Report of the Teleconference of the Containment Advisory Group on the
Revision of the WHO Global Action Plan for Poliovirus Containment (GAPIII, 2015) following the
Fifth Meeting of the Containment Advisory Group (CAG5) (Post-CAG5 TC1)
28 March 2022; 1400 – 1500 (CEST)

List of Abbreviations:

BIBO	Bag-In-Bag-Out system [relates to High-efficiency particulate arresting (HEPA) filters]
BRM	Biorisk management
CAG	Containment Advisory Group
CAG5	Fifth Meeting of the CAG, 2, 4 and 9 March 2022
CAG-ESG	CAG – Expert Support Group for Novel Poliovirus Strains
Post-CAG5 TC1	Teleconference of the CAG on the Revision of the WHO Global Action Plan for Poliovirus Containment (GAPIII, 2015) following CAG5
CCS	Containment Certification Scheme to support the WHO Global Action Plan for Poliovirus Containment
CMG	Containment Management Group
DTP3	Diphtheria-tetanus-pertussis vaccine third dose
GAPIII	WHO Global Action Plan to minimize poliovirus facility-associated risk after type-specific eradication of wild polioviruses and sequential cessation of oral polio vaccine use or WHO Global Action Plan for Poliovirus Containment (3rd ed., 2015)
Annex 2	BRM standard for poliovirus-essential facilities (PEFs) holding wild poliovirus (WPV) materials
Annex 3	BRM standard for PEFs holding only OPV/Sabin poliovirus materials (no WPV)
GCC – CWG	Global Commission for the Certification of the Eradication of Poliomyelitis - Containment Working Group
HEPA	High-efficiency particulate arresting filter
HVAC	Heating, ventilation and air-conditioning system
IPV	Inactivated poliovirus vaccine
IPV1	Inactivated poliovirus vaccine first dose
IPV2	Inactivated poliovirus vaccine second dose
NAC	National authority for containment
OPV	Oral poliomyelitis vaccine
PEF	Poliovirus-essential facility
PIM Guidance	Guidance to minimize risks for facilities collecting, handling or storing materials potentially infectious for polioviruses (2nd ed., 2021)
PPE	Personal protective equipment
R_0	Basic reproduction rate
SAGE	Strategic Advisory Group of Experts on Immunization
VDPV	Vaccine-derived poliovirus
VDPV1	Vaccine-derived poliovirus serotype 1
VDPV2	Vaccine-derived poliovirus serotype 2
VDPV3	Vaccine-derived poliovirus serotype 3
WPV	Wild poliovirus
WPV1	Wild poliovirus serotype 1
WPV2	Wild poliovirus serotype 2
WPV3	Wild poliovirus serotype 3

Background

The Teleconference of the Containment Advisory Group on the Revision of the WHO Global Action Plan for Poliovirus Containment (GAPIII, 2015) following the Fifth Meeting of the Containment Advisory Group (CAG5) (Post-CAG5 TC1) was held on 28 March 2022 (1400 – 1530 CEST). This is the first in a series of

teleconferences planned throughout the revision process of GAPIII[1]. The main agenda items for this teleconference were presentations and discussions on the subsequent changes made in the working revised GAPIII draft as recommended by CAG following the CAG5 meeting, 2, 4 and 9 March 2022.

The objectives of this teleconference were:

1. To present to CAG the subsequent changes made in the working revised GAPIII draft i.e., Post-CAG5 revised GAPIII draft version:
   a. For review, discussion and deliberation by CAG or for additional recommendations from CAG
   b. To request for approval from CAG to commence the public consultation of the revised draft (expected from 29 March 2022 to 1 May 2022)
2. To discuss any other issues associated with the revision of GAPIII

Post-CAG5 TC1 was attended by the following:

CAG:	Professor David HEYMANN (Chair of CAG), Dr Jagadish DESHPANDE, Dr Atef EL-GENDY, Professor George E GRIFFIN [also member of CAG-Expert Support Group for Novel Poliovirus Strains (CAG - ESG)], Dr Vibeke HALKJÆR-KNUDSEN, Dr Janice LO, Dr Stephen MCADAM (also member of CAG - ESG), Dr Mark PALLANSCH (also Chair of CAG - ESG and Co-Chair of the Containment Management Group (CMG)], Dr Åsa SZEKELY BJÖRNDAL, Professor Shahina TABASSUM and Mr Kenneth UGWU. Unable to attend: Mr Neil GODDEN
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 participants (Observers):	Gryphon Scientific LLC, Takoma Park, MD, USA: Dr Rocco Casagrande, Dr Ryan RITTERSON, Ms Erin LAUER, Dr Adam FLEMING, Ms Kelly KIM and Mr Rob DETTMANN.
WHO Secretariat	Poliovirus Containment Team, Department of Polio Eradication, WHO headquarters in Geneva, SWITZERLAND: Mr Aidan O'LEARY, Team Lead *a.i*. and Director, Department of Polio Eradication; 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. WHO Regional Containment Coordinators: WHO - Regional Office for Africa:

[1] Series of CAG teleconferences planned as part of the revision process of GAPIII

Date (2022)	Objectives
28 Mar Post-CAG5 TC1	(1) Subsequent changes following CAG5 recommendations resulting in post-CAG5 revised GAPIII draft presented to CAG for review, and (2) approval to commence public consultation (expected: 29 Mar - 1 May 2022).
20 May Post-CAG5 TC2	Outcome from public consultation is presented to CAG for review and recommendations on further changes to be made in the post-CAG5 revised GAPIII draft incorporating feedback received.
6 Jun Post-CAG5 TC3	(1) Subsequent changes following feedback from public consultation presented for CAG consensus, and (2) 'Kick-off' teleconference for CAG final review (expected: 7 – 29 Jun 2022) of the revised GAPIII draft.
30 Jun Post-CAG5 TC4	CAG endorsement of the revised GAPIII draft.

Dr Jacob Samson BARNOR; WHO - Regional Office for the Americas/Pan American Health Organization: Ms Gloria REY; WHO - Eastern Mediterranean Regional Office: Dr Humayun ASGHAR and Dr Salmaan SHARIF; WHO – European Regional Office: Dr Eugene Victor SAXENTOFF and Dr Maria IAKOVENKO and WHO – Western Pacific Regional Office: Dr Varja GRABOVAC.
Unable to attend: WHO – South-East Asia Regional Office: Dr Sigrun ROESEL.

All CAG members previously 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 teleconference. No CAG member was identified as having any relevant real or perceived conflict of interest.

CAG Recommendations on Issues Associated with the Revision of GAPIII following the Fifth Meeting of the Containment Advisory Group (CAG5). 2, 4 and 9 March 2022[2, 3, 4]

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

Containment Perimeter

Issue Raised :
Are airlocks, anterooms, HVAC spaces, and kill tank rooms required to be within the containment perimeter sealable for gaseous decontamination?

CAG Recommendation:
• Anterooms and personnel airlocks are to be considered within the containment perimeter and must meet the requirements of spaces within the containment perimeter. • Kill-tank rooms or equivalent must meet all construction, sealing, and HVAC requirements of the primary containment space and are required to have an anteroom/personnel airlock for controlled entry as described above.

Revised GAPIII draft (version presented to CAG5):
8.3.5 Controlled entry into the containment perimeter is through a double-door personnel airlock. Features include alarms, interlocking doors or an equivalent system to ensure that more than one door cannot be opened at a time and associated operating procedures to ensure the building systems function effectively at all times.

Post-CAG5 revised GAPIII draft [version following CAG5 recommendation(s)]:
8.3.5 Controlled entry into the containment perimeter is through a double-door personnel airlock. Features include alarms, interlocking doors or an equivalent system to ensure that more than one door cannot be opened at a time and associated operating procedures to ensure the building systems function effectively at all times. Anterooms and personnel airlocks for entry are considered to be within the

[2]The sections of the report that follows presents the issue raised and the associated CAG5 recommendation. For additional information e.g., relevant text or section in GAPIII, request to CAG and supporting background information or evidence, please see the Report of the Fifth Meeting of the Containment Advisory Group (CAG5), 2, 4 and 9 March 2022. Available at: https://polioeradication.org/tools-and-library/policy-reports/advisory-reports/containment-advisory-group/

[3]subsequent changes incorporating CAG5 recommendations i.e., post-CAG5 revised GAPIII draft are indicated as follows: underlined blue colored text represents edited or added text, while ~~strikethrough~~ text in red represents text that has been deleted.

