



Sixth Meeting of the Poliovirus Containment Advisory Group (CA6)

23 to 25 January 2023  
Geneva, SWITZERLAND

---

Note for the Record

Table of Contents	
	Page
List of Abbreviations.....	4
Executive Summary .....	7
Note for the Record	
Background.....	14
Session: Introduction	
Context and expected outcomes .....	16
Session: Update on Polio Eradication and Poliovirus Containment	
Current epidemiology of poliovirus transmission and progress with ongoing implementation of the Polio Eradication Strategy 2022 – 2026: Delivering on a Promise.....	18
WHO Containment Programme Update.....	19
Global immunization update with a focus on poliomyelitis immunization.....	21
Session: Collaboration with Other Units Performing Work Associated with Poliovirus Containment	
Rationale for local biological risk assessment-based approach in latest WHO manual on biosafety in laboratories.....	22
Long-term projections for polio vaccine supply by type of vaccine.....	24
Session: Collaboration between advisory groups supporting eradication and containment	
Independent views on polio eradication and containment.....	26
Role and geographical coverage of environmental surveillance.....	27
Criteria used by the Poliovirus IHR Emergency Committee for continued recommendation of a Public Health Emergency International Concern (PHEIC).....	30
Outcome from review of the period needed to certify the interruption of WPV1 transmission and criteria for the validation of the absence of cVDPV.....	32
Session: Polio research and commodities	
New products in pipeline for polio vaccine, diagnostics and treatment.....	34
Session: Immunization coverage and environmental safeguards	
Challenges with implementing the recommendations on immunization coverage- and environmental control- safeguards around facilities retaining polioviruses in GAPIV.....	36
Session: Containment requirements for novel poliovirus strains	
Novel oral poliomyelitis vaccine programmatic update and milestones.....	39
Genetic characterization of nOPV2 isolates from surveillance activities.....	40
Containment requirements for novel poliovirus strains.....	42
Session: Conformity Assessment Activities During the Transition Period from GAPIII to GAPIV	
Conformity Assessment Activities During the Transition Period from GAPIII to GAPIV.....	43
Session: Issues Associated with the Containment of Potentially Infectious Materials, Polioviruses	
Issues Associated with the Containment of Potentially Infectious Materials, Polioviruses.....	46
Session: Technical Issues Associated with Facility Containment Implementation	
Technical Issues Associated with Facility Containment Implementation.....	51
Session: Issues Associated with the Functioning of the CAG	
Terms of reference of CAG.....	52
Next meeting and teleconferences.....	52
Other matters.....	52

## Annexes

Annex 1: Sixth Meeting of the Poliovirus Containment Advisory Group (CAG6), 23 – 25 January 2023.....	54
Annex 1.1: Meeting objectives.....	54
Annex 1.2: Agenda.....	56
Annex 1.3: List of Participants.....	61
Annex 2: Global Polio Eradication Program Update with Chairs of Advisory- and Working- Groups Supporting Polio Eradication and Containment and Representatives of the GPEI Global Programme Support Groups, 23 – 24 January 2023.....	63
Annex 2.1: Meeting objectives.....	63
Annex 2.2: Agenda.....	64
Annex 2.3: List of Participants.....	71

## List of Figures

Figure 1: Polio Eradication Strategy 2022–2026: Milestones for Goal 1 and Goal 2 .....	4
Figure 2: ‘Most consequential geographies’ accounts for 80 to 90% of global poliomyelitis cases.....	7
Figure 3: Implementation status of indicator C4.2. Laboratory biosafety and biosecurity regime as reported using State Party Self-Assessment Annual Reporting (SPAR) tool (status as of January 2023).....	23
Figure 4: Baseline implementation status (%):of country capacity in technical area P7 (Prevent No 7) biosafety and biosecurity as reported using the IHR 2005: Joint External Evaluation (JEE) tool (accessed: January 2023).....	24
Figure 5: Overview of the global status of polio vaccine under development and production during the current eradication strategy and into the post-certification period.....	25
Figure 6: Number of paralytic poliomyelitis cases 2010 -o 2022 (by WPV cases and VDPV cases).....	28
Figure 7: Countries-level risk assessment (as of December 2022) for prioritization of implementation of the Global Polio Surveillance Action Plan (GPSAP) 2022–2024.....	29
Figure 8: Countries with environmental surveillance for poliovirus (as of December 2022).....	30
Figure 9: Confidence about no circulation in Pakistan and Afghanistan as a function of the detected event-free period (DEFP).....	33
Figure 10: cVDPV2 emergences and use of poliovirus serotype 2 containing vaccines: mOPV2, nOPV2 and tOPV..	40
Figure 11: nOPV2 use and supplementary immunization activities (SIA) in interruption of transmission of cVDPV2 in Tajikistan, January 2021.....	42
Figure 12: Conformity assessment activities during the transition from GAPIII (2015) to GAPIV (2022).....	46
Figure 13: Requirements for reporting retention- of poliovirus materials; and facility-, immunization coverage- and environmental- safeguard requirements for their retention and the associated accountability framework for facilities retaining poliovirus materials, post-eradication.....	50
Figure 14: Estimated poliovirus content of different sample types and infectious dose (ID <sub>50</sub> ).....	51

## List of Tables

Table 1: Novel poliovirus strains and their specific research usages temporarily waived from the biorisk management requirements for the handling of WPV and Sabin polioviruses described in GAPIV.....	10
Table 1: Goals, objectives, and country focus for the Strategy for Global Poliovirus Containment.....	20
Table 2: Current status of global poliovirus containment as per resolution WHA 71.16 (2018) Poliomyelitis – Containment of Polioviruses and other relevant recommendations.....	21
Table 3: Poliovirus types and serotypes that shall be notified to WHO under IHR (2005) .....	32
Table 4: New polio products and commodities in the development pipeline.....	36
Table 5: Facility–, immunization coverage- and environmental- safeguards for facilities retaining polioviruses as described in GAPIV.....	38
Table 6: Novel poliovirus strains and their specific research usages temporarily waived from the biorisk management requirements for the handling of WPV and Sabin polioviruses described in GAPIV.....	44
Table 7: Poliovirus materials: Facility retention reporting; facility- and - safeguard requirements and the associated oversight mechanism for the retention of poliovirus materials, post-eradication.....	49

## List of Abbreviations

9H2 huMoAb	Human monoclonal antibody 9H2
AFP	Acute flaccid paralysis
ASLM	African Society of Laboratory Medicine
CAG	Poliovirus Containment Advisory Group
CAG5	Fifth Meeting of the Poliovirus Containment Advisory Group (CAG6), 2, 4 and 9 March 2022
CAG6	Sixth Meeting of the Poliovirus Containment Advisory Group (CAG6), 23 to 25 January 2023
CAG7	Seventh Meeting of the Poliovirus Containment Advisory Group (CAG6), 15 to 16 June 2023
CAG – ESG	CAG – Expert Support Group for Novel Poliovirus Strains
CAPA	Corrective and Preventive Action Plan
CCS	Containment Certification Scheme
CP	Certificate of Participation
ICC	Interim Certificate of Containment
CC	Certificate of Containment
CCID <sub>50</sub>	Cell culture infectious dose 50%
COVID-19	Coronavirus disease 2019
DEFP	Detected event-free period
DTP3	Third dose of diphtheria, tetanus, and pertussis vaccine
ES	Environmental Surveillance
EUAL	WHO Emergency Use Assessment and Listing Procedure
EV-C	<i>Enterovirus</i> species C
GACVS	Global Advisory Committee on Vaccine Safety
GAPIII	Global Action Plan for Poliovirus Containment (short title) or Global Action Plan to minimize poliovirus facility-associated risk after type-specific eradication of wild polioviruses and sequential cessation of oral polio vaccine use (full title), 3rd edition, 2015
GAPIV	WHO Global Action Plan for Poliovirus Containment (4th edition, 2022)
GCC	Global Commission for the Certification of the Eradication of Poliomyelitis
GCC – CWG	GCC – Containment Working Group
GDG	Guidance Development Group
GMP	Good Manufacturing Practices
GPEI	Global Polio Eradication Initiative
GPS	GPEI Global Programme Support Groups
VSG	GPEI Vaccine Supply Group
CMG	GPEI Containment Management Group
GISRS	Global Influenza Surveillance and Response System
GMRLN	Global Measles and Rubella Laboratory Network
GPLN	Global Polio Laboratory Network
GRLN	Global Rotavirus Laboratory Network
GPSAP	Global Polio Surveillance Action Plan 2022- 2024
IA2030	Immunization Agenda 2030
IB-VPD	Global Invasive Bacterial Vaccine-Preventable Diseases Laboratory Network
ID <sub>50</sub>	Infectious dose
IHR	International Health Regulations, 3rd edition, 2005
IHRMEF	IHR Monitoring and Evaluation Framework
JEE	Joint External Evaluation
SPAR	IHR State Party Self-Assessment Annual Report
PHEIC	Public Health Emergency of International Concern
ISO	International Organization for Standardization
IPV	Inactivated poliovirus vaccine
IPV1	First-dose inactivated poliovirus vaccine

## List of Abbreviations

IPV2	Second-dose inactivated poliovirus vaccine
LBM4	WHO Laboratory Biosafety Manual and Associated Monographs, 4th edition, 2020
NAC	National authority for containment
NPEV	Non-poliovirus enterovirus
NPCC	National Poliovirus Containment Coordinator
OPV	Oral poliomyelitis vaccine
bOPV	Sabin bivalent oral poliomyelitis vaccine containing serotypes 1 and 3
mOPV1,2 or 3	Sabin monovalent oral poliomyelitis vaccine containing serotype 1, 2 or 3
nOPV1,2 or 3	Novel monovalent oral poliomyelitis vaccine containing serotype 1, 2 or 3
tnOPV	Novel trivalent oral poliomyelitis vaccine containing serotypes 1, 2 and 3
tOPV	Sabin trivalent oral poliomyelitis vaccine containing serotypes 1, 2 and 3
PEF	Poliovirus-essential Facility
PID	Primary immunodeficiency disorder
PIM	Potentially infectious materials, poliovirus
PIM Guidance 2018	Guidance for non-poliovirus facilities to minimize risk of sample collections potentially infectious for polioviruses, 1st edition, 2018
PIM Guidance 2021	Guidance to minimize risks for facilities collecting, handling or storing materials potentially infectious for polioviruses, 2nd edition, 2021
PRC	Polio Research Committee
PVSRIPO	Neuro-attenuated recombinant poliovirus; live attenuated Sabin serotype 1 poliovirus with heterologous internal ribosomal entry site (IRES) of human rhinovirus type 2.
$R_0$	Basic reproductive number
$R_e$	Effective reproductive number
RCA	Root cause analysis
R&D	Research and Development
S19	S19 with the structural (capsid) protein encoding P1-region (of WPV or Sabin polioviruses; of serotypes 1, 2 or 3)
S19/N18S	S19 with the structural (capsid) protein encoding P1-region (of WPV or Sabin polioviruses; of serotypes 1, 2 or 3) with mutation (substitution) of asparagine (N) by serine (S) at amino acid 18 of the non-structural protein 2A to allow better growth in Vero cells.
SAGE	Strategic Advisory Group of Experts on immunization
SDG	Sustainable Development Goals
SIA	Supplementary immunization activity
TIMB	Transition Independent Monitoring Board for Polio Eradication
IMB	Polio Transition Independent Monitoring Board
TRS	WHO Technical Report Series
V-7404	Direct-acting antiviral agent that irreversibly binds the Enterovirus 3C protease active site, making it a promising treatment for immunodeficient people excreting VDPV.
VAPP	Vaccine-associated paralytic poliomyelitis
VDPV	Vaccine-derived poliovirus
aVDPV1, 2 or 3	Ambiguous vaccine-derived poliovirus serotypes 1, 2 or 3
cVDPV1, 2 or 3	Circulating vaccine-derived poliovirus serotypes 1, 2 or 3
iVDPV1, 2 or 3	Immunodeficiency-associated vaccine-derived poliovirus serotypes 1, 2 or 3
WPV	Wild poliovirus
WPV1,2 or 3	Wild poliovirus serotypes 1, 2 or 3
VLP	Virus-like particle
rsVLP	Poliovirus recombinant stable VLP
WBE	Wastewater-based epidemiology
WHA	World Health Assembly

[List](#) of Abbreviations

WHO	World Health Organization
AFRO	WHO African Region
CNT	Poliovirus Containment Programme, WHO headquarters in Geneva, SWITZERLAND
EMRO	WHO Eastern Mediterranean Region
EURO	WHO European Region
NSB	Norms and Standards for Biological Products, WHO headquarters in Geneva, SWITZERLAND
PAHO/AMRO	Pan American Health Organization/WHO Regions of the Americas
PQT	WHO Vaccines Prequalification Programme, WHO headquarters in Geneva, SWITZERLAND
PRD	Research and Development, Polio Eradication, WHO headquarters in Geneva, SWITZERLAND
SEARO	WHO South East Asia Region
WPRO	WHO Western Pacific Region
WUENIC	WHO/UNICEF estimates of national immunization coverage

## Sixth Meeting of the Poliovirus Containment Advisory Group (CAG6), 23 to 25 January 2023 Executive Summary

The Sixth Meeting of the Poliovirus Containment Advisory Group (CAG6) was held from 23 to 25 January 2023 in Geneva, SWITZERLAND with the objective of presenting to the Poliovirus Containment Advisory Group (CAG) for discussion and recommendations, issues associated with the implementation of poliovirus containment and issues within the mandate of the CAG. This meeting also brought together the chairs of different advisory- and working- groups supporting polio eradication and containment and representatives of the Global Polio Eradication Initiative (GPEI) Global Programme Support groups<sup>1,2</sup> to a Global Polio Eradication Program Update Meeting, which took place on 23 and 24 January 2023, ahead of CAG6, with the objective of information exchange, ensuring alignment and raising awareness of the progress made in the polio eradication or poliovirus containment workstreams undertaken by these strategic bodies in line with their mandates. The CAG6 and Global Polio Eradication Program Update Meeting objectives, agenda and list of participants are included in Annexes 1 and 2.

The following are the reflections of the chairs of the different advisory- and working- groups attending the Global Polio Eradication Program Update Meeting:

### Meeting structure and organization

1. The organization of a global programme update on polio eradication and poliovirus containment with the involvement of different chairs of WHO advisory-, working- and other- supporting groups was a unique opportunity for collaboration and progress sharing. This allowed a better understanding, awareness and alignment of the different workstreams between these groups. The CAG recommends such practice be taken into consideration in the organization of future CAG- or other- meetings, whenever feasible.

### Collaboration with other units performing work associated with poliovirus containment

2. The alignment of the WHO Global Action Plan for Poliovirus Containment, 4th ed., 2022 (GAPIV) with the WHO Laboratory Biosafety Manual 4th ed., 2020 (LBM4) is important to ensure maximum protection of operators against the exposure to polioviruses due to the handling of infectious- and potentially infectious materials in facilities. CAG recommends that the WHO Containment (CNT) programme and the WHO Biosecurity and Health Security Protection (BSP) programme urgently strengthen links in the implementation of a unified and sustainable biosafety programme management<sup>3</sup> and biosecurity policies and practices.

---

<sup>1</sup> These included: the Poliovirus Containment Advisory Group (CAG); Global Commission for the Certification of the Eradication of Poliomyelitis (GCC); GCC – Containment Working Group (GCC – CWG); Poliovirus International Health Regulations (IHR) Emergency Committee; Independent Monitoring Board (IMB) and Transition IMB (TIMB); Strategic Advisory Group of Experts on immunization (SAGE); SAGE working group on polio; and the following GPEI Global Programme Support (GPS) groups: GPEI nOPV Working Group; GPEI Vaccine Supply Group (VSG) and GPEI Surveillance Group.

<sup>2</sup> The GPS groups provide strategic, financial and operational guidance and resources for implementation and in support of regional operations activities and are part of the GPEI Management and Advisory Structure. Available at: <http://polioeradication.org/wp-content/uploads/2022/03/GPEI-organigram-Oct-2021.pdf>

<sup>3</sup> the LBM4 defines biosafety programme management as the development, implementation and oversight of biosafety at the organizational level using a variety of information that includes institutional policies, guidance documents for practices and procedures, planning documents (training, recruitment, emergency/incident

3. The WHO prequalification programme for polio vaccines should include compliance verification of polio vaccine manufacturer against the containment requirements described in GAPIV, in addition to the assessment of vaccine quality, safety, efficacy data or relevant activities, as an essential component in the prequalification of polio vaccines. The CAG recommends continued dialogues between the WHO Containment (CNT) programme, WHO vaccines prequalification (PQT) programme and the Norms and Standards for Biological Products (NSB) unit to ensure that this is urgently addressed and resolved by the WHO.

#### Collaboration between advisory groups supporting eradication and containment

4. The CAG requests for representation at the meetings of the Strategic Advisory Group of Experts (SAGE) working group on polio, when the meeting agenda include polio immunization policies. This will help ensure feasibility of such policy recommendations (schedule, coverage, geographical extent of coverage) with the immunization coverage safeguard requirements in GAPIV for countries hosting facilities retaining polioviruses post-eradication.
5. There is a need to strengthen collaboration by establishing linkages between the CAG and the Global Commission for the Certification of the Eradication of Poliomyelitis (GCC) e.g., the CAG may provide inputs on the progress made with the containment criteria for the certification of polio eradication to the GCC for consideration. More specifically, these may include: status of biorisk management in facilities retaining potentially infectious materials, polioviruses<sup>4</sup> at the time of global certification of wild poliovirus (WPV) eradication and validation of absence of circulating vaccine-derived poliovirus (cVDPV).
6. Closer collaboration through consultations or discussions of similar nature is needed between the CAG and different groups, such as the Polio Research Committee (PRC), GPEI novel oral poliomyelitis vaccine (nOPV) working group, as well as groups involved in work related to poliovirus research to facilitate the alignment of the poliovirus containment requirements with the implementation of poliovirus research studies.

#### Polio research and commodities

7. The CAG recommends the development of an inclusive strategy for new polio vaccines, one that includes research, safe and cost-effective production technologies and in line with poliovirus containment requirements. Whenever possible, the CAG recommends the development of new vaccines that would require less stringent containment requirements to provide incentives to newer developments. This should involve WHO Containment (CNT) programme, WHO Polio Research (PRD) programme and the GPEI Vaccine Supply Group (VSG).

---

response) and record keeping (personnel, inventories, incident management). WHO Laboratory biosafety manual, 4th edition, 2020. Available at: <https://www.who.int/publications/i/item/9789240011311>

<sup>4</sup> GCC Recommendation (Containment) 4.1.1. Certification of WPV eradication should only occur when all WPV materials, in facilities designated for retaining them, are safely and securely contained<sup>5</sup>

<sup>5</sup> All facilities retaining WPVs should have a Containment Certificate, or a time-limited Interim Containment Certificate, with a clear end point for obtaining a CC agreed with the GCC. In addition, at the time of global WPV certification, the GCC will consider the status of biorisk management of potentially infectious materials and readiness plan to respond to containment breaches.

Source: Report from the Seventeenth Meeting of the GCC, Geneva, Switzerland, 26-27 February 2018.

Available at: <https://polioeradication.org/wp-content/uploads/2018/04/polio-eradication-certification-17th-meeting-global-commission-for-certification-of-poliomyelitis-eradication-20180412.pdf>



8. The CAG recommends the development an inclusive blueprint for polio research, if not already available with approaches for accelerating research in new polio products (polio vaccine, diagnostics and treatment) and other initiatives, expedited regulatory pathways such as using the WHO Emergency Use Assessment and Listing Procedure (EUAL), containment consideration, where applicable and other approaches modelled after the WHO R&D Blueprint for Action to Prevent Epidemics<sup>5</sup> for research on epidemic-prone emerging pathogens.
9. The achievement of safe and secure poliovirus containment must remain one of the core objective in the revision of the post-eradication strategy. This should also include other components, such as the prioritization of polio vaccine development, polio-associated research, containment requirements for novel poliovirus strains and potentially infectious materials, polioviruses in the post-OPV cessation period. The CAG requests to be consulted in this aspect, as several of these areas are within the mandate of the CAG.

The following are the recommendations from the Sixth Meeting of the Poliovirus Containment Advisory Group (CAG6):

#### Immunization coverage and environmental safeguards

1. The geographical extent of coverage (multinational, national, subnational data or as appropriate) used in the definition of immunization coverage safeguards in GAPIV is left to the decision of the national authority for containment (NAC) as determined by a risk assessment. The NACs should also ensure that infants in the geographical coverage area are provided with a primary 3-dose series of inactivated poliovirus vaccine (IPV), with an interval of 4 weeks for countries using only IPVs. For countries using oral poliomyelitis vaccine (OPV), two-doses of IPV with an interval of 4–8 weeks. The goal is to achieve a minimum IPV2 vaccination coverage of at least 90% as a precautionary measure, which may be modified as evidence accrues<sup>6</sup>.

[This recommendation does not constitute change in the relevant GAPIV text or section, at present]

2. With the ongoing implementation of the interim containment certification phase, the Global Commission for the Certification of the Eradication of Poliomyelitis – Containment Working Group (GCC – CWG) will review country evidence of appropriate implementation of environmental safeguards and will provide feedback to CAG on the feasibility of the revised approach and the definition used in GAPIV.

[This recommendation does not constitute change in the relevant GAPIV text or section, at present]

---

<sup>5</sup> WHO: An R&D Blueprint for Action to Prevent Epidemics, Plan of Action, May 2016. Available at: <https://www.who.int/teams/blueprint/about>

<sup>6</sup> As per Strategic Advisory Group of Experts (SAGE) on immunization recommendation for polio immunization policy after global OPV withdrawal published in the Meeting of the Strategic Advisory Group of Experts on immunization, April 2017 – conclusions and recommendation; Weekly Epidemiological Record; 92 (22); 301 – 320; 2 June 2017 (Available at: <https://www.who.int/publications/i/item/WER9222>) and Polio vaccines: WHO position paper – June 2022; Weekly Epidemiological Record; 97 (25); 277–300; 24 June 2022 (Available at: <https://www.who.int/publications/i/item/WHO-WER9725-277-300>).

### Containment Requirements for Novel Poliovirus strains

3. The following are the updated CAG recommendations on the containment requirements of novel poliovirus strains following an assessment of newly available data on novel poliovirus strains and their specified uses by the CAG - Expert Support Group (CAG-ESG) on Novel Poliovirus Strains:
- Continuation of the temporary waiver<sup>7</sup> currently in place for nOPV (nOPV1, nOPV2 and nOPV3) for the following specific usages: vaccine production, vaccine quality control, clinical trials and outbreak response.
  - Continuation of the temporary waiver<sup>8</sup> currently in place for S19 – poliovirus strains cassette for the following specific usages: IPV production, rat neutralization IPV potency assays, human serum neutralization test for poliovirus antibody determination and potency testing for immunoglobulin (human) lot control and release.
  - Continuation of the temporary waiver<sup>7</sup> currently in place for the following specific usages: trivalent formulation of nOPV1, nOPV2, and nOPV3; and nOPV formulation studies and clinical trials of trivalent nOPV (tnOPV).
  - Continuation of the temporary waiver<sup>8</sup> currently in place for the use of novel poliovirus strains for research purposes (Table 1).

Table 1: Novel poliovirus strains and their specific research usages temporarily waived from the biorisk management requirements for the handling of WPV and Sabin polioviruses described in GAPIV.

Strains	Specific Uses
<ul style="list-style-type: none"> <li>nOPV1 candidate 1 (aka nOPV1-c1, or S2/cre5/S15domV/rec1/hifi3/S1P1)</li> <li>nOPV2 candidate 1 (aka nOPV2-c1, or S2/cre5/S15domV/rec1/hifi3/S2P1)</li> <li>nOPV3 candidate 1 (aka nOPV3-c1, or S2/cre5/S15domV/rec1/hifi3/S3P1)</li> <li>nOPV1 candidate 2 (aka nOPV1-c2, or S2/cre6/S15domV/CpG30/rec1/hifi3/S1P1)</li> <li>nOPV2 candidate 2 (aka nOPV2-c2, or S2/S15domV/CpG40)</li> <li>nOPV3 candidate 2 (aka nOPV3-c2, or S2/cre6/S15domV/CpG30/rec1/hifi3/S3P1)</li> <li>nOPV2 candidate 3 (aka nOPV2-c3 or S2/cre6/S15domV/CpG40/rec1/hifi3)</li> <li>S19S1</li> <li>S19S2</li> <li>S19S3</li> <li>S19S1_N18S</li> <li>S19S2_N18S</li> <li>S19S3_N18S</li> </ul>	<ul style="list-style-type: none"> <li>Laboratory activities to support clinical trials and ongoing monitoring of continued use</li> <li>Viral concentration from environmental samples</li> <li>Development or refinement of methods for viral concentration and detection from environmental samples</li> <li>Frozen storage of stool specimens from clinical trials</li> <li>Determination of D-antigen content</li> <li>Determination of viral titer</li> <li>Stability studies, including for alternative nOPV formulations</li> <li>Characterization of aliquots from stability studies (e.g., pH, aggregation assays, HPLC)</li> <li>Immunogenicity assays in mice and rats</li> <li>Detection of nOPV and mucosal antibodies to nOPV in stool samples</li> <li>Neutralization assays</li> <li>Isolation of antibodies and virus from stool samples (human, mouse, rat)</li> <li>Mass spectroscopy</li> </ul>

<sup>7</sup> temporary waivers are time-limited, conditional to the specified usages only and temporarily waived from the biorisk management requirements for the handling of Sabin polioviruses described in GAPIV.

<sup>8</sup> temporary waivers are time-limited, conditional to the specified usages only and temporarily waived from the biorisk management requirements for the handling of WPV and Sabin polioviruses described in GAPIV.

Table 1: Novel poliovirus strains and their specific research usages temporarily waived from the biorisk management requirements for the handling of WPV and Sabin polioviruses described in GAPIV.

Strains	Specific Uses
<ul style="list-style-type: none"> <li>• S19Mah</li> <li>• S19MEF1</li> <li>• S19Skt</li> <li>• S19Mah_N18S</li> <li>• S19MEF1_N18S</li> <li>• S19Skt_N18S</li> </ul>	<ul style="list-style-type: none"> <li>• Small-scale propagation</li> <li>• Nucleic acid extraction</li> <li>• Sequencing</li> <li>• Potency testing for immunoglobulin (human) lot control and release</li> <li>• Testing effectiveness of inactivation and disinfection methods</li> <li>• Sterility studies to confirm inactivation and disinfection methods</li> <li>• Spiking biosolids (sewer sludge) or wastewater to demonstrate effectiveness of treatments</li> </ul>

- e. Continuation of the temporary waiver<sup>7</sup> currently in place for neuro-attenuated recombinant poliovirus (PVSRIPO) for the following specific usages: Phase II clinical trials (cancer immunotherapy) and production of these strains.
4. The CAG recommends that the CAG – ESG continue their previously initiated discussions to resolve the following, understanding that the recommendations may be in the *interim*:
- a. mechanism for the compliance monitoring of facilities with the terms of the temporary waiver (conditional usage)
  - b. duration of temporary waivers, if any
  - c. resolving the exemption from the containment requirements of novel poliovirus strains for specified uses after the end-validity of the waivers in the post-OPV cessation period when all live poliovirus are expected to be fully contained.

[CAG recommendations on novel poliovirus strains does not constitute change in the relevant GAPIV text or section]

#### Conformity Assessment Activities During the Transition Period from GAPIII to GAPIV

5. Initial ICC audits may be carried out against the requirements of GAPIV or GAPIII. However, should these initial audits be carried out against the requirement of GAPIII, these must be completed by 31 December 2023. From 1 January 2024, all ICC audits must be performed against GAPIV. ICC issued from the audits against GAPIII or GAPIV shall be valid for no longer than three years with any periodic- or follow-up- audits performed against the same standard (GAPIII or GAPIV) against which the ICC is issued. The transition from an ICC against GAPIII to a CC shall require a full audit against GAPIV which can be performed at any time but must be done by at least 3 months prior to the expiration date of the ICC certificate.

[CAG recommendation to be included in GAPIV >> Introduction >> Transition Period]

## Issues Associated with the Containment of Potentially Infectious Materials, Polioviruses

6. The following are the recommendations by the CAG on issues associated with the containment of potentially infectious materials, polioviruses:
  - a. Due to the short window for viremia in blood, the current consideration of blood being excluded from classified as potentially infectious materials, poliovirus remains valid, unless scientific evidence suggests otherwise.
  - b. Revision of the PIM Guidance<sup>9</sup> and harmonization with Annex 6 of GAPIII<sup>10</sup>, GAPIV<sup>11</sup> and other relevant documents<sup>12</sup> should be initiated. The revision and harmonization should emphasize raising awareness of operators in poliovirus and non-poliovirus facilities of the potential of handling materials that may contain polioviruses.
  - c. The retention of potentially infectious materials, WPV/VDPV are exempt from the requirements of GAPIV, but it should be subjected to WPV/VDPV Guidance, which is to be developed, with risk categorization (sample type and work) and mitigation measures recommended for different risk categories.
  - d. An accountability framework for facility compliance against the risk mitigation strategies for the retention of potentially infectious materials, polioviruses, to be developed under the responsibility of the national poliovirus containment coordinator (NPCC) for reporting through the certification commissions in the short-term<sup>13</sup>.
  - e. Immunization coverage- and environmental- safeguard requirements should be put in place for facilities retaining potentially infectious materials, poliovirus as described in GAPIV. The compliance responsibility is to be assigned to the NPCC, in the short-term.
  - f. Long-term issues, such as containment requirements of potentially infectious materials, polioviruses in the post-OPV cessation period (when all live polioviruses are expected to be contained) will be deliberated by the CAG at a later date.

