TAG 2011

Technical Advisory Group on Vaccine-Preventable Diseases

Vaccinate your family. Protect your community.

FINAL REPORT

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Pan American Health Organization

Regional Office of the World Health Organization

TECHNICAL ADVISORY GROUP ON

VACCINE-PREVENTABLE DISEASES

BUENOS AIRES, ARGENTINA, 6-8 JULY 2011

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ACRONYMS

AFP	Acute Flaccid Paralysis
ATAGI	Australian Advisory Group on Immunization
AVM	African Vaccination Week
BCG	Bacille Calmette-Guerin (vaccine against severe forms of tuberculosis)
CDC	Centers for Disease Control and Prevention of the United States
CRS	Congenital Rubella Syndrome
cVDPV	(circulating) Vaccine-derived Poliovirus
DALY	Disability-Adjusted Life Year
DTP3	Third doses of the Diphtheria-Tetanus-Pertussis vaccine
DVI	Dengue Vaccine Initiative
EIW	European Immunization Week
EPI	Expanded Program on Immunization
ESAVI	Events Supposedly Attributable to Vaccination and Immunization
EW	Epidemiological Week
FIOCRUZ	Foundation Oswaldo Cruz, Brazil
GBD	Global Burden of Disease
GBS	Guillain-Barré Syndrome
GRADE	Grading of Recommendations Assessment, Development and Evaluation
GSK	Glaxo-Smith-Kline
GSL	Global Specialized Laboratory
HAV	Hepatitis-A Virus
HBsAg	Hepatitis B Surface Antigen
HBV	Hepatitis-B Virus
hCG	Human Chorionic Gonadotrophin
HPV	Human Papilloma Virus
ICT	Information and Communication Technology
IEC	International Expert Committee (for the documentation and verification of measles, rubella, and CRS elimination in the Americas)
IgG	Immunoglobulin G
IPV	Inactive Polio Vaccine
KMC	Knowledge Management and Communication (area of PAHO)
LAC	Latin American and the Caribbean
MeaNS	Measles Nucleoid Surveillance
MMR	Measles-Mumps-Rubella vaccine
NITAG	National Immunization Technical Advisory Group
NL	National Laboratories
OLIVES	On-Line International Vaccine Economics and Statistics
OPV	Oral Polio Vaccine
PAHO	Pan American Health Organization
PCR	Polymerase Chain Reaction
PCV	Pneumococcal Conjugate Vaccine
PESS	Polio Eradication Surveillance System (software)
PoA	Plan of Action
ProVac	PAHO's Initiative for the evidence-based introduction of new vaccines
RF	PAHO's Revolving Fund for Vaccine Procurement
RRL	Regional Reference Laboratory
RT-PCR	Real-time Polymerase Chain Reaction
SAGE	Strategic Advisory Group of Experts on Immunization for the World Health

	Organization
SIREVA	Regional Vaccine System (Sistema Regional de Vacunas, in Spanish) – laboratory network for invasive bacterial pathogens
SNL	Sub-national Laboratory
TAG	PAHO's Technical Advisory Group on Vaccine-preventable Diseases
TRIVAC	Tool for Estimating the Cost-effectiveness of Influenza, Rotavirus and Pneumococcal Vaccines
UNICEF	United Nations Children's Fund
VAPP	Vaccine-associated Paralytic Polio
VWA	Vaccination Week in the Americas
VWEM	Vaccination Week in the Eastern Mediterranean
WHO	World Health Organization

VACCINATE YOUR FAMILY, PROTECT YOUR COMMUNITY

The XIX Meeting of the Technical Advisory Group (TAG) on Vaccine-preventable Diseases of the Pan American Health Organization (PAHO) was held in Buenos Aires, Argentina from 6 to 8 July 2011.

The meeting highlighted the achievements of the countries in the Region, as well as new challenges for continued protection of their populations. The motto for the meeting, "Vaccinate your family, protect your community", reflects the importance that the TAG and the Immunization Program attribute to expanding the benefits of immunization to the community as a whole.

The meeting aimed at eliciting TAG recommendations to address current and future challenges for immunization programs in the Americas. Secondary to decision sessions, the secretariat presented updates on progress of fulfilling selected previous TAG recommendations. Finally, the secretariat provided updates on ongoing initiatives and developments in the immunization field.

Dr. Ciro de Quadros, TAG Chair, opened the meeting applauding the Americas on their immunization program success and emphasizing the tremendous challenges ahead for immunization programs in the Region. Furthermore, Dr. de Quadros highlighted four main objectives for the fulfillment of a more equitable access to vaccines in the world, the achievement of which can be led by the Region of the Americas:

- Encourage international development organizations to increase their support for the poorest countries, and advocate for the access to affordable vaccine prices for Middle-income Countries.
- Support vaccine producers from emerging economies, so that they may provide better access to affordable vaccines.
- Advocate for and strengthen purchasing mechanisms, such as PAHO's Revolving Fund for Vaccine Procurement, in the other Regions of the World Health Organization (WHO).
- Reinforce and provide ownership to national immunization programs for all countries in the world. A call to leave behind the paternalistic ways of the past.

During his closing address, Dr. de Quadros announced the recipient of PAHO's Immunization Award. This award recognizes outstanding contributions to a national immunization program and to a country's efforts in controlling and/or eliminating vaccine-preventable diseases. The winner of the 2011 award was the Uru Chipaya community from Oruro, Bolivia for their activities to keep immunization coverage close to 100% in their area. As the organization itself was no in attendance the Bolivian delegation received the good news on their behalf. This award is to be presented in September 2011, during PAHO's Directing Council meeting; it includes a certificate of recognition, as well as a monetary gift in the amount of three thousand US dollars. Previous recipients have included Ms. Clarice Watson, EPI Nurse Coordinator in Guyana; Ms. Mirian Strul, EPI Manager of Peru; Dr. Rosario Quiroga, EPI Manager of Bolivia; and Dr. Miguel Angel Galindo, EPI Manager of Cuba.

The TAG recognized the contributions of the PAHO secretariat to the success of this meeting and thanked the Government of Argentina for hosting the meeting.

IMMUNIZATION PROGRAMS IN THE AMERICAS: CHALLENGES AND OPPORTUNITIES

Since the creation of the Expanded Program on Immunization (EPI) in 1977, the majority of PAHO Member States have considered immunization as a public good. Countries from the Region have also considered vaccination as a crucial component of preventive primary health care.

The Regional Immunization Program has made significant progress over the last few years but continues to face great challenges. Vaccination coverage rates at the regional level are among the highest in the world. According to 2009 WHO/UNICEF coverage estimates, the coverage levels in the Americas were: 94% for BCG, 91% for polio3, and 92% for DTP3 in children aged <1 year, and 93% for measles-containing vaccines in children aged 1 year.

In the Americas, vaccination schedules include an average of vaccines against 10 diseases, with countries including up to 21 antigens through the life cycle.

The introduction of new vaccines will certainly have an impact on reducing the morbidity and mortality caused by the diseases caused by those microorganisms. According the 2009 WHO/UNICEF estimates, 48% of the birth cohort of the Americas was born in countries using the pneumococcal conjugate vaccine (PCV) in their routine immunization schedule and 82% in countries using the rotavirus vaccine. Regarding the Human Papilloma Virus (HPV) vaccine, approximately 44% of girls aged 9-15 years live in countries of the Americas that use the HPV vaccine in their immunization schedule. These levels make the Americas a world leader in the use of new vaccines and highlight PAHO Member States' strong commitment to immunization.

Nevertheless, in 2009, 11 countries in Latin America and the Caribbean (LAC) and Canada reported national coverage rates ≤90% and 43% of LAC municipalities reported DTP3 coverage levels <95%. It is estimated that <53% of the LAC birth cohort lives in these municipalities. These pockets of low coverage represent a risk for the reintroduction or resurgence of vaccine-preventable diseases that have been eradicated or eliminated, or that are under epidemiological control. In 2010, during sub-regional meetings, LAC countries characterized their vulnerable populations and developed tailored plans of action to target these areas of low coverage, as well as areas with poor surveillance performance. Supervision and periodic evaluations continue to be key mechanisms to improve program performance at all levels. Since the 2009 TAG meeting, comprehensive international EPI evaluations were conducted in El Salvador (2009), Bolivia (2010), Nicaragua (2010), and Argentina (2011). Evaluations following the introduction of new vaccines were completed in Ecuador (2009) and immunization data quality assessments were carried out in Paraguay (2009) and Jamaica (2010).

It is in this context that the concept paper "Strengthening Immunization Programs" was presented to the 50th Meeting of PAHO's Directing Council held in September 2010. The Council approved Resolution CD50.R5 "Strengthening Immunization Programs", noting the advances in immunization and urging Member States to reiterate their endorsement of national immunization programs as a *public good*[1] and their commitment to the Regional Immunization Vision and Strategy in order to maintain the achievements,

[1] Public good: an item whose consumption is not decided by the individual consumer but by the society as a whole, and which is financed by taxation.

address the unfinished immunization agenda, and successfully tackle the new challenges that lie ahead. It also called for continued support for PAHO's Revolving Fund for vaccine procurement. As of the end of 2010, 40 Member States were purchasing vaccines, syringes, and other immunization supplies though the RF. The RF offered 45 different biologicals and the total amount of purchase orders was US$510 million.

Next Steps:

- Maintain immunization as a public good.
- Maintain the achievements in terms of vaccine-preventable disease control and elimination, in the current context of an inter-dependant world.
- Strive to attain coverage levels ≥95% for all vaccines in each municipality.
- Strengthen vaccination and surveillance activities at all levels to prevent the risk of reintroduction of vaccine-preventable diseases that have been already eradicated/eliminated from the Region.
- Strengthen communication, education, and information with and for the population about the benefits of the vaccines and immunization.
- Continue supporting the operations of the Revolving Fund for Vaccine Procurement.
- Continue to provide technical support to Member States for the strengthening of national immunization programs and the implementation of the recommendations put forward by TAG.

DOCUMENTATION AND VERIFICATION OF THE ELIMINATION OF MEASLES, RUBELLA AND CONGENITAL RUBELLA SYNDROME

Substantial progress has been made in the process to document and verify the elimination of measles, rubella and congenital rubella syndrome (CRS) in the Americas. Resolution CSP27.R2, adopted during the 27th Pan American Sanitary Conference in October 2007, authorized the formation of an International Expert Committee (IEC) and urged PAHO Member States to establish national commissions to document and verify elimination in each country of the Region. To date, the regional plan of action has been finalized and is available in all four official PAHO languages. The plan was formally endorsed by the TAG during its XVIII Meeting in August 2009 and was adopted by the IEC in December 2010. The regional plan of action provides an additional opportunity to place immunization programs as a high-ranking priority on the political agenda of countries, as well as strengthen vaccination activities and surveillance systems to maintain the achievements gained to date and face the new challenges.

Presently all countries and territories of the Region have formed national and/or sub-regional commissions. On 21-22 March 2011, the IEC recommended that all countries submit their final country reports by December 2011 to provide time for revision and for the preparation of the final regional report. This final report is to be presented before the Pan American Sanitary Conference in 2012.

