Pan American Health Organization

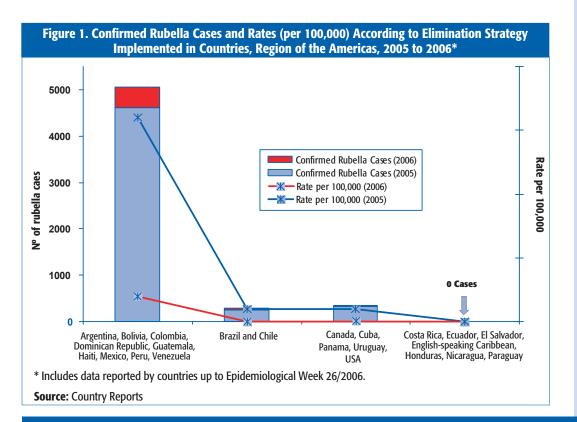
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XVII TAG Meeting - Protecting the Health of the Americas: Moving from Child to Family Immunization

The XVII Meeting of the Technical Advisory Group (TAG) on Vaccine-preventable Diseases of the Pan American Health Organization (PAHO) was held from 25-27 July 2006 in Guatemala City, Guatemala. TAG meets every two years and functions as the principal forum for providing advice to PAHO Member States on vaccine policies and disease control efforts. The following is a summary of TAG's technical deliberation and recommendations as presented in the final report.

TAG recognized the substantial progress achieved by member countries since the last meeting in 2004. This year's meeting focused on the new challenges involving the transition from child to family immunization and the unfinished agenda.

Dr. Ciro de Quadros, Chairman of the TAG, opened the meeting. He was followed by Dr. Rudy Eggers, WHO, Geneva, who reiterated the call for action on rubella elimination. Dr. Mercy Ahun presented on behalf of the Global Alliance for Vaccines and Immunization (GAVI), highlighting the need to continue to support the world's poorest countries. Dr. Gina Tambini, Manager, Family and Community Health Area, PAHO, provided participants with an update on the status of the follow-up of recommendations of the 2004 TAG meeting in Mexico City. Representatives from partner organizations such as the US Centers for Disease Control and Pre-



Ad-hoc Meeting of Experts to Establish Best Practices in CRS Surveillance

During the XVI Meeting of the Technical Advisory Group (TAG) on Vaccine-preventable Diseases in November 2004, recommendations were made to enhance the progress already achieved in the Region toward the goal of rubella and congenital rubella syndrome (CRS) elimination. One principal recommendation was the proposal for PAHO to convene an *ad-hoc* meeting of experts to define good public health practices for strengthening CRS surveillance.

The rubella and CRS elimination strategies implemented in the Americas have resulted in substantial progress to date. As countries of the Region progress towards elimination, new challenges for the detection of suspected CRS cases have become evident. Quality of rubella and CRS surveillance remains a key challenge.

The *Ad-hoc* Meeting of Experts to Establish Best Practices in CRS Surveillance was held in Washington, D.C., on 10-11 July 2006. Experts from Argentina, Australia, Brazil, Canada, Costa Rica, Ecuador, India, Mexico, Nicaragua, Peru, the United Kingdom, the United States, and Venezuela presented lessons learned from their experiences. Professionals in areas of ophthalmology, cardiology and audiology shared their experiences in working with CRS-affected children.

1 XVII TAG Meeting: Final Recommendations

1 Ad-hoc Meeting of Experts to Establish Best Practices in CRS Surveillance

See **AD-HOC MEETING** page 7

vention (CDC), GAVI, PATH, Sabin Vaccine Institute, and UNICEF made statements of support to immunization programs in the Region. Dr. Joxel García, Deputy Director, PAHO, and Marco Tulio Sosa, Minister of Health of Guatemala, officially opened the meeting by making remarks stressing the importance of achieving and sustaining Regional initiatives such as measles and rubella elimination. Dr. Jon Kim Andrus and Dr. Tambini served as *ad-hoc* Co-Secretaries of the meeting.

