7 - 8 Oct | 2013

7th Meeting of the SAGE Polio Working Group

Note for the Record

World Health Organization

DRAFT AS OF 10/21/13

Executive Summary

The seventh meeting of the SAGE Polio Working Group (WG) was held on 7-8 October 2013. The WG reviewed the plans to rapidly introduce IPV and prepare for potential cVDPV type 2 outbreaks following OPV2 cessation. The major conclusions of the WG are briefly outlined in this summary. A full review of the evidence and rationale for each decision are explained in this report.

The WG recommendation for the IPV schedule is:

- That all OPV-only using countries should introduce at least one dose of IPV into their immunization schedules by the third quarter of 2015.
- That IPV should be administered in addition to the 3-4 doses of OPV in the primary series. The dose should be administered during an immunization contact at or after 14 weeks.
- Example timing of the IPV dose is as follows:
    - 6, 10, 14 weeks or 2, 3, 4 months schedule: add IPV dose at the DPT3/OPV3 contact; or
    - 2, 4, 6 months schedule: add IPV dose at the DPT3-OPV3 contact (although the DPT2-OPV2 can be considered).
- For children starting the routine immunization schedule late (age > 3 months) the IPV dose should be administered at the first immunization contact.
- When communicating this recommendation, the following should be highlighted:
    - IPV is an additional dose to OPV and not a replacement (the combined schedule gives the optimal immunity);
    - The *primary* :purpose of IPV introduction is to mitigate the cVDPV type 2 following OPV2 withdrawal (it will also prevent VAPP due to OPV types 1 and 3.);
    - The immunization visit in which DTP3 and OPV3 (OPV4 if there is a birth dose) are administered was selected over DTP1/OPV1 because of the gains in immunogenicity of IPV at 14 weeks compared to earlier administration. The later visit gives time to allow decrease in the levels of maternally-derived transplacental polio antibodies in the infant, which can interfere with an immune response to IPV; and
    - The potential risk of an IPV only schedule should be explained to any country considering such a change (including the evidence from Israel, an IPV only using country, of prolonged transmission of wild poliovirus type 1 probably related to the inferior intestinal immunity IPV induces compared to OPV)

In regards to the global IPV supply, financing and introduction strategy:

- The WG applauds the collaboration between WHO, UNICEF, GAVI, and partners to create a comprehensive plan for the introduction of IPV. The WG is particularly encouraged by:
    - The commitment from GAVI to support rapid IPV introduction by adapting their policies to align with the timeline of the Polio Endgame.
    - The commitment from donors to allocate funds specifically for IPV; and
    - The extensive work done by the GPEI Immunization Systems Management Group (IMG) and its subgroups on country prioritization, demand forecast, financing, readiness for introduction, and planning.
- The WG recommends GPEI to continue the research to assess the feasibility of innovative and cost-saving IPV approaches (intradermal delivery, adjuvant, and product optimization) to ensure access to affordable IPV in the mid- to long-term, given the continuing concern over the price of IPV.
- The WG endorses the methodology of tiering countries, based on VDPV and wild virus importation risks, for focusing urgent technical support, but reinforces that introduction by the end of 2015 is essential in all four tiers (see annex 1).
- Recommends that all Tier 1 and 2 countries should have a detailed plan for IPV introduction by mid-2014 to facilitate global IPV supply and risk management; furthermore, all remaining countries should have such a plan for IPV introduction by end-2014.
- The WG encourages early IPV introduction in the remaining wild poliovirus endemic countries as part of the broader contingency planning for the accelerated interruption of wild poliovirus.

- The WG encourages a WHA resolution in 2014 on accelerated IPV introduction due to the tight timelines for global IPV introduction; this resolution is supported by evidence for sufficient global IPV supply and a financing strategy for introduction and use through 2018.

In regards to the global bOPV access strategy

- The WG endorses the strategy that has been developed to ensure sufficient quantities of bOPV. This strategy includes:
  (i) Label-change of bOPV products to allow for use in routine immunization (currently bOPV is for campaign use only) from all OPV suppliers
  (ii) Assuring that international suppliers are able to produce sufficient bOPV supply to meet the global demand
  (iii) Supporting countries that rely on domestic producers to rapidly develop, license and produce sufficient bOPV
  (iv) Registering bOPV in all OPV-using countries (for routine immunization use)
- The WG notes the continued importance of conducting mass campaigns with tOPV to increase type-2 population immunity prior to the switch from tOPV to bOPV for routine immunization globally.
- The WG supports a WHA resolution in 2015 on type-2 cessation (target date is 2016).

On the development of a post-cessation type 2 virus response strategy

- The WG recommends that the draft protocol for responding to a type 2 poliovirus detection and/or outbreak in the post-OPV2 era should consist of the following 5 major components: notification requirements for all type 2 viruses (including Sabin viruses), enhanced poliovirus surveillance activities (including expanded environmental surveillance), an mOPV2 stockpile and IPV emergency reserve capacity, outbreak/virus response protocols, and provisions for the vaccination of travelers into and out of any type 2-infected area**.**

Criteria for assessment and the trigger for OPV cessation

- To facilitate communications on OPV2 withdrawal with countries, the WG recommends that the programme differentiates between the criteria to determine global readiness for OPV2 withdrawal and the 'trigger' for initiating globally synchronized OPV2 withdrawal.
- The WG recommends the criteria for judging OPV2 withdrawal readiness globally include: the status of introduction of at least 1 dose of IPV into all OPV-using countries, access by all OPV-using countries to a bOPV licensed for routine immunization, implementation of surveillance and response protocols for type 2 poliovirus, completion of global Phase 1 containment activities for all wild poliovirus infectious materials and provisions for the appropriate handling of type 2 residual materials and production sites under GAP3, and GCC affirmation of wild poliovirus type 2 global eradication.
- The WG recommends that the trigger for OPV2 withdrawal would be the evidence for absence of all 'persistent' cVDPV2s for at least 6 months globally.

Annex 1: IPV Introduction Tier Definitions and Rationale

Tier 1: Countries with evidence of ongoing cVDPV2 transmission or cVDPV2 reported since 2000 OR WPV endemic countries

Rationale:

→cVDPV2 outbreak is the primary risk following OPV2 cessation

→Potential for IPV to accelerate wild poliovirus eradication by boosting immunity to wild poliovirus types 1 and 3.

Tier 2: Countries with any history of cVDPVs (types 1 and 3) since 2000
OR Countries that have repeatedly reported routine immunization coverage estimates of less than 80% over the past three years

Rationale:

→Risk factors for VDPV outbreaks are similar for all VDPV serotypes

→Persistent low routine immunization coverage is the most important predictor of VDPV emergence

Tier 3: Countries sharing a border with Tier 1 countries that have reported WPV since 2003
OR Countries that have experienced a WPV importation since 2011.

Rationale:

→Predicted future risk of cVDPV2 importations, based on trends for importation of wild virus

→Any WPV importation since 2011 (when India eradicated polio) reflects current risk of importation from remaining endemic countries.

Tier 4: All other remaining countries using only OPV