XXIII Meeting of PAHO’s Technical Advisory Group on Vaccine-preventable Diseases

The XXIII Meeting of the Technical Advisory Group (TAG) on Vaccine-preventable Diseases of the Pan American Health Organization (PAHO) was held in Varadero, Cuba on 1-3 July 2015. The slogan for the meeting was “Bye-bye rubella! Let’s go for more!” selected in recognition of the recent certification of the regional elimination of rubella and Congenital Rubella Syndrome (CRS). The objectives of this meeting were to present the regional adaptation of the Global Vaccine Action Plan (GVAP), to review the progress on several disease elimination and control initiatives and to issue recommendations to address the many challenges faced by national immunization programs in the Americas.

PAHO’s Assistant Director, Dr. Francisco Becerra, welcomed everyone and gave introductory remarks. Following Dr. Becerra, Dr. Peter Figueroa, was introduced as the newly appointed TAG Chair, a role he served in interim during the XXII TAG meeting after the passing of former chair Dr. Ciro de Quadros. Dr. Figueroa is a former member of the World Health Organization’s (WHO) Strategic Advisory Group of Experts on Immunization (SAGE), as well as a TAG member since 1991. He will now preside as PAHO TAG Chair for the next four year term.

This XXIII Meeting of the TAG was different from past meetings in many ways. These included that it was the first regional immunization meeting of its size and magnitude to be hosted in Cuba. Additionally, this XXIII TAG Meeting was the first time the Regional Immunization Action Plan (RIAP) was officially presented to the TAG and to all PAHO Member States.

This plan was approved by PAHO’s Executive Committee and was presented to and approved by the Directing Council in September 2015. The RIAP provides an outline for the next five years, serving not only as the regional adaptation of the GVAP but also as the official Regional Strategy and Plan of Action (2016 – 2020). The introduction of the RIAP serves to reinforce the Expanded Program on Immunization’s (EPI) foundations and provide additional guidance for meeting the ever-increasing challenges faced by programs in the Region. The RIAP has four strategic lines of action: a) sustain the achievements; b) complete the unfinished agenda in order to prevent and control vaccine-preventable diseases; c) tackle new challenges in the introduction of vaccines and assess their impact; and d) strengthen health services for effective vaccine administration. Finally, the RIAP intends to successfully guide PAHO Member States through the second half of the Decade of Vaccines.

Regional Immunization Action Plan

Since the inception of the Expanded Program on Immunization (EPI) 38 years ago, countries and territories in the Americas have made significant strides in protecting their populations against vaccine-preventable diseases. Many Member States consider immunization a public good and a political priority; national immunization programs have also contributed significantly to the progress towards reaching the Millennium Development Goals.

From 2005-2013, coverage with the third dose of DPT reached a sustained 90% or higher on average in the Region; however, coverage has stagnated in recent years. Provisional data for 2014, however, shows that regional DPT3 coverage dropped to 88%. As of 2013, the Americas ranked third in DPT3 coverage, when compared to other regions of the World Health Organization. The Region has remained on the forefront in the sustainable introduction of new vaccines; to date, 24 countries and territories have introduced the pneumococcal conjugate vaccine, 18 countries and territories have introduced the rotavirus vaccine and 22 countries and territories have introduced the vaccine against human papilloma virus. In 2015, the elimination of rubella and Congenital Rubella Syndrome (CRS) was officially declared and – with the exception of Haiti – neonatal tetanus is no longer a public health problem in the Region.

The work of national immunization programs protects individuals across the life cycle from deadly diseases and related suffering. The success of a program is based on strong performance across a multitude of areas, activities and strategies, including country ownership and financial sustainability by securing the political priority of the program and a legal framework for immunization, careful planning and coordination, procurement of a safe and uninterrupted supply of vaccines and injection supplies, maintenance of the cold chain, training, supervision and monitoring.

1 The topics presented in this issue of the Immunization Newsletter were marked “For decision” at the 2015 TAG Meeting. A complete list of topics and recommendations from the TAG Meeting can be found in the 2015 TAG Report, accessible online at http://www.paho.org/immunization/TAG-Reports.

2 Specific information and dates related to the RIAP referenced in this issue of the Immunization Newsletter have been updated to reflect progress made since July 2015.

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epidemiological surveillance and laboratory capacities, and communication and social mobilization. The efforts of national immunization programs also do not happen in isolation; they are instead an integral part of national health systems and contribute to the achievement of universal health coverage.

Upcoming immunization challenges facing the Region are numerous and include: certifying the elimination of the endemic transmission of measles; adding a dose of the injectable polio vaccine and switching from the use of tOPV to bOPV, in accordance with the Polio Eradication and Endgame Strategic Plan, 2013-2018; overcoming a limited global supply of certain biologicals; identifying better strategies to reach vulnerable populations at the local level and improve coverage; and improving the quality of immunization data and its use for decision-making and strategic intervention.

