Report of the Polio WG Meeting
11-12 February 2019

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World Health Organization

Polio WG: Objectives

To review

- GPEI program update and vaccine supply
- GCC scheme for certification of polio eradication
- Containment Breach Protocol
- Criteria for restarting use of OPV2
- “Readiness criteria” for bOPV withdrawal
- Pros & cons for early withdrawal of poliovirus type3 from bOPV

To recommend for endorsement

- Guidelines for iVDPV surveillance

Progress towards eradication (1)

- The WG noted the finalization of the new strategic document:

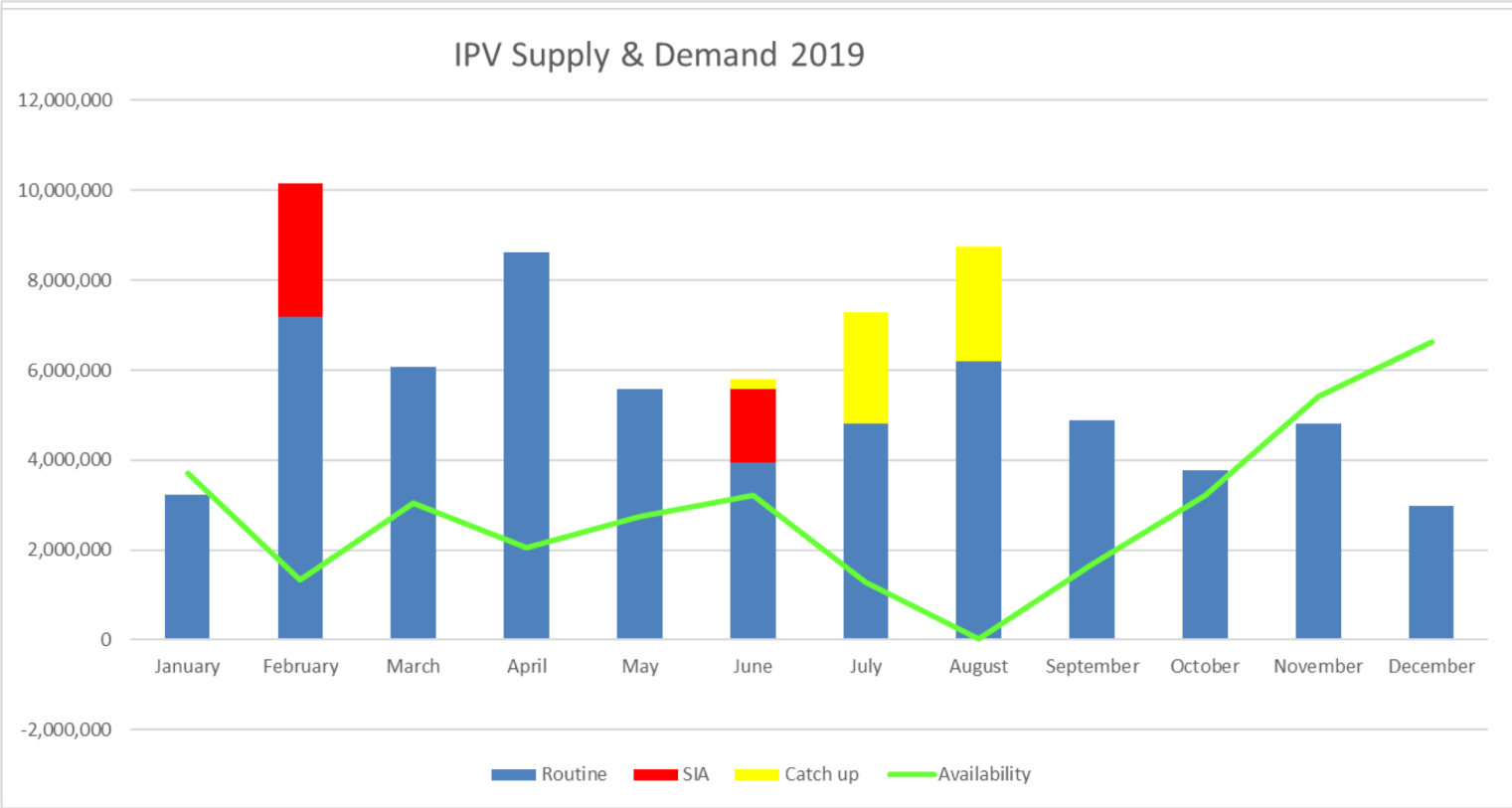
"*Polio Eradication, Integration and Certification:*
The Endgame Strategy 2019-2023"

- The WG highlighted the achievements of the eradication program in 2018/2019:
  - Nigeria remains wild poliovirus free
  - GPEI is able to effectively control most cVDPV outbreaks

Progress towards eradication (2)

- The WG highlighted the lack of progress to interrupt WPV1 in active corridors of transmission in Afghanistan and Pakistan
  - The WG recommends that WHO leadership at the highest-level supports country staff in Afghanistan and Pakistan to operate on an emergency basis
- The WG expresses concern over the risk of persistent cVDPV2 in DRC and Nigeria
  - WG emphasizes that mOPV2 is the only tool currently available to prevent spread of cVDPV2
  - WG recommends a rapid and high-quality outbreak response with mOPV2 for all cVDPV2 outbreaks

IPV supply & demand projections for 2019



Every country, except Zimbabwe and Mongolia, which are to introduce IPV in April 2019, has now introduced at least one dose of IPV into routine immunization.

