



Note for the record

Fifth Annual Consultation with National Authorities for Containment and  
the Global Certification Commission for the Eradication of Poliomyelitis -  
Containment Working Group

19 - 20 October 2021

1530 – 1800 CET

Virtual Meeting

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Meeting Report

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## List of abbreviations

AFMPS	Agency for Medicines and Health Products (Belgium)
AQAS	GAPIII Auditor Qualification and Audit Support Plan 2021–2023
AAT	Advanced Auditor Training
CEV	Country Engagement Visit
CAG	Containment Advisory Group
CAG – ESG	CAG – Expert Support Group for Novel Poliovirus Strains
CBB	Centre for Biosecurity and Biopreparedness (Denmark)
CBS	Canadian Biosafety Standard, 2nd Edition, 2015
CCS	Containment Certification Scheme
CC	Certificate of Containment
CP	Certificate of Participation
ICC	Interim Certificate of Containment
CDC	Centers for Disease Control and Prevention (United States of America)
CET	Central European Time (UTC+01:00)
CL	Containment Level
CL2	Containment Level 2
CL3	Containment Level 3
CMG	Containment Management Group
COVID-19	Coronavirus disease 2019
CPR	Center for Preparedness and Response (United States of America)
CEN	European Committee for Standardization
CWA	CEN Workshop Agreement
EUL	WHO Emergency Use Listing
FPS	Federal Public Service Health, Food Chain Safety and Environment (Belgium)
GACVS	Global Advisory Committee on Vaccine Safety
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 otherwise known as the WHO Global Action Plan for Poliovirus Containment (3 <sup>rd</sup> edition; 2014)
Annex 2	Biorisk management standard for poliovirus-essential facilities holding wild poliovirus materials
Annex 3	Biorisk management standard for poliovirus-essential facilities holding only OPV/Sabin poliovirus materials (no wild poliovirus)
Annex 6	Biorisk management standard for safe handling of new samples potentially containing poliovirus material in poliovirus-non-essential facilities
GCC	Global Commission for the Certification of the Eradication of Poliomyelitis
GCC – CWG	GCC – Containment Working Group
GMP	Good Manufacturing Practices
GPEI	Global Polio Eradication Initiative
HHS	United States Department of Health and Human Services (United States of America)
HPTA	Human Pathogens and Toxins Act (Canada)
HPTR	Human Pathogens and Toxins Regulations (Canada)
IEC	International Electrotechnical Commission
IHR	International Health Regulations (2005), 3rd Edition
NFP	National IHR Focal Point
ISO	International Organization for Standardization
IPV	Inactivated poliovirus vaccine
MOH	Ministry of Health
NAC	National authority for containment
NCC	National Committee for the Certification of the Eradication of Poliomyelitis
NIBSC	National Institute for Biological Standards and Control (United Kingdom)

NPCC	National Poliovirus Containment Coordinator
OPV	Sabin oral poliomyelitis vaccine
bOPV	Sabin bivalent oral poliomyelitis vaccine serotypes 1 and 3
mOPV2	Sabin monovalent oral poliomyelitis vaccine serotype 2

## List of abbreviations

nOPV2	Novel oral poliomyelitis vaccine serotype 2
OPV1	Sabin oral poliomyelitis vaccine serotype 1
OPV2	Sabin oral poliomyelitis vaccine serotype 2
OPV3	Sabin oral poliomyelitis vaccine serotype 3
tOPV	Sabin trivalent oral poliomyelitis vaccine serotypes 1, 2 and 3
OPHPR	Office of Public Health Preparedness and Response (United States of America)
PEF	Poliovirus-essential facility
PCA	Poliovirus Containment Activity (United States of America)
PHAC	Public Health Agency of Canada
PHEIC	Public health emergency of international concern
PIM	Potentially infectious materials, poliovirus
PIM Guidance	Guidance to minimize risks for facilities collecting, handling or storing materials potentially infectious for polioviruses – 2nd edition
POSE	Polio Outbreak Simulation Exercise
RCC	Regional Commission for the Certification of the Eradication of Poliomyelitis
RG	Risk Group (human or animal pathogen)
RG2	Risk Group 2 (moderate individual risk, low community risk)
RG3	Risk Group 3 (high individual risk, low community risk)
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
SBB	Service Biosafety and Biotechnology (of Sciensano, the Belgian Institute for Health, Belgium)
SV40	Simian virus 40
TRS	WHO Technical Report Series
VDPV	Vaccine-derived poliovirus
VDPV1	Vaccine-derived poliovirus serotype 1
VDPV2	Vaccine-derived poliovirus serotype 2
VDPV3	Vaccine-derived poliovirus serotype 3
cVDPV	Circulating vaccine-derived poliovirus
cVDPV1	Circulating vaccine-derived poliovirus serotype 1
cVDPV2	Circulating vaccine-derived poliovirus serotype 2
cVDPV3	Circulating vaccine-derived poliovirus serotype 3
WHA	World Health Assembly
WHO	World Health Organization
WPV	Wild poliovirus
WPV1	Wild poliovirus serotype 1
WPV2	Wild poliovirus serotype 2
WPV3	Wild poliovirus serotype 3