[4]Where relevant, *Italicized* font, in framed-boxes represents guidance which has been provided as aid in interpreting and means of achieving compliance with the requirement. The contents of the guidance should not in any way be construed as being requirements.

containment perimeter, must be sealable for gaseous decontamination and meet all requirements of spaces within the containment perimeter.

8.3.13 Kill-tank rooms or equivalent must meet all construction, sealing, and HVAC requirements of the primary containment space and are required to have an anteroom/personnel airlock for controlled entry as described in Element 8.3.5.

Operator IPV Immunization and Poliovirus Antibody Titer Determination Requirements

Issue Raised :

Evidence does not support the need for repeated adult IPV boosters. Annual titer checks represent a significant burden, and the frequency of the requirement is not supported by evidence. Alternatives should be suggested.

CAG Recommendation:

- Individuals associated with the poliovirus-essential facility must demonstrate established immunity to poliovirus through evidence of poliovirus antibodies prior to accessing the facility
- Subsequent need for IPV vaccination and antibody titre testing should be determined by a local risk assessment and should be consistent with national occupational health guidelines.

Revised GAPIII draft (version presented to CAG5):

3.2. Vaccination of Personnel

The need for vaccination is determined based on risk assessment and covers groups identified as susceptible to poliovirus exposure

Organizations should implement measures to identify those who are not protected after vaccination (depending on the vaccine's response rate) and implement a policy to address these individuals. Individuals considered unfit for work in the facility on health grounds should be identified and prevented from accessing areas with likelihood of exposure. Areas requiring vaccinations to enter should be posted.

Post-CAG5 revised GAPIII draft [version following CAG5 recommendation(s)]:

3.2. Vaccination of Personnel

Relevant personnel, contractors, and visitors must demonstrate established immunity to poliovirus through evidence of poliovirus antibodies before accessing the containment facility. The need for subsequent vaccination and antibody titre testing is determined based on risk assessment and is consistent with national occupational health guidelines. ~~covers groups identified as susceptible to poliovirus exposure.~~

The Global Polio Laboratory Network (GPLN) may provide support for assessing poliovirus antibody titres in workers to ensure demonstrable immunity to poliovirus. *Organizations should implement measures to identify those who are not protected after vaccination (depending on the vaccine's response rate) and implement a policy to address these individuals. Individuals considered unfit for work in the facility on health grounds should be identified and prevented from accessing areas with likelihood of exposure. Areas requiring vaccinations to enter should be posted.*

Risk-based Approach for Walk-through Exit Shower from the Containment Perimeter in line with the Most Recent CAG Recommendation.

Issue Raised :

The requirement for showering out should be changed to a risk-based requirement in response to a release only. There is no evidence that showering-out under routine operations reduces exposure or release risk.

CAG Recommendations:

- Exit shower requirement should be replaced with performance-based language which would generally be more applicable to the range of PEFs – this should emphasize the need for facility-specific risk assessment.
- Additional measures should be considered when exiting from the containment perimeter to prevent exposure to contaminated personal protective equipment (PPE) or personnel.

Revised GAPIII draft (version presented to CAG5):

8.3.8 Controlled exit from the containment perimeter includes appropriate steps and procedures to prevent exposure to contaminated PPE or personnel. Procedures for exiting the containment perimeter and the use of an exit shower must be determined by a facility-specific risk assessment.

Post-CAG5 revised GAPIII draft [version following CAG5 recommendation(s)]:

8.3.8 Controlled exit from the containment perimeter includes appropriate steps and procedures to prevent exposure to contaminated PPE or personnel. Procedures for exiting the containment perimeter and the ~~use~~ requirement ~~of~~ for an exit shower must be determined by a facility-specific risk assessment.

Risk-based Approach for Storage of Poliovirus Materials Outside of GAPIII Containment.