Rubella and Congenital Rubella Syndrome

TAG congratulates member countries for the significant progress made toward the goal of rubella and Congenital Rubella Syndrome (CRS) elimination by 2010. The number of confirmed rubella cases decreased by 96.2% between 1998 and 2005 (from 135.947 to 5.209).¹ The impact has been greater in countries that vaccinated men and women (0 rubella cases, after the campaigns) compared with countries where only women were vaccinated (N = 254, rate = 0.1 per 100,000). Rubella incidence was greater in the group of countries that have not yet implemented vaccination campaigns (N = 4,618, rate = 1.6 per 100,000) (Figure 1). By June 2006, 37 (80%) of the countries and territories of the Americas had implemented vaccination campaigns (accounting for 75% of the population of the Region), obtaining coverages of over 95%. The seven remaining countries are expected to complete their campaigns by June 2007.

Comprehensive surveillance of measles and

1 Provisional data as of Epidemiological Week 28, 2006.

How to Achieve Rubella Elimination:

In their efforts to achieve elimination, countries should conduct a one-time mass campaign, vaccinating both men and women with MR or MMR¹ vaccine. To ensure the implementation of the highest quality campaigns, the following criteria should be fulfilled:

- → The age group to be vaccinated should be determined based on the epidemiology of rubella in the country, an assessment of the susceptible population, the year of vaccine introduction, subsequent rubella vaccination campaigns, and the need to protect women of childbearing age (WCBAs).
- 1 Safety and supply/cost concerns should be considered when using MMR.

rubella has been strengthened. By epidemiologic week 26 of 2006, 97% of suspect cases had been discarded following laboratory testing. Prior to implementing the elimination strategy, less than 20% of rubella cases were confirmed by laboratory or epidemiological link; this figure rose to 96% in 2005.

The seven surveillance indicators endorsed by the 2004 TAG are as follows: the percentage of sites reporting weekly, the percentage of suspect cases with adequate epidemiological investigation, the percentage of cases with adequate blood sample, the percentage of samples received by the laboratory ≤ 5 days, the percentage of laboratory results reported ≤ 4 days, the percentage of cases discarded by laboratory, and the number of chains of transmission with representative samples for viral isolation. Overall, performance for three of these indicators is weak. Up to week 26 of 2006, the percentage of cases with adequate investigation was only 78%, only 56% of samples reached the laboratory within 5 days, and only 69% of laboratory results were reported within 4 days. Furthermore, very few samples for virus isolation have been collected to date.

The best public health practices are being identified to improve CRS surveillance at the primary care level, strengthen the capacity to diagnose deficiencies in health services, and ensure expert review of suspect CRS cases (see article on page 1). The goal of CRS surveillance is to monitor trends, help identify reservoirs of transmission, and to serve as a critical advocacy tool. In 2005, 1,952 suspect CRS cases were reported and 20 were confirmed.¹ By

- → Quality campaigns require vaccinating both females and males, including susceptible adults, and reaching coverage levels close to 100% of the targeted population.
- → The highest political commitment and participation should be ensured.
- → Full population participation requires intensive social mobilization and local micro-planning.
- \rightarrow Information system should be practical and useful.
- → Capacity to detect and rapidly respond to safety concerns and other emerging issues during campaigns.

epidemiological week 26 of 2006, 342 suspect CRS cases had been reported and one was confirmed.

Advances have been made in the development of laboratory capacity to detect and isolate rubella viruses, increasing knowledge of the endemic genotypes in the Region. The most frequent genotype is 1C, followed by 1E, and 1g. The last two genotypes were linked to imported cases in epidemiologic investigations. However, the number of specimens for rubella virus isolation is still limited (in 2005, only 93 specimens were collected for isolation) and should be substantially increased to better document endemic virus reservoirs and imported virus genotypes.

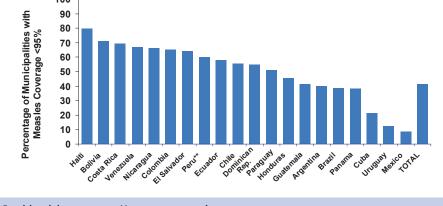
TAG was concerned that insufficient laboratory results are being reported within 4 days of receipt of the sample at the laboratory. In some countries, the timeliness of this indicator is being affected by the number of subnational laboratories that do not receive enough samples to process them immediately. These laboratories wait to accumulate samples before processing them in order to avoid wasting their kits. In other countries, the indicator is being affected by the delayed entry of the laboratory result into the national database.