## SESSION: Introduction

### Background and Objectives

The Fifth Annual Consultation with National Authorities for Containment (NAC) and the Global Certification Commission for the Eradication of Poliomyelitis - Containment Working Group (GCC – CWG) was held virtually on 19 – 20 October 2021. The objectives of this meeting were:

1. Update countries on the progress with the implementation of poliovirus containment certification since the Fourth Annual Consultation between NAC and GCC-CWG (October 2020);
2. Update on progress related to the revision of the Global Action Plan for Poliovirus Containment (GAPIII);
3. Discuss progress, updates and way forward in the implementation of poliovirus containment and certification;
4. Provide NACs opportunity to share best practices, discuss challenges and successes, etc.

The meeting agenda and list of participants are included in Annexes 1 and 2 of this report. Where relevant, reference to the web addresses (URL) of the cited poliovirus containment and other containment associated documents, tools or their derivative products mentioned in this report (updated as of 21 October 2021) are included in the footnotes.

### Opening Remarks and Welcome

Aidan O'LEARY, Director, Department of Polio Eradication, WHO  
Dr Arlene KING, Chair, GCC-CWG and Member, GCC

The meeting was opened by Aidan O'LEARY who welcomed a range of participants including NACs, GCC, GCC – CWG and Global Polio Eradication Initiative (GPEI) partners which underscores the importance of collaboration in progressing with containment implementation. Arlene KING, Chair GCC – CWG informed stakeholders that the consultation was an opportunity to raise issues faced with the implementation of poliovirus containment and certification and to collectively identify solutions.

### Global Polio Eradication Initiative Update

Aidan O'LEARY, Director, Department of Polio Eradication, WHO

The Polio Eradication Strategy 2022 – 2026: “Delivering on a Promise” which will come into effect in January 2022 has two goals: (1) permanently interrupt poliovirus transmission in endemic countries and (2) stop circulating vaccine-derived poliovirus (cVDPV) transmission and prevent outbreaks in non-endemic countries. It aims to interrupt transmission of wild poliovirus serotype 1 (WPV1) and report the last isolate of cVDPV serotype 2 (cVDPV2) by end-2023, stop all cVDPV transmission in 2028, and use of inactivated poliovirus vaccine (IPV) exclusively in routine immunization from 2030 and beyond. These milestones would imply that poliovirus survey and inventory activities will need to be dynamic and will persist for years.

The current epidemiological situation shows a sharp curtailment in cases and environmental isolates (WPV1 and cVDPV2) in the two remaining endemic countries with one WPV1 case each reported in Pakistan and Afghanistan till date. Novel oral poliomyelitis vaccine type 2 (nOPV2), granted a WHO Emergency Use Listing (EUL)<sup>1</sup> in November 2020 was endorsed by the Strategic Advisory Group of Experts (SAGE) on immunization on 5 October 2021 to transition from initial to wider use based on the assessment of the Global Advisory Committee on Vaccine Safety (GACVS)<sup>2</sup>.

<sup>1</sup> First ever vaccine listed under WHO emergency use. Available at: <https://www.who.int/news/item/13-11-2020-first-ever-vaccine-listed-under-who-emergency-use>

<sup>2</sup> Meeting of the Strategic Advisory Group of Experts (SAGE) on Immunization 4-7 October 2021: conclusions and recommendations. Available at: <https://www.who.int/publications/i/item/meeting-of-strategic-advisory-group-of-experts-on-immunization-october-2021-conclusions-and-recommendations>

## SESSION: Containment Programmatic Updates and Latest Guidance from GCC on the Implementation and Certification of Poliovirus Containment

### Update on implementation of the recommendations from the Fourth Annual Consultation between NAC and GCC – CWG (October 2020) and Seventy-First World Health Assembly Resolution WHA71.16 Poliomyelitis – Containment of Polioviruses

Liliane BOUALAM, Technical Officer, Poliovirus Containment, Department of Polio Eradication, WHO

The recommendations from the Fourth Annual Consultation between NACs and GCC – CWG, October 2020<sup>3</sup> i.e., GAPIII Auditor Qualification and Audit Support Plan 2021–2023 (AQAS)<sup>4</sup> -; containment certification scheme (CCS)<sup>5</sup> process and certification of facilities; beyond poliovirus type 2 containment; WHO Global Action Plan for Poliovirus Containment, 3rd edition, 2014 (GAPIII)<sup>6</sup> revision and revision of the guidance to minimize risks for facilities collecting, handling or storing materials potentially infectious for polioviruses (PIM Guidance)<sup>7</sup>, have been implemented or are ongoing with the exception of the timing for the commencement of WPV3 containment<sup>8</sup> which is expected to be discussed by the GCC in 2022.

