

04-05
September | 2018

16th Meeting of the SAGE Polio Working Group

Conclusions and recommendations

Note for the Record



World Health
Organization

Background

The 16th face-to-face meeting of the SAGE Polio Working Group (WG) was held on 04-05 September, 2018, 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 and recommendations.

Context and topics

1. To review the GPEI programme update, including VDPV epidemiology and IPV supply
2. To provide inputs into draft options appraisal for certification of eradication
3. To discuss “readiness criteria” for bOPV withdrawal
4. To review Containment Breach Protocol
5. To review scientific data and availability of ID devices (adaptors and needle-free devices); and discuss guidance on use for the program
6. To review Hexavalent landscape analysis (for information)
7. To review country-based assessment of risk of poliovirus re-emergence

Minutes of the meeting and SAGE WG recommendations

Polio Eradication – Global Update

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

The public health emergency of international concern for poliomyelitis was re-confirmed on 15 August 2018.

In 2018, as of 4 September 2018, 15 WPV1 cases have been reported worldwide (12 in Afghanistan, 3 in Pakistan), compared to 10 for the same period in 2017 (6 in Afghanistan, and 4 in Pakistan). In addition to WPV1 detected from paralyzed persons, WPV1 continues to be found in environmental samples: 64 samples in Afghanistan and 91 in Pakistan in the past 12 months. In Nigeria, there has been no detection of WPV1 since September 2016. No cases of WPV3 have been reported globally since November 2012.

Regarding cVDPVs, there have been several outbreaks detected in the last 12 months: the most significant were cVDPV2 outbreaks in Nigeria, Democratic Republic of Congo (DRC), and the Horn of Africa (Table 1). There has been a total of 10 separate cVDPV2 outbreaks detected since the tOPV to bOPV switch (April 2016) affecting 6 countries. In addition to cVDPV2, in 2018 a cVDPV1 outbreak has been detected in Papua New Guinea, and a cVDPV3 outbreak detected in Somalia (Table 1).

Country	Wild poliovirus		cVDPV2		cVDPV3		cVDPV1	
	Onset most recent case	Total WPV1	Onset most recent case	Total cVDPV2	Onset most recent case	Total cVDPV3	Onset most recent case	Total cVDPV1
Nigeria	NA	0	27-Jul-18	8	NA	0	NA	0
DRC	NA	0	22-Jul-18	26	NA	0	NA	0
AFR	NA	0	27-Jul-18	34	NA	0	NA	0
Pakistan	18-May-18	6	NA	0	NA	0	NA	0
Afghanistan	17-Jul-18	20	NA	0	NA	0	NA	0
Syria	NA	0	21-Sep-17	4	NA	0	NA	0
Somalia	NA	0	10-Jul-18	3	23-May-18	3	NA	0
EMR	17-Jul-18	26	10-Jul-18	7	23-May-18	3	NA	0
PNG	NA	0	NA	0	NA	0	29-Jul-18	9
WPRO	NA	0	NA	0	NA	0	29-Jul-18	9
Global	17-Jul-18	26	27-Jul-18	41	23-May-18	3	29-Jul-18	9

Table 1: Global wild poliovirus cases and cVDPV cases¹, in previous 12 months², NA: Not applicable

¹Excludes viruses detected from environmental surveillance

²Onset of paralysis 05 Sep. 2017 – 04 Sep. 2018

The SAGE WG was informed of the challenges to final eradication and cVDPV2 control:

- Access issues in Pakistan and Afghanistan. In Afghanistan, transmission of wild poliovirus in the Northern and Southern transmission corridors has not been interrupted, with circulation maintained in Kandahar Province for more than 1 year. This ongoing transmission in the Southern & Eastern regions is mainly due to inaccessibility and a security ban on house to house campaigns in Kandahar Province, with approximately 1.3 million children inaccessible during the August 2018 campaign.
- The cVDPV2 outbreak in DRC is of high concern as circulation is spreading to areas with conflict and bordering other countries. All efforts are to control this outbreak before the rainy season, with 2 SIAs planned, targeting 16 provinces in September and October 2018. Initially, the DRC government was slow to respond, as resources in the national health system have been stretched with concomitant outbreaks of Ebola virus disease, cholera and other infectious diseases in 2018. However, the GPEI and other international agencies have responded by deploying surge staff to the affected areas.