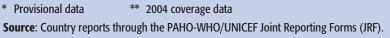
Recommendations:

1. Vaccination Strategies

- In accordance with previous TAG recommendations, all endemic countries are encouraged to implement a one-time mass vaccination campaign targeting both men and women and achieving >95% coverage.
- TAG recommends that the criteria for high quality campaigns outlined in the box at left be included in the design and implementation of rubella mass vaccination campaigns. Those countries that did not vaccinate all susceptibles in the population should analyze their data, in particular to identify the susceptible male population (in which sustained transmission can occur) that should be vaccinated. PAHO should provide support in this process.
- TAG encourages countries to document the experiences, successes, and lessons learned from their adult mass campaigns in order to share them with other countries. These lessons will be useful for the introduction of HPV vaccine and eventually a vaccine against HIV/ AIDS.
- 2. Surveillance
- Full integration of measles and rubella surveillance is required; integrated laboratories are an important aspect of this surveillance system. Emphasis must be placed on active surveillance. Except in outbreak settings, all







specimens must be tested for both measles and rubella.

- Countries should ensure that the seven indicators meet the recommended standards.
 Special attention should be given to checking clusters of suspect cases as well as "silent areas".
- 3. Laboratory
- The number of clinical specimens collected for viral isolation should be increased in order to document the endemic genotypes of rubella and the interruption of endemic transmission of rubella in the Americas.
- In a pregnant woman, IgM should be obtained only when there is a history of rash or contact with a rubella-like rash. IgM is NOT recommended for routine antenatal testing.
- The serological and virological laboratory testing of all suspected CRS cases should be encouraged.
- TAG recommends that PAHO review the laboratory network, with special attention to the subnational networks, to identify the possible bottlenecks and propose corrective actions.

Measles

Absence of widespread measles virus transmission since November 2002 is proof of the success of the measles elimination initiative in the Americas. However, the endemic measles virus circulation in other parts of the world puts our Region under constant threat of importations. Fifty-one percent of the 370 measles cases reported in the Americas between January 2003 and April 2006 were positively linked to an importation. Importations occurred from all other WHO Regions. Six outbreaks with >10 cases were detected since 2003 (range = 10-108 cases).

Countries must avoid becoming complacent to the risk of measles importation and the potential for reestablishment of endemic measles transmission. Occurrence of measles cases among children aged 1-4 years in outbreaks in Mexico and Venezuela indicates a weakening of routine vaccination. National follow-up campaigns that should have been conducted every 3 to 4 years have either been cancelled or postponed indefinitely in some countries. Finally, indicators of integrated measles/rubella surveillance have not shown improvement or have worsened. While coverage with measles-containing vaccine at regional level was 93% in 2004, 42% of municipalities had coverage below 95%- an indication that coverage remains uneven and that significant pockets of susceptible groups exist in our Region.

Recommendations:

- Countries should identify municipalities with less than 95% coverage for measlescontaining vaccine and devise strategies to reach and maintain coverage in the 95%– 100% range in every municipality.
- High-quality nationwide *follow-up* campaigns (achieving coverage ≥95% in every municipality) should be conducted every 3 to 4 years (earlier if a susceptible accumulation above 80% of a typical birth cohort has accumulated), irrespective of whether a second MMR dose is included in the national routine immunization schedule. Only where coverage ≥95% with each of the two MMR doses is

Routine Immunization

While the reported coverage at national level is high throughout the Region, heterogeneity in coverage exists at municipal level, with a significant proportion of municipalities reporting coverage <95% (Figure 2). TAG reaffirms the recommendation that all countries should achieve ≥95% vaccination coverage with all antigens in every municipality.

guaranteed for all municipalities can the *fol-low-up* campaigns be waived.

- Vaccination of at-risk professional groups, such as workers in the health care, transportation, and tourism sectors, is recommended and should be verified regularly through an established formal process.
- Any resident of the Americas traveling to areas with reported measles (or rubella) cases should be immune to measles (and rubella) before departure. Requesting proof of vaccination from incoming travelers is not advised.
- Integrated surveillance for measles/rubella should include private institutions, including those attended by tourists, to increase sensitivity and timely detection of imported cases.

Poliomyelitis

The Western Hemisphere was certified as free of the circulation of the indigenous wild poliovirus in 1994 and the last case of poliomyelitis caused by a wild poliovirus was detected in Peru in 1991. Acute flaccid paralysis (AFP) surveillance remains in place in the Region of the Americas. The AFP rate continues above 1/100,000 children aged <15 years and the proportion of adequate specimens remains at approximately 80%. The level of compliance with the last indicator underscores the need for an independent body to help every country with classifying the remaining 20% of cases (around 400–500 cases per year) without adequate specimens.