The implementation of the Seventy-First World Health Assembly Resolution WHA71.16 Poliomyelitis – Containment of Polioviruses<sup>9</sup> committed to by all WHO Member States in 2018 has shown progress although some areas are in need of urgent action i.e., five Member States hosting facilities retaining polioviruses are yet to designate a competent NAC despite the end-2018 deadline, and 15 facilities retaining polioviruses hosted by six Member States have yet to engage in the CCS despite the deadline of 31 December 2019.

### Update on Progress Related to the Revision of the Global Action Plan for Poliovirus Containment (GAPIII)

Harpal SINGH, Technical Officer, Poliovirus Containment, Department of Polio Eradication, WHO

The process and considerations taken in GAPIII revision are in line with the recommendations made by the Containment Advisory Group (CAG) at its third meeting held in December 2018<sup>10</sup>. The revision process was initiated on 14 September 2020 through a stakeholder solicitation of comments on Annexes 2 and 3<sup>11</sup> of GAPIII. A total of 339 submissions were received. Repeatedly cited issues were: need for harmonization with other relevant documents, repetitive and redundant requirements, cumbersome structure (tabular presentation) of the annexes; and the combination of performance- and polio-prescriptive requirements within a single standard is a challenge to

<sup>3</sup> Meeting Reports of Global and National Containment Certification Oversight Bodies. Available at: <https://polioeradication.org/meetings-and-reports/>

<sup>4</sup> GAPIII Auditor Qualification and Audit Support Plan 2021–2023. Available at: <https://polioeradication.org/wp-content/uploads/2021/03/GAPIII-Auditor-Qualification-and-Audit-Support-Plan-2021%E2%80%932023.pdf>

<sup>5</sup> Containment Certification Scheme to support the WHO Global Action Plan for Poliovirus Containment. 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>6</sup> 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 otherwise known as the WHO Global Action Plan for Poliovirus Containment (3<sup>rd</sup> edition; 2014). 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>7</sup> Guidance to minimize risks for facilities collecting, handling or storing materials potentially infectious for polioviruses (PIM Guidance) – 2nd edition. Available at: <https://polioeradication.org/polio-today/preparing-for-a-polio-free-world/containment/containment-resources/>

<sup>8</sup> GPEI PV3 Containment Statement. Poliovirus Type 3 Containment after Declaration of Wild Poliovirus Type 3 (WPV3) Eradication. Available at: <https://polioeradication.org/wp-content/uploads/2016/07/PV3-containment-statement-20190930.pdf>

<sup>9</sup> Seventy-First World Health Assembly Resolution WHA71.16 Poliomyelitis – Containment of Polioviruses. Available at: [https://apps.who.int/gb/ebwha/pdf\\_files/WHA71/A71\\_R16-en.pdf](https://apps.who.int/gb/ebwha/pdf_files/WHA71/A71_R16-en.pdf)

<sup>10</sup> Meeting Reports of the Reports of the Containment Advisory Group (CAG). Available at: <https://polioeradication.org/tools-and-library/policy-reports/advisory-reports/containment-advisory-group/>

<sup>11</sup> Annex 2 (Biorisk management standard for poliovirus-essential facilities holding wild poliovirus) and Annex 3 [Biorisk management standard for poliovirus-essential facilities holding OPV/Sabin (no wild)]

achieve. These findings, along with a review of relevant standards<sup>12</sup>, CAG recommendations, scientific literature, and stakeholder engagement, a revised GAPIII draft was developed which is now undergoing a critical review by CAG. A period of public consultation is expected to follow – the revised draft will be posted at: <https://polioeradication.org/polio-today/preparing-for-a-polio-free-world/containment/containment-resources/>.

A digital version of the PIM Guidance, 2nd edition, the PIM Identification Tool is now published at: <https://worldhealthorg.shinyapps.io/pim-app/> or <https://polioeradication.org/polio-today/preparing-for-a-polio-free-world/containment/containment-resources/>. The PIM Identification Tool utilizes the data in ‘Web Annex A: Country- and area-specific poliovirus data’ of the said guidance.

#### Containment Certification Status and Update

Liliane BOUALAM, Technical Officer, Poliovirus Containment, Department of Polio Eradication, WHO  
on behalf of the Poliovirus Containment Team, Department of Polio Eradication, WHO

Despite the challenges brought about by the global pandemic of coronavirus disease 2019 (COVID-19), progress, although slow, was made in poliovirus containment implementation and certification by most Member States achieved through the implementation of activities involving different containment work streams e.g., containment policy and guidance development, availability of tools, national capacity building in GAPIII auditing, and through recommendations made by GCC on containment certification.

The number of Member States hosting facilities retaining polioviruses has remained constant from 2019 till date (n = 25). However, the official designation of NACs showed a decrease from 23 in 2020 to 20 in 2021 attributed to the pending designation or dissolution of previously established NACs. The number of facilities designated as serving critical functions requiring the retention of polioviruses showed a decrease of 24% from 2018 (n = 89) to 2021 (n = 68). The number of facilities handling polioviruses awarded with a GCC-countersigned Certificate of Participation (CP) showed an increasing trend with 49 (83%) out of the 59 facilities’ CP applications received till date. As of October 2021, 15 facilities’ CP-applications are still expected from six Member States.