A primary challenge for the countries of the Americas and their national commissions is the constant threat of importations, increasing the risk of the reestablishment of endemic transmission. With nearly 148 million visitors to the Region in 2009, importations of measles and rubella from other regions are inevitable until these diseases are eradicated. Over the 2008-2010 period, 345 secondary measles cases resulted from a total of 136 measles importations, while for 88 cases the source was unknown. Sixty percent of measles importations to the Americas have come from Europe; these outbreaks occurred in Argentina, Brazil, Canada, Chile, Ecuador, French Guiana, Jamaica, Peru, and the United States. In 2011, up to epidemiological week (EW) 25, a total of 682 measles cases had been confirmed in 7 countries and in the three French Departments in the Americas. Epidemiological investigations and genotyping confirmed transmission of measles virus mainly from European countries (60%), but also from other WHO Regions such as Africa, South East Asia and the Western Pacific. The genotypes identified include D4, D8, D9, B3, H1 and G3. The most affected age-groups are adolescents and young adults (54%), mostly in Canada (90% of the cases in this age-group in the Region are from Canada). Approximately 70% of the cases were either not vaccinated (refusals and not yet eligible), had no proof of vaccination, or their vaccination status was unknown.

The Region recently celebrated the two-year anniversary of the interruption of endemic rubella virus circulation as the last confirmed endemic rubella case was reported in Argentina in epidemiological week 5 of 2009. For that same year, Canada and the United States reported 4 and 3 import-associated rubella cases (genotype 2B in the United States), respectively. In 2010, the Americas reported a total of 15 rubella cases: Canada (n=7), French Guiana (n=1), and the United States (n=7). As a result of the rubella outbreaks in 2009, a total of 27 CRS cases were reported in Argentina (n=13) and Brazil (n=14). No CRS cases were reported in 2010. In 2011, up to EW 25, a total of 4 rubella cases have been reported; all in the United States (1 importation from Kenya

and 1 importation from India with a secondary case, and 1 of unknown source). One CRS case (genotype 2B) imported from the Philippines was reported in Manitoba, Canada in 2011.

Other remaining challenges include: 1) limited collection of specimens for virus detection and isolation, and the occurrence of "hot cases,"[2] which present problems in final classification and follow-up, and 2) the weakening of surveillance systems and of immunization activities, thus increasing the risk for outbreaks following importations and the reestablishment of transmission. As an additional measure to prevent importations, PAHO has issued epidemiological alerts recommending vaccination against measles and rubella for all travelers visiting countries in the Americas, as well any resident of the Americas planning to travel to other regions. These alerts have been disseminated in advance of various cultural and sporting events hosted by countries in the Region.

The experience of the Americas in achieving and verifying the elimination of measles, rubella, and CRS demonstrates that endemic virus transmission can be interrupted when countries fully commit to an effective regional strategy. In light of the intense mobilization of resources and efforts to efficiently respond to an outbreak, it is vital that PAHO Member States continue to advocate for other Regions to implement the necessary interventions to eliminate measles and rubella.

An annual Meeting of the Measles and Rubella Laboratory Network for the Region of the Americas was held on 20-21 June 2011 at the CDC headquarters in Atlanta, GA. A full report from this meeting was presented before the TAG and can be found in Annex 1.

TAG congratulates Member States and their national commissions for the tremendous efforts made toward documenting and verifying the elimination of measles, rubella, and CRS in their respective countries.

Recommendations:

- TAG encourages countries to continue to adhere to previous TAG recommendations to maintain measles, rubella, and CRS elimination and for the rapid response to importations to the Americas. These recommendations include reaching coverage ≥95% of first and second (routine or in campaign) measles-rubella vaccine doses in all municipalities, strong integrated measles-rubella surveillance, and enhanced CRS sentinel site reporting.
- Countries should continue to ensure that resources are available to support surveillance and laboratory activities.
- TAG urges countries reporting measles cases and outbreaks to conduct detailed epidemiological and virological analysis to fully characterize the cases and outbreaks.
- TAG calls upon the other Regions of the world and the WHO to implement strong measures for the control of current measles outbreaks and to further advance their control and elimination initiatives. TAG also supports country requests to include the topic of a global measles and rubella eradication goal in the discussion at the next World Health Assembly.

[2] PAHO defines "hot cases" as those from tourist and industrialized areas; cases with unknown travel history; cases from border areas with high traffic; and suspected cases with a high likelihood of exposure.

- National commissions, in collaboration with ministries of health, should continue to implement a national plan of action for the documentation of measles, rubella, and CRS elimination, with technical cooperation from PAHO and the IEC.
- Countries should complete the analysis and evaluations of key components included in the regional plan of action and submit their final country report to the IEC by December 2011.
- The TAG endorses all of the recommendations that resulted from the annual Meeting of Measles and Rubella Laboratory Network (Annex 1).

MUMPS

The measles-mumps-rubella (MMR) vaccine has gradually been implemented in the routine program of all countries and territories of the Region of the Americas (with the exception of Haiti). Although data is limited, reductions in the number of reported mumps cases followed the introduction of routine first MMR dose (MMR1) are observed in several countries. Despite regional high coverage with routine MMR1 and the introduction of a second routine MMR dose in many countries, large mumps outbreaks have occurred in recent years. The TAG's recommendation in 2000 was to administer measles-rubella (MR) vaccine during campaigns, due to adverse events following vaccination with the mumps vaccine component in previous years.

Recent mumps outbreaks highlight the need to better understand the epidemiology of mumps in the Region and improve control and response strategies to guide public health policy. Available regional data on mumps cases reported over the last decade has been examined through the revision of country reports to PAHO, with particular emphasis placed on those countries that have experienced outbreaks since 2005. In addition, a TAG Working Group Meeting on Mumps in the Region of the Americas was convened in June 2011 to assess the situation of mumps in the Region and to propose practical recommendations based on country experiences.

The experience of several Latin American countries reporting mumps cases has been a gradual but significant reduction in disease incidence, ranging from 80% to 99% reduction of cases, followed by outbreaks on average 10 years or more post vaccine introduction. At the regional level, mumps incidence has increased from 3.39 per 100,000 in 2004 to 5.22 per 100,000 in 2007 due to recent outbreaks in countries such as Uruguay (2005-2006), El Salvador (2006), the United States (2006), Canada (2007), and Venezuela (2007-2008). Regional mumps incidence is gradually decreasing to 4.58 and 3.37 per 100,000 in 2008 and 2009 respectively, due to the intensification of vaccination and surveillance activities.

Potential contributors to regional mumps outbreaks include that the mumps component of the vaccine does not provide the same high level of protection as the measles and rubella components, waning immunity, as well as low coverage with the first MMR dose in poor performing municipalities.

Recommendations:

- Given that the MMR vaccine is used in the Region of the Americas, strategies to control mumps should be closely integrated with existing goals of measles and rubella elimination.

Vaccination

- Preventing mumps requires two doses of MMR vaccine in countries' national immunization programs, aiming at reaching coverage levels ≥95%, for all children and risk groups. The first dose should be given at 12 months of age as part of the routine immunization schedule. The second dose can be administered either through a campaign or through the routine immunization program and should be given at

least one month after the first dose, optimally during the second year of life but no later than school entry.

- During all mumps vaccination activities, regardless of the vaccination strategy (routine or campaign) any of the WHO prequalified vaccines can be used, independent of the mumps strain. When responding to outbreaks, it is preferred that the Jeryl-Lynn strain (or Jeryl-Lynn-derived strains) be used among adolescents and adults.
- When using the MMR vaccine in campaigns, health authorities should monitor, investigate, and train health workers about possible vaccine-related adverse events for all vaccine components, including possible instances of aseptic meningitis (AM). Countries also need to use effective communication strategies to inform the general public about possible events supposedly attributable to vaccination or immunization (ESAVI), to maintain a high level of public trust in vaccines and vaccination programs.
- Future studies of the safety profile of the MMR vaccine in campaigns should be well designed to investigate the incidence of adverse events. Such research should use standardized case definitions and standardized quantitative indicators to assess the severity of adverse events.
- Vaccine effectiveness studies should take into consideration the thermostability of the mumps component of the MMR vaccine and evaluate practical issues, such as the need to ensure vaccine reconstitution using cold diluents.

Surveillance

- Strengthened surveillance for mumps will be decisive in building the general knowledge base of mumps epidemiology in the Region of the Americas and in accelerating vaccination activities to prevent possible outbreaks and establish a disease control goal. Such surveillance efforts should evolve with the level of epidemiological control and should be adapted to each country to match regional and country-specific program goals and objectives. Surveillance should first focus on clusters of clinical cases to identify outbreaks of mumps. After an observed decline in the incidence of mumps cases, case-based surveillance should be implemented.
- All countries that have not yet made mumps a notifiable disease should do so. Countries should also strengthen their mumps surveillance systems to rapidly detect, investigate, and respond to mumps outbreaks.
- All the countries of the Region of the Americas should standardize mumps case definitions and surveillance indicators, using adequate data elements. PAHO will develop guidelines on mumps surveillance, outbreak response and investigation, as well as for laboratory diagnosis.

Outbreaks

- Every suspected outbreak should be adequately investigated in order to identify the characteristics of the outbreak, select appropriate control measures, and determine why the outbreak occurred. While the single most important outbreak control measure is vaccination, these interventions should target only the affected populations. If the number of susceptible persons is high, a vaccination campaign should be conducted in order to increase coverage levels.
- During an outbreak, laboratory diagnosis should also be used to confirm the occurrence of a mumps outbreak and to establish causality of vaccine-related adverse events.

Laboratory

- Capacity for laboratory confirmation of mumps should be part of the Measles and Rubella Laboratory Network for the Region of the Americas. Building laboratory capacity will require development of standard protocols for laboratory testing, data management and quality control as well as training.
- Laboratory testing should be used to confirm suspected outbreaks of mumps, but not to confirm every suspected case. Samples should be collected for serologic and virological assays. Molecular characterization should be used to establish a genetic baseline for wild-type mumps.
- Laboratories with existing capacity for polymerase chain reaction (PCR) should consider establishing the mumps real time PCR (RT-PCR) assay as a diagnostic method.

PLAN OF ACTION TO MAINTAIN THE AMERICAS FREE OF POLIO

In 1988, the World Health Assembly established the goal of global eradication of poliomyelitis by the year 2000 (Resolution WHA41.28), and in 1994 the Region of the Americas was certified as being free of the circulation of the indigenous wild poliovirus.

TAG expressed concern that after 20 years without cases caused by the wild poliovirus, the Region of the Americas still is at risk of having importations from any of the 13 countries where the virus is still circulating.

The Plan of Action to maintain the Americas free of poliomyelitis during the transition from the pre to post-eradication eras was presented during this session[3]. The Plan of Action provides a framework for the American Region to remain free of poliomyelitis during the pre- and post-eradication eras, as well as during the transition between both eras. The Plan articulates a comprehensive strategy to enhance all aspects of community protection and epidemiologic surveillance. Its implementation will be conducted in accordance with the priorities and strategies of PAHO's Family and Community Health Area (FCH).

