

TAG Meeting 2017

**XXIV Meeting of the Technical Advisory Group (TAG) on
Vaccine-preventable Diseases**

**12-14 July 2017
Panama City, Panama**



**Pan American
Health
Organization**



**World Health
Organization**
REGIONAL OFFICE FOR THE **Americas**

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TAG Members

J. Peter Figueroa

Professor Public Health, Epidemiology and HIV/AIDS
University of the West Indies
Kingston, Jamaica

TAG Chair

Jon K. Andrus

Adjunct Professor and Senior Investigator
Center for Global Health, Division of Vaccines and Immunization
University of Colorado
Washington, DC, United States

Roger Glass

Director
Fogarty International Center and Associate Director for International
Research, NIH/JEFIC-National Institutes of Health
Bethesda, MD, United States

Akira Homma

Chairman of Policy and Strategy Council
Bio-Manguinhos Institute
Rio de Janeiro, Brazil

Arlene King

Former Chief Medical Officer of Health
Ontario, Canada
Adjunct Professor
Dalla Lana School of Public Health
University of Toronto
Ontario, Canada

Nancy Messonnier

Director
National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention
Decatur, GA, United States

José Ignacio Santos

Professor
Experimental Medicine Unit
Faculty of Medicine
National Autonomous University of Mexico
Mexico City, Mexico

Cristiana Toscano

Professor
Federal University of Goiás
Goiana, Brazil

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Dr. Jeanette Vega*

Director
Chile's National Health Fund
Santiago, Chile

Dr. Cuauhtémoc Ruiz-Matus

Unit Chief, Comprehensive Family Immunization
PAHO/WHO
Washington, DC, United States

Ad hoc Secretary

*** Not present at TAG 2017**

Acronyms

AFP	Acute flaccid paralysis
BCG	Bacillus Calmette-Guérin vaccine against tuberculosis
bOPV	Bivalent oral polio vaccine
CAG	Containment Advisory Group
CCS	Containment Certification Scheme
CFR	Case fatality rate
CRS	Congenital rubella syndrome
cVDPV	Circulating vaccine-derived poliovirus
dPEF	Designated poliovirus-essential facilities
DTP3	Diphtheria-pertussis-tetanus containing vaccine, third dose
EIR	Electronic Immunization Registry
EPI	Expanded Program on Immunization
EVM	Effective Vaccine Management
EYE	Eliminating Yellow fever Epidemics
fIPV	Fractional dose of the inactivated polio vaccine
fYF	Fractional dose of the yellow fever vaccine
GAPIII	WHO Global Plan of Action to minimize poliovirus facility-associated risk after type-specific eradication of wild polioviruses and sequential cessation of oral polio vaccine use
GPEI	Global Polio Eradication Initiative
GVAP	Global Vaccine Action Plan
HPV	Human papillomavirus vaccine
HPV2	Bivalent human papillomavirus vaccine
HPV4	Quadrivalent human papillomavirus vaccine
ICG	International Coordinating Group
ID	Intradermal
IEC	International Expert Committee for Documenting and Verifying Measles and Rubella Elimination
IM	Intramuscular
IMD	Invasive meningococcal disease
IPD	Invasive pneumococcal disease
IPV	Inactivated poliovirus vaccine
ISIS	PAHO's Integrated Surveillance Information System
JRF	PAHO-WHO/UNICEF Joint reporting form
LAC	Latin American and the Caribbean
MCC	Meningococcal C conjugate
MCV	Measles-containing vaccine
MD	Meningococcal disease
mL	Milliliter
MMR1	Measles-mumps-rubella vaccine, first dose
MMR2	Measles-mumps-rubella vaccine, second dose
MOH	Ministry of Health
NAC	National Authority for Containment
NCC	National Certification Committee
NITAG	National Immunization Technical Advisory Group
OMV	Outer membrane vesicle
OPV	Oral polio vaccine
PAHO	Pan American Health Organization
PCV	Pneumococcal conjugate vaccine
PCV10	10-valent pneumococcal conjugate vaccine

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PCV13	13-valent pneumococcal conjugate vaccine
PEESP	Polio Eradication and Endgame Strategic Plan
RCC	Regional Certification Commission
RF	PAHO Revolving Fund for Vaccine Procurement
RIAP	Regional Immunization Action Plan
RIVS	Regional Immunization Vision and Strategy
RV	Rotavirus vaccine
SAGE	WHO Strategic Advisory Group of Experts on immunization
SC	Subcutaneous
TAG	PAHO Technical Advisory Group on Vaccine-preventable Diseases
tOPV	Trivalent oral polio vaccine
UNICEF	United Nations Children's Fund
VDPV2	Vaccine-derived poliovirus, type 2
VPD	Vaccine-preventable diseases
VSSM	Vaccination Supplies Stock Management software
WHA	World Health Assembly
WHO	World Health Organization
WPV	Wild poliovirus
WPV1	Wild poliovirus, type 1
WPV2	Wild poliovirus, type 2
wVSSM	Web-based Vaccine Supplies Stock Management software
YF	Yellow fever

Introduction

The XXIV Meeting of the Technical Advisory Group (TAG) on Vaccine-preventable Diseases of the Pan American Health Organization (PAHO) was held in Panama City, Panama on 12-14 July 2017. The slogan for the meeting was “40 years and counting,” selected in celebration of the 40th anniversary of the Expanded Program on Immunization (EPI), which was created in 1977.

The objectives of this meeting included reviewing the progress on several initiatives focused on controlling and eliminating vaccine-preventable diseases (VPDs) and issuing recommendations on ways to address the many challenges faced by national immunization programs in the Americas. The topics discussed during the meeting, *Plan of Action for Sustaining the Elimination of Measles and Rubella in the Americas 2018-2023*¹ and *Plan of Action on Immunization: Midterm Review*² will be presented at the Region’s upcoming Pan American Sanitary Conference in September 2017.

Panama’s Ministry of Health opened the meeting and expressed their happiness to host the event, recognizing how the meeting will greatly benefit public health at the national, regional and global levels. The importance of Panama’s EPI was also mentioned, as it provides the country’s population with free and equitable access to 23 vaccines, including to people in difficult-to-reach geographic and indigenous areas. The successes of Panama’s EPI, which can be attributed to its strong, committed healthcare staff, and the high acceptability of vaccines by its people, can be seen as an example for other countries, but also as contributing to the success of the Region as a whole. PAHO’s Assistant Director, Dr. Francisco Becerra, and TAG chair, Dr. Peter Figueroa followed the speech from Panama by welcoming participants to the meeting.

¹ Document CSP29/9, available at www.paho.org/hq/index.php?option=com_docman&task=doc_download&gid=40479&Itemid=270&lang=en

² Document CSP29/INF/7, available at www.paho.org/hq/index.php?option=com_docman&task=doc_download&gid=41308&Itemid=270&lang=en

Mid-term report on achieving the goals of the Regional Immunization Action Plan (RIAP)

In 2012, the World Health Assembly approved the Global Vaccine Action Plan (GVAP) 2010-2020. In the Region of Americas, the Regional Immunization Vision and Strategy (RIVS), 2010-2015, guided national immunization programs until the GVAP was adapted to the regional context and the Regional Immunization Action Plan (RIAP) took its place in 2016.

During the 2017 World Health Assembly, global health officials presented the GVAP Midterm Review, noting that adequate progress had been made in only one of the six targets set for this period. Unmet targets included reaching national and municipal coverage rate targets at $\geq 90\%$ and $\geq 80\%$, respectively, in all countries; global polio eradication; maternal and neonatal tetanus elimination; measles elimination in at least five regions; and rubella elimination in at least two regions. The only target on track was the one set for new vaccine introduction. The GVAP Midterm Review suggested that slow progress may be related to low levels of country commitment or ownership; areas or populations with difficult access to vaccination services; weak epidemiological surveillance; mismanagement at different organizational levels; failure to ensure routine and timely data collection and analysis; a disconnect between the immunization program and health systems strengthening activities; social or armed conflicts; and outbreaks and other competing health emergencies and priorities.

In light of the concern regarding slow progress at global level, the World Health Assembly adopted *Resolution WHA70/A70.14*³, which urges WHO Member States to:

- Demonstrate stronger leadership and governance of national immunization programs
- Ensure the use of current, real-time data
- Strengthen surveillance
- View the program from the life course perspective
- Comply with recommendations of the International Health Regulations
- Mobilize domestic financing for vaccine purchases and program operations
- Strengthen international cooperation and domestic manufacturing to guarantee availability of affordable vaccines and technologies

According to the mandate of the PAHO's governing bodies, the Midterm Review (2015-2016) of the RIAP will be presented at the Pan American Sanitary Conference in 2017. The Midterm Review describes the progress made to date, provides an in-depth evaluation of off-track targets, assesses the challenges and contextual factors that have delayed progress, and proposes solutions and actions that must be taken to achieve the targets by 2020.

The RIAP consists of four "Strategic Lines of Action": 1. Sustain the achievements; 2. Complete the unfinished agenda; 3. Tackle new challenges; and 4. Strengthen health services for effective vaccine administration. These four areas include seven General Objectives and six Strategic Objectives, and 29 indicators have been developed to monitor progress towards meeting the RIAP's objectives.

Since the inception of the Expanded Program on Immunization (EPI), PAHO and Member States have tracked vaccination coverage to monitor progress in immunization. The primary vaccination coverage indicator used to monitor program performance is the third dose of diphtheria-pertussis-tetanus containing vaccine (DTP3) in children aged < 1 year. For much of the EPI's history in the Americas, DTP3 coverage increased steadily, reaching levels that were among the highest of all WHO Regions. In the last five years, in a sharp reversal of the historical regional trend, average coverage rates at the national and regional levels have plateaued and even dropped in some cases. In 2015, the average global DTP3 coverage had reached 87%, while regional DTP3 coverage dropped from 94% in 2011 to 91% in 2015.

³ http://apps.who.int/gb/ebwha/pdf_files/WHA70/A70_R14-en.pdf

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To reduce risks associated with the reintroduction or the reemergence of eliminated or controlled vaccine-preventable diseases (VPDs), the RIAP set a goal for countries to reach $\geq 95\%$ coverage of all vaccines at national and municipal levels. In 2015, 20 countries and territories reported national coverage $\geq 95\%$; 13 reported coverage between 90-95%; six reported coverage between 80-90%; and four reported coverage $< 80\%$. Analysis at the sub-national level shows that 50% of municipalities in Latin America and the Caribbean (LAC) reported coverage $< 95\%$ in the same year.

While achieving high and homogeneous coverage with the routine EPI immunization schedule is a challenge for the Region, countries and territories in the Americas continue to be leaders in introducing new vaccines, and in most cases, secure domestic resources to procure these vaccines. By 2016, 34 countries and territories had introduced pneumococcal conjugate vaccine (PCV) into their national immunization schedules, 20 had introduced rotavirus (RV) vaccine, and 25 had introduced human papillomavirus (HPV) vaccine. This means that 90% and 85% of the regional birth cohort lives in countries where PCV or RV, respectively, is part of the routine schedule. Although HPV vaccine was introduced some years later, 80% of a typical adolescent girl cohort aged 9 years already has access to the vaccine through the routine program.

According to the Midterm Review presented to the Executive Committee of PAHO in June 2017, 16 of 29 monitoring indicators are on track, three are in progress, and 10 are off track.

