# TAG RECOMMENDATIONS **FOR POLIO**

Pan-American Health Organization (PAHO), 2024







# Contents

1999 Recommendations	)
General	)
Laboratory	)
2000 Recommendations	;
2002 Recommendations	ŀ
2004 Recommendations	;
Annex 3: Meeting of the polio laboratory network	;
2006 Recommendations	)
Polio Laboratory Network	)
2009 Recommendations	_
Polio laboratory network1	_
2011 Recommendations	)
2012 Recommendations	;
2013 Recommendations14	ŀ
2014 Recommendations1	;
2015 Recommendations	,
2016 Recommendations	3
2017 Recommendations	_
2018 Recommendations	;
2019 Recommendations	ŀ
2021 Recommendations	;
2022 Recommendations	,
2023 Recommendations	)



#### General

- Countries need to maintain 95% vaccination coverage with OPV in 80% of the districts or equivalent geopolitical area. Countries unable to reach this coverage level should carry out at least two National Immunization Days (NIDs). Measles follow-up vaccination campaigns should be used as an opportunity to administer OPV.
- Immunization coverage should be monitored at the lowest geopolitical level. In areas that have discrepancies in terms of target population, there should be verification of information using other sources, such as number of BCG doses applied, or number of DPT1 doses, or results of mop up operations, or household census used by malaria programs, or rapid assessment surveys.
- All countries should strengthen the key surveillance indicators of AFP reporting:
  - Surveillance systems must detect at least one AFP case per 100,000 population
    - <15 years of age per year.
  - At least 80% of the AFP cases should have an adequate stool sample collected within 15 days of paralysis onset.
- Oral polio vaccine (OPV) remains the vaccine of choice for the final phase of the global eradication of polio. OPV is the vaccine recommended for the eradication because it is easier to administer, is inexpensive and it provides better intestinal immunity which constitutes a special barrier to inhibit further spread of wild poliovirus.

#### Laboratory

- Stool samples must be received in laboratories within 14 days after collection. Once a sample has arrived in a laboratory, results should be available within 28 days.
- All laboratories should implement the use of RD and L20B continuous cell lines.
- Efforts are urgently needed to strengthen communication between polio laboratories and epidemiology units.
- All governments should ensure the implementation of WHO's Guidelines for Implementing Phase I of the Global Action Plan for Laboratory Containment of Wild Polioviruses.



- Countries need to maintain 95% vaccination coverage with OPV, the vaccine of choice, in all districts or equivalent geopolitical areas.
- All countries should strengthen their compliance with the key surveillance indicators, including at least one AFP case per 100,000 population <15 years of age per year, and at least 80% of the AFP cases with an adequate stool sample collected within 15 days of paralysis onset.
- Given the complexities that may surround the implementation of the GAPLC initiative for laboratory stocks of wild poliovirus, TAG recommends that the Americas initiate pilot studies building upon the experience of other regions that have already undertaken their own studies, to determine the feasibility and methodology of the Plan. PAHO should invite these regions to attend the next TAG meeting for exchange of experiences and findings.



- The TAG notes that a high number of AFP cases are being discarded that do not have an adequate evaluation or a stool sample. All countries in the Region should continue to use the recommended AFP case classification system and should establish a National Expert Group or Commission. This Commission should closely scrutinize those cases without an adequate stool specimen in an attempt to determine the etiology of the case's paralysis.
- All countries must maintain certification standard surveillance. Special efforts should be targeted to improve surveillance, especially in those countries whose non-polio AFP rate has fallen below 1/100,000.





- Countries of the Americas must maintain adequate AFP surveillance, sustain high OPV coverage in every municipality, strengthen the polio laboratory network, and comply with the Plan of Action for Laboratory Containment of Wild Poliovirus.
- The TAG reiterates previous recommendations and states that OPV must remain the vaccine of choice for the final phase of global polio eradication. OPV provides intestinal immunity, is substantially less expensive than IPV, is easy to administer, and protects contacts in the family and community, thereby conferring herd immunity.
- PAHO should not consider any change in current OPV policy of the Region until the world is certified polio-free.
- The Region should advance in the post-certification period in close accordance with the global policies stated by the Global Certification Commission on Polio Eradication.
- Ideally, all polio vaccination should be stopped globally after the world is certified polio- free. Based on an analysis of the risks and strategic options, in September 2003, a World Health Organization (WHO) Advisory Group recommended that plans be developed and steps be taken to prepare for the coordinated cessation of OPV use for routine immunization after the global interruption of wild poliovirus transmission. However, given that polio is still circulating in the world, the countries of Latin America and the Caribbean should continue to use OPV in their routine program to maximize population immunity until global polio eradication is achieved.
- An analysis of the vaccine-associated paralytic paralysis (VAPP) case incidence in the Region of the Americas should be presented at the next TAG meeting. That information should be used to better evaluate the risk that countries will face during the end game.
- PAHO should continue to more accurately define the cost-effectiveness of the post- certification vaccination options with concomitant analysis of opportunity costs.
- AFP cases need to be classified in a more timely fashion to reduce the unnecessary accumulation of pending cases being reported in the PAHO bulletin. Laboratory: A PAHO Polio Laboratory Network meeting was held immediately prior to this year's TAG meeting. The objective was to evaluate the status of the network and to define actions to be taken in order to improve it. The TAG endorses the report of the Polio Laboratory Network Meeting (Annex 3).