The current Polio Eradication and Endgame Strategic Plan 2013-2018 will be extended through 2019. A new strategic plan and budget will be developed for the period 2019-2023 and funding will need to be secured. The independent monitoring board (IMB) has completed an external review of the programme in the 3 endemic countries and the findings will be presented in September 2018, in London.

WG discussion:

- The WG emphasized that although the program has not reached an end to the circulation of endemic wild poliovirus type 1 and cVDPVs, we should not lose sight of what has been achieved. Specifically highlighted were:

- WPV1 transmission is limited to a few endemic zones, with no spread of virus out of active transmission corridors between Afghanistan and Pakistan.
- The surveillance has become more sensitive, especially because of the expansion of environmental sampling.
- The progress in reducing the number of unreached children in Nigeria from 600,000 in 2016 to 200,000 in 2018, in a context of continuing high insecurity.
- The exceptional response and apparent successful control of the cVDPV2 outbreak under very difficult circumstances in Syria.
- The working group expressed concern over reaching children in countries with inaccessible areas, which is essential to achieving the interruption of WPV. This concern was specifically stressed for Afghanistan and Nigeria.
- The WG viewed the development of the new strategic plan for GPEI (to cover the period 2019-2023), as an opportunity to strengthen strategic coordination and collaboration between GPEI, EPI and GAVI. There was consensus that to improve immunisation, we need to work across disease disciplines to strategically develop a primary healthcare system that can deliver high routine immunization coverage in those developing countries with the majority of under-vaccinated children. Better functioning primary healthcare systems can then serve as the basis for delivering specific health goals such as polio eradication or measles elimination. All partners and stakeholders must work together to help these priority countries take ownership for developing their primary healthcare systems.
- The WG discussed the poliovirus surveillance in a post-certification era and emphasised that preserving the functionality and high sensitivity of surveillance is critical during the transition.

Polio Vaccine Supply – Update as of September 2018

The WG was presented with an update on the IPV, mOPV1 and mOPV2 supply and stockpile outlook. Due to delays in manufacturer's scaling up production to meet committed quantities, 33 countries procuring IPV vaccines through UNICEF were unable to access IPV supply since the switch from tOPV to bOPV: 18 countries did not have access to IPV for routine introduction and 15 countries had supply interrupted post introduction.

In 2018, supply will meet UNICEF demand for at least 1 IPV routine immunization dose in all OPV using countries (85 countries) and two million doses for IPV full dose use in endemic zones to accelerate WPV eradication. However, other needs will not be met: such as for SIAs outside of endemic zones of around 3 million doses (e.g. Syria and Ukraine for campaigns, Uganda and Rwanda for refugee populations) and catch up of around 43 million doses (across 33 countries) to provide at least one dose of IPV to the cohorts of children that had been missed due to supply shortages.

There is a rich pipeline of manufacturers, with 9 new manufacturers expected to have their IPV WHO pre-qualification by 2022. UNICEF expects some additional supply by the end of 2019 from new supplier(s) and that total IPV supply will be sufficient to meet a 2-dose

schedule globally in 2023. With the increase of available manufacturers, the price of IPV should decrease.

Regarding mOPV1 production, following the June 2018 TAG meetings in Pakistan and Afghanistan, mOPV1 is planned to be used for some SNIDs. However, there are no contracts established with vaccine manufacturers. UNICEF has explored options to secure mOPV1 for immediate requirements of 23.7 million doses (2018). Due to i) production lead times and ii) licensure requirements in Pakistan, only one manufacturer can supply. While the full requirements can be met, supply of bOPV will be reduced with the same quantity.

The WG was updated on the mOPV2 stockpile availability. There is currently only one supplier for finished product: the 269 million doses of bulk under contract is fully used and the programme is accessing bulk outside of contract which will allow 45 million doses to be available for July 2019. Final discussions are ongoing with a second supplier for mOPV2 in finished presentation.