The following indicators are on track:

- No cases of acute flaccid paralysis (AFP) due to poliovirus
- No reestablishment of endemic measles or rubella transmission
- Fulfillment of indicators to monitor quality of epidemiological surveillance for measles, rubella, and congenital rubella syndrome (CRS)
- Administration of Hepatitis B vaccine within 24 hours of birth
- Existence of national plans of action for immunization
- Monitoring of vaccine beneficiary satisfaction during Vaccination Week in the Americas
- Completion of cost-effectiveness studies before the introduction of new vaccines
- Completion of studies after introduction of new vaccines (impact assessments, operational reviews, etc.)
- Vaccination of pregnant women against influenza and/or tetanus-diphtheria
- Financing for immunization using domestic resources for $\geq 90\%$ of total financing requirements
- Access to an adequate supply of quality vaccines
- Dropout rate $< 5\%$ between the first and third doses of DTP
- Improvement in quality of coverage data
- Implementation of electronic immunization registries at the country level
- Post-marketing surveillance of vaccines
- Vaccination of health workers

Indicators considered to be in progress are:

- Neonatal tetanus incidence $< 1/1,000$ registered live births
- Introduction of one or more new vaccines in the national schedule
- Integration of other preventive interventions with vaccination

Off-track indicators are:

- Indicators to monitor quality of epidemiological surveillance of AFP
- Existence of legal or administrative basis for immunization programs
- Existence of a National Immunization Technical Advisory Group (NITAG) meeting WHO criteria for good functionality

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- National DPT3 coverage $\geq 95\%$ in children aged <1 year
- DPT3 coverage $\geq 80\%$ in each district or equivalent in children aged <1 year
- Monitoring vaccination equity through coverage analysis by income quintile
- Accuracy of supply and demand for vaccines procured through the Revolving Fund (RF)
- National DPT3 coverage $\geq 95\%$ in children aged <1 year for three or more consecutive years
- Identification and correction of barriers to reaching unvaccinated or under-vaccinated populations
- Reporting of stock-outs of one or more vaccines or related supplies for more than one month at any level of the national structure

Based on the Midterm Review, the Executive Committee made the following recommendations to ensure adequate progress in achieving the goals of the RIAP:

- a) Improve legal frameworks
- b) Ensure that the benefits of immunization are equally shared by all
- c) Maintain and strengthen national commitments to immunization programs
- d) Strengthen disease surveillance
- e) Improve information systems
- f) Enhance communication and social mobilization

TAG noted that most unmet indicators involved the application of basic fundamentals of EPI strategies, such as coverage at the district level. While the EPI has ensured the control and elimination of VPDs in the Americas, governments need to recommit to the goals of the RIAP to sustain these significant achievements. The Midterm Review aims to increase awareness of challenges faced by the EPI in order to secure the necessary political commitment to address the crosscutting and program-specific vulnerabilities that put at risk decades of progress in the elimination and control of VPDs.

Recommendations

- TAG commends Member States of the Americas for their continued commitment to the control and elimination of VPDs as demonstrated by the EPI's 40-year existence.
- TAG expresses serious concern about declining DTP3 coverage levels reported at regional, subnational, and national levels. TAG urges countries, with the support of PAHO, to locally assess and diagnose the underlying causes (societal perceptions, sociopolitical, economic, programmatic, etc.) of falling vaccination coverage targets, so that corrective actions can be designed and implemented.
- TAG endorses recommendations made in the Midterm Review of the RIAP to be presented at the PAHO Pan American Sanitary Conference in September 2017.
- Member States and the Pan American Sanitary Bureau should implement the recommendations issued in *Resolution WHA70/A70.14* of the 2017 World Health Assembly, as well as the proposals of the Midterm Review of the RIAP.
- TAG urges PAHO and Member States to increase efforts to explain to policymakers and the public the importance of immunization and the considerable economic and health benefits arising from investments in strong national immunization programs.

Perspectives on the sustainability of immunization programs in the Americas

In recent years, Expanded Programs on Immunization (EPIs) have faced internal and external challenges that place at risk the progress made in the control and elimination of VPDs. For this reason, a key element of program success is monitoring and ensuring program sustainability—i.e., the capacity to maintain at least the level of achievement attained to date. PAHO and Member States monitor programmatic sustainability through various indicators, including vaccination coverage rates and morbidity and mortality due to VPDs.

In the past five years, regional DTP3 coverage, the standard indicator to monitor immunization progress globally, has fallen short of the regional goal (>95%) and, in fact, continues to fall. Some countries have increased coverage levels or kept them the same, but a significant number have reported declining coverage. What's more, analysis of subnational coverage levels shows wide variations, indicating the existence of high-risk areas and populations.

During the 1980s and 1990s, the EPI at the country and regional levels showed steady progress with broad political and institutional commitments from governments to the program, resulting in a steady rise in coverage rates. In the first decade of this century, however, regional vaccination coverage stagnated, and the trend has continued downward in the first years of the 2010s. National EPI programs have required carrying a greater operational and financial burden that threatens the gains that have been made. In addition, national programs face a number of challenges, such as the high costs of new vaccines, financial crises, commercial and political interests, health reforms, and misinformation about vaccines, among other factors.

Given these circumstances, the sustainability of the EPI should be prioritized at all levels of the organization. With this in mind, the financial, operational, and social sustainability of the program must be ensured. These three pillars, which are interdependent and yet have their own characteristics and dynamics, are key factors that threaten immunization program sustainability.

Challenges to financial sustainability include absent or insufficient legal frameworks, domestic financial crises, changes in resource mobilization and in financial resources allocation in countries, health reforms implemented without consideration of EPIs, high costs of new vaccines, and commercial interests. These conditions cause expenditures to be concentrated in vaccine procurement, delays in payment for vaccines, vaccine shortages, lack of infrastructure maintenance, scarcity of human resources, and lack of ongoing training and supervision.

Operational sustainability is affected by lack of financial resources, which can result in lack of trained health workers, lack of active supervision and oversight, absent or outdated infrastructure, and lack of supplies. Insufficient resources also result in missed opportunities for vaccination, lack of a timely and adequate response to outbreaks, lack of integrated immunization program management, poor coordination among program components, and waning commitment and failure to prepare the next generation due to lack of motivation among personnel.

The role of society is also key to program sustainability. Current conditions indicate that there is insufficient information about the benefits and safety of vaccines; that existing information is inaccurate or misleading; that there is a public perception of low risk of acquiring VPDs as a result of the program's achievement, meaning that the program is a victim of its own success; and that decisions on vaccination are often political and not evidence-based. Consequences of this misinformation include indecisions about vaccination ("hesitancy"), the emergence of anti-vaccination groups, lack of social and financial mobilization, higher program costs for communication campaigns, failure to prioritize the immunization program, missed opportunities for vaccination, and the resulting accumulation of susceptible persons.

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Monitoring the immunization program's sustainability indicators has revealed the risk of losing gains that have been made, putting the Region at risk for the reintroduction of eliminated or controlled VPDs. PAHO and Member States must therefore seriously consider the analysis and recommendations of the Midterm Review of the GVAP and RIAP, which call on governments to exercise strong leadership and governance of EPIs. Each country faces different challenges. However, case studies presented to TAG, including examples from Argentina, Dominican Republic, Haiti, Mexico, and Venezuela, show common themes.

Recommendations

- TAG urges Member States to secure adequate financing for their immunization programs. Financing should cover not only vaccine procurement but also continued investment in infrastructure, human resources, and the programmatic activities needed to achieve immunization goals.
- TAG reiterates the importance of establishing a legal basis for immunization activities and financing to protect the sustainability of historic gains in the Region. To continue strengthening the legal basis of programs, TAG calls on PAHO to collect lessons learned regarding immunization laws and to facilitate exchanges among Member States.
- TAG requests that PAHO support countries in efforts to monitor the operational, financial, and social sustainability of EPIs. These activities should include country-tailored approaches and discussions about common challenges at the highest political levels in the Americas.
- Given the turnover of human resources and the rapid growth of program scope and responsibility, Member States are encouraged to prioritize training at the administrative and operational levels of their EPIs.

Update on polio and progress towards the final phase of eradication

Global update

Countries worldwide have made important progress toward their commitments to global polio eradication. Each day more children in the remaining endemic countries (Afghanistan, Nigeria, and Pakistan) are fully protected. Along the Pakistan-Afghanistan border, considered a poliovirus reservoir, the number of zero-dose acute flaccid paralysis (AFP) children (a key surveillance indicator) has continued to fall from 24% in 2014 to 2% in 2016. In Nigeria, 95% of AFP cases aged 6–59 months received more than four oral polio vaccine (OPV) doses. In 2016, countries reported only 37 AFP cases, the lowest number ever. As of 4 July 2017, only six cases of wild poliovirus (WPV) have been reported, compared to 19 cases reported by the same date in 2016. However, these three countries have areas that are inaccessible due to insecurity, where WPV is still endemic. For example, in August 2016 in Nigeria, four WPV1 strains were isolated from AFP cases identified among internally displaced families in three districts of the Borno State. This was a major setback for global eradication efforts. In addition, the circulation of vaccine-derived poliovirus (cVDPV) continues to occur. In 2016, five cVDPV cases were reported, while as of 4 July 2017, 28 cases of cVDPV have already been reported, compared to three cases by the same date in 2016.

Regional update

In accordance with the Polio Eradication and Endgame Strategic Plan (PEESP), between 2015 and 2016, all countries in the Region that exclusively used the trivalent oral polio vaccine (tOPV), introduced one dose of the inactivated poliovirus vaccine (IPV). Subsequently, by April 2016, the 36 countries that were still using OPV in their routine schedule switched from tOPV to bivalent oral polio vaccine (bOPV). After the switch, all 36 countries completed supervision in 100% of warehouses and vaccination clinics and submitted reports, which were validated by both National Certification Committees (NCCs) and the Regional Certification Commission (RCC).

Over the last 15 years, regional vaccination coverage for three doses of polio vaccine (polio-3) has ranged from 90-94%. However, the Region has not met its goal of $\geq 95\%$ polio-3 coverage because too few countries have met the target at the national level. At the sub-national level, vaccination coverage is not uniform among municipalities.

The ability to detect and respond to outbreaks depends on the quality of polio surveillance, and AFP surveillance is the gold standard for monitoring the absence of WPV and cVDPV circulation. In the last five years, the Region has achieved a notification rate of ≥ 1 AFP case per 100,000 children aged <15 years; the percentage of cases with adequate stool samples obtained within 14 days of the onset of paralysis, which should reach at least 80%, has ranged from 73-79% in the 10 years and is 75% in the last 52 weeks⁴. The percentage of AFP cases investigated within 48 hours of notification, which should reach at least 80%, has ranged between 61-91%, and is 80% in the last 52 weeks⁴. In 2016, only Nicaragua and Paraguay have met these three indicators; in the last 52 weeks, only Paraguay achieved all three indicators.

Between 2012-2016, only four AFP cases were classified as polio-compatible. However, upon analyzing AFP data on a case-by-case basis, 568 AFP cases were discarded without adequate stool samples or follow-up to check for residual paralysis or sequelae. According to PAHO's Polio Field Guide (2006)⁵, cases without adequate samples and follow-up should be classified as compatible cases and should be considered failures of the surveillance system.

Polio risk assessment

It is important for countries to know the risks of importation of WPV and of a cVDPV event. As such, continued vigilance in the Region is needed to ensure high vaccination coverage and to improve the quality of AFP surveillance for timely detection and response to outbreaks.

⁴ Last 52 weeks, ending in epidemiological week 26 (1 July 2017).

