<sup>21-22 August</sup> | 2019

# 18th Meeting of the SAGE Polio Working Group

**Conclusions and recommendations Note for the Record** 



#### Background

The 18th face-to-face meeting of the SAGE Polio Working Group (WG) was held on 20-21 August, 2019 at the World Health Organization HQ in Geneva, Switzerland.

Dr. Ilesh Jani and Dr. Peter Figueroa co-chaired the meeting. Agenda and the List of Participants are attached as Annexes. This note presents a summary of the discussions and recommendations.

#### **Context and topics**

- 1. To review the GPEI programme update, including the WPV and VDPV epidemiology.
- 2. To take note of the specific challenges of eradicating WPV1 in Afghanistan and Pakistan and discuss potential solutions for acceleration of eradication.
- 3. To review scenarios for cVDPV2 outbreak response including OPV2 vaccine restart in routine immunization.
- 4. To review options for IPV only vaccination schedules in polio free regions.
- 5. To review results from one-drop mOPV2 study and, if positive, consider endorsing its use.

#### Summary of the meeting conclusions and recommendations

The WG expressed serious concerns with the status of the eradication program and the inadequacy of currently available tools, specifically: the ever-expanding outbreaks of circulating vaccine derived poliovirus 2 (cVDPV2) in Africa in the context of decreasing population immunity with sustained cVDPV2 transmission (>6 months) in Nigeria, Niger, Democratic Republic of Congo and Somalia; and the limited supply of mOPV2 vaccine to control these outbreaks. WG agreed that there is urgent need for a more genetically stable OPV2 vaccine (the novel OPV2 vaccine (nOPV2)) and agreed with the imperative to accelerate its clinical development and licensure.

The increased circulation of wild poliovirus 1 (WPV1) in Pakistan and Afghanistan, bans on vaccinations, and increasing community resistance to vaccination constitute another serious challenge to the program. These developments run the risk of undermining the entire polio eradication effort. There is an urgent need for the development of new strategies and tools.

The WG acknowledged the positive developments in polio eradication. There has been no WPV3 detected globally since November 2012, and no WPV of any serotype detected in the Africa continent since September 2016 while increased surveillance sensitivity in Nigeria was achieved. The introduction of at least one dose of IPV into routine immunisation of all OPV-using countries has been completed, with catch-up vaccination starting for the approximately 43 million children that did not receive IPV due to supply constraints. The WG noted the significant decrease in the estimated incidence of vaccine-associated paralytic poliomyelitis (VAPP) cases since the introduction of IPV and switch from tOPV to bOPV (a decrease estimated at 244 VAPP cases annually). Lastly, there is continued support from Gavi, The Vaccine Alliance, for the inactivated poliovirus vaccine (IPV) and in the future for IPV-containing whole-cell pertussis hexavalent vaccine.

Summary of key WG recommendations from 18<sup>th</sup> Meeting:

WG took an unprecedented step to brief WHO's Director General and ask him for immediate actions based on the recommendations below.

- 1) The WG was extremely concerned over the deterioration of the program in Afghanistan and Pakistan. Polio eradication must be prioritized in these countries. The number of WPV1 cases in Afghanistan and Pakistan has already surpassed 2018 totals, and will likely increase in the second half of 2019. There is an immediate risk of WPV1 exportation to neighboring countries (as demonstrated by repeated detections of WPV1 in environmental samples in Iran). High-level advocacy and immediate action to ensure government and community commitment is required in Pakistan and Afghanistan as well as in the neighbouring countries.
- 2) The WG was extremely concerned over the cVDPV2 outbreaks in sub-Saharan Africa. An effective response to cVDPV2 outbreaks is essential. The quality and time of the response by countries in Africa to outbreaks of cVDPV2 must improve. The WG agreed with the Cessation Risk Task Team (CRTT) on the necessity of changes to the Standard Operating Procedures (SOPs), which will be revised, on scope, quality and timeliness of the mOPV2 response.
- 3) **Recommended steps to secure adequate mOPV2 supply**. The WG stated that it is essential to ensure an un-interrupted supply of mOPV2, for short-term use to control outbreaks and contingency plans. The WG recommend:
  - a) Urgently identify sites capable of Fill and Finish of existing mOPV2 bulk for utilisation.
  - b) Restart bulk production of mOPV2, given the 15-18-month lead time required by manufacturers.