In order to provide strategic guidance to confront these challenges and achieve technical excellence, an overarching regional framework for immunization is critical. Over the last eight years (2007-2015), PAHO’s Regional Immunization Vision and Strategy (RIVS) – approved by the 50th annual Directing Council through Resolution CD50.R5 – has served this purpose, as the strategic roadmap for national immunization programs across the Region.

In 2010, the global health community began work on the Decade of Vaccines Collaboration, with the goal of establishing the global vision for national immunization programs through the year 2020. This participatory, multifaceted effort culminated in the development of the Global Vaccine Action Plan (GVAP), which was subsequently endorsed by the World Health Assembly in May 2012 through resolution WHA65.17. As part of this process, it was established that all regions of the World Health Organization would be responsible for adapting the GVAP to fit their own specific and unique contexts.

In October 2012, the contents of the GVAP were presented to the TAG and it was reaffirmed that the Region would move forward in tailoring the global goals and strategies to the fit needs of Member States in the Americas; this new Regional Immunization Action Plan (RIAP) will extend the RIVS framework when it expires in 2015 as the strategic document for immunization in the Americas. During the TAG meeting in July 2013, an additional presentation was given on the GVAP framework for monitoring, evaluation and accountability; this framework set forth a global structure for regular monitoring of the GVAP at all levels of implementation, including the global, regional and national levels.

In anticipation of the transition from the RIVS to the GVAP adaptation for the Americas, the PAHO Secretariat developed a proposal for the RIAP that was presented during the 156th session of the PAHO Executive Committee in June 2015. The RIAP was also presented and approved at the 54th Directing Council in September 2015. The draft proposal was the product of a wide consultation process over the past year. The proposed strategies, objectives and monitoring framework were developed considering PAHO’s Strategic Plan 2014-2019, as well as other regional and global level action plans, including the Polio Endgame. Within the Region, EPI managers and PAHO immunization focal points have provided feedback to align the document with the current challenges faced at the national level to move the immunization agenda forward. Other key partners have provided additional comments on the targets and monitoring framework proposed.

Through its four strategic areas of work, the RIAP 2016-2020 aims to provide Member States with the justification, guiding principles, objectives, and monitoring and evaluation (M&E) frameworks to enable national immunization programs in the Region to align successfully with the GVAP and implement strategies to ensure that all citizens of the Americas will benefit from immunization, regardless of where they are born, who they are, or where they live, until 2020 and beyond. The RIAP also encourages countries to take a more active role to achieve universal health coverage and address inequities and social determinants of health to ensure the protection of all individuals against vaccine-preventable diseases.

Recommendations:

- TAG commends countries for the significant achievements and health gains of their immunization programs, in particular the certification as the first Region to have eliminated rubella and Congenital Rubella Syndrome.
- At the same time, TAG notes with grave concern the decrease in DPT3, Polio3 and MCV1 coverage in the Americas at national, subnational and municipal levels in recent years. Therefore, TAG calls on countries and PAHO to recommit themselves to universal immunization coverage, based on the principles of equity and solidarity, in the context of achieving universal health coverage for all.
- The TAG endorses the Regional Immunization Action Plan as the overarching regional framework to realize the vision of well-integrated, comprehensive immunization programs in the countries of the Americas.
- TAG urges Member States and PAHO to sustain health gains, prevent the reintroduction of controlled or eliminated diseases, and successfully implement the RIAP.
- TAG recommends that the health benefits, economic benefits, and cost-effectiveness of immunization in the Americas be clearly documented for policy makers, so that they fully appreciate the compelling case for investing in national immunization programs and how these benefits are linked to achieving GVAP goals.
- TAG urges PAHO to develop a communication strategy, in order to better educate the people in all sectors of society of the Americas regarding the value of immunization, to promote the demand for vaccination and its recognition as a social responsibility, and the consequences of not sustaining high coverage in terms of lives, disease, and costs.
- TAG urges Member States to identify unvaccinated populations and reach them through prioritizing the most vulnerable, including populations living in remote, peri-urban and/or border areas, and belonging to special social groups (i.e. indigenous communities) in order to diminish inequities in health.
- TAG urges Member States to analyze their own data at the national, regional and local level in order to generate strategies to strengthen the routine immunization program and monitor the implementation of the RIAP/GVAP.
- TAG urges PAHO to identify ways to provide technical assistance and mobilize additional funding to support country efforts to implement the RIAP/GVAP, with an emphasis on improving coverage from the local to the national level and introduce new vaccines, where the evidence indicates. TAG urges Member States to assure adequate resources to strengthen the foundation of national immunization programs.
Monitoring Immunization Progress in the Americas with the PAHO/WHO-UNICEF Joint Reporting Form

Background
PAHO/WHO and UNICEF jointly collect information on the structure, policies, performance and impact of national immunization programs every year. Since the 1980’s, PAHO has collected immunization data using the EPI Tables, initially several times a year and then every six months. Historically, WHO and UNICEF have also collected immunization data. These organizations completed this data collection on separate timelines, despite the fact that each organization requested similar information from countries. Beginning in 1998, WHO and UNICEF merged their data collection and processing exercises through a Joint Reporting Form on Immunization (JRF) and in 2005, PAHO adapted the EPI tables to merge them with those of the WHO/UNICEF JRF. The structure and content of the JRF is now defined jointly by WHO headquarters and its regional offices (including PAHO), as well as by UNICEF. It is reviewed every 2 years and the last JRF review took place in September 2014.