⁵ Poliomyelitis Eradication Field Guide (2006), available in English and Spanish at www.paho.org/hq/index.php?option=com_content&view=article&id=787&Itemid=1617&lang=en

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With support from the RCC, PAHO developed a risk analysis methodology to evaluate the risk of poliovirus importation to the Americas. The methodology proposes four components for assessment: i) immunization coverage, as a proxy for the level of immunity in the population; ii) AFP surveillance; iii) outbreaks, including history of cVDPV or any other VPD and availability of an outbreak response plan; and iv) others that include population and health-system specific factors that could influence national capacity to detect and respond to WPV importations or cVDPV events.

The analysis was recently conducted and included collecting and analyzing pre-existing information from the PAHO-WHO/UNICEF joint reporting form (JRF), PAHO/WHO's Integrated Surveillance Information System (ISIS) and PAHO Health Situation in the Americas: Core indicators. Results of this assessment showed that three countries were at very high risk for polio importations, five countries were at high risk, nine countries were at medium risk, and three countries were at low risk (Table 1). To date, 31 countries have submitted plans to PAHO for the detection and response to poliovirus events or outbreaks.

Table 1 Risk Assessment for poliovirus importation into countries of Latin America; risk scores are classified as very high (score \geq 9), high (8-9), medium (6-7) and low (\leq 5)

No.	Country	Score
1	Guatemala	9.8
2	Haiti	9.6
3	Venezuela	9.2
4	Brazil	8.2
5	Dominican Republic	8.1
6	El Salvador	8
7	Peru	7.9
8	Ecuador	7.6
9	Paraguay	7.4
10	Panama	7.1
11	Colombia	7.1
12	Argentina	7
13	Honduras	6.9
14	Bolivia	6.5
15	Chile	6.2
16	Nicaragua	6.1
17	Costa Rica	6
18	Uruguay	5.6
19	Cuba	5.5
20	Mexico	4.9

Global containment status

Progress has been made to contain type 2 poliovirus since the publication, in December 2014, of the WHO *Global Plan of Action to minimize poliovirus facility-associated risk after type-specific eradication of wild polioviruses and sequential cessation of oral polio vaccine use (GAPIII)*.

As of 1 May 2017, 175 countries and territories reported that they no longer had wild or type 2 vaccine-derived poliovirus, 18 reported that they did, and 12 were completing reports. Thus far, 30 countries have designated 77 poliovirus-essential facilities (dPEF) to retain type 2 polioviruses, but some still have to nominate the National

Authority for Containment (NAC) that will be responsible for certifying that these facilities meet the containment requirements described in GAPIII.

The Containment Advisory Group (CAG) is developing guidelines to help facilities to identify samples that are likely to harbor type 2 polioviruses, which will include recommendations on their destruction or secure handling. To support Phase II implementation, WHO and its Regional Offices have raised awareness about containment and strengthened national capacity by training the staff of national authorities for containment and poliovirus-essential facilities about GAPIII implementation and certification.

Regional containment status

Aligned with GAPIII, the Regional Action Plan for poliovirus containment is being implemented in three phases linked to the milestones in the Global Polio Eradication Initiative (GPEI). The Regional plan is conducted in 44 countries and territories following WHO and RCC guidelines, and with PAHO technical support. A total of 44 polio containment coordinators have been designated in the Region.

In June 2017, the RCC reviewed 19 of 23 expected reports corresponding to 18 country reports and one report from the Caribbean sub region. All countries have submitted at least one phase I progress report on GAP III: Containment of WPV2 / VDPV2 / OPV2 / Sabin2. The RCC has fully validated three country reports for the survey process, inventory, and identification of infectious and potentially infectious material with WPV2/VDPV2/OPV2/Sabin2, 18 reports for materials infectious and potentially infection with WPV2/VPDV2, and 13 reports report for material infectious with Sabin 2.

Six countries of the Region have designated 31 Poliovirus Essential Facilities (dPEFs)—two in Brazil, four in Canada, one in Cuba, three in Chile, one in Mexico, and 20 in the United States. Only two of these countries have nominated a National Authority for Containment (NAC). A regional training workshop designed for GAPIII auditors to support NACs in their efforts to implement Containment Certification Scheme (CCS) was held in February 2017. Each dPEF should submit applications for the certification process to the NACs.

Use of fractional IPV doses (fIPV)

Current IPV supply situation

The two global IPV manufacturers, Bilthoven Biologicals and Sanofi Pasteur, have faced problems in their production processes and consequently made offers to the global market that fall short of meeting the global demand for IPV. Global IPV shortages are likely through at least 2018, with possible improvements foreseen by 2020.

Bilthoven Biologicals is the only manufacturer through the RF that offers IPV in vials (US\$1.90 per dose). The other IPV manufacturer offered a limited quantity of IPV doses in pre-filled syringes (US\$5.30 per dose), which has helped to reduce supply gaps but does not meet the Region's total demand.

As a result of efforts among countries, PAHO's Revolving Fund for Vaccine Procurement and the Comprehensive Family Unit (FGL/IM) have made adjustments to the vaccine delivery schedule. Thanks to maintaining opening lines of communications with manufacturers, countries have also received sufficient vaccine to complete polio vaccination schedules. However, even while maintaining these collaborative efforts, countries of the Region are estimated to begin facing IPV stock-outs as soon as July 2017.

Initial response to the limited IPV supply

In March 2016, based on available seroconversion data, SAGE recommended the use of two fIPV doses instead of one full IPV dose as an option to optimize available IPV supply at country level. In May 2016, TAG discussed the global IPV shortage and the supply situation in the Region in an ad-hoc virtual meeting. After reviewing evidence about the safety and immunogenicity of intradermal (ID) administration of two fIPV doses (0.1 ml or 1/5 of the complete dose), TAG recommended that countries reduce IPV wastage, prepare to respond to possible IPV

shortages, strengthen outbreak response, evaluate the capacity for the use of ID fIPV in the routine program, and strengthen epidemiological surveillance.

Since the last TAG recommendations on ID fIPV doses, the global supply situation has worsened. In March 2017, TAG held a subsequent ad-hoc virtual meeting to discuss the issue. At this meeting, TAG recommended that countries that administer more than 100,000 doses of IPV annually, and with the capacity to train healthcare workers and supervise ID fIPV implementation, should immediately begin preparing to implement a schedule of two fIPV doses followed by two or three doses of bOPV (Table 2). In the cases of Guatemala, Haiti, and the Dominican Republic, TAG recommended that these countries carefully evaluate their capacity to introduce a schedule with two fIPV doses, weighing the risk of stock-outs against training and supervision requirements and the need to achieve high coverage.

Table 2 Regional recommendation for polio vaccination schedule, the Americas, 2017

Vaccination Schedule	Basic			Booster	
	1 st	2 nd	3 rd	4 th	5 th
	fIPV	fIPV	bOPV	bOPV	bOPV

Scientific evidence on the use of two doses of fIPV

The available scientific evidence shows that two doses of ID fIPV offer higher seroconversion for all polio serotypes than one full dose of IPV administered intramuscularly (IM). Additionally, studies show that the longer the interval between fractional doses, the better the immune response. Adverse events occur do more frequently with ID than IM administration. However, these are generally mostly mild local reactions such as erythema and induration.

Programmatic and operational considerations of two doses of fIPV

Generally, ID administration of vaccines is generally more difficult than IM. Therefore, all healthcare workers should be adequately trained in safe vaccine administration. A timely supervision of ID fIPV implementation is needed to ensure the safety and effectiveness of the proposed change in strategy.

According to the WHO open-vial policy, IPV in multi-dose vials may be used for up to 28 days. For the application of fractional doses, a 0.1 mL 27G 3/8 syringe should be used, which is the same syringe used for BCG in some countries. However, some countries administer BCG in a 0.05 mL syringe and thus do not stock 0.1 mL syringes. According to information from the RF, most countries will likely not have 0.1 mL syringes available for BCG administration.

To introduce a fIPV schedule, updates to the registration system need to be taken into consideration during planning, training, and supervision. Additionally, the use of fIPV ID is based on scientific evidence but is not specified on the label, meaning that countries must follow the process of their respective National Regulatory Authority to use the vaccine off label.

TAG believes that as we get closer to the global polio eradication, several but all important recommendations will have to be considered:

Recommendations

- Due to the global IPV shortage and evidence that a two-dose fIPV schedule provides better protection than one full IPV dose, TAG urges Member States to consider the implementation of two ID fIPV doses, followed by two or three bOPV doses, in lieu of one full IPV dose. Member States, with support from PAHO, should begin preparing training and communication activities with health workers on the application of ID fIPV.
- TAG reaffirms recommendations from May 2016, calling on Member States to reduce IPV wastage. In anticipation of possible IPV stock-outs, Member States should prepare for the operationalization of

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delivering bOPV in place of IPV until IPV becomes available, always maintaining at least four weeks between vaccine doses.

- TAG calls on the RF to continue to closely monitor the global supplies of IPV vaccine and 0.1 mL syringes, and to collaborate with vaccine manufacturers to reestablish a safe and affordable supply of IPV for the Americas.
- TAG endorses the regional polio risk assessment methodology and encourages Member States to conduct annual national polio outbreak risk assessments to determine risk at the district level. While some countries may have higher risks than others, TAG stresses that all Member States in the Region remain at risk for polio importation until the disease is eradicated globally. Indeed, TAG expresses concern at the number of countries at high risk for poliovirus importation.
- TAG urges Member States that have not developed their national polio outbreak response plans (Bolivia, Brazil, Guatemala, Paraguay, and Uruguay) to do so and share these plans with PAHO.
- To maintain sufficient population-level immunity to keep the Region free of polio TAG urges Member States to ensure $\geq 95\%$ coverage of three doses of polio vaccine nationally and in all municipalities.
- TAG reminds Member States of the need to ensure capacity to detect and respond to polio importations, especially calling on Member States to meet the minimum standards for AFP surveillance.
- TAG urges Member States to classify AFP cases as outlined in PAHO's *Polio Field Guide* (2006), categorizing cases based on lab results and follow-up evaluation. Compatible case should be considered failures of the surveillance system, and the NCCs and RCC should review such cases.
- TAG encourages each country to complete at least one containment report and commends Member States that have completed all four required elements of the containment reports.
- TAG encourages Member States to advance on the finalization of inventory of facilities with poliovirus infectious and potentially infectious materials, following the Containment Advisory Group guidance for completion of Phase I of GAP III.
- TAG encourages Member States with designated Polio Essential Facilities to officially nominate their National Authorities for Containment, and for Polio Essential Facilities to submit applications for the Certificate of Participation to their National Authorities for Containment, according to the Containment Certification Scheme.

Status update on yellow fever outbreaks in the Americas

On 10 March 2017, TAG held an ad-hoc virtual meeting to discuss the ongoing yellow fever (YF) outbreak in Brazil and its implications for the Region in view of the global shortage of the YF vaccine. This outbreak has been deemed the largest in Brazil since the 1940s and has expanded to areas of the Atlantic coast that, according to the WHO, were not previously considered to be at risk for YF. Following a review of the epidemiological situation in Brazil and the national outbreak response, including immunization, TAG reemphasized the importance of both YF vaccination through the routine immunization program and of maintaining high coverage levels among populations of all ages in endemic areas in order to prevent the occurrence of disease cases and outbreaks. TAG reaffirmed that a single dose of the YF vaccine was sufficient to confer sustained life-long immunity against the disease, with no need for a booster dose.