Issue Raised :

Guidelines for the safe production and quality control of poliomyelitis vaccines, Annex 4, WHO TRS No 1016 and Annex 3, WHO TRS No 1028 (Amendment to Annex 4 of WHO TRS No 1016) and CAG recommendations provide provisions for storing poliovirus material outside the containment perimeter provided it is packaged appropriately and secured via a risk-based approach. This greatly reduces the burden of containment space required specifically for storage and should also be outlined in GAPIII.

CAG Recommendation:

- The current version of GAPIII does not address storage of polioviruses outside of the containment perimeter. Therefore, the BRM element associated with 'poliovirus inventory and information' should be expanded to include storage procedures for polioviruses outside of the containment perimeter including conditions to be met e.g., leak-proof containers, dedicated freezers, proper labelling and other biosecurity measures, etc. as determined by a facility-specific risk assessment with the approval from the NAC.

Revised GAPIII draft (version presented to CAG5) and Post-CAG5 revised GAPIII draft [version following CAG5 recommendation(s)]: No change in text

8.13.4 Storage of poliovirus must be performed under appropriate containment conditions, as determined by a risk assessment approved by the NAC and in line with the approach detailed in the CCS.
8.13.5 Whenever possible, manufacturing processes and transfer of intermediates must be carried out in closed systems that have been leak tested and certified.

Alternative Measures for Gaseous Decontamination and Guidance for Use.

Issue Raised :

Request that alternatives to gaseous decontamination should be provided if gaseous decontamination is not possible or feasible in a facility. These could include manual decontamination, spray decontamination, etc. as determined by risk assessment

CAG Recommendation:

- The containment perimeter for existing facilities must be an area sealable for gaseous decontamination. For new facilities or facilities undergoing renovation, retrofitting or refurbishing, alternative methods of decontamination e.g. physical decontamination, etc. may be considered provided it is guided by the performance of a comprehensive risk assessment.

Revised GAPIII draft (version presented to CAG5):

8.3.3 Existing facilities must provide a containment perimeter sealable for gaseous decontamination and with sealed penetrations to prevent uncontrolled outward airflow irrespective of the choice of primary containment. New facilities and those undergoing retrofitting or refurbishing must ensure the sealable containment perimeter, irrespective of the choice of primary containment.

if subsequent renovation, decommissioning or repurposing of a poliovirus laboratory (and its containment perimeter) is planned and gaseous decontamination of the duct work cannot be conducted due to leaky construction, a comprehensive risk assessment and control plan should be developed for alternative decontamination of the containment perimeter, including the exhaust ventilation system from the laboratory register to the downstream side of the HEPA filter.

HEPA filter caissons equipped with a bag-in-bag-out (BIBO) section provide an alternative to gaseous decontamination of HEPA filters. The BIBO system is designed to allow removal and replacement of HEPA filters while maintaining containment of the caisson.

Post-CAG5 revised GAPIII draft [version following CAG5 recommendation(s)]:

8.3.3 Existing facilities must provide a containment perimeter sealable for gaseous decontamination and with sealed penetrations to prevent uncontrolled outward airflow irrespective of the choice of primary containment. New facilities and those undergoing retrofitting or refurbishing must ensure the sealable containment perimeter, irrespective of the choice of primary containment.

if subsequent renovation, decommissioning or repurposing of a poliovirus laboratory (and its containment perimeter) is planned and gaseous decontamination of the duct work cannot be conducted ~~due to leaky construction~~, a comprehensive risk assessment and control plan should be developed for alternative decontamination of the containment perimeter, including the exhaust ventilation system from the laboratory register to the downstream side of the HEPA filter, utilizing validated decontamination methods.

HEPA filter caissons equipped with a bag-in-bag-out (BIBO) section provide an alternative to gaseous decontamination of HEPA filters. The BIBO system is designed to allow removal and replacement of HEPA filters while maintaining containment of the caisson.

HEPA Filtration on Exhaust Side As Requirement Prior to Final Containment of all WPV.

Issue Raised:

The requirement for HEPA filtration of exhaust prior to final containment represents an unnecessary burden

CAG Recommendation:

- The use of supply-side HEPA filters directly on the containment barrier if and when correctly maintained would functionally meet the intent of a dedicated HVAC system.
- This requirement i.e., HEPA filter on exhaust or its functional equivalent, is to be maintained for facilities retaining WPV polioviruses in the containment phase of all WPV serotypes.