The feasibility of global polio eradication in the near future was reaffirmed in 2005 by the Advisory Committee on Polio Eradication (ACPE)

PAN AMERICAN HEALTH ORGANIZATION

and at the World Health Assembly in May 2006. Indigenous polio transmission is still occurring in Nigeria, India, Pakistan, and Afghanistan, while several other countries previously free of polio have been recently re-infected. These include some African countries, such as Angola, which have close ties with the Americas. Therefore, after fifteen years of being free of wild polioviruses, the Region remains at constant risk of polio importations from countries where wild poliovirus still circulates widely. The number of polio cases worldwide was 1,255 in 2004, and 1,951 in 2005.

Recommendations:

- OPV remains the vaccine of choice in the final phase of global polio eradication.
- To reduce the risk of importations and to prevent another outbreak caused by a Sabin-derived poliovirus, countries that do not achieve OPV coverage ≥95% in every municipality must conduct annual OPV immunization campaigns for children aged <5 years, regardless of their vaccination status.
- Countries must maintain high quality AFP surveillance, strengthen the polio laboratory network, and complete phase I of laboratory containment of wild poliovirus by the end of 2006. PAHO should establish a panel of experts to review country reports on laboratory containment and provide feedback to the countries. All countries in the Region must maintain high polio vaccination coverage of at least 95% of children aged <5 years in every municipality.
- Countries should establish a national expert group or commission that closely scrutinizes the compatible polio cases without adequate stool specimens. Every one of those cases must have a written report specifying the final classification and the criteria used by the expert group to determine that classification.

New and Underutilized Vaccines

Several new vaccines have been developed in the last decade and several others are in the process of development. This extraordinary progress in biotechnology will provide the medical armamentarium with several new vaccines, and the countries will be faced with a major challenge of incorporating them into their national immunization programs whenever warranted.

Countries are therefore encouraged to review criteria for introduction of new vaccines, and use the lessons learned from the introduction of other vaccines such as *Haemophilus influenzae* type b (Hib) and hepatitis B. Burden of disease studies and economic analysis, along with several other activities, are essential to the decision-making process. Regarding the new vaccines against rotavirus, pneumococcus, and HPV, the main activity is to prioritize the coordination of work with organizations and groups that have already developed plans for control of diarrhea, acute respiratory diseases, and cervical cancer.

Because the price of these new vaccines will be substantially higher than that of traditional childhood vaccines, the introduction of new vaccines will have to be based on evidence that they are cost-effective. To that end, PAHO is developing a methodology for the training of national immunization program managers on the evaluation of the cost-effectiveness of these new technologies. This initiative is called Pro-Vac and will be launched in September 2006, with a regional workshop to be held in Washington, D.C.

Recommendation:

 Countries should conduct economic analyses to provide evidence for the assessment of the introduction of intervention measures. These analyses must follow standardized methodologies for result comparison, in accordance with the PAHO Pro-Vac initiative.

Recommendations for New and Underutilized Vaccines:

- 1. <u>Rotavirus</u>
- All countries of the Region should implement highly sensitive and standardized surveillance of rotavirus diarrhea in sentinel hospitals by the end of 2006. The objective is to characterize the epidemiological profile and burden of the disease in the Region, and obtain data allowing evidence-based decisiontaking regarding vaccine introduction.
- All countries should send rotavirus diarrhea surveillance data to the PAHO regional surveillance system on a monthly basis so they can be consolidated at regional level and fed back to the member countries.
- A great proportion of hospitalized diarrheal cases do not meet the standard proposed case definition. PAHO should assist countries to better understand the standard case definition and promote wide distribution of the guidelines and training of health professionals in its use.
- Countries must assess their cold chain capacity at all levels, immunization schedules, and availability of human resources and consider training of health providers on the use of ro-

tavirus vaccine as a step prior to its introduction.