The WG acknowledge that these activities are off-budget and the GPEI needs to come up with the resources/funding.

4) Clinical development and Emergency Use Licensure (EUL) of nOPV2. While sufficient supplies of mOPV2 are critical in the next 12-18 months, the ultimate solution to deal with cVDPV2 is the development and licensure of nOPV2. Current phase I/II clinical data demonstrate that nOPV2 is safe, immunogenic and genetically stable. The WG support the accelerated clinical development of nOPV2 and endorsed the accelerated assessment of nOPV2 under Emergency Use Listing (EUL). The WG acknowledged that at this stage of clinical development there are still some risks for nOPV2 development, which are estimated to be small, including the risk of reversion and immunogenicity in an outbreak setting, and that there are contingency plans in place with mOPV2 production. The WG emphasise that new serotype 1, 2 and 3 OPVs will not replace IPV in routine immunisation and is ultimately still not compatible with eradication of all polioviruses due to the very low but likely not zero risk of reversion of these more stable OPV strains.

- 5) One vs two drop of mOPV2. The WG recommended that the preference is to use two-drops (the standard dose) of mOPV2 vaccine. However, in the event that mOPV2 supply deteriorates to levels inadequate to cover the required population, the off-label use of one drop mOPV2 could be considered. This is based on data from a single, small clinical trial in Mozambique which showed a minor decrease in immunogenicity of one vs two-drop administration but given the small sample size, the 10% non-inferiority margin could not be statistically confirmed.
- 6) The WG is concerned that bOPV SIAs are being cut due to budget limitations. The WG recommends countries experiencing cVDPV2 outbreaks do not forget about the importance of SIAs with bOPV to prevent poliovirus type 1 and 3. To improve type 1 and type 3 immunity, combined administration of bOPV and mOPV2 during campaigns should be considered.
- 7) **IPV allocation criteria**. The WG recommended an updated prioritization order for IPV allocation:
  - a) Ensure routine immunization needs in all countries are met.
  - b) Allocate to the populations that are IPV-unvaccinated since the switch, due to IPV supply shortages, based on risk assessment.
  - c) Ensure requirements for the acceleration of the interruption of wild poliovirus transmission are fully met (requests from endemic countries for SIAs to interrupt WPV).

#### Minutes of the meeting and SAGE WG recommendations

Day 1 21 August 2019

#### Welcome and opening remarks

WG Chair

The WG and WHO secretariat announced that Dr Jacob John has withdrawn as a WG member. The group acknowledged the substantial contribution that Dr Jacob John made to polio eradication in India and globally over his career.

#### Programme update

M. Zaffran, WHO

On 14 May 2019, polio was reconfirmed as a Public Health Emergency of International Concern (PHEIC), ongoing since May 2014.

As of 21 August 2019, there have been 66 wild poliovirus (WPV) cases, compared with a total of 33 in 2018. WPV cases have been located in Afghanistan: 13 cases in 2019 (compared with 11 for the same period in 2018), and Pakistan: 53 cases in 2019 (compared with 3 for the same period in 2018). Additionally, there is wide-spread detection of WPV in environmental surveillance in both Pakistan and Afghanistan. As of 21 August 2019, there have been 53 cases of circulating vaccine-derived poliovirus (cVDPV). There has been continued detection of cVDPV2 in sub-Saharan Africa, with multiple emergences of new cVDPV2 outbreaks seeded by monovalent OPV2 (mOPV2) outbreak response campaigns.