---

<sup>9</sup> Guidance to minimize risks for facilities collecting, handling or storing materials potentially infectious for polioviruses, 2nd ed., 2021 (PIM Guidance). Available at: <https://polioeradication.org/polio-today/preparing-for-a-polio-free-world/containment/containment-resources/>

<sup>10</sup> Annex 6 (biorisk management standard for safe handling of new samples potentially containing poliovirus material in poliovirus-non-essential facilities) of the WHO Global Action Plan for Poliovirus Containment, 3rd ed., 2015 (GAPIII). Available at: [https://polioeradication.org/wp-content/uploads/2016/12/GAPIII\\_2014.pdf](https://polioeradication.org/wp-content/uploads/2016/12/GAPIII_2014.pdf)

<sup>11</sup> WHO Global Action Plan for Poliovirus Containment, 4th ed., 2022 (GAPIV). Available at: <https://polioeradication.org/wp-content/uploads/2022/07/WHO-Global-Action-Plan-for-Poliovirus-Containment-GAPIV.pdf>

<sup>12</sup> WHO Laboratory Biosafety Manual, 4th edition, 2020. Available at: <https://www.who.int/publications/i/item/9789240011311?sequence=1&isAllowed=y> and GPLN Guidance Paper 1 for safe handling and storage of type 2 poliovirus (PV2) in GPLN laboratories. Available at: <https://polioeradication.org/wp-content/uploads/2020/01/GP1-Handling-and-Storing-PV2-version3.pdf>

<sup>13</sup> Longer-term solution to be developed at a later stage adapted to the status of containment and containment infrastructure post-eradication. In countries that host poliovirus-essential facilities (PEFs), the National Authority of Containment (NAC) may assume this responsibility.

[CAG recommendations on issues associated with the containment of potentially infectious materials, polioviruses do not constitute change in the relevant GAPIV text or section at present. Relevant changes will be made following the implementation of these recommendations]

#### Issues associated with the functioning of the CAG

##### Terms of reference of the CAG

7. The CAG acknowledged their updated terms of reference (as of April 2022)<sup>14</sup> which was revised to conform with WHO corporate policies for advisory groups and to include the oversight function of the CAG for containment issues and documents following the transfer of oversight function from SAGE in 2018.

##### Next meeting and teleconferences

8. CAG members agreed that the Seventh Meeting of the Poliovirus Containment Advisory Group (CAG7) be held on 15 and 16 June 2023.
9. CAG members agreed to participate in a Post-CAG6 Teleconference in early February 2023 to discuss technical issues associated with facility containment implementation pending CAG recommendation and requested that Doodle poll be sent out by the CAG Secretariat.

#### Other matters

10. CAG recommends that a review of the implementation of CAG6 recommendations be conducted at the next CAG meeting i.e., CAG7, 15 – 16 June 2023.

---

<sup>14</sup> Terms of reference of CAG (as of April 2022) is available at: <https://polioeradication.org/wp-content/uploads/2022/06/CAG-TORs-20220430.pdf>. The updated TORs include oversight function for containment. See Page 2; Section: Function; ‘No. 5 Oversight function for issues related to poliovirus containment and containment documents e.g., WHO Global Action Plan for Poliovirus Containment, CCS, PIM guidance, etc., including the endorsement of these documents, when needed’.

## Note for the Record

### Background

The Sixth Meeting of the Poliovirus Containment Advisory Group (CAG6) was held from 23 to 25 January 2023 in Geneva, SWITZERLAND with the objective of presenting to the Poliovirus Containment Advisory Group (CAG) for discussion and recommendations issue associated with the implementation of poliovirus containment and issues within the mandate of CAG.

The CAG6 Meeting objectives, agenda and list of participants are included in Annex 1.

CAG6 was attended by the following:

CAG:	Professor David HEYMANN, Chair of CAG; Dr Mark PALLANSCH, also Chair of CAG – Expert Support Group (CAG – ESG) for Novel Poliovirus Strains and Chair, GPEI Containment Management Group (CMG); Professor Shahina TABASSUM; Professor George E GRIFFIN, also Member of CAG – ESG for Novel Poliovirus Strains; Dr Åsa Szekely BJORN DAL; Dr Janice LO; Dr Stephen McADAM, also Member of CAG – ESG for Novel Poliovirus Strains; Dr Vibeke HALKJÆR-KNUDSEN; Mr Kenneth UGWU and Dr Jagadish DESHPANDE (Virtual Participation). Unable to attend: Dr Atef M ELGENDY.
Representative of other containment supporting groups:	Dr Arlene KING, Liaison Member of the Containment Working Group of the Global Commission for the Certification of the Eradication of Poliomyelitis (GCC-CWG) to the CAG and Chair, GCC – CWG
Invited presenters:	Dr. Lia HAYNES SMITH, US National Poliovirus Containment Coordinator (NPCC) and Director, US National Authority for Containment of Poliovirus (US NAC), CDC, Atlanta, Georgia, USA
CAG Secretariat:	Dr Harpal SINGH, Technical Officer – Poliovirus Containment and Secretariat, CAG and Mr Derek EHRHARDT, Senior Technical Adviser, Poliovirus Containment.
Department of Polio Eradication, WHO headquarters in Geneva, SWITZERLAND:	Mr Aidan O’LEARY, Director; Poliovirus Containment Team, Department of Polio Eradication, WHO headquarters in Geneva, SWITZERLAND: Dr Nicoletta PREVISANI, Technical Officer; Ms Liliane BOUALAM, Technical Officer and Secretariat, GCC – CWG; Mr Joseph SWAN, Communications Officer and Ms Caroline NAKANDI, Assistant to the Team.
Rapporteur:	Ms Kailing MARCUS, Institute of Global Health, Faculty of Medicine, University of Geneva. <a href="mailto:kailing.marcus@unige.ch">kailing.marcus@unige.ch</a>

This meeting also brought together the chairs of different advisory- and working- groups supporting polio eradication and poliovirus containment and representatives of the GPEI Global Programme Support (GPS) groups<sup>15</sup> to a Global Polio Eradication Program Update Meeting which took place on 23 and 24 January 2023,

<sup>15</sup>These included: the Poliovirus Containment Advisory Group (CAG); Global Commission for the Certification of the Eradication of Poliomyelitis (GCC); GCC – Containment Working Group (GCC – CWG); Poliovirus International Health Regulations (IHR) Emergency Committee; Independent Monitoring Board (IMB) and Transition IMB (TIMB); Strategic Advisory Group of Experts on immunization (SAGE); SAGE working group on polio; and the following GPEI Global Programme Support groups: GPEI nOPV Working Group; GPEI Vaccine Supply Group (VSG) and GPEI Surveillance Group.

ahead of CAG6, with the objective of information exchange, ensuring alignment and raising awareness of the progress made in the polio eradication or poliovirus containment workstreams undertaken by these strategic bodies in line with their mandates.

The Global Polio Eradication Program Update Meeting objectives and agenda are included in Annex 2.

The Global Polio Eradication Program Update Meeting was attended by the following:

- CAG: Professor David HEYMANN, Chair of CAG; Dr Mark PALLANSCH, also Chair of CAG – Expert Support Group (CAG – ESG) for Novel Poliovirus Strains and Chair, GPEI Containment Management Group (CMG); Professor Shahina TABASSUM; Professor George E GRIFFIN, also Member of CAG – ESG for Novel Poliovirus Strains; Dr Ása Szekely BJORN DAL; Dr Janice LO; Dr Stephen McADAM, also Member of CAG – ESG for Novel Poliovirus Strains; Dr Vibeke HALKJÆR-KNUDSEN; Mr Kenneth UGWU and Dr Jagadish DESHPANDE (Virtual Participation).  
Unable to attend: Dr Atef M ELGENDY.
- WHO Advisory- and working- groups supporting polio eradication and poliovirus containment: Professor David HEYMANN, Chair of the Poliovirus Containment Advisory Group (CAG); Professor David SALISBURY, Chair of Global Commission for the Certification of the Eradication of Poliomyelitis (GCC); Dr Arlene KING, Chair of GCC – Containment Working Group (GCC – CWG) and Liaison Representative of the GCC – CWG to CAG; Dr Hanna NOHYNEK, Chair of Strategic Advisory Group of Experts (SAGE) on immunization (Virtual participation); Professor Shabir A MADHI, Chair of SAGE working group on polio (Virtual participation); Professor Sir Liam DONALDSON, Chair of Independent Monitoring Board (IMB) for Polio Eradication and Chair of Polio Transition IMB (TIMB); Ms Katherine HAYES, Secretariat- of IMB for Polio Eradication and Polio Transition IMB (TIMB); Professor Helen REES, Chair of Poliovirus International Health Regulations (IHR) Emergency Committee.
- Representatives of the GPEI Global Programme Support Groups (GPS): GPEI nOPV Working Group: Ms Simona ZIPURSKY, Special Adviser to the Director, Polio Eradication, WHO headquarters in Geneva, SWITZERLAND and Chair of GPEI nOPV Working Group; Mr Feyrouz KURJI Principal Consultant, FDK Consulting LLC, Kirkland, Washington, USA and Coordinator of GPEI nOPV Working Group (Virtual participation); Dr Ananda S BANDYOPADHYAY, Deputy Director, Technology, Research, and Analytics, Polio Team, Bill & Melinda Gates Foundation, Seattle, Washington, USA and GPEI nOPV Working Group (Virtual participation); Ms Kaija HAWES, Associate Program Officer, Technology, Research, and Analytics, Polio Team, Bill & Melinda Gates Foundation, Seattle, Washington, USA and Coordinator of nOPV Genetic Characterization Subgroup of the GPEI nOPV2 Working Group GPEI nOPV2 Working Group (Virtual participation); Dr Javier MARTIN, Principal Scientist, Division of Virology; Director, WHO Global Specialized Polio Laboratory, National Institute for Biological Standards and Control (NIBSC), Potters Bar, Hertfordshire, UNITED KINGDOM and nOPV Genetic Characterization Subgroup of the GPEI nOPV2 Working Group and Dr Cara BURNS Team Lead, Molecular Epidemiology and Surveillance Laboratory, Division of Viral Diseases, Centers for Disease Control and Prevention (CDC), Atlanta, Georgia, USA and nOPV Genetic Characterization Subgroup of the GPEI nOPV2 Working Group (Virtual participation). GPEI Vaccine Supply Group (VSG): Ms Ann E. OTTOSEN, Senior Manager, Vaccine Centre UNICEF Supply Division, Copenhagen, DENMARK and Chair of GPEI VSG (Virtual participation); Dr Vachagan HARUTYUNYAN, Team Leader, Detection & Interruption, Polio Eradication, WHO headquarters in Geneva, SWITZERLAND and GPEI VSG and Mr David WOODS,

Technical Officer, Detection and Interruption Unit, Department of Polio Eradication, WHO headquarters in Geneva, SWITZERLAND. GPEI Surveillance Group: Dr Graham TALLIS, Senior Scientific Adviser, Detection and Interruption, Polio Eradication, WHO headquarters in Geneva, SWITZERLAND; Co-Chair, GPEI Surveillance Group and Secretariat of- GCC and Poliovirus IHR Emergency Committee. GPEI Containment Management Group (CMG): Dr Tim PETERSEN, Deputy Director, Country Operations, Polio Team, Bill & Melinda Gates Foundation, Seattle, Washington, USA and Member of GPEI CMG (Virtual participation); Dr Steve WASSILAK, Global Immunization Division, Centers for Global Health, Centers for Disease Control and Prevention (CDC), Atlanta, Georgia, USA and Member of GPEI CMG (Virtual participation); Dr Ekkehart PANDEL, Rotary International and Member of GPEI CMG (Virtual participation); Dr Ousmane DIOP, Scientist, Surveillance, Lab and Data, Polio Eradication, WHO headquarters in Geneva, SWITZERLAND and Member of GPEI CMG and Dr Eugene SAXENTOFF, Polio Laboratory Network and Poliovirus Containment Coordinator, Vaccine-preventable Diseases and Immunization (VPI), Division of Country Health Programmes (CHP), WHO European Regional Office, Copenhagen, DENMARK and Member of GPEI CMG (Virtual participation).

Additional invited presenters:	Mrs Diana CHANG BLANC, Team Lead, Programme Strengthening, Essential Programme on Immunization, WHO headquarters in Geneva, SWITZERLAND; Dr Martin EISENHAWER; Scientist, Research and Development, Polio Eradication, WHO headquarters in Geneva, SWITZERLAND and Dr Kazunobu KOJIMA, Medical Officer, Biosafety and Biosecurity, Epidemic and Pandemic Preparedness and Prevention, WHO headquarters in Geneva, SWITZERLAND.
WHO Secretariat:	Mr Aidan O'LEARY, Director, Department of Polio Eradication, WHO headquarters in Geneva, SWITZERLAND; Poliovirus Containment Team, Department of Polio Eradication, WHO headquarters in Geneva, SWITZERLAND: Mr Derek EHRHARDT, Senior Technical Adviser; Dr Nicoletta PREVISANI, Technical Officer; Ms Liliane BOUALAM, Technical Officer and Secretariat, GCC – CWG; Dr Harpal SINGH, Technical Officer and Secretariat, CAG; Mr Joseph SWAN, Communications Officer and Ms Caroline NAKANDI, Assistant to the Team.

All CAG members, chairs of the WHO advisory- and working- groups supporting polio eradication and poliovirus containment, representatives of the GPEI Global Programme Support Groups (GPS) and other relevant meeting participants submitted a signed declaration of interest (DoI) form and were requested to inform the secretariat of any change in situation or circumstance requiring the need for new disclosure at this meeting. All DoI were assessed as per WHO Guidelines for Declaration of Interests (WHO Expert). No meetings participant was identified as having any relevant, real, or perceived conflict of interest.

Session: Introduction  
Context and Expected Outcomes of the Meeting

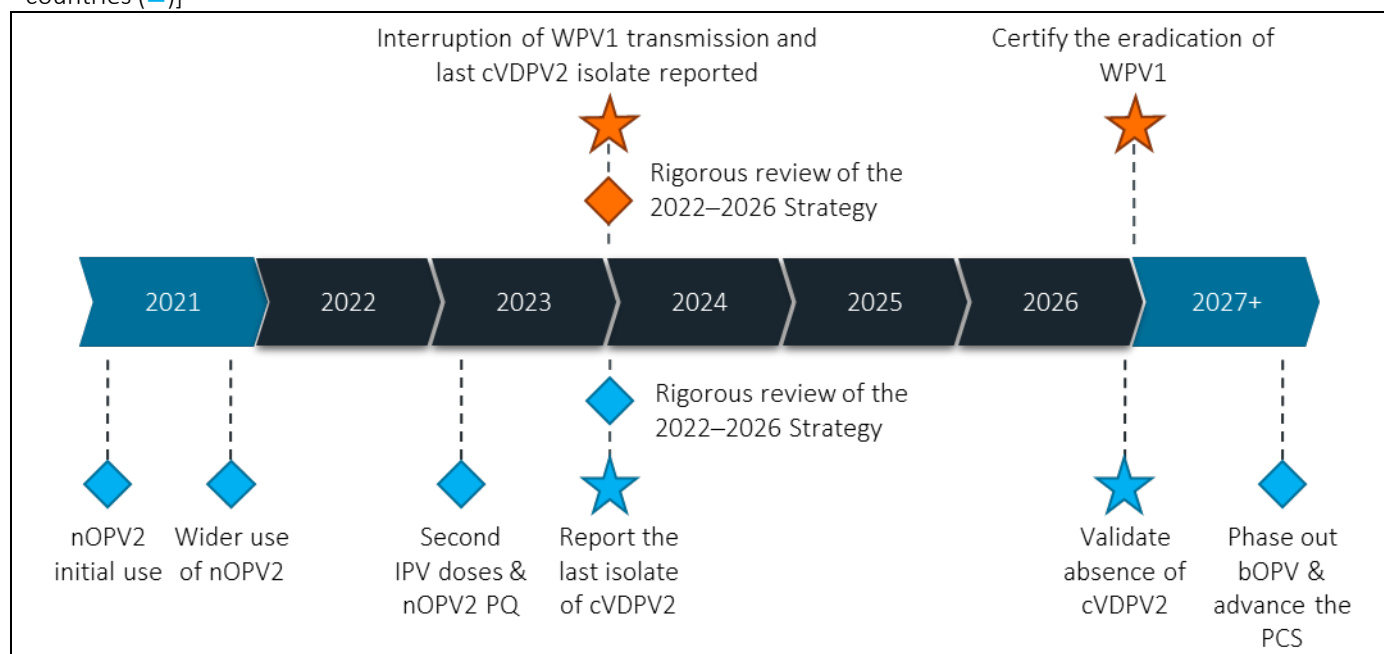
The Polio Eradication Strategy 2022-2026<sup>16</sup> has set vigorous benchmarks and milestones, with end-2023 being the target to permanently interrupt all wild poliovirus serotype 1 (WPV1)- and circulating vaccine-derived poliovirus serotype 2 (cVDPV2)- transmission (Figure 1). An independent in-depth review of the programme is planned for late-2023 and is aimed at assessing whether the programme is on-track to meet Goal 1 (permanently interrupt all poliovirus transmission in endemic countries) and Goal 2 (stop cVDPV transmission

<sup>16</sup> Polio Eradication Strategy 2022-2026: Delivering on a Promise. Available at: <https://polioeradication.org/gpei-strategy-2022-2026/>



and prevent outbreaks in non-endemic countries) of the strategy. Some of the most significant progress in the programme's history was achieved in 2022 despite the detection of emergence in New York and London. This has provided the programme with a unique epidemiological window of opportunity in 2023 to achieve interruption of polio transmission.

Figure 1: Polio Eradication Strategy 2022–2026: Milestones\* for Goal 1 [Permanently interrupt all poliovirus transmission in endemic countries (■)] and Goal 2 [Stop cVDPV transmission and prevent outbreaks in non-endemic countries (■)]



Abbreviations: bOPV: bivalent oral poliomyelitis vaccine (containing serotypes 1 and 3); cVDPV2: circulating vaccine-derived poliovirus serotype 2; IPV: inactivated poliovirus vaccine; nOPV2 = novel oral poliomyelitis vaccine serotype 2; PCS: Post-certification strategy; PQ: prequalification; WPV1: wild poliovirus serotype 1.

\*Source: Polio Eradication Strategy 2022–2026: Delivering on a Promise. Available at: <https://polioeradication.org/gpei-strategy-2022-2026/>

In line with the current eradication strategy<sup>16</sup>, the Global Polio Eradication Program Update Meeting with Chairs of Advisory- and Working- Groups Supporting Polio Eradication and Containment and Representatives of GPEI Global Programme Support Groups, 23 to 24 January 2023 included presentations and discussions on the workstreams undertaken by the different strategic bodies on issues associated with the current trajectory and future direction of the eradication programme, as well as progress and challenges in global poliovirus containment implementation. These included: current epidemiology of poliovirus transmission; global containment progress; global poliomyelitis immunization; work on the review period needed to certify interruption of WPV1 transmission; criteria for validation of cVDPV absence; Poliovirus IHR Emergency Committee criteria for the continued recommendation of a Public Health Emergency International Concern (PHEIC); role and geographical coverage of environmental surveillance; long-term projections for polio vaccine supply; new products in the pipeline for polio vaccine, diagnostics and treatment; novel oral poliomyelitis vaccine containing serotype 2 (nOPV2) programmatic- and long-term nOPV2 genetic stability- update; independent views on eradication and containment; evidence for immunization coverage- and environmental control- safeguard requirements for facilities retaining polioviruses. The CAG6 meeting, 24 to 25 January 2023 included discussions on issues and challenges associated with poliovirus containment implementation. These included: routine environmental surveillance for facilities retaining polioviruses; review of the 'temporary waivers' previously granted by CAG for novel poliovirus strains and their specified uses based on newer data;

containment requirements for potentially infectious materials, polioviruses and related issues; evidence used to determine the appropriate thresholds for effective safeguards aimed at minimizing the risk- and consequences- of a facility-associated release of polioviruses i.e., immunization coverage- and environmental control- safeguards and other issues associated with the 14 biorisk management elements of the WHO Global Action Plan for Poliovirus Containment, 4th edition, 2022 (GAPIV)<sup>17</sup>.

Chairs of WHO Advisory and Working Groups reflections:

#### Meeting structure and organization

1. The organization of a global programme update on eradication or containment with the involvement of the different chairs of advisory-, working- and other- groups supporting polio eradication and containment was a unique opportunity for collaboration between these groups and share progress made, allowing for a better understanding, awareness and alignment of the different workstreams of these groups. CAG recommends such a practice be taken into consideration in the organization of future CAG- or other- meetings, as and when feasible.

#### Session: Update on Polio Eradication and Poliovirus Containment

Current epidemiology of poliovirus transmission and progress with ongoing implementation of the Polio Eradication Strategy 2022 – 2026: Delivering on a Promise

Mr Aidan O'LEARY, Director, Department of Polio Eradication, WHO headquarters in Geneva, SWITZERLAND

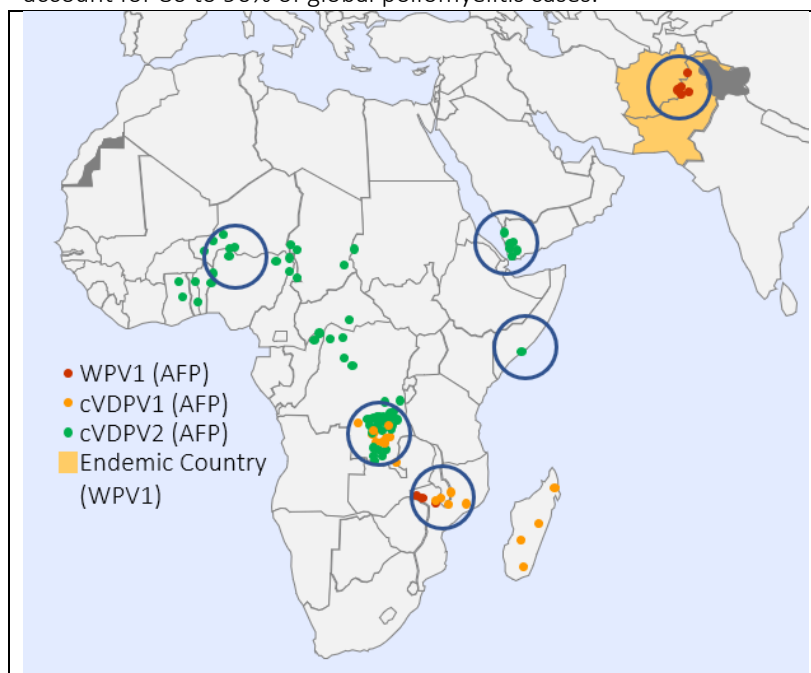
The Polio Eradication Strategy 2022 – 2026: Delivering on a Promise<sup>16</sup> has two goals: to permanently interrupt all poliovirus transmission in endemic countries and to stop all cVDPV transmissions and prevent outbreaks in non-endemic countries. The strategy aims to interrupt WPV1 transmission and report the last cVDPV2 isolate by end-2023, making 2023 a crucial year for the programme, which will be followed by certification of WPV1 eradication and validation of cVDPV2 absence by end-2026 (Figure 1).

The key to success in achieving eradication particularly for 2023 is to reach the remaining 'zero-dose' children (unvaccinated or under-vaccinated children) in seven, subnational 'most consequential geographies' (Figure 2). These areas account for 80% of global poliomyelitis cases, which have the greatest impact on global eradication efforts. These areas are eastern Afghanistan; southern Khyber Pakhtunkhwa, Pakistan; Tete province and its hinterland in northern Mozambique; eastern Democratic Republic of Congo; northern Yemen; northern Nigeria and south-central Somalia. These areas share certain key programmatic characteristics, including some of the highest and most densely populated proportions of zero-dose children, they constitute areas affected by broader humanitarian and complex emergencies, including insecurities. These characteristics create further challenges for vaccination efforts in the most marginalized areas and the outreach of the remaining under-vaccinated communities.

In Pakistan and Afghanistan, WPV1 transmission remains restricted within the country borders to date, with significant reduction in the number of genetic clusters and affected geographic areas in 2022. In Pakistan, interrupting transmission is now confined to six of the 180 districts southern Khyber Pakhtunkhwa, while in Afghanistan, it is constrained to two of the 34 provinces in eastern Afghanistan where WPV1 remains endemic.

<sup>17</sup> WHO Global Action Plan for Poliovirus Containment, 4th edition, 2022. Available at: <https://polioeradication.org/wp-content/uploads/2022/07/WHO-Global-Action-Plan-for-Poliovirus-Containment-GAPIV.pdf>

Figure 2: ‘Most consequential geographies’ (blue circles) currently account for 80 to 90% of global poliomyelitis cases.



Abbreviations: AFP: Acute flaccid paralysis; cVDPV1: circulating vaccine derived poliovirus serotype 1; cVDPV2: circulating vaccine derived poliovirus serotype 2 and WPV1: Wild poliovirus serotype 1.

#### WHO Containment Programme Update

Mr Derek EHRHARDT, Senior Technical Adviser, Containment on behalf of the Poliovirus Containment Team,  
WHO headquarters in Geneva, SWITZERLAND

In line with the commitments made by Member States through resolution WHA 71.16 Poliomyelitis – Containment of Polioviruses<sup>18</sup> to accelerate the implementation of poliovirus containment as described in GAPIV e.g., complete inventories of facilities retaining poliovirus serotype 2, destroy or transfer unneeded poliovirus serotype 2 materials to a poliovirus-essential facility (PEF), begin inventories for facilities retaining poliovirus serotypes 1 and 3 materials and to meet the ultimate milestone that all designated PEFs be certified to be in full compliance with GAPIV compliant by the time of global certification of WPV eradication.

The GPEI Strategy for Global Poliovirus Containment<sup>19</sup> defines high-level containment principles that must be carried forward by all containment stakeholders. It is intended as a further elaboration of the poliovirus containment principles outlined in the GPEI Polio Eradication Strategy 2022–2026<sup>16</sup>. To support GPEI partners and Member States with commitments towards poliovirus containment, the Global Poliovirus Containment Action Plan 2022–2024<sup>20</sup> presents goals and objectives for poliovirus containment as outlined in the Strategy for Global Poliovirus Containment (Table 1).

<sup>18</sup> World Health Assembly (WHA) 71.16 resolution (2018) Poliomyelitis – Containment of Polioviruses . Available at: [https://apps.who.int/gb/ebwha/pdf\\_files/WHA71-REC1/A71\\_2018\\_REC1-en.pdf](https://apps.who.int/gb/ebwha/pdf_files/WHA71-REC1/A71_2018_REC1-en.pdf)

<sup>19</sup> Strategy for Global Poliovirus Containment. Available at: <https://polioeradication.org/wp-content/uploads/2022/07/Strategy-Global-Poliovirus-Containment.pdf>

<sup>20</sup> Global Poliovirus Containment Action Plan 2022 – 2024. Available at: <https://polioeradication.org/wp-content/uploads/2022/07/GPCAP-2022-2024.pdf>

Table 1: Goals, objectives, and country focus for the Strategy for Global Poliovirus Containment

Goals	Objectives	Country Focus
1 Reduce to a minimum the number of facilities retaining poliovirus materials	1A. Establish and maintain inventories for all facilities retaining poliovirus materials – and destroy or transfer unneeded material 1B. Keep the number of poliovirus-essential facilities (PEFs) to a minimum	All countries
2 Ensure retained polio materials are handled according to international standards to maintain appropriate long-term containment	2A. Establish national authorities for containment (NACs) in all countries retaining poliovirus in PEFs. 2B. Achieve certification of all facilities continuing to work with poliovirus materials after WPV eradication, as compliant with global standards	Countries designating PEFs
3 Strengthen and support national and international programmes to ensure sustainability and continuity of poliovirus containment in the post-certification era	3A. Strengthen continued national ownership of polio containment activities and ensure regular review and recertification of all PEFs 3B. Maintain sufficient technical support capacity within the WHO and through external stakeholders for post-certification containment	All countries

Abbreviations: NAC: National authority for containment; PEF: poliovirus-essential facility; WPV: wild poliovirus

The newly revised GAPIV 2022<sup>11</sup>, which came into force on 1 July 2022 following endorsement by the CAG in June 2022, incorporates guidance updated in line with other relevant international standards, aligns facility requirements with available evidence and emphasizes utilizing risk-based approaches for risk control that can be applied across the range of PEFs, which vary by location, size, and purpose. The shift towards a risk- and evidence-based approach does not alter the tolerance for minimal risk of facility-associated release of poliovirus, but instead allows facilities to control their unique risks through mitigations that are locally relevant, proportionate and sustainable.