- 2. <u>Pneumococcus</u>
- Based on the guidelines that will be prepared, countries should implement epidemiological surveillance of pneumonias and meningitis in children aged <5 years to assess the burden of disease and its profile in the population.
- PAHO should support the expansion of the laboratory network capacity developed with the original SIREVA project to strengthen its capacity for the serotyping of pneumococcus isolates.
- Support for pneumococcus surveillance is a top priority and the support now provided by PAHO should be sustained beyond the current two-year grant period for which resources have been made available.
- 3. Human Papillomavirus
- TAG acknowledges PAHO's work in taking a regional approach for the introduction of HPV vaccine and strongly recommends that it continue this process. TAG encourages countries to take all necessary steps to ensure early introduction, particularly in countries that have poor screening programs.
- PAHO should convene an *ad-hoc* meeting of experts to discuss the most appropriate strategies and effective tools for HPV surveillance in Latin America and the Caribbean.
- PAHO should support the conduct of HPV surveillance pilot projects in some selected member countries in order to demonstrate how the surveillance system would be operationalized, its costs, and the required information system.
- PAHO should continue to work with its partners and manufacturers to ensure that HPV vaccines are affordable and available equitably in Latin America and the Caribbean.
- TAG endorses the recommendations of the Second Meeting on Partnering for HPV Vaccine Introduction held in Guatemala on 24 July 2006.
- 4. Yellow Fever
- Countries with enzootic areas should consider yellow fever a public health priority, gathering all the political, technical, and financial support to continue with implementation of national plans for yellow fever prevention and control.
- It is essential to complete vaccination of all the population residing in enzootic areas and in communities where immigration to enzootic areas originates. The strengthening of the

information system and analysis is crucial to evaluate and monitor the plans in order to focus vaccination in municipalities or areas with low vaccination coverage.

- The three remaining countries that have not yet done so, should include yellow fever vaccine in their national schedule so the vaccine is administered at the same time as MMR to children reaching one year of age.
- Countries should continue to improve the quality and sensitivity of the epidemiological surveillance for yellow fever. In non-enzootic areas, outbreak control measures should be strengthened and include increasing the sensitivity of the surveillance system, improving the capacity for adequate outbreak response, maintaining a vaccine supply at national level, and conducting vector control to avoid re-urbanization of the disease.
- 5. Seasonal Influenza
- All countries must strengthen the surveillance system to determine the burden of influenza, the cost-effectiveness of introducing influenza vaccine, and its impact, and to decide on the best vaccination strategy to use and when, particularly in tropical areas. PAHO should provide and disseminate guidelines on the use of the vaccine to countries.
- TAG recommends that all countries establish a seasonal influenza vaccination policy that aims to vaccinate children aged 6-23 months, health care workers, chronically ill individuals, and elderly adults.
- Countries using the vaccine should generate vaccination coverage data and document experiences and lessons learned from targeting high-risk groups. This will be useful for countries currently introducing the vaccine and in the event of a pandemic.
- PAHO should continue to promote mechanisms for the transfer of technology to increase Regional vaccine production capacities and keep track of global supply.
- 6. Pandemic Influenza
- All countries should continue strengthening, updating, and implementing their influenza pandemic preparedness plans. It is essential these plans be implemented at local level. TAG encourages countries to operationalize country plans by implementing drills with local involvement.
- PAHO should continue to hold the workshops for the preparation of national plans and stimulate the exchange of information on national preparedness through simulation exercises.

Strengthening Program Management

Countries of the Americas have used several mechanisms for managing and supervising their immunization programs. These include periodic program evaluation, plans of action, microplans at the local level, interagency coordination committees (ICCs), national immunization advisory committees, periodic supervision, feedback to the local level that includes coverage rates and surveillance data, periodic evaluation of immunization data quality, budget line for vaccine purchase and immunization program implementation, and vaccine legislation. PAHO regularly monitors several of the components listed using the annual EPI tables for immunization data collection (now also known as PAHO-WHO/ UNICEF Joint Reporting Form for the Americas or JRF).

An analysis of selected program management components using data available at the Regional level for 2004 and 2005 found that most countries are conducting internal evaluations of their programs. Although some countries have had an international EPI evaluation, TAG noted that the number of these important multidisciplinary program reviews has diminished. Additionally, all countries of Latin America and the Caribbean reported having annual plans of action and most also have 5-year plans; most of these plans are shared with PAHO. In 2005, 13 Latin American and 4 Caribbean countries reported having ICCs. With regards to national immunization advisory committees. 3 countries in Latin America have vet to create such committees. Most countries submitted their EPI tables in May, one month after the requested deadline. Countries that submitted the tables late were more likely to send incomplete information, usually including only coverage and/or morbidity data. Feedback to the local level, usually including at least coverage and surveillance data, seems to be adequate for countries reporting this information.