The JRF is a tool used for a comprehensive data collection process. Ultimately, the objective of this process is to obtain accurate, up-to-date data on the progress of immunization programs from all WHO/UNICEF Member States globally and disseminate information to all immunization stakeholders. The data reported through the JRF is the official information source from countries and is available on the web at www.paho.org/immunization/data. It is also disseminated in at least three of PAHO’s printed publications: the Immunization Newsletter, the annual brochure “Immunization in the Americas” and in immunization country profiles. Similarly, WHO and UNICEF use JRF data to produce six annual publications, articles and reports with worldwide distribution.

The process of completing the JRF also aids countries in standardizing, organizing and producing useful data for the management of their own immunization programs, as well as in evaluating the progress made. At the regional level, the data collected through the JRF helps PAHO identify the strengths and challenges faced by its Member States. This data also contributes to the formulation of regional immunization strategies, including prioritizing areas of technical cooperation with countries.

At the 2012 World Health Assembly, all WHO Member States endorsed the Global Vaccine Action Plan (GVAP) and its monitoring and accountability framework. During the 2015 Directing Council, PAHO Member States approved the adoption of the Regional Immunization Action Plan (RIAP), which is the adaptation of the GVAP for the context of the Americas. The RIAP will provide a regional roadmap for achieving immunization goals at both the regional and global (GVAP) level. The JRF will be the official data source for monitoring the implementation of the RIAP and the progress towards achieving the targets set forth at both the regional and global level.

While the JRF offers a standardized structure and process for reporting against key indicators, this data is only useful in as far as the country-level reporting is complete, adhering to high-quality standards and submitted in accordance with the regional and global level deadlines. Late submissions and incomplete reporting result in significant data gaps and misinformation, which may impede informed policymaking and the development of regional and global strategies. In the Americas, only 20 countries and territories submitted their 2015 JRFs by April, the official cutoff for submissions. An additional 20 countries and territories completed the submission process for JRFs during the months of May and June (as of 25 June). Beginning in 2015, PAHO has made efforts to produce automated country reports from the JRF data to provide a feedback loop to countries as a means of validation.

Other challenges related to reporting inconsistencies and missing data can also have repercussions, including more delays in the publication of official data at the regional and global level, incorrect conclusions from the data and, in general, the dissemination of misinformation. In the worst case scenario, analysis of some indicators becomes impossible due to poor quality and/or missing data points. Examples that illustrate some of these challenges in terms of JRF data are presented in the following sections, related specifically to vaccination financing data and overall vaccination coverage.

Monitoring sustainable financing for immunization in the Americas
For nearly two decades, PAHO Member States have routinely reported their expenditures on vaccines and vaccination supplies. More recently, countries have reported on the operational budget and execution for immunization services, including recurrent costs such as salaries, maintenance of vehicles and cold chains, social mobilization activities, to name a few. Historically, Member States have matched expenditures against the same planning categories used for the annual plans of action and draw from official budget execution reports. Since 2006, the WHO-UNICEF JRF has included six immunization expenditure indicators.

Four indicators are expressed in absolute values (US$ or local currency):

- Total expenditure on routine immunization, including vaccines
- Government expenditure on routine immunization, including vaccines
- Total expenditure on vaccines - used for routine immunization
- Government expenditure on vaccines only - used for routine immunization

Two indicators expressed in percentages (%):

- Percentage of routine immunization expenditure financed by government
- Percentage of vaccine only expenditure used for routine immunization - financed by government

The overall objective of these indicators is to indicate the extent to which countries are moving towards financial sustainability and greater country ownership, while introducing new vaccines and increasing universal access to immunizations. As countries in the Region and elsewhere have consistently reported against these six indicators, analysis reveals that the operational definition of the indicators and understanding of their use has changed over the years, resulting in challenges both for the countries reporting and the regional and global levels using the data to monitor trends. The WHO and PAHO are committed to supporting countries in their understanding, estimation, and use of immunization expenditure data, in order to track progress towards sustainable financing. PAHO has developed guidance for categorizing expenditures in the annual plans of action, which should ideally facilitate how expenditures are reported. Also, some countries have received support from PAHO to estimate the cost of immunization services, including the health systems shared costs – though, these expenditures should not be included in the official JRF expenditure indicators.

