Pan American Health Organization

World Health Organization
REGIONAL OFFICE FOR THE Americas

Regional Polio Meeting
Eradication & Endgame Plan

Final Report

17-19 August 2015
Bogotá, Colombia

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Acronyms

AFP	Acute flaccid paralysis
bOPV	Bivalent oral polio vaccine; containing serotypes 1 and 3
cVDPV	Circulating vaccine-derived poliovirus
EPI	Expanded Program on Immunization
GCC	Global Certification Commission
IPV	Inactivated polio vaccine
mOPV	Monovalent oral polio vaccine
NCC	National Certification Committee
OPV	Oral polio vaccine
PAHO	Pan American Health Organization
RF	PAHO Revolving Fund
RCC	Regional Certification Commission for the Polio Endgame in the Region of the Americas
SAGE	Strategic Advisory Group of Experts on Immunization of the World Health Organization
the Endgame	Polio Eradication & Endgame Strategic Plan 2013-2018
TAG	Technical Advisory Group on Vaccine-preventable Diseases of the Pan American Health Organization
tOPV	Trivalent oral polio vaccine
VAPP	Vaccine-associated paralytic poliomyelitis
WHO	World Health Organization
WPV	Wild poliovirus
WPV2	Wild poliovirus type 2

Introduction

The *Regional Polio Meeting: Eradication & Endgame Plan* was held from 17-19 August 2015 in Bogotá, Colombia.

Dr. Jose Fernando Valderrama, representing the Ministry of Health of Colombia, gave the welcoming words and official opened the meeting, accompanied by Dr. Gina Watson, Representative of the Pan American Health Organization (PAHO) in Colombia, Dr. Michel Zaffran, Coordinator of the Expanded Programme on Immunization at the World Health Organziation (WHO), and Dr. Cuauhtémoc Ruiz Matus, Chief of the Comprehensive Family Immunization Unit at PAHO.

Global and Regional progress on the implementation of the Polio Eradication & Endgame Strategic Plan 2013-2018 (Endgame) was discussed in detail, including polio eradication, guidelines for the switch from trivalent oral polio vaccine (tOPV) to bivalent oral polio vaccine (bOPV), and poliovirus containment in laboratories, and working groups were formed to evaluate progress on the development of the national switch plans.

29 countries in the Region participated, along with representatives from the Regional Certification Commission for the Polio Endgame in the Region of the Americas (RCC), PAHO/WHO, WHO, UNICEF, CDC, the Task Force for Global Health, the Bill and Melinda Gates Foundation. .

This report provides a summary of each topic discussed, together with the final recommendations and agreements.

History of Polio Elimination in the Americas

In 1985, the PAHO/WHO 31st Directing Council passed a resolution declaring to eradicate polio in the Americas by 1990. The last endemic case of wild polio virus in the Region occurred on 23 August 1991 in Pichinaki, Department of Junín, in Peru, and in 1994, the International Commission for the Certification of Poliomyelitis Eradication, an independent commission tasked with overseeing regional polio eradication efforts, declared the Americas to be polio-free.

The Region achieved polio eradication through high vaccination coverage, active and high quality acute flaccid paralysis (AFP surveillance, laboratory diagnostic capacity, and aggressive outbreak control. The countries of the Americas did not create a special structure for polio eradication, but rather eliminated polio through strengthening the routine immunization programs that were already in place. This created a lasting legacy that not only impacted immunization programs, but also supported other health systems in the Americas, which was documented in the 1995 Report of the "Taylor Commission".

Following the leadership and success of polio control in the Americas, the World Health Assembly passed a resolution in 1988 aiming to eradicate polio by the year 2000. The Americas Region has now been free of wild polio for more than 24 years.

Global update on the implementation of the Polio Eradication and Endgame Strategic Plan 2013-2018 (the Endgame)

Tremendous progress has been made towards the global eradication goal. 80% of the world's population now lives in WHO Regions certified as polio free: the Americas in 1994, the Western Pacific Region in 2000, the European Region in 2002, and the South East Asia Region, which includes India, in 2014. In the last year, there have been no identified cases caused by wild polio virus in the African Region. However, challenges remain in three endemic: Pakistan, Afghanistan and Nigeria.

