

12-13 February
Geneva

2019

17th Meeting of the SAGE Polio Working Group

Conclusions and recommendations

Note for the Record



World Health
Organization

Background

The 17th face-to-face meeting of the SAGE Polio Working Group (WG) was held on 12-13 February, 2019 at the World Health Organization HQ in Geneva, Switzerland.

Agenda and the List of Participants are attached as Annexes 1 and 2.

Dr. Ilesh Jani and Dr. Peter Figueroa co-chaired the meeting.

This note presents a summary of the discussions.

Context and topics

Expected outcomes of the meeting:

1. To review the GPEI programme update, including the WPV and VDPV epidemiology and overview of the Polio Eradication, Certification, and Integration: The Endgame Strategy 2019-2023
2. To take note of the new scheme for certification of polio eradication proposed by the Global Certification Commission in October 2018
3. To further discuss “readiness criteria” for bOPV withdrawal including whether the withdrawal of poliovirus type 3 from bOPV should be considered and, if so, the timing and pre-conditions for such withdrawal
4. To review and endorse guidelines for surveillance of VDPVs among persons with primary immunodeficiency (iVDPV surveillance)
5. To note the current version of the previously reviewed Containment Breach Protocol currently put out for public comment

Minutes of the meeting

Programme update

The WG reviewed the global epidemiology of WPV (wild poliovirus) and circulating vaccine derived poliovirus (cVDPV).

In 2018, 33 WPV1 cases were reported worldwide (21 in Afghanistan, 12 in Pakistan), compared to 22 in 2017 (14 in Afghanistan, 8 in Pakistan). As of 12 February 2019, 3 WPV1 cases have been reported this year (1 in Afghanistan, 2 in Pakistan).

In addition to paralytic cases, there is continued detection of WPV1 through environmental surveillance (ES) in the Northern, Central and Southern corridors of transmission in Afghanistan and Pakistan. Genetic analysis of the isolates indicates that there are several independent chains of transmission persisting: there have been detections of 6 different genetic clusters since January 2018. In Nigeria, there have been no cases or environmental

samples of WPV1 since September 2016. However, approximately 100,000 children remain inaccessible for vaccinations in Borno.

Regarding cVDPV, 104 cases of cVDPV were reported in 2018: 20 cVDPV2 in the Democratic Republic of Congo (DRC), 34 cVDPV2 in Nigeria, 26 cVDPV1 in Papua New Guinea (PNG), 12 cVDPV in Somalia (5 cVDPV2, 6 cVDPV3 and 1 co-infection), 10 cVDPV2 in Niger, 1 cVDPV2 in Mozambique and 1 cVDPV1 in Indonesia. As of 12 February 2019, there have been no cases of cVDPV in 2019.

The WG was updated regarding ongoing challenges to achieving interruption of transmission in endemic and outbreak countries, specifically:

- In Pakistan, the program is struggling to implement key National Emergency Action Plan (NEAP) priorities and TAG recommendations, related to regular oversight functions (regular meetings of provincial task forces and PM Focus Group) and creating an enabling environment for the program (national and international staff do not have visa/clearance to enter the country or access certain high-risk areas).
- In Afghanistan, the main challenge is accessibility in Kandahar and part of Gazni, where for over a year there has been a ban on house-to-house campaigns in Taliban controlled areas.
- In Nigeria, there is hesitance to using mOPV2 in outbreak response, due to the risk of seeding VDPV2. However, this may be leading to poor quality response and campaign coverage.
- In DRC, there are concomitant outbreaks of cholera and Ebola. This has resulted in reduced government commitment to responding to VDPV2 outbreaks and presents a risk of poliovirus spread to neighbouring countries.

Lastly, an update was provided on the development of Polio Eradication, Integration and Certification: The Endgame Strategy 2019-2023. This new strategy comprises three themes:

1. Eradication: Stopping transmission of the wild poliovirus and preventing, detecting, and responding to outbreaks.
2. Integration: Collaborating with immunization and emergency partners to eradicate polio and to protect populations.
3. Certification: Certify eradication and containment of all WPVs and ensure long-term polio security.