Much progress has been made with global poliovirus containment implementation through the efforts of Member States and advocacy efforts by the different WHO advisory group and other advocacy efforts by WHO. These efforts include: progress reports to the WHO Governing Bodies, letters from the Director-General, WHO to Member States, country advocacy visits, etc. (Table 2).

Several containment issues are still awaiting resolution: the extensive use of type 2 vaccine to address VDPV outbreaks, incomplete poliovirus serotype 2 inventories in several countries, suboptimal containment certification progress in several countries hosting facilities retaining polioviruses, lack of national legal frameworks to enforce containment requirements, longer-term sustainability of national and global containment oversight in the post-certification era.

Table 2: Current status of global poliovirus containment as per resolution WHA 71.16 (2018) Poliomyelitis – Containment of Polioviruses and other relevant recommendations

Commitments described in resolution WHA 71.16 (2018) Poliomyelitis – Containment of Polioviruses*	Deadline	Status (as of 20 January 2023)
<b>Line of Effort: Inventory and Destruction</b>		
i. Complete PV2 inventories, destroy unneeded PV2	End-2016	Pending: 5 countries
ii. Begin inventories and destruction of PV1 and 3	End-2022	Pending: 28 countries
<b>Line of Effort: Containment</b>		
iii. Reduce to a minimum facilities retaining polioviruses prioritizing those with critical national or international functions	NA	59 facilities in 23 countries (2018: 89 facilities in 26 countries)
iv. Appoint, soonest and no later than end-2018, a competent NAC	End-2018	21 NACs established of 23 countries retaining PV2
v. Designated facilities to engage in CCS through CP applications to NACs, soonest and no later than 31 December 2019	End-2019	Facilities in 14 of 23 countries retaining PV2 granted a GCC-countersigned CP (Remaining nine countries account for 25 facility CP applications)
<b>GCC recommendations†</b>		
vi. Countries with facility ICC applications planned for 2023	End-2021	17 of 22 countries (No response received: 5 countries)
vii. Countries with facility ICC application under CWG review	End-2023	Five facilities in three of 17 countries with facility ICC applications planned for 2023
viii. Countries with facilities granted a GCC-countersigned ICC	NA	One

\*World Health Assembly (WHA) 71.16 resolution (2018) Poliomyelitis – Containment of Polioviruses . Available at: [https://apps.who.int/gb/ebwha/pdf\\_files/WHA71-REC1/A71\\_2018\\_REC1-en.pdf](https://apps.who.int/gb/ebwha/pdf_files/WHA71-REC1/A71_2018_REC1-en.pdf)

†22nd meeting of the Global Commission for the Certification of Eradication of Poliomyelitis, Geneva, Switzerland, 28 - 29 June 2022. Available at: <https://polioeradication.org/wp-content/uploads/2021/09/21st-GCC-report-20210906.pdf> and 21st meeting of the Global Commission for the Certification of Eradication of Poliomyelitis, virtual 28 July 2022. Available at: <https://polioeradication.org/wp-content/uploads/2022/09/22nd-GCC-report-20220907.pdf>

Global immunization update with a focus on poliomyelitis immunization

Mrs Diana CHANG BLANC, Team Lead, Programme Strengthening, Essential Programme on Immunization, Department of Immunization, Vaccines and Biologicals (IVB), WHO

The Immunization Agenda 2030 (IA2030)<sup>21</sup> aims to make vaccination available to everyone, everywhere, by 2030. It sets an ambitious, overarching global vision and strategy for vaccines and immunization for the decade 2021–2030. The success of IA2030 will depend on ensuring partnerships are built within and outside the health sector as part of a coordinated effort towards improving access to high-quality, affordable primary health care, achieve universal health coverage and accelerate progress towards the 2030 Sustainable Development Goals (SDGs).

<sup>21</sup> immunization Agenda 2030: A global strategy to leave no one behind (IA2030). Available at: <https://www.who.int/teams/immunization-vaccines-and-biologicals/strategies/ia2030>

The COVID-19 disease pandemic has caused unprecedented backsliding in immunization. Coverage of the third dose of diphtheria, tetanus, and pertussis vaccine (DTP3) dropped from 83% in 2020 to 81% in 2021 resulting in 25 million children un-or under-vaccinated in 2021, making them vulnerable to vaccine-preventable diseases. The COVID-19 disease pandemic, associated disruptions, and COVID-19 vaccination efforts have strained health systems in 2020 and 2021, resulting in a 6-million increase of “zero-dose” children, those missing out on any vaccination, since 2019 and the highest number since 2008. In comparison, the number of zero-dose children was increased from 13 to 18 million from 2019 to 2021<sup>22</sup>.

In October 2020, the SAGE on immunization recommended a second inactivated poliovirus vaccine (IPV) dose be introduced by all countries that currently administer one IPV dose and bivalent oral poliomyelitis vaccine containing serotypes 1 and 3 (bOPV) in their routine immunization<sup>23,24</sup>. The global introduction of one-dose IPV in 126 OPV-using countries was completed in 2019 with all 194 Member States currently providing at least one-dose IPV with a global IPV1 near parity with DTP3 in 2021<sup>22</sup>. As of January 2023, 143 countries (74%) have 2 or more doses of IPV in their immunization schedules. For the remaining 51 countries (26%) that have one dose only of IPV, the supply of IPV is currently for these countries to implement IPV2 introduction as soon as possible.

#### Session: Collaboration with Other Units Performing Work Associated with Poliovirus Containment

Rationale for local biological risk assessment-based approach in latest WHO manual on biosafety in laboratories

Dr Kazunobu KOJIMA, Medical Officer, Biosafety and Biosecurity, Epidemic and Pandemic Preparedness and Prevention, WHO headquarters in Geneva, SWITZERLAND

The International Health Regulations (IHR 2005)<sup>25</sup> Monitoring and Evaluation Framework (IHRMEF)<sup>26</sup> was developed by WHO to support State Parties’ assessment and obligation under ‘Article 54 of IHR 2005 – Reporting and review’ to the WHA on country implementation of IHR core public health capacities – one of which is the establishment of laboratory capacity. The IHR 2005 State Party Self-Assessment Annual Reporting (SPAR) 2021 tool<sup>27</sup> consists of 35 indicators that cover 15 capacities, of which laboratory capacity (Capacity No 4) involves the establishment of specimen referral and transport system; laboratory biosafety and biosecurity regime (Figure 3); laboratory quality system; laboratory testing capacity modalities and effective national

<sup>22</sup> Progress and Challenges with Achieving Universal Immunization Coverage, 2021 WHO/UNICEF Estimates of National Immunization Coverage (WUENIC) (Estimates as of 15 July 2022). Available at: <https://www.who.int/publications/m/item/progress-and-challenges>

<sup>23</sup> Meeting of the Strategic Advisory Group of Experts on Immunization, October 2020: conclusions and recommendations, Weekly Epidemiological Record, 95 (48): 585 – 607. Available at: <https://www.who.int/publications/i/item/WER9548>

<sup>24</sup> Polio vaccines: WHO position paper – June 2022, Weekly Epidemiological Record, 2022, vol. 97, 25. Available at: <https://www.who.int/publications/i/item/WHO-WER9725-277-300>

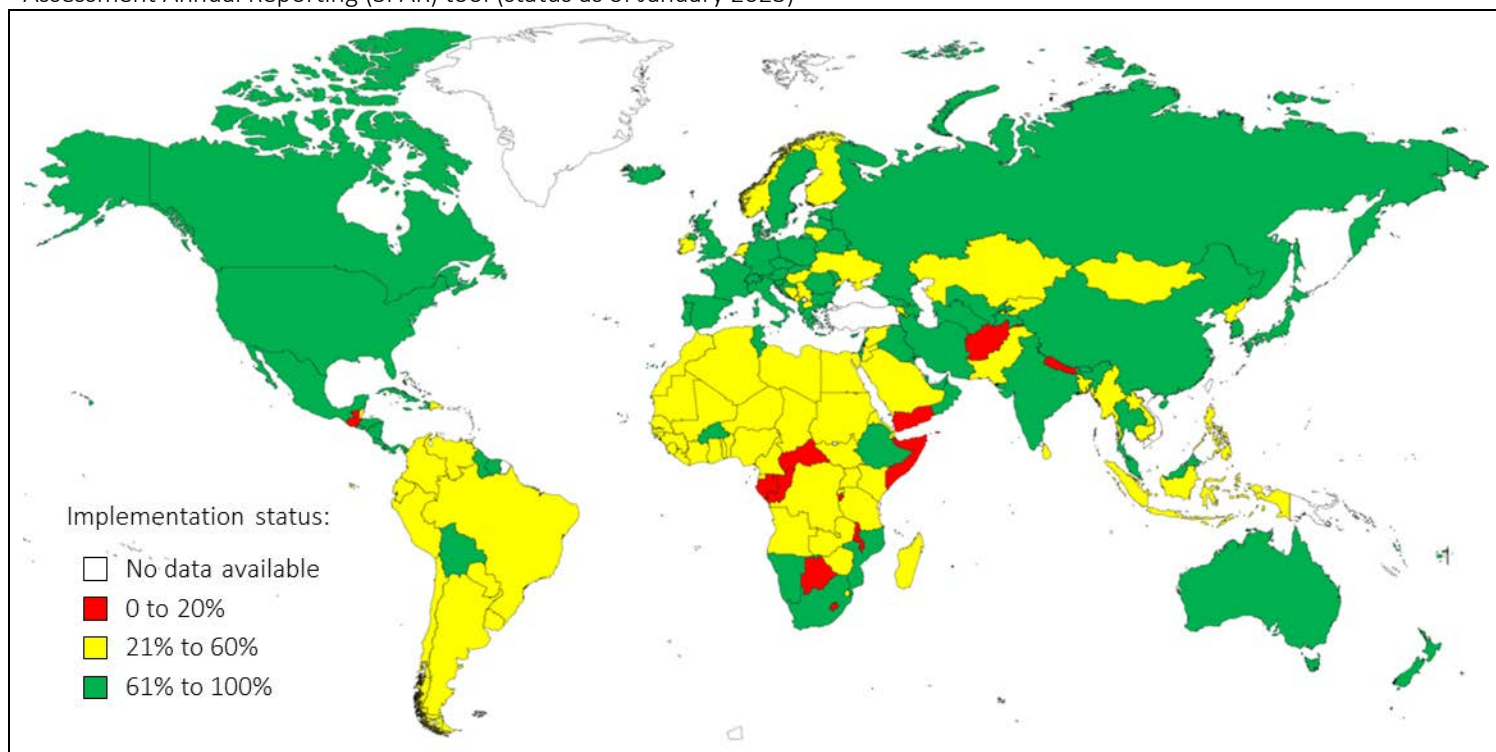
<sup>25</sup> International Health Regulations (2005) (IHR 2005), 3rd edition, 2016. Available at: <https://www.who.int/publications/i/item/9789241580496>

<sup>26</sup> International Health Regulations (IHR 2005) Monitoring and Evaluation Framework (IHRMEF). Available at: <https://www.who.int/emergencies/operations/international-health-regulations-monitoring-evaluation-framework>

<sup>27</sup> International Health Regulations (2005): State Party Self-assessment annual reporting tool, 2nd edition, 2021. Available at: <https://www.who.int/emergencies/operations/international-health-regulations-monitoring-evaluation-framework/states-parties-self-assessment-annual-reporting>

diagnostic network. The IHR 2005 Joint External Evaluation (JEE)<sup>28</sup> tool uses multiple approaches, in addition to self-evaluation to assess country implementation of IHR core public health capacities, consists of 56 indicators that cover 19 technical areas – two of these technical areas are P7 biosafety and biosecurity (Prevent 7) (Figure 4) and D1 national laboratory system (Detect 1). Lower middle- and low- income countries reported a lower baseline measurement for biosafety and biosecurity capacities compared to high-income countries. This may be attributed to the lack of resources allocated to the development of national frameworks for biosafety and biosecurity and its oversight (Figure 3 and Figure 4).

Figure 3: Implementation status of indicator C4.2. Laboratory biosafety and biosecurity regime as reported using State Party Self-Assessment Annual Reporting (SPAR) tool (status as of January 2023)\*



\* International Health Regulations (2005): State Party Self-assessment annual reporting tool, 2nd edition, 2021. Available at: <https://www.who.int/emergencies/operations/international-health-regulations-monitoring-evaluation-framework/states-parties-self-assessment-annual-reporting>

The WHO Laboratory Biosafety Manual, 4th edition, 2020 (LBM4)<sup>29</sup> serves as a de facto global biosafety standard represents best practices, especially where resources are less plentiful and regulatory frameworks are less well developed<sup>30</sup>. With an emphasis on a thorough, evidence- and local risk-based approach, it allows the implementation of biosafety measures that are balanced with the actual risk of working with biological agents on a case-by-case basis. Compared with conventional equation of pathogen risk group and biosafety levels, this approach enables optimized resource use and for sustainable laboratory biosafety and biosecurity

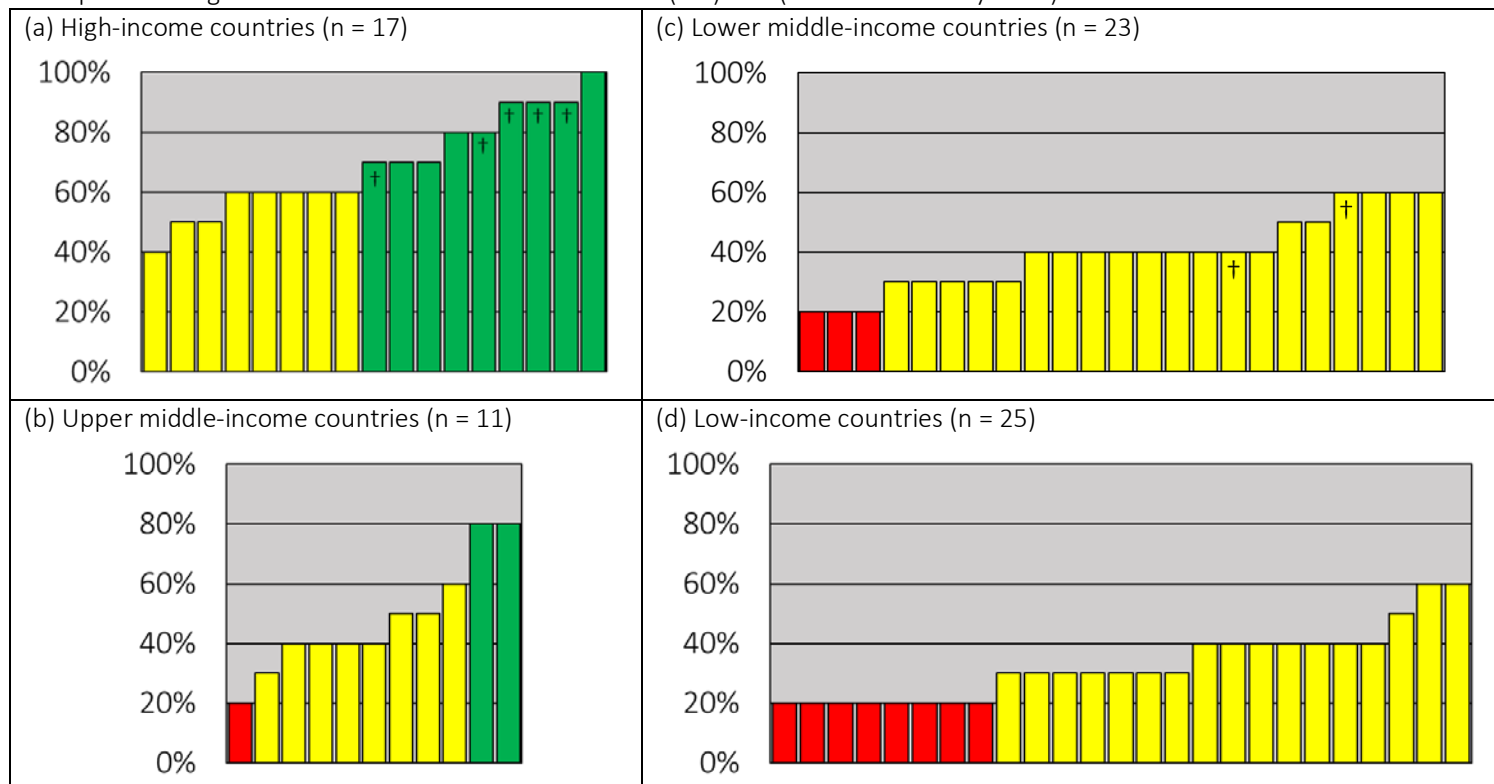
<sup>28</sup> International Health Regulations (2005): Joint External Evaluation (JEE) tool, 3rd edition, 2022. Available at: <https://www.who.int/publications/i/item/9789240051980>

<sup>29</sup> WHO Laboratory Biosafety Manual, 4th edition, 2020 (LBM4) and Associated Monographs. Available at: <https://www.who.int/publications/i/item/9789240011311?sequence=1&isAllowed=y>

<sup>30</sup> Kojima K, Booth CM, Summermatter K, Bennett A, Heisz M, Blacksell SD, McKinney M. Risk-based reboot for global lab biosafety. *Science*. 2018 Apr 20;360(6386):260-262. doi: 10.1126/science.aar2231.

policies and practices to be put in place relevant to facility work, circumstances and priorities without compromising safety of the operators or the neighboring community.

Figure 4: Baseline measurement [implementation status (%): ■ 0 to 20%; ■ 21 to 60% and ■ 61 to 100%] of selected country capacity in technical area P7 (Prevent No 7) biosafety and biosecurity arranged by World Bank income level country classification as reported using the IHR 2005: Joint External Evaluation (JEE) tool (accessed: January 2023)\*,†



\*International Health Regulations (2005): Joint External Evaluation (JEE) tool, 3rd edition, 2022. Available at:

<https://www.who.int/publications/i/item/9789240051980>

†Countries hosting facilities retaining polioviruses post-eradication

The LBM4 suite has one core document that provides general overarching concepts that are essential for understanding the evidence- and risk-based approach and seven subject-specific monographs. One of these, the risk assessment monograph<sup>31</sup> describes the process of carrying out risk assessments of working with biological agents to inform decisions on the risk control measures needed for the work to be conducted safely. The approach and requirements in GAPIV are fully aligned with other relevant global standards, such as the WHO LBM4.

Long-term projections for polio vaccine supply by type of vaccine

Dr. Vachagan HARUTYUNYAN, Team Lead, Detection & Interruption, Polio Eradication, WHO headquarters in Geneva, SWITZERLAND and GPEI Vaccine Supply Group<sup>32</sup>

<sup>31</sup> WHO Laboratory Biosafety Manual, 4th edition, 2020 (LBM4): Risk Assessment. Available at:

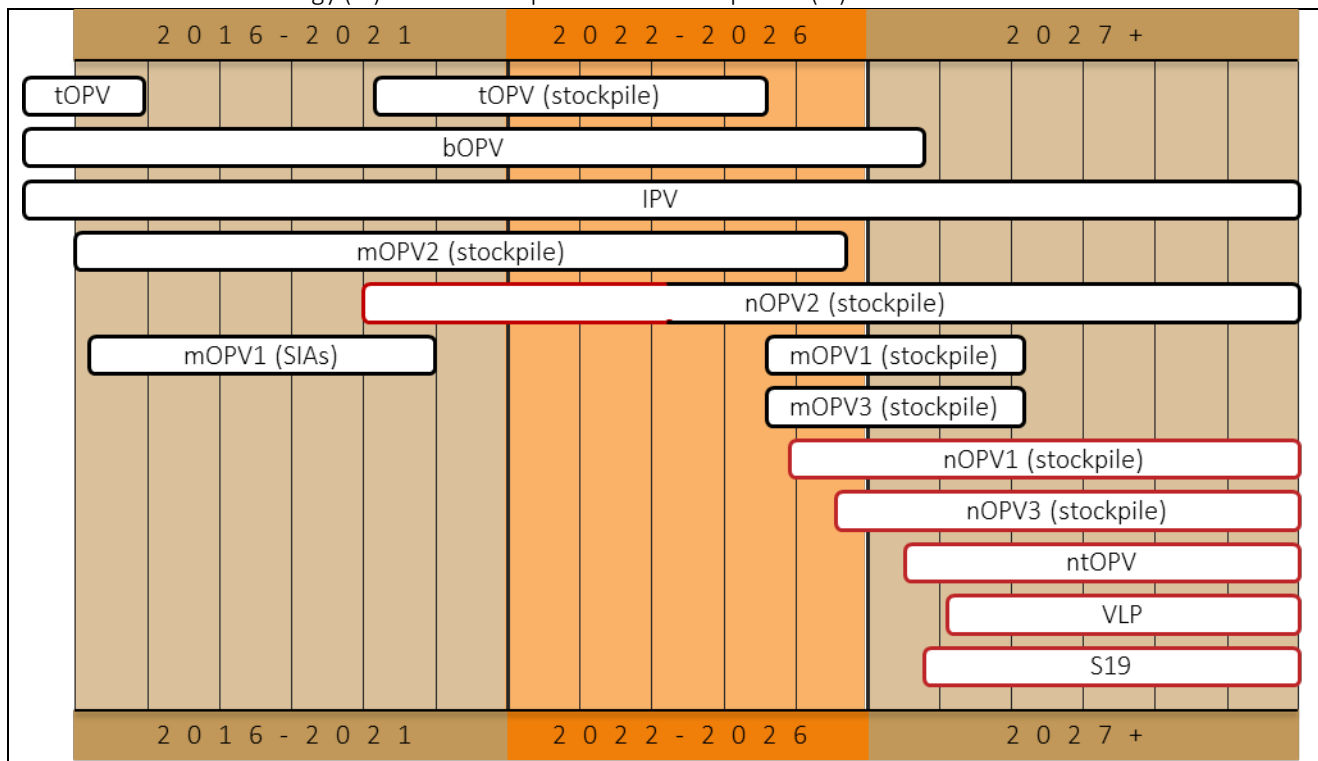
<https://www.who.int/publications/i/item/9789240011458>

<sup>32</sup> With support from Ms Ann E. OTTOSEN, Senior Manager, Vaccine Centre UNICEF Supply Division, Copenhagen, DENMARK and Chair of GPEI Vaccine Supply Group (Virtual participation) and Mr David WOODS,



Polio vaccine supply security is a long-term mechanism to ensure timely, sustained and uninterrupted supply of affordable polio vaccines of assured quality beyond the current eradication strategy<sup>16</sup> (Figure 5). There currently is a healthy IPV market composed of a geographically diverse supplier base many of which are bulk producers. In contrast, the dwindling number of manufacturers for bOPV presents a high risk for supply interruptions as the number of suppliers exiting the market may continue to rise due to volatile demands for bOPV. For serotype 2 containing OPV vaccine stockpile, nOPV2 vaccines are currently experiencing supply interruptions due to production being limited to a single manufacturer and large quantities already deployed in the field. On the other hand, there are huge stockpiles of Sabin monovalent oral poliomyelitis vaccine containing serotype 2 (mOPV2) and trivalent oral poliomyelitis vaccine containing serotypes 1, 2 and 3 (tOPV2), but there is limited or no demand for these vaccines.

Figure 5: Overview of the global status of polio vaccine under development (□) and production (□) during the current eradication strategy (■) and into the post-certification period (■).



Abbreviation: bOPV: Sabin bivalent oral poliomyelitis vaccine containing serotypes 1 and 3; mOPV1, 2 and 3: Sabin monovalent oral poliomyelitis vaccine containing serotypes 1, 2 and 3; nOPV1, 2 and 3: Novel oral poliomyelitis vaccine containing serotypes 1, 2 or 3; ntOPV: trivalent novel oral poliomyelitis vaccine serotypes 1, 2 or 3; S19: S19 with the structural (capsid) protein encoding P1-region (of WPV or Sabin polioviruses; of serotypes 1, 2 or 3); SIA: supplementary immunization activity; tOPV: Sabin trivalent oral poliomyelitis vaccine serotypes 1, 2 and 3 and VLP: Virus-like particle.

There are issues that remain to be addressed. First, there is a need to identify the types and quantities of polio vaccines needed for eradication and to mitigate risks of transmission. Second, a medium- to long-term plan needs to be implemented for the supply of the different types of polio vaccines, where supplies and demands must be maintained in balance, by diversifying supplier base. Third, further research is needed to find the

Technical Officer, Detection and Interruption Unit, Department of Polio Eradication, WHO headquarters in Geneva, SWITZERLAND and GPEI Vaccine Supply Group.

safest and most cost-effective technologies for polio vaccine production. Fourth, identify the optimal number and distribution of polio vaccine manufacturers that allow balance between polio vaccine security and containment. Finally, to identify safe and cost-effective polio vaccine distribution and delivery.

Three areas of collaboration are identified between polio vaccine supply, polio research and poliovirus containment. These include the design and the implementation of: GAPIV, polio vaccine supply strategy and plan for the periods pre- and post-certification and research into polio vaccines and their distribution and delivery.

Chairs of WHO Advisory and Working Groups reflections:

#### Collaboration with other units performing work associated with poliovirus containment

2. The alignment of the WHO Global Action Plan for Poliovirus Containment, 4th ed., 2022 (GAPIV) with the WHO Laboratory Biosafety Manual 4th ed., 2020 (LBM4) is important to ensure maximum protection of operators against the exposure to polioviruses due to the handling of infectious- and potentially infectious materials, polioviruses in facilities. CAG recommends that the WHO Containment (CNT) programme and the WHO Biosecurity and Health Security Protection (BSP) programme urgently strengthen links in the implementation of a unified and sustainable biosafety programme management<sup>33</sup> and biosecurity policies and practices.
3. The WHO prequalification programme for polio vaccines should include compliance verification of polio vaccine manufacturer against the containment requirements as described GAPIV in addition to assessment of vaccine quality, safety, efficacy data or relevant activities as an essential component in the prequalification of polio vaccines. CAG recommends continued dialogue between the WHO Containment (CNT) programme, WHO vaccines prequalification (PQT) programme and the Norms and Standards for Biological Products (NSB) unit to ensure that this urgently addressed and resolved by WHO.

Session: Collaboration between advisory groups supporting eradication and containment

#### Independent views on polio eradication and containment

Professor Sir Liam DONALDSON, Chair of Independent Monitoring Board (IMB) for Polio Eradication and Chair of Polio Transition Independent Monitoring Board (TIMB)<sup>34</sup>

The number of paralytic poliomyelitis cases and WPV cases have been significantly reduced since 2010, but a resurgence was observed 2019 to 2022 (Figure 6), particularly in Afghanistan and Pakistan. Several factors, including political unrest, violence, gender issues, socioeconomic disruptions and cultural barriers were among the key barriers that impede the progress of achieving polio eradication in the remaining endemic areas. It is

<sup>33</sup> LBM4 defines biosafety programme management as the development, implementation and oversight of biosafety at the organizational level using a variety of information that includes institutional policies, guidance documents for practices and procedures, planning documents (training, recruitment, emergency/incident response) and record keeping (personnel, inventories, incident management). WHO Laboratory biosafety manual, 4th edition, 2020. Available at: <https://www.who.int/publications/i/item/9789240011311>

<sup>34</sup> With support from Ms Katherine HAYES, Secretariat- of Independent Monitoring Board (IMB) for Polio Eradication and Polio Transition Independent Monitoring Board (TIMB).

thus clear that polio eradication cannot be achieved by a technical process alone, and that it should always be considered an apolitical humanitarian endeavour.

At the time of the launch of the current eradication strategy<sup>16</sup>, a commitment was made for the rigorous review of implementation of the strategy in 2023. This review will be conducted by the IMB for Polio Eradication, an independent group of public health experts established at the request of the WHA in 2010, to monitor and independently verify progress towards the achievement of polio eradication.

The IMB has a long history in evaluating the GPEI cross-cutting work and recommending measures to help strengthen strategic approaches. Its long-standing and independent input and analyses has over the years significantly contributed to sensitizing strategic approaches. The independent review is being planned specifically to: evaluate progress towards Goals 1 and 2 of the Polio Eradication Strategy 2022-2026; assess whether the strategic plan is on track, at risk, off track or missed; and to identify areas where corrective action plans are required and evaluate the quality, implementation and impact of corrective action plans.

The IMB for Polio Eradication has set out eight principles of eradication and these include: unambiguous country ownership; political commitment, consensus and alignment; technical excellence in programme, planning, organization and delivery; supportive communities; good levels of essential immunization coverage; capability to get to ‘hard to reach’ populations and sanitary environments. Since its establishment, the IMB for Polio Eradication has added value to the programme in numerous ways over the years, such as pushing the technical aspects of the programme to consider human factors; country- and programme- accountability by having their leaders attend IMB meetings to publicly account for performance; relentless focus on critical success factors and intractable problems affecting the programme; confronting leadership denial; encouraging “out of the box” thinking; emphasizing the reason for its recommendation rather than just the recommendation content, etc.