The GVAP has given high priority to country ownership and the financial sustainability of immunization programs. In its accountability and monitoring framework, “domestic expenditures for immunization per person targeted” is one of the key indicators to monitor progress toward government commitment to national immunization programs. These indicators are becoming more strategic and increasingly used to evaluate and to inform immunization policy at the global, regional and country levels. Interest in improving the quality and completeness of fiscal data has increased since 2000 as governments in the Americas and elsewhere have substantially increased their investment in expanding immunization services, both in terms of the populations targeted and the vaccines offered. For example, the proportion of total available financing from government sources has on average reached 90% or more, and in most years surpassed 99% during the period between 2009 and 2013. The increase in total financing with origin from domestic revenue sources indicates a strong push in the Region towards sustainability for the program. Despite the absolute large incremental hike in resource needs, governments have consistently been able to source their programs with national funds.

However, the current quality, timeliness and accuracy of immunization and vaccine expenditure data for the full range of countries in the Region are weak and vary considerably among countries and reporting year. Errors,
Inconsistencies, and missing data are frequently identified when compiling and analyzing the data in time series. There are a number of issues that have contributed to reporting problems, including the limited clarity and understanding of the indicators and instructions; difficulty in accessing actual expenditure data; and lack of capacity, skills and incentives to collect, estimate, validate, and report the correct data. These limitations are hindering efforts to assess progress towards sustainable financing objectives and to make financing and strategic decisions based on strong evidence at the global, regional and country levels.

Immunization coverage trends in the Americas

With the approval of the GVAP’s M&E framework, the World Health Assembly established a series of four immunization coverage indicators on which progress should be reported annually. These indicators were adapted for the Region and incorporated into the RIAP. Based on preliminary JRF data received for 2014 (from 40 out of 42 countries and territories), regional results for these indicators are listed as follows:

1) Number of countries reporting national average coverage of at least 95% with DPT3 in children less than 1 year old.
   - Preliminary reported regional DPT3 coverage for 2014 was 88%, compared with 90% in 2013. Looking at overall trends, reported regional DPT3 coverage has steadily decreased over the last four years. In 2014, 15 out of 40 countries and territories reported national DPT3 coverage greater than 95%; 20 countries and territories reported coverage between 80% and 94%; and three reported coverage between 50% and 79%.

2) Number of countries reporting coverage of at least 95% in each district or equivalent with DPT3 in children less than 1 year old.
   - When examining equity in coverage at the subnational level, 42% of all municipalities in the Region reported coverage of at least 95% for DPT3 in 2014; this was a decrease in comparison to 2013 (46% of all municipalities).

3) Number of countries and territories that have a dropout rate below 5% between the first and the third dose of DPT.
   - Across the Region, in 2014 the DPT dropout rate was below 5% in 22 countries and territories. Seven countries reported negative dropout rates, or having administered more third doses than first doses of DPT.

4) Number of countries and territories with coverage of at least 95% for DPT3 sustained for three or more consecutive years.
   - Twelve countries or territories reported coverage of at least 95% over the last 3 or more years (2012–2014); in contrast, over the last three years, 23 countries and territories have never reported national DPT3 coverage greater than 95%. Additionally, three countries reported a drop in DPT3 coverage greater than 5%, when comparing 2013 to 2014.

The combination of the decreasing trend in reported regional DPT3 coverage, with decreases in the percentage of municipalities reporting coverage over 95% is of great concern. Given that viruses such as measles, rubella, and polio continue to circulate in other regions of the world, stagnant or decreasing coverage in the Americas places the immunization achievements of the entire Region at risk and requires collective action in order to confront.

Recommendations:
- PAHO should work with countries to identify obstacles encountered in the proper completion of the JRF and to streamline the reporting and data collection processes.
- In turn, TAG calls on countries to improve the quality, completeness and timeliness of JRF reporting, as the JRF is the official tool for reporting against global and regional immunization program targets in the GVAP and RIAP.
- TAG encourages countries to routinely assess the financial sustainability of their programs, using the tools in the JRF and other tools from PAHO, such as COSTVAC and the expenditure tracking tool in the quarterly Plans of Action Reporting of Expenditures.
- PAHO should develop training materials and distribute specific guidance on the data sources and methods required for correctly collecting data used in the JRF; using new technologies where applicable.
- PAHO should further the dissemination of JRF data and systematize the production of immunization country profiles.

Update on the Status of Measles, Rubella, and Congenital Rubella Syndrome Elimination

On the 22nd and 23rd of April, 2015, the International Expert Committee (IEC) for Measles and Rubella Elimination in the Americas reviewed epidemiological evidence presented by PAHO/WHO Member States and determined that the Region had eliminated the endemic transmission of rubella and Congenital Rubella Syndrome (CRS). The last confirmed endemic rubella case was reported in February of 2009 in Argentina, while the date of birth of the last confirmed CRS case was August 26, 2009 in Brazil.