In view of the global YF vaccine shortage and the ongoing outbreak in Brazil that resulted in regional vaccine shortage, TAG recommended that YF-endemic countries consider postponing childhood vaccination in non-zoonotic areas in order to re-allocate doses for priority areas until the vaccine is more available at the regional and global levels. TAG also endorsed the 2016 SAGE recommendation to use fractional yellow fever (fYF) doses in response to outbreaks occurring in situations of limited vaccine supply. SAGE considered that the available evidence was sufficient to determine that fractional dosing of YF vaccine to one fifth of the standard dose (0.1 mL instead of 0.5 mL, administered subcutaneously [SC]), could be a safe and effective option for mass vaccination campaigns to control urban outbreaks in situations of acute vaccine shortage. TAG emphasized that endemic countries should only consider fYF dose as a short-term measure and not for routine immunization, as there is insufficient data to show that fractional dosing would confer the life-long protection provided by vaccination with one full dose. Thus, individuals who receive a fYF dose may require revaccination. Studies are underway to address the duration of immunity following fYF doses.

Since the ad-hoc virtual TAG meeting, the YF outbreak has spread to nine Federal States, including the Federal District of Brazil, and has affected 17 Federal States (as of 31 May 2017). The Ministry of Health reported 3,240 suspected cases, of which 792 were laboratory-confirmed cases and 519 remain under investigation. Confirmed cases were reported from Goiás, Distrito Federal, Mato Grosso, Tocantins, Pará, Minas Gerais, Espírito Santo, São Paulo, and Rio de Janeiro. The southeast region has been most significantly affected, with the states of Minas Gerais and Espírito Santo concentrating 94% of confirmed cases: 260 (33%) in Espírito Santo and 487 (61%) in Minas Gerais. São Paulo and Rio de Janeiro were also affected, reporting 20 (2.5%) and 17 (2%) human confirmed cases of YF, respectively. Of the 792 laboratory-confirmed YF cases, 35% (274) resulted in death (case fatality ratio [CFR] among confirmed cases). In addition to human disease cases, 3,850 epizootics have been reported to date (31 May), of which 642 (17%) were confirmed as related to the YF virus. Since 1 May 2017, no further confirmed human cases of YF have been reported. All reported cases were consistent with sylvatic transmission and no urban YF transmission by *Aedes aegypti* has been confirmed to date.

In response to the outbreak, Brazilian health authorities⁶ have expanded the list of areas in which YF vaccination was recommended for all residents aged >9 months and travelers to the areas, adding 240 new municipalities to the 3,529 municipalities that previously had recommendations in place. The Ministry of Health recently decided to maintain these new areas in YF vaccination recommendations until the outbreak is controlled. Therefore, YF vaccination is currently recommended in a number of municipalities in the state of Bahia, and in all municipalities of Espírito Santo, Rio de Janeiro, and São Paulo, with the exception of urban municipalities in the metropolitan areas of São Paulo and Rio de Janeiro.

⁶ For further details on the epidemiological situation in Brazil, cf. the Ministry of Health of the Public Health Emergency Operations Center, (*Informe do centro de operações de emergências em saúde pública sobre febre amarela no Brasil nº 43/2017*, Ministry of Health, Brazil, May 31, 2017). Available from: <http://portal.arquivos.saude.gov.br/images/pdf/2017/junho/02/COES-FEBRE-AMARELA---INFORME-43---Atualiza---o-em-31maio2017.pdf>

From January-May 2017, the Ministry of Health distributed approximately 26.3 million doses of YF vaccine to Minas Gerais (7.5 million), Espirito Santo (3.6 million), São Paulo (5.7 million), Bahia (2.2 million), and Rio de Janeiro (6.3 million) in an effort to intensify vaccination. In addition, around 7 million doses were distributed for routine vaccination and travelers across the country. Brazil has also distributed 3.5 million doses, received from the global emergency stockpile of the International Coordinating Group on vaccine provision for yellow fever (ICG), to municipalities with vaccination recommendations.

Global strategy for eliminating YF epidemics

On 12 September 2016, a coalition of partners working to stop YF outbreaks met in Geneva to develop a new strategy called Eliminating Yellow fever Epidemics (EYE). The strategy aims to protect the populations at highest risk, ensure a ready supply of YF vaccine, build resilience in urban centers, and prevent international YF spread. It is a partnership among WHO, Gavi, and UNICEF whose main purpose is to decide on the allocation of stocks for preventive, pre-emptive, and routine vaccination. During its latest meeting in May 2017, PAHO's RF was invited to join the group to ensure equitable access of YF vaccines to the Americas. There is also an agreement between EYE and the ICG to help countries respond to outbreaks.

Recommendations

- TAG calls on endemic countries to optimize vaccination delivery, maintain high vaccination coverage among target groups, and strengthen the monitoring of vaccination coverage and of adverse events following immunization (AEFIs).
- TAG reiterates its endorsement of the use of subcutaneous (SC) fractional YF vaccine in response to outbreaks occurring in a context of limited vaccine availability. PAHO should support endemic countries in the rollout and implementation of SC fractional YF vaccination as needed.
- TAG also reminds endemic countries that have temporarily postponed routine childhood vaccination in areas that are not currently at high risk of YF as a dose-sparing strategy, that they should resume routine vaccination as soon as vaccine supply allows it.
- In the case of Brazil, TAG emphasizes the importance of continuing vaccination activities among residents of and travelers to all affected areas beyond the duration of the outbreak. Priority should be given to closing the vaccination gap with the aim to achieve 95% coverage of all residents eligible for vaccination. TAG also commends Brazil's MOH for adopting a single-dose YF vaccine schedule and supports the Ministry's decision to adopt universal vaccination of all children eligible for vaccination in the country in 2018.
- TAG urges endemic countries to strengthen YF epidemiological, virological, vector, and zoonotic surveillance and to reassess YF risk, taking into account ecological factors, migration, and other population movements, vaccination coverage levels, and entomological trends, among others. The assessment should also consider the specific risk of YF re-urbanization. Information from surveillance activities and the risk assessment should be used to prioritize vaccination and control measures.
- TAG endorses the Global EYE Strategy and credits its initiative in providing visibility to YF in the global public health agenda, and in including PAHO's RF as a member of its governing body.
- In the context of global YF vaccine shortage, TAG recognizes the efforts of the RF in ensuring the YF-endemic Member States' vaccine needs are met.

Pneumococcal conjugate vaccination in the Americas

In Latin America and the Caribbean (LAC), pneumococcus has been estimated to cause 12,000-28,000 deaths, 182,000 hospitalizations, and 1.4 million clinic visits annually. Countries in the Americas have been among the first developing nations to introduce pneumococcal conjugate vaccines (PCVs) into their EPIs. As of July 2017, 34 countries and territories in the Region of the Americas provide PCV10 or PCV13 as part of their routine national schedule. Twenty-seven countries have introduced PCVs, representing 90% of the birth cohort in LAC. Currently, eight countries use PCV10 and 19 countries use PCV13, representing 47% and 53% of the birth cohort in LAC, respectively. Almost all LAC countries use a PCV 2+1 schedule, though four countries use the 3+0 schedule.

In December 2016, a systematic review aimed at summarizing evidence of impact and effectiveness of PCVs on hospitalizations and deaths due to pneumonia, meningitis, and invasive pneumococcal disease (IPD) among children aged <5 years in LAC was published.⁷ The search was conducted using Medline, WoS, Lilacs, Scopus and Central databases and gray literature published in any language from 2009 to January 2016. Inclusion criteria for this systematic review considered studies addressing the outcomes of interest among children in the target age group and the following designs: randomized trials, cohort or case-control studies, interrupted time series studies with at least three data points before and after the intervention, and before-after studies.

The screenings identified 1,085 citations, 892 from databases and 193 from other sources. Of these, 22 were included for analysis: 15 focused on PCV10 and seven on PCV13. Studies were from Brazil, Chile, Uruguay, Argentina, Peru, and Nicaragua. A descriptive analysis was performed based on effectiveness measurements provided or derived from the data available in each study and sensitivity analysis. Effectiveness estimates ranged from 8.8-37.8% for hospitalizations due to x-ray-confirmed pneumonia, 7.4-20.6% for clinical pneumonia hospitalizations, 13.3-87.7% for meningitis hospitalizations, and 56-83.3% for IPD hospitalization, varying by age, outcome definition, type of vaccine, and study design. The main conclusions of the systematic review were that the available evidence indicates significant impact for both PCV10 and PCV13 in the outcomes studied. There was no evidence of the superiority of one vaccine over the other with regards to impact and effectiveness on hospitalization and mortality outcomes in children aged <5 years. These results provide immunization programs with information for decision-making on PCV use.⁸

Another global systematic review reported in the report “Pneumococcal Conjugate Vaccine Product Assessment,” also concluded that there is no systematic evidence of superiority of one vaccine over another (PCV10 or 13) on pneumonia outcomes. A broad range of estimated impact was observed (13-68% for clinical pneumonia and 34-66% for chest x-ray confirmed pneumonia). Additionally, the report concludes that there is strong evidence from immunogenicity studies in all regions to support the use of either immunization schedules: two primary doses with a booster (2+1) at age ≥9 months or three primary doses (3+0). A significant reduction in IPD caused by vaccine serotypes was observed following PCV10 and PCV13. In addition, most published studies have demonstrated PCV impact on mortality following the routine use of both available products in a range of high and low-income countries. In summary, the global review supports the findings from the systematic review in LAC.

Recommendations

- TAG reviewed evidence on the safety, impact, and effectiveness of PCV10 and PCV13 and concluded that neither vaccine is superior to the other, with similar safety, effectiveness, and impact profiles. Accordingly, Member States should introduce and/or maintain PCV10 or PCV13 in their routine schedule based on logistics and cost considerations.
- Member States should use either a 2+1 or 3+0 schedule based on local epidemiological profile of the disease and the ability to achieve high coverage.

⁷ De Oliveira, PLOS ONE | DOI:10.1371/journal.pone.0166736

⁸ *Pneumococcal Conjugate Vaccine Product Assessment*; Kate O'Brien, April 2017, Available at www.jhsph.edu/research/centers-and-institutes/ivac/resources/pcv-product-assessment-april-25-2017.pdf

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- Member States should further strengthen bacterial pneumonia and meningitis surveillance, conduct additional epidemiologic and laboratory studies to continue monitoring the trends of the disease, measure PCV impact, and evaluate circulating pneumococcal serotypes.

Update on the progress towards strengthening immunization data quality and electronic immunization registries in the Americas

The Global Vaccine Action Plan (GVAP) and the Regional Immunization Action Plan (RIAP) highlight the importance of collecting and collating reliable data to guide operational, managerial, and strategic decisions related to immunization. Reliable data is also important to monitor EPI performance and to fulfill the objectives of the GVAP, RIAP, and country action plans.

Countries have made great strides in strengthen their vaccination information systems. With support from PAHO, they have worked to improve data quality, availability, and utilization.

- Since 2006, 27 data quality assessments have been carried out in LAC, in addition to two pilot exercises conducted in Bolivia and Nicaragua in 2002.
- In 2013, PAHO developed and piloted a “Toolkit for monitoring coverage of integrated public health interventions,”⁹ which has since then been used to train 442 health workers from eight countries in the Region.
- In terms of Electronic Immunization Registry systems (EIRs):
 - Thirteen countries currently use EIR systems at the national, subnational, and/or local levels.¹⁰
 - Eight countries are planning, designing, developing, or implementing these systems.¹¹

To support countries in the assessment of EIR introduction feasibility, development, and implementation, and taking into account their national eHealth strategies, PAHO has worked closely with countries to develop a document of practical considerations¹² to guide countries in the consideration and implementation of such systems. Three regional meetings—in Colombia (2011), Brazil (2013), and Costa Rica (2016)—resulted in the development of this document, which also benefitted from the input of countries from PAHO and other WHO regions with experience in establishing EIRs.