#### Role and geographical coverage of environmental surveillance

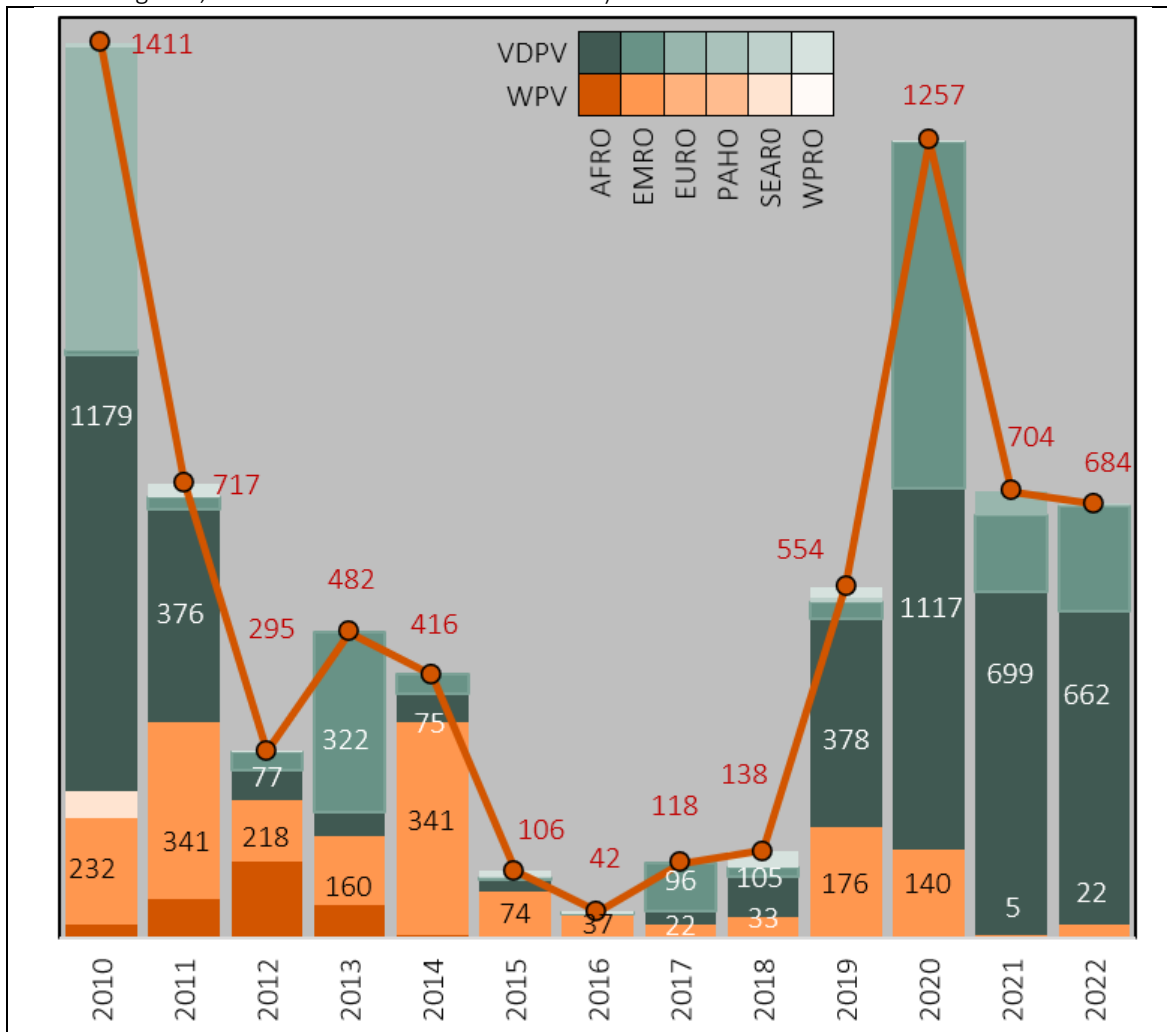
Dr Graham TALLIS, Senior Scientific Adviser, Detection & Interruption, Polio Eradication, WHO headquarters in Geneva, SWITZERLAND; Co-Chair, GPEI Surveillance Group and Secretariat- of GCC and Poliovirus IHR Emergency Committee

Recognizing poliovirus surveillance as one of the key pillars of the eradication effort, the Global Polio Surveillance Action Plan (GPSAP) 2022–2024<sup>35</sup> was developed to be aligned with the surveillance component of the current eradication strategy<sup>16</sup>. It includes ‘optimization of the environmental surveillance network for timely detection of polioviruses’ as one of its six objectives (objective 2). Although global in nature due to its alignment with the current eradication goals, the implementation of GPSAP 2022 – 2024 is focused on priority countries - those identified as very high-, high-, and medium-high-risks to the programme due to persistent gaps in surveillance and vulnerability to poliovirus transmission (Figure 7).

---

<sup>35</sup> Global Polio Surveillance Action Plan 2022-2024. Available at: <https://polioeradication.org/wp-content/uploads/2022/05/GPSAP-2022-2024-EN.pdf>

Figure 6: Total number of paralytic poliomyelitis cases (red text) represented by WPV cases (by WHO regions in shades of orange, number indicates total WPV cases) and VDPV cases (by WHO regions in shades of green, number indicates total VDPV cases) from 2010 to 2022.

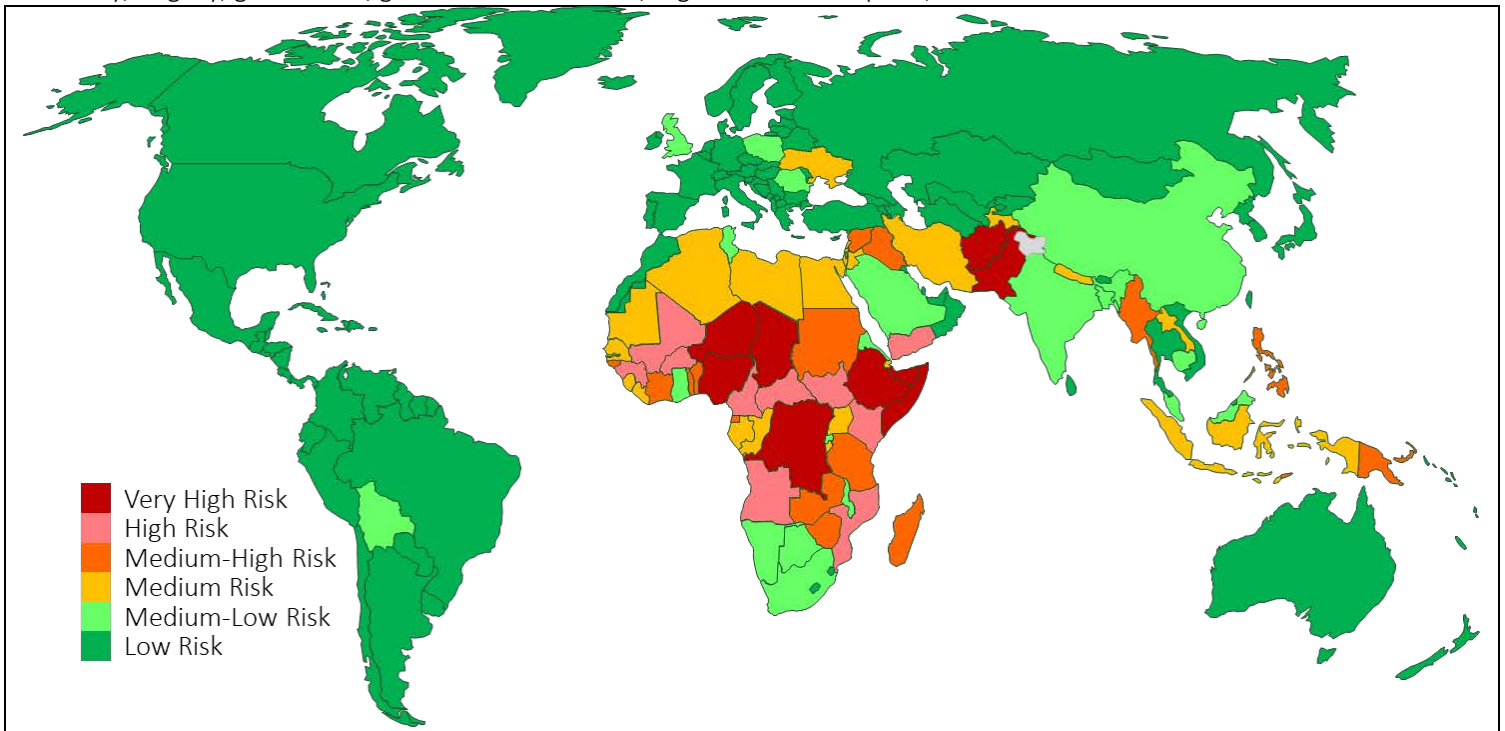


Abbreviation: AFRO: WHO African Region; EMRO: WHO Eastern Mediterranean Region; EURO: WHO European Region; PAHO: WHO Regions of the Americas; SEARO: WHO South East Asia Region; VDPV: Vaccine-derived poliovirus; WPRO: WHO Western Pacific Region and WPV: wild poliovirus.

The achievement of the goals of the current eradication strategy<sup>16</sup> requires continued improvements of surveillance quality and timeliness of detection. To do so, it relies on three types of surveillance systems to detect poliovirus: acute flaccid paralysis (AFP) surveillance (primary approach), environmental surveillance (supplementary) and surveillance among individuals with primary immunodeficiency disorders (PIDs), referred to as immunodeficiency-associated vaccine-derived poliovirus (iVDPV) surveillance. Five major activities are associated with objective 2 (optimize the environmental surveillance network to contribute to the timely detection of polioviruses) of the GPSAP 2022 – 2024: 1) improve and maintain the quality of environmental sites; 2) improve the timeliness of environmental sample collection and shipment; 3) expand and optimize environmental surveillance in high-risk, geographically diverse areas; 4) facilitate a skilled workforce and 5) promote integration and expand the use of electronic data collection tools.

Well-implemented environmental surveillance can significantly increase the sensitivity of the poliovirus surveillance system. Environmental surveillance has been used for many years to detect and monitor the reintroduction of WPV into polio-free countries and provide confidence in the successful elimination of WPV in previously endemic countries. In fact, environmental surveillance has repeatedly detected transmission in areas undetected by AFP surveillance in the past, highlighting its value as a supplement to AFP surveillance. Since 2016, progress has been made in expanding the global environmental surveillance network, with the GPEI now supporting over 500 sites (Figure 8).

Figure 7: Countries-level risk assessment (as of December 2022). Priority countries are identified by risk assessments based on several factors such as WHO regional prioritization; programme factors e.g., outbreak status and surveillance performance; polio-specific risks e.g., WPV/cVDPV risk, population immunity; country variables e.g., health security, human resources, health system, economy, fragility, governance; global risk assessments; regional transition plans, etc.\*

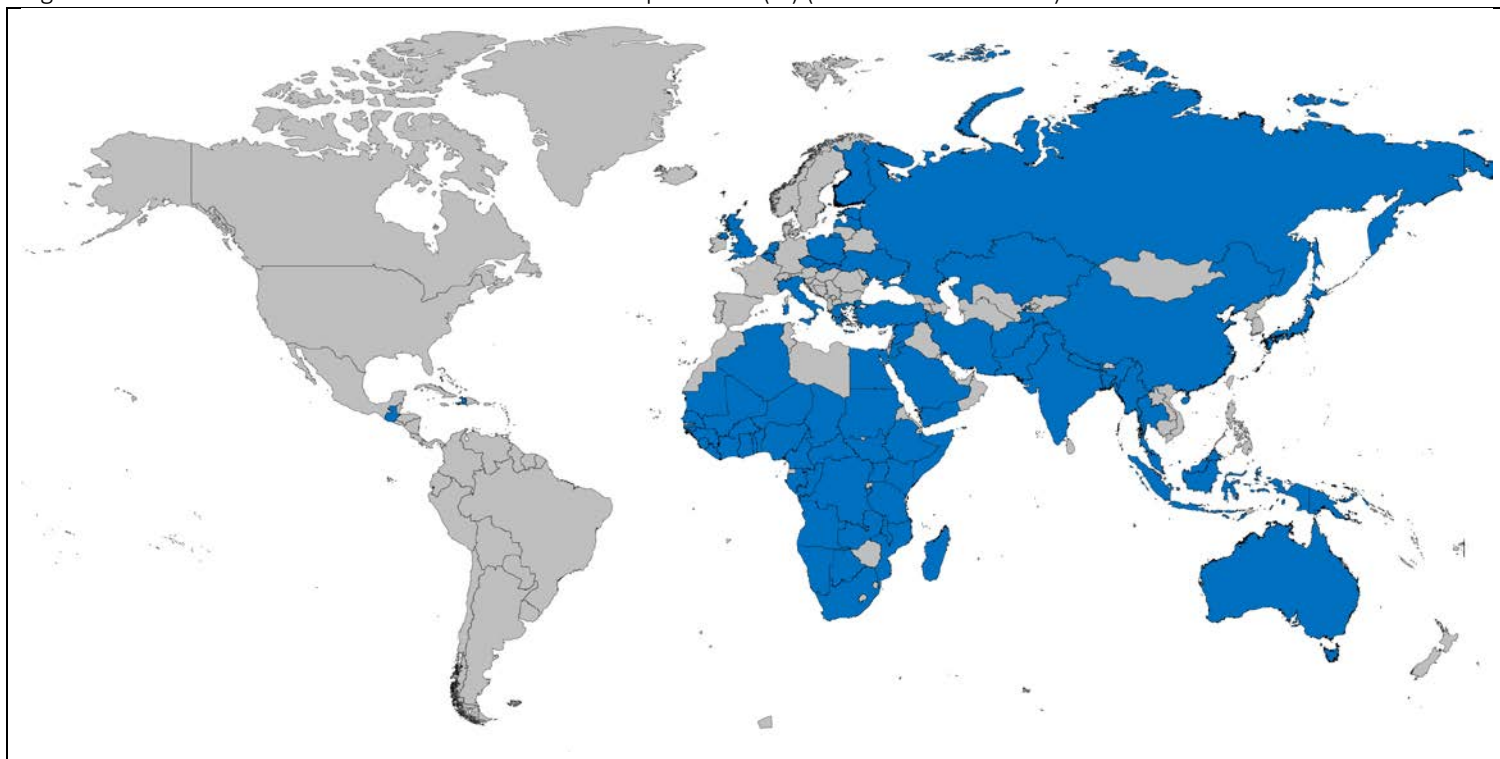


Abbreviations: cVDPV: circulating vaccine-derived poliovirus and WPV: Wild poliovirus.

\*Country prioritization is adjusted biannually to take into account new events or outbreaks with detailed review of data-driven country risk assessments and classification performed annually.

Long-used to monitor the presence of enteric viruses, in particular polioviruses, recent successes of the use of wastewater to monitor SARS-CoV-2 levels allowing the forecasting of disease trends to aid preparedness and response, has regenerated interest in wastewater-based epidemiology (WBE) to extend the same approach to other human pathogens, such as adenoviruses, enteroviruses, noroviruses, rotavirus, hepatitis viruses, mpox virus, etc. However, the hallmark principle of WBE is to translate the upstream detection of the target product e.g., pathogen, substance, etc., into useful public health outcomes, such as monitoring disease prevalence and trends especially those of epidemic- and pandemic-potential; early warning system; pathogens' genetic diversity and evolution and as evidence of the impact of public health interventions, etc.

Figure 8: Countries with environmental surveillance for poliovirus (■) (as of December 2022)



Criteria used by the Poliovirus IHR Emergency Committee for continued recommendation of a Public Health Emergency International Concern (PHEIC)

Professor Helen REES, Chair of the Poliovirus IHR Emergency Committee

The IHR Emergency Committee concerning ongoing events and context involving transmission and international spread of poliovirus convened by the Director-General of WHO held its first meeting in April 2014. On 5 May 2014, on the advice of the Committee, the Director-General of WHO declared the international spread of WPV a Public Health Emergency of International Concern (PHEIC)<sup>36</sup> and issued corresponding temporary recommendations<sup>37</sup>. Under IHR (2005), Temporary recommendations automatically expire three months after their issuance and as such, the Committee has continued to reconvene at least every three months to assess the ongoing epidemiological situation, to review if the event continues to be a PHEIC and to determine if changes need to be made to the temporary recommendations<sup>38</sup>.

In May 2014, temporary recommendations issued to the ten State Parties with active transmission of WPV ('infected countries') based on risk stratification (State Parties currently exporting WPV and State Parties infected with WPV but not currently exporting) were: officially declare the interruption of poliovirus transmission as a national public health emergency; ensure polio vaccination of all long-term visitors (> 4

<sup>36</sup> A 'Public health emergency of international concern (PHEIC)' is an extraordinary event which is determined, as provided under IHR (2005) (i) to constitute a public health risk to other States through the international spread of disease and (ii) to potentially require a coordinated international response.

<sup>37</sup> 'Temporary recommendations' are non-binding advice issued by WHO pursuant to Article 15 of IHR 2005 for application on a time-limited, risk-specific basis, in response to a PHEIC, so as to prevent or reduce the international spread of disease and minimize interference with international traffic.

<sup>38</sup> Statements of the Poliovirus IHR Emergency Committee. Available at:

<https://www.who.int/groups/poliovirus-ih-er-emergency-committee>

weeks) in infected countries prior to international travel and departing travellers from exporting countries; and to provide all international travellers with an International Certificate for Vaccination and Prophylaxis (ICVP) for recording- and proof- of polio vaccination. Although international spread of cVDPV was uncommon at that time, Temporary recommendations for cVDPV which were the same as those for WPV1 were added in November 2015 as there was concern that the risk would increase following the 'tOPV (containing serotypes 1, 2 and 3) to bOPV (containing serotypes 1 and 3) switch' in April 2016. Following the 'switch', Temporary recommendations were updated for WPV1, cVDPV1 and cVDPV3 countries to ensure vaccination with bOPV to those relevant and encourage use of IPV for cVDPV2, wherever relevant (Table 3).

Table 3: Poliovirus types and serotypes that shall be notified to WHO under IHR (2005)

Events detected by national surveillance system*	Assessment*	Notification*
Laboratory confirmed case of poliomyelitis due to WPV serotypes 1, 2 and 3	Unusual or unexpected events that may have serious public health impact	
Isolation of WPV serotypes 1, 2 and 3 or VDPV serotypes 1, 2 and 3 from other human or non-human sources (from persons without paralysis, or from environmental samples)	Events which may constitute a PHEIC	Notify WHO via IHR national focal point
Isolation of serotype 2 Sabin and Sabin-like viruses from any source including human or non-human sources.		

\* Annex 2: Decision instrument for the assessment and notification of events that may constitute a public health emergency of international concern of the International Health Regulations (IHR), 2005. 3rd Edition. Available at: <https://apps.who.int/iris/rest/bitstreams/1031116/retrieve>

† Case definitions for the four diseases requiring notification in all circumstances under the International Health Regulations (2005). Available at: [https://www.who.int/ihr/Case\\_Definitions.pdf?ua=1](https://www.who.int/ihr/Case_Definitions.pdf?ua=1)

A study modeling the costs and benefits of temporary recommendations for poliovirus exporting countries found that the benefits of temporary recommendations outweighed the costs in 77% of models used, resulting in expected incremental net economic benefits of USD 210 million. Despite the considerable costs of implementing temporary recommendations, the study provided health and economic justifications for such investments, in the context of managing a disease in advanced stages of global eradication<sup>39</sup>.

The evolving epidemiological situation has created a lengthy polio PHEIC with temporary recommendations going far beyond the duration provisioned by IHR (2005)<sup>40</sup>. Although these extended temporary recommendations were supported by Member States through WHA resolutions, alternatives should be explored. For instance, the Poliovirus IHR Review Committee's standing recommendations strongly advise that sustained efforts are needed at this critical phase of the polio eradication program, and the grading of health emergencies under WHO emergency framework can ensure extended operational support required to address programmatic gaps.

<sup>39</sup> Duintjer Tebbens RJ, Thompson KM. Modeling the costs and benefits of temporary recommendations for poliovirus exporting countries to vaccinate international travelers. *Vaccine*. 2017 Jul 5;35(31):3823-3833. doi: 10.1016/j.vaccine.2017.05.090.

<sup>40</sup> Article 15 Temporary recommendations of the International Health Regulations (IHR) 2005: Temporary recommendations may not continue beyond the second World Health Assembly after the determination of the public health emergency of international concern to which they relate

Outcome from review of the period needed to certify the interruption of WPV1 transmission and criteria for the validation of the absence of cVDPV

Professor David SALISBURY, Chair, Global Commission for the Certification of the Eradication of Poliomyelitis (GCC)

Since 2018, the criteria used for the certification of polio eradication include: no WPV transmission detected from any population source for the previous three years with an adequate global poliovirus surveillance and safe and secure containment of WPV retained in facilities<sup>41</sup>.

The three-year period was selected based on experience with certification of smallpox eradication, which was 2 years – an additional year was added for non-paralytic polio infections. This period was also based on the experience of the WHO Region of the Americas which was the first Region to undertake certification of interruption of transmission. While there was little scientific basis for the three-year period, post-hoc modelling analysis shows this period to be likely correct.

A process to review the three-year period of non-detection was initiated in 2021, following recommendations from the 21st Meeting of the GCC, which continued into 2022<sup>42</sup>. An Expert Working Group was appointed to review the period needed to certify the interruption of transmission of WPV1 (maintain the current criteria or alter the existing certification criteria to remove a fixed three-year period of non-detection of WPV), as well as to review and propose criteria for the validation of absence of cVDPV. Several modelling studies were also commissioned to support the work of the Expert Working Group. One study showed that depending on the amount of poliovirus excreted into the sewage system and the quality of sampling sites, good quality environmental surveillance used in addition to a good quality Acute Flaccid Paralysis (AFP) surveillance could reduce the time to reach high confidence by about 16 months, compared to perfect AFP surveillance alone, and by up to 36 months compared to the worst performing AFP system (Figure 9)<sup>43,44</sup>.

Modelling supported the idea that the ‘three-year rule’ was not absolute, and shorter periods could be justified, noting that this was highly dependent on the quality of surveillance. Surveillance has changed since the first WHO Region was certified, especially with the widespread use of environmental surveillance. The modelling review pertained to the Afghanistan and Pakistan epidemiological situation and did not apply to the risk of missed importation and transmission elsewhere, which consequently did not consider the recent southern Africa cases. In hindsight, the certification of five WHO Regions in the past was correctly done, and much experience in certification has thus been gained.

---

<sup>41</sup> Safe and secure containment of WPV retained in facilities is defined as all facilities retaining WPV should have a Containment Certificate, or an Interim Containment Certificate. In addition, at the time of global WPV certification, the GCC will consider the status of biorisk management of facilities retaining potentially infectious materials, poliovirus and facility readiness to respond to containment breaches.

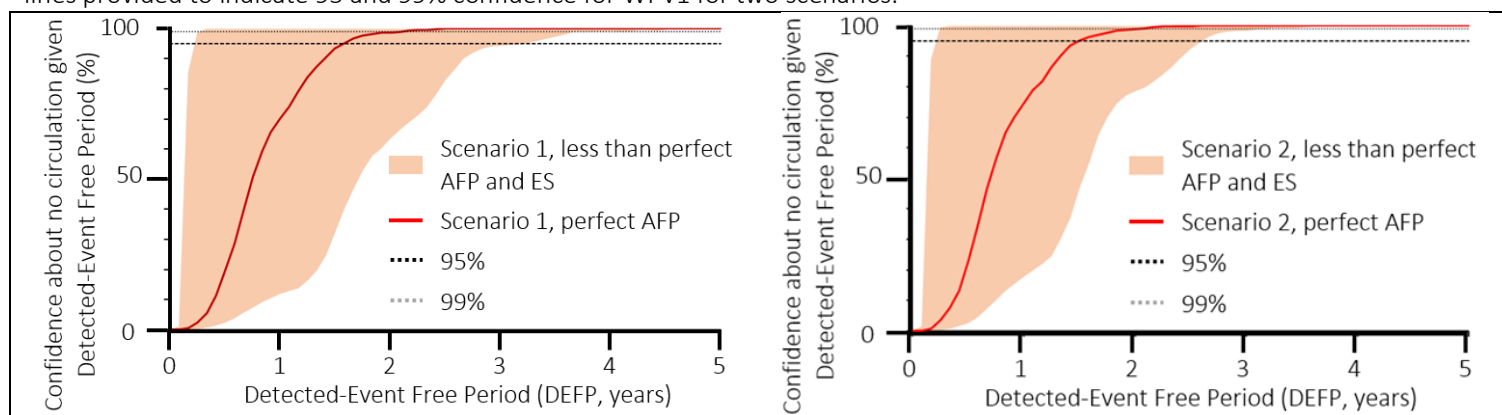
<sup>42</sup> Reports of the Meetings of the Global Commission for the Certification of Eradication of Poliomyelitis (GCC). Available at: <https://polioeradication.org/tools-and-library/policy-reports/certification-reports/global-certification-commission/>

<sup>43</sup> Kalkowska, D. A., Badizadegan, K., & Thompson, K. M. (2022). Modeling undetected live type 1 wild poliovirus circulation after apparent interruption of transmission: Pakistan and Afghanistan. *Risk Analysis*, 1–9. <https://doi.org/10.1111/risa.13982>

<sup>44</sup> Kalkowska, D. A., Badizadegan, K., & Thompson, K. M. (2022). Modeling scenarios for ending poliovirus transmission in Pakistan and Afghanistan. *Risk Analysis*, 1–17. <https://doi.org/10.1111/risa.13983>



Figure 9: Confidence about no circulation in Pakistan and Afghanistan as a function of the detected event-free period (DEFP) assuming a range of less than perfect AFP surveillance and a range of ES, with perfect AFP surveillance without ES, and reference lines provided to indicate 95 and 99% confidence for WPV1 for two scenarios.



Abbreviations: AFP: Acute Flaccid Paralysis and ES: Environmental Surveillance.

The Expert Working Group recommended that the retrospective application of a three-year non-detection period be replaced by a flexible interactive prospective review of the surveillance quality at around six-month intervals, until the non-detection indicates a high confidence level of WPV1 transmission cessation in Afghanistan and Pakistan. The recommendation was accepted and endorsed by the GCC.

Regarding the review of and proposal of validation criteria for the absence of cVDPV, early consideration from the Expert Working Group indicate the possibility to certify the eradication of cVDPV based on the following reasons: while number of cVDPV cases remains high, a decrease in outbreaks were observed (44 new emergences in 2019 with a steady decrease of new VDPV2 emergences since 2019, with only five reported in 2022); increase availability and use of nOPV2 is encouraging in stopping outbreaks without seeding further outbreaks; nOPV1, nOPV2 and nOPV3 will provide tools for wider use to halt cVDPV outbreaks; encouraging progress in development of antivirals and long-acting monoclonal antibodies to treat chronic excretors (essential for reducing risks from iVDPV provided such individuals can be identified); development of virus-like particles (VLP) offers the possibilities to avoid the use of live poliovirus for IPV production, which carries implications for risk reduction from containment breaches, etc. The Expert Working Group is expected to reconvene in February 2023 for further work.

Chairs of WHO Advisory and Working Groups reflections:

#### Collaboration between advisory groups supporting eradication and containment

4. CAG request for representation at meetings of the SAGE working group on polio when agenda items include polio immunization policies in order to ensure feasibility of such policies (schedule, coverage, geographical extent of coverage) with the immunization coverage safeguard requirement in GAPIV for facilities retaining polioviruses post-eradication.
5. There is a need to strengthen collaboration by establishing linkage between CAG and the GCC e.g., for CAG to provide inputs to GCC on the assessment of containment considerations consideration

e.g., facility biorisk management of potentially infectious materials, polioviruses<sup>45</sup> at the time of certification of WPV eradication and validation of absence of cVDPV.

6. Closer collaboration through consultations or similar is needed between CAG and the different groups such as the Polio Research Committee (PRC), GPEI nOPV working group and other groups involved in work related to poliovirus research to facilitate alignment of the poliovirus containment requirements with the implementation of poliovirus research studies.

#### Session: Polio research and commodities

##### New products in pipeline for polio vaccine, diagnostics and treatment

Dr Martin EISENHAWER, Scientist, Research and Development, Department of Polio Eradication,  
WHO headquarters in Geneva, SWITZERLAND

Current polio products, such as IPV and OPV have many strengths: they are safe, effective, have a secure supply, licensed and are WHO prequalified. However, unlike OPV, IPV does not induce mucosal immunity. Further, the production of IPV and OPV require the use of live polioviruses; production facilities must therefore implement containment requirements as described in GAPIV. There is still treatment for immunocompromised individuals who shed polioviruses for extended periods of time (known as chronic excretors), who are consequently the reservoir of the virus in the post-certification and post-OPV cessation period.

As such, several new products are under development as potential alternatives to current polio vaccine (OPV, Salk- and Sabin-IPV) as they do not require the use of live polioviruses, and research into antiviral treatment for chronic excretors (Table 4).