The current containment challenges faced include: the official nomination of NAC (n = 5) and initiation of containment certification in Member States retaining polioviruses (n = 6), continued use of Sabin monovalent oral poliomyelitis vaccine serotype 2 (mOPV2) for outbreak response causing the need for repeated rounds of survey and inventories, low prioritization of poliovirus containment in the ongoing COVID-19 pandemic, varying levels of readiness among Member States retaining polioviruses to move to the subsequent certification steps i.e., Interim Certificate of Containment (ICC) application phase.

#### Guidance from GCC on Sustaining Containment Certification During the COVID-19 Pandemic

Dr Arlene KING, Chair, GCC-CWG and Member, GCC

Several factors including the COVID-19 pandemic have delayed the implementation of containment certification activities e.g., CCS auditor qualifying activities, and facility containment certification. This has hindered Member States from having the capacity to perform the steps necessary for the issuance of an ICC which now places CP-holding facilities at risk of not being able to be awarded an ICC before or by the CP end-validity date of 30 April 2022<sup>13</sup>.

In May 2021, a NAC communicated to GCC its intention to pursue the ICC phase using in the absence of national-level qualified CCS auditors. This request to use in-country auditors with competence and qualifications

<sup>12</sup> Such as but not limited to: all CAG recommendations, relevant SAGE recommendations, GAPIII – CCS, PIM Guidance 2nd edition, Guidelines for the safe production and quality control of poliomyelitis vaccines, Annex 4, WHO Technical Report Series (TRS) No 1016 and Annex 3, WHO TRS No 1028 (Amendment to Annex 4 of WHO TRS No 1016), European Committee for Standardization (CEN), CEN Workshop Agreement CWA15793 – Laboratory biorisk management (2011); WHO Laboratory Biosafety Manual and Associated Monographs, 4th edition (2020), ISO 35001: Biorisk management for laboratories and other related organisations (2019), etc.

<sup>13</sup> Communication: Letter from Chair, Global Commission for the Certification of the Eradication of Poliomyelitis to National Authorities for Containment on COVID-19 pandemic impacts on implementation of CCS activities. Dated: 8 October 2020.



considered equivalent to those described in the CCS to effectively perform and manage audits supported by a detailed plan of action was submitted to the GCC for consideration. This submission was reviewed jointly by GCC in an ad-hoc meeting in July 2021. At the 21st GCC meeting <sup>14</sup>, in the context of the COVID-19 pandemic impacting containment certification activities and the impending end-validity of all CPs on 30 April 2022, GCC discussed this request and provided the following recommendations for all NACs to sustain global containment progress (Table 1):

Table 1: GCC recommendation to sustain progress on containment during the COVID-19 pandemic.

Extension of CP end-validity (beyond 30 April 2022)
<ul style="list-style-type: none"> <li>• NACs lacking qualified GAP III auditors in the Member States with facilities awarded a GCC-countersigned CP may submit a formal request to GCC – CWG for an extension of CP end-validity (up to 31 Dec 2022) by 1 Nov 2021.</li> <li>• Supporting documentation should include a time-bound action plan for facilities to achieve an ICC by or before 31 December 2022.</li> <li>• Consideration will be granted on a case-to-case basis.</li> </ul>
Pursue subsequent national containment certification steps
<ul style="list-style-type: none"> <li>• Ahead of further certification steps, NACs lacking qualified GAP III auditors may submit a formal request to GCC – CWG to pursue the ICC application phase for facilities awarded a GCC-countersigned CP.</li> <li>• Supporting documentation should include timeframe, audit team composition, experience (as per CCS), and a detailed audit plan process.</li> <li>• Consideration will be granted on a case-to-case basis.</li> </ul>
Establish national containment certification infrastructure and initiate containment certification
<ul style="list-style-type: none"> <li>• Member States that have not designated NACs, with non-designated facilities that continue to handle polioviruses in the absence of national oversight (i.e., no valid CP), should provide GCC – CWG with a clear plan of action to comply with resolution WHA71.16 Poliomyelitis – Containment of Polioviruses i.e., designation of a NAC and formalization of the eligibility of facilities retaining polioviruses in CCS, by 30 September 2021.</li> </ul>

#### Containment Certification Process and Associated Tools (CP extension, ICC, etc.)

Liliane BOUALAM, Technical Officer, Poliovirus Containment, Department of Polio Eradication, WHO

In advance of the meeting, a request for updates from the CWG on containment certification of facilities was sent to NACs (n = 19).. Of the responding NACs (n = 13), representing 34 facilities retaining polioviruses, the majority (n = 31) of facilities intend to request for an extension of the CP end-validity through their NACs.

Guidance on the implementation of the latest recommendations made by the GCC on sustaining containment progress during the COVID-19 pandemic was shared during the meeting. This guidance describes the information to be submitted, associated deadlines, and instructions for the Member States in the different stages of containment certification.