Despite countries’ efforts, problems persist regarding the availability, quality, and use of vaccination data to monitor EPI performance indicators. Countries face the challenges of ensuring the availability of systematic, complete, and consistent data that respond to the EPI’s needs for evaluation (e.g., need to consider all sectors administering vaccines—private, non-governmental organization, etc.) and of strengthening the collection, analysis, and use of data at all levels of responsibility, starting by ensuring that information systems and tools used (both paper and electronic) are efficient and adaptable to different types of users.

Recommendations

- TAG recognizes the progress made by the Region in improving immunization data quality and establishing electronic immunization registries that respond to specific needs of immunization programs.
- Where needed, Member States and PAHO should collaborate to strengthen policies and governance related to immunization information systems and data quality.
- With support from PAHO, Member States should encourage data analysis and use at all levels of immunization programs. Data quality may be strengthened by training health workers in the analysis of vaccination coverage, monitoring vaccine administration and supply, following up on target populations, identifying inequalities in vaccination access, and performing complementary analyses linking EPI data to other data sources such as household surveys.

⁹ To access the Toolkit, please visit: <http://www.paho.org/immunization-toolkit/>

¹⁰ Argentina, Belize, Brazil, Chile, Colombia, Costa Rica, Granada, Guatemala, Honduras, Panama, Uruguay, almost every state in the United States and some Canadian provinces.

¹¹ Dominican Republic, Ecuador, Peru, Venezuela and some Caribbean Islands, such as Turks & Caicos, Montserrat, Saint Kitts and Nevis and Saint Vincent & the Grenadines.

¹² To access the “Electronic Immunization Registry: Practical Considerations for Planning, Development, Implementation and Evaluation” document, please visit: http://www.paho.org/immunization-toolkit/?page_id=7

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- Countries should reinforce the use of the basic tools available, such as index cards, follow-up notebooks, and vaccination cards, ensuring the latter are adequately completed, as well as the use of more complex tools like electronic immunization registries.
- Countries and PAHO should share experiences and best practices for improving data quality and use.

Plan of Action for sustaining the elimination of measles and rubella in the Americas

During PAHO's 55th Directing Council on 27 September 2016, the International Expert Committee (IEC) for Documenting and Verifying Measles and Rubella Elimination announced that after reviewing all of the epidemiological evidence presented by Member States for the period 2011-2016, the Region of the Americas had eliminated measles. The Region had reached the goal of eliminating endemic transmission of the measles virus in 2002 and had maintained this elimination for over a decade, despite constant importations of the virus from other regions in the world. It is worth noting that because the outbreak in Brazil lasted over a year, the last endemic case in the Americas has been redefined to have occurred in July 2015.

Currently, the six WHO regions have adopted the goal of eliminating measles by 2020 and two have committed to eliminating rubella by the same year. However, with the exception of the Americas, no other WHO region has met the targets for measles and rubella elimination in 2015. In this global context, PAHO issued an epidemiological alert on 4 May 2017 due to the increase in reported measles cases in Europe and other regions. From early January 2016 to 1 May 2017, 37 European countries reported 7,847 measles cases, with 34% of these reported in 2017. Romania (3,181 cases) and Italy (1,549 cases) reported most of the cases. This situation puts the sustainability of measles elimination in the Region of the Americas at risk.

TAG also noted that situations in Haiti and Venezuela are very concerning for sustaining measles and rubella elimination in the Americas. Accordingly, PAHO will support these countries in organizing follow-up campaigns and building preparedness and response capacities in the case of importations of measles and rubella cases from other regions. Another challenge for the sustainability of measles elimination relates to arbovirus outbreaks (e.g., Zika, Chikungunya, and dengue) in the Americas. Due to shared syndromic case definitions with measles, coordinated action and integrated analysis of febrile rash illness surveillance must be strengthened.

Finally, although MMR1 regional coverage has been 93-94% in recent years, there continue to be variations in coverage levels between and within countries at the municipal level. Accordingly, TAG has reaffirmed recommendations from other meetings, emphasizing the need to apply four criteria for quality—efficacy, efficiency, homogeneity, and opportunity, which PAHO is promoting by planning, executing, and evaluating follow-up vaccination campaigns. Likewise, it is important to remember that reducing the age of vaccination to 18 months (or to the age at which the country applies the first DTP booster) for MMR2 implies that Member States must guarantee that at least ≥95% of children that have not received this dose in the routine program or during other follow-up campaigns are vaccinated.

PAHO/WHO is proposing a *Plan of Action for the Sustainability of Measles, Rubella and Congenital Rubella Syndrome Elimination in the Americas 2018-2023* at the next Pan American Sanitary Conference in September 2017. The plan aims to sustain a high level of immunity in the general population and to maintain high-quality surveillance systems to avoid the re-establishment of endemic transmission. The plan has four strategic lines of action with corresponding objectives and indicators:

1) Guarantee universal access to measles and rubella vaccination services for the population targeted in the routine vaccination program and other at-risk age groups.

Member States should implement activities to reach homogeneous coverage of ≥95% in all municipalities with two doses of MMR vaccine in children aged <5 years, through the regular vaccination program in health services and follow-up vaccination campaigns that have been planned and conducted using high-quality criteria.

2) Strengthen the capacity of epidemiological surveillance systems for measles, rubella, and congenital rubella syndrome.

Countries should implement activities to ensure fulfillment of surveillance indicators, which have suffered in the past two years, particularly with the low reporting of suspected measles and rubella cases in most countries.

3) Develop national operational capacity to maintain measles and rubella elimination.

The roles of the national commissions and regional commission should be maintained, with new terms of reference to monitor sustainability plans for measles and rubella elimination in future years.

4) Establish standard mechanisms for rapid response to imported cases of measles, rubella, and CRS to prevent the reestablishment of endemic transmission.

Creating, maintaining, or reactivating an immediate response group in each country is vital, with training in standard reporting, research, and outbreak closure mechanisms for measles and rubella to ensure and verify the interruption of viral transmission. PAHO will make the necessary tools available to countries to improve response quality and time for measles and rubella outbreaks, starting with imported cases of these viruses.

Recommendations

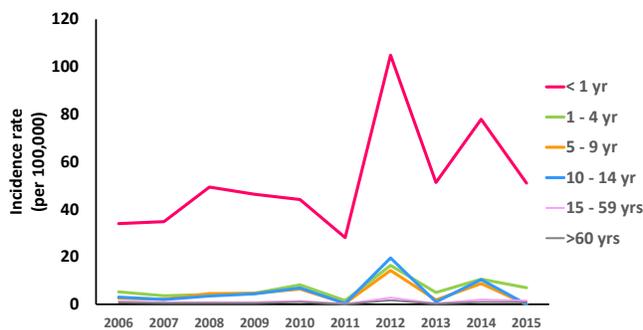
- TAG urges Member States to prepare to implement the Plan of Action for the Sustainability of Measles and Rubella Elimination (2018-2023) following its adoption by the Pan American Sanitary Conference in September 2017.
- TAG emphasizes the importance of achieving and sustaining vaccination coverage $\geq 95\%$ with two doses of measles and rubella vaccine.
- Member States should adhere to the previously recommended schedule that includes the second dose of the measles and rubella vaccine at the age of 18 months.
- TAG urges Member States to introduce the second dose of measles-containing vaccine (MCV), if they have not already done so. The two-dose series must be complemented by periodic follow-up vaccination campaigns as needed to close the immunity gaps.
- TAG emphasizes the need to strengthen the surveillance of fever and rash for measles and rubella and integrate it with that of dengue, Zika, Chikungunya viruses, and other illnesses that use the same syndromic definition, taking into account the epidemiology of such diseases in each country.
- Member States should continue building capacity for the early detection of imported cases and subsequent rapid response.
- TAG urges Member States to conduct risk assessments and identify susceptible populations that should be targeted with vaccination interventions, such as follow-up MR vaccination campaigns when indicated. These activities should minimize or mitigate the risk of importation and subsequent reestablishment of measles and rubella in the Region.

Update on the response to pertussis in the Americas

Following the implementation of DTP vaccination, there was an accelerated reduction of pertussis, or whooping cough, cases at the beginning of the 1980s. Nevertheless, there has been an increase in the number of cases since 2004, with an average of 41,068 cases reported annually. While all age groups are affected, children aged <1 year represent 23% of reported cases and children aged <5 years represent 85% of total deaths reported from 2008–2015 (Figures 1 and 2).

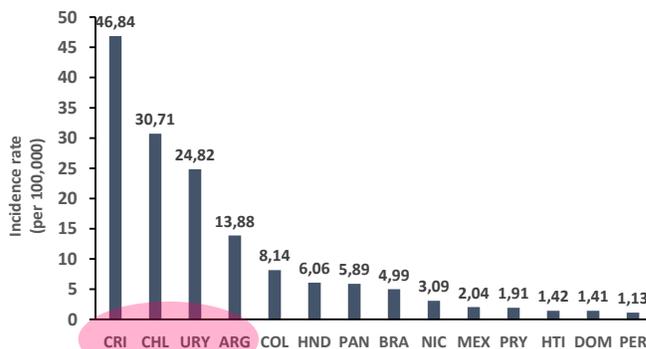
Epidemic cycles of the disease occur every four to six years. The decrease in incidence has not affected the timing of the epidemic cycles, suggesting continuous circulation of *Bordetella pertussis*.

Figure 1 Reported pertussis incidence by age group, Region of the Americas, 2006–2015



Source: EPI Tables, PAHO-WHO/UNICEF Joint Reporting Form (JRF), and country reports.

Figure 2 Reported pertussis incidence in children under 12 months of age, Region of the Americas, 2006–2015



Source: EPI Tables, PAHO-WHO/UNICEF Joint Reporting Form (JRF), and country reports.

With respect to the vaccination schedule, the TAG recommended in 2009, that Member States add a 4th booster dose of DTP to prolong immunity and indicated that coverage achieved with this booster dose should be monitored. In 2012, the TAG recommended that Member States using pertussis whole-cell vaccine as part of the routine immunization schedule should not consider switching to acellular vaccine, due to evidence suggesting a shorter duration of immunity conferred by the acellular vaccine.

On several occasions, the TAG has made recommendations on the importance of timely vaccination, the achievement of homogeneous coverage $\geq 95\%$, and the strengthening of epidemiological surveillance, including

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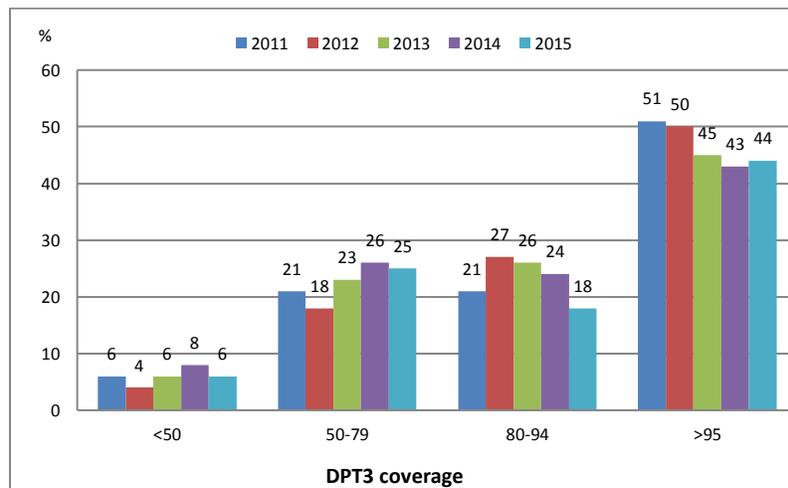
outbreak investigation and documentation. Nevertheless, surveillance of the disease across the region continues to be challenging, partly because countries use different case definitions and types of epidemiological surveillance.