Revised GAPIII draft (version presented to CAG5):

8.3.10 Throughout the strain-specific containment period where evidence of the satisfactory implementation of facility, population immunity, and environmental control safeguards (described in this standard) is provided, the controlled air system maintaining directional airflow will not require HEPA filtration on exhaust.

WPV Final Containment Only: The controlled air system maintains directional airflow via a dedicated ventilation system with ductwork sealable for gaseous decontamination, HEPA filtration of exhaust, backflow protection on supply, and monitors/alarms to ensure directional airflow can be readily validated.

Use of supply-side HEPA filters directly on the containment perimeter in the absence of interconnections (supply connections to other spaces or return exhaust from other spaces) between the supply-side HEPA filter and the exhaust-side, if correctly maintained and routinely tested, are functionally equivalent to providing a dedicated heating, ventilation and air-conditioning (HVAC) system. While this meets the intent of being a dedicated system, other requirements should also be in place airflow is controlled to maintain supply-to-exhaust unidirectional flow, with all passageways for distribution or extraction of air ('ductwork') sealable for gaseous decontamination, has an exhaust-side HEPA filter and supply-side, backflow prevention (e.g., damper) and has detectors to monitor the unidirectional airflow.

When BSC exhaust air is discharged through the building exhaust air system, the air handling system should be designed so it does not disturb the air balance of the BSC or of the room in which the cabinet is located.

Post-CAG5 revised GAPIII draft [version following CAG5 recommendation(s)]:

8.3.10 Throughout the strain-specific containment period where evidence of the satisfactory implementation of facility, immunization coverage ~~population immunity~~, and environmental ~~control~~ safeguards (described in ~~this standard~~ GAPIV) is provided, the controlled air system maintaining directional airflow will not require HEPA filtration on exhaust.

WPV Final Containment Only: The controlled air system maintains directional airflow via a dedicated ventilation system with ductwork sealable for gaseous decontamination, HEPA filtration of exhaust, backflow protection on supply, and monitors/alarms to ensure directional airflow can be readily validated.

Use of supply-side HEPA filters directly on the containment perimeter in the absence of downstream interconnections ~~(supply connections to other spaces or return exhaust from other spaces) between the supply-side HEPA filter and the exhaust-side~~, if correctly maintained and routinely tested, ~~are~~ is functionally equivalent to providing a dedicated ~~heating, ventilation and air-conditioning (HVAC~~ ventilation~~)~~ system. ~~While this meets the intent of being a dedicated system, other requirements should also be in place airflow is controlled to maintain supply-to-exhaust unidirectional flow, with all passageways for distribution or extraction of air ('ductwork') sealable for gaseous decontamination, has an exhaust-side HEPA filter and supply-side, backflow prevention (e.g., damper) and has detectors to monitor the unidirectional airflow.~~

When BSC exhaust air is discharged through the building exhaust air system, the air handling system should be designed so it does not disturb the air balance of the BSC or of the room in which the cabinet is located.

Changes made in primary, secondary and tertiary safeguards as described in GAPIII

.Replacement of GAPIII Jargon 'Primary, Secondary and Tertiary Safeguards' with Technical Language or Definition

Issue Raised :

The terminology of primary, secondary and tertiary safeguards is unique to GAPIII and thus unfamiliar to those outside poliovirus containment.

CAG Recommendation:

Replace the term 'primary safeguards' to 'facility safeguards', 'secondary safeguards' to 'immunization coverage safeguards' and 'tertiary safeguards' to 'environmental control safeguards'.

Operationalization of Population Immunity Safeguards Within the Context of SAGE Current Recommendations

Issue Raised :

Data stratified by infants and geographical area of 100 km is not available and would entail the need for serosurveys. In some countries the 100 km radius extend to another country. In addition, some countries do not have an IPV2 dose schedule implemented.