#### Discussion

Arlene KING, Chair, GCC-CWG and Member, GCC

- a) The opportunity for NACs to provide feedback on the use of the NAC platform or to raise questions will be addressed through a survey which will be conducted over the next few weeks and aims to identify shortcomings, if any, areas for improvement and to re-evaluate the usefulness of the NAC platform going forward.
- b) The list of country names used in the Potential Infectious Material (PIM) Identification Tool input interface is in line with the official and latest list of the WHO Member States and Associate Members list. The data source used in the PIM Identification Tool is taken from Web Annex A: Country- and area-specific poliovirus data of the PIM Guidance, 2nd Edition<sup>7</sup> and is based on data available in the literature and official reports received from the Member States

<sup>14</sup> Meeting reports of the Global Commission for the Certification of Eradication of Poliomyelitis. Available at: <https://polioeradication.org/tools-and-library/policy-reports/certification-reports/global-certification-commission/>

and has these references cited. The output page of the PIM Identification Tool does not cite these references. As such, the references cited in Web Annex A should be used to determine the source of data used.

- c) Clarification on the definition of a breach in poliovirus containment was raised including polioviruses currently notifiable to WHO through the National International Health Regulations (IHR), 2005 Focal Point (NFP). Endorsed by GCC in October 2019, the 'Public health management of facility-related exposure to live polioviruses: Guidance in managing exposed persons for countries hosting facilities that maintain live polioviruses<sup>15</sup>' defines a poliovirus breach as a release from a poliovirus-essential facility (PEF) of any poliovirus subject to containment, now or in the future, under GAPIII. Under Annex 2: Decision instrument for the assessment and notification of events that may constitute a public health emergency of international concern (PHEIC) of IHR, 2005<sup>16</sup> events that shall be notified to WHO includes: laboratory-confirmed cases of poliomyelitis due to WPV serotypes 1, 2 and 3; 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) and isolation of Sabin poliovirus serotype 2 and Sabin-like viruses from any source including human or non-human sources.
- d) In some Member States hosting facilities retaining polioviruses, there are well-qualified and experienced auditors in related fields e.g., Good Manufacturing Practices (GMP), biocontainment laboratories, select agents and toxins, etc. Member States intending to pursue the ICC application phase in the absence of a CCS lead auditor or auditor, may opt to use national experienced auditors with qualification determined to be at par with the CCS. As per GCC recommendations (Table 1) and guidance for the Member States intending to pursue the ICC application phase in the absence of CCS lead auditors or auditors, a comparative analysis of the proposed national ICC plan with the CCS should be performed and included in the submission to GCC- CWG together with timelines; and audit team composition, etc.

#### Session: National Implementation and Certification of Poliovirus Containment

##### Country Experience: Reducing the Number of Poliovirus-essential Facilities (PEF)

Andréanne BONHOMME, Director, Canadian National Authority for Containment and Director, *ad interim*, Office of Biosafety and Biocontainment Operations, Centre for Biosecurity, Public Health Agency of Canada, Ontario, Canada

The Centre for Biosecurity of the Public Health Agency of Canada (PHAC) is the national authority for biosafety and biosecurity of human pathogens and toxins and is responsible for the enforcement of the Human Pathogens and Toxins Act (HPTA)<sup>17</sup> and Human Pathogens and Toxins Regulations (HPTR)<sup>18</sup> established to protect public health and safety against risks posed by human pathogens. The Centre for Biosecurity serves as the Canadian NAC.

The strategies used by the Canadian NAC to reduce the number of facilities storing or handling polioviruses include:

- a. Close-collaboration with facilities to encourage destruction or transfer of poliovirus materials to facilities already designated as serving critical functions.
- b. Destruction and disposition of poliovirus materials among facilities not serving critical functions which is documented by the use of a 'Poliovirus Destruction or Transfer Form' attesting to the destruction or transfer of poliovirus materials by the facility.
- c. Active engagement with facility management, staff and relevant personnel using tailored dissuasion strategies e.g., upgrade needs for physical laboratory space and design; tertiary (facility location and associated

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<sup>15</sup> Public health management of facility-related exposure to live polioviruses: Guidance in managing exposed persons for countries hosting facilities that maintain live polioviruses. Available at: <https://polioeradication.org/wp-content/uploads/2021/05/Public-Health-Management-of-Facility-related-Exposure-to-Live-Polioviruses-EN-20210520.pdf>

<sup>16</sup> International Health Regulations (IHR), 2005. 3<sup>rd</sup> Edition. Available at: <https://apps.who.int/iris/rest/bitstreams/1031116/retrieve>

<sup>17</sup> Human Pathogens and Toxins Act (S.C. 2009, c. 24), Current to 20 October 2021 (2015). Available at: <https://laws-lois.justice.gc.ca/PDF/H-5.67.pdf>

<sup>18</sup> Human Pathogens and Toxins Regulations (SOR/2015-44), Current to 11 November 2021 (2015). Available at: <https://laws.justice.gc.ca/PDF/SOR-2015-44.pdf>

environmental control) safeguard requirements and local provincial considerations; operator training in the implementation of GAPIII, etc.