Priority activities for the Global Polio Eradication Initiative (GPEI) were outlined as:

#### Global

• Mobilise resources to rapidly and fully finance the program

## **Endemic countries (WPV)**

- High level Political advocacy with Pakistan to reset the program
- Fully staff and operationalize Pakistan/Afghanistan hub
- Resume vaccination in Afghanistan

## **Outbreak Countries (cVDPVs)**

- Radically improve speed and quality of vaccination responses
- Secure sufficient quantities of mOPV2 for stockpile (identify new Fill and Finish capacity)
- Accelerate development and EUL of nOPV2
- Further improve surveillance in all outbreak countries and beyond
- Collaborate with EPI to build capacity to mitigate risks

# IPV Supply update and update on mOPV stockpile

A. Ottosen, I. Lewis

#### IPV supply:

At the 16<sup>th</sup> meeting of the WG in September 2018, the prioritization order for IPV allocation was recommended as follows:

- *I.* Ensure that routine immunization needs in all countries are met. At the same time, ensure national and sub-national monitoring of IPV stocks.
- *II.* Ensure requirements for interruption of wild poliovirus transmission are fully met (requests from endemic countries for SIAs to interrupt WPV).
- *III.* After these 2 requirements, excess doses should be allocated to populations that are IPV-unvaccinated since the switch, based on risk assessment.

As of 2019, at least one dose of IPV has been introduced into routine immunization (RI) in all countries. The overall availability of IPV is increasing: in 2019, supply fully meets requirements for RI, supplementary immunization activities (SIAs) in endemic countries, and for catch up campaigns in 5 priority countries. It is forecasted that there will be sufficient supply for the majority of countries to be offered IPV for catch-up campaigns in 2020, and a gradual move from 1 dose to 2 doses in RI in countries can start from 2021.

## mOPV2 supply:

A total of 303 million doses (Mds) of mOPV2 have been deployed since April 2016. Current stock levels are at 58Mds, with +200Mds for supply secured for the next 12 months. Due to on-going cVDPV2 outbreaks, the projected mOPV2 demand can't be met in 2020 with current suppliers. Securing filling, licensure and prequalification of mOPV2 from alternative supplier(s) in 2020 of 160-295Mds would achieve the goals. The decision and funding are urgently needed to ensure timely availability in 2020.

- The mOPV2 bulk in the stockpile in the understanding funded by GPEI and kept under contract – which is not currently in process of being converted into finished product against awards, amounts to 220Mds
- mOPV2 bulk outside of the stockpile available to be procured for addition to the stockpile, released by the NRA of producing country – is 500Mds.

## Discussion:

- There was consensus in the WG that the prioritization order for IPV allocation recommended in September 2018 should be updated, based on the evolving cVDPV2 epidemiology, program experience and time since OPV2 withdrawal.
- The WG recommended an updated prioritization order for IPV allocation:
  - a) Ensure routine immunization needs in all countries are met.
  - b) Allocate to the populations that are IPV-unvaccinated since the switch, due to IPV supply shortages, based on risk assessment.
  - c) Ensure requirements for the acceleration of the interruption of wild poliovirus transmission are fully met (requests from endemic countries for SIAs to interrupt WPV).

- The WG stated that it is essential to ensure an un-interrupted supply of mOPV2, for short-term use to control outbreaks and contingency planning. The WG recommend immediate action on:
  - 1. Fill and Finish of existing mOPV2 bulk for utilisation.
  - 2. Restart the bulk production of mOPV2 for contingency plans, given the 15-18-month lead time required by manufacturers.

The WG acknowledge that these activities are off-budget and the GPEI needs to come up with the resources/funding.