 However, the TAG is especially concerned about the need to strengthen logistical and technical cooperation, and overall management of the PAHO laboratory network. It recommends that PAHO appoint a regional advisor to coordinate the polio laboratory network. This person would coordinate all technical and operational support pertaining to accreditation issues, logistics, and data management. The TAG also recognizes that IM will require two additional staff members to coordinate the other laboratory networks.

#### Annex 3: Meeting of the polio laboratory network

#### PAHO Polio Laboratory Network Management and Support

- The links of PAHO laboratories with the global polio laboratory network should be strengthened to assure access to WHO weekly reports, current technical documents and other relevant publications. This information will be used to improve surveillance of possible importation of wild polioviruses from endemic countries or the emergence of circulating VDPVs.
- To assure effective management, improvements should be made within the PAHO network to improve the process of performance monitoring. Regular communication on laboratory data and performance issues should be established between the laboratories of the Region, the Institutions/Ministries of Health, PAHO, and WHO/ HQ.
- To accomplish the previous recommendations, the appointment of a regional laboratory coordinator should be expedited.

#### Laboratory Accreditation

- To update information about laboratories in the Americas and share this data with WHO/HQ, accreditation checklists will be distributed by the Global Polio Laboratory Coordinator to be completed by laboratories and returned within one month of receipt. The forms, covering performance in the 12 months prior to 30 September 2004, will be reviewed with the assistance of WHO/HQ and reports will be sent to laboratories within three months and will be linked with a plan of action to address any deficiencies identified.
- Results and feedback from the 2004 polio isolation and intratypic differentiation (ITD) proficiency tests will be sent to laboratories by PAHO. These results will contribute to assessment of laboratory performance.
- Only two laboratories in the Region are currently accredited by WHO as ITD laboratories, Fiocruz (Brazil) and CDC (USA). Poliovirus isolates should be sent to one of these two laboratories for characterization within 7 days of detection following global requirements.



• For the program to use ITD results from other laboratories in the network, priority should be given to formal accreditation of appropriate laboratories. The cost effectiveness and resource implications of accrediting new laboratories for ITD within the Region should be evaluated by PAHO in consultation with WHO/HQ. Decisions are needed about accrediting 2-3 additional laboratories to do ITD tests.

#### **Quality Assurance**

- The above accreditation and management activities will be used to help identify the major obstacles to high-quality laboratory performance. The existing system should be refined to assure the rapid reporting of polio laboratory data, including all critical laboratory performance indicators to provide appropriate feedback on a continuous basis and effective regional and global monitoring of laboratory performance.
- Internal quality assurance (QA) with an aim to rapidly detect and correct possible performance deficiencies should be an integral part of daily laboratory activity. Assessment of QA programs for laboratory procedures will be emphasized as part of the current accreditation process to assure appropriate implementation within the regional laboratories.
- Laboratories should complete implementation of cell sensitivity testing as part of the routine internal quality control program and complete performance of three valid tests of NIBSC and LQC reference standards in parallel as soon as possible.

#### **Communication and Data Management**

 Reporting is an essential aspect of the quality control of laboratory work and of maintaining satisfactory records of laboratory results and activities. PAHO should provide a standardized format for data sharing which should include the information required, the frequency of reporting, the appropriate recipients, and feedback to the laboratory/institution. A pilot computerized system with these capabilities for data management and reporting should be implemented in two laboratories and reviewed before the next laboratory meeting.

#### Future of the Polio Laboratories

- Maintenance of polio laboratory activities in the future will require advocacy with partners and governments to assure continued support for surveillance activities that are a part of the WHO Strategic Plan.
- Within the Region, many laboratories and institutions continue to expand their technical capabilities to perform ITD and/or viral nucleic acid sequencing. To enhance the rapid detection of poliovirus as part of response strategies during the period of OPV cessation, or when shipment of polio isolates is less cost-



effective, accreditation requirements for sequencing activities should be formulated before the next global laboratory network meeting.

As wild poliovirus transmission will be interrupted in the near future, network • laboratories are encouraged to set an example by implementing containment requirements of virus holdings. Laboratories should be encouraged to destroy all non-needed wild poliovirus materials.