In 2002, TAG recommended that all countries use standardized supervision protocols covering program components, and that sufficient financial resources be allocated for the implementation of regular supervision. In 2004 and 2005, only about half of Latin American and Caribbean countries reported on the proportion of municipalities supervised at least once each year. Of those countries reporting, supervision took place in all municipalities in roughly 60% and 85% of Latin American and Caribbean countries, respectively.

Recommendations:

- The components included in the program management section of PAHO's EPI tables (*JRF for the Americas*) are time-tested tools and need to be fully implemented and documented by countries.
- International program evaluations should be performed in each country at least every three years.
- TAG reiterates the previous recommendation that supervision should be strengthened at all levels of the health system.

Vaccination Week in the Americas

The yearly initiative for Vaccination Week in the Americas (VWA) was endorsed by Resolution CD44.R1 of PAHO's 2003 Directing Council. VWA is based on the principles of equity, access, and Pan Americanism. This initiative provides an opportunity to strengthen the routine immunization program, reach vulnerable populations with low vaccination coverage, and promote regional and border cooperation.

In its four years of existence, participation in the VWA has increased from 19 countries during its first year (2003) to 40 countries and territories in 2006. These countries have incorporated VWA activities into their annual operational plans.

Emulating the experience in the Americas, the WHO Region for Europe launched its first vaccination week in October 2005, and the second one is planned for October 2006. In 2007, the vaccination week in the WHO Region for Europe will take place in April 2007, to coincide with the 2007 VWA.

Recommendation:

 VWA should be bolstered as a Regional strategy that allows the strengthening of the regional program and reducing of immunization inequities. Efforts should continue to identify and vaccinate vulnerable populations and measure the impact of interventions in those groups.

Vaccine Safety

As vaccine-preventable diseases become less prevalent thanks to the implementation of effective immunization programs, greater attention must be paid to events supposedly attributable to vaccination or immunization (ESAVIs). ESAVIs must be fully investigated in order to discard them or establish a cause-andeffect relationship with the vaccine. Vaccination safety is a priority component of immunization

Financial Sustainability of National Immunization Programs

New generation vaccines against killer infections will ultimately help countries meet the targets of WHO's Global Immunization Vision and Strategy (GIVS) and the Millennium Development Goals (MDGs). Countries will be challenged to sustain the gains, while completing the unfinished agenda of reaching all children, eliminating rubella, and introducing new vaccines when appropriate. To achieve the targets, countries will require substantial additional financing for national immunization programs. PAHO proposes a Regional strategy directed to:

- Reduceinequitybyreachingtheunreached in districts with poor coverage;
- Strive to reach mortality reduction targets toward the achievement of the MDGs and targets outlined in GIVS for diseases caused by rotavirus and pneumococcus, while strengthening information and surveillance systems;
- Support strengthened national capacity to make evidence-based policy decisions regarding vaccine introduction through strategic partnerships with key global and regional institutions;
- Transition from childhood to family immunization;
- Expand fiscal space for resource allocation to national immunization programs; and
- Attain unprecedented levels of participation in the PAHO Revolving Fund for Vaccine Procurement through clear demonstration of the benefits to countries.

programs. Its purpose is to guarantee the use of quality vaccines, safe injection practices, ESAVI monitoring, and strengthening of partnerships with the media. These activities are crucial to maintain the credibility of immunization programs within the community.

The definition of a safe injection is based on three essential aspects: security for the individual receiving the injection, security for the health worker, and security for the community and environment. This includes the use of disposable syringes, preferably AD syringes, the disposal of waste in safety boxes, and the adequate management of these materials for final disposal through incineration. National leadership in immunization and public health is at a cross-roads. Best practice in making and implementing informed decisions for public health requires policy makers to consider the usual epidemiologic, demographic, and management data. Evidence to assess the balance between economic costs of vaccination and economic savings and health benefits from disease prevention is also key to responsible decision-making.