There was a discussion on the containment of PV2 and the implications on mOPV2 vaccine production. It was emphasised that containment is a key strategy developed by the GPEI, with significant progress made over the past few years, and something that is essential for eradication. Containment is not inflexible and is developed to minimize polio risks, which can accommodate and advise on the best approach for mOPV2 production. However, containment is not just about vaccine production facilities, but all poliovirus-containing facilities, and is a global issue. The GPEI containment management group, the containment working group and the containment advisory group have been working together to achieve bio-risk management and ensure that mOPV2 can be produced to meet programmatic needs, in a secure environment.

# Update on IPV catch-up campaigns

# A. Ramirez Gonzalez

Globally, approximately 42 million children were missed in 36 countries due to supply shortages. Analyses showed that coverage of one dose of IPV through RI tends to improve following the first 1-2 years of introduction. However, on average it continues to be low compared to coverage of DTP3 (diphtheria, tetanus toxoids and pertussis vaccine third dose) and might have resulted in approximately 98 million children missed in the last 3 years. This was not due to vaccine shortage but due to poor EPI performance.

Based on a risk assessment by Imperial College London, prioritization and allocation of available supply for catch-up immunization has started in 2019. Doses have been made available for Angola, Liberia, Sudan, Iran, Tanzania, and Zambia and additional countries have conducted catch ups without global support. Therefore, 35% of the cohort missed due to IPV shortage could be completed by end 2019.

## Discussion:

- The WG welcomed the fact that catch-up campaigns have started in countries with prioritization based on the risk assessment.
- The WG stated that it is important that every child receives at least one dose of IPV.
- The WG also welcomed that the IPV catch-up campaign in Tanzania was combined with a measles vaccination campaign.
- It was noted that Angola is considering an IPV/mOPV2 combined campaign, as they are conducting both catch-up IPV campaigns and responding to cVDPV2.
- It was highlighted that when introducing a new vaccine into RI, it often takes a couple of years to reach the coverage levels achieved by reference, established

vaccines. However, if we continue to see low coverage of IPV compared to DTP3 in the next few years, specific initiatives to improve coverage may be required.

## Presentation on challenges in last WPV1 endemic areas

J. M. Olivé/ Ch. Maher (absent)

Following a request at the 17th SAGE WG meeting, a more in-depth review of the program challenges in Pakistan and Afghanistan was presented to the WG.

In Afghanistan, there has been a ban on house-to-house campaigns from May 2018 and a ban in May 2019 on WHO activity in the country. The first SIA campaign after the WHO activity ban, conducted in August 2019 had 50.6% target missed, due to issues of access. However, the number of detected WPV1 cases has not yet increased despite surveillance even in compromised areas.

In Pakistan, there have been significant challenges in 2018-2019 resulting in vaccine resistance at the community level. Following an increasing number of security incidents involving health-care workers, there is a pause in SIAs from April to November 2019. The opportunity presented by the SIA pause should not be missed to regain and improve on the capacity in Pakistan from 2014-2018 and correct identified gaps.

#### Discussion:

- The WG expressed serious concern over the program in Afghanistan and Pakistan.
- It was discussed that the pause of SIAs in Pakistan until November 2019 provides an opportunity for rebuilding the program and community engagement.
- The WG highlighted the risk of exporting WPV1 to neighboring countries, demonstrated by the recent exportation to Iran. An exportation to Yemen, Syria or Iraq, could lead to WPV1 outbreaks due to the weak healthcare systems in those countries.
- The WG recommend it is essential to ensure polio eradication is prioritized in Afghanistan and Pakistan. High-level advocacy and immediate action to ensure the community commitment is required in the endemic countries as well as in the neighbouring countries.