The session discussed the risks of receiving an importation of wild poliovirus or of a vaccine-derived poliovirus (cVDPV), as well as on the risk of having an outbreak of cVDPV similar to the one that occurred in Dominican Republic and Haiti in 2000-2001.

The risk of having an outbreak was defined as the risk of receiving an importation (related to travelers), of failing to rapidly detect it (quality of surveillance) or of the potential for transmission in the community (levels of coverage/immunity, personal hygiene and sanitation).

In order to evaluate the risk of importation a regional analysis was conducted, and the following variables were taken into consideration for each country: OPV3) and DPT3 coverage in children aged <1 year, at national and district levels; proportion of the population living in districts with OPV3/DPT3 coverage $\geq$80% and $\geq$95%; Acute Flaccid Paralysis (AFP) surveillance indicators; sanitary conditions; clean water supply; closed sewage systems; population movements; and exposure to international travelers.

TAG's recommendations considered the above mentioned risk analysis, the current global epidemiological situation, the success of the Region at remaining polio-free, its previous recommendations, and the position paper "Polio vaccines and polio immunization in the pre-eradication era" (published in WHO's Weekly Epidemiological Record on 4 June 2010).

The most recent WHO position paper on polio (2010) recommends the use of inactive polio vaccine (IPV) alone, in countries with moderate potential for receiving importations and with low transmission potential after receiving an importation of wild poliovirus. The low transmission potential is defined as having DPT3 coverage >90%, good personal, domestic and environmental hygiene standards, closed sewage systems, secondary or

[3] The transition between eras is defined in this Plan as the period since the last reported case of wild poliovirus in the world until the declaration of global eradication by the Global Certification Commission (GCC)

greater sewage treatment. The Position Paper also noted that IPV vaccination is not cost-effective and that at current prices the opportunity-costs of introducing IPV are high. TAG noticed that in the Region of the Americas only Canada, the United States, and Uruguay fulfill the requirements of the WHO Position Paper.
Existing data from the Polio Eradication Surveillance System (PESS) suggests that vaccine-associated paralytic polio (VAPP) may be less common than what had been estimated in India and the USA before the interruption of wild polio transmission.

TAG has decided to add to the above requirements the quality of AFP surveillance and the proportion of the population living in high risk districts.

Recommendations:

- Countries of the Region of the Americas should continue to use the OPV vaccine until global polio eradication is achieved.
- Countries of the Americas using only IPV in their immunization schedules should only do so where they comply fully with the minimum requirements recommended by WHO and PAHO, as described above.
- Countries considering the use of IPV before the global eradication of poliomyelitis should use sequential schedules that include OPV and/or conduct periodic OPV campaigns.
- Countries that do not achieve polio vaccine coverage ≥95% in every municipality must conduct annual OPV immunization campaigns for children aged <5 years, regardless of their vaccination status.
- Countries must maintain certification standards of AFP surveillance (in compliance with surveillance indicators).

PERTUSSIS (WHOOPING COUGH)

There is evidence of a high burden of pertussis in developing countries, and this disease is regarded as a major cause of childhood morbidity and mortality. An estimated 50 million cases and 300,000 deaths occur every year, with case-fatality rates in developing countries estimated to be as high as 4% of infants <12 months. At present, pertussis surveillance is based on a passive system designed to document trends in disease occurrence. This system has limitations in the identification of cases, reporting, specific laboratory diagnostics, data collection and analyses, and with the critical implementation of appropriate prevention and control measures in most LAC countries.

In the Region of the Americas, vaccination coverage with DPT3 reached approximately 93% in 2009. This is a considerable improvement from an estimated DTP3 coverage of 74% in 1990. However, despite high vaccination coverage, pertussis outbreaks continue to be reported in Latin American countries indicating that new measures have to be taken in order to increase the degree of protection.

Diagnostic testing for pertussis remains inadequate for surveillance and clinical management. Culture, the gold standard testing, is specific but not sensitive. LAC countries report “probable” or “compatible” pertussis cases, and laboratory confirmation is performed by immunofluorescent techniques, culture, and PCR. Due to the fact that confirmed pertussis case definition is based on laboratory confirmation, laboratory-based reports represent the only source of accurate information. A project entitled *Improving Pertussis Surveillance in Latin America* is now underway in Argentina, Mexico, and Panama. This is a collaborative study between the US CDC, PAHO, Sabin Vaccine Institute, and the above mentioned countries. The objectives of the study include: to develop a model for improving pertussis surveillance to guide prevention and control strategies for the disease in Latin America, to improve diagnostic capacity, data collection, and to develop a reliable and valid method for improving pertussis surveillance in Latin America. To date, the surveillance system has been evaluated in all three countries and laboratory personnel and epidemiologists have participated in workshops. The findings and results of the project will be available by the end of 2012.

Recommendations:

- TAG commends the efforts that countries are undertaking to improve pertussis surveillance and reiterates all previous recommendations on case definitions, quality of surveillance, and vaccination coverage.
- TAG urges countries to undertake initiatives to improve pertussis surveillance.
- For the optimal protection of new born children, TAG recommends immunizing pregnant women in outbreak situations.

VACCINATION AGAINST SEASONAL AND PANDEMIC INFLUENZA

Progress continues to be made in the introduction of seasonal influenza vaccine in the Region. As of 2010, 39 countries and territories of the 45, or 86.6%, are using the vaccine in the public sector. This includes 36 countries and territories that vaccinate the elderly, 34 vaccinate heath care workers, 29 vaccinate children, 26 vaccinate persons with chronic diseases, and 17 vaccinate pregnant women. In spite of widespread use of the vaccine, data on coverage of target populations continues to be very limited, especially for pregnant women and people with chronic diseases. The experience with seasonal influenza vaccine in the Region served to prepare countries for the massive vaccination campaigns required during the pandemic.

On 25 April 2009, WHO reported the emergence of a new influenza (H1N1) virus detected in North America and on 11 June 2009, the WHO declared the first pandemic of the XXI century. PAHO's technical cooperation was provided along four main lines: 1) supporting use of seasonal influenza vaccination in 2009 for countries and territories not yet using the vaccine; 2) assisting countries in drafting pandemic vaccination plans of action; 3) supporting pandemic influenza vaccine acquisition; and 4) monitoring the implementation of vaccination, vaccine safety, and disseminating this information.

Approximately 350 million doses of pandemic vaccine were acquired in the Region. Vaccine access in the Americas was far from equitable, both in the timeliness and quantity of vaccine available. Canada and the United States acquired the vaccine by direct purchase from vaccine manufacturers and received the vaccine first in October 2009. Argentina, Brazil and Mexico have influenza vaccine technology transfer agreements underway and received vaccines from December 2009 to April 2010. Countries that procured vaccine exclusively from the RF received vaccine from January-May 2010. Recipient countries of WHO donation began to receive vaccine in March-June 2010.

LAC countries established specific vaccination goals for high-risk groups[4], targeting approximately 147 million people. However, estimating the size of target populations was challenging for high risk groups, as these populations are not well characterized in many countries. In total, an estimated 144 million doses were administered in LAC, representing a 98% completion of the pre-established goal. There were large variations by country in vaccination coverage of high risk groups (Table 1).

[4] High-risk groups: people who live in areas of low coverage or with poor immunization program performance.

Table 1. Implementation of pandemic (H1N1) vaccination campaigns in LAC.

Countries and Territories	Doses Administered	Total Population Coverage	Coverage of Prioritized Risk Groups: Health Personnel and Essential Services	Pregnant Women	Chronic Diseases	Others
Anguilla	-	-	-	-	-	-
Argentina	8,258,009	20.7%	104.7%	101.4%	132.5%	116.2%
Bahamas	5,006	1.5%	18.0%	18.6%	15.8%	-
Barbados	4,360	1.7%	64.2%	3.3%	11.5%	-
Belize	10,146	3.4%	-	-	-	-
Bermuda	1,053	1.6%	-	-	-	-
Bolivia	1,249,049	12.9%	67.1%	32.0%	69.2%	144.7%
Brazil	92,000,000	47.9%	120.1%	77.1%	163.2%	81.8%
Cayman Islands	2,318	4.8%	1.8%	5.6%	0.0%	5.0%
Chile	3,084,124	18.4%	107.0%	54.4%	80.1%	77.3%
Colombia	2,037,301	4.5%	53.4%	58.5%	101.3%	59.5%
Costa Rica	180,000	4.0%	-	-	-	-
Cuba	1,123,526	10.0%	101.8%	100.7%	98.8%	100.7%
Ecuador	973,480	7.2%	101.7%	80.8%	92.8%	104.4%
El Salvador	1,690,101	27.6%	186.0%	44.7% -		114.6%
Grenada	396	0.4%	5.1%	0.4%	1.1%	-
Guatemala	1,295,742	9.6%	81.0%	58.0%	67.0%	100.0%
Guyana	170,601	22.4%	-	-	-	-
Honduras	1,810,783	23.0%	106.0%	75.0%	136.0%	81.0%
Mexico	26,903,232	24.8%	94.9%	71.7%	101.9%	82.2%
Montserrat	1,245	24.9%	-	-	-	-
Nicaragua	251,759	4.4%	91.3%	88.1%	37.5%	15.7%
Panama	254,286	7.5%	50.1%	32.1%	374.8%	85.3%
Paraguay	1,087,661	17.4%	85.5%	37.3%	77.1%	103.3%
Peru	2,237,053	7.8%	42.5%	9.1%	24.5%	249.7%
Suriname	24,674	4.8%	23.4%	4.5%	10.4%	-
Trinidad and Tobago	23,985	1.8%	57.0%	0.7%	-	-
Turks and Caicos Islands	2,837	12.9%	25.9%	6.3%	12.7%	57.4%
Uruguay	538,057	16.1%	-	-	-	-
Venezuela[a]	500,000	-	-	-	-	-
TOTAL[b]	144,456,183					

(-) Data not available. Vaccination coverage over 100% may represent inadequate denominator estimates.

[a]Doses purchased

[b]The total number of applied doses does not include doses purchased by Venezuela.

The lowest vaccination coverage was reported for pregnant women, with 67% coverage of the pre-established goal (and a median coverage of 46%), in spite of the available evidence indicating increased risk of complications and mortality due to pandemic influenza (H1N1). In some countries, it was observed that health care professionals were reluctant to recommend pandemic influenza (H1N1) vaccination for pregnant women.

Surveillance systems for adverse events following immunization were strengthened before the beginning of pandemic influenza vaccinations. At the conclusion of influenza (H1N1) vaccination, the number of severe adverse events reported in LAC related to vaccination was lower than what is expected with the seasonal influenza vaccine and no deaths were identified as being causally related to the vaccine. By October 2010 a total of 13,621 ESAVI cases had been reported to PAHO, of which 846 were classified as severe cases (5.9 cases per million doses). Of those, 389 cases were classified as related to vaccination (2.7 cases per million doses).