World Health Organization

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

#### **Polio Laboratory Network**

- PAHO should continue to support members countries in mobilizing resources from partner agencies necessary for continued support and maintenance of the polio laboratory network activities.
- All institutions that currently house polio laboratories must be committed to ensure technical quality and performance of all laboratory personnel to minimize the risk of infectious material spreading to workers and the environment.
- Network laboratories should submit cell sensitivity test results to the regional laboratory coordinator within 48 hours after test completion. Should there be evidence of reduced sensitivity for poliovirus detection, the lab coordinator should assist in implementing a follow-up plan.
- Poliovirus isolates should be sent to one of the three regional laboratories accredited as intratypic differentiation (ITD) laboratories (Fiocruz in Brazil, Malbrán in Argentina, and CDC in the US) within seven days of detection. The ITD test results should be reported by the ITD laboratory within 14 days after receiving polio isolates.
- To facilitate early implementation of public health interventions, laboratories must report within 24 hours all discordant ITDs and wild poliovirus results to national authorities and the PAHO regional laboratory coordinator.



The laboratory network must continue to participate in activities to ensure ٠ completion of Phase 1 containment throughout the Region and advocate for polio containment in appropriate scientific venues and with national governments. All wild poliovirus potential materials should be destroyed.



World Health Organization

- While there is poliovirus circulating in the world and the danger of importations continues, TAG recommends that the vaccine of choice remain OPV as stated in previous TAG reports and as recommended by WHO. This recommendation will continue to be reviewed as the global situation evolves.
- To reduce the risk of importations and to prevent another outbreak caused by a Sabin- derived poliovirus, countries that do not achieve OPV coverage >95% in every municipality should conduct annual OPV immunization campaigns for children aged <5 years, regardless of their vaccination status.</li>
- Countries should maintain certification standards of AFP surveillance (compliance with surveillance indicators).
- To prevent reintroduction of wild poliovirus into their communities, all American countries should conclude phase I of wild poliovirus containment in the laboratories as requested by the Regional Commission on Containment.

#### Polio laboratory network

- The laboratory network should have implement by October 2009 the new test algorithm for cell culture and intratypic differentiation (ITD) with current updates to provide faster results. Resource mobilization may be required for implementation in some settings.
- The data management systems (PESS or ISIS) should accommodate the changes in reporting to reflect the new algorithm and the surveillance indicator for laboratory of up to 14 days for cell culture results and up to 21 days for polio and non-polio positive specimens.
- The network laboratories should ensure that all poliovirus isolates are appropriately screened for the presence of vaccine-derived poliovirus (VDPVs); detection should be conducted by screening with genetic ITD test followed by analysis of the complete sequence of the VP1 poliovirus protein.
- All network laboratories should continue to implement Quality Assurance processes, including preparation, use, and periodic update of Standard Operating Procedures and ensure compliance.



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



- TAG awaits the World Health Organization's comprehensive polio eradication and endgame strategy, as well as results from ongoing and planned research to revisit its recommendations for the Region of the Americas. At the present time, the trivalent oral poliomyelitis vaccine (tOPV) remains the vaccine of choice for the Americas. To this end, PAHO, in collaboration with WHO, should negotiate with providers to ensure sufficient supply of tOPV for countries of the Americas.
- Countries considering the introduction of the inactivated polio vaccine (IPV) should first fulfill the sanitation and vaccination coverage conditions recommended during TAG's previous meeting (Argentina 2011). If a country does not meet these basic conditions, it should conduct at least two annual vaccination campaigns, administering the tOPV to every child aged <5 years, without taking into account their previous vaccination status. Countries making plans to introduce the IPV should be able to guarantee its long-term supply, in addition to considering the price of the vaccine.</li>
- Countries should reinforce surveillance of AFP, attain adequate levels in all basic surveillance indicators, and continue working to achieve ≥95% polio coverage in every municipality.
- As IPV will be considered for use in the polio endgame requested by the WHA, it will be important for WHO to maintain a fluid dialogue with vaccine manufacturers to ensure an adequate IPV supply at an affordable price for countries of all income levels, as this will be a factor in the rapid adoption of the vaccine.
- PAHO is in an advantageous position to work with the GPEI, in the development
  of the endgame strategy and for the synchronized cessation of vaccines
  containing poliovirus type 2, and supporting cost-effectiveness studies for
  different scenarios. Additionally, the World Immunization Week could be used as
  an effective platform for globally coordinated actions.



- Countries of the Americas must wait for the fulfillment of the conditions stated by SAGE for the cessation of the use of Sabin type 2 containing vaccines; these conditions must be met before making any change in vaccination policy. As long as there are outbreaks caused by cVDPV type 2 and the wild poliovirus continues to circulate in the world, the trivalent oral polio vaccine (tOPV) remains the vaccine of choice for the Americas.
- PAHO should convene a Working Group to develop a strategic plan describing current options and scenarios, as well as the timelines for the implementation of the polio endgame in the Americas. This plan should discuss the feasibility of using different OPV/IPV schedules; the availability of combination vaccines containing IPV, where the ideal situation would be having an hexavalent DTwP-Hib-IPV-HepB vaccine, among other issues.
- All countries must reinforce the activities aimed to achieve or maintain vaccination coverage >95% in every district or municipality. If countries do not achieve that coverage they must evaluate the accumulation of non-immunized and conduct vaccination campaigns.
- All countries must continue to maintain adequate acute flaccid paralysis (AFP) surveillance in order to timely detect any importation or emergence of VDPVs, and must report to PAHO on a timely fashion to allow the proper monitoring of the Regional situation.
- TAG reinforces its previous recommendations (Argentina 2011) for countries considering the introduction of inactivated polio vaccine (IPV): compliance with sanitary conditions and vaccination coverage guaranteeing an adequate protection to their communities.
- PAHO must continue to maintain a dialogue with vaccine suppliers in order to guarantee the provision of polio vaccines for the Americas.



