and 4,000 cases of meningitis annually in children aged <5 years in Latin America and the Caribbean.

In the Region of the Americas, support is being provided for an epidemiological surveillance network for pneumonia and bacterial meningitis cases in children aged <5 years in sentinel hospitals to support the information obtained through laboratory testing of samples in the SIREVA II network. Seven countries (Bolivia, Ecuador, El Salvador, Guatemala, Honduras, Panama, and Paraguay) conduct epidemiological surveillance of pneumonia and bacterial meningitis. Brazil only reports data on hospitalized cases of bacterial meningitis. In 2008, 8,829 suspect pneumonia cases were hospitalized, 79% of them with a chest x-ray, and classified as probable bacterial pneumonia, with a case-fatality of 5%.

Two conjugate pneumococcal vaccines are currently on the market: the heptavalent and the decavalent. The heptavalent vaccine is recommended by WHO, and the decavalent vaccine is in the prequalification process. The United States (2001), Canada (2002), Bermuda (2008), Mexico (2008), Uruguay (2008), Costa Rica (2009), and Peru (2009) have introduced this vaccine in their vaccination schedule for children aged <1 year. A 13-valent vaccine was recently licensed in some countries.

Recommendations:

- Countries should improve or begin sentinel surveillance of rotavirus diarrhea, pneumonia, and bacterial meningitis in children aged <5 years, so that the impact of vaccine introduction can be adequately assessed and the prevalence of circulating strains and changes in the epidemiological profile of the disease monitored.
- All countries should systematically report their surveillance data for rotavirus diarrhea, pneumonia, and bacterial meningitis to facilitate the development of an epidemiological profile for the diseases in the Region, compare the profiles of different countries, geographical areas, and seasonality, and evaluate the epidemiological changes in these diseases that could occur with the introduction of the vaccine.
- Before introducing any new vaccine, countries should develop a plan of action, based on PAHO guidelines, that includes basic activities such as the evaluation of the cold chain at all levels, logistics, training, and strengthening of the ESAVI network.
- PAHO should continue to support the countries and encourage them to conduct special studies on the introduction of a new vaccine when necessary.
- Rotavirus and pneumococcus vaccines should be universally introduced in the immunization schedule, using vaccination regimens with evidence of efficacy in developing countries. Introducing those vaccines in priority areas (i.e., only in certain municipalities/towns or provinces) makes it more difficult to assess the impact of the intervention and might create logistical and programming problems for the EPI. Therefore, these vaccines should be

introduced nationwide whenever feasible. If a country can only introduce them to priority groups, this should be done as a first step toward universal introduction.

Human Papillomavirus

In September of 2006, PAHO's Directing Council called for countries to expand fiscal and legal space to allow equitable access to human papillomavirus (HPV) vaccine. These and other Directing Council resolutions leading over the years to the successful eradication of polio and measles are grounded in the guiding principle of reaching the poorest of the poor in our Region. Of the >36,000 cervical cancer deaths occurring annually in the Region, >80% are from developing countries. Perhaps, no other disease exemplifies the existing inequities in health among the global community of women.

Prophylactic HPV vaccines are proven to be immunogenetic, safe, and efficacious. They have the potential to prevent up to 70% of the cervical cancer disease burden. As new data continue to become available from HPV vaccine trials, these data need to be considered for future vaccine policy decisions.

In 2008, PAHO's Directing Council approved the regional plan for integrated prevention and control of cervical cancer. The plan calls for increased action to strengthen programs through an integrated package of services: health information and education, screening and pre-cancer treatment, invasive cancer treatment and palliative care, and evidence-based decisions on whether and how to introduce HPV vaccines. The greatest barriers to providing equity and access to HPV vaccines and new screening technologies for HPV virus detection are the prices of the products.

Recommendations:

- HPV vaccine should be delivered as part of an integrated package including screening, health promotion, pre-cancer and cancer treatment, and palliative care.
- Countries should conduct cost-effectiveness studies to make evidence-based decisions regarding HPV vaccine introduction into the regular program. PAHO should continue to provide technical cooperation to conduct these studies and gather the framework of evidence needed to make informed decisions.
- The PAHO Secretariat should report back to the next TAG on the progress of the implementation of the Regional Plan for integrated prevention and control of cervical cancer, including studies being conducted in Jamaica and elsewhere on disease burden, surveillance implementation, and economic analyses.