There were also a total of 101 cases of Guillain-Barré Syndrome (GBS) identified following influenza vaccination (0.7 cases per million doses). In addition, there were 72 cases of anaphylaxis that were classified as being related to vaccination (0.5 per million doses), and 20 febrile seizures were reported (0.1 cases per million doses).

Recommendations:

- Ensure that pandemic preparedness plans include the vaccination component as an integral part of the response measures.
- Reiterate previous recommendations that countries vaccinate older adults, children, those with underlying conditions, and healthcare workers. Because of the vulnerability of pregnant women to complications from influenza infection, TAG urges countries to increase vaccine uptake of pregnant women.
    - Encourage countries to strengthen their risk communication efforts and to engage scientific/professional organizations and societies in order to reach target populations.
    - Urge countries to document influenza vaccination coverage in high-risk populations. As more countries in the Region are introducing influenza vaccine, it becomes more important to assess the impact of influenza and conduct vaccine effectiveness studies in high-risk populations.
    - PAHO should continue to promote the transfer of technology for influenza vaccine production in the Region, in order to increase its availability.

UPDATE ON THE USE OF HUMAN PAPILLOMA VIRUS (HPV) VACCINES IN THE REGION

Cervical cancer is a striking symbol of enduring health inequities in the Americas. In 2010, 84,000 women were diagnosed with and 38,000 women died of cervical cancer in LAC. In this part of the Western Hemisphere, cervical cancer mortality rates are six times higher than in Canada and the United States (age-standardized rates of 10.8 and 1.7 per 100,000 women, respectively). This disparity will grow further if no improvement in cervical cancer prevention and control is made. Due to a demographic effect alone (current large cohorts of young people becoming adults), 18,000 additional deaths per year (47% increase) might occur in 2030.

Together with new screening methods for HPV infections, HPV vaccines can boost cervical cancer prevention. As of July 2011, five countries (Canada, Mexico, Panama, Peru, and the United States) have structured HPV vaccination programs at either the national or sub-national levels. Publicly funded HPV vaccination also occurs in an unknown number of localities throughout the Region or on demand in some Caribbean territories. Demonstration projects with vaccine donations were carried out in Bolivia, Haiti, and Peru. Overall, these experiences show relevant programmatic and communication challenges of reaching and vaccinating adolescents. Careful planning is key to successful HPV vaccination.

While advances have been made, HPV vaccine uptake in the Americas is slower than that of rotavirus and conjugate pneumococcal vaccines. Three reasons might explain this relative delay. First, most national programs perceive HPV vaccine as unaffordable. However, PAHO's EPI Revolving Fund can now purchase HPV vaccines at prices comparable to those of conjugate pneumococcal vaccines. Vaccination strategies focused on female adolescents should further increase affordability. Second, global development goals favor public health investments against diarrhea and pneumonia in children and maternal mortality. Even though the ratio of cervical cancer deaths to maternal deaths is 3.4 in LAC, cervical cancer still fails to arouse advocacy efforts and political will. Finally, programmatic uncertainty persists on best practices for vaccination of pre-adolescents and adolescents and the integration between cervical cancer screening and HPV vaccination.

Integrated with screening, detection, and treatment of pre- and cancerous lesions, HPV vaccination can reduce the incidence and mortality of cervical cancer in the Americas. Early concerns were that HPV vaccines would be introduced without proven cost-effectiveness and coherent planning. These concerns are valid and call on PAHO and its Member States to systematize ongoing experiences and define cost-effective and sustainable delivery options that can lead to high coverage in different national and local settings. However, a case should also be made that HPV vaccine introduction in pre-adolescent girls is an historical opportunity to reduce the future burden of HPV-related diseases. While improvements in screening are necessary to reduce the disease burden in today's women, we should also recognize that HPV vaccination is a necessary investment to avoid creating larger disease burden in tomorrow's women.

The Global Strategy for Women and Child Health, launched in September 2010 during the Millennium Development Goal summit, should be an opportunity to work with countries for the introduction of the HPV vaccine.

Recommendations:

- PAHO should continue to work with countries to increase the uptake of HPV vaccine in the Region, in the context of a comprehensive cervical cancer prevention and treatment strategy.
- Special projects and HPV vaccine donations should only be undertaken after considering the sustainability of the intervention after the end of the project or donation.
- PAHO should develop a regional monitoring strategy to assess the impact of HPV vaccination.

PNEUMOCOCCAL CONJUGATE VACCINES

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

In LAC, an epidemiological surveillance network of bacterial pneumonia and meningitis in children aged <5 years in sentinel hospitals has been supported and has come to match the laboratory network of SIREVA II. The following 10 countries in the Region report their epidemiological surveillance data for bacterial pneumonias and meningitis to PAHO: Brazil (meningitis), Bolivia, Ecuador, El Salvador, Guatemala, Honduras, Panama, Peru, Paraguay, and Venezuela.

There are currently 3 pneumococcal conjugate vaccines (PCVs) available on the market and prequalified by the WHO: the 7-valent (PCV7), the 10-valent (PCV10), and the 13-valent (PCV13). The WHO, in its last position paper on pneumococcal conjugate vaccine in 2007, considered the vaccine a priority for the vaccination schedules of the countries. Moreover during the 2006 and 2009 meetings, the TAG recommended that all countries of the Region implement surveillance systems in order to know the profile of the disease and monitor the impact of the introduction of the vaccine.

As of May 2011, the following 17 countries in the Region have introduced the PCV to their national immunization programs: The United States (2001); Canada (2002), Costa Rica (2007); Bermuda, Mexico, Uruguay (2008); Barbados, Peru (2009); Brazil, Ecuador, El Salvador, Panama, Nicaragua (2010); Chile, Colombia, Honduras, and Guyana (2011). Three territories have also introduced this vaccine: Aruba, the Cayman Islands, and French Guiana.

With the recent introduction of this conjugate vaccine in the various national vaccination programs within LAC, knowledge gaps with regards to vaccine effectiveness in the different possible schedules and the interchangeability between vaccines with different components still remain.

On 12 January 2011, an *ad hoc* scientific consultation on PCV schedules was conducted in Washington DC. Experts on pneumococcal vaccines met to discuss and recommend an appropriate pneumococcal conjugate vaccine schedule. Based on the available scientific evidence, experts also discussed interchangeability among the pneumococcal conjugated vaccine PCV7 and the newly introduced PCV10 and PCV13 in LAC. The group of experts included professionals from PAHO/WHO, IVB/WHO, CDC, Sabin Institute of Vaccines, Emory University, School of Medicine and Dentistry of New Jersey University, University of Bern, and the National University of Buenos Aires. The experts recommended a minimum of three doses of PCV be included in the childhood vaccine schedule: 3 doses without a booster or 2 doses with a booster for children aged between 12 and 15 months. Regarding interchangeability of PCVs, the experts recommend that vaccination schedules be completed with the same type of vaccine. Taking into consideration the recent introduction of PCV10 and PCV13, experts urged that research continue to be conducted to monitor immunogenicity, vaccination series, effectiveness, safety, vaccine interchangeability, and replacement of serotypes.

Recommendations:

- TAG endorses the recommendations of the *ad hoc* scientific group.
- Countries should consider three doses of the pneumococcal conjugate vaccine as the minimum for a vaccination schedule. The administration options can be 3 doses (primary series) without a booster or 2 doses (primary series) with a booster for children aged between 12 and 15 months, taking into account the epidemiological profile of the disease in each country.
- Countries should base the decision regarding the option of opting for a 3 dose schedule (primary series) without booster or a 2 dose schedule (primary series) with a booster for children aged between 12 and 15 months, mainly on the burden of the pneumococcal disease of the country and pneumonia mortality in children aged <2 years. If the country has a high burden of disease and a high mortality in children aged <7 months, the country should opt for the 3 dose schedule in the primary series; if the burden of disease and mortality is more important in children aged >7 months, the country could consider using the 2 dose schedule in the primary series with a booster.
- Considering that there is currently no direct data available regarding interchangeability among the various PCVs, and only indirect evidence is available:
    - Vaccination schedules should be completed with the same type of vaccine;
    - If the same vaccine is not available, the series should preferably be completed with a vaccine that has the same carrier, or;
    - If it is not possible to complete the series with the same type of vaccine, any other type of PCV can be used;
    - The options are therefore: If one begins a series with PCV7, one can complete the primary series with the vaccine available (PCV10 or PCV13) and if the primary series was completed with PCV7, the child can receive a booster dose with PCV10 or PCV13.
- Countries, and other stakeholders, should continue to research: immunogenicity, vaccination series, effectiveness, safety, vaccine interchangeability, and replacement of serotypes.
- Countries should implement and/or strengthen the surveillance of pneumococcal caused diseases in sentinel hospitals, in accordance with PAHO/WHO recommendations, in order to know the epidemiological profile of the disease and acquire evidence for decision-making with respect to the use of the PCVs.
- Countries should study the impact of PCV on hospitalization and mortality trends caused by pneumococcal disease.
- Countries, and other stakeholders, should continue cost-effectiveness studies on PCV introduction.
- Countries where interchangeability between PCV7 and PCV10 occurs, should document their results.

EVIDENCE-BASED DECISIONS

New vaccines hold the potential to reduce substantial death and morbidity but come at increased costs to governments. Since newly available vaccines often cost significantly more than traditional childhood vaccines, the universal introduction of these vaccines can present formidable challenges. In 2006, TAG recommended that countries perform economic analyses and assess other relevant evidence to inform decisions to introduce new vaccines. In response, PAHO's ProVac Initiative has been strengthening national capacity to make more informed, evidence based decisions regarding new vaccine introduction. Specifically, the Initiative aims to:

- Strengthen national infrastructure for decision-making;
- Develop tools for economic analyses and provide training to national multidisciplinary teams on their use;
- Support countries to collect data, conduct analyses, and gather framework of evidence;
- Advocate for evidence-based decisions; and
- Effectively plan for vaccine introduction when evidence supports it.

Since the Initiative's formal launch in 2004, ProVac received a generous grant award from the Bill and Melinda Gates Foundation to carry out operational activities to meet the decision support needs of countries in LAC. In its third year of funding, the Initiative has held two regional workshops to address decision-making challenges and to train countries on the use of economic evaluations for the introduction of rotavirus vaccines and pneumococcal conjugate vaccines in 2010 and 2008, respectively. In each of these regional workshops, ProVac trained more than 120 public health professionals from national immunization programs. To date, several countries have requested and received direct support to conduct cost-effectiveness analyses in the Region, of which seven evaluated pneumococcal conjugate vaccines, two evaluated rotavirus vaccines, and one evaluated HPV vaccines. Findings and implications of the study results for new vaccine decisions in Bolivia and Paraguay were presented to TAG.