The Polio Antivirals Initiative founded in 2016 aimed to develop a safe and effective antiviral treatment as the only approach to stop iVDPV excretion in immunodeficient individuals, particularly the development of two antiviral agents with independent, direct mechanisms of action, to maximize antiviral activity and reduce potential for drug resistance. These are:

- a) Pocapavir, a viral capsid inhibitor that has been shown to stop excretion in mOPV challenge study recipients [iVDPV and non-polio enterovirus infections (NPEV)], although drug resistance has been observed.
- b) V-7404, an irreversible viral protease inhibitor that has synergistic antiviral activity with pocapavir (*in-vitro*) and reduces potential for resistance by > 4 logs (*in-vitro*).

The polio monoclonal antibody projects aim to develop an antibody therapeutic modality for the peri- and post-bOPV cessation period, with the ability to clear cVDPV including iVDPV from chronically shedding immunocompromised patients, thereby reducing the risk for VDPV outbreaks. This initiative also aims to partner with other relevant projects and stakeholders, to develop an infrastructure that allows the

---

<sup>45</sup> GCC Recommendation (Containment) 4.1.1. Certification of WPV eradication should only occur when all WPV materials, in facilities designated for retaining them, are safely and securely contained<sup>5</sup>

<sup>5</sup> All facilities retaining WPVs should have a Containment Certificate, or a time-limited Interim Containment Certificate, with a clear end point for obtaining a CC agreed with the GCC. In addition, at the time of global WPV certification, the GCC will consider the status of biorisk management of potentially infectious materials and readiness plan to respond to containment breaches.

Source: Report from the Seventeenth Meeting of the GCC, Geneva, Switzerland, 26-27 February 2018.

Available at: <https://polioeradication.org/wp-content/uploads/2018/04/polio-eradication-certification-17th-meeting-global-commission-for-certification-of-poliomyelitis-eradication-20180412.pdf>

identification and treatment of chronic VDPV shedders. Human monoclonal antibody 9H2 (huMAb 9H2) shows high neutralizing antibody titers against all three poliovirus serotypes, studies are currently under way to improve antibody half-life. This will be followed by Good Manufacturing Practices (GMP) batch production. Clinical and regulatory plans are in preparation with the first in-human trials planned for early 2024.

Table 4: New polio products and commodities in the development pipeline

Vaccines	
nOPV2	Potential replacement for mOPV2 used for cVDPV2 response, production temporarily waived from containment requirements of GAPIV
nOPV1 and nOPV3	Potential replacement for mOPV1 and mOPV3 used for cVDPV1 and cVDPV3 response, production temporarily waived from containment requirements of GAPIV
Virus-Like Particles	Potential replacement for IPV, IPV production from such strains does not require containment
Sabin IPV	Address IPV supply constraints
S19 – poliovirus	Potential replacement for IPV, IPV production from S19 poliovirus strains temporarily waived from containment requirements of GAPIV
Monoclonal Antibodies	
9H2 huMAb	Potential to clear cVDPV including iVDPV from chronically-shedding immunocompromised patients
Antivirals	
Pocapavir	Potential to clear iVDPV from chronically-shedding immunocompromised patients
V-7404	Potential to clear iVDPV from chronically-shedding immunocompromised patients

Abbreviations: 9H2 huMAb: human monoclonal antibody 9H2; cVDPV: circulating vaccine-derived poliovirus; IPV: inactivated poliovirus vaccine; iVDPV: Immunodeficiency-associated vaccine-derived poliovirus; OPV1, 2, 3: Oral poliomyelitis vaccine containing serotypes 1, 2 or 3; S19: S19 with the structural (capsid) protein encoding P1-region (of WPV or Sabin polioviruses; serotypes 1, 2 or 3) and V-7404: direct-acting antiviral agent that irreversibly binds the Enterovirus 3C protease active site, making it a promising treatment for immunodeficient people excreting VDPV.

With poliovirus being largely eradicated, containment concerns associated with polio vaccine production, for both inactivated and live-attenuated, has triggered research and development for alternative, safer vaccine platforms. A research consortium established by the WHO in 2011 and led by the University of Leeds has been researching and developing a novel polio vaccine using a VLP platform, utilizing yeast, the microorganism *Pichia pastoris*, as an expression platform expression system with baculovirus as back-up. The VLP vaccine platform eliminates the need for containment, as it does not use live polioviruses, nor does it contain any genetic material. Polio recombinant stable VLP (rsVLP) contains the capsid proteins ('coat') that mimics the structure of poliovirus and can induce an immune response. The stability and immunogenicity in transgenic mice of rsVLP show similar or superior effects compared with IPV. While the immunogenicity of rsVLP in rats is similar or inferior to IPV, the addition of an aluminum adjuvant causes its immunogenicity to be similar or superior to IPV. The overall goal of the polio VLP is to replace the use of live polioviruses in IPV production post-eradication.

Chairs of WHO Advisory and Working Groups reflections:

#### Polio research and commodities

7. CAG recommends the development of an inclusive strategy for new polio vaccines including research-, safe and cost-effective production technologies- and containment. Whenever possible, CAG recommends the development of new vaccines that would require less stringent containment

- requirements to provide incentives to newer developments. This should involve WHO Containment (CNT) programme, WHO Polio Research (PRD) programme and the GPEI Vaccine Supply Group (VSG).
8. CAG recommends the development an inclusive blueprint for polio research, if not already available with approaches for accelerating research in new polio products (polio vaccine, diagnostics and treatment) and other initiatives, expedited regulatory pathways such as using the WHO Emergency Use Assessment and Listing Procedure (EUAL), containment consideration, where applicable and other approaches modelled after the WHO R&D Blueprint for Action to Prevent Epidemics<sup>46</sup> for research on epidemic-prone emerging pathogens.
  9. The achievement of safe and secure poliovirus containment must remain core in the revision of the post-eradication strategy which should also include components such as prioritization of polio vaccine development, polio-associated research, containment requirements for novel poliovirus strains and potentially infectious materials, polioviruses in the post-OPV cessation period. CAG request to be consulted in this aspect as several of these areas are within the mandate of CAG.

### Session: Immunization coverage and environmental safeguards

Challenges with implementing the recommendations on immunization coverage- and environmental control- safeguards around facilities retaining polioviruses in GAPIV

Dr Harpal SINGH, Technical Officer and Secretariat of the Poliovirus Containment Advisory Group (CAG), Poliovirus Containment, Department of Polio Eradication, WHO headquarters in Geneva, SWITZERLAND

The biorisk management of facilities designated as serving critical function requiring the retention of polioviruses post-eradication is achieved through the implementation of facility-, immunization coverage- and environmental- safeguards as described in GAPIV<sup>11</sup>. Facility-, immunization coverage- and environmental- safeguards are required for facilities that retain poliovirus infectious materials, WPV/VDPV and OPV/Sabin and poliovirus potentially infectious materials, WPV/VDPV as described in GAPIV<sup>11</sup>.

The immunization coverage safeguards in GAPIV are aligned to SAGE recommendations for polio immunization after global OPV withdrawal<sup>47</sup> and the WHO position paper on polio vaccine (June 2022)<sup>48</sup> for countries-hosting PEFs. The operationalization of immunization coverage safeguards (IPV schedule, IPV coverage target and geographical extent in coverage), which were addressed during the revision process of GAPIII took into consideration differences in the inherent risk of polioviruses transmission, should there be a facility-associated poliovirus release into the community. This makes the application of a single standard or single set of requirements non-equivalent in different populations. Wherever locally applicable, identifiable at-risk sub-populations e.g., underimmunized or unimmunized communities in areas surrounding the facility should also be taken into consideration (Table 5).

The intent of environmental safeguards is to protect the neighboring community in the event of failure of facility safeguards e.g., incomplete effluent inactivation or malfunction of the effluent decontamination system (EDS), contaminated effluent from the facility would not be released into the local environment untreated, but

<sup>46</sup> WHO: An R&D Blueprint for Action to Prevent Epidemics, Plan of Action, May 2016. Available at: <https://www.who.int/teams/blueprint/about>

<sup>47</sup> Meeting of the Strategic Advisory Group of Experts on immunization, April 2017 – conclusions and recommendation; Weekly Epidemiological Record; 92 (22); 301 – 320; 2 June 2017. Available at: <https://www.who.int/publications/i/item/WER9222>

<sup>48</sup> Polio vaccines: WHO position paper – June 2022; Weekly Epidemiological Record; 97 (25); 277–300; 24 June 2022. Available at: <https://www.who.int/publications/i/item/WHO-WER9725-277-300>

would be subjected to sewage treatment steps in the community prior to release into the environment. This requires primary inactivation of effluent on-site (as part of facility safeguards), followed by the transfer of inactivated effluent through some form of ‘closed’ or ‘piped’ system to a public or community sewage treatment plant. The terms ‘on-site’ treatment and ‘off-site’ treatment are engineering terms. ‘Closed systems’ are used to differentiate between systems those where effluent is treated on-site prior to release, and those where untreated effluent is discharged into the environment.

Environmental safeguards include all locally relevant environmental features that reduces the risk of transmission of polioviruses in a fully susceptible population [basic reproductive number ( $R_0$ )], such as in the post-OPV cessation era or in both a fully susceptible and non-susceptible population [effective reproductive number ( $R_e$ )], such as in the pre-OPV cessation period.

The current approach, the risk-based determination of environmental safeguards in the vicinity of the PEF aims the use of all locally relevant environmental features that would reduce risk of onward transmission of polioviruses should a facility-associated release of poliovirus happen. This approach, which was address during the revision process of GAPIII, was adopted as they can be applied across the range of PEFs, which vary by location, size, and purpose. Environmental surveillance, while it has shown to have been useful in the detection of containment breaches, are associated with numerous technical (high negative predictive value, selection of sites and extent of catchment areas, frequency of collection, available response in case of detection, etc.) and other issues (funding, capacity to process sewage samples for poliovirus, etc.).

Nonetheless, if deemed needed by the NAC, environmental surveillance may be implemented based on a site-specific risk assessment (Table 5).

Table 5: Facility– (A), immunization coverage- (B) and environmental- (C) safeguards for facilities retaining polioviruses as described in GAPIV\*

(A) Facility safeguards			
Aim	Minimizes the likelihood of a facility-associated release of poliovirus.		
Definition	Containment precautions and stipulations designed to minimize a facility-associated poliovirus risks of release.		
Requirements	Facility containment requirements designed to prevent operator infection or the release of contaminated materials. Consists of 14 elements and sub-elements based on the principles of biorisk management systems and is specified in the biorisk management standard for poliovirus-essential facilities holding WPV/VDPV and Sabin/OPV polioviruses of GAPIV*.		
(B) Immunization coverage safeguards			
Aim	Minimizes the consequence of a facility-associated poliovirus release into the community.		
Definition	Population immunization coverage consistent with minimizing the consequence of a poliovirus release from a poliovirus-essential containment facility.		
Indicators†‡	IPV doses§	IPV coverage	Age-group and Geographical Extent of Coverage
Pre-OPV cessation	1	IPV1 ≥90%	Infants; the geographical extent of coverage is to be determined by a risk assessment performed with the
Post-OPV cessation	2	IPV2 ≥90%	NAC. In some cases, it may be multinational, national, or subnational level, as appropriate (Figure 8).
Risk assessments to determine the geographical extent of coverage should consider populations at risk of exposure to polioviruses from unknowingly infected facility operators, those in immediate proximity of a poliovirus containment breach from PEF and those who may be indirectly exposed to contaminated effluent, etc. Where locally applicable, heterogeneity in coverage data due to identifiable at-risk sub-populations e.g.,			

underimmunized or unimmunized communities in areas surrounding the facility or other relevant circumstances e.g., interruption of IPV supply, etc. should be taken into consideration and indicated in the facility CCS application.	
<b>(C) Environmental safeguards</b>	
Function	Further minimizes the consequence of a facility-associated poliovirus release into the community and reestablishment of poliovirus transmission.
Definition	The environmental, sanitation and hygiene conditions (good personal, domestic, and environmental hygiene standards; closed sewage systems with secondary or greater effluent treatment; low population density in surrounding areas) that minimize the risk of reestablishing the circulation of highly transmissible poliovirus.
Indicators	Includes locally relevant environmental features that reduces the risk of transmission of poliovirus [basic reproductive number ( $R_0$ ) or effective reproductive number ( $R_e$ )] in the areas surrounding the facility. Such features may include: areas with closed sewage systems with a minimum of secondary treatment of effluents; low population density; demonstrated low fecal-oral disease transmission; low diarrhea-associated mortality; good water, sanitation and hygiene conditions (may require proxy indicators to quantify hygiene and sanitation services e.g., handwashing, safely managed drinking water, etc.), demographics, socioeconomic and climatic factors; etc. Additional safeguards may be instituted e.g., environmental surveillance around facility determined through a risk assessment in coordination with the NAC.

\* WHO Global Action Plan for Poliovirus Containment, 4th edition, 2022 (GAPIV). Available at: <https://polioeradication.org/wp-content/uploads/2022/07/WHO-Global-Action-Plan-for-Poliovirus-Containment-GAPIV.pdf>. This table should be read in conjunction with ‘Table 1. Required Safeguards for Poliovirus-essential Facilities Handling WPV/VDPV and Sabin/OPV Polioviruses’ of GAPIV (Page 28).

† Meeting of the Strategic Advisory Group of Experts on Immunization, April 2018: conclusions and recommendations. Weekly Epidemiological Record, 93 (23), 329 - 343. Available at: <https://www.who.int/publications/i/item/WER9323>

‡ Countries with PEFs should continue to use IPV as long as mandated by GAPIV. Countries without PEFs should maintain IPV in their routine immunization schedule for at least 10 years after global OPV withdrawal. Meeting of the Strategic Advisory Group of Experts on Immunization, April 2017: conclusions and recommendations. Weekly Epidemiological Record, 92 (22), 301 - 320. Available at: <https://www.who.int/publications/i/item/WER9222>

§ Countries with single dose IPV should adjust their IPV schedule, coverage targets and geographical scope as soon as possible and no later than at the time of all OPV cessation, to implement a routine immunization schedule with a minimum of 2 IPV doses (full or fractional, standalone or in combination vaccines), with the first dose administered at 4 months and second dose at an interval of at least 4 months after the first dose.

CAG recommendations:

#### Immunization coverage and environmental safeguards

1. The geographical extent of coverage (multinational, national, subnational data or as appropriate) used in the definition of immunization coverage safeguards in GAPIV is left to the decision of the national authority for containment (NAC) as determined by a risk assessment. The NACs should also ensure that infants in the geographical coverage area are provided with a primary 3-dose series of IPV (with an interval of 4 weeks) in IPV-only using countries and two-doses of IPV (with an interval of 4–8 weeks) in OPV-using countries achieving a minimum vaccination coverage of at least 90% as a precautionary measure, which may be modified as evidence accrues.

[This recommendation does not constitute change in the relevant GAPIV text or section, at present]

2. With the ongoing implementation of the interim containment certification phase, the Global Commission for the Certification of the Eradication of Poliomyelitis – Containment Working Group (GCC – CWG) will review country evidence of appropriate implementation of environmental safeguards and will provide feedback to CAG on the feasibility of the revised approach and definition used in GAPIV.

[This recommendation does not constitute change in the relevant GAPIV text or section, at present]

#### Session: Containment requirements for novel poliovirus strains

##### Novel oral poliomyelitis vaccine programmatic update and milestones

Ms Simona ZIPURSKY, Special Adviser to the Director, Polio Eradication, WHO headquarters in Geneva, SWITZERLAND and Chair of GPEI nOPV Working Group<sup>49</sup>

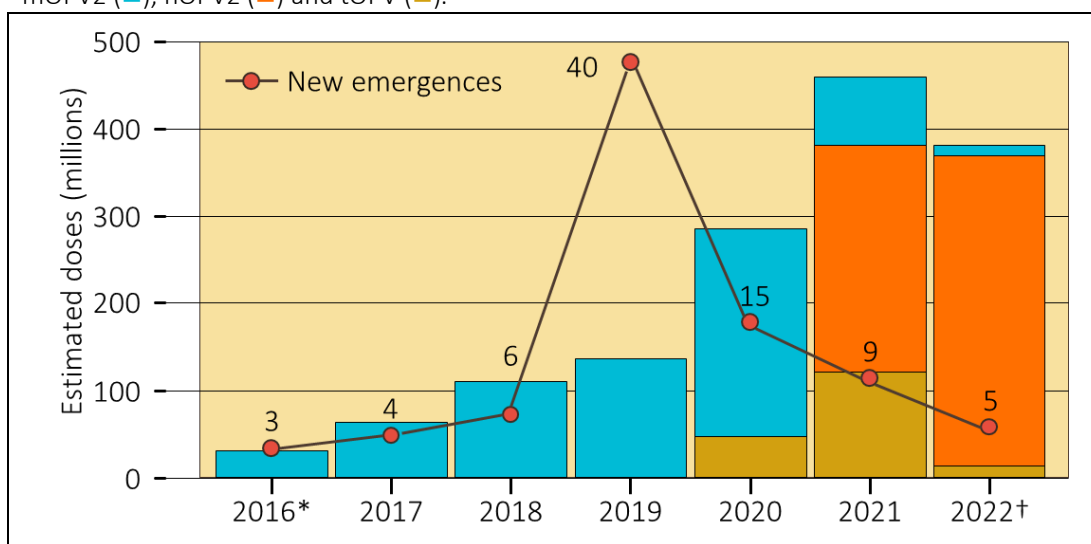
Since 2017, there have been more annual cases of paralytic poliomyelitis caused by cVDPV2 than WPV1. There were 76 distinct cVDPV2 emergences since the switch in 2016, with 40 emergences in 2019 followed by a period of significant decline from 2020 to date (Figure 10). Of the seven ‘consequential geographies’, four are affected, namely northern Nigeria, south and central Somalia, eastern Democratic Republic of Congo and northern Yemen. Emergences from northern Nigeria and the Lake Chad Basin infected 19 countries, accounting for 70% of all cVDPV2 detections in the WHO African Region. VDPV2 has also been detected in environmental samples in the United Kingdom and Israel, with one paralytic poliomyelitis case reported in the United States.

The WHO Vaccine Prequalification program issued an Emergency Use Listing (EUL) recommendation for nOPV2 on 13 November 2020, and was first used as part of outbreak response in Nigeria on 13 March 2021. 560 million doses of nOPV2 have now been administered across 26 countries for outbreak response. The Global Advisory Committee on Vaccine Safety (GACVS) established an nOPV2 sub-committee, to provide an independent assessment of safety data of nOPV2 use under the EUL. After a review using safety data from over 253 million doses of nOPV2 administered across 13 countries, the sub-committee concluded that the data showed no safety concerns. The ongoing aim is to generate, analyze and use field data and information from ongoing clinical studies to inform policies on outbreak response, and to strengthen the evidence-base support of full licensure and WHO Prequalification of the vaccine, to transition out of the use of nOPV2 under EUL. The WHO prequalification of nOPV2 is targeted for end-2023.

---

<sup>49</sup> With support from: Dr Ananda S BANDYOPADHYAY, Deputy Director, Technology, Research, and Analytics, Polio Team, Bill & Melinda Gates Foundation, Seattle, Washington, USA and GPEI nOPV Working Group (Virtual participation); Dr Cara BURNS, Team Lead, Molecular Epidemiology and Surveillance Laboratory, Division of Viral Diseases, Centers for Disease Control and Prevention (CDC), Atlanta, Georgia, USA and nOPV2 Genetic Characterization Subgroup of the GPEI nOPV Working Group (Virtual participation); Mr Feyrouz KURJI, Principal Consultant, FDK Consulting LLC, Kirkland, Washington, USA and Coordinator of GPEI nOPV Working Group (Virtual participation) and Ms Kaija HAWES, Associate Program Officer, Technology, Research, and Analytics, Polio Team, Bill & Melinda Gates Foundation, Seattle, Washington, USA and Coordinator of nOPV Genetic Characterization Subgroup of the GPEI nOPV Working Group GPEI nOPV Working Group (Virtual participation).

Figure 10: cVDPV2 emergences and the use of poliovirus serotype 2 containing vaccines: mOPV2 (■), nOPV2 (■) and tOPV (■).



Abbreviations: nOPV2: novel monovalent oral poliomyelitis vaccine serotype 2; mOPV2: Sabin monovalent oral poliomyelitis vaccine serotype 2 and tOPV: trivalent oral poliomyelitis vaccine serotypes 1, 2 and 3.

\*after 1 May 2016; †as of 9 December 2022

Close monitoring on the genetic stability and effectiveness as part of EUL use confirms that nOPV2 is performing as expected: enhanced stability was observed, with a lower likelihood to revert to a form that can cause paralysis in under-immunized communities. Following the transition to a predominantly nOPV2 use over Sabin OPV2, there was an overall decline in the reported new or emergence cases in 2022. The use of nOPV2 as outbreak response to cVDPV2 is urgently needed, due to the demonstrated risk of reseeding from Sabin mOPV2. Nonetheless, the ability to stop outbreaks with nOPV2 is dependent on the sufficient implementation of timely, high-quality outbreak response.

#### Genetic characterization of nOPV2 isolates from surveillance activities

Dr. Javier Martin, Director, WHO Global Specialized Polio Laboratory, National Institute for Biological Standards and Control (NIBSC), Potters Bar, Hertfordshire (United Kingdom) and Co-Chair, nOPV Genetic Characterization Subgroup of the GPEI nOPV Working Group

The most consequential risks associated with use of Sabin mOPV2 were VDPV2 emergence from reversion to neurovirulence, circulation of the vaccine strain in certain population settings, and the rare cases of vaccine-associated paralytic poliomyelitis (VAPP) in vaccine recipients or their close contacts. Since the 'tOPV (containing serotypes 1, 2 and 3) to bOPV (containing serotypes 1 and 3) switch' in April 2016, the risk of seeding cVDPV2 emergence and spread from Sabin mOPV2 as cVDPV2 outbreaks response in low immunity areas has been a growing concern. While nOPV2 is not expected to eliminate these risks from a biologic perspective, one of the goals of nOPV2 development and deployment was to substantially reduce these risks.

Between June 2021 and September 2022, the whole-genome sequences of 1006 nOPV2 isolates from 13 countries were determined. In all except three, Domain V remains unmodified. The three isolates from a single environmental sample from Uganda showed reversion at the primary attenuation site (Domain V and *cre*) due



to recombination<sup>50</sup>. Other findings include: 38 nOPV2 isolates had more than five nucleotide changes in the P1-region encoding capsid (structural) protein VP1, of which 37 isolates were from two immunodeficient patients; 10 nOPV2 non-recombinant isolates had more than five nucleotide changes in the P1-region encoding capsid (structural) protein VP1 but were not genetically linked and domain V was preserved; 67 nOPV2 isolates were found to be recombinants between nOPV2 and Sabin polioviruses, or *Enterovirus* species C (EV-C) in the non-structural genomic region, implying a mutation loss in the P3-region encoding viral RNA-dependent RNA polymerase (3D<sup>pol</sup>) of nOPV2; two primary immunodeficient disease (PID) patients (non-AFP cases) were found to chronically excrete nOPV2 (191 and 309 days, respectively); the reversion to neurovirulence of nOPV2 is slower compared to Sabin2; few, if any, of the mutation combinations identified in nOPV2 isolates would cause the nOPV2 strain to approach the neurovirulence of Sabin 2 with the A481G reversion ('gatekeeper' mutations for reversion to occur) in Domain V, a reversion is typically observed within 14 days of replication in most recipients of OPV2; limited generation of isolates showed or are expected to have high (cVDPV2-like) neurovirulence, etc. High coverage campaigns with nOPV2 effectively induces immunity against cVDPV2 in vaccine recipients. Further, as is evidenced in the case of Tajikistan (Figure 11), nOPV2 is shown to be an effective and appropriate tool in interrupting cVDPV2 transmission during outbreaks<sup>51,52</sup>.

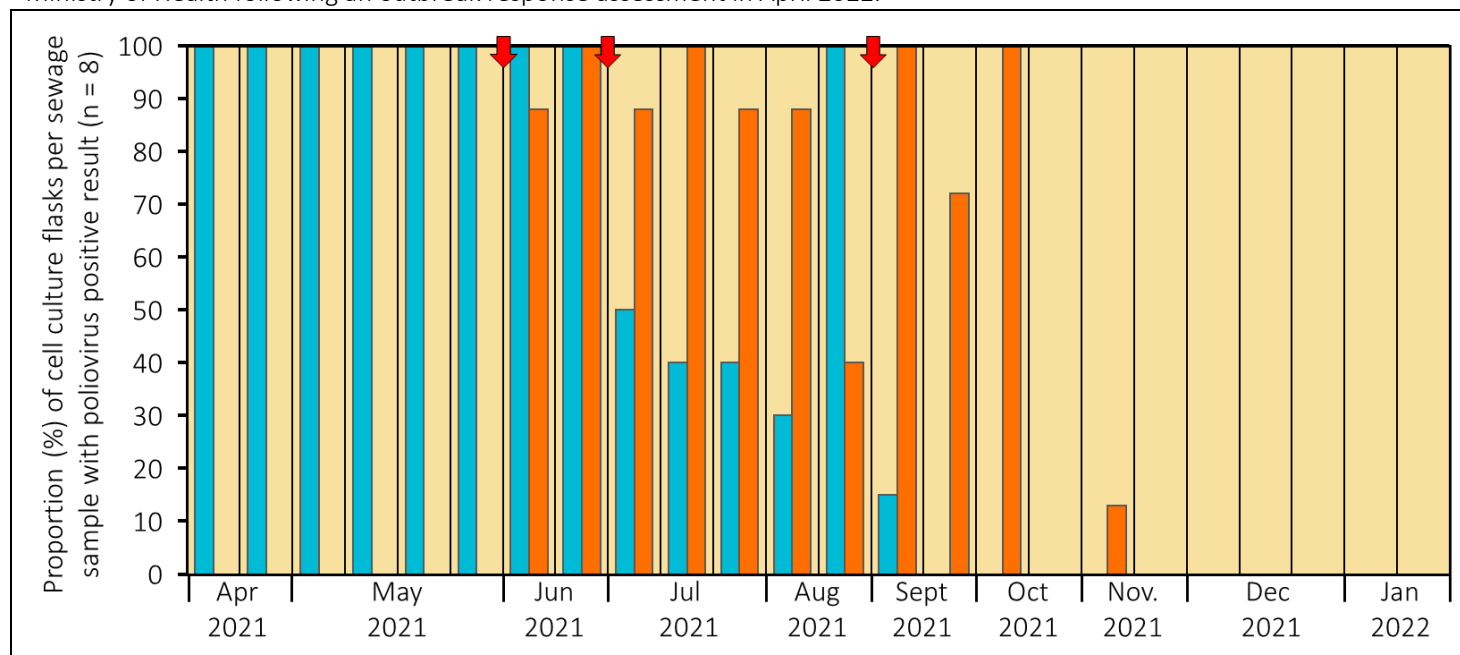
---

<sup>50</sup> Such reversions are considered Category 1 (wild-type Domain V restored; likely neurovirulent) as per the 'Classification scheme of nOPV isolates into nine categories based on genome sequence composition (risk profile and loss of key attenuating nOPV mutations)'. Category groups are ranked according to level of concern based on expected neurovirulence, with 1 being the highest and 9 being the lowest. Available at: Martin J, Burns CC, Jorba J, et al. Genetic Characterization of Novel Oral Polio Vaccine Type 2 Viruses During Initial Use Phase Under Emergency Use Listing — Worldwide, March–October 2021. *MMWR Morb Mortal Wkly Rep* 2022;71:786–790. DOI: <http://dx.doi.org/10.15585/mmwr.mm7124a2>

<sup>51</sup> Mirzoev A, Macklin GR, Zhang Y, Mainou BA, Sadykova U, Olsavszky VS, Huseynov S, Ruziev M, Saidzoda F, Bobokhonova M, Mach O. Assessment of serological responses following vaccination campaigns with type 2 novel oral polio vaccine: a population-based study in Tajikistan in 2021. *Lancet Glob Health*. 2022 Dec;10(12):e1807-e1814. doi: 10.1016/S2214-109X(22)00412-0.

<sup>52</sup> Thompson KM. Effectiveness of a new vaccine for outbreak response and the increasingly complicated polio endgame. *Lancet Glob Health*. 2022 Dec;10(12):e1697-e1698. doi: 10.1016/S2214-109X(22)00452-1.

Figure 11: nOPV2 use (■) and nOPV2 supplementary immunization activities (SIA) (↓) in the interruption of transmission of cVDPV2 (■) in Tajikistan, January 2021. 36 cVDPV2 cases (onset of paralysis: 1 Nov 2020 - 31 Jul 2021) and 17 cVDPV2 environmental isolates (1 Feb 2021 - 10 Sep 2021) were reported across subnational areas of Districts of Republican Subordination, Khatlon Province, and the capital city Dushanbe. The outbreak was officially closed by WHO and the Tajik Ministry of Health following an outbreak response assessment in April 2022.



Abbreviations: cVDPV2: circulating vaccine-derived poliovirus serotype 2; nOPV2: novel monovalent oral poliomyelitis vaccine serotype 2 and SIA: supplementary immunization activity.