To accomplish this goal, PAHO developed a rubella and CRS elimination strategy, aligned with the measles elimination strategies. This strategy calls for the (1) introduction of a rubella-containing vaccine into routine immunization programs for children aged 12 months, reaching >95% coverage in all municipalities; (2) implementation of a one-time mass vaccination campaign among adolescents and adults, in an estimated range of 15-49 years of age (“acceleration campaigns”) and periodic follow-up campaigns among children aged 5 years; and (3) the integration of rubella surveillance with measles surveillance and the implementation of CRS surveillance.

Since 2010, 57 imported rubella cases have been reported in eight countries: Argentina (4), Brazil (1), Canada (17), Chile (1), Colombia (2), French Guyana (1), Mexico (2) and the United States (29). Regarding CRS, 4 imported cases have been reported in Canada (1 in 2011) and United States (3 in 2012). In 2015, no imported cases of rubella or CRS have been reported.

The IEC also noted that, in the near future, it hopes to be able to declare the Region free of measles. Endemic measles transmission had been interrupted in the Region in November 2002. Nevertheless, in recent years, imported cases from other regions of the world have produced significant measles outbreaks in several countries. The total count across the Americas of imported cases from 2003 to 2014 reached 5,086 cases, most of which occurred in 2011 (n=1,369) and 2014 (n=1,824). In 2015, a total of 543 cases have been reported“ mainly in Brazil (n=161), Canada (n=195), Chile (n=7), Mexico (n=1), Peru (n=4) and the United States (n=175).

During the April meeting with the IEC, Brazil presented the current epidemiological situation of the sustained measles outbreak affecting the states of Ceara and Pernambuco. After updating
the figures through the weekly measles bulletins, the number of confirmed cases reached 1,109\(^6\) for the period 2013-2015. The outbreak remains active in the state of Ceará (n=855), specifically in the municipalities of Fortaleza (n=395) and Caucaia (n=87). Adolescents and adults remain the most affected group by this outbreak (44.4%), followed by children aged 6-11 months (24.8%). For this reason, Brazil started vaccinating children aged >6 months in 2014 (dose zero) and continued administering the first and second doses at 12 months and 15 months. The genotype identified was D8. Slow but continuous transmission (“drop by drop” transmission) showcased failure to implement an aggressive and quick outbreak response, as well as the presence of several unvaccinated individuals dispersed in areas with reported high vaccination coverage.

In late February 2015, Ceará implemented a mop-up vaccination campaign targeting individuals aged 5-29 years in Fortaleza and Caucaia. The campaign may be extended to additional municipalities (n=20) in order to get ahead of the virus. Strong political commitment is being demonstrated at all levels (federal/state/municipality) to halt the current epidemic within the next 60 days, as strongly recommended by the IEC in April 2015. However, despite improvements, the outbreak continues, with rash onset of the last confirmed case on 2 June 2015.

Today, endemic measles virus transmission has been re-established in Brazil, as virus circulation has persisted for over 24 months in the country, on the vast experience gained in all countries and therefore will propose complementary surveillance and vaccination activities (i.e. active case finding) to add to existing evidence in the documentation of the absence of measles and rubella cases in the Region. The sustainability of measles and rubella elimination should be annually monitored in each country, following a standardized process.

Several technical consultations were held for defining the surveillance indicators, including a working group meeting with renowned country experts and PAHO's immunization focal points, which took place in Bogota, Colombia on June 2-3, 2015. The working group underscored the need of having complete, reliable, timely and consistent surveillance data. To this end, it was proposed to replace the indicator that collects information on the number of surveillance sites reporting weekly with indicators to monitor the number of municipalities reporting suspected cases, as well as the number of countries reporting weekly measles-rubella data to PAHO. Finally, the working group recommended that countries adopt and use PAHO's confirmed case definition for measles and rubella, and the CRS suspected case definition.

Following recommendations from TAG in 2014 requesting that PAHO carefully study the transmission patterns and age-distribution of cases in the recent measles outbreaks, PAHO presented this data, in particular evidence from recent outbreaks in Brazil, Ecuador and the United States, to the June 2015 technical consultation working group members. Based on this evidence, the working group agreed to continue recommending vaccination against measles (one or two doses depending on the age) for all individuals over 6 months of age living in areas with documented measles virus circulation.

Recommendations:

- TAG recognizes the efforts of Brazil in the face of the ongoing outbreak of measles. Nonetheless, TAG urgently calls on the government to take decisive measures to end the outbreak of measles in Ceará. Following the last confirmed measles case in Ceará, the government will need to document the interruption of measles virus circulation in the affected areas, in accordance with the verification criteria established by PAHO.
- TAG urges countries to fully implement the currently recommended surveillance indicators, in order to have a sensitive and timely surveillance system, which produces reliable and consistent data.
- TAG recommends vaccinating infants 6-11 months of age in outbreak situations. (This dose will be considered to be a “zero dose”). These infants should then receive the first dose of measles-rubella-mumps (MMR) containing vaccine when they reach 1 year of age, and a second dose according to the country's national schedule, preferably at 18 months of age.
- TAG strongly recommends that WHO raise progress towards the global elimination of measles as a resolution at the next World Health Assembly (WHA), to strengthen the commitment of the other regions in achieving the goals of the Global Vaccine Action Plan (GVAP).