#### Country Experience: Containment Certification Implementation in Belgium

Yseult NAVEZ, Expert Advisor, Belgian National Authority for Containment, Public Health Emergencies Team, Federal Public Service (FPS) Health, Food Chain Safety, and Environment, Brussels, Belgium

As the requirements of GAPIII include different aspects of poliovirus biology, biosafety, biosecurity and quality management systems, the establishment of containment certification infrastructure and processes in Belgium involved a multidisciplinary approach involving different government agencies. In 2017, the Public Health Emergencies Team of the Federal Public Service (FPS) Health, Food Chain Safety and Environment was designated as the Belgian NAC. The NAC has put in place agreements for GMP auditors from the Agency for Medicines and Health Products (AFMPS) as well as technical experts e.g., poliovirus biosafety and biosecurity, as and when needed, from the Service Biosafety and Biotechnology (SBB), Sciensano Belgian Institute for Health, to be engaged as members of the audit team.

In 2019, legislation on various provisions in the field of pharmaceutical specialties, custody of pharmacists and prophylactic measures in the field of poliomyelitis<sup>19</sup> and the Royal Decree of December 11, 2019 establishing the procedures for handling and storing type 2 polioviruses<sup>20</sup> were brought into effect for legal implementation of GAPIII and to define the certification procedures for facilities that will continue working with poliovirus serotype 2. Four facilities have been designated as serving critical functions (polio vaccine production and quality control, research and development and storage) in Belgium. Submission of CP applications from these facilities are currently being processed.

In April 2021, the development of national audit and containment certification procedures by the Belgian NAC in alignment with the CCS, local conditions e.g., requirements described in the Royal Decree of December 11, 2019; and principles and practices as set out in ISO/IEC 17021-1:2015 Conformity assessment – Requirements for bodies providing audit and certification of management systems – Part 1: Requirements<sup>21</sup> is underway. The Belgian NAC (in consultation with the AFMPS) considers their candidate auditors qualified at par with CCS and AQAS requirements and will instead propose an alternative mechanism for auditor qualification to the GCC – CWG in order to pursue containment certification of its facilities.

#### Country Experience: Containment Certification Implementation in Denmark

Johannes Rosenstand JØRGENSEN, Analyst and GAPIII Coordinator, National Authority for Containment of Denmark, Center for Biosecurity and Biopreparedness (CBB), Copenhagen, Denmark

The Centre for Biosecurity and Biopreparedness (CBB) was designated as the Danish NAC on 30 November 2019 through the Executive Order on Control Measures Against Infectious and Potentially Infectious Materials, Poliovirus (Containment Of Poliovirus): BEK NR 1247 AF 28/11/<sup>22</sup> giving the NAC the following mandates:

1. National Licensing and Certification: facilities intending to retain polioviruses must apply for a permit from CBB and fulfill the relevant legal requirements. In addition, facilities must apply for a CCS certificate.

<sup>19</sup> 7 Avril 2019. - Loi portant des dispositions diverses en matière de spécialités pharmaceutiques, garde des pharmaciens et des mesures prophylactiques en matière de poliomyélite or Law of April 7, 2019 on various provisions in the field of pharmaceutical specialties, custody of pharmacists and prophylactic measures in the field of poliomyelitis. Available at: <http://www.ejustice.just.fgov.be/eli/loi/2019/04/07/2019012217/justel>

<sup>20</sup> 11 Decembre 2019. — Arrêté royal fixant les modalités de manipulation et stockage des poliovirus de type 2 or Royal Decree of December 11, 2019 establishing the procedures for handling and storing type 2 polioviruses. Available at: [http://www.ejustice.just.fgov.be/mopdf/2019/12/31\\_1.pdf#Page16](http://www.ejustice.just.fgov.be/mopdf/2019/12/31_1.pdf#Page16)

<sup>21</sup> ISO/IEC 17021-1:2015 Conformity assessment — Requirements for bodies providing audit and certification of management systems — Part 1: Requirements. Available at: <https://www.iso.org/standard/61651.html>

<sup>22</sup> Executive Order on Control Measures Against Poliovirus And Material that Potentially Contain Infectious Poliovirus (Containment Of Poliovirus): BEK nr 1247 af 28/11/2019 or Bekendtgørelse om kontrolforanstaltninger mod poliovirus og materiale, der potentielt indeholder infektiøst poliovirus BEK nr 1247 af 28/11/2019. Available at: <https://www.retsinformation.dk/eli/lta/2019/1247>

2. Monitor transfer of poliovirus materials: facilities not intending to retain polioviruses should destroy poliovirus materials or transfer them to a facility already designated as serving a critical function.
3. Inspections and audits: performs inspections to ensure facilities are in compliance with the legal requirements and for the issuance of a CCS certificate (ICC and CC).