Pakistan and Afghanistan still have cases of wild poliovirus type 1 (WPV1) and Nigeria still has persistent circulating vaccine-derived poliovirus type 2 (cVDPV), with the last case detected on 16 May 2015.

In September 2015, the Global Certification Commission (GCC) will officially declare the eradication of wild poliovirus type 2.

Globally, all countries have plans to introduce the inactivated poliovirus vaccine (IPV) before the switch. In total, 156 countries and territories across the world will be participating in the switch from tOPV to bOPV, planned for 17 April – 1 May 2016. These dates for the switch window will be confirmed by the Strategic Advisory Group of Experts on Immunization (SAGE) in October, and once confirmed, the decision is irrevocable.

Regional update on the implementation of the Endgame in the Americas – AFP surveillance, coverage and IPV introduction

Acute flaccid paralysis (AFP) surveillance continues to be the priority mechanism for the detection of poliovirus circulation. Investigation should always be done for:

- any AFP case detected in children less than 15 years of age, for any reason other than severe trauma;
- any AFP case detected in any person, of any age, in whom polio is suspected; and
- any outbreak of AFP to discard polio diagnosis.

Environmental surveillance can complement AFP surveillance in selected areas based on risk criteria.

Regarding quality surveillance indicators, the Region of the Americas has consistently achieved the notification rate of 1 AFP case per 100,000 children under 15 years, since 1986. However, in recent years, the Region has not reached 80% of AFP cases with adequate samples and investigation of cases within 48 hours.

The quality of surveillance is heterogeneous among countries. During 2014, only two countries in the Region met these three quality indicators: Mexico and Nicaragua.

In the last 52 weeks, epidemiological weeks 33/2014 to 31/2015, there have been an increasing number of countries that are not achieving the surveillance indicators.

The PAHO Weekly Polio Bulletin is a simple tool that can be used to check the quality of AFP surveillance at the country level.

Through analyzing the data from the Polio Bulletin, there are some notable surveillance errors:

- delay in registering new cases;
- sending samples to reference laboratory months after they are collected;
- delay in final classification of AFP cases, and
- closing of cases without laboratory result.

Regional vaccination coverage against polio, which reached 94% in 2011, has declined over the past three years, reaching 90% in 2014. Additionally there are notable coverage differences between and within countries. In 2013 and 2014, most countries did not reach polio vaccination coverage of 95%. According to 2014 data, 6 million children under 1 year of age live in the 60% of municipalities in Latin America and the Caribbean that reported coverage less than 95% for OPV3.

To fulfill the Endgame guidelines, the countries of the Region will be introducing at least one dose of IPV, by the end of 2015, in their routine immunization program as part of a sequential schedule: IPV followed by 3 or 4 doses of OPV. Countries that had planned to introduce IPV in the first semester of 2015 have done so; 27 countries will introduce IPV in the second semester of 2015; and Curacao will introduce in January 2016.

Out of the 51 countries and territories in the Region, 15 do not use OPV and the remaining 36 are currently preparing their national switch plans.

To contain wild and vaccine polioviruses, all countries should officially designate a National Poliovirus Containment Coordinator. To date, out of a total of 45 expected coordinators, excluding the French and Dutch territories, 28 coordinators have been officially designated.

The region of the Americas has formed the Regional Certification Commission for the Polio Endgame in the Region of the Americas (RCC), which met for the first time in June 2015. The Region is expecting a total of 23 national committees and one subregional committee for the Caribbean. To date, PAHO has received notification that 11 of these committees have been formed, including the Subregional Caribbean Certification Committee.

At the end of August 2015, the RCC will officially report to the Global Certification Commission (GCC), that the region of the Americas has been free of wild poliovirus type 2 (WPV2) for more than 26 years. The last isolation of WPV2 was detected in a fecal sample taken in March 1989 in Peru.