Missed Vaccination Opportunities

Strategic Objective 3 of the Global Vaccine Action Plan (GVAP) calls for the benefits of immunization to be distributed equitably to all people. PAHO, in its Regional Immunization Action Plan (RIAP), shares this goal. PAHO and other partners have helped countries in Latin America and the Caribbean (LAC) implement plans of action to raise immunization coverage in vulnerable municipalities. Countries are encouraged to determine local causes of under-vaccination and to implement interventions to overcome barriers in achieving high vaccination coverage.

In response to recent country requests for assistance in conducting Missed Opportunities for Vaccination (MOV) studies with the goal of increasing immunization coverage in vulnerable municipalities, PAHO is publishing a standardized methodology to evaluate MOVs in children aged <5 years in primary and secondary health facilities and to evaluate the vaccine-related attitudes and knowledge of health workers. The methodology was adapted from the original WHO methodology published in 1988 and other immunization studies implemented in the Region, and takes into account the best practices in immunization surveys from LAC.

Based on a review of available data, PAHO developed the study methodology and two questionnaires: one to measure MOVs in children aged <5 years and one to evaluate the knowledge, practices, and attitudes of health workers. A guiding principle for the inclusion of information to be collected was its usefulness in the field and its potential for identifying corrective measures. The method was designed such that both questionnaires would be implemented on the same day at the same health facility, with the first being administered by interviewers to caregivers of children aged <5 years and the second being anonymously
completed by individual health workers. The methodology seeks information from a broad range of participants and is designed to evaluate health practices in visits intended for vaccination and in those sought for other reasons (e.g., well child check-ups). Caregivers of children aged <5 years are eligible to participate following a visit to a health center for any reason. Healthcare professionals who do not routinely administer vaccines, including those who work in nutrition and well child clinics, may also be included in the health worker surveys.

The methodology allows for a cross-sectional evaluation of MOVs. Because the evaluation serves as an operational tool for the identification of MOVs in municipalities that do not meet target coverage levels, quota sampling rather than probability sampling is recommended. Geographical areas (municipalities) are first selected based on coverage rates, indices of unmet basic needs, and other indicators. Health facilities are then selected, taking into account the proportion of the population residing in rural versus urban areas and the proportion of patients who use hospitals versus primary care centers.

In October 2012, the Dominican Republic piloted the updated methodology using the methodology and questionnaires written in Spanish. In 99 health centers in low-coverage municipalities, 1,500 parents and guardians of a child aged <5 years were interviewed and 398 healthcare professionals completed the health worker survey. Of 782 opportunities for 527 eligible children to receive needed vaccines, a total of 262 MOVs were observed.

To evaluate the completeness, implementation and understanding of the methodology, PAHO professionals participated in all stages of the evaluation. Implementation was considered successful: the assessment was feasible to implement in two weeks, target sample sizes were obtained, and a large proportion of health workers participated, recognized the findings as problems in their health facilities, and proposed solutions to these problems.

To implement the assessment, a country must adapt the questionnaires and MOV algorithm to its vaccination schedule. The methodology provides guidelines to aid investigators in determining eligibility, timely doses, and windows of opportunity. The country should then select an implementation team. Implementation teams should consist of a general coordinator, supervisors, interviewers, and data entry personnel (if data are collected using paper forms), and the inclusion of a statistician in the study team is recommended. The team may be composed of non-immunization health professionals, or the country may hire an independent polling company or an academic institution to conduct the assessment. Training sessions for team members, a pilot test, and procedures to ensure data quality are required. Before implementing the study, investigators must ensure that it will be conducted according to national regulations for the use of health data. Investigators are encouraged to conduct univariate and stratified analyses to identify factors associated with MOVs and under-vaccination in the surveyed population, with the understanding that the results are not generalizable to the entire country as sampling is non-probabilistic.

The final step is the preparation of reports that facilitate the design of specific strategies to reduce MOVs. The first report should be brief and highlight major findings for national health authorities and partners where applicable. Another more detailed report should be presented to the subnational and national EPI managers, and to those in charge at the local level.

As the results were presented in the Dominican Republic to both national and subnational EPI managers, and subnational officials, many of whom are responsible for immunization services in evaluated health centers, they suggested interventions and helped ascertain underlying factors related to identified barriers. Moreover, the inclusion of local-level immunization officials in the MOV assessment increases the involvement and commitment of the officials who are ultimately responsible for implementing interventions.

Lastly, countries should document studies they conduct on MOVs and under-vaccination. The limited number of published studies in developing countries, particularly in LAC, that evaluate immunization programs, validate coverage data, or assess the effectiveness of interventions is well known. Among other benefits, increased documentation of operational studies on immunization will help countries establish a baseline for progress, advocate for increased political commitment and external funding, promote evidence-based decision-making, and share experiences with the rest of the immunization community.