In October 2016, in response to the TAG's recommendation to standardize pertussis surveillance, PAHO/WHO convened a working group to update the existing "PAHO field guide on pertussis surveillance" published in 2005. The field guide, to be finalized during 2018, will propose epidemiological surveillance strategies, including case definitions, type of diagnostic tests, and surveillance indicators that should be used. Additionally, and given that WHO is currently revising global guidelines for pertussis surveillance and therefore, the TAG will review the regional proposal for standardizing and strengthening pertussis surveillance and issue recommendations on this matter once the WHO review process is complete.

Monitoring inequalities in vaccination coverage in the Americas

Both the GVAP and RIAP have established a coverage indicator at the municipal level. The RIAP goal is that by 2020, 35 countries or territories achieve a minimum of 80% coverage for DTP3 in all of their districts or equivalent areas. By 2015, 13 countries met the goal of having 100% of their municipalities with coverage >80%. Temporal analysis of this indicator is strongly affected by such factors as the lack of political priority for immunization at the municipal level and the weak coordination among different administrative levels with overlapping responsibilities, which leads to monitoring and accountability activities not being completed.

Figure 1 Percentage of municipalities by coverage range (DTP3), Region of the Americas, 2011-2015



Approximately half of the Region’s 15,000 municipalities have coverage levels <95%, and there are countries with municipalities that have coverage below 50% (Figure 1).

In light of PAHO’s strategic plan and the vision of the GVAP and RIAP, one area for impact is ensuring that immunization reaches everyone “no matter where they are born, who they are, or where they live.” It is for this reason that in addition to an analysis of aggregate municipal data, PAHO has promoted analysis of inequalities in immunization.

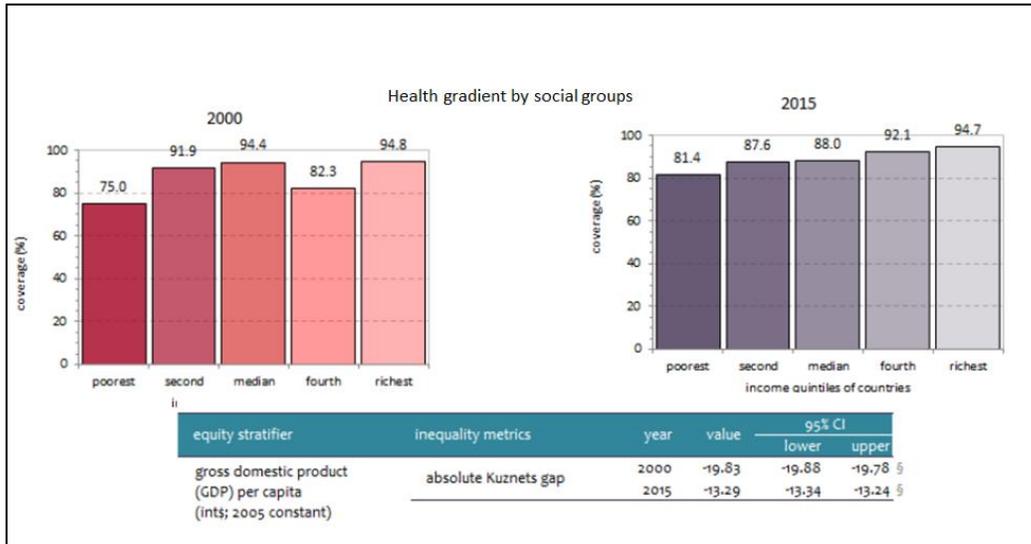
Although routine immunization has reached approximately 90% of children in the Region and has resulted in such achievements as the elimination of polio, measles, rubella, and CRS, it must be recognized that 10% of the population is not being reached. To address these immunization inequalities, a broader understanding of the social determinants associated with completing vaccination schedules may be required. Likewise, in 2008, the Commission on the Social Determinants of Health made three general recommendations about working in the health sector: 1) prioritize universality in health, 2) view all policies in terms of health, and 3) organize the evidence—e.g., measure the magnitude of the problem using a dual approach, evaluating population health as a function of changes in social inequity: *improving overall population health by reducing inequalities*.

In an exploratory analysis by PAHO’s Sustainable Development Program, which showed inequalities in DTP3 coverage among countries by income level both globally and regionally (Figures 2 and 3); the following findings were noted for the period 2000–2015:

- 1) During this period, the Region of the Americas maintained 91% coverage, while the world increased coverage from 72% in 2000 to 86% in 2015.

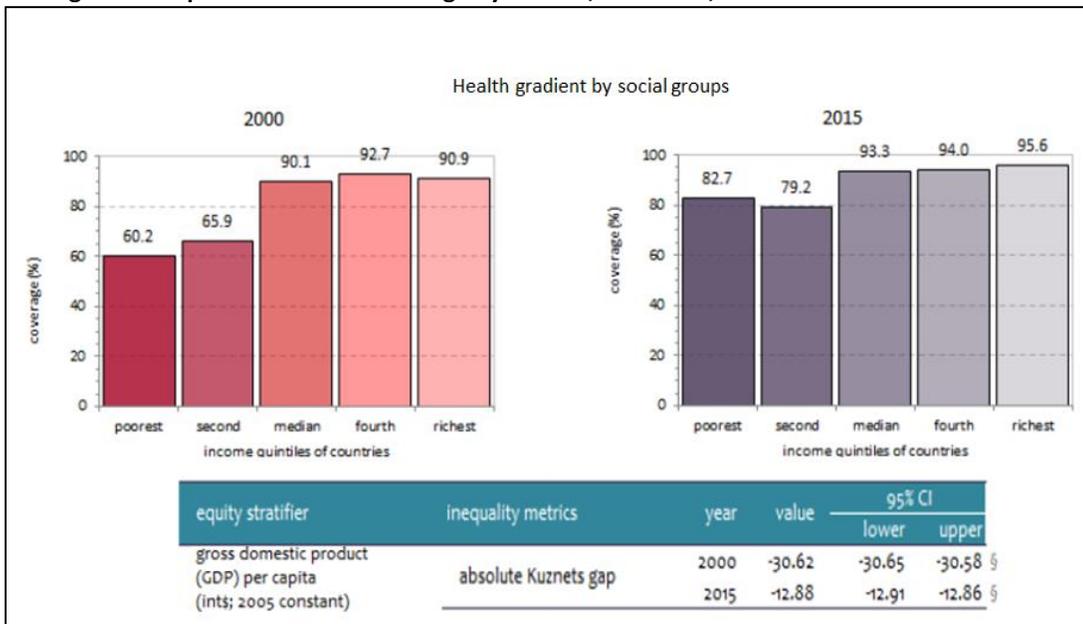
- 2) For the world and for the Americas, DTP3 coverage remained much lower in the two lowest income quintiles in both 2000 and 2015.
- 3) The absolute gap between the first and fifth quintiles (by income) in the Americas was almost 20 points in 2000 but decreased to 13 points in 2015 (this difference is statistically significant).

Figure 2 Inequalities in DTP3 coverage by income, Latin America and the Caribbean, 2000-2015



- 4) Inequalities persist throughout the world. However, the absolute gap in immunization coverage decreased from 30 to 12 percentage points during the same period, demonstrating that the world has made major progress in improving coverage in the poorest countries and quintiles. The impact of international cooperation in other regions of the world such as Africa is evident here.

Figure 3 Inequalities in DTP3 coverage by income, the world, 2000-2015



Recommendations

- The Region is committed to universal immunization coverage, based on principles of equity and solidarity, in the context of achieving universal health coverage for all. Member States should demonstrate this commitment through investing in and sustaining all areas of the immunization programs.
- TAG recommends that immunization programs integrate interventions with health services to increase access to vaccination.
- TAG urges Member States to reinforce strategies to monitor inequalities in immunization, identify underserved subpopulations, and reach these groups through tailored immunization strategies.

Strengthening the decision making capacity of national immunization programs

Ministries of health in the Americas have established National Immunization Technical Advisory Groups (NITAGs) or equivalent independent groups to strengthen decision-making processes and outcomes regarding vaccines and immunization. Comprised of a multidisciplinary membership, these advisory bodies provide independent, evidence-based guidance to national health authorities on immunization policy. While the roles and responsibilities of NITAGs in policy formulation vary by country, the committees are generally considered vital to ensuring a transparent and credible process for decision-making for a range of immunization issues, including changes in schedules, adoption of new vaccines and immunization strategies, and monitoring of immunization-related progress and impact.

Both WHO and PAHO have recommended the establishment of NITAGs since the early 2000s. Following the regional adaptation of the GVAP, PAHO Member States adopted a commitment to establishing functional NITAGs in ≥18 countries by 2020. In accordance with global standards, the Americas consider NITAGs to be functional if they meet the following indicators:

1. Legislative or administrative basis for the advisory group
2. Formal written terms of reference
3. At least five different areas of expertise represented among core members
4. At least one meeting per year
5. Circulation of the agenda and background documents at least one week prior to meetings
6. Mandatory disclosure of any conflict of interest

In 2016, 20 countries and territories reported having an active NITAG. Of these, 15 met the minimum criteria for “good functionality.” Three countries that had previously reported active NITAGs either did not provide a report on NITAG activity or reported that their advisory committees were no longer active. In all three cases, countries lacked a strong administrative or legal basis for their NITAG. Notably, Haiti was the latest country to establish a NITAG and held a formal induction meeting for newly appointed members in March 2017.

Experience during the last decade has shown that establishing and strengthening NITAGs is critical for improving leadership in making informed decisions about the introduction and financial sustainability of vaccines. To maintain the progress made and achieve the goals set forth for this decade, countries must continue to strengthen NITAGs or establish these committees where they do not yet exist. In this respect, English-speaking countries in Caribbean represent a special situation in which nations and territories in a sub-region have worked together to standardize immunization policies. This model is unique, and governments in this sub-region could consider strengthening the formality of this model.

Recommendations

- TAG reiterates the importance of Member States establishing independent technical advisory bodies on immunization to provide evidence-based policy guidance to governments on immunization.
- TAG stresses the importance of ministries of health and NITAGs in implementing procedures for managing real or perceived conflicts of interest related to policy guidance to ensure transparency and credibility. All NITAG members must submit written declaration of interests.
- TAG calls on Member States to continue strengthening their local capacity for evidence-based decision-making around immunization. This requires investing in the Secretariat and NITAGs.
- TAG requests that PAHO continue to support Member States in their efforts to standardize methods for evidence review and presentation as support to NITAG deliberations and policy formulation.
- TAG encourages Member States to join the Global NITAG Network to share experiences and lessons learned as well as assessments of evidence on immunization.

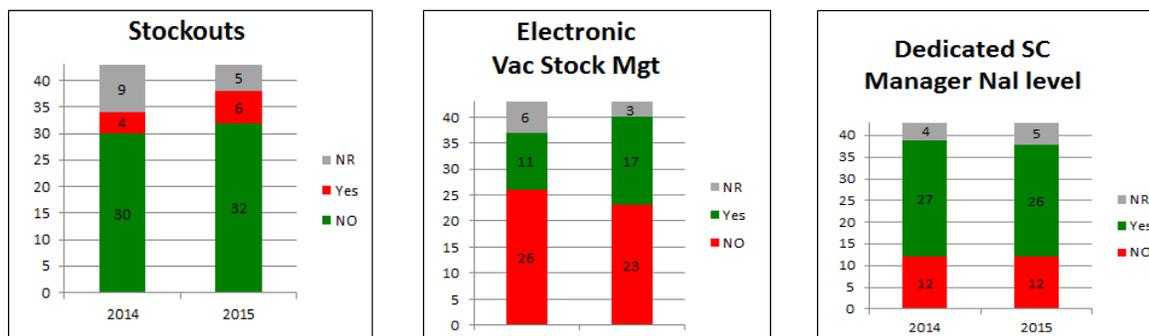
Strengthening management of the cold and supply chains in the Americas

Since the EPI's inception in 1977, the expansion of cold chain and supply chain operations have been two critical pillars for ensuring that vaccines remain potent until administration and thus have enabled numerous achievements in public health. PAHO has supported these operations in the countries by providing technical guidance and trainings and by supporting monitoring and evaluation activities of cold chain and supply operations.