WG decisions/recommendations

- The SAGE WG emphasised that country ownership and achieving high routine immunisation coverage is essential to stopping poliovirus transmission and sustaining interruption. This will require collaboration with Gavi, the Vaccine Alliance and the Expanded Programme on Immunization (EPI) for all high-risk countries.

- The WG acknowledged the continued efforts of GPEI staff in Afghanistan and Pakistan. However, concern was expressed over the lack of progress to interrupt WPV1 in the active corridors of transmission, illustrated by continued detection of several independent genetic lineages of WPV1. The WG highlighted that the circulation of several lineages indicates that for each lineage there is a sufficient pool of susceptible individuals to sustain transmission, and a reduction in number of lineages is usually seen prior to interruption.
- The WG recommended that WHO leadership at the highest-level supports country staff in Afghanistan and Pakistan to operate on an emergency basis. This includes work to overcome operational barriers such as the access of staff to security high risk areas.
- The SAGE WG acknowledged that the development of a proactive GPEI hub in the EMRO region in Amman, Jordan could relieve pressure on the staff operating in these areas.
- The WG expressed concern over the persistence of cVDPV2 outbreaks, with emphasis on the situation in Nigeria and DRC. The WG highlighted the importance of country commitment to conduct a rapid outbreak response and emphasised that mOPV2 is the only tool currently available to prevent spread of cVDPV2.
- The SAGE WG recommends a rapid and high-quality outbreak response with mOPV2 to all cVDPV2 outbreaks.
- The WG recommended WHO to support the recommendations of the independent monitoring board (IMB) and external reviews and that these are incorporated into the GPEI strategy.

IPV Supply and mOPV stockpile updates

The SAGE WG was presented with an update on the IPV, bOPV and mOPV2 supply and stockpile outlook. Due to the IPV supply shortage, 33 countries procuring IPV vaccines through UNICEF were unable to access IPV supply following the switch from tOPV to bOPV in April 2016. As of February 2019, 31 out of 33 countries have reintroduced at least one dose of IPV into their routine immunization, with Mongolia and Zimbabwe planning for introduction later in 2019.

Available IPV doses in 2019, projected around 78 million doses (Mds), have been allocated based on programmatic prioritisation: 61 Mds allocated to routine immunization requirements; 6Mds allocated to endemic countries for accelerating interruption of transmission of WPV1 (Afghanistan, Pakistan and Nigeria); 5.2Mds allocated to catch up campaigns (in Angola, Sudan and Liberia); and 6Mds yet to be allocated. Future projections indicate there will be sufficient IPV supply for the introduction of 2 doses in all countries

procuring through UNICEF countries by 2022 and to catch-up children that had been missed due to the supply shortage in 2020/2021 (requiring 43Mds).

Countries that are self-procuring IPV, such as China and India, and countries procuring through the PAHO Revolving Fund continue to have access to at least one dose of IPV.

As of February 2019, the current mOPV2 stockpile is at 31Mds, with a pending request from Nigeria for 3Mds. Over 2019, the current forecast projects a utilization of 62Mds and incoming supplies of 100Mds, which would in theory result in ~70Mds in the stockpile at the end of 2019. However, this prediction is highly sensitive to additional needs for mOPV2 to respond to cVDPV2 outbreaks. The stockpile is under close and ongoing review by GPEI.