#### Containment requirements for novel poliovirus strains

Dr Harpal SINGH, Technical Officer and Secretariat of the Poliovirus Containment Advisory Group (CAG), Poliovirus Containment, Department of Polio Eradication, WHO headquarters in Geneva, SWITZERLAND

The CAG - Expert Support Group (CAG-ESG) on Novel Poliovirus Strains reviewed the status of all 'temporary waivers' previously granted by CAG for the use of specific novel poliovirus strains and their specified uses based on existing information or the availability of newer data e.g., genetic stability of nOPV2 as was presented at this meeting.

CAG recommendations:

3. The following are the updated CAG recommendations on the containment requirements of novel poliovirus strains following an assessment of newly available data on novel poliovirus strains and their specified uses by the CAG - Expert Support Group (CAG-ESG) on Novel Poliovirus Strains:
  - a. Continuation of the temporary waiver<sup>53</sup> currently in-place for nOPV (nOPV1, nOPV2 and nOPV3) for the following specific usages: vaccine production, vaccine quality control, clinical trials and outbreak response.

<sup>53</sup> temporary waivers are time-limited, conditional to the specified usages only and temporarily waived from the biorisk management requirements for the handling of Sabin polioviruses described in GAPIV.

- b. Continuation of the temporary waiver<sup>54</sup> currently in-place for S19 – poliovirus strains cassette for the following specific usages: IPV production, rat neutralization IPV potency assays, human serum neutralization test for poliovirus antibody determination and potency testing for immunoglobulin (human) lot control and release.
  - c. Continuation of the temporary waiver<sup>53</sup> currently in-place for the following specific usages: trivalent formulation of nOPV1, nOPV2, and nOPV3; and nOPV formulation studies and clinical trials of trivalent nOPV (tnOPV)
  - d. Continuation of the temporary waiver<sup>54</sup> currently in-place for the use of novel poliovirus strains for research purposes (Table 6).
  - e. Continuation of the temporary waiver<sup>53</sup> currently in-place for PVSRIPO for the following specific usages: Phase II clinical trials (cancer immunotherapy) and production of these strains.
4. CAG recommends that the CAG – ESG continue their previously initiated discussions to resolve the following, understanding that the recommendations may be in the *interim*:
- a. mechanism for the compliance monitoring of facilities with the terms of the temporary waiver (conditional usage)
  - b. duration of temporary waivers, if any
  - c. resolving the exemption from the containment requirements of novel poliovirus strains for specified uses after the end-validity of the waivers in the post-OPV cessation period when all live polioviruses are expected to be fully contained.

[CAG recommendations on novel poliovirus strains does not constitute change in the relevant GAPIV text or section]

Table 6: Novel poliovirus strains and their specific research usages temporarily waived from the biorisk management requirements for the handling of WPV and Sabin polioviruses described in GAPIV.

Strains	Specific Uses
• nOPV1 candidate 1 (aka nOPV1-c1, or S2/cre5/S15domV/rec1/hifi3/S1P1)	• Laboratory activities to support clinical trials and ongoing monitoring of continued use
• nOPV2 candidate 1 (aka nOPV2-c1, or S2/cre5/S15domV/rec1/hifi3/S2P1)	• Viral concentration from environmental samples
• nOPV3 candidate 1 (aka nOPV3-c1, or S2/cre5/S15domV/rec1/hifi3/S3P1)	• Development or refinement of methods for viral concentration and detection from environmental samples
• nOPV1 candidate 2 (aka nOPV1-c2, or S2/cre6/S15domV/CpG30/rec1/hifi3/S1P1)	• Frozen storage of stool specimens from clinical trials
• nOPV2 candidate 2 (aka nOPV2-c2, or S2/S15domV/CpG40)	• Determination of D-antigen content
• nOPV3 candidate 2 (aka nOPV3-c2, or S2/cre6/S15domV/CpG30/rec1/hifi3/S3P1)	• Determination of viral titer
• nOPV2 candidate 3 (aka nOPV2-c3 or S2/cre6/S15domV/CpG40/rec1/hifi3)	• Stability studies, including for alternative nOPV formulations
• S19S1	• Characterization of aliquots from stability studies (e.g., pH, aggregation assays, HPLC)
• S19S2	• Immunogenicity assays in mice and rats
• S19S3	• Detection of nOPV and mucosal antibodies to nOPV in stool samples
• S19S1_N18S	• Neutralization assays
• S19S2_N18S	• Isolation of antibodies and virus from stool samples (human, mouse, rat)

<sup>54</sup> temporary waivers are time-limited, conditional to the specified usages only and temporarily waived from the biorisk management requirements for the handling of WPV and Sabin polioviruses described in GAPIV.

Table 6: Novel poliovirus strains and their specific research usages temporarily waived from the biorisk management requirements for the handling of WPV and Sabin polioviruses described in GAPIV.

Strains	Specific Uses
<ul style="list-style-type: none"> <li>• S19S3_N18S</li> <li>• S19Mah</li> <li>• S19MEF1</li> <li>• S19Skt</li> <li>• S19Mah_N18S</li> <li>• S19MEF1_N18S</li> <li>• S19Skt_N18S</li> </ul>	<ul style="list-style-type: none"> <li>• Mass spectroscopy</li> <li>• Small-scale propagation</li> <li>• Nucleic acid extraction</li> <li>• Sequencing</li> <li>• Potency testing for immunoglobulin (human) lot control and release</li> <li>• Testing effectiveness of inactivation and disinfection methods</li> <li>• Sterility studies to confirm inactivation and disinfection methods</li> <li>• Spiking biosolids (sewer sludge) or wastewater to demonstrate effectiveness of treatments</li> </ul>

#### Session: Conformity Assessment Activities During the Transition Period from GAPIII to GAPIV

##### Conformity Assessment Activities During the Transition Period from GAPIII to GAPIV

Dr Harpal SINGH, Technical Officer and Secretariat of the Poliovirus Containment Advisory Group (CAG), Poliovirus Containment, Department of Polio Eradication, WHO headquarters in Geneva, SWITZERLAND

The intent of the transition period from GAPIII 2015 to GAPIV 2022 is to sustain stakeholder progress with the ongoing implementation of the interim containment certification (ICC) phase<sup>55</sup>. This progress is attributed to the efforts undertaken by facilities retaining polioviruses to meet the requirements of GAPIII and GAPIV, as well as the NACs in sustaining national containment certification processes and activities, such as initiation, planning and conduct of initial ICC audits, reporting and follow-up, etc. This transition period also includes sufficient time for facilities to work with the NACs to prepare for full-compliance with GAPIV, while maintaining compliance with GAPIII and addressing non-conformities identified during the initial ICC audits.

The initiation, planning and full-scope initial ICC audits may be performed for the requirements of GAPIII or GAPIV. Where compliance verification is performed against GAPIII, initial audits must meet the 31 December 2023 deadline for completion. From 1 January 2023, all initial audits must be performed against GAPIV. In line with this, all associated post-audit activities such reporting (e.g., audit report), follow-up [e.g., audit findings, corrective action plan (CAP), root cause analysis (RCA), including closure or plan for closure of non-conformities], technical review and approval by the NAC and the GCC must be performed using the same standard (GAPIII or GAPIV) against which the ICC was issued. Facilities with a GCC-countersigned ICC against GAPIII will require a full-scope audit against GAPIV, which can be performed anytime during the 3-year ICC certification cycle, but must be done at least 3 months prior to the ICC end-validity, when transitioning to a certificate of containment (CC) (Figure 12).

The criteria for the certification of eradication as recommended by GCC has been unchanged since 2018, including poliovirus containment<sup>56</sup>. In line with the WPV1 transmission interruption by end-2023 milestone,

<sup>55</sup> In line with the recommendations made at the 21st Meeting of the Global Commission for the Certification of Eradication of Poliomyelitis, 28 July 2021. Available at: <https://polioeradication.org/wp-content/uploads/2021/09/21st-GCC-report-20210906.pdf>

<sup>56</sup> GCC Recommendation (Containment) 4.1.1. Certification of WPV eradication should only occur when all WPV materials, in facilities designated for retaining them, are safely and securely contained<sup>5</sup>

and certification of WPV1 eradication by end-2026 [Goal 1 (Permanently interrupt all poliovirus transmission in endemic countries)] of the Polio Eradication Strategy 2022-2026<sup>16</sup>, these guidance on conformity assessment activities will enable facilities retaining infectious- and potentially infectious-materials, WPV, to meet the containment component of the criteria for the certification of eradication.

CAG recommendations:

Conformity Assessment Activities During the Transition Period from GAPIII to GAPIV

5. Initial ICC audits may be carried out against the requirements of GAPIV or GAPIII. However, should these initial audit be carried out against the requirement of GAPIII, these must be completed by 31 December 2023. From 1 January 2024, all ICC audits must be performed against GAPIV. ICC issued from the audits against GAPIII or GAPIV shall be valid for no longer than three years with any periodic- or follow-up- audits performed against the same standard (GAPIII or GAPIV) against which the ICC is issued. The transition from an ICC against GAPIII to a CC shall require a full audit against GAPIV which can be performed at any time but must be done by at least 3 months prior to the expiration date of the ICC certificate.

[CAG recommendation to be included in GAPIV >> Introduction >> Transition Period]

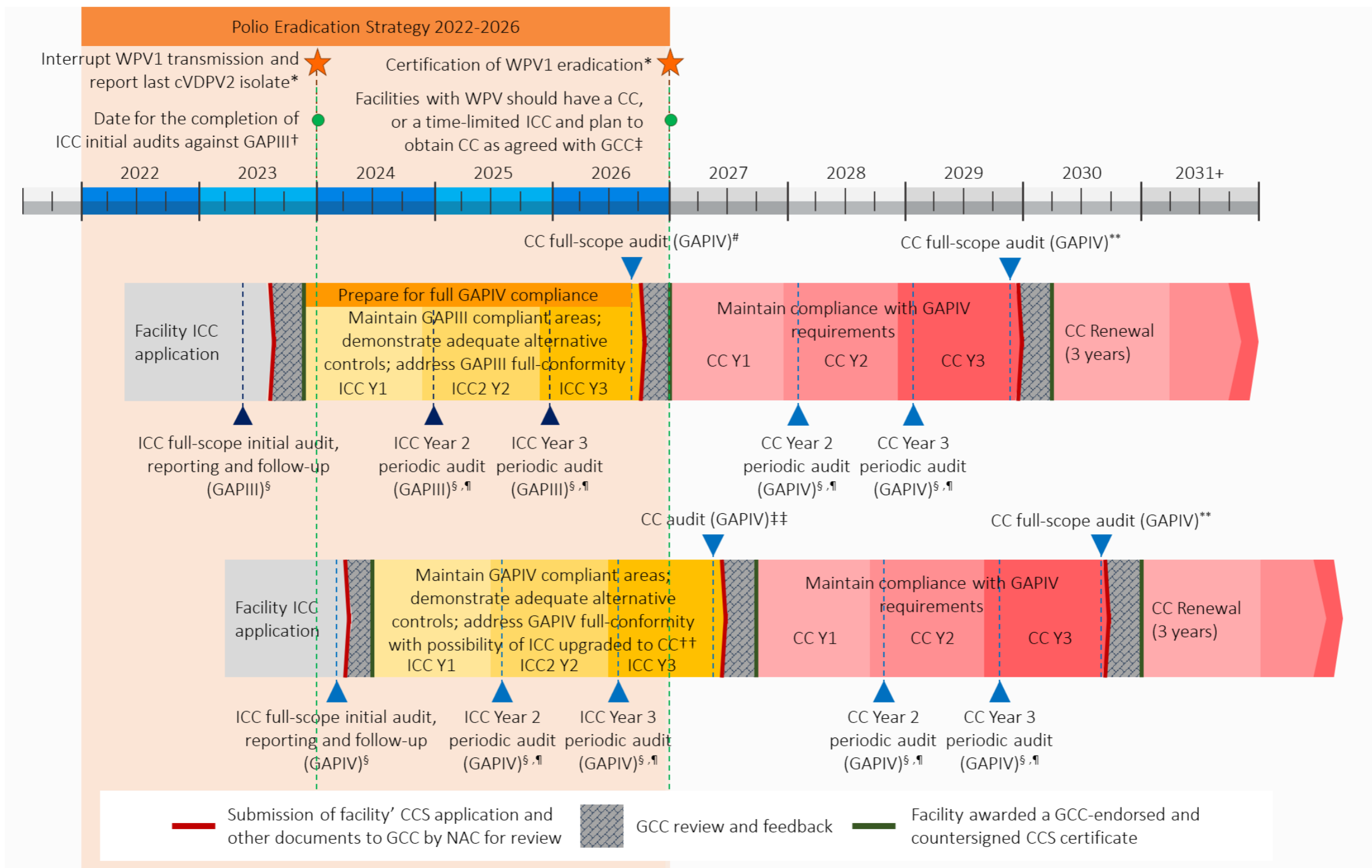
---

<sup>5</sup> All facilities retaining WPVs should have a Containment Certificate, or a time-limited Interim Containment Certificate, with a clear end point for obtaining a CC agreed with the GCC. In addition, at the time of global WPV certification, the GCC will consider the status of biorisk management of potentially infectious materials and readiness plan to respond to containment breaches.

Source: Report from the Seventeenth Meeting of the GCC, Geneva, Switzerland, 26-27 February 2018.

Available at: <https://polioeradication.org/wp-content/uploads/2018/04/polio-eradication-certification-17th-meeting-global-commission-for-certification-of-poliomyelitis-eradication-20180412.pdf>

Figure 12: Conformity assessment activities during the transition from GAPIII (2015) to GAPIV (2022).



Abbreviations: cVDPV2: circulating vaccine-derived poliovirus serotype 2; CC: certificate of containment; CC Y1, Y2 and Y3: certificate of containment 1st-, 2nd- and 3rd- year; GAPIII: WHO Global Action Plan for Poliovirus Containment, 3rd edition, 2015; GAPIV: WHO Global Action Plan for Poliovirus Containment, 4th edition, 2022; GCC: Global Commission for the Certification of the Eradication of Poliomyelitis; ICC: interim certificate of containment 1st-, 2nd- and 3rd- year; WPV: Wild poliovirus and WPV1: Wild poliovirus serotype 1.

\*Milestones for Goal 1 (Permanently interrupt all poliovirus transmission in endemic countries) of the Polio Eradication Strategy 2022-2026.

<sup>†</sup>ICC full-scope initial audits may be conducted against GAPIII or GAPIV. Where compliance verification is performed against GAPIII, initial audits must be completed by 31 December 2023. All initial audits from 1 January 2024 must be performed against GAPIV. An ICC is standard-specific (GAPIII or GAPIV) – the validity of an ICC issued against GAPIII or GAPIV shall be no longer than three years.

<sup>‡</sup>constitutes the poliovirus containment component of the criteria for the certification of eradication since 2018 as per recommendation from GCC (Report of the Seventeenth Meeting of the GCC, Geneva, Switzerland, 26-27 February 2018. Available at: <https://polioeradication.org/wp-content/uploads/2018/04/polio-eradication-certification-17th-meeting-global-commission-for-certification-of-poliomyelitis-eradication-20180412.pdf>) and in line with milestones for Goal 1 (Permanently interrupt all poliovirus transmission in endemic countries) of the Polio Eradication Strategy 2022-2026.

§All associated post-audit activities such reporting (e.g., audit report), follow-up [e.g., audit findings, corrective action plan (CAP), root cause analysis (RCA), including closure or plan for closure of non-conformities], technical review and approval by the NAC and the GCC, including periodic audits must be performed using the same standard against which the ICC (GAPIII or GAPIV) or CC (GAPIV) is issued.

¶Periodic audits, are conducted in the second and third years and within 12 months of a previous audit using the same standard (GAPIII or GAPIV) against which the ICC (GAPIII or GAPIV) or CC (GAPIV) is issued.

#Facilities with a GCC-countersigned ICC against GAPIII, will require a full-scope audit against GAPIV which can be performed anytime during the 3-year ICC certification cycle but must be completed at least 3 months prior to the ICC end-validity, when transitioning to a CC. The validity of CC shall be no longer than three years.

\*\*A full-scope CC audit is repeated at the end of the three-year cycle, where successful completion will result in renewal of the CC for a further three years.

††A CC can be awarded to a facility with a GCC-countersigned ICC against GAPIV as an upgrade to the ICC following the presentation of evidence by the facility to the NAC in consultation with the GCC that all GAPIV requirements have been met. If the ICC is upgraded to a CC during the three-year period validity of the ICC, the certification cycle remains unchanged (i.e., it is upgraded to CC within an ongoing three-year cycle).

‡‡If transitioning to a CC, a facility with a GCC-countersigned ICC against GAPIV will require a reduced-scope audit – the appropriate audit and verification measures will be defined by the NAC based on the number and nature of the ICC-non-conformities in place.

#### Session: Issues Associated with the Containment of Potentially Infectious Materials, Polioviruses

##### Issues Associated with the Containment of Potentially Infectious Materials, Polioviruses

Dr Harpal SINGH, Technical Officer and Secretariat of the Poliovirus Containment Advisory Group (CAG), Poliovirus Containment, Department of Polio Eradication, WHO headquarters in Geneva, SWITZERLAND

The current requirements for facility reporting of retention or destruction of poliovirus materials, facility-immunization coverage- and environmental- safeguards for their retention, as well as the associated accountability framework for facilities retaining poliovirus materials are described in containment documents and in line with the recommendations by CAG<sup>11,57,58,59</sup> (Table 7 and Figure 13).

The risk mitigation measures for the handling of potentially infectious materials, polioviruses should be aligned with the actual risk associated with the sample type and use. The handling of potentially infectious materials, WPV/VDPV and OPV/Sabin polioviruses were previously subject to GAPIII.

<sup>57</sup> WHO Global Action Plan for Poliovirus Containment – Containment Certification Scheme (CCS). Available at: [https://polioeradication.org/wp-content/uploads/2017/03/CCS\\_19022017-EN.pdf](https://polioeradication.org/wp-content/uploads/2017/03/CCS_19022017-EN.pdf)

<sup>58</sup> Guidance to minimize risks for facilities collecting, handling or storing materials potentially infectious for polioviruses, 2nd ed., 2021 (PIM Guidance). Available at: <https://polioeradication.org/polio-today/preparing-for-a-polio-free-world/containment/containment-resources/>

<sup>59</sup> Meeting Reports of the Poliovirus Containment Advisory Group (CAG). Available at: <https://polioeradication.org/tools-and-library/policy-reports/advisory-reports/containment-advisory-group/>

Table 7: Poliovirus materials: Facility retention reporting; facility- and - safeguard requirements and the associated oversight mechanism for the handling of such materials as described in various containment documents\*†‡

Type of Poliovirus Material		Facility Retention Reporting Process	Facility- and Host Country-poliovirus Retention Requirements			Accountability Framework
			Facility Safeguards	Immunization coverage safeguards	Environmental safeguards	
Infectious Materials	WPV VDPV§	National poliovirus survey and inventory*	Biorisk management standard for WPV/VDPV and Sabin/OPV*	Polio immunization*	Local features which reduce poliovirus transmission*	National oversight with global confirmation of poliovirus containment†
	Sabin OPV§					
Potentially Infectious Materials	WPV VDPV§	Web Annex C: Form 1 – Facility reporting form‡	Risk mitigation strategies for potentially infectious materials, Sabin/OPV‡	No requirement	No requirement	None
	Sabin OPV¶					

\*WHO Global Action Plan for Poliovirus Containment, 4th ed., 2022 (GAPIV). Available at: <https://polioeradication.org/wp-content/uploads/2022/07/WHO-Global-Action-Plan-for-Poliovirus-Containment-GAPIV.pdf>

†WHO Global Action Plan for Poliovirus Containment – Containment Certification Scheme (CCS). Available at: [https://polioeradication.org/wp-content/uploads/2017/03/CCS\\_19022017-EN.pdf](https://polioeradication.org/wp-content/uploads/2017/03/CCS_19022017-EN.pdf)

‡Guidance to minimize risks for facilities collecting, handling or storing materials potentially infectious for polioviruses, 2nd ed., 2021 (PIM Guidance). Available at: <https://polioeradication.org/polio-today/preparing-for-a-polio-free-world/containment/containment-resources/>

§Retention of such materials, as defined in GAPIV, are subject to facility-, immunization coverage- and environmental-safeguards described in GAPIV.

¶Retention of such materials involves risk categorization based on sample type and work to be performed, with specific mitigation measures recommended for different risk categories.

However, several concerns were raised by containment stakeholders. First, such requirements were not evidence-based; second, far exceeding national laboratory biosafety standards for such materials would have an adverse impact on specimen archives, research studies, vaccine trials; and third, numerous facilities – non-polio and poliovirus laboratories alike – have been identified as retaining potentially infectious materials, polioviruses, which would require designation, implementation of GAPIII and activities associated with the CCS process. This led to the publication of the Guidance for non-poliovirus facilities to minimize risk of sample collections potentially infectious for polioviruses (PIM Guidance), 1st edition in 2018. The PIM Guidance 2018 was revised following the declaration of WPV3 eradication in October 2018 and to include poliovirus and non-poliovirus laboratories in its implementation. The Guidance to minimize risk for facilities collecting, handling or storing materials potentially infectious for polioviruses, 2nd edition<sup>58</sup> was endorsed by CAG in November 2020 and published in 2021. A digital version of the PIM Guidance 2021, the *Potentially Infectious Materials, Poliovirus (PIM) Identification Tool*, was also published<sup>60</sup>.

The PIM Guidance 2021 subjects the retention of potentially infectious materials, WPV/VDPV to GAPIV (Figure 13). The PIM Guidance 2021 was developed on the basis that the handling of potentially infectious materials, OPV/Sabin polioviruses represented a lower risk (risk for the potential of a facility-associated release of

<sup>60</sup> Potentially Infectious Materials, Poliovirus Identification Tool, 2021. Available at: <https://worldhealthorg.shinyapps.io/pim-app/>



poliovirus), difference in the poliovirus infectious dose and the reduced likelihood of OPV/Sabin polioviruses being present in the materials (Figure 14). The PIM Guidance 2021 utilizes a risk stratification approach (sample type and procedure) to determine the risk mitigation measures for potentially infectious materials, OPV/Sabin polioviruses.

Currently, there are concerns regarding the lack of immunization coverage- and environmental safeguards for facilities retaining potentially infectious materials, OPV/Sabin polioviruses, and the absence of any accountability framework to ensure facility compliance with the biorisk management requirements for the retention of these materials. Particularly in the post-OPV cessation period, when all live polioviruses are expected to be contained and with waning population immunity to poliovirus.

Several issues associated with potentially infectious materials, polioviruses have been raised by stakeholders e.g., NAC, non-poliovirus laboratories, PEFs, NPCCs including CAG members during the revision of GAPIII and at the CAG5 meeting in March 2022 (Table 8). These issues were deliberated by CAG at this meeting.

Table 8: Issues associated with the containment of potentially infectious materials, polioviruses pending CAG recommendations.

1. To update the 'biorisk management standard for safe handling of new samples potentially containing poliovirus material in poliovirus-non-essential facilities' (previously, Annex 6 of GAPIII)\* to be in-line with GAPIV†, WHO LBM4‡ and the GPLN Guidance Paper 1 for safe handling and storage of type 2 poliovirus in GPLN laboratories§, and harmonization and incorporation in the PIM Guidance¶.
2. Containment requirements for handling of potentially infectious materials, WPV/VDPV
3. Accountability framework for facility' compliance with the risk mitigation strategies for the retention of potentially infectious materials, polioviruses
4. Containment requirements for the retention of potentially infectious materials, polioviruses in the post-OPV cessation period when all poliovirus materials are expected to be fully contained.
5. Immunization- and environmental- safeguard requirements for facilities retaining potentially infectious materials, polioviruses.

Abbreviations: GAPIII: WHO Global Action Plan for Poliovirus Containment, 3rd edition, 2015; GAPIV: WHO Global Action Plan for Poliovirus Containment, 4th edition, 2022; GPLN: Global Polio Laboratory Network; LBM4: WHO Laboratory Biosafety Manual, 4th edition, 2020 (LBM4); OPV: Oral poliomyelitis vaccine; PIM: potentially infectious materials, poliovirus; VDPV: vaccine-derived poliovirus and WPV: Wild poliovirus;

\* WHO Global Action Plan for Poliovirus Containment, 3rd ed., 2015 (GAPIII). Available at:

[https://polioeradication.org/wp-content/uploads/2016/12/GAPIII\\_2014.pdf](https://polioeradication.org/wp-content/uploads/2016/12/GAPIII_2014.pdf)

†WHO Global Action Plan for Poliovirus Containment, 4th ed., 2022 (GAPIV). Available at:

<https://polioeradication.org/wp-content/uploads/2022/07/WHO-Global-Action-Plan-for-Poliovirus-Containment-GAPIV.pdf>

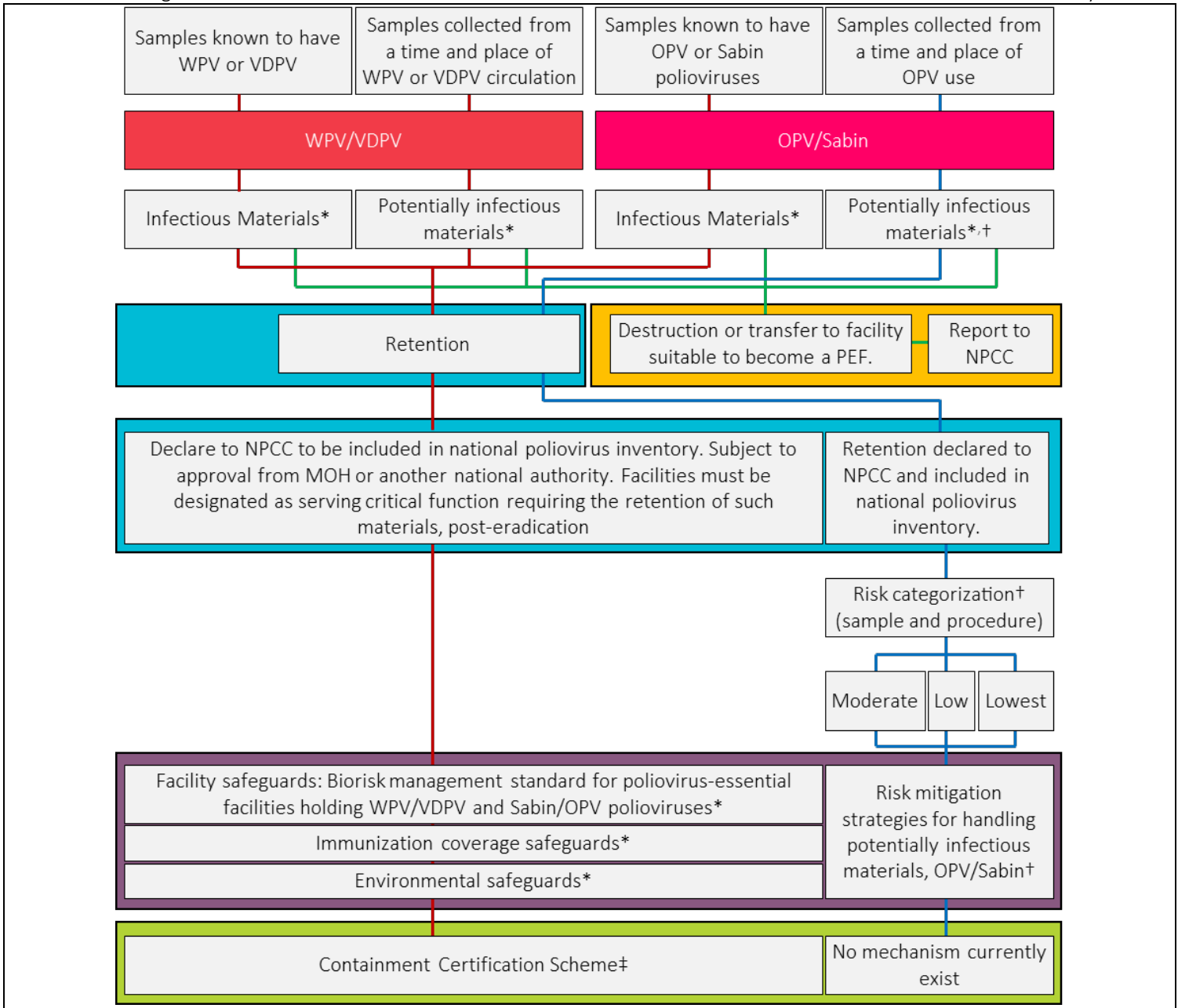
‡ WHO Laboratory Biosafety Manual, 4th edition, 2020 (LBM4) and Associated Monographs. Available at:

<https://www.who.int/publications/i/item/9789240011311?sequence=1&isAllowed=y>

§Guidance to minimize risks for facilities collecting, handling or storing materials potentially infectious for polioviruses, 2nd ed., 2021 (PIM Guidance). Available at: <https://polioeradication.org/polio-today/preparing-for-a-polio-free-world/containment/containment-resources/>

¶ Guidance to minimize risks for facilities collecting, handling or storing materials potentially infectious for polioviruses, 2nd ed., 2021 (PIM Guidance). Available at: <https://polioeradication.org/polio-today/preparing-for-a-polio-free-world/containment/containment-resources/>

Figure 13: Requirements for reporting facility retention (■)- or destruction (■)- of poliovirus materials; and facility-, immunization coverage- and environmental- safeguard (■) requirements for their retention and the associated accountability framework (■) for facilities retaining such materials is described in various containment documents and in line with the recommendations by CAG

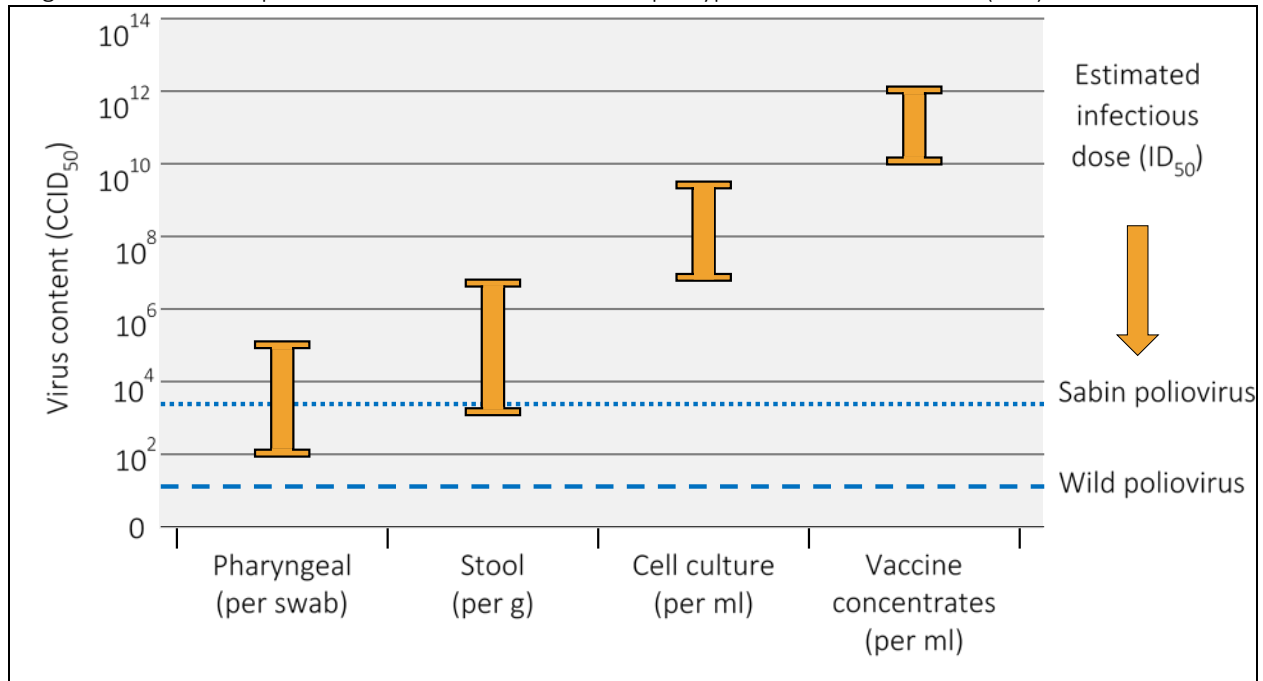


Abbreviations: NPCC: national poliovirus containment coordinator; OPV: Oral poliomyelitis vaccine; PEF: Poliovirus-essential facility; VDPV: Vaccine-derived poliovirus and WPV: Wild poliovirus.