- TAG expresses concern regarding the reported decline in Polio3 coverage at the national and sub-national levels in the Americas. As such, TAG strongly urges countries to ensure high, homogenous polio coverage to maintain the achievement of polio elimination in the Region.
- TAG notes the confirmed isolation of WPV1 in Brazil from environmental sampling in the state of Sao Paulo in March 2014 and commends Brazil for its response to this isolation. This finding confirms that the risk of WPV is real for the Region.
- In light of the newly confirmed risk of WPV importation in the Americas, TAG calls upon PAHO Member States to urgently take action to strengthen AFP active surveillance. The reported decline in the proportion of laboratory specimens of quality collected and timeliness of case investigations jeopardizes the opportune detection of imported WPV (or VDPVs) and rapid deployment of response activities.
- Due to its high cost and involved methods, expansion of environmental surveillance networks in the Region needs further assessment. TAG recommends that PAHO assess the strengths and weaknesses of existing environmental sampling methods and based on this risk assessment and evaluation of existing methods, PAHO should propose potential options for environmental sampling in selected settings in the Region.
- PAHO should conduct a risk analysis to identify areas in the Region with a high concentration of WPV importation (and VDPV) risk (i.e. geographic areas with suboptimal polio3 coverage and a large number of international visitors from polio endemic or at risk areas).
- TAG reiterates the recommendations issued during the extraordinary TAG Meeting on Polio conducted in April 2014:
  - TAG agrees with the renewed efforts towards eradicating polio and the objectives of the polio endgame. These efforts include the ongoing removal of Sabin oral polio vaccine from the routine immunization schedule.
  - TAG reiterates its previous recommendations, emphasizing:
    - 1. The importance of achieving and maintaining high and homogenous vaccination coverage rates to reduce risk of importations of WPV and cVDPV, and
    - 2. The need for continued strengthening of



#### epidemiological AFP surveillance.

- TAG urges implementation of environmental surveillance towards validating the elimination of cVDPVs and WPV.
- TAG agrees with the six prerequisites stated by SAGE to switch from tOPV to bOPV.\*
- The countries of the Americas are already in the process of introducing IPV. At the end of 2015, approximately 80% of the birth cohort in the Americas will be covered with IPV. PAHO is providing technical cooperation to the countries on this process.
- The remaining countries must decide when they will be able to introduce IPV, taking into consideration affordability (price for vaccines and operational costs), current opportunity costs, and sustainability. PAHO should continue working with the countries to help remove barriers for such introduction.
- When introducing IPV, countries should consider sequential schedules. Ideally, countries should consider two IPV doses followed by two OPV doses. However, if a country is considering only one IPV dose, this should be with the first DTP dose and followed by three OPV doses.
- Countries should not consider moving directly to an IPV only schedule at this time, unless they meet the criteria previously recommended by TAG and WHO (low risk of transmission and importation, high homogeneous coverage, and good sanitation).

\*According to the SAGE's recommendations, prior to the withdrawal of OPV2 – by replacing tOPV with bOPV in all OPV-using countries, six prerequisites must be in place:

- 1. Validation of the elimination of persistent cVDPV type 2 and confirmation of WPV2 eradication;
- 2. A mOPV type 2 stockpile and response capacity;
- 3. Surveillance capacity and an international notification requirement for all Sabin, Sabin-like, and cVDPV type 2 viruses;
- 4. Sufficient bOPV products for all OPV-using countries;
- 5. Affordable IPV option(s) for all OPV-using countries;
- 6. Phase II bio-containment of all cVDPVs type 2 and WPV.



- All countries should have a comprehensive national switch plan developed by July 2015 and should introduce at least a single dose of IPV by the end of 2015 in order to ensure a safe switch from tOPV to bOPV.
- Countries should achieve and maintain high vaccination coverage with IPV >95% in every district and municipality. They should strengthen AFP surveillance for the early detection of polio cases caused by cVDPV or WPV. The risk of polio outbreaks caused by cVDPV2 after discontinuing use of tOPV will remain for a limited time during the transition period. After the switch from tOPV to bOPV, countries should apply at least one dose of IPV followed by two doses of bOPV, to ensure full immunity.
- Countries that have not already formed a National Certification Committee should do so as soon as possible in order to fulfill the requirements and demands of the Global and Regional Certification Commissions.
- Countries should be prepared to follow TAG recommendations on the introduction of a second IPV dose as soon as the available IPV supply is sufficient.
- TAG reaffirms that the containment of poliovirus is needed in order to protect the achievement of poliovirus eradication. TAG endorses the Regional Action Plan for containment of poliovirus that is aligned with GAP-III.
- TAG invites all countries to designate a national polio containment coordinator (NPCC).
- TAG encourages countries to carefully document the national poliovirus inventory according to the recommendations outlined in the containment plan.
- TAG reaffirms that countries must define the poliovirus essential facilities that will satisfy the GAP-III requirements to be classified as certified essential facilities.