In the last year, the ProVac Initiative has established the Network of ProVac Centers of Excellence. The network of academic centers has helped to address identified gaps in existing national data and to standardize methods for country level economic evaluations. The six academic centers are collaboratively working together to:

- Develop guidelines to conduct national disease burden studies on pneumococcal disease and rotavirus;
- Develop standardized methodologies to generate data on health service utilization, cost of illness, and productivity loss;
- Build a national immunization program costing tool and a new vaccine introduction budget impact tool, as well as guidelines for their use;
- Identify key drivers of ProVac's TRIVAC cost-effectiveness model for Hib, rotavirus, and pneumococcal conjugate vaccines, or parameters that drive model results, to help countries identify which input variables require the most precision;
- Create online courses for national immunization program professionals on economic evaluations and evidence-based decision-making for new vaccine introduction, and
- Launch OLIVES, an online data repository with best available estimates for health economics data in LAC.

As factors driving the potential costs and benefits of new vaccine introduction vary across countries, the ProVac Initiative will continue to respond to country requests to conduct economic analyses and assessments of other relevant technical, programmatic and social criteria to help inform a more evidence-based decision making process. In particular, the ProVac Initiative will continue to help countries address challenges associated with decision making for HPV vaccine introduction in the Region. A comprehensive cervical cancer prevention model to estimate the costs, health gains and cost-effectiveness of HPV vaccination and of different cervical cancer screening strategies is currently under development. This tool will be made available to countries in the Region during a workshop planned for November 2011, where participants will be trained on the tool's use. Looking to the future, the ProVac Initiative will build upon existing infrastructure and capacity to address challenges associated with the evidence-based introduction of future dengue vaccines and second-generation new vaccines.

Recommendations:

- PAHO should help countries in the Region to develop an evidence base to inform future decisions with regards to dengue and second generation vaccines by rolling out a phase II of the ProVac Initiative, while continuing to build the Member States´ capacities to use economic analyses to inform the decision making process for the introduction of new vaccines.
- TAG encourages PAHO to extend technical support to Member States with the use of economic analyses in order to assess the costs and benefits of Hepatitis A vaccine introduction.

SYSTEMATIC DOCUMENTATION OF THE INTRODUCTION OF NEW VACCINES

With the development of newer vaccines, particularly rotavirus and PCV and their availability earlier in this decade, the countries in this Region have been among the first developing countries to introduce such vaccines into their national immunization schedule. The experiences and lessons learned from these countries can be valuable for decision-makers, donors, and immunization partners in the Region and globally.

From March 2010 to April 2011, a study to enhance knowledge and understanding of the process of new vaccine introduction in the Region of the Americas, focusing particularly on rotavirus and PCV, was initiated by PAHO. Its main objectives are to assess the decision-making process for new vaccine introduction, documenting the structure in place, main factors influencing the decision of introducing a new vaccine, available morbidity and mortality data prior to vaccine introduction, funding mechanisms and sources of funding for vaccine introduction, main challenges in the implementation process, and strategies used for documenting vaccine impact.

A systematic qualitative and quantitative assessment of a sub-set of countries in the Region which have introduced either rotavirus or PCV (or both) in the past 5 years was conducted. The following criteria were considered for country selection, assuming that these criteria are important determinants of the vaccine introduction decision and process: GAVI eligibility, surveillance in place prior to vaccine introduction, introduction of two new vaccines, and technology transfer agreements in place for vaccine introduction. Based on these criteria, the following countries were considered for this assessment: Bolivia, Brazil, Peru, Nicaragua, and Venezuela. All countries agreed to participate in this assessment, and their Ministries of Health officially provided authorization for data review and country level data collection and interviews.

Extensive review of available published data, official documentation, and grey literature from each country, and country specific health indicators was conducted. Interviews with key informants at the country level were conducted on site for each of them. Standardized questionnaires were developed, one for each of the key informants to be interviewed, addressing issues relevant to the particular interview.

In all countries, the potential to reduce mortality reaching the Millennium Development Goals were described as important for vaccine introduction. The decision-making process varied by country, but existing body of evidence, availability of funds for vaccine introduction, and anticipation of sustainability of the new vaccine were important factors in all countries. All countries have identified challenges during vaccine introduction. Few countries had surveillance and local disease burden data available prior to vaccine introduction. Various sources of evidence were sought to support decision making and all of the countries have implemented surveillance during or post-vaccine introduction and are planning or conducting some kind of impact assessment evaluation.

Recommendations:

- TAG welcomes this study and encourages similar experiences as other countries introduce new vaccines.
- The documentation of new vaccine introduction should include economic and cost analyses when feasible.

CHOLERA VACCINATION

After a century without cases in Haiti, a cholera outbreak erupted in mid-October 2010. As of 3 July 2011, over 202,028 hospitalized cases and 5,609 patient deaths have been reported since the beginning of the outbreak. It is a distinct possibility that cholera is now endemic in Haiti and may remain so for years to come.

At the onset of the outbreak, PAHO decided against recommending cholera vaccination in Haiti. The need to focus efforts on the provision of highly effective and time-tested rehydration treatment and on the implementation of emergency sanitation measures were key elements for that decision. Additionally, the limited availability of the pre-qualified vaccine and anticipated logistical challenges to deploy a vaccine in the post-earthquake setting were additional considerations. However, PAHO recognized that, as the epidemic progressed rapidly, the position might need reconsideration.

In mid-December 2010, PAHO convened an expert consultation. After having considered that only <300,000 vaccine doses were available in the following three months, the experts recommended using the vaccine to assess logistical and operational implications to large-scale deployments. At that time, the Haitian Government concluded that cholera vaccination would only be acceptable if large population strata were included. For that reason, discussions turned in the subsequent months towards reviving the country's routine immunization and introducing new childhood vaccines.

During the first semester of 2011, the Haitian Ministry of Health together with PAHO and other partners prepared a five-year strategic immunization plan. This plan aims to improve vaccination coverage and vaccine management, to maintain the country free of polio, measles, and rubella, to eliminate neonatal tetanus, as well as to introduce new vaccines. The latter vaccines would be pentavalent (DTP-Hib-Hep B), PCV, and rotavirus. Preliminary results indicated that the expected disease burden that is preventable by those three vaccines in children would be greater than that caused by cholera, if and when cholera was endemic in Haiti. Currently, however, all age groups are still at risk because the Haitian population was immunologically naïve to cholera prior to October 2010.

The continuation of the cholera epidemic in Haiti, despite efforts to improve water and sanitation, has made a reassessment of the potential role of cholera vaccines necessary. Over the last few months, recognized figures and opinion-makers in academia and non-governmental organizations have made repeated calls for cholera vaccination to be part of a comprehensive approach to curtail cholera in Haiti. Quantitative models have been used to show the potential impact of cholera vaccines under different scenarios and assumptions.

Cholera thrives in unsanitary environments. Sustained cholera transmission can only occur in areas with poor sanitary and hygienic conditions. Long-term improvement in water and sanitation will be essential elements in the continuing efforts to rebuild Haiti in the post 2010 earthquake era; they are also key measures towards eliminating cholera eventually. Fortunately, while repeated cholera exportations from Haiti to other countries of the Region have occurred, none has yet resulted in sustained outbreaks.

A WHO statement relating to international travel to and from countries experiencing outbreaks of cholera released in November 2010 states that vaccination of travelers is unnecessary. Travelers to cholera-prone areas should ensure respect of sanitary norms to protect themselves from water- and food-borne pathogens and not to expose the local population (should they be carrier of the cholera pathogen).

Recommendations:

- TAG sees the cholera outbreak in Haiti as a manifestation of a wider and deeper humanitarian crisis in the country and a risk for repeated exportations to countries in the Region. The outbreak thus needs to be addressed in a definitive way with the support of the regional and international communities. TAG calls on regional governments to work with the Haitian government and people towards this end.
- TAG endorses the recommendations from the December 2010 *ad hoc* Scientific Consultation on Potential Role of Cholera Vaccination in the Americas, and suggests that cholera vaccination be considered as an important complimentary tool for the control and prevention of cholera on the island of La Hispaniola. It is of critical importance to do so while ensuring that the coverage of EPI vaccines, including follow-up polio and measles-rubella campaigns, improves in a sustainable manner. TAG recognizes that cholera vaccination should not compete with the provision of other health interventions to prevent and control cholera or associated with other vaccine-preventable diseases and may thus require additional human and/or financial resources.
- TAG recognizes that in addition to the immediate benefits for the vaccinated persons, vaccination in underserved urban and rural areas could provide an invaluable opportunity to assess logistical and operational challenges in cholera vaccine deployment that are specific to Haiti. These initiatives should include the commitment and options to sustain and possibly expand the vaccination if the National Authorities decided to do so.
- TAG does not recommend vaccination of health care workers and responders present in Haiti and vaccination of international travelers to Haiti. Observation of hygienic and sanitary precautions should offer reasonable protection to oneself and others.
- Currently, cholera vaccination is not advised in any other area of the Region. Vaccination of specific groups should only occur if a risk assessment showed significant risks of cholera importation, propagation, and sustained transmission.
- Considering the global shortage of cholera vaccines, PAHO should work towards assuring a timely supply of prequalified vaccines for those countries where vaccination would be warranted. PAHO and partners should work together to mobilize resources to ensure access to and deployment of available vaccines in the Hispaniola, as necessary.

VACCINE SAFETY

Vaccination against childhood diseases is one of the greatest medical success stories of the last half century. From the perspective of the immunization programs, it is of utmost importance to guarantee vaccination safety and to respond promptly to any concerns raised by the public, so as to maintain the public confidence in immunization. Nevertheless, the implementation of mass vaccination campaigns in the past years for eliminating rubella and CRS and maintaining measles elimination, the introduction of new vaccines (rotavirus, pneumococcal, influenza A H1N1 in 2009, among others), the expansion in the use of underutilized vaccines (such as yellow fever), and the appearance of new vaccine manufacturers in emerging markets underscore the need for the successful monitoring of vaccine safety by the immunization programs. To this end, it is important to define the areas of work related to immunization safety:

- Production: ensuring that the countries acquire vaccines that are pre-qualified by the WHO.
- Logistics: ensuring that the vaccine is perfectly maintained and stored from the time it leaves the manufacturer to the time of administration.
- Administration: ensuring that safe injection practices and standards are thoroughly followed.
- ESAVI monitoring: making sure that ESAVI monitoring is implemented and when they occur, that there is a rapid and efficient response and investigation, including the final classification of the case.
- Crisis prevention: being prepared to prevent and manage a crisis, which can generate the population's mistrust towards vaccines and the immunization program. Ensuring alliances between the immunization programs and the news media and other trusted sources (for instance, scientific societies) are crucial for manage this component.

Recent events such as the influenza pandemic (H1N1) of 2009, highlighted times of uncertainty and risk that tested the public trust in the immunizations services and the vaccines. Likewise, rumors arose claiming that the vaccine contained human chorionic gonadotrophin (hCG) to confer a contraceptive effect. The rumor began anonymously, through chain emails, stating that mass vaccination activities were "genocide", by inducing sterility among vaccinated women.