IPV supply will be sufficient for the catch-up of 43 million missed children in 2020/2021, and to introduce 2nd IPV dose into routine immunisation in 2022.

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OPV Vaccine Supply Update

- The SAGE WG was concerned about the limited availability of mOPV2 in finished form during 2019.
- As of February 2019, the mOPV2 stockpile is at 31M doses
- The current forecast projects a use of 62M doses in 2019 and incoming supplies of 100M doses, which would result in ~70M doses in the stockpile at the end of 2019
- This prediction is highly sensitive to additional needs for cVDPV2 outbreak response

Update on Certification of eradication from the Global Certification Committee (GCC)

SAGE WG reviewed the conclusions from the recent GCC meeting and noted that:

- The GCC recommended to the WHO Director General a **sequential approach** to global certification of eradication:

– WPV3 certification to take place in 2019 or 2020

– WPV1 certification three years after last detection

– The absence of cVDPVs would be verified or ‘confirmed’ after appropriate lengths of time (to be defined)

Sequential certification: SAGE WG's Commentary

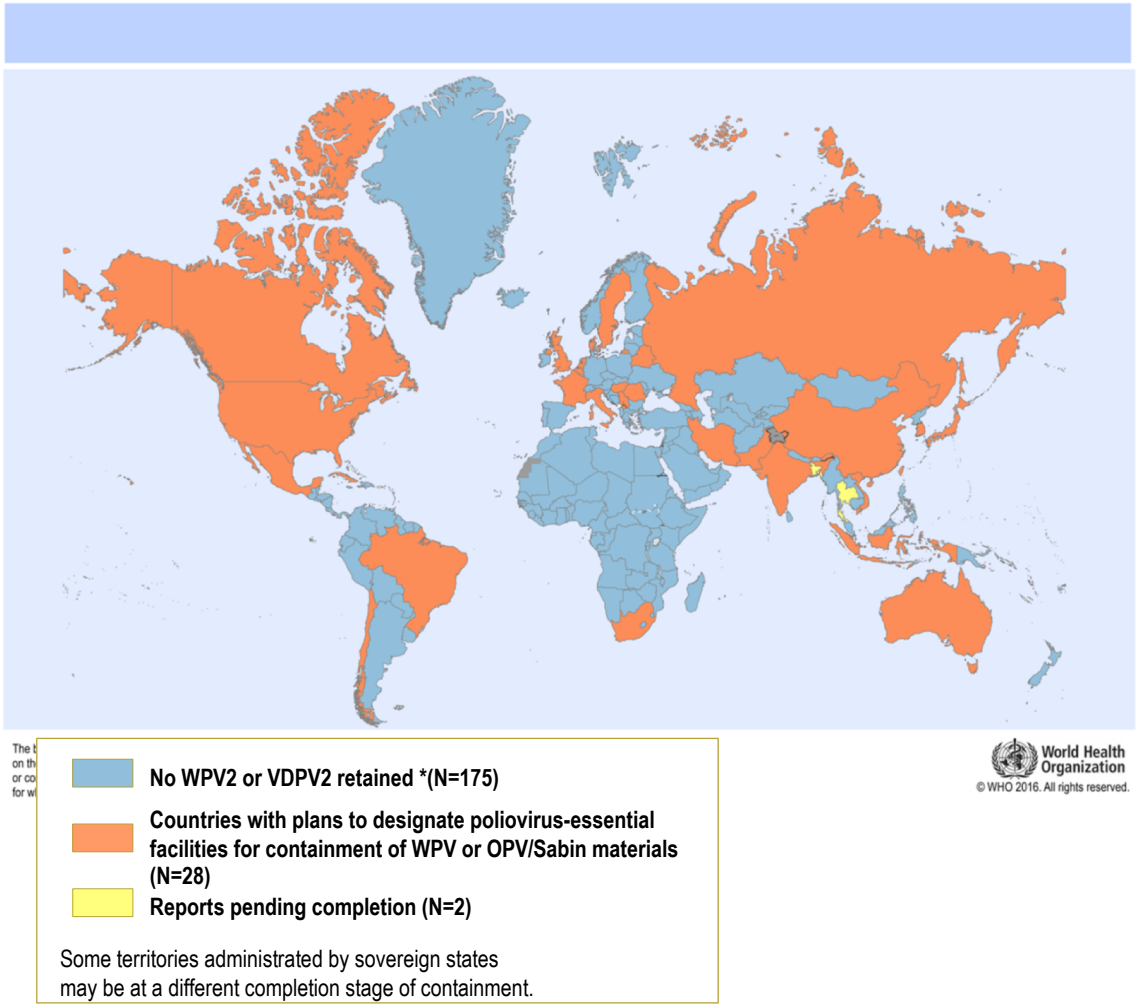
- The SAGE WG agrees that WPV3 certification should proceed in a timely manner
- The WG suggests that WPV3 certification should only proceed once AFRO and EMRO regions can communicate this milestone without negatively impacting the performance of country eradication programs.
- This requires a clear, effective communication plan to be developed.