# Global IPV Supply Situation: How to Manage the Limited IPV Supply and Deal with Potential Stockouts

- The TAG reiterates its concern about the insufficient global supply of IPV and recognizes that the RF and the Immunization Unit are closely monitoring the situation and adjusting IPV delivery schedules in order to avoid stockouts in countries of the Region.
- Due to the overall global deficit of IPV that will last through 2017, the TAG recommends that countries:

#### 1. Reduce IPV wastage

- Ensure strict adherence to the vaccination schedule, using IPV only with children that have turned two months of age after the official introduction date of IPV in the country.
- Fully implement the WHO open vial policy, which permits the use of open vials of IPV for up to 28 days, provided that the defined criteria are met as outlined in the WHO policy on the use of opened multi-dose vaccine vials.
- To reduce wastage of the vaccine, avoid, whenever possible, the use of IPV in extramural activities, prioritizing vaccination strategies that use fixed or mobile vaccination posts.
- Closely monitor IPV supply in the country to assure that all services are supplied and all possible service points that could have excessive vaccine wastage are identified, for providing appropriate recommendations. 11

#### 2. Prepare to respond to possible IPV shortages

- All health workers should be informed about a possible shortage of IPV and prepared to respond to this eventuality.
- In the absence of IPV for administration as the first dose of vaccination against polio, children should receive bOPV as the first dose in the schedule. In these cases, IPV should be applied at the first contact as the second, third or booster dose in the schedule, always respecting the minimum interval of 4 weeks between doses of polio vaccines.
- Due to the uniqueness of this recommendation, it is necessary to inform all vaccinators about the importance of clearly registering which vaccine was used, in both the national registry and on the child's vaccination card, so that for the next



visit, it will be clear if the child has already received a dose of IPV or if this dose is still pending.

### 3. Prepare to respond to polio outbreaks

- All countries should review their polio outbreak response plans, considering the guidelines presented in the documents published by the Global Polio Eradication Initiative, on 20 April 2016: Standard Operating Procedures for responding to poliovirus events and outbreaks, Part 1: General Standard Operating Procedures, and Part 2: Specific protocol for type 2 poliovirus (both available on the PAHO website: www.paho.org/polio).
- Countries should ensure that they can receive mOPV2 in a very short time from the global stock pile for outbreak response, which will be sent through UNICEF.
- IPV will not be needed to respond to all type 2 polio outbreaks. However, if it is assessed that IPV use is necessary, the WHO recommends that countries use fractional doses, administered intradermally, to make sure there is sufficient supply to serve all countries in need.
- Countries should evaluate their capacity in terms of skilled human resources to implement a vaccination campaign with fractional doses of IPV administered intradermally. Furthermore, countries should ensure that they can use the IPV vaccine this way, as recommended by the WHO for outbreak response. The recommendation is based on scientific evidence, but it is not indicated so on the vaccine inserts, therefore that means that countries must use fractional IPV as off label use.

### 4. Evaluate the capacity for use of ID fIPV in routine program, if needed

- At this time TAG does not recommend that countries begin an ID fIPV schedule, but this option could be considered if the supply situation continues to worsen.
- Another TAG meeting should be convened if there is a change in the current IPV supply situation that justifies further assessment and recommendations.
- In the meantime, all countries should begin to evaluate the capacity of the program to implement an ID fIPV schedule. This includes evaluating the availability of trained personnel to apply ID vaccine, BCG syringes, programmatic cost and feasibility. Also, countries should evaluate if any changes need to be made to the national registry system.
- Due to the fact that the ID fIPV recommendation is based on scientific evidence, but is not included in the vaccine inserts, countries should ensure they can use ID fIPV off label.



#### 5. Strengthen surveillance

- The TAG reiterates that due to the risk of the emergence of cVDPV type 2 in the post-switch period, all countries must maintain sensitive surveillance systems in order to rapidly detect and interrupt any type 2 circulating poliovirus.
- Countries should strive to meet the following AFP quality surveillance indicators:
  - 1 AFP case per 100,000 children less than 15 years old

World Health Organization

- > 80% cases with adequate samples
- > 80% cases investigated within 48 hours or less.



# How to face the global IPV shortage. The TAG reiterates its recommendations made in May 2016:

#### 1. Reduce IPV wastage

- Ensure strict adherence to the vaccination schedule, using IPV only with children that have turned two months of age after the official introduction date of IPV in the country.
- Fully implement the WHO open vial policy, which permits the use of open vials of IPV for up to 28 days, provided that the defined criteria are met as outlined in the WHO policy on the use of opened multi-dose vaccine vials.
- Avoid, whenever possible, the use of IPV in extramural activities, prioritizing vaccination strategies that use fixed or mobile vaccination posts.
- Closely monitor IPV supply in the country to assure that all services are supplied and all possible service points that could have excessive vaccine wastage are identified, for providing appropriate recommendations.