Agreements and recommendations

1 Strengthening AFP surveillance is fundamental in preparation for the switch, due to the risk of cVDPV2 emergence in the period post-Switch.

2 Countries that are not achieving a notification rate of 1 AFP case per 100,000 children less than 15 years of age, for the last 52 weeks, should conduct active searches for cases.

3 Countries should analyze vaccination coverage and implement vaccination activities with tOPV to improve coverage in areas with low tOPV coverage prior to the Switch.

4 Countries should stay on track with IPV introduction plans and guarantee that the vaccine is introduced in the planned period, in order to assure a safe switch from tOPV to bOPV.

5 When sufficient IPV supply is available, countries should be prepared to follow the TAG recommendation on the introduction of a second dose of IPV.

6 Countries should complete National Switch Plans and share with PAHO by 30 September 2015.

7 Countries that have not yet designated a National Poliovirus Containment Coordinator, should do so by 31 August 2015, notify PAHO, and begin the activities outlined in the Regional Containment Plan.

8 Countries that have not yet formed their National Certification Committee should immediately form the committee and notify PAHO by 31 August 2015.

Polio Eradication Certification: Regional Commission and National Committees

To fulfill the recommendations outlined in the Polio Eradication and Endgame Strategic Plan (the Endgame) 2013–2018, PAHO has formed a Regional Certification Commission for the Polio Endgame in the Region of the Americas (RCC).

The RCC will be responsible for certifying that the Region of the Americas has fulfilled the necessary requirements for the Endgame. The role of the RCC is to assess the achievement of the four main objectives of the Endgame in the Americas.

The RCC will have the support of the independent National Certification Committees (NCC) that will assess, verify and present the required national documentation.

The NCCs should be composed of independent experts in different areas of public health, acting in a personal capacity, without direct responsibility for polio eradication in their country. The NCCs will assess, verify and present the required national documentation, requested by the GCC, to the RCC.

NCCs will be responsible for:

- following up with AFP surveillance quality and polio vaccination coverage;
- validating and submitting report on the withdrawal and disposal of tOPV to the RCC;
- validating and submitting a formal report to the RCC on the implementation of containment measures taken to reduce risk of poliovirus reintroduction;
- conducting field visits, as required, to review or verify the fulfillment of Endgame objectives; and
- fulfilling further requests from the RCC and GCC.

Recommendations and Next Steps:

1 Immediately, countries that have not yet done so, should form their NCC

2 It is recommended that NCCs have an odd number of members, around five, to facilitate the working dynamics and the decision making processes.

3 It is required that NCC members do not have any responsibility for the polio eradication in their country, including the containment of poliovirus.

4 NCCs and the RCC should periodically review country progress on the preparation for the switch and the achievement of the Endgame goals.

5 By January 2016, NCCs should submit the WPV containment report to RCC.

6 In February 2016 the RCC will review WPV containment reports and submit a summary report to the GCC.

7 In May 2016 the NCCs should submit tOPV withdrawal and disposal reports to RCC.

8 In June 2016, the RCC will review the tOPV withdrawal and disposal reports from the NCCs and submit a Regional report to the GCC.

9 In August 2016, NCCs should submit Sabin poliovirus 2 containment reports to RCC.

10 In September 2016, the RCC will review the NCC Sabin poliovirus type 2 containment reports and submit a Regional report to the GCC.

Findings from studies on IPV+ bOPV sequential schedules in the Americas

Based on the WHO recommendation that all countries in the world introduce at least one dose of IPV in their routine immunization schedules by the end of 2015, in preparation for the switch from tOPV to bOPV, studies were conducted in Latin America to assess the immunological response to sequential vaccination schedules of IPV followed by bOPV. The main results of these studies indicate that:

1. One dose of IPV at 2 months of age or later provides more than 90% protection against polio type 2, when considered the additional 10% of children that seroconvert after exposure to the virus due to immunological memory (priming).
2. Two doses of IPV provide seroconversion in 100% of vaccinated children.
3. As for intestinal immunity, two doses of IPV decreased the peak and duration of poliovirus excretion, in response to the monovalent type 2 oral polio vaccine (mOPV2) challenge.
4. bOPV provides protection against types 1 and 3 in more than 95% of children after 2 doses.
5. bOPV proved to be safe, with no evidence of serious or moderate adverse events supposedly attributable to the vaccine.