After 40 years of expanding cold and supply chain operations, and introducing new more expensive vaccines, cold chain and logistics managers need real-time, quality information to support optimal operation of these systems and to support planning and quality improvement activities for the future. Another issue facing managers is the increase in target populations for vaccination. Therefore, having a first-class operation in each country will require that managers at all levels have the best data available to ensure that health services have the optimal doses of each vaccine so as not to disrupt the provision of immunization due to stock-outs. Countries should thus have robust vaccine management inventory systems to track each vaccine dose and other immunization ancillary equipment (syringes, cotton swabs, etc.). Each country should review the capacity of its inventory system to provide quality data and key reports such that managers at all levels can plan and make effective decisions.

Analysis of data from PAHO/WHO's JRF country reports on cold chain indicators for the period 2014-16 shows that four countries (12%) in the Region experienced stock-outs during 2014 and six (16%) during 2015. Additionally, 11 (30%) countries and 17 (42%) reported using electronic vaccines stock management systems. In 2014 and 2015, 27 countries and 26 countries, respectively, reported having dedicated supply chain managers at the national level.

Graph 1 Selected cold chain indicators, Latin America and the Caribbean, 2014-2015



*Source: Country reports to PAHO-WHO-UNICEF (JRF), 2014-2015

The 20 countries without stock-outs have electronic vaccine stock management systems at the district level. Conversely, the 10 countries with reported stock-outs indicated that they lacked electronic vaccine stock management systems at the district level. Of note, 33 countries indicated that they do not have a supply chain manager. Only three countries did not submit a response for these two indicators (Graph 1).

The number of countries that reported stock-outs or could not provide an answer on this issue suggests that several countries need to evaluate the management inventory system to assess their current stock management system or to consider installing a digital inventory management information system.

Based on the above information, countries should continue strengthening: 1) management of cold and supply chain operations; 2) investment of resources to obtain first-class operations in cold and supply chains; 3) training in the use and understanding of the JRF form, such that reliable data are collected from all countries.

Due to the high cost of new vaccines and those in the pipeline, including the increasing number of doses, countries must also have a stock records management system to track each vaccine dose and its location. Countries lacking real-time information systems that cannot provide this information are highly encouraged to acquire the required software. PAHO offers a free version of such software, *Vaccination Supplies Stock Management (VSSM)*. Managing the stocks of vaccines and immunization-related supplies is essential to ensuring that each dose of vaccine remains potent and can be safely administered. To this end, PAHO has provided technical cooperation to install and train managers using the VSSM software.

VSSM provides managers with lot tracking, knowledge of vaccines and syringes expiration dates, monitoring of vaccine and supply stocks in each facility to avoid stock-outs, maximum and minimum stocks levels (including available storage capacity), and estimates of wastage rates for each vaccine and syringe. VSSM can also provide more than 40 status reports. The most recent version can be installed using a web-based platform and can be used to manage inventories of other medical supplies. In addition, the web-based version (wVSSM) provides all users with real-time information on the stocks of vaccines and immunization supplies. The wVSSM provides national managers the ability to “see” the vaccines and other supplies stocks, their conditions, expiration dates of products and the available quantities of vaccines and supplies, including the availability of storage capacity. These data permit managers to make the best decisions regarding the cold chain, supply chain, and logistics operations. VSSM is now installed in five countries, and 12 countries have been trained to use it. Three countries use wVSSM, and one country has expanded the use of wVSSM to other health services for managing stocks of other medical supplies (pharmaceuticals and medical devices).

Effective Vaccine Management (EVM) is a tool to assess the performance of a country’s vaccine supply and cold chain operations. EVM uses nine criteria that cover the management and performance of cold and supply chain operations, from the point where vaccines arrive into the country, after being delivered from the vaccine manufacturer, to the point of delivery to the user. Since 2014, PAHO has supported four EVM assessments in Bolivia, Guyana, Honduras, and Nicaragua. (UNICEF supported the EVM assessment in Haiti). All four PAHO-supported countries achieved EVM scores of >80% with Honduras earning the highest at 97%. These evaluations also revealed the need to replace aging cold chain equipment and the vehicles needed to distribute vaccines. Countries will be responsible for allocating financial resources to replace the aforementioned equipment. Decisions to purchase more equipment or to increase supply chain operations, to ensure that vaccine or supply stock-outs are avoided in all facilities, will depend upon economic and logistical evaluations. Accordingly, PAHO recommends that each country implement an EVM. Therefore, training in use of the EVM is urgently needed. This situation also indicates that all countries need to carry out a cold chain inventory every year at the national level.

PAHO will need resources to provide technical cooperation to support cold and supply chain assessments using EVM and to install VSSM as requested by countries. PAHO will also need funding to conduct trainings on cold chain management and vaccine handling, building cold rooms and use of new refrigeration technologies, and improving management information systems to support all operations. These activities will allow countries to document the safe storage of vaccines and avoid stock-outs in all health facilities.

Recommendations

- To improve all components of their cold and supply chains and vaccines operations management, Member States are encouraged to conduct effective vaccine management assessments and use findings to develop an action/improvement plan.
- Member States should be able to generate information in a timely and systematic manner to evaluate the critical aspects of vaccine supply and other operations. Member States are encouraged to enhance or adapt existing information systems to meet this objective. Member States may request assistance from PAHO to introduce and use VSSM.
- Member States should ensure periodic and standardized training of all healthcare staff, particularly in situations with high staff turnover, on the standards of cold chain and vaccine supply management.
- TAG calls on Member States to continue investing in cold and supply chains to maintain the Region’s achievements in vaccination and to respond to the needs of new vaccine introductions.

Update on the use of HPV vaccines in the Americas

As of June 2017, 29 countries and territories in the Americas have introduced the vaccine against human papillomavirus (HPV) in their publicly funded immunization programs. An estimated 80% of a typical birth cohort of adolescent girls aged 9 years has access, via the routine schedule, to HPV vaccine in the Americas. While the application of more than 1.7 million HPV vaccine doses has been reported, actual vaccination coverage data at the country level are not readily available. In 2016, only 14 of 29 countries and territories reported HPV vaccination coverage for the full recommended series in their national schedules, either two or three doses. Among these countries, the highest full-series coverage reported was 86% and the lowest 6%, with a median range of 47-55%. There is confusion regarding the selection of denominator populations for each dose in the series as well as additional challenges in making inter- or intra-country comparisons because of differing target populations.

While the Americas have generally pioneered the accelerated introduction of new vaccines, many countries in the Region have lagged in introducing HPV vaccine. The underutilization of HPV vaccine is seen in the sub-optimal coverage achieved at the country level. Since 2015, only six additional countries or territories have adopted the vaccine. Nonetheless, many countries and territories in the Caribbean sub-region have recently introduced the vaccine or plans to do so in 2017. Real and perceived barriers to introduction still exist, including affordability, communication challenges, and competing health and immunization priorities. PAHO and Member States have been working together to overcome these obstacles.

While affordability concerns are real, particularly in the Americas, HPV vaccine costs have been a major obstacle to introduction owing to PAHO's RF for vaccine procurement negotiations with manufacturers that secured lower prices. More than ten countries in the Americas have conducted economic evaluations to support decisions on HPV vaccine, and the results unequivocally have demonstrated HPV vaccination to be a very cost-effective measure for preventing cervical cancer in women. Lower prices in combination with the two-dose immunization schedule—i.e., the revised schedule recommended by both TAG and SAGE—are expected to alleviate some concerns around initial affordability and long-term sustainability of HPV introduction into the routine program.

While the global burden of HPV-related disease is considered a significant public health problem, cervical cancer burden represents 84% of all HPV-related cancers and therefore should remain the focus of HPV immunization. All countries and territories in LAC that have introduced HPV vaccine prioritize vaccination among adolescent girl cohorts aged 9-14 years. Additionally, six countries and territories have included adolescent boys as a secondary target group. Some policy decisions to include males in the HPV vaccination program target aim to reduce concerns about equity. However, evidence suggests that achieving high coverage rates in girls (>80%) provides indirect benefit to non-vaccinated populations (e.g., boys).

Communication and crisis response preparedness have demonstrated to be critical components of any successful HPV vaccine introduction plan. While abundant evidence affirms the safety and efficacy of HPV vaccines, increased public opposition to the vaccine in some countries/territories and sub-regions due to rumors, misinformation, and ill-prepared crisis management responses threatens achievements made with the introduction of HPV vaccine in the Region. Vaccine demand may have dropped due to some of the clustered anxiety associated with the event of HPV immunization that has been observed in some countries. Without adequate communication and crisis management preparedness plans and swift action in the event of such problems, HPV vaccine introduction and scale-up plans at the national and regional level will continue to achieve sub-optimal results. With support from partners, PAHO is working with Member States to prepare adequate communication and crisis response plans.

In April 2017, SAGE reaffirmed that the current evidence supports a two-dose schedule (with HPV2 or HPV4) with a six-month interval between doses for individuals receiving the first dose before age 15 years. Intervals no greater than 12-15 months are suggested to ensure prompt completion of the schedule before the start of sexual activity. Three-dose schedules are only recommended for individuals that initiate vaccination at >age 15 years, or those of any age who are immunocompromised and/or HIV-positive. TAG and SAGE have noted the need for further

research on a reduced one-dose schedule as well as application of the vaccine in children aged <9 years. Until more information is available, countries and territories should implement and monitor the two-dose strategy.

With more than ten years of experience and over 200 million HPV vaccine doses administered, immunization programs have generated evidence on the safety and substantial effectiveness of the vaccines, including their impact on reducing HPV prevalence and associated precancerous cervical lesions in young women. Mass HPV vaccination at sustained, high coverage levels can substantially reduce the burden of cervical cancer and other HPV-related disease within a single generation. Concerted efforts to build and deliver targeted communication message to relevant audiences about the safety and effectiveness of vaccines will be important for continued progress in securing region-wide protection against HPV diseases.

Recommendations

- TAG congratulates PAHO Member States that have recently decided to introduce HPV vaccine into their routine immunization programs. TAG reiterates the importance of prioritizing high coverage in girl cohorts aged 9–14 years to ensure full protection against HPV among girls and induce herd immunity among boy populations. Currently available vaccines have comparable safety profiles and provide similar protection against cervical cancer.
- Given the substantial health benefit of HPV vaccination, TAG encourages Member States that have not yet introduced the vaccine into their routine immunization schedules to evaluate its feasibility, cost-effectiveness, and other relevant criteria for decision-making at the national level in order to consider including this vaccine in the routine immunization schedule.
- TAG urges PAHO Member States to carefully consider their approaches to communication around the HPV vaccine, making sure to generate audience-specific messages. Additionally, TAG calls on PAHO to support intercountry exchanges on lessons learned regarding communication on the safety of HPV vaccine and crisis management.
- TAG requests that PAHO support Member States' efforts to better document HPV vaccination coverage at the subnational and national levels and to use these data to target strategies and achieve optimal coverage among target groups for the full vaccination series.
- Whenever possible, Member States should monitor the impact of HPV vaccination.