The Region of the Americas has a strong vaccination culture built over the course of more than 30 years. The emergence of rumors and the manipulation of information related to possible adverse events following immunization threat the ability of children, adolescents, and adults to be timely and fully immunized. Therefore, it is imperative that countries in the Americas implement effective and timely strategies to handle rumors and manage the occurrence of ESAVIs, in order to maintain the public trust in vaccines and immunization programs, thus, protecting the gains in immunization.

Recommendations:

- Countries should develop risk communication plans as a fundamental component of their risk management (plan outlining the strategies to prevent and manage crisis), taking into account political, societal, cultural, and economical factors. The strategy of risk communication should be part of the national immunization annual plan of action, in order to ensure adequate planning before the occurrence of a crisis.

- During a crisis, transparency should be guaranteed by promptly and frequent communication with the public of what it is known and not known, and what is being done, using simple messages that consider a wide and diverse audiences.
- Countries should establish and institutionalize mechanisms for the coordination and participation of the different stakeholders (inside and outside of the health sector) involved in a rapid response to a crisis (e.g. mass media, scientific societies, medical and scientific experts, civil society organizations such as cancer leagues, women's associations and patient groups). Roles and responsibilities, and the most adequate flow of information and communication should be clearly established before a crisis emerges.
- Countries should properly document the occurrence of ESAVIs through rigorous and timely investigation, with the purpose of generating strong scientific evidence to guarantee the safety profile of all the vaccines used.
- Countries should limit the occurrence of programmatic errors by implementing adequate and permanent training and supervision to health workers, to ensure that general vaccination principles are followed.
- PAHO should continue working with countries, in collaboration with partners, to strengthen local capacity on vaccine safety through workshops for healthcare workers and journalists, with particular emphasis on fostering alliances with the media.

POST-MARKETING SURVEILLANCE OF THE ROTAVIRUS VACCINE IN THE AMERICAS

Since 2006, several countries of the Region of the Americas have initiated the introduction of the rotavirus vaccine. This Region was the first to introduce this vaccine in its national immunization programs. As of May 2011, 16 countries and territories in the Region have introduced this vaccine; 13 countries use the monovalent vaccine (Brazil, Bolivia, Cayman Islands, Colombia, Ecuador, El Salvador, Guatemala, Honduras, Mexico, Panama, Paraguay, Peru, and Venezuela), 2 use the pentavalent vaccine (Guyana and Nicaragua), and the United States uses both vaccines. In December 2009, the WHO recommended that all children receive the rotavirus vaccine as part of the regular immunization schedule.

Considering the fact that the first vaccine against rotavirus (Rotashield®, 1998) was associated with an increase in the incidence of intestinal invagination or intussusception, clinical trials of the vaccines that are currently licensed evaluated the possibility of intussusception. No increased risks were observed in any of them, even when considering that every trial involved more than 70,000 participants. Meanwhile, safety studies could not have always detected a rare event, for this reason studies and post marketing surveillance are fundamental.

PAHO has been conducting several effectiveness, safety, and impact studies with the countries of the Region in collaboration with the US CDC. The effectiveness studies that have already been published have shown that the rotavirus vaccine has had a significant impact on the reduction of severe diarrhea-caused hospitalizations and deaths in children aged <5 years.

Available information on the safety of the rotavirus vaccine includes:

- A recent safety study conducted among the Ministries of Health of Brazil and Mexico, PAHO and the US CDC, looking at risks and benefits using a methodology of case-series and case-controls, showed an intussusception risk associated with the vaccine, mainly related to the first dose in Mexico, which was not found in Brazil. According to the risks found, an excess of 1 intussusception case attributable to the monovalent vaccine out of 52,000 children in Mexico and 1 out of 76,000 children in Brazil. However, the monovalent vaccine prevents 80,000 hospitalizations and 1,300 deaths in these two countries. In Brazil, an even smaller risk was found, but associated with the second dose.
- A similar study was carried out by GSK in Mexico and also found a minimal risk of intussusception for the first dose of the monovalent vaccine.
- In Australia, post-marketing surveillance found an increase of intussusception risk for the first dose and a smaller risk for the second dose for both vaccines used in three countries (monovalent and pentavalent), meaning that there were 2 additional intussusception cases for 100,000 dose of administered vaccine. However, from the introduction of these vaccines, rotavirus diarrhea-caused hospitalizations reduced 70%. The Australian Advisory Group on Immunization (ATAGI) analyzed this information and recommended that the country continue to use the vaccine.
- In the United States, data from the CDC and an evaluation financed by Merck & Co., Inc., did not find any evidence of an increase intussusception risk when using the pentavalent vaccine. However, the analyzed data did not have a sufficient size (power) to evaluate the risk in the first week after the vaccination.

Recommendations:

- Countries should continue using the rotavirus vaccine in their routine vaccination programs because the benefits of the rotavirus vaccine with regards to diarrhea-caused hospitalizations and deaths in children aged <5 years are much greater than the risk of intussusception that this vaccine can present.
- ESAVI surveillance which evaluates any warning signals with regard to the increase of intussusception cases and complementary studies should continue to be carried-out in order to better clarify this subject.

DENGUE

During the last decade, dengue incidence has dramatically increased in LAC. Except for Uruguay and continental Chile, dengue virus transmission now occurs in all countries. In 2010, 1,663,276 clinical cases were reported throughout the Americas. Of these cases, 717,875 cases were laboratory confirmed, 48,954 cases were classified as clinically severe and 1,194 case-patients died. Since 2003, PAHO has supported Member States with the implementation of an integrated strategy for dengue prevention and control. This strategy has five components: 1) patient care, 2) social communication, 3) epidemiological surveillance, 4) vector control, and 5) laboratory capacity. As several dengue vaccines are in development, concrete prospects exist that dengue vaccination could, in a near future, be an additional component of the integrated strategy. In particular, a live-attenuated vaccine against all four dengue viruses may complete its phase III clinical trials as early as 2013 and could be licensed in 2014–2015. Consequently, an incentive exists for Member States and PAHO to prepare for the evidence-based and timely introduction of dengue vaccines, in the context of an integrated control approach.

Recommendations:

- PAHO's ProVac Initiative should continue to support national level decision-making through the use of economic evaluations grounded in local data, when available, for the future introduction of dengue vaccines. PAHO should work in coordination with other initiatives, such as the Dengue Vaccine Initiative (DVI) .
- The PAHO Secretariat should review surveillance systems to ensure that they can inform vaccination policies and allow vaccination impact monitoring.

VACCINATION AGAINST HEPATITIS

In 2010, the WHO's Strategic Advisory Group of Experts on Immunization (SAGE) asked for a Hepatitis A Working Group to review changes in immunization policy and to give input to revision of hepatitis A prevention and control policies. A working group was formed with 2 SAGE members and 5 external members including one from a PAHO country. The objective of this hepatitis A working group was to prepare for a new position paper that could be submitted following the November 2011 SAGE meeting. The last WHO position paper on hepatitis A was published in 2000. Due to the10 year time lapse, the WHO's SAGE asked the WHO secretariat to re-address the issue of a hepatitis A vaccine. As input to this work, a new module on hepatitis A vaccines was developed in the WHO Immunological Basis of Immunization series.

The Gates Foundation-funded Global Burden of Disease (GBD) Study includes death and disability-adjusted life year (DALY) estimates for hepatitis A virus (HAV) infection. As part of this project, data on the seroprevalence of HAV infection was reviewed systematically according to the GBD Study guidelines. Many countries are experiencing epidemiological transitions that may leave many persons at risk for infection and increase the benefits of use of hepatitis A vaccine. This data has been used in disease modeling to derive death and DALY estimates.

The age-specific hepatitis A vaccine prevalence was used to model age-specific forces of infection. Overall, the results suggest an increase from 117 million infections in 1990 to 121 million infections in 2005 (the rate decreased slightly but the absolute numbers increased because of the increase of the world population size). Deaths increased from 30,283 in 1990 to 35,245 in 2005. Beyond pure burden of disease estimations, economic analyses might be particularly relevant to intermediate countries and emerging economies that may face hepatitis A control issues in the coming years.

The WHO has noted an increase in the number of countries universally using hepatitis A vaccines among young children. These countries include: Argentina, Bahrain, China, Greece, Iraq, Israel, Kazakhstan, Panama, Saudi Arabia, the United States, and Uruguay with many more countries using the hepatitis A vaccine in some parts of the country. It is important to take note of the decision-making processes and experiences, especially the single-dose use of vaccine in Argentina. Countries that have introduced universal hepatitis A have noted a dramatic decrease in acute hepatitis A incidence.

The next steps are to complete systematic reviews and GRADE key evidence with respect to efficacy of vaccine for prevention pre and post exposure, provision of herd immunity, and long-term protection, as part of a report to SAGE in November 2011. This report is to serve as basis for a revision of WHO hepatitis A position paper.

Tremendous progress has been made in the prevention of hepatitis B related morbidity and mortality globally. The WHO last revised its position with respect to hepatitis B vaccines in 2009. In this document, the use of the birth dose (hepatitis B vaccine within 24 hours of birth) was recommended for all countries. Countries were also encouraged to develop goals for hepatitis B control. Prior to that, the SAGE hepatitis B working group presented information on feasibility for the elimination of hepatitis B virus (HBV) transmission; however, SAGE chose a controlled approach. Despite this global approach, a number of countries have adopted elimination strategies, including Cuba

and the United States. Much has been published on the feasibility of this approach. Clear definitions of elimination have not been developed; however, a recent PAHO mission to Cuba showed that this can be best described by data on protected birth cohorts. In Cuba, by 2010, the majority of persons born in the previous 30 years have been protected with high coverage of hepatitis B vaccines. The impact of vaccine delivery is important to document. The WHO has developed guidance on conducting serosurveys of hepatitis B surface antigen (HBsAg) among children as one method of documenting impact. Other methods include acute and chronic HBV infection surveillance and disease registry data (for cirrhosis, liver cancer).

Both the WHO's Western Pacific and Eastern Mediterranean Regions have adopted time-limited goals for hepatitis B control based on HBsAg prevalence in children. Other regions are in various stages of setting similar goals. The Western Pacific Region has a validation process for assessing the progress of HBV control using country submitted seroprevalence data and coverage data and review by an Expert Review Panel. The Eastern Mediterranean Region has a comprehensive approach that includes immunization as well as screening, care and treatment. The 2010 World Health Assembly adopted Resolution 63.18 as sponsored by Brazil, calling for the WHO to adopt a comprehensive approach to hepatitis prevention and control, and to mark World Hepatitis Day on 28 July.

Recommendations:

- All countries are encouraged to maintain high Hepatitis B (Hep-B) vaccine coverage and adhere to the 2009 WHO recommendation of using a Hep-B birth dose of the vaccine.
- Countries are encouraged to conduct epidemiological and cost-effectiveness studies for the introduction of hepatitis A vaccine to support evidence-based decisions in light of existing public health priorities.
- Countries in the Americas are urged to join the celebration of the Global Hepatitis Day on 28 July as a day to commemorate the accomplishments in the control of hepatitis and to advocate for further efforts.