IPV, tOPV, y bOPV procurement through the Revolving Fund

The Revolving Fund (RF) has actively participated in the planning process for the final phase of polio eradication in the Region.

With the decision to introduce IPV globally, as part of the Endgame, the production capacity for IPV needed to be expanded. This scale up is still in progress and has not yet generated sufficient supply to meet the demand for all countries.

In order to ensure that all of the countries in the Region have access to IPV before the switch, for the countries that are introducing IPV in 2015, it was necessary to limit the delivery of IPV to a schedule of one dose of IPV followed by 3 or 4 doses of OPV, until the IPV supply is sufficient to meet the demand of all countries.

Countries that had planned schedules with 2 or 3 IPV doses will receive the additional doses once there is sufficient production capacity to meet this demand. The availability of doses for 2016 will not be enough to meet the demands of these countries.

For the countries introducing IPV in 2015, price estimates from the producer have already been requested and the vaccine will be sent to countries between August and November, according to the planned introduction date.

In preparation for the switch, the RF requested that countries conduct an inventory of existing tOPV at all levels and revise the tOPV needs for the 3rd and 4th quarters of 2015 and for the period between January and April 2016.

All purchase orders for tOPV will be submitted in 2015 to meet the needs of countries until April 2016. There will be no purchase orders for this vaccine in 2016.

In preparation for the switch, the RF made a bid for bOPV, and five providers offered enough doses, at similar prices to tOPV, of this vaccine to meet the quantity required for the countries participating in the RF.

As soon as the bidding process is completed, the RF will send price estimates to the countries, in order to submit the purchase orders in 2015 for delivery in early 2016.

Agreement:

1 All countries will need to accept price estimates for IPV and bOPV within a maximum of 5 working days, after receiving the price estimates.

Available tools for IPV introduction and the Switch

To support countries with the introduction of IPV, there are documents available on the PAHO website directed to 3 target audiences: EPI managers, health care workers, and specialists in communication.

These documents will:

- support EPI managers develop and implement the IPV introduction plan;
- provide health care workers with in-depth training on all of the aspects related to IPV introduction, including multiple injections; and
- help communication specialists define key messages to share with the media and prepare for unexpected situations.

A separate set of materials for the switch are also available to countries on the PAHO webpage for the same main target audiences: EPI managers, health care workers, and specialists in communication.

The objectives of these documents are to support countries:

- prepare national switch plans,
- train health care workers, and
- develop an appropriate communication plan, including how to detect unexpected situations, evaluate the possible repercussions, and prepare an appropriate response.

Given the technical nature of the switch, and that it will not impact parents or caretakers, since it is a practical change from one oral vaccine to another, it is not recommended to communicate the switch at the community and household level. However, for crisis communication efforts, a risk-based communication planning approach for communities and households should be ready.

To support countries develop a proper switch communication plan and prepare for unexpected situations with implications for public communications, a switch communication planning guide and issues management guide have been developed.

All materials for IPV introduction and the Switch are available at: www.paho.org/immunization/polio.

For direct links:

IPV Introduction: http://bit.ly/1PJOp0K
Switch: http://bit.ly/1G6yl6y

Planning and preparation for the Switch from tOPV to bOPV

SAGE recommended the switch because WPV type 2 (WPV2) has not been detected since 1999, and around 90% of polio cases due to cVDPV and 40% of all vaccine-associated paralytic poliomyelitis (VAPP) cases are caused by poliovirus type 2. For this reason, continued use of tOPV generates more risks than benefits and threatens global polio eradication.