WG decisions/recommendations

- The SAGE WG welcomed the update that every country, except Zimbabwe and Mongolia, which are planning to introduce IPV in April 2019, have now introduced at least one dose of IPV into routine immunization.
- The SAGE WG emphasised the importance of all countries achieving high routine immunization coverage with IPV.
- The SAGE WG further highlighted the need for timely organization of catch-up campaigns of the 43 million missed children that accumulated due to IPV supply shortage in lower risk countries.
 - However, the SAGE WG took note that current vaccine supply projections indicate that it is very unlikely that there will be sufficient vaccine to complete the vaccination of missed cohorts before 2020.
 - The SAGE WG emphasized that independently of when vaccine supplies are available for vaccination of missed cohorts, countries must conduct these catch-ups. Not vaccinating these children will represent a long-term risk for countries that should be avoided. It was acknowledged that in 2019 IPV has already been allocated for 3 countries to conduct catch-up campaigns.
- The SAGE WG recommends the gradual introduction of a 2nd IPV dose (either full IM or fractional ID) into routine immunization of all countries currently using only one dose as soon as supply becomes available.
- The SAGE WG re-iterated earlier statements on the adoption of fractional IPV. The clinical trial results of intramuscular administration of fIPV from Cuba were discussed and SAGE WG encouraged additional data to be generated from another setting.
- The SAGE WG was concerned about the limited availability of mOPV2 in finished form during the 2019 calendar year.

Presentation of sequential certification for polio eradication

An update from the Global Certification Committee (GCC) meeting in October 2018 was provided to SAGE. The GCC recommended to the Director General of WHO that a sequential approach to global certification be adopted, with WPV3 certification to take place as soon as appropriate in 2019 or 2020, and independently of WPV1 certification. Between WPV3 and WPV1 global certification, the absence of cVDPV3 could be verified. The GCC also advised that the eradication programme should conduct a comprehensive review of the programmatic implications of sequential certification.

The SAGE WG was presented with the epidemiology of WPV3, which has not been detected globally since November 2012. The Americas, European, South-East Asian and Western-Pacific regional certification committees (RCC) have certified elimination of WPV3. The last reported case of WPV3 was in the African region, isolated from an infant aged 11 months in Yobe, Nigeria, who had onset of paralysis on November 10, 2012 and the last environmental WPV3 isolate was from a sample collected in Lagos, Nigeria, on November 11, 2012. The SAGE WG were notified that the African region is planning to certify elimination of all WPV by late 2019 or early 2020.

The GPEI director, Michel Zaffran, requested members of the SAGE WG to discuss the implications of the timing of the certification of WPV3 eradication. Concerns have been expressed from the Eastern Mediterranean and African regions that the certification of eradication of WPV3 may send confusing messages to the countries and the public and be detrimental to intensified activities that are on-going in these regions. In the African region, the programme is putting pressure on countries to strengthen surveillance, moving towards regional certification of all WPV. In Pakistan and Afghanistan, the programme is trying to intensify efforts to interrupt transmission of WPV1 in the middle of the low season.

WG decisions/recommendations

- The SAGE WG agreed that WPV3 certification should proceed in a timely manner and be celebrated as a global achievement.
- It was suggested that WPV3 certification should only proceed once AFRO and EMRO regions can communicate this milestone without negatively impacting the performance of country programme. This requires a clear, effective communication plan to be developed.
- The SAGE WG emphasised that WPV3 certification should not necessarily be dependent upon - or combined with - certification of all WPV in the African region.

Update of public comments on Containment Breach Protocol

The SAGE WG were provided with the revised guidance document “Public Health Management of Facility-Based Exposure to Live Polioviruses - Guidance in managing exposed persons for countries hosting facilities that maintain live polioviruses”. The original draft protocol was reviewed by the SAGE WG in September 2018, the GCC in October 2018 and the WHO public health ethics committee. The revised document will be uploaded to GPLN containment page as interim guidance for a period of public comments and the final version will be presented to full SAGE in October 2019.

WG decisions/recommendations

- The SAGE WG acknowledged the progress made with the Containment Breach Protocol and were comfortable with the revised protocol.