## Update from the Cessation Risk Task Team (CRTT)

J. Wenger

This presentation provided an Update from the Cessation Risk Task Team (CRTT), who met on 19-20 August 2019 to discuss current cVDPV2 epidemiology, potential future scenarios for cVDPV2 outbreaks, methods to control outbreaks including the potential role of new, more stable oral vaccines (nOPVs) and criteria for the restart of tOPV production and use. The summary of the CRTT meeting, and areas to discuss with the SAGE polio working group, were outlined:

- 1. Communication of emergency cVDPV2 situation
- 2. Accelerating development, licensure and production of nOPV2
- 3. Innovation required to implement effective outbreak response now

- a. Change mOPV2 response strategy
- b. Studies of simultaneous mOPV2/bOPV administration
- c. Evaluation of single drop mOPV
- 4. mOPV2 supply (need to restart bulk production and filling)

## Discussion:

- The SAGE WG stated that the cVDPV2 situation is an emergency of unprecedented nature. The current strategy is not working and current tools are inadequate.
- There was consensus amongst the WG that the main conclusions and action points presented by the CRTT were comprehensive and appropriate.
- The WG recommended that changes in strategy of outbreak response will be reflected in revised standard operating procedures (SOPs).
- It was highlighted that simultaneous mOPV2/bOPV administration may cause confusion amongst vaccinators and could have a risk of interaction between vaccines. CDC is planning a trial to study simultaneous mOPV2/bOPV administration. In the study design, the field team composition will change to include an additional vaccinator and 2 finger markings will be used. Within the study CDC also intend to do a clinic-based investigation with seroprevalence to see if there is any interaction effect when vaccines are administered concomitantly.

# Reducing Outbreak Risks Associated with Oral Polio Vaccine Withdrawal

J. Vertefeuille

A pathway to mitigate cVDPV1 and cVDPV3 risks in advance of bOPV withdrawal was proposed, incorporating the lessons learnt from the 2016 OPV2 withdrawal. The budget cuts in SIAs to medium-high risk countries could result in emergent cVDPV1 and 3 in the near or medium term and increased vulnerability to WPV1. Risk mitigation efforts through rigorous preventative SIAs should target the highest risk districts in highest risk countries. These efforts should be combined with broader vaccine-preventable disease gains.

- The WG welcomed the proposed pathway to reducing outbreak risks, through focusing on the highest risk geographies. The WG agreed with the critical need to learn from post-switch experience to better prepare for OPV cessation.
- The WG was concerned over the reduction in preventative SIAs leading to a risk in cVDPV1 and cVDPV3 outbreaks and WPV1 vulnerability. The WG recommended that those countries effected by cVDPV2 and conducting mOPV2 campaigns do not overlook bOPV SIAs.
- The WG approved of the approach to combine preventative SIAs with vaccines or other health interventions in these vulnerable populations that are often hard to reach.

# Consideration for IPV only schedules for polio-free regions

R. Sutter

The continued use of OPV has a risk of VAPP and VDPV emergence and therefore, some polio-free regions are considering regional implementation of IPV-only schedules. Since 2016, SAGE guidance is available for countries moving to IPV-only schedules. This raises the

question whether there should be criteria to guide Regions/Sub-Regions to adopt all IPV schedules. In addition, it was highlighted that SAGE could update guidance on IPV-only schedules for pre-cessation of all OPV use and post-cessation.

Discussion points:

- In WPRO there has been no WPV for almost 20 years; however, the cVDPV1 outbreak in Papua New Guinea in 2018 cost more than USD 30 million to control. This has started discussions in WPRO over whether IPV-only schedules should be implemented across the region, to prevent VDPV outbreaks.
- Previous SAGE recommended schedules are: post-OPV cessation schedule: 2-dose IPV schedules (14 weeks and 9 months); and SAGE early schedule: 3-4 dose IPV schedule administered at 6, 10, 14 weeks and <u>></u>9 months, or 2, 4, 6 months.
- There was consensus that it is necessary to update the WHO polio vaccine position paper, including to provide guidance for a 2 dose IPV schedule prior to OPV cessation.
- Since there are no tailored IPV-only schedules, especially for the polio-free Regions (from now until all OPV cessation), the WG needs to review this need in the future meetings

# Day 2 22 August 2019

# nOPV2 and nOPVs 1&3

J. Modlin

The preliminary data from the two Phase II nOPV2 clinical trials were reviewed – a) study in adults conducted in Antwerp, Belgium and b) study in infants and toddlers in Panama. To date, there are no safety signals and both nOPV2 candidate strains appear immunogenic. Both candidates replicate in the human gut as expected. The planned regulatory pathway for nOPV2 includes pre-licensure via WHO Emergency Use Listing (EUL), and eventually licensure (Badam POM) and WHO pre-qualification.