NATIONAL IMMUNIZATION TECHNICAL ADVISORY GROUPS (NITAGS)

Since the early 1990s, PAHO has been supporting countries to establish or strengthen existing National Immunization Advisory Technical Groups (NITAGs) to support evidence-based immunization policy. NITAGs are independent advisory boards that make technical recommendations on immunization practices to ministries of health. Whereas PAHO's TAG and the WHO's SAGE serve to set forth policy at the regional and global level, NITAGs make specific immunization recommendations that reflect local conditions. Since disease burden, available resources and health priorities differ between countries, NITAGs serve to transfer regional and global level immunization policy into the local context.

Many LAC countries have well-established, active NITAGs. Out of nine reporting countries, five countries in Central America have established NITAGs. In South America, nine of ten countries reporting have active NITAGs. However, the degree of functionality and formality of these committees vary between countries.

Following the 2006 TAG recommendations calling for PAHO to help countries build national capacity to make evidence-based immunization policy, PAHO's ProVac Initiative began facilitating exchanges between countries in the Americas to share lessons and experiences regarding their NITAGs. Since 2008, 28 committee members from 14 countries have observed advisory committee meetings on immunization practices in Canada and the United States. During such meetings, the delegates exchange experiences about their committees and explore opportunities to continue strengthening their committees. In addition, NITAG chairs from 19 countries participated in PAHO sub-regional meetings on vaccine-preventable diseases in 2010. The XIX TAG included the participation of NITAG chairs from the entire Region.

PAHO has developed operational guidelines for NITAGs. These guidelines aim to help countries establish NITAGs or strengthen existing NITAG practices. The guidelines call for NITAGs to be independent and chartered through an administrative or legal decree. These guidelines lay out how countries should clearly define the membership selection process, term limits, roles and responsibilities of members, and committee operational procedures. Since operational standards and procedures for NITAGs may vary between countries, PAHO seeks a TAG recommendation to encourage countries to formalize NITAG practices and procedures through the use of formal administrative or legal decrees and national operational guidelines.

Recommendations:

- TAG underscores the role of NITAGs in providing technical and policy advice to national immunization programs and governments.
- PAHO should continue to facilitate the sharing of experiences and best practices among NITAGs and other related mechanisms.
- Countries should formalize the roles, responsibilities and procedures of NITAGs through an administrative or legal decree, underscoring the committees' independence from the ministry of health.
- Countries should draft national guidelines for NITAG procedures and practices. Guidelines should address membership selection processes, including steps to ensure multidisciplinary representation on the committee, term limits, voting

procedures, and process by which committee recommendations are presented to national authorities. In addition, there is a need to have clear procedures for managing and disclosing both real and perceived conflicts of interest.

NOMINAL IMMUNIZATION REGISTRIES

Following a presentation on coverage data quality in 2009, TAG restated its recommendation calling for the systematic and periodic assessment of coverage data accuracy, consistency, completeness, and timeliness as a regular activity within national immunization programs, in the context of ongoing supervision activities; among other related recommendations. Noting that nominal immunization registries, such as those used in Uruguay (since 1987) and in Mexico (since 1998), facilitate monitoring coverage by birth cohort and following-up children with incomplete vaccination schedules, TAG also recommended that countries using national computerized nominal immunization registries documented their experiences, successes, and lessons learned in order to share them with other countries.

National computerized nominal immunization registries have been defined as computerized population-based and confidential information systems/databases that include data on vaccine doses administered nationwide. Two characteristics of these registries are highly desirable: 1) it should provide reports and other outputs to facilitate monitoring vaccination coverage by vaccine, dose, geographical area, age (or other target group) and provider and 2) it should provide outputs to facilitate the individualized and timely follow-up of vaccination schedules and the identification of defaulters.

Following the 2009 TAG recommendation on nominal immunization registries, PAHO has been facilitating visits from representatives of countries developing nominal registries to countries that are already using such registries or that are more advanced in the process. In February 2011, PAHO also conducted a workshop in Bogotá, Colombia where information technology and immunization professionals from 20 countries of the Americas shared lessons learned on the development and implementation of national computerized nominal immunization registries. It is expected that the topic of nominal immunization registries also be covered during the Caribbean EPI managers meeting in late 2011.

Countries currently using national nominal immunization registries include Mexico, Panama, Uruguay, and some Caribbean islands. Currently, Brazil, Belize,[5] Chile, Colombia, Costa Rica, and Paraguay are in different stages of implementation of their national nominal immunization registries. Argentina, the Dominican Republic, Ecuador, Honduras, and Peru are all in the earlier stages of developing this type of registry. Also, as of the end of 2010, 49 of 50 states plus Washington D. C. and three other cities in the United States have implemented a functional nominal immunization registry.

Participants of the Bogotá workshop agreed on the following good practices: 1) clear objectives and scope for a computerized immunization registry must be defined, 2) a collaborative and transparent decision-making process is essential, 3) agreeing on technical and functional standards beforehand is highly important, and 4) once implemented in the field, training and supportive supervision of staff and data managers must be ongoing to ensure that accurate and reliable information is routinely captured by the system. The participants expressed their desire to have PAHO's TAG comment on the issue of national nominal immunization registries.

[5] As part of the Belize Health Information System (BHIS)

A community of practice i.e., an Internet-based site for all stakeholders to share documents, experiences, and exchange ideas and information is being set up. Additionally, a document that will summarize lessons learned, best practices, and problems and proposed solutions for issues related to the development, and implementation of national computerized nominal immunization registries in the Region is being developed.

Recommendations:

- TAG welcomes the progress on the development and implementation of national computerized nominal immunization registries in the Region.
- Countries and PAHO should continue documenting and exchanging experiences on the development and implementation of computerized nominal immunization registries.
- Nominal immunization registries should aim at ensuring interoperability with other information systems.
- PAHO should work in coordination with other sectors and initiatives related to e-government, information and communication technologies (ICTs), birth registration, among others.

VACCINE LAWS AND FINANCING

Established in 1977, the Expanded Program on Immunization (EPI) in the Americas received substantial support from external donors throughout the 1980s for polio eradication efforts. During this time, countries drafted Plans of Action (PoA) to guide external donor resource allocation based on identified needs and priorities. By the early 1990s, the EPI had achieved a substantial reduction in vaccine-preventable diseases, attracting new stakeholders such as parliaments and civil society actors. In recognition of the need to maintain EPI gains and confront new challenges for vaccine-preventable diseases, many governments and parliaments passed vaccine legislation to protect budget lines for vaccine purchasing and program financing. From 1987 to 2008, national funding for EPI expenditures increased by 20%. Today, LAC countries cover 99% of the cost of their national programs.

In the past decade, TAG has made several recommendations calling for countries to establish vaccine laws to protect budget lines and to spur improvements in vaccination coverage rates, particularly in low-coverage municipalities. In 2004, TAG declared that efforts should be made to follow examples of countries in the Americas that have developed legislation to establish a specific budget line in the national budget in order to commit resources for recurrent costs associated with supply purchasing. In 2010, PAHO undertook an analysis of vaccines laws in the Americas to assess the legal landscape for immunization and identify best practices to share with countries without national vaccine laws. The content analysis identified three primary characteristics of vaccine laws: declarative, financial, and operational. Declarative aspects of vaccine legislation protect vaccines as a public good and guarantee gratuity. Financial and operational aspects protect financing mechanisms, charter technical advisory bodies and establish operational procedures for outbreak control, among other features. While the scope and reach of legislation varies, at least 27 countries have passed or are crafting national immunization legal frameworks. In 1988, the Americas had enacted only six national vaccine laws. Two decades later, almost 20 countries have endorsed vaccine laws. Experience demonstrates that vaccine laws have enabled national immunization programs to secure fiscal space to sustain programmatic gains, address the unfinished agenda and confront new challenges associated with new, more costly vaccines.

Bolivia has enacted a comprehensive legal framework protecting program financing and vaccine purchasing, establishing operational procedures and endorsing vaccines as a free, public good. As such, the experience of Bolivia, among other countries, should be shared both with countries entering the process of crafting and passing vaccine legislation and with countries seeking to improve their existing legal frameworks. PAHO will continue disseminating lessons learned about vaccine legislation to advocate that countries ensure financial sustainability of EPI activities to protect programmatic gains.

Recommendations:

- TAG reemphasizes previous recommendations regarding vaccine legislation and financing.
- TAG encourages countries to follow the example of Member States that have established legal frameworks to protect and ensure financial sustainability of national immunization programs.

VACCINATION WEEK IN THE AMERICAS

In 2011, Vaccination Week in the Americas (VWA) was celebrated for the 9th time in the Region under the theme "*Vaccinate your Family, Protect your Community".* This is an initiative which seeks to promote equity and access to vaccination, the transition from child to family immunization, and Pan Americanism or solidarity between countries. Over the history of the initiative more than 350 million individual of all ages have been vaccinated under the framework of VWA. In 2011, 45 countries and territories targeted approximately 41 million individuals in a wide variety of vaccination campaigns. Additionally, countries carried out a diverse range of social communication and educational activities and some chose to integrate other preventative interventions with their vaccination efforts. As in prior years, multiple VWA launching events were held throughout the Region. Such events received high level political priority, counting on the participation of high level authorities and international partners and highlighting the work of national immunization programs to the general public.

The success of VWA has come to serve as a model for the implementation of simultaneous sister initiatives in other WHO Regions, inspiring a growing movement towards a World Vaccination Week.

- In 2011, the European Region celebrated the sixth anniversary of European Immunization Week (EIW) which was launched during a Regional ceremony in Brussels, Belgium on 26 April. Fifty-two countries participated in the initiative this year, under the theme of *"Shared solutions to common threats,"* to highlight the importance of collaboration for the control of vaccine-preventable diseases, such as the recent measles outbreaks in this Region.
- Despite the political instability the Eastern Mediterranean Region witnessed first few months of 2011, a majority of their Member States' participation in the second celebration of Vaccination Week in the Eastern Mediterranean (VWEM). This year's slogan was *"Partnership for Immunization".* A Regional launching ceremony was held in Cairo, Egypt and national launches were celebrated in all participating countries, including the participation of high level authorities.
- Both the African and Western Pacific Regions celebrated their first vaccination week initiatives in 2011. The slogan chosen for African Vaccination Week (AVM) was *"Vaccinated communities, Healthy communities,"* and the theme for the 2011 initiative was "Put mothers and children first; Vaccinate and stop polio now". Approximately 35 countries participated in the inaugural AVM which was launched in Kinshasa, Democratic Republic of the Congo. The slogan for the first Vaccination Week in the Western Pacific was *"A healthy future for your family."* The initiative was launched during the 100th meeting of WHO Country Representatives and Liaison Officers in Manila, Philippines and thirty-one countries, including China, took part.