\*As described in the WHO Global Action Plan for Poliovirus Containment, 4th ed., 2022 (GAPIV). Available at: <https://polioeradication.org/wp-content/uploads/2022/07/WHO-Global-Action-Plan-for-Poliovirus-Containment-GAPIV.pdf>

+As described in the Guidance to minimize risks for facilities collecting, handling or storing materials potentially infectious for polioviruses, 2nd ed., 2021 (PIM Guidance). Available at: <https://polioeradication.org/polio-today/preparing-for-a-polio-free-world/containment/containment-resources/>

‡WHO Global Action Plan for Poliovirus Containment – Containment Certification Scheme (CCS). Available at: [https://polioeradication.org/wp-content/uploads/2017/03/CCS\\_19022017-EN.pdf](https://polioeradication.org/wp-content/uploads/2017/03/CCS_19022017-EN.pdf)

Figure 14: Estimated poliovirus content of different sample types and infectious dose (ID<sub>50</sub>)\*

\*Estimated infectious doses (ID<sub>50</sub>) are based on studies with infants and children. Immunized adult laboratory workers are likely much more resistant than immunologically naïve children. However, dose-related resistance may be overcome by ingesting sufficient poliovirus particles

Source: Dowdle WR, Wolff C. Post-eradication poliovirus facility-associated community risks. *Biologicals*. 2006 Jun;34(2):127-32. doi: 10.1016/j.biologicals.2006.03.003. Epub 2006 May 8. PMID: 16682225.

CAG recommendations:

#### Issues Associated with the Containment of Potentially Infectious Materials, Polioviruses

6. The following are the recommendations by CAG on issues associated with the containment of potentially infectious materials, polioviruses (as of CAG6, January 2023):
  - a. Due to the short window for viremia in blood, the current consideration of blood being excluded from classified as potentially infectious materials, poliovirus remains valid, unless scientific evidence suggests otherwise.
  - b. Revision of the PIM Guidance should be initiated and harmonization with Annex 6 of GAPIII, GAPIV and other relevant documents. Emphasis should be placed on raising awareness of operators in poliovirus and non-poliovirus facilities of the potential of handling materials that may contain polioviruses
  - c. The retention of potentially infectious materials, WPV/VPV are exempt from the requirements of GAPIV but should be subject to WPV/VPV Guidance which is to be developed involving risk categorization (sample type and work) with mitigation measures recommended for the different risk categories.
  - d. An accountability framework for facility compliance against the risk mitigation strategies for the retention of potentially infectious materials, polioviruses to be developed under the responsibility of the national poliovirus containment coordinator (NPCC) for reporting through the certification commissions in the short-term

- e. Immunization coverage- and environmental- safeguard requirements should be put in-place for facilities retaining potentially infectious materials, poliovirus as described in GAPIV. The compliance responsibility is to be assigned to the NPCC, in the short-term.
- f. Issues of longer-term such as the containment requirements of potentially infectious materials, polioviruses in the post-OPV cessation period (when all live polioviruses are expected to be contained) will be deliberated by CAG at a later date .

[CAG recommendations on issues associated with the containment of potentially infectious materials, polioviruses do not constitute change in the relevant GAPIV text or section, at present. Relevant changes will be made following the implementation of these recommendations]

Post-meeting notes on CAG recommendations for issues associated with the containment of potentially infectious materials, polioviruses

The Guidance Development Group (GDG) was previously established for the development of the Guidance for non-poliovirus facilities to minimize risk of sample collections potentially infectious for polioviruses, 1st edition, 2018 (PIM Guidance 2018) has been reconstituted to support the implementation of CAG recommendations on issues associated with the retention of potentially infectious materials, polioviruses made at CAG6, January 2023.

The implementation of these recommendations is expected to begin in the second quarter of 2023 with an end-date expected by the Eight Meeting of the Poliovirus Containment Advisory Group (CAG8) planned for December 2023 for endorsement purposes by CAG.

The GDG is chaired by a member of CAG, supported by the secretariat of CAG and includes the following representation:

1. Polioviruses – Global Polio Laboratory Network
2. Rotavirus - Global Rotavirus Laboratory Network (GRLN)
3. Measles, Mumps and Rubella - Global Measles and Rubella Laboratory Network (GMRLN)
4. Influenza - Global Influenza Surveillance and Response System (GISRS)
5. Bacterial diseases - Global Invasive Bacterial Vaccine-Preventable Diseases (IB-VPD) Laboratory Network
6. COVID-19 diseases - WHO COVID-19 Reference Laboratory Network
7. African Society of Laboratory Medicine (ASLM) due to the VDPV samples collected in the context of ongoing outbreaks of cVDPV2 and COVID-19.

Session: Technical Issues Associated with Facility Containment Implementation

Technical Issues Associated with Facility Containment Implementation

Dr Harpal SINGH, Technical Officer and Secretariat of the Poliovirus Containment Advisory Group (CAG), Poliovirus Containment, Department of Polio Eradication, WHO headquarters in Geneva, SWITZERLAND

A summary of issues associated with facility containment implementation submitted to the CAG by NACs for deliberation and recommendations were presented to the CAG. These issues were: (by the biorisk management element in GAPIV)

Element No 8: Facility Physical Requirements

1. Poliovirus-dedicated and non-dedicated laboratories
  2. Kill-tanks within the containment perimeter
- Element 10 Poliovirus Inventory and Information
3. Storage outside the containment perimeter
- Element 11 Waste Management, Decontamination, Disinfection and Sterilization
4. Management of poliovirus facility waste across the containment perimeter

Considering the need for in-depth deliberations and discussions by the CAG, it was recommended that a teleconference be organized as follow-up from CAG6 (Post-CAG6 TC1) in mid-February 2023 to discuss these issues.

The Report of the Teleconference of the Poliovirus Containment Advisory Group on Technical Issues Associated with Facility Containment Implementation following the Sixth Meeting of the Poliovirus Containment Advisory Group (CAG6) (Post-CAG6 TC1), 17 February 2023, 1500 – 1630 (CET) is available at: <https://polioeradication.org/tools-and-library/policy-reports/advisory-reports/containment-advisory-group/>

### Session: Issues Associated with the Functioning of the CAG

#### Issues Associated with the Functioning of the CAG

Professor David HEYMANN, Chair of the Poliovirus Containment Advisory Group (CAG)  
Dr Harpal SINGH, Technical Officer and Secretariat of the Poliovirus Containment Advisory Group (CAG),  
Poliovirus Containment, Department of Polio Eradication, WHO headquarters in Geneva, SWITZERLAND

CAG recommendations:

#### Issues Associated with the Functioning of the CAG

##### Terms of reference of CAG

7. CAG acknowledged the updated terms of reference (as of April 2022)<sup>61</sup> which was revised to conform with WHO corporate policies for advisory groups and to include the oversight function of CAG for containment issues and documents following the transfer of oversight function from SAGE in 2018.

##### Next meeting and teleconferences

8. CAG members agreed that the Seventh Meeting of the Poliovirus Containment Advisory Group (CAG7) be held on 15 and 16 June 2023.
9. CAG members agreed to participate in a Post-CAG6 Teleconference in early February 2023 to discuss technical issues associated with facility containment implementation pending CAG recommendation and requested that Doodle poll be sent out by the CAG Secretariat.

##### Other matters

10. CAG recommends that a review of the implementation of CAG6 recommendations be conducted at the next CAG meeting i.e., CAG7, 15 – 16 June 2023.

---

<sup>61</sup>Terms of reference of CAG (as of April 2022) is available at: <https://polioeradication.org/wp-content/uploads/2022/06/CAG-TORs-20220430.pdf>. The updated TORs include oversight function for containment. See Page 2; Section: Function; 'No. 5 Oversight function for issues related to poliovirus containment and containment documents e.g., WHO Global Action Plan for Poliovirus Containment, CCS, PIM guidance, etc., including the endorsement of these documents, when needed'.

Annexes

- Annex 1 Sixth Meeting of the Poliovirus Containment Advisory Group (CAG6), 23 – 25 January 2023
  - Annex 1.1 Meeting objectives
  - Annex 1.2 Agenda
  - Annex 1.3 List of Participants
- Annex 2 Global Polio Eradication Program Update with Chairs of Advisory- and Working- Groups Supporting Polio Eradication and Containment and Representatives of the GPEI Global Programme Support Groups, 23 – 24 January 2023
  - Annex 2.1 Meeting objectives
  - Annex 2.2 Agenda
  - Annex 2.3 List of Participants

Annex 1.1: Meeting objectives



Sixth Meeting of the Poliovirus Containment Advisory Group (CAG6)

Date: 24 and 25 January 2023

Time: 1400 – 1700 (24 January) and 0830 – 1700 (25 January) (CET)

Venue: Meeting Room L018, Ground Floor, Building LII, WHO headquarters, 20 Avenue Appia, 1211 Geneva 27, SWITZERLAND

(Remote Participation: Zoom – only for invited observers)

Meeting Objectives

1. To present to CAG pending issues from the revision of GAPIII, or those associated with the implementation of GAPIV and other issues associated with the implementation of poliovirus containment for discussion and recommendation. These include:
  - a. Routine environmental surveillance in areas surrounding the PEF.
  - b. Status of the 'temporary waiver' granted by CAG previously for the use of novel poliovirus strains for specific use based on availability of newer data.
  - c. Issues associated with performing- and evaluating- risk assessments from facilities that vary in location, work, type, viruses used, etc.
  - d. Issues associated with potentially infectious materials, polioviruses including the containment requirements for their retention in the short- and longer-term, accountability framework, safeguard requirements, etc.
  - e. Other issues associated with the 14 Biorisk Management Elements of GAPIV
2. To present to CAG, evidence used to establish recommendations for facility-, immunization coverage- and environmental control- safeguards in and around facilities retaining polioviruses and where needed, the proposed way forward in determining the appropriate thresholds for effective safeguards aimed at minimizing risk- and consequences- of a facility-associated release of polioviruses for discussion, recommendation and consensus.
3. To discuss administrative issues associated with the effective functioning of CAG including updated TORs (as of April 2022), memberships and rotation-off policy, potential dates for next TCs, as needed, and dates for next CAG meeting, etc.
4. To discuss any other issue associated with the implementation of poliovirus containment or the mandate of CAG

24 January 2023: For Discussion and CAG Recommendation

Time	Agenda Topic	Reference Doc No	Purpose and Expected Outcome(s) of Item, And Questions for CAG	Duration
Session: Introduction			Session Chair: Professor David HEYMANN, Chair of CAG	
1400 - 1410	Opening and welcome  Opening: Professor David HEYMANN, Chair of CAG 5 min Mr Aidan O'LEARY, Director, Polio Eradication, WHO. 5 min	Verbal	Opening of the Plenary Meeting.	10 min.
1410 - 1430	Meeting objectives, summary issues for discussion and recommendations, rules of procedures for CAG meetings, declaration of interest, invited observers/presenter, etc.  Dr Harpal SINGH, Technical Officer, Containment and CAG Secretariat, Polio Eradication, WHO.	Verbal, DOC. 1, DOC. 2	Brief overview of the meeting objectives and expected outcomes, agenda structure, reminder of the rules of procedures for CAG meetings and list of invited observers will be shared. CAG members and other participants are requested to inform the CAG secretariat if there has been a change in circumstances requiring a new declaration of interest.	20 min
Session 3: Sustaining Safe and Secure Poliovirus Containment with Evidence-based Safeguards			Session Chair: Professor David HEYMANN, Chair of CAG	
1430 - 1515	Evidence to establish recommendations on facility-, immunization coverage- and environmental control- safeguards around facilities retaining polioviruses in GAPIV  Dr Harpal SINGH, Technical Officer, Containment and CAG Secretariat, Polio Eradication, WHO.	DOC. 3	<u>For discussion and recommendation:</u> This presentation will describe the evidence, wherever available, for facility-, immunization coverage- and environmental control- safeguards used as basis in the requirements in GAPIV. Where needed, the proposed way forward in determining the appropriate thresholds for effective safeguards aimed at minimizing risk- and consequences- of a facility-associated release of polioviruses will be presented for discussion, recommendation and consensus. These include: <ul style="list-style-type: none"> <li>determination of coverage and dose requirements, and environmental control parameters and their combination</li> <li>role of routine environmental surveillance and its impacts on confidence of no detection of polioviruses in areas surrounding the PEFs</li> <li>hierarchy, if any of effectiveness or importance of the different safeguards in minimizing the risk- or mitigating the consequences- of a facility-associated release of poliovirus</li> </ul>	45 min.
1515 – 1530	Discussion (Part 1)			15 min.



Time	Agenda Topic	Reference Doc No	Purpose and Expected Outcome(s) of Item, And Questions for CAG	Duration
	Professor David L HEYMANN, Chair of CAG.			
1530 – 1540	Coffee break			10 min.
1540 – 1600	Discussion (Part 2)			20 min.
	Professor David L HEYMANN, Chair of CAG.			
1600 – 1615	Conclusions and way forward on determining the appropriate thresholds for effective safeguards aimed at minimizing risk- and consequences- of a facility-associated release of polioviruses:	Verbal		15 min.
	Professor David L HEYMANN, Chair of CAG. Dr Harpal SINGH, Technical Officer, Containment and CAG Secretariat, Polio Eradication, WHO.			
1615 - 1630	Environmental surveillance in areas surrounding the poliovirus-essential facility as environmental control safeguards.	DOC. 3	<u>For discussion and recommendation:</u> To determine the role of routine environmental surveillance and its impacts on confidence of no detection of polioviruses in areas surrounding the PEFs. As this is not currently a requirement in GAPIV, CAG is requested to determine if such a measure should be made a requirement especially in the post-eradication and post-cessation periods.	20 min.
	Dr Harpal SINGH, Technical Officer, Containment and CAG Secretariat, Polio Eradication, WHO.			
1630 - 1650	Discussion and Recommendation			20 min
	Professor David L HEYMANN, Chair of CAG.			
1650 - 1700	Overview of issues for CAG deliberation and recommendations for 25 January 2023	Verbal		15 min.
	Dr Harpal SINGH, Technical Officer, Containment and CAG Secretariat, Polio Eradication, WHO			
1700 - 1710	Closing Day 1 of CAG6	Verbal		10 min.
	Mr Aidan O'LEARY, Director, Department of Polio Eradication, WHO headquarters. 5 min.			
	Professor David L HEYMANN, Chair of CAG. 5 min.			

Time	Agenda Topic	Reference Doc No	Purpose and Expected Outcome(s) of Item, And Questions for CAG	Duration
0830 – 0900	Welcome Coffee			30 min.
Session 3: Sustaining Safe and Secure Poliovirus Containment with Evidence-based Safeguards			Session Chair: Professor David HEYMANN, Chair of CAG	
0900 - 0910	Administrative announcements, if any.	Verbal		10 min.
0910 - 0930	Status of the 'temporary waiver' granted by CAG previously for the use of novel poliovirus strains for specific use based on availability of newer data.  <ul style="list-style-type: none"> <li>Genetic stability of nOPV2. 15 mins.</li> </ul> <p>Dr Mark PALLANSCH, Member, CAG and Chair of the CAG – Expert Support Group on Novel Poliovirus Strains</p>		<u>For discussion and recommendation:</u> The review of available newer data on genetic stability of nOPV2 and inputs to CAG by CAG -ESG to determine the status of the 'temporary waiver' (continue/discontinue).	20 min
0930 – 0950	Discussion and Recommendation  Professor David L HEYMANN, Chair of CAG.			20 min.
0950 - 1010	Issues associated with performing- and evaluating- risk assessments from facilities that vary in location, work, type, viruses used, etc.  Dr Harpal SINGH, Technical Officer, Containment and CAG Secretariat, Polio Eradication, WHO.	DOC. 6	<u>For discussion and guidance:</u> With the shift towards a risk-based approach in GAPIV and the ongoing implementation of the interim certificate of containment phase, the implementation of risk assessments to determine alternative measures of compliance or risk mitigation measures are expected to create variation in methodologies used for risk assessments and their implementation as well as the evaluation of these reports. Request is being made to CAG to provide guidance on standardization or harmonization of implementing risk assessments and their evaluation e.g., minimum set of questions to be answered, etc. Proposed way forward in addressing this issues will be presented for consensus from CAG.	20 min.
1010 - 1040	Discussion and Recommendation  Professor David L HEYMANN, Chair of CAG.			30 min.
1040 – 1050	Coffee break			10 min.
1050 - 1120	Conformity Assessment Activities During the Transition Period from the WHO Global Action Plan	DOC. 7	<u>For endorsement:</u> The secretariat has developed the guidance paper addressing the implementation of	30 min.

Time	Agenda Topic	Reference Doc No	Purpose and Expected Outcome(s) of Item, And Questions for CAG	Duration
	for Poliovirus Containment 3rd ed, 2015 (GAPIII) to the WHO Global Action Plan for Poliovirus Containment, 4th ed, 2022 (GAPIV)		conformity assessment activities during the transition period from GAPIII to GAPIV. This document is in line with the principles of the Containment Certification Scheme (CCS) where relevant, for the issuance of an interim certificate of containment (ICC) to a facility holding a valid GCC-countersigned Certificate of Participation (CP) and is applicable only during the overall allowable transition period of three years from the date of the publication of GAPIV i.e., 1 July 2022 to July 2025. The secretariat request CAG members to discuss the contents of this guidance for purposes of its endorsement.	
1120 - 1150	Discussion and Endorsement  Professor David L HEYMANN, Chair of CAG.			30 min.
1150 - 1230	Issues associated with the retention requirement of potentially infectious materials, polioviruses (Part 1) and Discussion  Dr Harpal SINGH, Technical Officer, Containment and CAG Secretariat, Polio Eradication, WHO.	DOC. 8	This session will begin by providing a brief background and evolution of issues associated with the handling of potentially infectious materials, polioviruses, that have been raised from the First CAG meeting till date. This briefing is to prepare CAG members for the in-depth discussions on these issues for recommendation.  <u>For discussion and recommendation:</u> Issues associated with potentially infectious materials, polioviruses have been raised by CAG, other stakeholders e.g., NAC, over the course of the revision process of GAPIII and at CAG5. In line with the TORs of CAG, these issues require further deliberations and recommendations. Pending issues: <ul style="list-style-type: none"><li>● Issue 1: To update the 'biorisk management standard for safe handling of new samples potentially containing poliovirus material in poliovirus-non-essential facilities' (previously, Annex 6 of GAPIII)' in-line with GAPIV the WHO LBM4 and, GPLN Guidance Paper 1 for safe handling and storage of type 2 poliovirus (PV2) in GPLN laboratories, and harmonization and incorporation in the PIM Guidance.</li></ul>	40 min.
1230 - 1330	Lunch			60 min.

Time	Agenda Topic	Reference Doc No	Purpose and Expected Outcome(s) of Item, And Questions for CAG	Duration
1330 - 1400	<p>Issues associated with the retention requirement of potentially infectious materials, polioviruses (Part 2) and Discussion</p> <p>Dr Harpal SINGH, Technical Officer, Containment and CAG Secretariat, Polio Eradication, WHO.</p>	DOC. 8	<ul style="list-style-type: none"> <li>● Issue 2: Containment requirements for handling of potentially infectious materials, WPV/VDPV</li> <li>● Issue 3: Accountability framework for facilities expected to implement the risk mitigation strategies for <b>the</b> retention of potentially infectious materials, Sabin/OPV described in the PIM Guidance</li> <li>● Issue 4: Containment requirements for the retention of potentially infectious materials, polioviruses in the post-OPV cessation period when all poliovirus materials are expected to be fully contained</li> <li>● Issue 5: Safeguard requirements for facilities retaining potentially infectious materials, polioviruses (Sabin)</li> </ul> <p>Submitted issue:</p> <ul style="list-style-type: none"> <li>● Sample types of potentially infectious materials, polioviruses (blood)</li> </ul>	30 min.
1400 - 1420	<p>Risk-based approach in addressing the retention of potentially infectious materials, polioviruses and country-level challenges associated with facilities retaining potentially infectious materials, polioviruses in the US</p> <p>Dr Lia Haynes SMITH, US National Poliovirus Containment Coordinator (NPCC) and Director, US National Authority for Containment of Poliovirus (US NAC), CDC, Atlanta, Georgia, USA</p>		<p><u>For information:</u> Risk mitigation measures should be aligned with the actual risk of the different sample types of potentially infectious materials, polioviruses. The handling of all potentially infectious materials, polioviruses were previously subject to GAPIII requirements resulting in concerns raised by stakeholders of non-evidence-based and burdensome requirements. The risk stratification approach used in the PIM Guidance (sample type and type of manipulation) provided flexibility by introducing risk mitigation measures aligned to the actual risk of the sample (potentially infectious materials, OPV/Sabin only). To address the concerns raised by stakeholders, a risk-based approach is in place addressing the retention of potentially infectious materials, polioviruses. This presentation will also describe national challenges in addressing the large number of facilities intending to retain potentially infectious materials, polioviruses.</p>	20 min.
1420 – 1450	<p>Discussion, recommendation and consensus on the way forward</p> <p>Professor David L HEYMANN, Chair of CAG.</p>			30 min.
1500 - 1510	Coffee break			10 min.

Time	Agenda Topic	Reference Doc No	Purpose and Expected Outcome(s) of Item, And Questions for CAG	Duration
1510 - 1610	<p>Other issues associated with the implementation of 14 Biorisk Management Elements of GAPIV.</p> <p>Dr Harpal SINGH, Technical Officer, Containment and CAG Secretariat, Polio Eradication, WHO.</p> <hr/> <p>Discussion and recommendations</p> <p>Professor David L HEYMANN, Chair of CAG.</p>	DOC. 9.	<p><u>For discussion and recommendation:</u> the following issues have been submitted to CAG for recommendation:</p> <ul style="list-style-type: none"> <li>● poliovirus dedicated or non-dedicated facilities</li> <li>● appropriate containment conditions for storage outside containment</li> <li>● kill-tank rooms and the containment perimeter</li> <li>● transport of infectious materials, poliovirus waste across the containment perimeter</li> </ul>	60 min.
Session 4: Issues associated with the functioning of CAG		Session Chair: Professor David HEYMANN, Chair of CAG		
1610 – 1620	<p>Revision in the TORs of CAG (as of April 2022)</p> <p>Dr Harpal SINGH, Technical Officer, Containment, Polio Eradication, WHO</p>	DOC. 10	<p><u>For information:</u> The TORs of CAG were revised to be compliant with WHO corporate policies and to include the transfer of oversight function from SAGE to CAG on containment issues and containment documents.</p>	10 min.
1620 – 1640	<p>Discussions on CAG membership and rotation-off policy</p> <p>Professor David L HEYMANN, Chair of CAG.</p>			20 min.
1640 – 1650	<p>AOB</p> <p>Dr Harpal SINGH, Technical Officer, Containment, Polio Eradication, WHO</p>			10 min.
Session: Closing		Session Chair: Professor David HEYMANN, Chair of CAG		
1650 – 1700	<p>Closing</p> <p>Mr Aidan O'LEARY, Director, Department of Polio Eradication, WHO headquarters.</p> <p>Professor David L HEYMANN, Chair of CAG.</p>			10 min.