CAG Recommendation:

- Based on the Polio Eradication Strategy 2022 – 2026: Delivering on a Promise, the complete phase out of all oral poliomyelitis vaccine (OPV) is anticipated in 2030+ and this provides sufficient time for countries hosting PEF to achieve these requirements i.e., two-IPV doses and IPV2 coverage.
- In line with the recommendation made by the Strategic Advisory Group of Experts (SAGE) on immunization which permits countries-hosting PEFs to implement this requirement no later than time of all OPV cessation, the approach to be taken in the revised GAPIII should be adjusted to make it more globally implementable and pragmatic based on data availability and local circumstances. In the interim period (before complete phase out of all OPV), the immunity requirements should consider the current IPV supply, IPV in routine immunization, and availability of IPV coverage data, etc. with the goal of achieving the recommendation made by SAGE by the time of all OPV cessation. Therefore, two options are recommended for the operationalization of these safeguards: (1) pre-OPV cessation period and (2) post-OPV cessation period. The post-OPV cessation period is to be considered the deadline for countries hosting PEFs to meet this requirement, but CAG encourages an early compliance with this requirement.

	OPV/Sabin	WPV/VDPV
Population Immunity Safeguards		
IPV1 or IPV2 coverage during the pre-OPV cessation period	= DTP3 coverage or ≥90%	= DTP3 coverage or ≥90%
IPV2 coverage during the post-OPV cessation period	≥90%	≥90%

Depending on the country context and location of the PEF, coverage data may represent national level or subnational level, whichever appropriate.

Local Risk-based Approach for Environmental Control Safeguards

Issue Raised :

There are no indicators stated in GAPIII to assess tertiary safeguards. In addition, the parameters indicated in the present definition may not represent actual PEF-location circumstances e.g., population density, etc.

CAG Recommendation:

- The requirement for PEFs to be located in areas with closed sewage systems with secondary or greater treatment of effluents in the community should be replaced with risk-based language that maximizes the utilization of local environmental parameters that reduces the risk of poliovirus transmission (R_0).
- Consideration should also be provided for the implementation of additional environmental safeguards by the NAC e.g., environmental surveillance for communities living close to the PEF.
- Thus, the definition is to be expanded to include local context in the determination of the R_0 of poliovirus and is risk-based in approach tailored to local situations i.e., 'The environmental, sanitation and hygiene conditions (e.g., 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 re-establishing the circulation of highly transmissible wild poliovirus in the event of reintroduction'

Post-CAG5 revised GAPIII draft [version following CAG5 recommendation(s)]:

The recommendations by CAG issues associated with safeguards as indicated above have been incorporated throughout the post-CAG5 revised GAPIII draft, wherever appropriate.

Revision Made in the Survey, Inventory and Destruction Activity Section of GAPIII.

Issue Raised :

Many of the timelines, and activities in the current version of GAPIII do not represent the actual implementational level in countries. In addition, verification/validation processes are not described in the current version of GAPIII. Since the publication of the current version of GAPIII, several other guidance documents have been published e.g., PIM Guidance, PIM Tool and the development of novel poliovirus strains.

CAG Recommendation:

- CAG noted that the revision of this section was based on the outputs from the 'Kick-off' meeting held on 15 April 2021 and consented to the following recommendations:
    - Definitions (previously Annex 1) moved to the beginning of the document
    - Revision and update of the introduction
    - Addition of the 'Roles and Activities' section to describe poliovirus containment stakeholders and their terms of reference in the context of this document
    - Addition of 'Containment Requirements for Novel Poliovirus Strains' section based on previous CAG requirements
    - Complete removal of the 'Phases' approach from GAPIII
        - Replaced with 'Inventory and Destruction' and 'Containment' phase.
        - 'Inventory and Destruction' described as ongoing and in-effect for all strains, WPV and Sabin/OPV, globally.
    - Containment' requirements to be implemented in stages by strain as determined by GCC based on eradication progress and involves four parts:
        - 'Establishment' (as needed),
        - 'Verification' (in-transition for all strains),
        - 'mOPV stockpiles' (in-transition for all OPV strains), and
        - 'Final Containment' (in-transition for WPV2 and WPV3)

Post-CAG5 revised GAPIII draft [version following CAG5 recommendation(s)]:

The recommendations by CAG on the proposed changes for the section on Survey, Inventory and Destruction activities have been incorporated throughout the post-CAG5 revised GAPIII draft, wherever appropriate.

Containment Requirements for Potentially Infectious Materials, WPV/VDPV.