WG discussion:

- The WG discussed that the programme needs to establish clear communication with vaccine manufacturers and develop a supply requirements plan, especially if mOPV1 is to be reintroduced into the program outside endemic countries.
- Countries receiving mOPV2 for outbreak response need better accountability and better systems to be put in place for retrieving mOPV2 vials after SIAs.

Appraisal of Options for Certification of Global Poliovirus Eradication

In April 2018, the chairs of the expert committees, which advise and support the GPEI requested the Secretariat of the Global Certification Commission (GCC) to prepare an appraisal of options for certification of global poliovirus eradication. The document presented to the SAGE WG addressed the advantages and disadvantages of different options. The Options Appraisal will be considered by the GCC at its meeting in October 2018.

Options 1A and 1B limit the scope of certification only to the interruption of transmission of WPV alone and differ by whether to consider cVDPV status in the final declaration of WPV eradication. Both include a separate process for validating the absence of VDPVs. Option 2 proposes to frame the concept of certification as a multi-stage process including all polioviruses.

WG discussion:

- The WG welcomed the certification options appraisal as a suitable tool for reviewing the criteria for certification of eradication of polioviruses.
- The WG recalled that the 1988 World Health Assembly (WHA) resolution called for the global eradication of poliomyelitis, with later consideration that the certification of eradication referred to wild polioviruses: “elimination of indigenous wild polio virus transmission”; however, since then VDPVs have been recognized as viruses capable of establishing circulation. The WG agreed that the GCC should respond to the present

circumstances acknowledging the challenge of certifying absence of cVDPVs in the development of eradication certification criteria. The “absence of cVDPVs” denotes that no VDPV is being transmitted anywhere, and that all VDPVs are under containment.

- Through interactive discussion, the WG provided input into the appraisal paper, with the chair of the GCC in attendance. The 3 presented options and additional ones will be reviewed by the GCC in October 2018.

Certification of Wild Poliovirus Type 3

The GCC had proposed using the certification of WPV3 eradication as a trial run of final certification of polio eradication. Following the completion of the Options appraisal (above), the GCC Chair undertook a review of the strengths and weaknesses of sequential certification of WPV3 followed by WPV1 with a potential roadmap to certification of eradication.

The WG was presented with data on WPV3 epidemiology over the past decade. There has been no WPV3 detected through AFP or environmental surveillance globally since November 2012. During the same period, poliovirus surveillance efforts have increased in most high-risk areas. Since the last detected WPV3 cases in April 2012 in Pakistan and November 2012 in Nigeria, there have been over 150,000 and 92,000 samples, respectively, from AFP cases that have tested negative for WPV3 across AFRO and EMRO, while all other WHO Regions have obtained Regional Certification of absence of WPVs including WPV3.

The global certification of WPV3 eradication might be possible in 2019. This could be followed by the cessation of OPV3 use, further reducing the risk of VAPP and VDPV3, and creating the potential to validate disappearance of VDPV 2&3 by 2021.

The GCC will consider the option of sequential certification at its meeting in October 2018.

WG discussion and recommendations:

- The WG recognized that WPV3 is unlikely to be currently circulating and it is a valid option to work on certifying eradication of WPV3 ahead of WPV1 certification. The WG agreed that this could energize the programme and highlight progress.
- The WG considered the programmatic and ethical reasoning to move from bOPV to mOPV1, and recommended that advantages and disadvantages of such switch should be articulated. However, the Director of WHO’s Polio Department emphasized that certification of eradication of WPV3 does not automatically mean there has to be switch from bOPV to mOPV1. There is strong concern that the programmatic and communications implications of yet another switch might overwhelm the program.
- It was noted that a potential benefit of withdrawing OPV3 and validating the disappearance of cVDPV3 sooner would be to complete these activities before GPEI is reduced as a consequence of its winding down.

The Public Health Management of Facility-Based Exposure to Live Polioviruses

The safe containment of polioviruses is one of the objectives of the Polio Eradication and Endgame Strategic Plan 2013-2018, and the GAP III protocol describes the necessary conditions for poliovirus containment and requirements for safe handling of polioviruses in designated poliovirus-essential facilities (PEF).

The WG was presented with a draft Containment Breach Protocol, which has been developed to provide guidelines for a public health response to a human exposure or infection related to a breach of poliovirus containment. This protocol is primarily aimed at PEF hosting countries.

