SAGE Polio Working Group

Monday 8th June 2015

Conference Call Notes

INTRODUCTION

A SAGE Polio Working Group (WG) teleconference was held on 8th June 2015 to discuss the epidemiology of persistent cVPDV2 transmission; the preparations for OPV2 withdrawal, including the IPV supply strategy and monitoring framework for tOPV withdrawal. 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, Yagob Al-Mazrou, Nick Grassly, Antoine Kabore, Francis Nkrumah. Zulfiqar Bhutta was 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 the updated global SIA calendar. (**Information**)
2. Review the preparations for OPV2 withdrawal (**Information**), including
    a. Global IPV introduction schedule for OPV-only using countries, including IPV supply situation for 2015 and 2016
    b. bOPV licensure
    c. mOPV2 stockpile
    d. Monitoring system for tOPV withdrawal
    e. Containment
    f. Verification and certification of wild poliovirus type 2

PRESENTATIONS, DISCUSSIONS AND CONCLUSIONS

TOPIC 1 **Epidemiological status of persistent cVDPV2 transmission in Nigeria and Pakistan (Information)**
WG reviewed the epidemiology of persistent cVDPV2 in Nigeria and Pakistan. To date in 2015, the program made considerable progress in eliminating persistent cVDPV2 cases, but the virus continued to be detected in environmental samples collected from certain sites in Nigeria and Pakistan. In Nigeria, no cVDPV2 cases have been reported in 2015, with only one isolate of persistent cVDPV2 detected from one environmental surveillance site in Kaduna, in March 2015. Nigeria conducted two successive tOPV rounds in March and April 2015; both were NIDs. IPV was co-administered with tOPV in the affected LGAs of Kaduna during the April NID. All subsequent environmental samples from Kaduna for the months of April and May 2015 have been confirmed as negative. Further rounds are planned for July (SNID) and September (SNID) 2015. Nigeria is currently on track to stop persistent cVDPV2 circulation within the first half of 2015 with its aggressive use of tOPV SIAs and the addition of IPV in selected high-risk areas. Also, in Pakistan, there have been no persistent cVDPV2 cases reported in 2015. A new persistent cVDPV2 emerged in July 2014, and continued to be detected in environmental surveillance in Gaddap, Karachi until March 2015, with all subsequent environmental surveillance samples from Gaddap for the months of April and May 2015 confirmed as negative. A single positive environmental sample was also detected in Quetta, Balochistan in March 2015, with all subsequent samples collected from Quetta during April and May confirmed as negative. Pakistan conducted 4 tOPV campaigns during the first half of 2015 in areas affected by persistent cVDPV2 in 2014, 1 in March (NID), and 2 in May (SNIDs), with IPV added in selected highest-risk areas, such as in Quetta.

In Gaddap, specific activities targeting missed children were initiated last month, with female community volunteers vaccinating children <5 years of age twice a month. More tOPV rounds are planned for June (local SIA in Karachi) and September (SNID) 2015. Thereafter, the epidemiology of cVDPV2 will be reviewed and further tOPV rounds will be added after September 2015 as necessary.

Both Nigeria and Pakistan are mopping up in any infected areas. In addition, Nigeria introduced IPV in February 2015, and Pakistan is forecast to introduce IPV in July 2015 in their national routine immunization schedules.

WG comments

The WG acknowledged the significant progress made towards eliminating persistent cVDPV2 in Nigeria and Pakistan. However, it expressed concern over potential ongoing cVDPV2 circulation in Pakistan and requested the program to continue aggressive tOPV rounds especially in infected areas. The WG requested another review of progress of the epidemiology of persistent cVDPV2 status in advance of the face to face meeting in September. Most members of the WG agreed that IPV should be selectively used in addition to OPV in previously inaccessible areas to fully utilize the opportunity to immunize children.

TOPIC 2
Global preparations for OPV2 withdrawal (Decision)

The WG reviewed the different aspects of preparations for the OPV2 withdrawal.

Global IPV supply situation for 2015 and 2016:
Since January 2013, among the 126 tOPV-only using countries, 20 have introduced IPV and the remaining 106 have either formally committed to or have expressed intent to introduce IPV by the end of 2015. There are currently only 2 suppliers of IPV and global IPV supply is extremely tight, due to manufacturing constraints and use in SIAs. The situation is further exacerbated by the request to set aside IPV supply for use in outbreak response campaigns. From a supply perspective, all Tier 1 and 2 countries can introduce IPV in 2015, however given the supply scenario, some Tier 3 and 4 countries will need to postpone IPV introduction to 1Q 2016, but before the anticipated switch date of April 2016. However, should there be additional requests for doses for IPV or problems with production at one of the manufacturers, some Tier 3 and Tier 4 countries may need to postpone introduction to mid-2016.

bOPV licensure for routine immunization:
Out of 149 countries with tOPV in their immunization schedule, 16 have already licensed bOPV, and 102 countries either accept WHO prequalification or have used bOPV in SIAs such that routine use should not represent a major issue. WHO and partners are providing focused support to the remaining 31 countries.