Evidence-based Decisions

PAHO's ProVac Initiative is working to enhance national capacity to make informative, evidence-based decisions regarding new vaccine introduction. ProVac's five objectives are as follows:

1. Strengthening infrastructure for decision-making;
2. Developing tools for economic analysis and providing training to national multidisciplinary teams;
3. Collecting data, conducting analysis, and gathering framework of evidence;
4. Advocating for evidence-based decisions; and
5. Effectively planning for vaccine introduction when evidence supports it.

Since its inception in 2004, and subsequent funding in 2008, substantial progress has been made, including:

- Organization of a ProVac Expert Advisory Committee that specifically monitors the technical aspects of project implementation.
- Development of models for economic studies on rotavirus, pneumococcal, HPV, and influenza infections. This work has been strongly supported by a network of scientists based at CDC, Harvard, the London School of Hygiene and Tropical Medicine, New Jersey Medical School, and PAHO.
- Three completed cost-effectiveness studies on pneumococcal vaccine introduction (2008 in Paraguay, Ecuador, and Honduras).
- Regional workshops on pneumococcal and HPV disease economic studies (Paraguay on pneumococcus in Dec 2008) and (Jamaica on HPV in July 2009).

The next year's work plan of the Initiative includes the following tasks:

- Complete modifications of the pneumococcal model.
- Hold the first meeting of Economic Centers of Excellence.
- Continue to develop the OLIVES⁷ on-line database of the ProVac website which will serve as a repository of data for developing country use when conducting economic analyses.
- Strengthen influenza tools to provide an opportunity for countries to evaluate the impact of pandemic vaccine.
- Strengthen disease e-learning tools for evidence-based decision making.
- Conduct country-specific economic studies in Jamaica, Trinidad & Tobago, and Honduras on HPV vaccination program costs.
- Convene first meeting of an ad-hoc scientific panel of experts to review the scientific basis of the economic tools being developed.

Examples of work were presented from Bolivia and Ecuador. The cost-effectiveness of rotavirus and pneumococcal vaccine introduction, respectively, were analyzed using data on the incidence of the disease, health services utilization and costs, vaccination program costs, and vaccine coverage and efficacy rates. In Bolivia the data were collected from sentinel sites over a one-year

⁷ OLIVES (On-Line International Vaccine Economics and Statistics) is a website presenting country-specific statistical parameters used in economic evaluations, bringing together internationally comparable statistics from a variety of data sources (WHO, UNICEF, UN, Demographic and Health Surveys, World Bank). Available at <http://gcpsys.com/>.

period and were analyzed from the perspective of the health system. Using US \$19 to fully vaccinate a child, they estimated that with rotavirus vaccination the cost of averting a DALY to be \$213. In Ecuador, data were analyzed from the perspective of the society. Using \$79.05 to fully vaccinate a child, Ecuador determined the cost of averting a DALY to be \$2,640.

Recommendations:

TAG fully supports the implementation of the ProVac initiative.

- The ProVac initiative should assist countries with the development of impact studies for influenza and other vaccines and assist them with reporting results at the next TAG.
- ProVac should continue its efforts to standardize approaches, to the extent possible, when conducting economic studies.

Vaccination Week in the Americas

Vaccination Week in the Americas (VWA) has been celebrated seven times in the Region. Originally endorsed in 2003 by PAHO's Directing Council, VWA is an initiative based on the principles of equity, access and Pan Americanism. VWA activities strengthen national immunization programs by targeting populations with otherwise limited access to regular health services, such as those in border and rural areas, urban margins, indigenous communities, and poor performing municipalities. Over its tenure in the Region, VWA has resulted in the vaccination of more than 288 million individuals, the implementation of multiple social communication and awareness campaigns and the integration of other preventative interventions together with immunization.

In recent years, VWA has been granted progressively more political priority. Presidents, ministers of health, Regional Directors of United Nations (UN) agencies, and other international, national, and local leaders have increasingly participated in VWA launching events and activities. This participation has resulted in important media attention being focused on immunization. VWA has also fostered interagency, intersectoral, and inter-programmatic ties, essential components to the success of the initiative. In 2008, a formal statement encouraging UN country team involvement in VWA activities was signed by nine Regional Directors of UN Agencies for Latin America and the Caribbean. On a national level, the implementation of VWA activities has required collaboration to occur between governmental sectors, such as health, labor, and education in many countries, while integrated initiatives with other areas of the health sector, such as occupational health and HIV/AIDS, are also increasing.

