

SAGE Polio Working Group

Thursday, 19 February 2015

Conference Call Notes

INTRODUCTION

A SAGE Polio Working Group (WG) teleconference was held on 19 February 2015 to discuss persistent cVDPV2 transmission in relation to the OPV2 withdrawal “trigger,” and the process of verification of poliovirus containment in essential facilities. The call was attended by the following WG members: Peter Figueroa (Chair), Walter Orenstein, Walter Dowdle, T Jacob John, Elizabeth Miller, Kimberly Thompson, Hyam Bashour, Antoine Kabore, and Francis Nkrumah. Nick Grassly, Zulfiqar Bhutta and Yagob Al-Mazrou were unable to attend.

This note presents a summary of the presentations, key discussion points, decisions and recommendations from the call.

OBJECTIVES

The objectives of the meeting were to:

1. Review the current status of persistent cVDPV2 transmission in Nigeria and Pakistan and mitigation approaches in each country. **(Information)**
2. Endorse a proposal for contingency actions that would enable OPV2 withdrawal on the planned date of April 2016, in the event that persistent cVDPV2 continues to circulate after March 2015. **(Decision)**
3. Endorse a proposal for the verification process of poliovirus containment in essential facilities **(Decision)**

PRESENTATIONS, DISCUSSIONS AND CONCLUSIONS

TOPIC 1
Current situation of persistent cVDPV2 in Nigeria and Pakistan (Information)
<p>In 2014, persistent cVDPV2 transmission was identified in only Nigeria and Pakistan. Overall, incidence of cVDPV2 decreased in the second half of 2014 following tOPV/IPV campaigns in affected areas, although AFP cases caused by cVDPV2 viruses occurred with onset as late as November 2014 in Nigeria and December 2014 in Pakistan.</p> <p>In Nigeria, two lineages of persistent cVDPV2 circulated in 2014, but cVDPV2 detection declined in Borno, Sokoto and Kano states following two rounds of large-scale tOPV SNIDs in northern Nigeria starting in mid-2014 supplemented with targeted tOPV+IPV campaigns in Borno and parts of Yobe. cVDPV2-related AFP cases or cVDPV2-positive environmental surveillance (ES) samples have not been identified since the most recent tOPV SNID conducted in November 2014. To ensure that current persistent cVDPV2 transmission is interrupted within the first half of 2015, Nigeria is planning an aggressive programme of tOPV SIAs and targeted mop-up campaigns. Two tOPV SIAs are planned for March (NID) and April (SNID), with IPV added in selected high-risk areas.</p> <p>In Pakistan, two persistent cVDPV2 lineages stopped circulating during the first half of 2014. A new persistent lineage emerged in Gadap, Karachi, in July 2014, and continued to circulate as of January 2015. Pakistan will implement 4 tOPV campaigns during the first half of 2015 in the areas affected by persistent cVDPV2 in 2014, 1 in March (NID), 1 in April (SNID), and 2 in May (SNIDs), with IPV added in selected highest-risk areas.</p>
TOPIC 2
Contingency plan to monitor and stop cVDPV2 in advance of OPV2 withdrawal (Decision)
<p>For Decision:</p> <p>Context: Contingency actions to interrupt persistent cVDPV2 transmission during the second half of 2015 to ensure global withdrawal of OPV2 in April 2016 remains on track.</p> <p><i>After reviewing the progress and the contingency plans for cessation of persistent cVDPV2 in Pakistan and Nigeria in 2015, does the WG agree to review the epidemiology of persistent cVDPV2 in June and again in September 2015 in the event that persistent cVDPV2 continues to circulate after March 2015, to facilitate the final SAGE endorsement of OPV2 withdrawal date of April 2016?</i></p> <p>Epidemiology: Transmission of all persistent cVDPV2 lineages circulating in Nigeria and Pakistan at the beginning of 2014 declined substantially, although a new lineage was confirmed in Pakistan in January 2015 indicating persistent programmatic failures that could delay planned OPV2 withdrawal.</p>

Confidence in surveillance: Both Nigeria and Pakistan have maintained surveillance indicators (i.e., non-polio AFP rate and % stool adequacy) at international standards during the past 12 months, although with some sub-national heterogeneity largely related to insecurity (Borno, FATA, Karachi). Importantly, Nigeria expanded its environmental surveillance sites to 34 in 2014 with plans to improve sensitivity further (particularly with respect to sampling frequency), and has started contact-sampling of all AFP cases in Borno and Yobe states. In addition, Nigeria has been conducting sero-prevalence surveys in high-risk states to monitor serotype-specific immunity children under age 5 years in order to assess progress and target immunization activities.