In preparation for the ICC application phase, the following steps have been taken with some more challenging than others:

1. Establishing a contract with the CP-holding facility
2. Implementation of AQAS 2022 – 2023 activities: CEV – AAT was held from 15 – 29 March 2021 with auditor trainees from the Danish NAC. These activities highlighted challenges for the Danish NAC to sustain its auditor qualification programme as it will eventually only host one PEF.
3. Establishment of certification procedures requires further work including alignment with CCS, local conditions e.g., if they could be developed in accordance with existing national inspection procedures addressing biosecurity and biopreparedness and in adherence to the principles and practices as set out in ISO/IEC 17021-1:2015 Conformity assessment – Requirements for bodies providing audit and certification of management systems – Part 1: Requirements<sup>21</sup>.
4. Formal request maybe submitted to GCC- CWG for Denmark to pursue the national containment certification phase i.e., ICC application phase in the absence of national-level qualified GAPIII auditors.

**Country Experience: Containment Certification Implementation in the United States of America**  
 Christy OTTENDORFER, Auditor, U.S. National Authority for Containment of Poliovirus,  
 Center for Preparedness and Response, Centers for Disease Control and Prevention, Atlanta, Georgia, USA

On 31 January 2018, the U.S. Department of Health and Human Services (HHS) designated the Center for Preparedness and Response as the US National Authority for Containment of Poliovirus. The NAC is responsible for implementing poliovirus containment in the US, including survey and inventory activities and compliance verification of facilities retaining polioviruses post-eradication. Cooperation from facilities is voluntary as there are no regulations in the US to enforce GAPIII implementation – hence the adoption of a collaborative approach through proactive communication and outreach with facilities. A step-wise approach is taken towards full compliance with GAPIII requirements. During the period of CP validity and transition period to GAPIII, facilities must comply with the ‘current containment conditions in effect for poliovirus type 2 infectious materials’ as established by the US NAC.

As of June 2021, all facilities that have been designated as serving critical functions requiring the retention of polioviruses in the US (n = 11) have a valid GCC-countersigned CP. Of these 11 facilities, five have expressed intention of pursuing an ICC/CC while six plan to cease work by the CP end-validity in 2022. Through numerous outreach activities and efforts, the US NAC has been able to reduce the number of facilities designated as PEFs from 26 to 11 (as of June 2021) located across nine states from 14 states for the period 2017 – 2020. Improvements have been observed in the current containment practices in these facilities – although GAPIII containment is expected to be more complex and challenging highlighting the importance of close coordination between the relevant stakeholders e.g., facilities, NACs, WHO, containment advisory bodies and working groups.

#### Discussion

Facilitated by Arlene KING [Chair, Global Commission for the Certification of the Eradication of Poliomyelitis –  
 Containment Working Group (GCC-CWG) and Member, GCC]

- a) The biosafety and biosecurity programme requirements for Canadian facilities handling human pathogens e.g., polioviruses are regulated by legislations<sup>17,18</sup>, are in-line with the requirements set-out in the CBS<sup>Error! Bookmark not defined.</sup> i.e., RG2 pathogens such as polioviruses must be handled at CL2, and covers the 16 elements of GAPIII. To support facilities retaining polioviruses, GAPIII pre-assessment involving interviews, document reviews, and on-site visits have been integrated into the Compliance and Enforcement Program of the Center of Biosecurity.
- b) In Canada, like many other countries, the COVID-19 pandemic diverted many resources away e.g., biosecurity program inspectors to COVID-19 pandemic response, inspector travels were cancelled due to restrictions, etc. In the first quarter of 2021, as part of the modernization of regulatory oversight efforts, the Center of Biosecurity introduce the use of digital solutions and tools e.g., video feeds during laboratory inspections, to assess the

feasibility of a virtual or off-site inspection model. Amid ongoing public health restrictions, virtual inspections, implemented in the same format as on-site inspections aimed to minimize the impact on laboratories currently undertaking critical COVID-19 response efforts. Virtual inspection pilots were carried out with several organization which helped in the development of its audit and certification procedures. The Center of Biosecurity, designated as the Canadian NAC is exploring a similar virtual inspection model for the audit of its CP-holding facilities.

- c) As part of the Belgian NAC containment certification process for the issuance of an ICC, initial visits and gap assessments although not required as per CCS, are included in the potential initial audit activities to be performed by the NAC– this is seen as an advantage in the given instance that an unsatisfactory certification audit results in major challenges e.g., need for repeat on-site visits or could result in an extensive list of non-conformities, etc.

## SESSION: Way forward

### The Way Forward Poliovirus Containment Strategic Plan

Mark PALLANSCH, Chair, Containment Management Group (CMG) and  
Member, Containment Advisory Group (CAG)

The dynamic nature of eradication and the delayed implementation of containment certification activities have contributed to challenges in the current containment timelines requiring a flexible and adaptable approach..

To address the containment challenges faced by the dynamic nature of eradication; the impact of the COVID-19 pandemic on country-level capacity building to perform GAP III audits and necessary steps for the issuance of ICC certification of facilities while sustaining progress on poliovirus containment and certification, a Poliovirus Containment Strategic Plan is currently under development. This strategic plan is expected to be aligned with the Polio Eradication Strategy 2022 – 2026: Delivering on a Promise; will define the roles, responsibilities and functions of key containment stakeholders at all levels including NACs; will feature clear statements of containment goals, objectives, outcomes and updated strategic process for containment implementation and certification taking into consideration the impacts of the COVID-19 pandemic; will include a communication and advocacy component at all levels; integrate a gender lens; etc.