Recommendations:

- Countries should use available tools and information for economic analysis to assist decision-making on sustaining national immunization programs and new vaccine introduction. Countries are encouraged to participate in the planned Pro-Vac workshop in September 2006, organized by PAHO.
- Countries should assess existing health legislation and regulations to ensure that national laws (a) promote family immunization through specific provisions including no-cost, obligatory vaccination; (b) recognize the importance of immunization within the health budget and make specific provision for purchase of vaccines; (c) contribute to low transaction costs for vaccine procurement; and (d) create a supportive environment for national vaccine production where relevant.
- Countries should assess fiscal space for new vaccine introduction and investigate new sources of sustainable funding for immunization, including new indirect taxes

on consumable goods with negative health impacts.

- TAG strongly encourages countries to strengthen their participation in the Revolving Fund, benefiting from savings obtained through bulk purchasing, contributing where relevant to vaccine and syringe supply, and sharing immunization assets in times of crisis, in a spirit of Pan Americanism.
- PAHO should explore the possibilities of increasing the capitalization of the Revolving Fund through negotiations with partners, including GAVI, as well as the donation of funds from member countries.
- PAHO should continue to support regional and country efforts to reduce total vaccine supply chain costs and improve the quality and timeliness of Revolving Fund operations.
- TAG strongly supports and is pleased to learn of the recommendation of PAHO's Executive Committee to endorse the above-summarized Regional Strategy for Sustaining National Immunization Programs in the Americas. TAG recommends that the document that will be presented to the September 2006 Directing Council meeting be expanded to include a discussion of the situation of the capitalization of the Revolving Fund for Vaccine Procurement.

National Regulatory Agencies (NRAs) are responsible for ensuring the use of safe and effective vaccines to support immunization programs. A new challenge for NRAs is the introduction on the market of new vaccines (rotavirus and human papillomavirus) not registered in the country of origin, nor previously used in other countries.

Recommendations:

- Countries should strengthen their ESAVI reporting and investigation systems. This will allow early detection and adequate investigation. Establishing causality and responding to the population quickly with transparency will help maintain the credibility of immunization programs.
- Cooperation at country level between the national immunization programs and NRAs is essential to monitor adverse events due to new vaccines in order to better appreciate the safety of new vaccines.
- Countries that are part of the network for notification of adverse events due to new vaccines should exchange information on a regular basis so they are ready to act in case of unusual events or greater occurrence of events than expected. Those countries that are not yet participating in the network should do so as soon as possible.

Note: For a complete copy of the report, please contact the Immunization Unit at <u>fch-im@paho.org</u> or refer to the unit's webpage at www.paho.org/immunization.

PAN AMERICAN HEALTH ORGANIZATION

AD-HOC MEETING from page 1

The goal of the meeting was to develop best practices for the detection and surveillance of suspect CRS cases in the Region. Meeting participants shared experiences and lessons learned in order to generate recommendations for enhanced detection and improved surveillance of suspect CRS cases. They upgraded the existing guidelines to be disseminated to public health workers, and also identified opportunities to increase awareness among physicians and other health workers regarding CRS detection.

The following table summarizes the final conclusions and recommendations of the meeting.