#### 2. Prepare to respond to possible IPV shortages

- All health workers should be informed about a possible shortage of IPV and prepared to respond to this eventuality.
- In the absence of IPV for administration as the first dose of vaccination against polio, children should receive bOPV as the first dose in the schedule. In these cases, IPV should be applied at the first contact it is available, as the second, third, or booster dose in the schedule, always respecting the minimum interval of 4 weeks between doses of polio vaccines.
- Due to the uniqueness of this recommendation, it is necessary to inform all vaccinators about the importance of clearly registering which vaccine was used, in both the national registry and on the child's vaccination card, so that for the next visit it will be clear if the child has already received a dose of IPV or if this dose is still pending.

#### 3. Prepare to respond to polio outbreaks

- All countries should review their polio outbreak response plans, considering the PAHO guidelines, available on the website: www.paho.org/polio.
- Countries should ensure that they can receive the monovalent oral polio virus vaccine type 2 (mOPV2) in a very short time from the global stock pile for



outbreak response, which will be sent through UNICEF.

- IPV will not be needed to respond to all type 2 polio outbreaks. However, if it is assessed that IPV use is necessary, the WHO recommends that countries use fractional doses, administered intradermally, to make sure there is sufficient supply to serve all countries in need.
- Countries should evaluate their capacity in terms of skilled human resources to implement a vaccination campaign with fractional doses of IPV administered intradermally. Furthermore, countries should ensure that they can use the IPV vaccine in this way, as recommended by WHO for outbreak response. The recommendation is based on scientific evidence, but is not indicated so on the vaccine inserts, therefore that means that countries must use fractional IPV as off-label use.

#### 4. Strengthen surveillance

- The TAG reiterates that due to the risk of the emergence of cVDPV type 2 in the post-switch period, all countries must maintain sensitive surveillance systems in order to rapidly detect and interrupt any type 2 circulating poliovirus.
- Countries should strive to meet the following quality surveillance indicators for acute flaccid paralysis (AFP):
  - $\circ$  1 AFP case per 100,000 children less than 15 years old
  - > 80% cases with adequate samples
  - > 80% cases investigated within 48 hours or less



- All countries should strive to achieve and maintain 95% coverage with IPV in every district and municipality.
- TAG commends the countries that have begun preparation to switch to a fractional schedule of IPV, and encourages them to proceed with implementation of the fIPV schedule.
- TAG commends PAHO for the efforts to improve the IPV supply for the Region. However, recognizing that the ongoing global IPV supply constraints could still affect countries of the Region, TAG recommends that all countries of the Region without exception - be prepared to respond in the event of a shortage.
- In case IPV is not available, children should receive bOPV as the first or second dose of the schedule, and receive IPV as a later dose, always respecting the minimum interval of 4 weeks between doses of polio vaccine. It is important that health care workers always clearly record what vaccine was given to each child.
- TAG reaffirms recommendations made previously (May 2016, March and July 2017) regarding reducing IPV wastage, and the importance of reaching and maintaining vaccination coverage ≥95% in each district or municipality.
- The post-certification polio vaccination policy recommends countries have two doses of IPV in their routine immunization schedule for at least ten years after global OPV withdrawal, either full or fractional doses. All countries that switch to fIPV will be able to continue using fIPV through the post-certification era. For countries that do not switch to fIPV, they should be prepared to introduce a second full dose of IPV, once there is sufficient global supply.
- As IPV is no longer recommended for outbreak response, TAG recommends that countries update their national poliovirus outbreak response plans according to the individual recommendations that were provided by PAHO in December 2017.



- TAG urges countries to fully implement the end game strategy for polio eradication, including maintaining high vaccination coverage, conducting active AFP surveillance, meeting poliovirus containment requirements, conducting risk assessments, developing and implementing mitigation plans and updating outbreak response plans.
- The TAG strongly recommends that the 192 countries that currently use only one dose of IPV, introduce a second IPV dose into their routine immunization schedules.
- In countries where VDPV is detected through environmental surveillance, such as Guatemala, TAG underlines the importance of countries maintaining high vaccination coverage and high-quality surveillance. TAG supports the decision of Guatemala to conduct a nationwide vaccination campaign using bOPV and MMR vaccines. Other high-risk countries in the Region should take appropriate measures to prevent the re-introduction of WPVs or emergence of cVDPVs.
- TAG recommends that PAHO adapt the SAGE Primary Immunodeficiency Guidelines for the Region.