The main components and strategies used in the response to a breach of containment and prevention of potential establishment of further transmission include: risk assessment, isolation/quarantine of exposed persons and their family and contacts, infection control and disinfection, targeted vaccination, and intensification of surveillance.

For each country with PEF, it is necessary to consider what public health measures can be implemented within their existing national regulations.

WG discussion and recommendations:

- The WG was comfortable with the approach taken. The document could provide guidance for countries to develop specific protocols in the context of national legislation.
- The WG agreed that the document needed to be further refined and should be presented to SAGE WG for endorsement during its next meeting in early 2019.
- The WG highlighted some specific comments on sections of the guidelines, including:
 - The protocol should include recommendations about use of antiviral therapy.
 - The importance of communication strategies around breaches and ensuring the privacy of exposed persons in question should be highlighted in the protocol.
 - The WG suggested to include a clause in work-contracts for staff of PEFs, that a certain requirement or process would need to be followed if they are exposed to PVs.

Readiness Criteria for bOPV Withdrawal

In September 2017, the SAGE WG endorsed the concept of developing trigger and readiness criteria for bOPV withdrawal and proposed to continue discussions over the next 12-18 months.

The withdrawal trigger was stated as the certification of wild poliovirus eradication, followed by 4 readiness criteria:

1. Adequate population immunity, especially in high-risk communities
2. No poliovirus type 2 outside of containment

3. No persistent cVDPV1 or 3 circulation (circulation beyond the six months after the first notification)
4. Availability of sufficient IPV supply for all countries to adopt two IPV dose schedule (either IM or ID)

The proposed revised criteria removed #2 (no poliovirus type 2 outside of containment) because of iVDPV2 chronic excretors, and added criteria on iVDPV surveillance and management:

- Surveillance for PIDs established
- Therapeutic options for clearing infections among iVDPV available

WG discussion and recommendations:

- The WG agreed that the readiness criteria still serve a useful purpose.
- The WG agreed with the need for additional criteria for PID surveillance, with input expected to be provided from the iVDPV WG
- The WG emphasized that we need to ensure we learn from lessons of the tOPV to bOPV switch before bOPV withdrawal
- Regarding the planning and activation timeline, there was agreement:
 - o The trigger point for withdrawal of bOPV is GCC certification, and should plan to withdraw 6-18 months after certification.
 - o The programme needs to start planning for withdrawal well in advance of certification.
 - o Possible early certification of WPV3 and its implications need to be considered
 - o Potential regional withdrawal of bOPV could be considered

IPV Allocation Options for 2019-2020

The UNICEF IPV supply availability for 2019 is 71,650,000 doses. This exceeds the estimated requirement to cover routine immunization needs of 64,183,000, by an excess of 7,467,000 doses, however, other requirements for IPV outside of routine immunization include:

- SIAs with IPV planned in endemic countries in 2019: 5.9 million doses
- Request from Nigeria for fIPV use for cVDPV2 response: 1.6 million doses
- Additional doses for SIAs in outbreak countries/refugees: 3 million doses
- Approximately 42 million doses needed for catch-up campaigns to cover cohorts of children missed due to IPV shortage in Tier 3 and 4 countries,

An assessment conducted by Imperial College London for country prioritization of IPV catch-up immunization was presented.

SAGE WG was asked:

- Whether the allocation principles still apply
 1. Ensure routine requirements for all countries is met
 2. Requirements for objective 1 (eradication of WPV) are fully covered

3. After meeting these two requirements doses can be allocated for catch up immunization
- How to treat additional requests (Refugees in Rwanda & Uganda; catch up immunization in older age groups, Ukraine and Syria; etc)
 - To reconfirm that IPV should not be used as a primary tool in response to cVDPV2

WG discussion and recommendations:

- WG members agreed with the prioritization order for IPV allocation as follows:
 1. Ensure that routine immunization needs in all countries are met. At the same time, ensure quarterly periodic (for example quarterly) national and sub-national monitoring of IPV supply and use.
 2. Ensure requirements for the acceleration of the interruption of wild poliovirus transmission are fully met (requests from endemic countries for SIAs to interrupt WPV)
 3. After these 2 requirements, excess doses should be allocated to populations that are IPV-unvaccinated since the switch, based on risk assessment
- SAGE WG emphasized that in the current climate of IPV supply constraints, countries need more accountability of IPV stock in the country. The WG expressed concern regarding Nigeria's request for additional IPV, when the country has received sufficient IPV to meet their birth cohort, yet coverage is only 42%. This highlighted the issue of requesting additional IPV supplies without adequate accounting of the supplies already received. SAGE recommended that countries provide periodic national and sub-national level reports of IPV stock, both for routine immunisation as well as for SIAs.
- Refugee groups were highlighted as an important group in requirement (3) that may be IPV-unvaccinated since the switch. SAGE WG recommended that a risk-ranking is conducted for refugee populations based on country of origin.
- Countries using fIPV should be prioritized for supply.
- The SAGE WG re-endorsed their previous statement on use of IPV (or fIPV) to control cVDPV2 outbreaks (from 15th SAGE WG meeting: *The group did not change its position on regarding the role of IPV use in cVDPV2 outbreak response. mOPV2 should be the primary response tool. The scope and number of mOPV2 campaigns should be appropriate for the outbreak, and should not be influenced by IPV use. IPV may prevent paralysis and, among OPV2 recipients, boost mucosal immunity.*)

Needle-free injector for administration of fIPV (Tropis): Review of field experience and immunogenicity data AND Prioritization of Tropis devices

WHO recently prequalified Tropis for delivery of intradermal vaccines including fractional IPV (fIPV), 0.1 ml volume. SAGE WG was presented with existing data from use of Tropis in pilot campaigns and immunogenicity studies. In summary, the data from Pakistan, Cuba and Gambia confirmed that Tropis is a device that is feasible to use in a vaccination campaign. It

provides for better comfort for children, is quicker to use than tradition BCG needle and syringe and is easy to train.

In Gambia, the number of doses per vial and the total storage and weight per 1,000,000 vaccinations were for BCG needle and syringe, ID adapter, and Tropis respectively: 50 doses per vial, 24.3m³ and 3,477kg; 57 doses per vial, 89.0m³ and 13,197kg; and, 63 doses per vial, 80.5m³ and 6, 423kg.

In terms of immunogenicity, the studies in Gambia and Cuba concluded that the seroconversion rates achieved with fIPV administered with Tropis are non-inferior to those achieved with BCG needle and syringe.

Current procurement of Tropis will secure 5,000 devices (1 device ~20,000 doses), 5,000,000 disposable syringes and 1,000,000 vial adapters by April 2019. This would allow for ~2.5 million children to receive 2 doses of fIPV using Tropis.

When prioritizing the use of Tropis, the following criteria were suggested:

- Regulatory environment for use of fIPV
- Size of population
- Risk level

Economic analysis of campaign delivery of fIPV was presented. In this analysis, Tropis was the most expensive method for intradermal administration of fIPV, however it was still cheaper than using full dose IPV. Economic analysis of fIPV delivery was developed by PATH.

WG discussion and recommendations:

- SAGE WG emphasised that the performance and pre-qualification of Tropis device was an exciting development which could have applicability to other antigens.
- SAGE WG suggested that it is important to gain more implementation experience both in routine and campaign settings to guide future policy; this should be well documented.
- Tropis device should initially be allocated where it makes most programmatic sense and using the above proposed criteria; evaluation of use should be carried out at all times.
- SAGE WG added that the Immunization Practices Advisory Committee (IPAC) should be consulted.

IPV and Hexavalent Supplier Landscapes and Country-Based Assessment of Risk of Poliovirus Re-emergence for Gavi's post-2020 IPV considerations

In 2013, the GAVI Board decided to support introduction of IPV as part of GPEI's Endgame Strategy (2013-18) to facilitate the introduction of a single dose of stand-alone IPV into routine immunisation schedules in 71 GAVI countries. Substantial supply of whole cell pertussis hexavalent vaccine (wP -hexavalent) is expected in 2023-24, with one licensed product currently available and four other manufacturers' products in development. This

will provide options of how IPV antigens are introduced into routine immunisation schedules, and the logistical and programmatic advantages for wP-hexavalent versus pentavalent + IPV were presented.

