TAG RECOMMEDATIONS FOR POLIO

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1999 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.

2000 Recommendations

- 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.

2002 Recommendations

- 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.

2004 Recommendations

- 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.

2006 Recommendations

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

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 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.

2009 Recommendations

- 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.
- 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.

2011 Recommendations

- 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).

2012 Recommendations

1. 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.
2. 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.
3. 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.
4. 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.
5. 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.

2013 Recommendations

- 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.

2014 Recommendations

- 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.

2015 Recommendations

- 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.