- The TAG endorses the GPEI's "Global Polio Eradication Strategy 2022-2026 Delivering on a Promise," which should be adopted by countries of the Americas.
- The TAG is extremely concerned with the inadequate polio vaccination coverage and the weak surveillance systems, which are unable to sustain and verify polio eradication in the Americas; unless these are urgently improved, it fears that WPV1 and/or cVDPV outbreaks may occur in the Region.
- The TAG urges countries to achieve 95% coverage with Polio3, and strongly recommends governments to invest resources in achieving and maintaining this target. This immunization coverage target also applies to IPV1 and IPV2.
- The TAG noted the SAGE evaluation of the systematic review of IPV immunogenicity. The TAG then considered the previous TAG criteria regarding the use of IPV as the first dose to prevent VAPP and the need to sustain gut immunity by administering bOPV. The TAG recommends the following vaccination schedule for the 13 countries that have not yet introduced the second dose of IPV:

	Basic			Booster		
Vaccination	<b>1</b> <sup>st</sup>	2 <sup>nd</sup>	3 <sup>rd</sup>	4 <sup>th</sup>	5 <sup>th</sup>	
schedule	2 months	4 months	6 months	12-18 months	4-5 years	
	IPV	bOPV	IPV	bOPV	bOPV	

#### Regional recommendation for polio vaccination schedule, the Americas, 2021

- Countries that have already introduced two doses of IPV may consider adopting the above schedule or consider the interval of 4 months between IPV1 and IPV2. Their final decision should be based on a programmatic and epidemiological analysis.
- The TAG congratulates Ecuador for conducting a study on the effectiveness of the use of fractional dose of IPV. The results of this study should be used to determine if the current schedule is appropriate or if changes are needed.
- Given the constraints of the COVID-19 pandemic, the TAG does not recommend that countries discontinue the use of bOPV in favor of an IPV-only schedule at this time.



- The TAG endorses the recommendations given by the SAGE regarding the interchangeability of sIPV with wIPV. As of July 2021, sIPV is not recommended as a fractional dose.
- Given that the Region's AFP rate has reported only a slight increase between 2014 and 2019 (1.19 and 1.33, respectively), and stool adequacy has remained constant during the same period (76% and 77%, respectively), the TAG recommends that efforts must be made to improve the performance of both indicators to avoid missing cases of paralysis caused by polioviruses.
- Considering the sharp drop in vaccination coverage and surveillance rates, countries at very high risk of outbreaks (Haiti and Bolivia) or at risk due to ongoing population movement with a high-risk country (Dominican Republic) should consider the collection of a second stool sample. Given the workload and costs of collecting a second sample, these countries should implement this temporary recommendation while strengthening their immunization program and surveillance systems.
- If a stool sample cannot be collected from the AFP case within 14 days of the onset of paralysis, or if a stool sample arrives at a laboratory in poor condition, The TAG recommends that countries collect one stool sample from each of three contacts, preferably from close family members, household contacts, neighbors, or playmates (all younger than 5).
- The TAG strongly recommends consistent implementation of the 60-day follow-up visit to assess the presence of residual paralysis. (This assessment is currently completed in fewer than 20% of cases.)
- Environmental surveillance is an excellent addition to the national surveillance system. However, considering its very high cost, a country should consider implementing environmental surveillance only after improving the sensitivity of its AFP surveillance systems.



- TAG expresses grave concern regarding the serious decline in DTP3, polio3 and MMR2 vaccination coverage across the Americas and is disheartened to see that the achievements of 40 years are at risk of collapse. TAG strongly recommends that countries focus their political, technical, and financial commitments to halt the decline in vaccination coverage by December 2023. Countries must increase vaccination coverage for all antigens of the regional immunization program to achieve the 95% coverage threshold. These objectives must be prioritized given finite financial and human resources to address essential health needs and emerging health threats.
- TAG strongly encourages PAHO to address this crisis at both the technical and political levels. Unless the political discourse leads to urgent action supported with the necessary resources, children are likely to die from several of the vaccinepreventable diseases. The first step is to stop the continued trend in declining vaccination coverage. The following objective will be to reach levels of coverage that the programs were so successful at attaining a decade ago.
- In addition to ongoing consultations with ministries of health, PAHO must engage heads of government and ministries of finance as well as regional and global organizations such as the Organization of American States, the Inter-American Development Bank, and the World Bank, among other partners. PAHO unequivocal commitments to strengthen should obtain the regional immunization program, and work with these entities to establish clear goals and milestones to monitor progress. Further, PAHO should engage a broad range of donor organizations and partners to create a coalition for supporting national immunization programs at all levels. Such efforts should be a clear call to action to the governments and all stakeholders of the Americas to support action plans and multi-year budgets to implement the recommendations of Resolution CE168.R15 – Reinvigorating immunization as a public good for universal health. Resources should be provided to the PAHO regional secretariate to expand its field presence for prevention of VPDs in priority countries.
- TAG is deeply concerned with the accumulation of large, multiple cohorts of under-vaccinated children across the Region. In 2021, 2.7 million children younger than 1 year across the Americas are unvaccinated or under-vaccinated, leaving them susceptible to many VPD (notably polio, measles, pertussis, diphtheria, rotavirus, and pneumococcal diseases). Countries must assess their vaccination coverage rates at the national and subnational levels to identify and vaccinate susceptible children. Where DTP3, polio3 or MMR2 coverage rates fall below 80%,



countries should strengthen routine immunization service delivery and implement multi-antigen catch-up vaccination operations – periodic intensification of routine immunization (PIRI) activities, innovative local strategies (e.g., mobile vaccination teams, outreach activities, events where multiple health services are offered to the public in one location) – to close the immunity gap.