Recommendations:

- TAG commends the work of countries to identify and remove barriers to vaccination with the aim of achieving high vaccination coverage at all levels.
- PAHO, in conjunction with other partners, will continue to review studies regarding the regional causes of under-vaccination.
- PAHO should make information available on the best practices to reduce missed opportunities for vaccination, describing how successful interventions are developed, cost-effectively implemented, monitored, and evaluated.
- Countries should document interventions and repeat this type of study, ideally with a costing component, in three to five years, to evaluate whether the interventions implemented were successful in reducing MOVs and contributed to more equitable immunization coverage rates.

Transitioning to the Use of Auto-Disable Syringes

Background

Injections are one of the most common health care procedures. Sixteen billion injections are administered annually worldwide and only five to 10 percent of these injections are provided by health care workers for the administration of a vaccine.

Safe injection practices, in the field of immunization, prevent the possibility of diseases like hepatitis B, hepatitis C and HIV from being transmitted, and the occurrence of events supposedly attributable to vaccination or immunization (ESAVI). In addition to promoting occupational health to workers in the health services, safe injection practices reduce the environmental risk to communities. Another aspect to consider is that the practice of safe injection, one of the key components of vaccine safety, is a measure that guarantees the progress being made by immunization programs and therefore has a significant impact on global vaccination coverage.

In 1999, the WHO, the United Nations Children’s Fund (UNICEF) and the United Nations Population Fund (UNFPA) issued a joint policy declaration on the use of auto-disable syringes (AD) in immunization services. This declaration recommended that all countries adopt this document and implement the use of AD syringes in immunizations by the end of 2003.
According to this policy, this recommendation was based on the possible reuse of single-use syringes and needles, a practice that poses a high risk to public health. The community at large is also at risk when used injection equipment is not safely discarded. AD syringes lower the risk of disease transmission from person to person because they cannot be reused, since they have a mechanism that disables the syringe from further use.

The WHO policy is focused on the use of AD syringes, which are pre-qualified after a review process of the dossiers. The WHO and the International Organization for Standardization (ISO) have developed quality standards.

The countries of Latin America and the Caribbean (LAC) continue utilizing single use disposable syringes (SUDS), purchased through the PAHO Revolving Fund (RF), for their immunization programs. The quality of syringes and needles provided by the PAHO RF are verified through laboratory tests. In addition, PAHO also supports countries in building their testing capacity to carry out their own quality testing and verification.

The current recommendations regarding safe injections from PAHO’s Technical Advisory Group (TAG) XIII meeting, held in Canada in April 1999, are:

- The only way to ensure that used injection equipment is not reused is solely through the use of auto-disable syringes.
- All health workers should be informed on the danger posed by recapping a used needle.
- All countries using or introducing single use disposable syringes for vaccine administration should secure the funds to purchase: sufficient syringes, sufficient safety boxes for disposing used syringes and needles, supervision to document safe syringe disposal, and for the adequate collection/incineration of used injection equipment.
- PAHO should support studies to develop new technologies in the administration of safe injections.

In line with WHO policy, PAHO has begun promoting the use of AD syringes. The acquisition and use of AD syringes has been taking place in a progressive manner according to the ability of countries. Prior to introducing AD syringes, each country has to train health care workers in the handling and proper use of the new syringe designs. PAHO has informed all managers involved in the vaccination process on the benefits gained for the safety of the patient and the health professionals. Based on the training in the proper use of AD syringes and good safe injection practices, countries have partially begun introducing AD syringes into their programs. By 2005, only 5 countries had incorporated the use of AD syringes into their program. By 2015, 14 countries were using AD syringes for certain injections. Currently, 2 countries are using only AD syringes. Other countries have purchased a mix of AD syringes and conventional SUDS.

The benefits of using AD syringes are:

1. Reduction in the risk of re-use, thereby improving the safety of the patient, the health workers, as well as safety of the community.
2. The AD syringes come with a single scale, according to the administered dose for each vaccine, thereby reducing the risk of administering more or less dose-specific dosage of the vaccine.
3. There is less dead space in the hub of the needle, resulting in less vaccine remaining in the hub; therefore there is less vaccine wastage.

PAHO has strengthened the mechanisms for the procurement of syringes, not only in the review of documents and verification of compliance with the established requirements by the providers, but PAHO also performs quality verification through testing under specific standards of manufacturing, design and quality.

PAHO’s priorities are:

- Promoting the practice of safe injections as a component of vaccine safety.
- Introducing new technologies, like AD syringes.
- Ensuring syringe quality.
- Developing capacity in countries for verifying quality assurance.
- Training in risk management, management of new technology, waste disposal of sharps.
- Providing technical cooperation in following-up good safe injection practices in disposing of sharps.
- Providing technical assistance to countries to assess syringe quality, as well as developing and implementing a national policy for safe injection.