Outside of the Americas, the WHO European Region celebrated the fourth annual European Immunization Week (EIW) in 2009, an initiative modeled after the success of the Americas; in 2008 both VWA and EIW received the endorsement of the Director-General of the World Health Organization, Dr. Margaret Chan. This year, a technical immunization meeting was held between Suriname and French Guiana, an overseas department of France, as a means to link these two initiatives and to establish a platform for future collaborative work. In 2010, the Eastern Mediterranean Region is planning to pilot a vaccination week and is collaborating with both PAHO and EURO in the planning process, advancing work towards a Global Vaccination Week in the near future.

Recommendations:

- VWA should continue to be supported as a Regional initiative that targets hard-to-reach populations for vaccination, while helping to highlight the importance of disease prevention and health promotion in public forums and in the media.
- The political commitment given to VWA should be maintained to help ensure that national EPI programs are prioritized.
- Inter-programmatic activities with occupational health, HIV/AIDS, and other areas, integrating other health services and preventative interventions with vaccination should be continued.
- The establishment of vaccination weeks in other WHO Regions should be supported, working towards a global initiative.

Financial Sustainability: The PAHO Revolving Fund for Vaccine Procurement

For thirty years, as part of the Expanded Program on Immunization established in 1977, PAHO has been managing the Revolving Fund for Vaccine Procurement (RF), on behalf of participating countries in the Americas, as a mechanism of cooperation and solidarity offering quality vaccines at accessible prices.

The RF was first formed with 8 participating countries and initially offered 6 antigens. Currently, the RF offers 28 antigens, in addition to syringes, needles, and cold chain equipment. In 2008, 41 countries and territories bought vaccines through the RF for a total amount of US \$271.7 million. Demand forecast for 2009 is approximately \$369.5 million.

By ensuring an interrupted vaccine supply, at stable and accessible prices, the RF has been a critical mechanism supporting the immunization efforts of PAHO Member States. Polio has been eradicated, measles eliminated, and, in so doing, high vaccination coverage rates were obtained, thus providing wide protection for all the children of the Region.

In a large measure, the RF has been a major catalyst for the rapid, equitable, and sustainable introduction of new and underutilized vaccines, including vaccines against measles, mumps and rubella (MMR), yellow fever, hepatitis B, *Haemophilus influenzae* type b (Hib), seasonal influenza, rotavirus, and pneumococcus.

As part of the EPI, the RF not only provides access to vaccines, it also promotes the operational development of immunization programs and research since it benefits the strengthening of epidemiological surveillance systems, laboratory networks, infrastructure, and human resources training.

The RF has also benefited the development of a more structured and reliable vaccine market in the Region. At the same time, as a result of EPI activities, vaccine manufacturers have benefited from stronger epidemiological surveillance systems, ESAVI investigation and follow-up, and operational investigations.

New and more expensive vaccines against priority diseases in the Region (including those against rotavirus, pneumococcus, and HPV) represent significant challenges for countries and the RF. Based on previous successes (with MMR, pentavalent, Hib, and seasonal influenza), the RF is now focusing on providing all individuals at risk in the Region with sustainable access to those new generation vaccines. It is therefore necessary to guarantee the financial capacity of the RF's line of credit in order to respond to the requirements of Member States.

During its 30 years of existence, the RF has faced many challenges and risks. Current challenges include the introduction of new vaccines at high prices and with a single provider, the participation of new actors in the field of immunization, and the development of new market mechanisms. Member States have manifested their desire to see the RF adapt to those new conditions while maintaining the principles of Pan Americanism, equity, solidarity, and universal access.