Pakistan expanded its environmental surveillance sites to 36, with a number of new sites becoming functional in late 2014. Pakistan will start conducting sero-prevalence surveys in 2015.

Confidence in SIA quality and regimen: Multiple tOPV campaigns (some with IPV co-administration in highest risk areas) were conducted during the second half of 2014, with evidence from lot quality assurance sampling (LQAS) of improving quality of rounds, particularly in Nigeria, and improved access to inaccessible populations in Pakistan. Both countries have co-administered IPV in campaigns to vaccinate specific high-risk populations. Both countries have established plans for multiple tOPV campaigns in the first half of 2015 and the SIA plan for the second half of 2015, which will be finalized in April, will also include additional tOPV SIAs to ensure interruption of any residual cVDPV2 transmission and prevention of the development of future cVDPVs. The SAGE endorsed the GPEI approach for using a risk-based tOPV SIA regimen to reduce the risk of new cVDPV2 emergence at its October 2014 meeting.

Country readiness for OPV2 withdrawal: Countries continue to make progress towards achieving the 5 readiness criteria recommended by the WG. The SAGE concluded in October 2014 that global preparations were on track for OPV2 withdrawal in April 2016, and recommended that Member States accelerate their preparations.

In its 136th session, the Executive Board of WHO decided to call on Member States to ensure global readiness by the end of 2015 for the coordinated withdrawal of oral poliovirus vaccines containing the type 2 component and directed the Secretariat to draft a resolution for submission to the World Health Assembly scheduled in May 2015.

The WG discussed the GPEI's capacity to ensure the absence of persistent cVDPV2 preceding OPV2 withdrawal in April 2016. The WG was encouraged by progress made in Nigeria and Pakistan, including the expansion of environmental surveillance and the specific efforts to interrupt persistent cVDPV2 transmission with tOPV and tOPV+IPV campaigns during the second half of 2014 in line with SAGE recommendations. The WG was also encouraged by the plans for multiple tOPV SIAs planned for the first half of 2015 in Nigeria and Pakistan, the opportunity to conduct additional tOPV campaigns in the second half of 2015, and the plan endorsed by SAGE to include multiple tOPV campaigns in the SIA calendar in the months preceding the switch.

Decision and Recommendations: *The WG agreed to review the epidemiology of persistent cVDPV2 in June and again in September 2015 in the event that persistent cVDPV2 continues to circulate after March 2015, to facilitate the final SAGE endorsement of OPV2 withdrawal date of April 2016. The WG made the following recommendations:*

1. *The program should maintain the target of April 2016 for OPV2 withdrawal.*
2. *Nigeria and Pakistan should ensure sufficient numbers of high quality tOPV or tOPV+IPV SIAs and mop-ups during the first half of 2015 to interrupt any ongoing persistent cVDPV2 transmission.*
3. *A teleconference should be held in June 2015 and either a teleconference or a face-to-face meeting should be held in September 2015.*

TOPIC 3

Verification of essential facilities' compliance with GAP III (Decision)

For Decision: *Does the WG endorse the approach proposed below for certification and verification of containment of polioviruses in essential facilities?*

Proposal: *Essential facilities implement GAPIII, and National Regulatory Authorities for containment (NRACs) certify facilities against GAPIII and submit certification reports to Regional Certification Commissions (RCCs). In support of this process, RCCs may request that WHO verify the compliance of certified facilities against GAPIII, and countries or concerned facilities may also request WHO's verification in advance of RCC evaluation.*

NRACs and WHO will use GAPIII as the basis to verify that essential facilities meet GAPIII requirements. Verification reports will be shared with all concerned stakeholders (e.g., facilities, NRAs and WHO). Responses to verification reports will be 3-fold:

- Facilities will address any non-compliance within an agreed timeframe, including follow-up and additional visits,

if necessary.

- NRAs will undertake an informed decision to revoke or maintain certification against GAPIII.
- RCC will undertake an informed decision as to whether the facility complies with GAPIII.

The WG discussed the verification process and was encouraged by the plan for GAPIII training for national regulatory bodies responsible for assessment and certification of facilities.

Decision and Recommendation: *The WG agreed to the proposed approach to containment verification and made the following recommendation:*

- *Data on progress towards implementation timelines should be provided to evaluate readiness to contain type 2.*