Proposed criteria for OPV2 restart

Since the tOPV to bOPV switch in April 2016, VDPV2 incidence and emergencies have been higher than expected. Persistent transmission of cVDPV2 has resulted in multiple mOPV2 campaigns to control outbreaks, which has likely seeded the emergence of new VDPV2 events and outbreaks. In the context of declining mucosal immunity against poliovirus serotype 2, it was proposed that the GPEI programme evaluate what criteria would need to be met to request restart of OPV2 containing vaccine in routine immunization and campaigns.

There are several possibilities for vaccination schedule, such as re-introduction of tOPV or mOPV2 into routine immunization or supplementary immunization campaigns (SIAs), which could be on a sub-regional, regional or global scale. Example criteria were suggested, including: disease criteria, such as a higher incidence of VDPV2 after tOPV withdrawal, relative to before; epidemiologic criteria, such as endemic cVDPV2, expansive geographic spread or new cVDPV2(s) seeded outside of a response zone; and vaccine / stockpile criteria, such as depletion of (finished) stockpile or failure of nOPV2 development.

The UNICEF Supply Division provided input on the timeline that would be required for tOPV restart from a vaccine manufacturing perspective. Initially, the vaccine bulk would need to be prepared, which would take around 8 months and necessitate containment requirements to be waived. As there would be a sole bulk producer globally, this would put a limit on production. After the bulk vaccine is available, there would be need for vaccine fill/finish, testing and application for licensure. Therefore, advance notification and preparation would be critical with the entire process likely to take about three years, under the assumption that OPV is still in production.

WG decisions/recommendations

- The SAGE WG agreed that discussions on restart criteria are important and should be on the agenda for the next SAGE WG meetings.
- The SAGE WG acknowledged the points made by the UNICEF Supply Division that the re-introduction of OPV2 would require advance preparation of several years to produce the vaccine and achieve testing.
- Members of the SAGE WG emphasized that due to the shortage of IPV supplies, IPV-only vaccination with high coverage has not yet been fully examined as a strategy for eliminating transmission.

Guidelines for Implementing Poliovirus Surveillance among Patients with Primary Immunodeficiency Disorders (PIDs)

SAGE in its meeting in October 2016 recommended that GPEI establishes surveillance capable of detecting iVDPV excretors among PID patients, especially those PID patients that do not present with paralysis. To that end, a working group on iVDPV surveillance has been established and its first task was to develop guidelines to provide clear, concrete instructions to introduce and conduct surveillance for poliovirus among patients diagnosed with primary immune deficiency.

The epidemiology of iVDPV patients was presented to the WG followed by an overview of the proposed guidelines. The SAGE WG was asked to review the guidelines in advance of the meeting and provide comments with the objective to submit the draft to the full SAGE for review and endorsement.

WG decisions/recommendations:

- The SAGE WG acknowledged that iVDPV cases will continue to present a challenge after WPV eradication and therefore it is important to continue understanding the burden of iVDPV excretion and having the ability to identify these cases.
- The SAGE WG provided feedback on the guidelines and suggested revisions:
 - The guidelines should clearly emphasize that PID children and their close contacts should never receive OPV;
 - The guidelines should expand and provide more details regarding how to conduct community investigations around iVDPV cases;
 - The potential of survival of PID individuals in low-income countries should not be ignored, due to availability of private healthcare in some areas.
- The SAGE WG recommended that after the suggested revisions are made, the guidelines will go to full SAGE for review and endorsement.

Readiness criteria for bOPV withdrawal

The presentation discussed the readiness criteria for bOPV withdrawal that were outlined by SAGE in September 2018 and how the criteria could be defined as successfully met. The readiness criteria recommended by SAGE in September 2018 were:

1. Adequate population immunity, especially in high-risk communities
2. No persistent cVDPV1 or cVDPV3 circulation (circulation beyond the 6 months after first notification)
3. Availability of sufficient IPV supplies for all countries to adopt a two IPV dose schedule (either IM or ID)
4. Established Primary Immunodeficiency Disorder (PID) surveillance
5. Therapeutic options for clearing infections among iVDPV excretors are available

A potential additional criterion was suggested as:

6. Progress toward nOPV1 and/or nOPV3 vaccine development.

WG decisions/recommendations:

- The SAGE WG agreed that the current criteria need refining to provide specific and objectively measurable definitions. It was highlighted that measuring and defining adequate population immunity would need the most substantial analysis.
- The SAGE WG agreed that refining criteria should be on the agenda of upcoming SAGE Polio WG meetings, with a presentation and discussion for each of the criteria.
- Some members of the SAGE WG suggested criteria could be classified into two groups: essential criteria and preferable criteria, with the latter being desirable not absolutely critical to achieve before bOPV withdrawal can proceed.
- The SAGE WG did not agree that progress towards nOPV1 and/or nOPV3 vaccine development should be an essential criterion for bOPV withdrawal; however, it could be a preferable criterion.
- The SAGE WG agreed that the criteria for removal of OPV3 and OPV1 may differ, and this would need to be defined if the programme decided to withdraw sequentially.

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

An evaluation of the epidemiology of vaccine-associated paralytic poliomyelitis (VAPP) and VDPV caused by type 3 was provided to SAGE WG. AFP data from India demonstrates the proportion of VAPP cases associated with PV3 (either as mixture with PV1 or exclusively) was 42% between July and December 2015 and 49% between July and December 2016. As the global pre-switch burden in OPV using countries was estimated at 400 cases/year, approximately 130 VAPP cases are likely associated with PV3 worldwide every year and could be averted through removal of OPV3. However other measures, such as introduction

of IPV into the immunization schedule at an early age, may provide protection against VAPP including type 3 associated VAPP.

The WHO Expanded Programme on Immunization (EPI) provided the logistical and programmatic dimensions of a bOPV to mOPV1 switch. The gargantuan efforts from all levels of GPEI partners, regional offices, in-country partners and Ministries of Health to conduct the tOPV to bOPV switch in 2016 was described together with the lessons learnt from this effort. Concerns were expressed over the political leverage it would require to motivate and mobilise countries to conduct the removal of type 3 OPV as an interim step prior to full withdrawal, as this added step may divert resources and attention at a critical time for GPEI and may negatively impact the final quality of OPV cessation.

The implications on vaccine supply and licensing were outlined by the UNICEF Supply Division. Currently, there are supply commitments for bOPV of 4 billion doses on contract; therefore, a switch would ideally take place during 2022 to allow full utilization of this supply. A switch to mOPV1 before 2022 would require negotiations and cancellations of existing contracts and potential financial compensation. A budget will be necessary to secure bOPV production in the final stages, including residual stocks at the time of the switch and a budget for an mOPV3 stockpile.

WG decisions/recommendations:

- The SAGE WG agreed that there is an imperative to avert unnecessary cases of paralytic disease due to vaccine poliovirus. However, the SAGE WG also acknowledged the “gargantuan” task to implement a switch from bOPV to mOPV1, especially considering a possible final switch looming on the horizon. SAGE WG agreed that the missed opportunity to secure wild virus eradication may in the end result in more children being paralyzed because of the resources being diverted for type 3 withdrawal.
- The SAGE WG agreed that the current priorities for GPEI are to stop transmission of WPV1 in endemic countries and to stop persistent cVDPV2 outbreaks. Therefore, SAGE WG concluded that the removal of OPV3 in the current landscape should not be considered due to the substantial time and resources it would require that would disrupt focus on the above priorities and a resulting lost opportunity to concentrate on WPV eradication in the first place.
- The SAGE WG also discussed with no firm conclusion that there are several options for implementing a change from bOPV to mOPV1, should this be considered, including a gradual product replacement of bOPV to mOPV1 into routine immunization over a pre-defined time-period, on a sub-regional or regional level, rather than globally synchronised however the potential risk of this approach regarding emergences of cVDPV3 would need to be understood

- The SAGE WG suggested that an in-depth review of the epidemiological data, and the logistical and political considerations involved are conducted to guide future decision-making and communications strategy.
- The SAGE WG agreed to revisit this topic on a regular basis as the programmatic situation evolves.