Containment Breach Protocol

WG reviewed the revised draft of the protocol

Guidelines for a public health response to a human exposure or infection related to a breach of poliovirus containment

SAGE WG is comfortable with the revised protocol, which will be presented to the SAGE in October after a period of public comment



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Primary Immunodeficiency Disorder Surveillance Guidelines

SAGE WG reviewed the guidelines and recommends that they are presented to SAGE for comment and potential endorsement

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Criteria for starting OPV2 production

Background:

In the context of persistent cVDPV2 transmission and declining mucosal immunity, it is proposed that SAGE starts to consider criteria for potential production of OPV2 containing vaccine.

Possible Criteria:

1. Disease – e.g. higher incidence after tOPV-switch, relative to before (72 VDPV cases/year)
2. Epidemiology - e.g. failure to eradicate type 2 poliovirus, expansive geographic spread.
3. Vaccine/ stockpile – e.g. depletion of (finished) stockpile

Next steps:

The WG agreed that discussions on criteria to restart use of OPV2 are important and should be on the agenda for the next SAGE WG meetings.

Trigger and Readiness criteria for bOPV withdrawal

Trigger:

- Certification of polio eradication

Revised Readiness Criteria:

1. Adequate population immunity
2. No persistent cVDPV1 or cVDPV3 circulation
3. Sufficient IPV supply for all countries to adopt 2 IPV dose schedule
4. Established Primary Immunodeficiency Disorder (PID) surveillance
5. Therapeutic options for clearing infections among iVDPV excretors are available

An additional criterion was suggested as progress toward nOPV1 and/or nOPV3 vaccine development.

Trigger and Readiness criteria for bOPV withdrawal

- The WG agreed that the current criteria need refining to provide specific and objectively measurable definitions.
- The WG suggested criteria could be classified into two groups: essential criteria and preferable criteria.
  - nOPV1/nOPV3 development would be preferable, but not essential criteria.
- The WG agreed that criteria for removal of OPV3 and OPV1 may differ and should be defined if the programme withdraw sequentially.
- **Next steps:** refining criteria should be on the agenda of upcoming SAGE Polio WG meetings, with a presentation and discussion for each of the criteria

Weighing PROs and CONs of a withdrawal of poliovirus type 3 from bOPV

PROs

- Ethically right thing to do to prevent unnecessary paralysis
- Could provide impetus to the eradication program
- Enables earlier validation of VDPV3 disappearance

CONs

- Gargantuan programmatic task
- Regulatory nightmare
  - 150 countries will need to licence OPV1
  - Require manufacturers' commitment
- Unchartered territory regarding VDPV3 epidemiology in absence of OPV3
- Given situation with type 2 which was not fully expected, same could happen with type 3

Weighing PROs and CONs of a withdrawal of poliovirus type 3 from bOPV

- **WG concluded** that while there is an imperative to avert unnecessary cases of paralytic disease due to vaccine poliovirus, the removal of OPV3 in the current landscape should not be considered due to the substantial time and resources it would require and this would disrupt the primary focus of interrupting WPV and cVDPV

Next steps:

1. WG agreed to revisit this topic on a regular basis as the programmatic situation evolves.
2. WG suggested that an in-depth review of the epidemiology and logistical/political considerations is conducted.

Summary of SAGE WG Recommendations and Considerations

1. WG expresses concern with the persistence of WPV1 & cVDPV2 transmission.
   I. WG recommends that WHO leadership supports country staff in Afghanistan and Pakistan to operate on an emergency basis
   II. The WG urges countries to conduct rapid and high-quality outbreak response with mOPV2 to all cVDPV2 outbreaks.
2. The WG noted the sequential certification proposed by GCC and provided input to the programmatic implications of WPV3 certification timing
3. WG recommends endorsement of the iVDPV surveillance guidelines
4. WG concludes that the removal of OPV3 from bOPV in the current landscape should not be considered. This is to be revisited on a regular basis
5. WG proposes that the criteria for a) bOPV withdrawal and b) OPV2 restart are refined at future meetings