Issue Raised:

- In its current version, GAPIII requires all potentially infectious materials (PIM),polioviruses to be handled according to Annex 2 (WPV/VDPV) or Annex 3 (Sabin/OPV) of GAPIII.
- The current PIM guidance does not subject Sabin/OPV PIM to Annex 3 of GAPIII but rather that a risk determination be conducted based on both the sample type and nature of the work to be performed, and specific risk mitigation measures taken to minimize the risk of handling and storing such material.
- The PIM guidance continues to require WPV/VDPV PIM be subjected to Annex 2 of GAPIII.
- Consideration should be provided for the requirements for WPV/VDPV PIM to be subjected to a risk determination process and the containment requirements for handling and storing WPV/VDPV PIM be in line with the risk mitigation approach by risk stratification as was done for Sabin PIM as per PIM Guidance.
- This is because, in several countries hosting many laboratories, implementation of the PIM surveys have indicated a large number of facilities planning to retain WPV/VDPV PIM only. At present, these facilities will have to implement Annex 2 of GAPIII and enter the CCS placing a burden on the NACs in their performance of audits and associated activities. In the 2004 PIM survey implemented in the US, a total of 56 laboratories were identified as planning to retain WPV/VDPV PIM only.

CAG Recommendation:

- CAG noted the concerns raised by the NACs of the need for facilities retaining for potentially infectious materials, WPV/VDPV to implement the containment requirements in GAPIII, undergo compliance verification as per CCS which places an additional burden on the NACs in countries with numerous facilities retaining only such materials.
- CAG recommends the following:
    - In line with the strategy for the implementation of GAPIII i.e., risk elimination, the concerned NACs should encourage these facilities to destroy such materials.
    - The containment requirements for the retention of potentially infectious materials, WPV/VDPV will remain in line with the requirements of GAPIII or its revised version for now. A more in-depth review of the containment requirements of potentially infectious materials, WPV/VDPV in regards to the applicability of GAPIII or its revised version, will be undertaken by the Potentially Infectious Materials, Polioviruses Guidance Development Group (previously established and tasked with the development of the PIM Guidance, 1st edition) in 2022.
- In addition, CAG also highlighted several issues associated with the retention of potentially infectious materials, polioviruses which require resolution and encourages the Secretariat to coordinate with the Potentially Infectious Materials, Polioviruses Guidance Development Group to deliberate on the following:
    - The compliance verification mechanism, which the Potentially Infectious Materials, Polioviruses Guidance (PIM Guidance) currently lacks, for facilities retaining potentially infectious materials, Sabin/OPV materials against the risk mitigation strategies described in the PIM Guidance.
    - In line with the current goal of eliminating the use the of all type 2 polioviruses (including Sabin serotype 2 poliovirus and OPV2), the longer-term containment requirement for the retention of potentially infectious materials, Sabin specifically in the post-OPV cessation period should be discussed.

Revised GAPIII draft (version presented to CAG5) and Post-CAG5 revised GAPIII draft [version following CAG5 recommendation(s)]:
No change required throughout the post-CAG5 revised GAPIII draft.

Updated Recommendations from the CAG - Expert Support Group (CAG-ESG) on Novel Poliovirus Strains.

Post-CAG5 revised GAPIII draft [version following CAG5 recommendation(s)]:
Due to the temporary nature of the waiver granted by CAG associated with specific novel poliovirus strains for specific uses, and the ongoing work of the CAG-ESG to deliberate on the duration of validity of the temporary waivers and the associated containment requirements for their handling after the end-validity of these waivers including the role of CAG in resolving the exemption from the containment requirements of novel poliovirus strains for specified uses in the post-OPV cessation period when all live poliovirus are expected to be fully contained, the section on novel poliovirus strains in the revised GAPIII is drafted generically to encompass the possibility of new poliovirus strain that may be developed in the future. As such, this section of the revised GAPIII highlights the 'Criteria for the evaluation of improved safety of novel poliovirus strains to determine the containment requirements for their storage and handling' (Aavailable at: http://polioeradication.org/wp-content/uploads/2017/08/criteria-evaluation-novel-pv-june-2019-eng.pdf). Recommendations made by CAG on specific novel poliovirus strains and their specific uses will not be described in the relevant section of the revised GAPIII, however, the outcome of the recommendations from CAG on specific issues will be published at: http://polioeradication.org/tools-and-library/policy-reports/advisory-reports/containment-advisory-group/