Over the last several years, PAHO has provided technical support to other Regions as they have come on board with their own initiatives. Technical staff members have participated in vaccination/immunization week planning workshops in Europe, the Eastern Mediterranean and Africa to share experiences and lessons learned from the Americas. PAHO's area of Knowledge Management and Communication (KMC) has also collaborated with other Regions in the design of their graphic logos and initiative branding, and in the production of communal promotional videos. PAHO has also hosted technical staff from Europe (October 2010), Africa (May 2010) and Southeast Asia (May 2011) on study tours to the Americas to learn about the planning and implementation of

VWA at the Regional level. The South East Asian Region has expressed its commitment to implement a vaccination week initiative in 2012; with this addition all WHO Regions will be implementing their own vaccination week efforts, ten years after VWA first began in the Americas.

TAG congratulates all countries and territories in the Region for their exemplary achievements over the history of VWA.

Recommendations:

- VWA should continue to be supported as an initiative that strengthens routine vaccination programs in the Region by targeting hard-to-reach populations for vaccination, enhancing collaboration across borders and highlighting 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 immunization programs are prioritized.
- VWA should continue to be used as a platform for the integration of other preventative interventions with immunization.
- Countries should explore different methodologies to evaluate the impact of VWA on the regular immunization program.
- TAG also recommends that countries advocate for and support a Resolution to be brought before the World Health Assembly in 2012 to formalize the implementation of a World Vaccination Week.

ANNEX 1

Meeting of the Measles and Rubella Laboratory Network for the Region of the Americas

The annual Meeting of the Measles and Rubella Laboratory Network for the Region of the Americas was held at the Centers for Disease Control and Prevention (CDC) Headquarters in Atlanta, GA, USA on 20-21 June 2011. Representatives from the Regional Reference Laboratories (RRLs), the Global Specialized Laboratory (GSL), WHO, PAHO, representatives from 24 countries, and the Caribbean Epidemiological Centre (CAREC), in representation of the English-Speaking Caribbean, participated in the meeting. It was co-chaired by Dr. Paul Rota (CDC) and Dr. Marilda Siqueira (FIOCRUZ).

This meeting highlighted the achievements of the countries in the Region, addressed new challenges for diagnosing measles, rubella, and CRS, and challenges for the final classification of sporadic cases.

The objectives of this meeting were to:

- Review progress and identify the challenges in meeting laboratory-based requirements for documentation of regional elimination of measles, rubella, and CRS in 2011 and 2012.
- Gather information to help develop the laboratory training course on methods to achieve and maintain measles, rubella, and CRS elimination to be taught in FIOCRUZ in late August 2011.
- Facilitate, through presentations and discussions, the ability of participating national laboratories to support surveillance to monitor the maintenance of elimination of measles, rubella, and CRS beyond 2011.
- Review laboratory management and develop a plan for continued management of the laboratory network.
- Facilitate interactions between laboratories and with the Regional Reference Laboratories (RRLs: FIOCRUZ, CDC and Canada) and GSL (CDC) on technical laboratory issues.
- Provide laboratories with updated information about laboratory methods and data reporting.
- Develop strategies to strengthen communication between laboratory and public health epidemiology.

The presentations and discussions included:

- Guidelines for laboratory testing with an emphasis on testing strategies to be used in low-incidence settings.
- Utility of additional laboratory tests/algorithms/guidelines in low-incidence settings (e.g. avidity testing).
- Turnaround time for various laboratory tests (for measles, rubella and CRS).
- Discussions of the importance of inclusion of both laboratory and epidemiologic/demographic data in final case classifications, especially in a low-incidence setting.
- Presentations/discussions on specific criterion for elimination of measles and rubella from PAHO.

- Small group discussions with RRL, GSL and WHO/HQ staff on technical issues.

Draft recommendations:

Documentation of elimination of measles, rubella, and CRS in the Region of the Americas

- Laboratories should collect and evaluate laboratory data required for documentation and maintenance of national elimination goals for measles, rubella, and CRS.
    - In the next 6-10 months, national laboratories should seek advice from RRLs and GSLs on case classification when necessary and, after discussions with these laboratories, submit appropriate specimens to RRLs or other network laboratories for additional testing. This should include confirmation of positive IgM results when necessary, and additional testing, such as RT-PCR, avidity, which may not be available in the national laboratory. Laboratories should use the PAHO Laboratory Guidelines and the checklist for sporadic cases (Appendix the Lab Guidelines) for guidance on determining the need for additional testing.
    - A plan of action for testing should be developed which will be used to test samples for sporadic cases and outbreaks and monitor the maintenance of elimination. RRLs and the regional laboratory coordinator will develop a plan of action. It is anticipated that this plan will include establishing molecular diagnostics in most national laboratories and performing specialized testing in specific network laboratories through a defined referral system.
- Develop strategies to strengthen communication between the measles and rubella laboratory and public health epidemiology units. Laboratories should take appropriate steps to develop organizational arrangements necessary for the documentation and maintenance of national elimination goals for measles, rubella, and CRS. These include coordinated case classification using all available epidemiologic and laboratory data through direct discussions between epidemiology and laboratory teams regarding all available data. Laboratory and epidemiological staff should meet at least once a month to reconcile data, identify data omissions and decide on any further specimen collection and testing required for the classification of cases.
- In order to verify measles, rubella and CRS elimination every lab in the network should monitor all the indicators referring to the lab as described in the components of the Plan of Action for the documentation and verification of the elimination.

Laboratory Management

- PAHO headquarters should work with RRLs and GSL to manage the laboratory network in the Americas. PAHO will continue to manage kit distribution and other essential organizational activities, and facilitate and support essential technical activities in RRLs and GSL such as accreditation of laboratories and development and evaluation of testing protocols.
- Because of the demand for laboratory support for regional documentation and verification of measles, rubella and CRS, and because of the compressed timeline that network laboratories will require to receive the additional training and support needed to establish new testing procedures and strategies, PAHO

should support a laboratory coordinator dedicated to measles, rubella and CRS for at least a period of 2 years.

- PAHO, the GSL and RRLs should work to improve communications between the network laboratories and develop methods to rapidly disseminate information regarding new methods, recent outbreaks, and changes in testing procedures. PAHO should consider developing a newsletter that can be distributed to the laboratories. In addition, periodic web based meetings should be held with laboratory staff, epidemiologists, RRLs, CDC, and PAHO to discuss case classification. Ad hoc meetings should be also be considered for consultation on complex case classifications.
- A meeting of the regional and sub-regional reference laboratories should take place in 2011.

Challenges for the diagnosis of measles, rubella, and CRS in low incidence settings.

- Laboratories should be aware of important information on case classification other than the results of laboratory testing, including timing of the use of various diagnostic tests and the effectiveness of diagnostic tests in specific situations (e.g. PPV of 1 and multiple defect suspected CRS cases). Laboratories should bring this type of information to discussions with epidemiologic teams concerning case classification.
- Laboratories should achieve and maintain the level of technical expertise necessary to maintain laboratory surveillance capacity to monitor measles, rubella, and CRS elimination. This expertise should include molecular testing. To facilitate this, PAHO will support a regional laboratory training workshop at FIOCRUZ in August 2011 and another workshop at a location to be determined in the first quarter of 2012.
- National laboratories with sufficient capacity are encouraged to use molecular tests, especially real time RT-PCR for measles and rubella to aid in case confirmation.
- The validated avidity test for measles IgG that is performed at the CDC is not available in commercial format. Laboratories should send samples requiring measles avidity testing to CDC after consultation with PAHO and CDC. To facilitate this process, laboratories should use the checklist developed by CDC to help determinate the need for avidity testing. The CDC avidity test will be transferred to other RRLs if there is an increased demand for testing or to improve turnaround time.
- The avidity test for rubella IgG is commercially available, and PAHO, the RRLs and GSLs should conduct a workshop or meeting to standardize the methods and the interpretations of results and to develop a specimen referral protocol as well as a quality control program for the laboratories that are performing avidity testing.
- Recognizing that laboratory confirmation of CRS cases requires an understanding of the timing of various diagnostic tests relative to the appearance of markers of disease; laboratories should become familiar with this timing and with managing receipt of specimens from sources outside the rash and fever surveillance network such as neonatologists and pediatricians. Laboratories need to report findings to the epidemiologic teams in the country.

Molecular epidemiology

- Laboratories should encourage collection of samples for virus detection in an attempt to obtain genetic information from at least 80% of confirmed outbreaks of measles and rubella.
- Timely reporting of genotype information and sequence data are essential for rapid confirmation of viral importation. NLs that are performing sequencing should report measles sequences to and rubella genotype information to the WHO database. RRLs performing sequence analysis for NLs should submit the sequence information to MeaNS and the WHO database after obtaining permission from the NL. It is important that all relevant epidemiological data be included with the sequence information so that the submitting laboratory can submit complete reports. Laboratories are reminded of the need to share sequence data within at least 2 months of sample collection and that this performance indicator is monitored in the WHO accreditation process.
- Future training workshops should include activities to increase the regional capacity for sequencing and sequence analysis in addition to molecular diagnostic techniques.
- Molecular epidemiologic data are often limited for countries in the region, especially for rubella viruses. Nevertheless, laboratories must seek to use such data to the extent possible in support of documentation of elimination of measles, rubella, and CRS as required by the Plan of Action.

Quality Control

- Laboratories should continue to perform quality control for serologic testing as required for WHO accreditation. National labs are strongly encouraged to provide a proficiency testing program for any sub national labs in their country.
- The WHO accreditation process is an important component of the quality control process and laboratory results to support documentation of elimination must be provided by an accredited laboratory. Laboratories should be accredited on an annual basis either by paper accreditation or by a site visit. PAHO should conduct site visits to the NLs and RRLs on a rotating basis so that all laboratories are visited once every 3 years. A priority list of laboratories to be reviewed should be developed in consultation with PAHO, RRLs and GSLs. PAHO will conduct site visits in 4 countries by the end of 2011.
- Sub-national laboratory (SNL) proficiency testing is a critical measure of the quality of the laboratory surveillance program in countries which have SNLs, but identifying sufficient volumes of IgM positive samples has been a challenge in many countries. Efforts should be made globally to collect large volumes of IgM positive measles and rubella serum for use in the SNL LabNet in the region and support RRLs in the region to produce a SNL proficiency testing panel.
- In many countries, the SNLs perform a critical role in surveillance for measles and rubella by conducting a large volume of the primary serologic testing. However, successfully, managing a network of SNLs requires a substantial effort from the NL. To document these management activities, the WHO accreditation checklist for NLs should be modified to include a summary of the performance of each SNL and a description of the management activities performed by the NL.
- Laboratories in the PAHO network should work with the LabNet laboratories in other regions to develop a quality control program for molecular testing.

- Laboratories are strongly encouraged to use the standard PCR controls and standardized kits provided by CDC for molecular testing and confirmation of viral isolation.
- Laboratories should document any suspected problems with the performance of the Siemens kits for detection of IgM to measles and rubella. The laboratory coordinator, in consultation with the GSL and RRLs, will develop a protocol to assist laboratories with monitoring assays performance. Problems with assay performance should also be reported to WHO/HQ and CDC.