The objectives of GAVI's review of wP-Hexavalent strategic position were presented:

- Analyse the parameters relevant to the potential value of wP-Hexavalent in the context of Gavi's support of the global polio eradication initiative (GPEI)
- Describe the decision pathways that Gavi would need to follow to potentially support the procurement of wP-Hexavalent
- Integrate programmatic, financial and supply considerations related to wP-Hexavalent into the overall Vaccine Investment Strategy (VIS) investment case to be presented to the Board for decision-making in November 2018

In accordance with GAVI'S next strategic period 2021-2025, the Gavi Board had agreed that any investments in IPV beyond 2020 should be considered as part of Gavi's periodic Vaccine Investment Strategy (VIS) to be presented at the end of 2018. The Board recommended that a tailored assessment approach be applied given IPV's low impact in terms of traditional metrics (i.e., lives saved and value for money) yet unique role in mitigating the re-emergence of poliovirus. In recognition of this, Gavi and WHO have developed a risk assessment to categorise countries as high, medium or low risk for poliovirus re-emergence, which has been stratified by country ability to co-finance vaccine cost.

WG discussion and recommendations:

- The WG welcomed the progress with wP-hexavalent vaccine and increasing options for IPV delivery into routine immunisation schedules.
- The WG welcomed Gavi support to help countries secure IPV.
- The WG were comfortable with the methodology and purpose of the risk assessment model that has been developed by Gavi and WHO. The WG suggested that the model should be periodically evaluated and updated.
- The WG expressed concern over the group of middle-income countries that are assessed as having a high-risk for polio re-emergence but are in Gavi-transition or fully-self-financing groups.



16th Meeting of the SAGE Polio Working Group (WG)

Salle D, WHO, Geneva

September 4-5, 2018

AGENDA

Expected outcomes of the meeting:

1. To review the GPEI programme update, including the VDPV epidemiology and IPV supply situations
2. To provide inputs into draft options appraisal for certification of eradication
3. To discuss “readiness criteria” for bOPV withdrawal
4. To discuss Containment Breach Protocol
5. To review scientific data and availability of ID devices (adaptors and needle-free devices); and discuss guidance on use for the program
6. To review Hexavalent landscape analysis (for information)
7. To review country-based assessment of risk of poliovirus re-emergence

Day 1 (Sept 4)

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	M. Zaffran, WHO
	IPV Supply update and update on mOPV stockpiles (10 mins)	A. Ottosen , I. Lewis
10:30 – 11:00	Coffee break	
11:00 - 11:30	Presentation of draft options appraisal for certification of eradication	B. Burkholder
11:30 – 12:00	Discussion	
12:00 – 12:30	WPV3 certification of eradication “dry run”	D. Salisbury
12:30 - 13:30	Lunch	

13:30 – 14:30	Presentation of draft Containment Breach Protocol AND Discussion	G. Tallis
14:30 – 15:30	“Readiness criteria” for bOPV withdrawal AND Discussion	R. Sutter
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: plan for 2019-2023)</i>	
Day 2 (Sept 5)		
9:00 – 9:30	IPV allocation options	A. Ottosen , I. Lewis
9:30 – 10:00	Tropis: Review of field experience and immunogenicity data	O. Mach
10:00 – 10:30	Prioritization of Tropis devices in the context of Tropis availability and IPV supply	J. Vertefeuille
10:30 – 11:00	Coffee break	
11:00 – 11:30	Hexavalent landscape analysis	D. Hein
11:30 – 12:00	Country-based assessment of risk of poliovirus re-emergence	S. Sosler
12:00– 12:30	Discussions	
12:30 - 13:30	Lunch break	
13:30 - 16:00	Closed session: Finalizing WG recommendations (Continued; Coffee break at 15:30)	WG members WHO secretariat

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

- Draft options appraisal for certification of eradication
- Draft Containment Breach Protocol
- Draft Country-based assessment of risk of poliovirus re-emergence



World Health Organization

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16th Meeting of the SAGE Polio Working Group
4 – 5 September 2018
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