Other issues associated with the Revision of GAPIII

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

Timelines for the Revision of GAPIII

The timelines of several activities in the revision process of GAPIII were adjusted as they coincide with the Seventy-fifth World Health Assembly, 22 to 28 May 2022. These adjustments are not expected to impact the planned early-July 2022 release of the revised GAPIII and are reflected in the table below (* indicate adjusted timelines; ~~strikethrough~~ text indicated previous timelines; text in orange are adjusted timelines)

Date(s) [2022]	Days	Activity or Steps
†28 Mar	1	CAG TC on the changes made to GAPIII draft post-CAG5 and to obtain approval from CAG to pursue public consultation.
29 Mar – 1 May	24	Public consultation period..
*~~2 – 15 May~~ 2 – 12 May	~~10~~ 7	Analysis of submissions received from public consultation including categorization of comments, frequency of issue raised, originator of submission, prioritization of comments, justification/evidence and other relevant information, etc.
*~~16 – 22 May~~ 13 -19 May	5	Analysis of comments from public consultation with log-sheet of all submissions is shared with CAG ahead of TC (~~23~~ 20 May).
*,† ~~23 May~~ 20 May	1	CAG TC to discuss comments from public consultation and to seek recommendations from CAG for further revisions to be made in the draft document based on the comments received.
*~~24 May - 5 Jun~~ 23 May – 5 Jun	~~9~~ 10	Comments or suggestions from public consultation are incorporated into the working GAPIII draft based on recommendations made by CAG at

Date(s) [2022]	Days	Activity or Steps
		previous TC (~~23~~ 20 May) and preparation of draft document for final review and endorsement by CAG.
		⬇
†6 Jun	1	CAG TC .on changes made based on comments from public consultation as per CAG recommendation and TC to mark the 'kick-off' for final review and endorsement by CAG of the revised GAPIII draft.
		⬇
7 – 29 Jun	17	Final review of by CAG and for purposed of endorsement of the revised GAPIII draft.
		⬇
†30 Jun	1	TC for endorsement of the revised GAPIII draft by CAG.
		⬇
1 July	1	Publication of CAG-endorsed 'advanced unedited version' of the revised GAPIII
		⬇
4 July onwards	TBD	Translations into official UN languages, document graphic-design and layout followed by web publication of the document.
	1	Potential launch event with Chair of CAG, Director, Polio Eradication, WHO headquarters in Geneva, SWIITZERLAND and other relevant stakeholders.
	TBD	Preparations to inform the Governing Bodies of WHO i.e., EB (2022) and WHA (2023) of the following: • Completion of the GAPIII revision process resulting in a revised document which has been endorsed by CAG. • Revised version supersedes the previous version with effect from 1 July 2022 - due to the changes required, relevant stakeholders have a three year transition period to meet the requirements of the revised GAPIII. • In line with its mandate, CAG has been involved through the revision process including the endorsement of the revised GAPIII. The endorsement by CAG was due to the transfer of the oversight function of containment documents, previously held by SAGE, to CAG in late-2018.

*Changes made in timelines

†Planned CAG teleconferences on the revision process of GAPIII as agreed by CAG.

Naming of the Revised GAPIII

Issue Raised :
• This revision is to be considered a major revision in the current GAPIII, as the changes proposed have involved a substantive change in the structure, requirements and approach in the revised document.

CAG Recommendations:
CAG recommends the following: WHO Global Action Plan for Poliovirus Containment (full- and short-titles) and GAPIV (abbreviation).

Post-CAG5 revised GAPIII draft [version following CAG5 recommendation(s)]:
Wherever appropriate, the title of the revised GAPIII will be the 'WHO Global Action Plan for Poliovirus Containment' abbreviated as 'GAPIV'.

The next teleconference of the CAG associated with the revision process of GAPIII (Post-CAG5 TC2) is scheduled for: 20 May 2022

For questions or clarifications, please contact Dr Harpal SINGH hsingh@who.int