On May 26th 2015, the World Health Assembly (WHA) adopted the resolution that calls on member states to expedite the process of bOPV registration for routine immunization use, and if necessary to authorize bOPV use on the basis of its WHO prequalification while full registration is ongoing. Following the WHA, formal correspondence was sent from WHO to all Ministries of Health. In addition, 3 bOPV manufacturers and fillers (GSK, Sanofi Pasteur, and Panacea) applied for bOPV label change to include routine use, with approval already granted by the Belgian NRA for GSK in June 2015, and approvals expected for Sanofi Pasteur and Panacea, by their respective NRAs, in mid-2015.

mOPV2 stockpile:
The procurement and management of the mOPV2 stockpile has one key objective, which is to have the capacity to rapidly deploy mOPV2 for emergency vaccination in the event of a poliovirus type 2 outbreak. Regarding mOPV2 preparations, two mOPV2 manufacturers have already been contracted to supply 519 million doses in bulk form. This quantity is already available and secured at -40°C. 100 million doses of this bulk is being filled in vials (50 million doses by April 2016, and another 50 million doses before the end of July 2016). The contract with GSK (to fill 50M doses of mOPV2) has already been finalized, and the contract with Sanofi (to fill the additional 50M doses) is currently in progress.

Monitoring strategy for tOPV withdrawal:
The 3 key objectives of monitoring the switch from tOPV to bOPV were outlined: a) to ensure that tOPV is no

longer available for use after the national switch date; b) to assess the performance of the switch; and c) to assess the status of bOPV and IPV introduction at the monitored facilities. Balancing technical rigor with cost/feasibility, the proposed monitoring strategy will focus efforts on visiting all cold chain stores of vaccines down to the district level, where the largest stocks of tOPV are held in-country, and assuring that these stocks have been removed from the cold chain and sent/marked for destruction. At the health facility level (the point of service delivery), a non-random purposive sampling will be conducted (10% of targeted facilities per district), as these facilities typically store stock for about one month. In the event of a finding of opened or unopened vials of tOPV in the cold chain at these visited facilities, an additional 5% of facilities would be visited; if tOPV stocks continue to be found in the cold chain in these additional facilities then the whole district would be swept to identify any remaining tOPV vials.

Containment

In preparation for OPV2 withdrawal in April 2016, all Regions need to update their inventories according to the revised phase I of GAP III, and contain, transfer or destroy WPV2 infectious or potentially infectious material including cVDPV2 by the end of 2015, and all OPV2/Sabin 2 virus by the end of 2016. To facilitate the process, WHO will provide GAP III implementation training to Global Polio Laboratories, vaccine manufacturers, and national oversight bodies. WHO is also finalizing the Containment Certification Scheme (CCS) which provides guidance to stakeholders (facilities, national oversight bodies, RCCs, WHO) on the implementation of containment.

Verification and certification of wild poliovirus type 2 eradication

In March 2015, the six WHO Regional Directors sent communication to all the member states in their respective regions requesting them to present existing data on the last WPV2 detection in country (if any) and requested Ministers to confirm data, or provide additional findings. In September 2015, WHO will organize a meeting of the Global Certification Commission (GCC) to review the evidence submitted to WHO ROs / RCCs, and this will be followed by formal GCC declaration that WPV2 was eradicated > 15 years ago.

WG comments

Overall, the WG is comfortable with the progress with the preparations. It agreed with the proposed approach to manage the tight IPV supply, including prioritizing IPV introduction in Tier 1 and 2 countries, as well as judiciously allocating IPV for SIAs in polio-infected areas and for cVDPV2 outbreak response after type 2 OPV withdrawal.

The WG discussed whether IPV introduction in every country is a pre-requisite for OPV2 withdrawal, and WHO clarified that IPV introduction is one of the criteria to assess readiness for the switch, rather than a pre-requisite per se. The introduction of IPV is a means to reduce the risks associated with VDPVs and other risks of emergence in the medium and longer terms, and it will be important for Tier 1 and 2 (high risk) countries to have introduced IPV by the end of 2015. While the WG agreed that all countries should have introduced IPV by the time of the switch, some members considered that the relatively low risk of cVDPV2 emergence in lower risk countries (Tier 3 and 4 countries) could still be managed adequately if, because of the constraints in IPV supply, a few of them introduced IPV within a short interval after the switch.

The WG endorsed the strategy for monitoring the switch at country level, highlighting the importance of in-country communication to ensure all tOPV vials are collected or destroyed and that health workers understand the importance of not using these vials after the date of the switch. Regarding containment preparations, the WG emphasised that WHO should further strengthen efforts to actively communicate with relevant virological laboratories on GAPIII requirements.

During the face to face meeting in September 2015, the WG requested to review the different aspects of preparation for the OPV type 2 withdrawal in more detail, specifically:

- Epidemiology of persistent cVDPV2 in Nigeria and Pakistan
- IPV introduction status and global IPV supply situation
- Progress report on the implementation of containment plan (including phase I and phase II progress, by Region)
- Revised type 2 outbreak response protocol
- Detailed switch monitoring guidelines