- Because of the dangerous decline in population immunity for polio and measles, TAG strongly urges countries, where appropriate, to conduct multi-antigen vaccination follow-up campaigns in collaboration with PAHO technical assistance. For the priority groups at high risk for COVID-19 hospitalization and death, vaccination should be offered in these campaigns.
- Given the risk of importations and cVDPV, TAG strongly recommends that countries that have not yet introduced the second dose of inactivated polio vaccine (IPV) in their national immunization schedule should do so immediately, in order to reduce the pool of children susceptible to poliovirus type 2 (PV2). Furthermore, countries should offer catch-up IPV1 and IPV2 doses to all eligible children immediately.
- TAG reiterates its previous recommendation that countries do not discontinue the use of bOPV in favor of an IPV-only schedule at this time. Countries that have been classified as "very high risk", "high risk" or "medium risk" for polio by the RCC for at least one of the last three consecutive years should not stop the use of bOPV. It should be noted that many countries in the Region currently fall into this category.
- Given the widening immunity gaps reported in all countries and territories of the Americas, TAG urges countries to expand the age range of their surveillance operations to include adolescents and adults who present with symptoms and signs of a VPD. For example, acute flaccid paralysis (AFP) cases should be investigated thoroughly for polio, even if the person is older than 15 years.



- Countries and territories of the Americas are commended for recognizing the Region's low vaccination coverage rates against vaccine-preventable diseases (VPDs) and for taking steps to address these serious immunity gaps. Member States are encouraged to continue on the road to recovery by focusing their political, technical, and financial resources on halting and reversing the decline in vaccination coverage for all antigens of the regional immunization program.
- Polio events or outbreaks must be implemented rapidly (i.e., within 30 days of laboratory confirmation) using an appropriate oral polio vaccine (OPV), and that high vaccination coverage must be achieved through enhanced microplanning, social mobilization, and strategies tailored to reach populations at risk.
- The recommendation of the SAGE on March 2023 regarding the use of inactivated polio vaccine (IPV) to supplement the use of OPV—whether it be novel OPV or Sabin OPV—must be implemented in the Region of the Americas during vaccination campaigns to enhance mucosal immunity and reduce the likelihood of ongoing poliovirus circulation or to close immunity gaps to type 2 polio. However, this strategy must be employed in hard-to-reach areas where immunity gaps are widest or in response to polio events or outbreaks as a strategy to bolster population immunity quickly and effectively. Member States should not delay OPV response operations if IPV vaccine doses are not immediately available.
- In situations where under-vaccinated communities are in situations of vulnerability or in hard-to-reach areas, polio vaccination operations (including the co-administration of IPV and OPV) should add the administration of all antigens included in the national immunization program for children younger than five years. These operations should include active case search operations for suspected VPD cases in health facilities and in the community. These actions will minimize the risk of new events or outbreaks and reduce viral transmission where an event or outbreak has already occurred.



- The PAHO Comprehensive Immunization Program should develop a decisionmaking algorithm to determine which vaccination strategy (OPV alone; OPV and IPV) to use, depending on the epidemiological situation, immunity gaps, affected population, level of community engagement and resources available. Also, PAHO should provide operational guidance to Member States on how to co-administer IPV and OPV.
- Countries should not discontinue the use of bOPV in favor of an IPV-only schedule at this time. Countries that have been classified as "very high risk", "high risk," or "medium risk" for polio by the RCC for at least one of the last three consecutive years should not stop the use of bOPV. It should be noted that many countries in the Region currently fall into this category.
- In July 2021, countries and territories were recommended a five-dose vaccination series against polio (three doses in the primary series and two booster doses), using a combination of IPV and bivalent OPV doses.

	Primary series			Booster	
Vaccination schedule	1 <sup>st</sup>	2 <sup>nd</sup>	3 <sup>rd</sup>	4 <sup>th</sup>	5 <sup>th</sup>
July 2021	2 months	4 months	6 months	12-18 months	4-5 years
	IPV	bOPV	IPV	bOPV	bOPV

 Considering the forthcoming availability of the wP hexavalent vaccine, Member States should consider a revised vaccination schedule that incorporates this vaccine into the national immunization schedule without disruptions or the need for additional training. This proposed schedule also uses five doses (three doses in the primary series and two booster doses) for the same age groups but replaces IPV with the wP hexavalent vaccine and adds one dose of the wP hexavalent vaccine as a booster.

Vaccination schedule	:	Primary series	Booster		
	1 <sup>st</sup>	2 <sup>nd</sup>	3 <sup>rd</sup>	4 <sup>th</sup>	5 <sup>th</sup>
May 2023	2 months	4 months	6 months	12-18 months	4-5 years
	Hexavalent	Hexavalent + bOPV	Hexavalent	Hexavalent + bOPV	bOPV