Assessing the risk of poliovirus circulation and the role of OPV preventive SIAs pre-cessation

This presentation was to provide the SAGE WG with an updated analysis of the impact of preventative SIAs and did not require decision or recommendations from SAGE WG. Current risk assessments have largely identified the same countries at high and medium-high risk over time. The risk-assessment task team (RATT) focus is on a national scale, while the true risk and SIAs are subnational. Future preventive SIAs have been planned as per SAGE recommendation, with the emphasis on cVDPV prevention. The scope of GPEI-funded preventive SIAs will not increase in the pre-cessation period, but the risk remains of potential outbreaks in countries without preventive SIAs.

ANNEX 1: Agenda

ANNEX 2: List of Participants



17th Meeting of the SAGE Polio Working Group (WG)

M205, WHO, Geneva

February 12-13, 2019

AGENDA

Expected outcomes of the meeting:

1. To review the GPEI programme update, including the WPV and VDPV epidemiology and overview of the Polio Eradication, Certification, and Integration: The Endgame Strategy 2019-2023
2. To take note of the new scheme for certification of polio eradication proposed by the Global Certification Commission in October 2018
3. To further discuss “readiness criteria” for bOPV withdrawal including whether the withdrawal of poliovirus type 3 from bOPV should be considered as a first step and, if so, the timing and pre-conditions for such withdrawal
4. To review and endorse guidelines for surveillance of VDPVs among persons with primary immunodeficiency (iVDPV surveillance)
5. To note the current version of the previously reviewed Containment Breach Protocol currently put out for public comment

Day 1 (Feb 12)

09:00 - 09:15	Welcome and opening remarks	WG Chair
09:15 - 10:30	Programme update <ul style="list-style-type: none">• Progress toward interruption of WPV and cVDPV2• Progress with the other objectives of the Polio Eradication and Endgame strategic plan• Overview of the Polio Eradication, Certification, and Integration: The Endgame Strategy 2019-2023	M. Zaffran, WHO
10:30 – 11:00	IPV Supply update and update on mOPV stockpile	A. Ottosen , I. Lewis
11:00 – 11:30	Coffee break	
11:30 – 12:00	Presentation of sequential certification for polio eradication (update from GCC meeting)	G. Tallis

12:00 – 12:30	Update of public comments on Containment Breach Protocol	G. Tallis
12:30 – 13:30	Lunch	
13:30 – 14:30	Proposed criteria for tOPV restart (and discussion)	J. Modlin
14:30 – 15:30	iVDPV Surveillance:	
	<i>Presentation of draft guidelines for iVDPV surveillance</i>	O. Mach
	<i>Update on Antiviral development</i>	J. Modlin
15:30 – 16:00	Coffee break	
16:00 – 17:00	Discussions and wrap up of the day <i>(Working Dinner Restaurant: Cafe du Soleil, topic: “TBD”)</i>	

Day 2 (Feb 13)

9:00 – 10:30	“Readiness criteria” for bOPV withdrawal AND weighing PROs and CONs of a withdrawal of poliovirus type 3 from bOPV INCLUDING DISCUSSION	R. Sutter O. Mach, D. Chang-Blanc A. Ottosen
10:30 – 11:00	Coffee break	
11:00 – 11:30	Assessing the risk of poliovirus circulation and the role of OPV preventive SIAs pre-cessation	S. Wassilak
12:30 - 13:30	Lunch break	
13:30 - 16:00	Closed session: Finalizing WG recommendations (Coffee break at 15:30)	WG members & Secretariat

Background materials that will be shared with WG members at least 2 weeks prior to the meeting:

- Updated draft of the Containment Breach Protocol
- Draft iVDPV surveillance guidelines



World Health Organization

List of Participants
17th Meeting of the SAGE Polio Working Group
12 – 13 February 2018
WHO-HQ, Salle M205

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