Topics	Conclusions and Recommendations
Goals of CRS surveillance	 The mains goals of CRS surveillance should include: a) Monitoring trends; b) Assessing the impact of immunization programs; c) Identifying reservoirs of transmission; d) Helping to develop or modify program policy, if appropriate; e) Verifying the interruption of endemic transmission of rubella virus in the Americas, including identification of imported cases; and f) Serving as a critical advocacy tool.
Defects and key findings in a neonate or infant that should alert a physician to a suspect CRS case	 Hearing impairment is the most common defect, followed by cardiac and eye defects. Key findings that may alert a physician include: a) Suspicion of hearing impairment by simple observational testing; b) Sweating, palpitations, rapid heart beat, and changes of skin color for cardiac problems; and c) Absence of red eye reflex.
Sensitivity and quality of CRS surveillance	 A sensitive case definition should be implemented by using key findings/signals that can be detected at the primary care level. Clinical guidelines and practical tools should be developed for use at the primary care level to improve detection of signals/alerts for hearing impairment, cardiovascular problems, and eye defects. Awareness of health workers, health students, communities, and families should be increased through training. Sentinel site reporting – including secondary and tertiary hospitals, specialty clinics, specialists, and the use of TORCH¹ as a differential diagnosis – should be strengthened. Serological and virological laboratory testing of all suspect CRS cases should be encouraged. Partnerships with specialists should be built and interprogrammatic coordination strengthened. Quality and flow of information should be maintained through staff training and feedback to all levels of health services.
Role of routine screening for certain defects such as hearing impairment or red eye reflex	 Because of limited resources, many countries will not be able to use OAEs² or ABRs.³ These countries may want to explore the use of simple observational hearing tests. Routine screening of major defects can lead to early treatment and intervention. This is particularly important for infants with hearing impairment. Routine auscultation of the heart can assist in the diagnosis of congenital heart defects. A majority of cataracts can be identified by using simple techniques such as red reflex.
CRS awareness among physicians and other health workers in hospitals and primary care settings for detecting suspect CRS cases in their patient populations	 Health workers, including students in health careers, should be trained on CRS signs and clinical findings. Health promoters, midwives, families, and communities should be trained on how to detect CRS signals/alerts. A training plan for health workers to increase awareness about the clinical, laboratory, and epidemiologic aspects of rubella and CRS should be developed. Training materials must be designed with the participation of different health programs. New educational technology such as long distance learning and "virtual public health campus" can be used.
Systems that can be used to identify CRS cases	 CRS cases can also be identified by: a) Reviewing birth defects registers such the National Congenital Malformation Registers and ECLAMC⁴ for compatible signs and symptoms; and b) Strengthening the interprogrammatic use of information from sources such as the Perinatal Information Systems of CLAP,⁵ and national databases related to child and maternal health.
Role of the laboratory in CRS surveillance in the context of rubella and CRS elimination	 Laboratory confirmation of cases is critical. The collection of specimens for viral isolation is necessary to understand the molecular epidemiology and differentiate between endemic transmission and imported cases. The coordination between epidemiologist and the laboratory is critical. Both groups should actively participate in activities pertaining to the surveillance system.
Rubella IgM in a pregnant woman	• IgM should be obtained ONLY when there is a history of rash or contact with a rubella-like rash. IgM is NOT recommended for routine antenatal testing.

1 TORCHS stands for Toxoplasma gondii; other viruses (HIV and more); rubella (German measles); cytomegalovirus; herpes simplex; and syphilis.

2 Otoacustic emissions testing.

3 Auditory brainstem response.

4 ECLAMC: Spanish acronym for the Latin American Collaborative Study on Congenital Malformations.

5 CLAP: Spanish acronym for the Latin American Center for Perinatology and Human Development.

Activities to be coordinated between the epidemiology and laboratory groups	 A practical guide should be developed for specimen collection, description, and indication for use, and interpretation of laboratory tests and results. Appropriate training material should be developed, including topics such as clinical manifestations, epidemiology, and laboratory. A group of national experts should be formed that would meet regularly to examine the current epidemiology, evaluate the status of the vaccination program, and address unresolved issues.
Coordination of rubella and CRS activities	 Rubella and CRS surveillance activities should be coordinated at all levels of the health care system. Proper CRS case follow-up (including diagnosis, treatment, and classification) should be ensured by designating a surveillance coordinator. The use of the information system supported by PAHO should help to ensure consistency and opportunity of data collection and analysis. A multidisciplinary team should be established to evaluate and classify suspect rubella and CRS cases and regularly assess the adequacy of the surveillance system.
Role of non-physicians such as audiologists and personnel from schools for the deaf and/or blind	 Inclusion of personnel caring for deaf and/or blind children and adults is important when setting up a CRS surveillance system. Personnel can be included as part of the multidisciplinary teams and networks to disseminate and share information.
Role of professional societies	 There should be a strong partnership between public health institutions and professional societies in all countries. CRS surveillance can be promoted through congresses, conferences, web pages, bulletins, and journals of these societies.
Evaluation and monitoring of CRS surveillance for completeness of reporting and verification of rubella and CRS elimination	 Three aspects of the system need to be evaluated periodically: a) Completeness of CRS reporting. This may include retrospective searches in secondary and tertiary hospitals and schools for the deaf or blind; b) Functionality and efficiency of the system at the peripheral and national levels; and c) Evaluation of quality and completeness of data, specimen collection, and transportation.
Mechanisms for sharing and disseminating information	 Networks that include physician groups, professional and academic societies, and NGOs should be formed. PAHO should assist with these CRS information dissemination efforts.

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