## Annex 1.3: List of Participants

## Sixth Meeting of the Poliovirus Containment Advisory Group (CAG6)

Date: 24 and 25 January 2023

Time: 1400 – 1700 (24 January) and 0830 – 1700 (25 January) (CET)

Poliovirus Containment Advisory Group (CAG)	
1.	Professor David HEYMANN Chair, Containment Advisory Group and Professor of Infectious Disease Epidemiology, London School of Hygiene and Tropical Medicine, London, UNITED KINGDOM OF GREAT BRITAIN AND NORTHERN IRELAND.
2.	Dr Mark PALLANSCH Chair, Containment Management Group; Chair, CAG – Expert Support Group for Novel Poliovirus Strains; and Centres for Disease Control and Prevention, Atlanta, Georgia, UNITED STATES OF AMERICA
3.	Professor Shahina TABASSUM Professor and Chairman, Department of Virology, Bangabandhu Sheikh Mujib Medical University (BSMMU), Dhaka, PEOPLE'S REPUBLIC OF BANGLADESH
4.	Dr Atef M ELGENDY (Unable to attend) Former Head, Bacteriology Section and Biological Safety Coordinator, United States Naval Medical Research Unit (NAMRU-3), Cairo, ARAB REPUBLIC OF EGYPT
5.	Professor George E GRIFFIN Emeritus Professor of Infectious Diseases and Medicine, St George's University of London, London, UNITED KINGDOM OF GREAT BRITAIN AND NORTHERN IRELAND.
6.	Dr Jagadish DESHPANDE (Virtual participation) Member, National Authority for Containment of India, Mumbai, REPUBLIC OF INDIA
7.	Dr Åsa Szekely BJORN DAL Chair, National Authority for Containment of Sweden and Senior Expert Advisor/Specialist; Biosafety Professional and Microbiologist, Department of Microbiology, Public Health Agency of Sweden (PHAS), Solna, KINGDOM OF SWEDEN
8.	Dr Janice LO Public Health Laboratory Services Branch, Centre for Health Protection, Department of Health, HONG KONG SPECIAL ADMINISTRATIVE REGION OF THE PEOPLE'S REPUBLIC OF CHINA.
9.	Dr Stephen McADAM Global Healthcare Director, DNV GL Business Assurance, Oslo, KINGDOM OF NORWAY
Poliovirus Containment Advisory Group (CAG) (Continued)	
10.	Dr Vibeke HALKJÆR-KNUDSEN Former, Principal Member of Technical Staff, Engineering Program/Project Lead, International Biological and Chemical Threat Reduction Program (SNL/IBCTR), Sandia National Laboratories, Albuquerque, New Mexico, UNITED STATES OF AMERICA
11.	Mr Kenneth UGWU Senior Biocontainment Advisor, Global Affairs Canada, Ottawa, Ontario, CANADA

Representatives of Other Containment Supporting Groups	
1.	Dr Arlene KING Chair, Global Commission for the Certification of the Eradication of Poliomyelitis - Containment Working Group (GCC – CWG), Member, GCC and Chair, Regional Commission for the Certification of the Eradication of Poliomyelitis of the Americas, Toronto, Ontario, CANADA
Observers (Selected Presenters)	
1.	Dr Lia HAYNES SMITH US National Poliovirus Containment Coordinator (NPCC) and Director, US National Authority for Containment of Poliovirus (US NAC), CDC, Atlanta, Georgia, USA
2.	Mr Brian SHELBY, Auditor, US National Authority for Containment of Poliovirus (US NAC), CDC, Atlanta, Georgia, USA
Department of Polio Eradication, WHO headquarters in Geneva	
1.	Mr Aidan O'LEARY Director, Polio Eradication, WHO headquarters in Geneva, SWITZERLAND
2.	Ms Caroline NAKANDI Assistant to the Team, Containment, Polio Eradication, WHO headquarters in Geneva, SWITZERLAND
CAG Secretariat	
1.	Dr Harpal SINGH Technical Officer, Containment and CAG Secretariat, Polio Eradication, WHO headquarters in Geneva, SWITZERLAND
2.	Mr Derek EHRHDART Senior Technical Adviser, Polio Eradication, WHO headquarters in Geneva, SWITZERLAND
Meeting Rapporteur	
1.	Ms Kailing Marcus, kailing.marcus@unige.ch Epidemiologist, Institute of Global Health, Faculty of Medicine, University of Geneva, SWITZERLAND



Global Polio Eradication Program Update with Chairs of Advisory- and Working- Groups Supporting Polio Eradication and Containment and Representatives of GPEI Global Programme Support Groups

Date: 23 to 24 January 2023

Time: 0830 – 1700 (23 January) and 0830 – 1300 (24 January) (CET)

Hybrid Meeting: In-person: Meeting Room M505, 5th Floor, Building M, World Health Organization (WHO) headquarters, 20 Avenue Appia, 1211 Geneva 27, SWITZERLAND and Remote: Zoom (Virtual participation)

## Meeting Objectives

To exchange information including updates and progress in the workstreams of the different advisory- and working- groups supporting polio eradication and poliovirus containment and GPEI Global Programme Support Groups<sup>62</sup>, to ensure alignment and raising awareness of the areas of work undertaken by the different strategic bodies in line with the Polio Eradication Strategy 2022-2026: Delivering on a Promise. These include:

- Current epidemiology of poliovirus transmission
- Global progress in containment implementation and certification
- Global poliomyelitis immunization update
- Outcome from review period needed to certify the interruption of WPV1 transmission and criteria for the validation of absence of cVDPV
- Criteria used by IHR Emergency Committee for continued recommendation of a Public Health Emergency International Concern (PHEIC)
- Role and geographical coverage of environmental surveillance
- Outbreak response of countries to ongoing cVDPV outbreaks
- Long-term projections for polio vaccine supply by type of vaccine
- New products in the pipeline for vaccine, diagnostics and treatment
- nOPV2 programmatic update and update on long-term nOPV2 genetic stability
- Independent views on polio eradication and containment
- Evidence to establish recommendations on immunization coverage and environmental control safeguards around facilities retaining polioviruses
- Safeguard requirements for facilities retaining potentially infectious materials, polioviruses

---

<sup>62</sup>These include: Poliovirus Containment Advisory Group (CAG), Global Commission for the Certification of the Eradication of Poliomyelitis (GCC), GCC – Containment Working Group (GCC – CWG), Poliovirus IHR Emergency Committee, Independent Monitoring Board (IMB), Transition IMB (TIMB), Strategic Advisory Group of Experts on immunization (SAGE), SAGE working group on polio, GPEI nOPV Working Group, GPEI Vaccine Supply Group (VSG) and GPEI Surveillance Group.



Annex 2.2: Agenda

23 January 2023 (Day 1): For Information and Update

Time	Agenda Topic	Reference Doc No	Purpose and Expected Outcome(s) of Item, And Questions for CAG	Duration
0830 – 0900	Welcome Coffee			30 min.
Session: Introduction		Session Chair: Professor David HEYMANN, Chair of CAG		
0900 - 0910	Opening and welcome  Opening: Professor David HEYMANN, Chair of CAG 5 min Mr Aidan O’LEARY, Director, Polio Eradication, WHO. 5 min	Verbal	Opening of the Plenary Meeting.	10 min.
0910 - 0925	Self-introduction		Self-introduction of participants.	15 min.
0925 - 0935	Meeting structure, objectives and expected outcomes, list of invited observers/presenters, etc.  Dr Harpal SINGH, Technical Officer, Containment and CAG Secretariat, Polio Eradication, WHO.	Verbal, DOC. 1, DOC. 2. and DOC. 3.	Brief overview of the meeting objectives and expected outcomes, agenda structure, background documents and list of invited observers will be shared. Participants are requested to inform the CAG secretariat if there has been a change in circumstances requiring a new declaration of interest.	10 min.
0935 – 0950	Group photo		Photo session will take outside Room M505	15 min.
Session 1: Update on Polio Eradication and Poliovirus Containment		Session Chair: Professor David HEYMANN, Chair of CAG		
0950- 1020	Current epidemiology of poliovirus transmission and progress with ongoing implementation of the Polio Eradication Strategy 2022 – 2026: Delivering on a Promise. 20 min.  Mr Aidan O’LEARY, Director, Polio Eradication, WHO	DOC. 4	<u>For information and update:</u> Develop a shared understanding of the progress made towards interruption of WPV1 transmission and stopping of cVDPV outbreaks (Goal 1 and 2 of current eradication strategy) including the current trajectory in progress with milestones (Fig 2 and 5 of current eradication strategy), process towards certification of polio eradication and validation of absence of VDPV including the thresholds needed to meet these milestones. Containment considerations in the overall eradication programme and certification of eradication will also be included.	30 min.
1020 - 1040	WHO Containment Programme Update  Mr Derek EHRHARDT, Senior Technical Adviser, Containment on behalf of the Poliovirus Containment Team, WHO headquarters in Geneva, SWITZERLAND: <ul style="list-style-type: none"> <li>• Dr Nicoletta PREVISANI, Technical Officer, Containment</li> <li>• Ms Liliane BOULAM, Technical Officer, Containment; Co-Chair, Containment Management Group (CMG) and GCC – CWG Secretariat, WHO</li> </ul>	DOC. 5 and DOC. 6	<u>For information and update:</u> Introduction to the recently published Global Poliovirus Containment Strategy and Action Plan, and other associated documents and plans for its implementation, planned revision of other guidance documents e.g., CCS, PIM Guidance, etc. Support to national stakeholders for GAPIV implementation or oversight, implementing CCS, etc. Also included: global progress with poliovirus survey, inventory and destruction activities and verification, if any and containment certification (as per WHA	20 min.

Time	Agenda Topic	Reference Doc No	Purpose and Expected Outcome(s) of Item, And Questions for CAG	Duration
	<ul style="list-style-type: none"> <li>• Dr Harpal SINGH, Technical Officer, Containment and CAG Secretariat, WHO.</li> <li>• Mr Joseph SWAN, Communications Officer, Resource Mobilization &amp; Communications, WHO.</li> <li>• Ms Caroline NAKANDI, Assistant to the Team, Containment.</li> </ul>		71.16). An update on the latest recommendations made by the GCC to sustain containment certification efforts by Member States will be shared as well as their implications in meeting the timelines and milestones in the Global Poliovirus Containment Strategy and containment criteria for the certification of eradication previously determined by GCC.	
1040 - 1050	Coffee Break			10 min.
1050- 1120	Discussion  Professor David L HEYMANN, Chair of CAG.			30 min.
1120 – 1140	Global immunization update with a focus on poliomyelitis immunization  Mrs Diana CHANG BLANC, Team Lead, Programme Strengthening, Essential Programme on Immunization, Department of Immunization, Vaccines and Biologicals (IVB), WHO		<u>For information and update:</u> An update on global poliomyelitis immunization will be presented with specific focus on global: zero-dose children, IPV coverage, number of IPV doses and pockets of unimmunized population (as per WUENIC data). This presentation is in the context of the recent outbreaks of cVDPV in high-income countries where there is high IPV coverage and response strategies using IPV only (no OPV).	20 min.
Session 2: Updates from other groups supporting polio eradication and poliovirus containment			Session Chair: Professor David HEYMANN, Chair of CAG	
1140 - 1210	Outcome from review of the period needed to certify the interruption of WPV1 transmission and criteria for the validation of the absence of cVDPV  Professor David SALISBURY, Chair, Global Commission for the Certification of the Eradication of Poliomyelitis (GCC)	DOC. 7	<u>For information and update:</u> Findings from three modelling studies used to guide recommendations from Expert Working Group tasked to review the period needed to certify the interruption of transmission of WPV1 . Final recommendation made by GCC on the period needed to certify the interruption of WPV1 transmission. Findings from the recently concluded meeting of the Expert Working Group on the criteria for validation of absence of cVDPVs and final recommendation made by GCC on this issue, the body responsible for this work, etc.	30 min.
1210 - 1240	Discussion Professor David L HEYMANN, Chair of CAG.			30 min.
1240 – 1340	Lunch			60 min.

Time	Agenda Topic	Reference Doc No	Purpose and Expected Outcome(s) of Item, And Questions for CAG	Duration
1340 - 1400	<p>Criteria used by IHR Emergency Committee for continued recommendation of a Public Health Emergency International Concern (PHEIC)</p> <p>Professor Helen REES, Chair, Polio IHR Emergency Committee (EC)</p>	DOC. 8	<p><u>For information and update:</u> Rationale, background and criteria used by the Polio IHR EC on the continued risk of international spread of poliovirus thus considered a PHEIC, concerns on lengthy polio PHEIC, alternatives being considered in line with IHR, if any.</p>	20 min.
1400 - 1430	<p>Independent views on polio eradication and containment</p> <p>Professor Sir Liam DONALDSON, Chair, Independent Monitoring Board (IMB).</p>	DOC. 9	<p><u>For information and update:</u> The IMB provides an independent assessment of the progress being made by GPEI in the detection and interruption of poliovirus transmission globally. This presentation will cover independent views on the progress and most crucial gaps within the eradication programme including containment.</p>	30 min.
1430 - 1500	<p>Discussion</p> <p>Professor David L HEYMANN, Chair of CAG.</p>			30 min.
1500 - 1510	Coffee break			10 min.
1510 - 1550	<p>nOPV2 programmatic update and milestones. 20 min.</p> <p>Ms Simona ZIPURSKY, Special Adviser to Director Polio Eradication and Chair of GPEI nOPV Working Group, Polio Eradication, WHO</p> <p>Update on long-term nOPV2 genetic stability. 20 min.</p> <p>Dr Javier MARTIN, Director, WHO Global Specialized Polio Laboratory, National Institute for Biological Standards and Control (NIBSC), Potters Bar, Hertfordshire, UNITED KINGDOM and Co-Chair, nOPV Genetic Characterization Subgroup of the GPEI nOPV Working Group.</p> <p>Virtual participation:</p> <ul style="list-style-type: none"> <li>● Dr Ananda S BANDYOPADHYAY, Deputy Director, Technology, Research, and Analytics, Polio Team, Bill &amp; Melinda Gates Foundation, Seattle, Washington, USA and GPEI nOPV Working Group</li> <li>● Dr Cara BURNS, Team Lead, Molecular Epidemiology and Surveillance Laboratory, Division of Viral Diseases, Centers for Disease Control and Prevention (CDC), Atlanta, Georgia, USA</li> </ul>		<p><u>For information and update:</u> Updates on status of nOPV2 roll-out, deployment, findings to support the use of nOPV2 towards achieving eradication and containment consideration of nOPV2 use in outbreak response and handling of PIM, nOPV2, development of nOPV1 and 3. nOPV2 isolates detected through AFP and ES till date, nucleotides changes, concerns, impact of nOPV2 use in SIAs and in comparison with mOPV2, evidence availability to provide assurance on nOPV2 genetic stability.</p>	40 min.

Time	Agenda Topic	Reference Doc No	Purpose and Expected Outcome(s) of Item, And Questions for CAG	Duration
	<p>and nOPV2 Genetic Characterization Subgroup of the GPEI nOPV2 Working Group</p> <ul style="list-style-type: none"> <li>• Mr Feyrouz KURJI, Principal Consultant, FDK Consulting LLC, Kirkland, Washington, USA and Coordinator of GPEI nOPV Working Group</li> <li>• Ms Kaija HAWES, Associate Program Officer, Technology, Research, and Analytics, Polio Team, Bill &amp; Melinda Gates Foundation, Seattle, Washington, USA and Coordinator of nOPV Genetic Characterization Subgroup of the GPEI nOPV2 Working Group</li> </ul>			
1550 – 1610	<p>New products in pipeline for polio vaccine, diagnostics and treatment.</p> <p>Dr Martin EISENHAWER, Scientist, Research and Development, Polio Eradication, WHO</p>		<p><u>For information and discussion:</u> Brief landscape presentation of the different initiatives undertaken : VLP, mAB and antivirals</p>	20 min.
1610 - 1640	<p>Discussion</p> <p>Professor David L HEYMANN, Chair of CAG.</p>			30 min.
1640 – 1710	<p>Open forum for exchange of information, update and discussions on polio eradication and poliovirus containment issues by the Chairs of the different advisory and working groups</p> <p>Professor David L HEYMANN, Chair of CAG.</p>	Verbal	<p><u>For discussion:</u> Open discussion and exchange of information and recent developments by the different groups supporting polio eradication and poliovirus containment and their implications on achieving and sustaining safe and secure poliovirus containment and to discuss containment security moving forward.</p>	30 min.
1710 – 1720	<p>Overview of agenda topics for Day 2 (24 January 2023) and other announcements.</p> <p>Dr Harpal SINGH, Technical Officer, Containment and CAG Secretariat, Polio Eradication, WHO.</p>	Verbal		10 min.
1720 – 1730	<p>Closing Day 1</p> <p>Mr Aidan O’LEARY, Director, Department of Polio Eradication, WHO headquarters. 5 min.</p> <p>Professor David L HEYMANN, Chair of CAG. 5 min.</p>	Verbal		10 min.
1730 - 1900	Cocktail Reception		<p>This reception is open to all participants and will take place at the WHO HQ Cafeteria (Restaurant OMS), Floor SS2, Building B, WHO headquarters.</p>	90 min.

24 January 2023 (Day 2): For Information and Update

Time	Agenda Topic	Reference Doc No	Purpose and Expected Outcome(s) of Item, And Questions for CAG	Duration
0830 – 0900	Welcome Coffee			30 min.
Session 2: Updates from other groups supporting polio eradication and poliovirus containment (Continued)			Session Chair: Professor David HEYMANN, Chair of CAG	
0900 - 0920	New products in pipeline for polio vaccine, diagnostics and treatment.  Dr Martin EISENHAWER, Scientist, Research and Development, Polio Eradication, WHO		<u>For information and discussion:</u> Brief landscape presentation of the different initiatives undertaken : VLP, mAB and antivirals	20 min.
0920 – 0935	Discussion  Professor David L HEYMANN, Chair of CAG.			15 min.
0935 – 1000	Rationale for local biological risk assessment-based approach in latest WHO manual on biosafety in laboratories.  Dr Kazunobu KOJIMA, Medical Officer, Biosafety and Biosecurity, Epidemic and Pandemic Preparedness and Prevention, WHO headquarters in Geneva, SWITZERLAND	DOC 10	<u>For information and update:</u> The WHO Laboratory Biosafety Manual, 4th ed, 2020 (LBM4) is considered the de-facto global biosafety standard. In its latest version emphasizing evidence, local biological risk assessment and personnel competence, LBM4 presents a novel approach that allows each facility to take a feasible and most effective combination of risk control measures. This flexibility, as opposed to conventional equation of pathogen risk group and biosafety level, enables optimized usage of limited resources. It provides both overarching theory and practical guidance, including risk assessment. This technology-neutral approach will help attain much desired equitable, adequate and sustainable access to necessary laboratory services and life science research across all countries, without compromising safety.	25 min.
1000 - 1015	Discussion  Professor David L HEYMANN, Chair of CAG.			15 min.
1015 - 1025	Coffee break			10 min.
1025 - 1050	Role and geographical coverage of environmental surveillance.  Dr Graham TALLIS, Senior Scientific Adviser, Detection & Interruption, Polio Eradication, WHO headquarters in Geneva, SWITZERLAND; Co-Chair, GPEI Surveillance Group and Secretariat- of GCC and Poliovirus IHR Emergency Committee	DOC. 11	<u>For information and update:</u> Outcome from the implementation of the Polio Environmental Surveillance Expansion Plan (Global Expansion Plan under the Endgame Strategy 2013-2018), progress with ongoing implementation of Objective 2: Optimize the environmental surveillance network to contribute to the timely detection of polioviruses	25 min.

Time	Agenda Topic	Reference Doc No	Purpose and Expected Outcome(s) of Item, And Questions for CAG	Duration
			of the Global Polio Surveillance Action Plan 2022–2024 and global picture of ES sites (including in high-income countries). ES contribution to poliovirus surveillance systems, role in early detection, ongoing work to review ES sites e.g., desk-review in AFRO, etc., finalizing ES sites, current distribution of ES sites - map (in all countries including high-income countries), etc.	
1050 – 1105	Discussion  Professor David L HEYMANN, Chair of CAG.			15 min.
1105 - 1125	Long-term projections for polio vaccine supply by type of vaccine  Dr Vachagan HARUTYUNYAN, Team Leader, Operations, Detection and Interruption Unit, Department of Polio Eradication, WHO headquarters in Geneva, SWITZERLAND  Ms Ann E. OTTOSEN, Senior Manager, Vaccine Centre UNICEF Supply Division, Copenhagen, DENMARK  Mr David WOODS, Technical Officer, Detection and Interruption Unit, Department of Polio Eradication, WHO headquarters in Geneva, SWITZERLAND  For the GPEI Vaccine Supply Group (VSG)		<u>For information and discussion:</u> Projections done (basis and evidence) to determine polio vaccine needs and supply by the different vaccine types to ensure polio vaccine supply security. Vaccine production and QC and containment interphase. A global overview of polio vaccine supply will be presented as well as the identification of areas where supply planning and containment require interface while meeting the global need for polio vaccines. Outcomes from the Consultation between the GPEI and Polio Vaccine Manufacturers, National Authorities for Containment and National Regulatory Authorities, 11 October 2022 will also be included.	20 min.
1125 – 1140	Discussion  Professor David L HEYMANN, Chair of CAG.			15 min.
1140 - 1155	Evidence to establish recommendations on immunization coverage and environmental control safeguards around facilities retaining polioviruses  Dr Harpal SINGH, Technical Officer, Containment and CAG Secretariat, Polio Eradication, WHO	DOC 12.1.	Challenges in setting the safeguard requirements aimed to minimize the consequences of a facility-associated release of poliovirus (immunization coverage- and environmental control-safeguards).  <ul style="list-style-type: none"> <li>● safeguards effectiveness as it is currently described</li> <li>● polio vaccination coverage and doses, environmental control parameters or their combination</li> <li>● role of routine environmental surveillance in areas surrounding the PEF</li> </ul>	15 min.

Time	Agenda Topic	Reference Doc No	Purpose and Expected Outcome(s) of Item, And Questions for CAG	Duration
1155 - 1210	Safeguard requirements for facilities retaining potentially infectious materials, Sabin/OPV  Professor David L HEYMANN, Chair of CAG.	DOC 12.2	The impact of the lack of immunization coverage or environmental control safeguards for facilities retaining PIM, Sabin and the current lack of an accountability framework to ensure compliance with the biorisk management requirements for the retention of PIM, Sabin during the current/pre-OPV cessation period and post-OPV cessation period will vary greatly in minimizing the risk or consequence of a poliovirus release from such a facility.	15 min.
1210 - 1225	Discussion  Professor David L HEYMANN, Chair of CAG.			15 min.
1225 - 1245	Open forum for discussion on all previous topics  Professor David L HEYMANN, Chair of CAG.	Verbal	<u>For discussion:</u> Open discussion and exchange of information and recent developments by the different groups supporting polio eradication and poliovirus containment and their implications on achieving and sustaining safe and secure poliovirus containment and to discuss containment security moving forward.	20 min.
1245 - 1300	Closing  Mr Aidan O'LEARY, Director, Department of Polio Eradication, WHO headquarters.  Professor David L HEYMANN, Chair of CAG.			15 min.
1300 - 1400	Lunch			60 min.

Annex 2.3: List of Participants

Global Polio Eradication Program Update with Chairs of Advisory- and Working- Groups Supporting Polio Eradication and Containment and Representatives of GPEI Global Programme Support Groups

Date: 23 to 24 January 2023

Time: 0830 – 1700 (23 January) and 0830 – 1300 (24 January) (CET)

Poliovirus Containment Advisory Group (CAG)	
12.	Professor David HEYMANN Chair of CAG
13.	Dr Mark PALLANSCH also Chair of CAG – Expert Support Group on Novel Poliovirus Strains (CAG – ESG) and Co-Chair of GPEI Containment Management Group
14.	Professor Shahina TABASSUM
15.	Dr Atef M ELGENDY (Unable to attend)
16.	Professor George E GRIFFIN also Member of CAG – ESG on Novel Poliovirus Strains
17.	Dr Jagadish DESHPANDE (Virtual participation)
18.	Dr Åsa Szekely BJORN DAL
19.	Dr Stephen McADAM also Member of CAG – ESG on Novel Poliovirus Strains
20.	Dr Vibeke HALKJÆR-KNUDSEN
21.	Mr Kenneth UGWU
22.	Dr Janice LO
Advisory- and Working- Groups Supporting Polio Eradication and Containment and Representatives of GPEI Global Programme Support Groups	
23.	Professor David SALISBURY Chair of Global Commission for the Certification of the Eradication of Poliomyelitis (GCC)
24.	Dr Arlene KING Chair of GCC – Containment Working Group (GCC – CWG) and Liaison Representative of the GCC – CWG to CAG
25.	Dr Hanna NOHYNEK (Virtual participation) Chair of Strategic Advisory Group of Experts on immunization (SAGE)
26.	Professor Shabir A MADHI (Virtual participation) Chair of SAGE working group on polio
27.	Professor Sir Liam DONALDSON Chair of Independent Monitoring Board (IMB) for Polio Eradication and Chair of Polio Transition IMB (TIMB)
28.	Ms Katherine HAYES Secretariat- of IMB for Polio Eradication and Polio Transition IMB (TIMB)
29.	Professor Helen REES Chair of Poliovirus International Health Regulations (IHR) Emergency Committee
30.	Ms Simona ZIPURSKY Special Adviser to the Director, Polio Eradication, WHO headquarters in Geneva, SWITZERLAND and Chair of GPEI nOPV Working Group
31.	Mr Feyrouz KURJI (Virtual participation) Principal Consultant, FDK Consulting LLC, Kirkland, Washington, USA and Coordinator of GPEI nOPV Working Group



Advisory- and Working- Groups Supporting Polio Eradication and Containment and Representatives of GPEI Global Programme Support Groups (Continued)	
32.	Dr Ananda S BANDYOPADHYAY (Virtual participation) Deputy Director, Technology, Research, and Analytics, Polio Team, Bill & Melinda Gates Foundation, Seattle, Washington, USA and GPEI nOPV Working Group
33.	Ms Kaija HAWES (Virtual participation) Associate Program Officer, Technology, Research, and Analytics, Polio Team, Bill & Melinda Gates Foundation, Seattle, Washington, USA and Coordinator of nOPV Genetic Characterization Subgroup of the GPEI nOPV2 Working Group GPEI nOPV2 Working Group
34.	Dr Javier MARTIN Principal Scientist, Division of Virology; Director, WHO Global Specialized Polio Laboratory, National Institute for Biological Standards and Control (NIBSC), Potters Bar, Hertfordshire, UNITED KINGDOM and nOPV Genetic Characterization Subgroup of the GPEI nOPV2 Working Group
35.	Dr Cara BURNS (Virtual participation) Team Lead, Molecular Epidemiology and Surveillance Laboratory, Division of Viral Diseases, Centers for Disease Control and Prevention (CDC), Atlanta, Georgia, USA and nOPV Genetic Characterization Subgroup of the GPEI nOPV2 Working Group
36.	Ms Ann E. OTTOSEN (Virtual participation) Senior Manager, Vaccine Centre UNICEF Supply Division, Copenhagen, DENMARK and Chair of GPEI Vaccine Supply Group (VSG)
37.	Dr Vachagan HARUTYUNYAN Team Leader, Detection & Interruption, Polio Eradication, WHO headquarters in Geneva, SWITZERLAND and GPEI VSG
38.	Mr David WOODS Technical Officer, Detection and Interruption Unit, Department of Polio Eradication, WHO headquarters in Geneva, SWITZERLAND and GPEI VSG
39.	Dr Graham TALLIS Senior Scientific Adviser, Detection & Interruption, Polio Eradication, WHO headquarters in Geneva, SWITZERLAND; Co-Chair, GPEI Surveillance Group and Secretariat of- GCC and Poliovirus IHR Emergency Committee
Strategic Committee of GPEI	
40.	Mr Aidan O'LEARY Chair of the Strategic Committee of GPEI and Director, Polio Eradication, WHO headquarters in Geneva, SWITZERLAND
GPEI Partners (Containment Management Group)	
41.	Dr Tim PETERSEN (Virtual participation) Deputy Director, Country Operations, Polio Team, Bill & Melinda Gates Foundation, Seattle, Washington, USA and Member of GPEI Containment Management Group (CMG)
42.	Dr Steve WASSILAK (Virtual participation) Global Immunization Division, Centers for Global Health, Centers for Disease Control and Prevention (CDC), Atlanta, Georgia, USA and Member of GPEI CMG
43.	Dr Ekkehart PANDEL (Virtual participation) Rotary International and Member of GPEI CMG
44.	Mr Ian LEWIS (Virtual participation) Contracts Manager, Polio Unit Vaccine Center, UNICEF Supply Division, Copenhagen, DENMARK and Member of GPEI CMG
45.	Dr Ousmane DIOP Scientist, Surveillance, Lab and Data, Polio Eradication, WHO headquarters in Geneva, SWITZERLAND and Member of GPEI CMG

GPEI Partners (Containment Management Group) (Continued)	
46.	Dr Eugene SAXENTOFF (Virtual participation) Polio Laboratory Network and Poliovirus Containment Coordinator, Vaccine-preventable Diseases and Immunization (VPI), Division of Country Health Programmes (CHP), WHO European Regional Office, Copenhagen, DENMARK and Member of GPEI CMG
Secretariat, CAG	
47.	Dr Harpal SINGH Technical Officer, Containment and Secretariat of the Poliovirus Containment Advisory Group (CAG), Polio Eradication, WHO headquarters in Geneva, SWITZERLAND
48.	Mr Derek EHRHDART Senior Technical Adviser, Polio Eradication, WHO headquarters in Geneva, SWITZERLAND
Observers (Selected Presenters)	
49.	Mrs Diana CHANG BLANC Team Lead, Programme Strengthening, Essential Programme on Immunization, WHO headquarters in Geneva, SWITZERLAND
50.	Dr Martin EISENHAWER Scientist, Research and Development, Polio Eradication, WHO headquarters in Geneva, SWITZERLAND
51.	Dr Kazunobu KOJIMA Medical Officer, Biosafety and Biosecurity, Epidemic and Pandemic Preparedness and Prevention, WHO headquarters in Geneva, SWITZERLAND
Department of Polio Eradication, WHO headquarters in Geneva	
52.	Dr Ondrej MACH Team Lead, Research and Development, Polio Eradication, WHO headquarters in Geneva, SWITZERLAND and Secretariat, SAGE working group on polio
53.	Ms Liliane BOUALAM Technical Officer, Containment, Polio Eradication, WHO headquarters in Geneva, SWITZERLAND, Co-Chair, GPEI Containment Management Group (CMG) and Secretariat of GCC-CWG
54.	Mr Joseph SWAN Communications Officer, Containment, Polio Eradication, WHO headquarters in Geneva, SWITZERLAND
55.	Dr Nicoletta PREVISANI Technical Officer, Containment, Polio Eradication, WHO headquarters in Geneva, SWITZERLAND
56.	Ms Caroline NAKANDI Assistant to the Team, Containment, Polio Eradication, WHO headquarters in Geneva, SWITZERLAND
Meeting Rapporteur	
57.	Ms Kailing MARCUS, kailing.marcus@unige.ch Epidemiologist, Institute of Global Health, Faculty of Medicine, University of Geneva, Geneva, SWITZERLAND



**World Health  
Organization**

Report of the Sixth Meeting of the Poliovirus  
Containment Advisory Group (CA6), 23 to 25  
January 2023, Geneva, SWITZERLAND

For questions or clarification: [hsingh@who.int](mailto:hsingh@who.int)