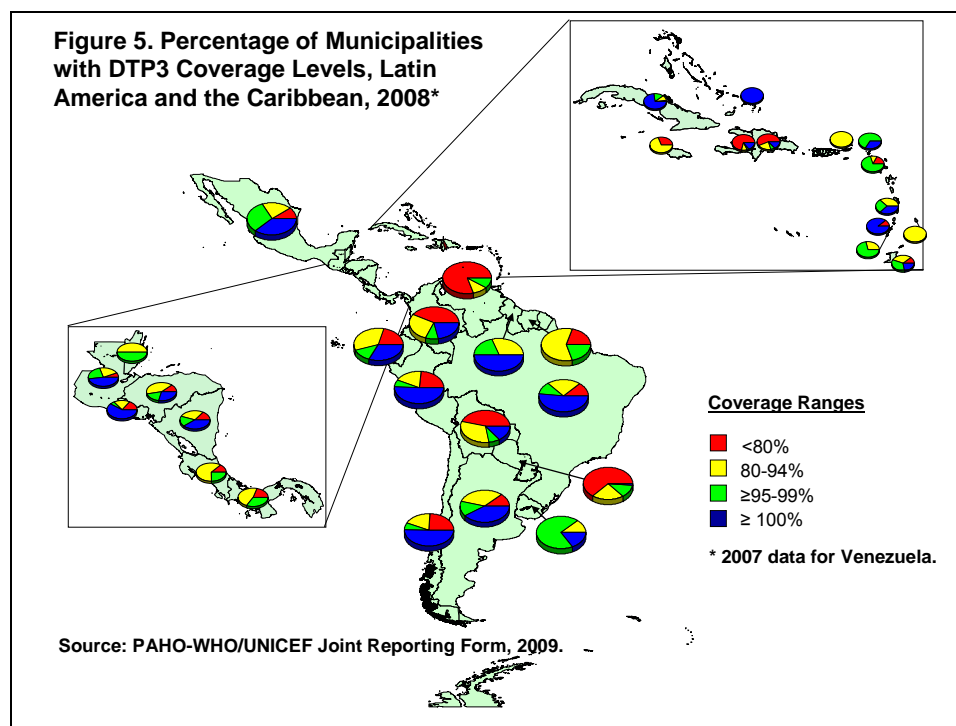
Recommendations:

- TAG recommends the continued and strengthened participation of Member States in the Revolving Fund, in order to benefit from the consolidated purchase of vaccines, syringes, and other supplies, and to maintain the Revolving Fund as a mechanism of collaboration and solidarity.
- PAHO must continue to find ways to increase the level of capitalization of the Revolving Fund in order to maintain the line of credit at levels allowing for an adequate and timely response to the needs of Member States.
- PAHO must work internally with all parties involved in the management of the Revolving Fund in order to improve its operational efficiency.
- In view of current challenges, the PAHO Revolving Fund for vaccine procurement must remain faithful to its principles of Pan Americanism, equity, universal access, and solidarity.

Coverage Data Quality

Immunization coverage levels are a key indicator to measure immunization program performance. Administrative coverage calculation has been the method of choice to assess and monitor vaccination coverage levels in the Americas. It is the most common method used in Latin America and the Caribbean, followed by nominal computerized immunization registries. Canada and the United States rely on periodic coverage surveys.

Quality assessment (numerator and denominator consistency⁸ and accuracy,⁹ and coverage validity¹⁰) of national immunization coverage data for countries with a population >500,000 reported to PAHO continues to identify data inconsistencies in numerators and denominator in several countries. Examining 2002-2008 coverage data for DTP, we identified frequent changes >5% in year-to-year numerators and negative drop-out rates, especially between DTP2 and DTP3. The source of denominators varies between countries, with most (11/19 providing this information) using census projections, followed by number of live births from the previous year, and the nominal immunization registry in the three countries using them. In 17 of 23 countries, the denominators used to calculate coverage changed by >5% between one year and the next at least once; in 7 of them this change was >10%. Nine out of 22 countries reported more doses of BCG than children in their denominator. Denominator problems at sub-national levels seem to be prevalent as approximately 43% of the over 15,000 municipalities in Latin America reported coverage levels $\geq 100\%$ for 2008 (Figure 5).



⁸ Consistency: data are coherent and do not contradict each other.

⁹ Accuracy: refers to whether the data correctly records the event it represents.

¹⁰ Validity: the indicator measures what it intends to measure without systematic bias.

Between 2002 and 2008, we identified 27 surveys (14 Demography and Household Surveys/DHS, 5 Multiple Indicator Cluster Survey/MICS, and 8 others) in 18 countries that examined vaccination coverage. For 19 data was available. Thirteen surveys (in 9 countries) found DTP3 coverage lower than the administrative coverage reported (for 11 of them the difference was $\geq 10\%$); four surveys (in 3 countries) found similar coverage rates; and 2 surveys found higher coverage rates than reported. These differences, generally resulting in lower survey coverage estimates than administrative coverage, may be the result of overestimation of administrative coverage or problems with the survey ascertainment of vaccination, survey precision, or a combination of these factors. Immunization programs are rarely aware of these surveys, in terms of formulation of the immunization questions, the training provided to interviewers on immunization matters, and survey results.