The countries of the Region received guidelines to develop switch plans and should already have a preliminary plan, including a timeline and budget, which should be finalized by the end of September 2015, to ensure that all requirements for a safe switch will be met.

The plan guidelines as well as other supporting technical documents can be found in the following website: http://bit.ly/1G6yl6y

Recommendations:

1 All countries should complete their national switch plan and share with PAHO by 30 September 2015.

2 Countries should begin or continue preparation activities outlined in the National Switch Plan, and should consider appropriate training for all health care workers as a high priority.

3 Countries should update PAHO on fulfillment of switch activities on a monthly basis using the form that PAHO will share with the countries, and inform PAHO immediately if any problem arises that could delay switch preparation.

4 Countries should review the switch budget, developed by WHO and available on the PAHO immunization switch page, to assure that all of the switch components are included in national budgets.

5 Countries should review the country norms for vaccine destruction to define protocols for the destruction of tOPV.

6 To facilitate the identification of tOPV and bOPV, countries should design stickers that indicate the final date allowed for use of tOPV and the first date allowed for bOPV use.

National Switch Plan - Peru

Peru presented a summary of their national switch plan, highlighting the following activities:

- Formation of national and departmental committees with clear definition of responsibilities.
- Indentification of support teams.
- Definition of information flow.
- tOPV inventory and demand needs.
- Timeline for vaccine distribution.
- Revision of national guidelines for transport and disposal of vaccines.
- Evaluation of the cold chain capacity at all levels.
- Timeline for switch preparation, implementation and validation.
- Development of plans for: health care worker training, communication, monitoring and supervision of switch implementation and withdrawal and disposal of tOPV validation and supervision.

The technical team identified some gaps and challenges in their plan:

- Setting a definitive Switch date for the country.
- Establishing a disposal mechanism for the elimination of the vaccine at all levels.
- Ensuring the budget for the implementation plan.
- Fullfilling established timelines.

Switch “Dry Run” Experience in other Regions

“Dry runs” for the switch from tOPV to bOPV have been held in various countries. The key take away from these “dry runs” is that the switch is totally feasible at country level as long as clear guidelines are available and good planning starts in advance.

The principal lessons learned were:

- The timely identification of a management structure within ministries of health to oversee the initial steps needed is critical.
- Quality training materials are necessary, specifically for logistics and cold chain.
- Engagement of scientific societies, the private sector and other partners is important.

Switch Working Groups

Four working groups, of 24 countries evaluated the progress of national plans as well as strengths, challenges and solutions for the switch.

In the first section of the working groups, each country evaluated the advances in their national plan, looking at the following plan components:

- Executive summary
- Management and operational oversight of switch - national coordination mechanisms
- Situation Analysis on aspects related to the plan
- Preparation phase: financial and human resources, supply, logistics and supervision
- Formation of the national certification committees

During the second section of the working groups, the participants discussed:

- Strengths for the switch,
- Challenges for the switch,
- Possible solutions to overcome the challenges, and
- Technical support required.

At the end of the session, each working group presented a 10 minute presentation in the plenary on the aspects that were most relevant and that would have the most impact on the development of the plans. The experiences shared among the countries will be useful in order to finalize the national switch plans.

Copies of the presentations were shared on the USBs distributed to meeting participants at the end of the meeting.

Protocol for notification, risk assessment, and response following detection type 2

Following OPV2 cessation, there will be a relatively higher, but time-limited, risk of the emergence of cVDPV type 2, and there is a lower, but long term risk of poliovirus re-introduction from a manufacturing site or laboratory. For these reasons, all countries must maintain sensitive surveillance systems in order to rapidly detect and interrupt any circulating poliovirus.

Detection of any poliovirus type 2, in any sample of any source, will be considered a Global Public Health Emergency that requires rapid and high-quality response.

The type and magnitude of the response will depend on:

- Time between the withdrawal of OPV2 and the detection of PV2.
- History of the transmission of WPV or cVDPV in the area or region affected.
- Characteristics of the affected population, such as population immunity level.