Meningococcal vaccine use in the routine immunization program

Though its epidemiology varies substantially by capsular group, meningococcal disease (MD) is a global problem that affects all countries. Virulent strains of *Neisseria meningitidis* have a polysaccharide capsule, which is the major virulence factor of this bacterium. There are 13 diverse polysaccharide capsules, but only A, B, C, W, and Y commonly cause invasive infections. Information available on the epidemiology of meningococcal disease is incomplete, in part due to the absence of surveillance in many countries and inadequate bacterial detection methods. Due to the dynamic nature of the epidemiology of invasive meningococcal disease (IMD), the global distribution of the different serogroups of *N. meningitidis* may change over time.

The incidence of IMD is highest among infants aged <1 year and remains relatively high until children are about 5 years old. Although incidence tends to decrease among older children, it usually spikes during adolescence and young adulthood when individuals are living in close quarters. Incidence again tapers off in older adults.

While the current incidence of endemic MD in Latin American countries is typically <2 cases/100,000 population per year, epidemic disease has broken out in all parts of Latin American at different times in the past 40 years. The available data highlight the occurrence of MD epidemics in Latin American countries associated with different serogroups and reflect the unpredictable nature of the disease's epidemiology. The highest incidence rates were reported in Argentina, Brazil, Chile, and Uruguay, which are also countries with well-established surveillance systems. Brazil is the only country with information on age-specific incidence rates. In recent years, incidence rates have remained stable in LA countries, ranging between 1.5-1.8 cases per 100,000 inhabitants.

Between 2008-2010, the incidence in Argentina was 0.4-0.7 cases per 100,000 people. Among available isolates, 71% were serogroup B, 12% were serogroup C, and 10% were serogroup Y. In Uruguay, reported incidence rates ranged from 1.5-2 cases per 100,000 inhabitants. Venezuela reported incidence rates between 0.2-0.4 cases per 100,000 inhabitants during the last decade. In Cuba, from 1998 to 2003, the annual reported incidence of meningococcal meningitis among children aged 1–18 years ranged from 0.6-0.7 cases per 100,000 from 1998-2000 to 0.3 cases per 100,000 in 2003.

The case fatality rate (CFR) is high in Latin American, ranging from 10-20% in recent years in several countries within LA, including Chile (14% in 2010), Argentina (7%–15%), Panama (12-15%), Mexico (18% in 2005–2008), and Uruguay (15%). In Brazil, during outbreaks before the introduction of the meningococcal C conjugate vaccine, CFR reached about 40% in those infected with this serogroup. Many survivors experience permanent debilitating sequelae, such as hearing loss, lost limbs, or neurological impairments.

Available meningococcal vaccines against serogroups A, C, W, and Y include both polysaccharide vaccines and polysaccharide-protein conjugate vaccines based on the meningococcal capsule. For serogroup B, vaccine development has included protein vaccines based on the meningococcal outer membrane vesicle (OMV), and the application of new genomic and proteomic approaches has led to the identification of a large number of novel protein vaccine antigens to prevent meningococcal disease.

Polysaccharide vaccines: Their use is now limited because they do not generate adequate immune response among children aged <2 years. Moreover, among patients aged >2 years, polysaccharide vaccines offer protection of limited duration and do not induce immune memory.

Polysaccharide-protein conjugate vaccines: Conjugate vaccines use a carrier protein to present polysaccharide antigen to the immune system, in a manner that induces a T-cell immune response. Although these vaccines have a good safety profile, questions remain regarding their long-term effectiveness and how to optimize vaccination programs.

To date in Latin America, four countries use a meningococcal vaccine in their routine immunization programs: Argentina (ACWY conjugate), Brazil (C conjugate), Chile (ACWY conjugate), and Cuba (B polysaccharide).

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In Brazil, routine infant immunization with meningococcal C conjugate (MCC) vaccination started in November 2010, scheduled at age 3 and 5 months, plus a booster at age 12-15 months without catch-up. Recent studies have shown that the vaccination of infants and toddlers reduced meningococcal C invasive disease in the target population and the upcoming catch-up dose at age 12–13 years will accelerate the decrease in meningococcal C incidence rates among adolescents in Brazil.

Available vaccines tend to be costly. Given the high price of introducing this vaccine into routine immunization programs, countries considering its inclusion in the routine immunization schedule should consider the sustainability over time and ensure that other aspects of the immunization program such as training, supervision, and activities to increase vaccination coverage and epidemiological surveillance, are not affected by the vaccine's introduction.

The Revolving Fund should play a key role in negotiating vaccine prices with manufacturers, in order to reach a more affordable price for countries considering introduction of meningococcal vaccine into their routine programs. However, the lack of alternative manufacturers to stimulate competition is a major barrier to successful negotiations.

Recommendations

- TAG urges Member States to expand from sentinel to nationwide surveillance of bacterial meningitis to better understand the epidemiology of the disease (including the age and serogroups distribution) and to detect outbreaks in a timely manner.
- In their decision-making on meningococcal vaccine introduction, TAG reminds Member States that they should review the disease's epidemiology, its burden and costs, the vaccine efficacy, safety, price, and duration of protection, and logistical and operational aspects of the immunization program.
- For a more accurate assessment of the vaccines' cost-effectiveness, TAG recommends that Member States include assessments of the long-term sequelae of meningococcal disease in these analyses.
- TAG reminds Member States that carriage studies contribute valuable information about disease transmission. However, these studies are not essential for decision-making on the use of a vaccine; they tend to be costly, complicated, and difficult to interpret.

Improving access and timely supply of vaccines/syringes through the PAHO Revolving Fund

The PAHO Revolving Fund for Vaccine Procurement (RF) continues to be a key component of technical cooperation for immunization in the Americas and for the timely access of high quality vaccines to 41 countries and territories in the Region at the lowest prices. In addition to its contributions in eliminating VPDs, the RF continues to support the rapid uptake of new and under-utilized vaccines. Success has been a shared responsibility across the Region in confronting the challenges of global vaccine markets, implementing appropriate procurement strategies, refining accurate country vaccine demand plans, and aligning with national budgets to minimize the risk of interruptions in vaccine supply.

Challenges of global vaccine market and supply

Vaccine markets are unique and unlike those of other pharmaceuticals. The markets are more prone to manufacturing failure and require high-quality manufacturing standards with resulting regulatory oversight and costs. Production timelines are often lengthy and require considerable and careful advance planning. There are a limited number of manufacturers, which restricts the global supply base of some vaccines and limits competition and affordable prices. Nevertheless, the RF continued its outreach to suppliers by participating in events such as the annual meeting of the Developing Country Vaccine Manufacturers Network (DCVMN) in Buenos Aires, Argentina, in October 2016.

Supplies of IPV and YF vaccines have presented unique challenges for the Region. Together with regional immunization colleagues, the RF supported the vast majority of countries and territories in introducing IPV during 2016 and in transitioning from tOPV to bOPV. In light of the deteriorating global supply situation, RF officials consistently made IPV supply briefings to Ministers of Health and EPI Managers. Both global suppliers of IPV were monitored frequently for changes in their respective supply plan availability, as recommended by the ad hoc TAG meetings to date.

The YF outbreak in Brazil also impacted the availability of YF vaccine supply to endemic countries in the Region, reducing by approximately 60% the RF supply plan for 2017. Proactively, the RF engaged with WHO and UNICEF colleagues in the evolving governing structure for the new global EYE Strategy, resulting in the RF being named to the Leadership Group together with WHO, UNICEF, and GAVI representatives. The result has been a realignment of YF global vaccine supply between the Americas and Africa Regions in the second half of 2017.

Finally, as a result of negotiations of HPV and PCV prices in the past few years, the RF has contributed an estimated US\$ 30 million in annual cost savings for participating Member States.

Demand planning and monitoring

Careful preparation and forecasting of vaccine demand from countries and territories is necessary to support PAHO's procurement strategy. Still, opportunities to improve accuracy of country demand plans exist. In 2016, only four countries had a demand planning accuracy of >80% on >80% of the vaccines requested and procured through the RF. Increased national financial burden, special initiatives such as the introduction of IPV and switch of tOPV to bOPV, were among the reasons why countries did not procure the quantities planned originally.

Accurate demand plans need to be backed up with reliable budget and timely payments of invoices for vaccines procured. In 2016, many countries experienced difficulties with timely payment of vaccines and syringes procured using the RF credit line. As of 30 November 2016, 29 of the 34 countries and territories with obligations under the RF credit line were in arrears (seven with 60-90 days, and 22 with outstanding payments >90 days). Timely payment to the RF is important to avoid any delays with the placement of orders on behalf of countries using the RF credit line. The RF is working closely with PAHO leadership in leveraging the use of the new PAHO's Management Information System (PMIS) deployed in January 2016 to make available accurate procurement and financial data for country offices and Member States. The RF has developed reports and dashboards for piloting

and subsequent deployment in Country Offices during the second half of 2017. These tools will monitor financial obligations and purchase requests in real time.

In 2016, RF officials made technical cooperation visits to 11 countries in the Region to update authorities on vaccine markets, resolve supply issues, and facilitate actions to improve demand planning and financial performance.

In May 2017, a review of the demand planning policies, procedures, metrics and systems took place, with the participation of country and PAHO representatives, under the guidance of an expert on forecasting and demand planning using probability and statistical tools. To continue strengthening RF's planning and demand systems, PAHO is considering various initiatives, including a training network to improve country knowledge and practices.

Efforts to improve the RF performance are also taking place at the strategic and operational levels. In July 2017, the RF is launching an assessment funded from a variety of resources, including Member States (1.25% fee) and PAHO's regular budget. Additionally, a WHO grant from the Bill and Melinda Gates Foundation will look at the RF's strategy, as well as its financial and operational systems in order to improve its customer value proposition (CVP) to countries as primary stakeholders and its relationships with vaccine and syringe suppliers.

Global efforts to improve access to affordable vaccines

The RF collaborates closely with WHO and other partners in the Vaccine Product, Procurement, and Price (V3P) initiative to disseminate the contributions of the RF model and its pooled procurement approach to sustain vaccine access at low prices in the Region. The PAHO-GAVI Cooperation Agreement has facilitated close collaboration with GAVI colleagues in the PCV negotiations previously mentioned.

Other regions in the world continue to show interest in pooled vaccine procurement initiatives—for example, EMRO/WHO in 2013. More recently, RF officials spoke at a National Vaccine Conference (July 2017) in Thailand and are exploring a collaborative initiative with WPRO/WHO to share lessons learned.

Recommendations

- TAG reaffirms its recognition of PAHO's Revolving Fund's current principles as a pillar in the progress and success of immunization programs in the Americas. In turn, TAG acknowledges the importance of Member States in providing accurate demand plans and securing budgets to support collectively the Revolving Fund.
- TAG continues to recommend that Member States ensure the development of increasingly accurate demand forecasts with greater long-term visibility. PAHO should support Member States in demand planning and monitoring.
- TAG encourages PAHO to keep updating Member States on vaccine markets and to implement proactive procurement responses to specific vaccine issues.
- TAG encourages PAHO to continue supporting global efforts to improve access to affordable vaccines, including regional pooled procurement initiatives.
- TAG welcomes the Revolving Fund assessment of its business model and proactive positioning for future years, while maintaining its core principals. TAG also welcomes the opportunity to participate in this assessment and encourages Member States to do the same.

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