PAHO, through the EPI and the RF, acquires an average of 188,224,000 syringes annually. 69% are SUDS and 31% are AD syringes for EPI programs in the Region. To ensure the quality, effectiveness, and safety of syringes and other products used in the immunization programs, PAHO’s Comprehensive Family Immunization Unit (FGL/IM) conducted an analysis of the processes for planning, procurement and distribution, the use of injection equipment and disposal for both types of syringes. The resulting analysis shows the need to establish an action plan to validate compliance with the international standards of quality, safety, and the WHO guidelines for these products, as well as to develop the institutional capacity in developing countries for testing and verifying product quality.

7 This joint policy revises and replaces the document WHO-UNICEF policy statement for mass immunization campaigns, WHO/EPI/LHIS/97.04Rev.1. It is issued by the World Health Organization, Geneva, Switzerland (Department of Vaccines and Biologicals), the United Nations Children’s Fund (UNICEF) Programme Division, New York, USA and UNICEF Supply Division, Copenhagen, Denmark) and the United Nations Population Fund, New York. This policy is also the adopted practice of the international Federation of Red Cross and Red Crescent Societies in their operations.
8 Standards for auto-disable syringes (ISO 7886-3; 7886-4), Performance specifications E8/DS1 and DS2 – WHO.
9 TAG Recommendations, Meeting XIII in Canada, April 1999.

**Recommendations:**

- TAG recommends that, by the end of 2020, all countries should only use auto-disable (AD) syringes for immunization.
- Training must be conducted before introducing new AD syringe technology.
- Countries should plan the training, supervision and sensitization activities with assistance from PAHO.
- All countries should follow and strengthen good injection safety practices and the management of safe waste disposal operations.
- All countries using standard syringes or introducing AD syringes for vaccine administration should seek funding for:
  - The purchasing of sufficient syringes and safety boxes to safely dispose of syringes and sharp materials.
  - The documentation of safe syringe disposal.
  - The proper collection/incineration of used injection equipment.
Starting in 2015, the Immunization Newsletter will be published four times a year, in English, Spanish, and French by the Comprehensive Family Immunization Unit of the Pan American Health Organization (PAHO), Regional Office for the Americas of the World Health Organization (WHO). The purpose of the Immunization Newsletter is to facilitate the exchange of ideas and information concerning immunization programs in the Region, in order to promote greater knowledge of the problems faced and possible solutions to those problems.


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COLUMN: What I Have Learned…

By J. Peter Figueroa, the newly elected chair of PAHO’s Technical Advisory Group on Vaccine-preventable Diseases (TAG).

I have learned so much from being a part of the immunization movement in the Americas and working alongside so many talented and dedicated persons. When I first met Ciro De Quadros, I was the national epidemiologist in Jamaica, a small Caribbean island. Ciro and I were drawn to each other by our passion for public health and the belief that we could make a difference. His vision, commitment, insistence on high standards and hard work showed the importance of good leadership and what can be achieved in health regardless of the challenges. Ciro was very creative in getting policy makers to take ownership of their EPI programs by letting them set disease elimination goals and take credit for achieving them. To ensure sustainability, he worked to have countries purchase their own vaccines and to have governments pass immunization laws requiring children to be immunized and to protect their EPI budget.

Following a meeting of Caribbean EPI Managers in Jamaica in 1989, which I chaired, Ciro recognized my talent for chairing meetings and appointed me to chair the annual meetings. In 1991 he invited me to join the PAHO TAG. By arranging TAG meetings with the EPI managers present, Ciro ensured that the scientific experts understood the many challenges that the EPI managers faced and benefited from their wide experience and practical wisdom. In turn, the EPI managers heard first hand and participated in the discussion of highly technical issues and thereby understood the basis for the decisions made by TAG. Other WHO regions need to adopt this approach, which has contributed greatly to the success of EPI in the Americas. I recall my early TAG meetings with Dr. D. A. Henderson in the chair praising the commitment and work of the EPI managers and their teams.

Each of us has to work hard at keeping abreast of developments in the field of immunization and remain open to new learning and approaches. My involvement in polio eradication advisory committees, consultancies, WHO SAGE, TAG and other committees has impressed on me the importance of working in teams, learning from one another and collective decision-making. Conditions and cultures vary greatly, perspectives differ, and science is dynamic. Our talents, expertise and experience are a source of insight and wisdom, but are nevertheless limited and incomplete and need to be complemented and critically interrogated by other perspectives and experiences. Working together we are stronger, wiser and more resilient in tackling new challenges and achieving our goals.

“What I have learned…” is a new column, written in the first person, that will be published in the Immunization Newsletter. The objective of the column is to provide a space for immunization professionals from across the Americas to share their unique experiences and lessons learned. Individuals who are interested in authoring a column are encouraged to contact Hannah Kurtis at kurtisha@paho.org.