Outline of clinical development of novel OPV 1 and 3 were presented.

- The WG welcomed the availability of preliminary data from the adult, toddler and infant trials of both nOPV2 candidate vaccines.
- The WG supported the clinical development of nOPV2 and recommended <u>the</u> <u>accelerated assessment of nOPV2 under EUL.</u>
- The WG acknowledged that there are risks associated with nOPV2 development, and contingency plans that include mOPV2 production must be put in place.
- The WG emphasised that nOPV will not replace IPV in routine immunisation and nOPV2 ultimately still not compatible with eradication of all polioviruses.
- There was discussion that there will be a time when nOPV2 and mOPV2 are both available for outbreak response in the global stockpile, and it will be necessary to decide where the available nOPV2 doses should be prioritised.

# Update on Antiviral development

J. Modlin

An update on the development timeline was provided for the two antiviral drugs against poliovirus: Pocapavir and V-7407.

Discussion:

- WG agreed that development of polio antivirals is a priority in addressing chronic poliovirus infections among immunodeficient persons
- The highly active antiretroviral therapy (HAART) for treatment of human immunodeficiency virus (HIV), requires the combination of multiple antivirals to prevent resistance developing. Therefore, it shouldn't be assumed that combination of two poliovirus antivirals will be fully effective to prevent resistance.

# Results from mOPV2 one-drop immunogenicity study

O. Mach

A randomised control trial was conducted to compare humoral immunogenicity for poliovirus 2 after one dose with either 1-drop or 2-drop administration of mOPV2. The study was carried out in 360, 9-22-month-old children residing in Mocuba, Mozambique, during the mOPV2 outbreak response campaign in 2019. The immune response was 53.6% (CI: 95%: 44.5–62.6) for 1 drop vs 60.3% (CI: 95%: 56.1–73.4) for 2 drops. Due to high drop-out rates, the final study size was underpowered to confirm or not whether 1 drop was non-inferior to 2 drops with a 10% margin.

Discussion:

- There are no plans for an additional study, due to the difficulty of conducting a study with mOPV2 under containment.
- It is important to consider the potency of the vaccine product when considering one or two drops. This study was conducted with a medium-potency vaccine from a single supplier.
- The WG recommended that the preference for mOPV2 vaccination is to use twodrops (the standard dose) of vaccine. However, in the event that mOPV2 supply deteriorates to levels inadequate to cover the required population, the off-label use of one drop mOPV2 could be considered as a measure to stretch mOPV2 supply.
- WG recommended that GPEI should establish a minimum level of mOPV2 stocks which would avoid the need for one-drop use.

# Update on decisions regarding IPV/Hexa financing

GAVI, The Vaccine Alliance.

In June 2019, the Gavi determined the post-2020 IPV support modality and approved principles of IPV support and investment options. The scope consists of 70 currently IPV-supported countries, for 10 years of support following global bOPV cessation with different levels of financial contributions. Guidance from the SAGE is required on pre-cessation IPV 2 dose immunization schedule and wP Hexavalent vaccine schedules.

Discussion:

• The WG welcomed the continued support of IPV by GAVI.