The potential magnitude of a PV2 outbreak will rise exponentially with time elapsed since OPV2 cessation, due to declining mucosal immunity to type 2. The real magnitude of an outbreak after the switch will depend on the humoral immunity, meaning, the vaccination coverage reached with IPV.

The WHO will have a world reserve of mOPV2 and IPV to be used in case of any poliovirus type 2 outbreak after the switch. In order to receive access to these vaccines, that are free of charge, countries will need to send a complete risk evaluation report to the WHO, through the country and regional PAHO office. This evaluation should start within 72 hours of detection and be completed within 7 days.

A protocol for poliovirus type 2 notification, investigation, risk assessment, and response has been developed to support country planning and is available at: www.paho.org/immunization/polio.

Regional Poliovirus Containment Plan

The containment of poliovirus is necessary in order to guarantee global polio eradication.

In December 2014, the WHO published the third edition of the Global Action Plan (GAPIII) to minimize poliovirus facility-associated risk after polio eradication and the sequential withdrawal of OPV.

The Global Action Plan aligns the safe handling and containment of poliovirus infectious and potentially infectious materials with the Endgame.

Achieving this goal requires implementation of poliovirus safe handling and containment measures to minimize the risks of a facility-associated reintroduction of virus into the polio-free community.

The global strategy for minimizing poliovirus facility-associated risks consists of *risk elimination* by destruction of poliovirus materials in all but certified essential poliovirus facilities and *biorisk management* of such facilities by strict adherence to required safeguards.

Risk elimination in non-essential facilities is achieved through destruction, or transfer to essential poliovirus facilities, of infectious and potentially infectious WPV and OPV/Sabin materials. Destruction applies to all materials potentially contaminated with any type or strain of WPV or OPV/Sabin poliovirus, or where the presence of polioviruses cannot be ruled out.

The adaption of the containment plan for the Americas takes two issues into consideration: 24 years without AFP cases caused by wild poliovirus and OPV use in most of the countries.

Similar to the Global Action Plan, the Regional GAPIII is implemented in three phases that are linked to international milestones in polio eradication.

The primary activities that need to take place in the Region during the Coordination Phase for preparation are:

By 31 December 2015	**By 31 July 2016:**
National laboratory survey and inventory of facilities that store infectious and potentially infectious poliovirus material: wild, vaccine derived and Sabin polioviruses.	Destruction of unneeded vaccine poliovirus type 2 (Sabin2) materials.
Governments, institutions, and polio facilities are informed about the upcoming need for poliovirus containment.	Transfer of needed vaccine poliovirus type 2 (Sabin2) materials to essential poliovirus facilities.
Transfer of needed wild poliovirus materials to essential poliovirus facilities.	Destruction of unneeded samples potentially containing vaccine poliovirus type 2 (Sabin2).
Destruction of unneeded samples potentially containing poliovirus materials.	
Destruction of unneeded wild poliovirus materials, which includes VDPV.	
Designated essential poliovirus facilities obtain certification for containment.	

Recommendations and Next Steps

1 Countries should designate a National Poliovirus Containment Coordinator before 31 August 2015, inform PAHO, and begin implementing the activities outlined in the regional plan.
2 Countries should conduct an inventory of laboratories and facilities that store infectious or potentially infection poliovirus material: WPV, VDPV and Sabin.
3 The destruction, transfer or containment of infectious or potentially infectious WPV and VDPV materials should be completed by 31 December 2015.
4 The country should submit the report on the inventory of facilities and the containment of WPV and VDPV to the NCC in January 2016.
5 The destruction, transfer or containment of infectious or potentially infectious Sabin2 materials should be completed before 31 July 2016.
6 The country should present the report on the inventory of facilities that contain poliovirus Sabin2 to the NCC in August 2016.
7 Designated essential poliovirus facilities should obtain certification for containment by 31 December 2015.

More information on the Regional GAPIII can be found at: www.paho.org/immunization/polio.