Efforts to improve the accuracy, consistency, completeness, and timeliness of coverage data should be a top priority of every country. Immunization programs should monitor numerator trends by month and year and calculate drop-out rates between 1st, 2nd, and 3rd DTP doses at all levels. Rapid coverage monitoring (RCM), as recommended by PAHO, provides a quick validity check on reported coverage levels and helps direct vaccination activities. Twenty-five countries/territories reported doing RCM in 2008; however, in most cases they are not systematically conducted. TAG has recommended assessing data quality in the context of regular on-going evaluation and supervisory activities. While there are good examples in the Region of including the monitoring of data consistency in the items checked during supervision, most supervisory visits do not include this aspect. Furthermore, only 22 countries reported keeping track of how many municipalities receive supervision in a year. Finally, data quality assessments as stand-alone activities, or more recently as integral part of international EPI evaluations, have provided good insights on problems regarding the data, and most importantly regarding shortcomings in the procedures, forms, data flow, or systems that produce the data. Since 2005, eight countries (Costa Rica, 2005; El Salvador, 2006; Uruguay, 2006; Honduras, 2007; Grenada, 2008; Guatemala, 2008; Guyana, 2008; and Suriname, 2009) have assessed their immunization data with PAHO support and developed plans to improve them, as appropriate. As an interesting example, the immunization program of Honduras, in 2008, received PAHO's support, in the form of a demographer who provided the technical elements for the National Institute of Statistics to request CELADE (the Population Division of the UN Economic Commission for Latin America and the Caribbean –ECLAC) support to review the census projections at sub-national level.

Uruguay (1987), Mexico (1991), and Panama (2007) are using national computerized nominal immunization registries to track the individual vaccination status of each child. These registries facilitate monitoring coverage by birth cohort and following-up children with incomplete vaccination schedules. Honduras is in the process of developing a national immunization registry and Peru has just started the process.

Recommendations:

- TAG reaffirms the recommendation that systematic and periodic assessment of coverage data accuracy, consistency, completeness, and timeliness should become a regular activity within national immunization programs. This assessment should be conducted within the context of regular on-going evaluation and supervisory activities.
- Monitoring numerator trends by month and year and calculating drop-out rates between all doses, including DTP2, and monitoring denominator variations should be done systematically at all levels.

- Immunization programs should be aware of the conduction of surveys that, among other health indicators, calculate vaccination coverage in order to ensure that questionnaires are adequate and interviewers properly trained to assess vaccination status, and that the results are internally consistent between biologicals.
- PAHO's immunization program should develop guidelines regarding coverage monitoring and data quality, and establish strategic alliances with entities specializing in vital statistics and demography to promote the generation and availability of accurate denominators figures to calculate vaccination coverage.
- PAHO should continue supporting countries to improve their immunization data quality by promoting the evaluation of the quality of their immunization data and information systems.¹¹ PAHO should also support the implementation follow-up of the recommendations resulting from such assessments.
- Countries using national computerized nominal immunization registries should document their experiences, successes, and lessons learned in order to share them with other countries.

¹¹ These systems are defined as the people involved in data collection and processing, data recording practices, and activities that process and aggregate the data and information, including software if available, in a given country.

Integrated Surveillance

In 2007, the World Health Organization issued a document entitled “*Global Framework for Immunization Monitoring and Surveillance*,”¹² with the object of recommending actions to improve the surveillance of vaccine-preventable diseases, primarily taking advantage of the strengths of the existing surveillance systems. In the Region of the Americas, Costa Rica was selected for the project’s pilot study, with the endorsement of the country’s national authorities and the collaboration of the Pan American Health Organization and U.S. Centers for Disease Control and Prevention.

The objectives of this integrated surveillance are basically geared to ensuring better use of human and financial resources, improving the effectiveness of activities, and maintaining the quality of services and information.

Although the ability of health services to monitor existing vaccine-preventable diseases is the ideal, it is difficult to operationalize, demanding teamwork and coordination of functions.

The pilot project will be a way to identify strengths and weaknesses of the integrated surveillance process, document its progress, and recognize advances, disadvantages, advantages, and lessons learned. The information can be shared with all countries interested in adapting the methodology and contributing to the implementation of integrated surveillance in the Region and other regions as well.

Recommendation:

- The different phases of the pilot project for integrating the surveillance of vaccine-preventable diseases in Costa Rica should be strengthened, monitored, and evaluated to identify obstacles to project implementation so that it serves as an example for other countries.

¹² Global framework for immunization monitoring and surveillance. Available at: http://www.who.int/immunization/documents/WHO_IVB_07.06/en/.