# VAPP analysis

G. Macklin

A refined analysis of VAPP (vaccine associated paralytic-poliomyelitis) burden was requested by the WG at the 17<sup>th</sup> WG meeting in February 2019. VAPP is a rare but serious consequence of the administration of OPV. The global VAPP burden in 2019 was estimated to be 168 cases per year, reduced from 400 prior to IPV introduction and OPV2 withdrawal. The introduction of IPV into RI has significantly reduced the incidence of VAPP from any serotype. The removal of OPV2 has reduced the incidence of VAPP2 to zero (in countries with no mOPV2), but is likely to have led to an increase in VAPP1 and VAPP3 because of the greater immunogenicity of these serotypes in bivalent versus trivalent OPV.

# Discussion:

- The WG welcomed the refined analysis and the reduction in VAPP incidence with IPV introduction.
- It was requested that estimates of the reduction of VAPP cases since the introduction of IPV and removal of OPV2 from routine immunisation is shared for communication.
- There was discussion over the underlying reason for an increase in VAPP1 and VAPP3 after the switch from tOPV to bOPV, observed in the data.
- The definition used for VAPP in this analysis an AFP case with residual paralysis at 60 days follow up, and excretion of Sabin-like virus is not a confirmation of poliovirus-induced paralysis; therefore, there will be an underlying rate of AFP not caused by poliovirus vaccine.



# 18th Meeting of the SAGE Polio Working Group (WG)

Salle D, WHO, Geneva August 21-22, 2019

#### AGENDA

#### Expected outcomes of the meeting:

- 1. To review the GPEI programme update, including the WPV and VDPV epidemiology
- 2. To take note of the specific challenges of eradicating WPV1 in Afghanistan and Pakistan and discuss potential solutions for acceleration of eradication
- 3. To review scenarios for cVDPV2 outbreak response including PV2 vaccine restart in routine immunization
- 4. To review options for IPV only vaccination schedules in polio free regions
- 5. To review results from one-drop mOPV2 study and, if positive, consider endorsing its use

#### Day 1 (Aug 21)

09:00 - 09:15	Welcome and opening remarks	WG Chair
09:15 - 10:30	Programme update	M. Zaffran, WHO
	Progress toward interruption of WPV and cVDPV2	
	Progress with the other objectives of the Polio Eradication and End	game strategic plan
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	Update on IPV catch-up campaigns	D. Chang-Blanc
12:00 - 12:30	Presentation on challenges in last WPV1 endemic areas (DISCUSSION AFTER THE FOLLOWING PRESENTATION)	J. M. Olive/ Ch. Maher (absent)
12:30 - 13:30	Lunch	
13:30 – 15:00	Update from the Cessation Risk Task Team (CRTT) and discussion on scenarios for cVDPV2 outbreaks; methods to control cVDPV2 outbreaks and criteria for tOPV restart (INCLUDING DISCUSSION)	J. Wenger

15:00 – 15:30	Risk assessment and mitigation analysis of high-risk countries: clear identification of the highest risk countries and communities for PV outbreaks & discussion on criteria for preventive SIAs with bOPV	J. Vertefeuille
15:30 - 16:00	Consideration for IPV only schedules for polio-free regions	R. Sutter
16:00 – 16:30	Coffee break	
16:30 - 17:00	Discussions and wrap up of the day	

(Working Dinner Restaurant: Cafe du Soleil, topic: "TBD")

# Day 2 (Aug 22)

9:00 - 10:00	Product development updates:	
	nOPV2 and nOPV 1&3	J. Modlin
	Update on Antiviral development	J. Modlin
10:00 - 10:30	Results from mOPV2 one-drop immunogenicity study	O. Mach
10:30 - 11:00	Coffee break	
11:00 - 11:30	Update on decisions regarding IPV/Hexa financing	GAVI
11:30 - 12:00	VAPP analysis	G. Macklin
12:00 - 12:30	Final discussion before the closed session	
12:30 - 13:30	Lunch break	
13:30 - 16:00	Closed session: Finalizing WG recommendations	WG members
	(Coffee break at 15:30)	& Secretariat



#### List of Participants 18<sup>th</sup> Meeting of the Polio SAGE Working Group 21–22 August 2019 WHO-HQ, Salle D

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