### Conclusions and Recommendations

Several guidance documents including relevant further GCC recommendations e.g., revised GAP III, Poliovirus Containment Strategic Plan are expected to be made available in 2022 and are in line with the strategies for GAP III implementation i.e., reduce the number of facilities retaining poliovirus materials (risk elimination) and to assure that remaining poliovirus materials are handled according to relevant standards (risk mitigation through the biorisk management of facilities by strict adherence to safeguards with containment certification implementation i.e., GAP III, CCS). The objectives of the documents and recommendations would collectively aim at minimizing the number of poliovirus-essential facilities globally to further reduces the magnitude of a facility-associated risk of release, facilitates national and international oversight, and strengthens the likelihood that global containment standards can be met and successfully maintained.

To address the challenges associated with poliovirus containment implementation and certification brought about by the dynamic nature of eradication and associated milestones e.g., OPV cessation, absence of cVDPV and delays caused by the COVID-19 pandemic, several mitigations options have been identified to progress and sustain containment implementation and certification:

1. Challenges and mitigation options associated with the risk elimination strategy for the implementation of GAPIII i.e., poliovirus survey, inventory and destruction activities.

Associated Challenges	Way Forward
<ul style="list-style-type: none"> <li>• Surveys will be dynamic, repetitive in several instances and will persist for years</li> <li>• Like surveys, inventories will be regularly updated and maintained to ensure accuracy;</li> <li>• Validation or verification will need to be vigorous and regularized with survey and inventory activities to ensure completeness and accuracy.</li> </ul>	<ul style="list-style-type: none"> <li>• Clear plan is needed for implementation and verification of survey and inventories e.g., survey frequency (including novel poliovirus strains); updates of inventories; triggers to commence or to repeat, and deadlines to complete activities; accountability mechanism for PIM Guidance (implementation and compliance with risk mitigation strategies for handling PIM, OPV/Sabin); etc.</li> </ul>

2. Challenges and mitigation options associated with the risk mitigation strategy for the implementation of GAPIII i.e., biorisk management of facilities retaining polioviruses by strict adherence to safeguards and containment certification implementation

Associated Challenges	Way Forward
<ul style="list-style-type: none"> <li>• Disconnect between the need to commence serotype-specific poliovirus containment and other containment activities e.g., containment certification with its epidemiology e.g., handling of WPV3 outside GAPIII containment despite the declaration of WPV3 eradication</li> <li>• Delayed implementation of containment certification activities due to the COVID-19 pandemic and other factors</li> </ul>	<ul style="list-style-type: none"> <li>• Trigger-based approach needed compared to its current use of timelines.</li> <li>• The ongoing revision of GAPIII attempts to move away from linking containment implementation to eradication and OPV cessation timelines by using relevant triggers e.g., absence of cVDPV2.</li> <li>• Implementation of recommendations by GCC to sustain progress on containment during the COVID-19 pandemic i.e., extension of CP end-validity (beyond 30 April 2022), pursue subsequent national containment certification steps and establish national containment certification infrastructure and initiate containment certification (Table 1).</li> </ul>

## Annexes

Annex 1: Agenda

Annex 2: List of participants

## Annex 1: Agenda



Fifth Annual Consultation with National Authorities for  
Containment and the Global Certification Commission for  
the Eradication of Poliomyelitis - Containment Working  
Group  
19 – 20 October 2021  
Virtual Meeting

Rapporteur: Harpal SINGH

Tuesday, 19 October 2021		Chair: Arlene KING
<b>SESSION : Introduction</b>		
15:30-15:40	Welcome and opening remarks	Aidan O'LEARY
15:40-15:50	Remarks from the Chair of the GCC – CWG	Arlene KING
15:50-16:00	Meeting arrangements and outline of the agenda	Liliane BOUALAM
16:00-16:15	Global Polio Eradication Initiative update	Aidan O'LEARY
<b>SESSION : Containment Programmatic Updates and Latest Guidance from GCC on the Implementation and Certification of Poliovirus Containment</b>		
16:15-16:20	Update on the implementation of the recommendations from the Fourth Meeting between NAC and GCC – CWG (October 2020) and Seventy-First World Health Assembly Resolution WHA71.16 Poliomyelitis – Containment of Polioviruses	Liliane BOUALAM
16:20-16:35	Update on the revision of GAPIII	Harpal SINGH
16:35-16:55	Containment certification status and update	Joseph SWAN Nicoletta PREVISANI Liliane BOUALAM
17:00-17:30	Guidance from GCC on containment certification <ol style="list-style-type: none"> <li>1. Guidance Discussion</li> <li>2. Certification process and associated tools (CP extension, ICC, etc.)</li> </ol>	Arlene KING Liliane BOUALAM
17:30-18:00	Discussion Summary and wrap-up	Arlene KING
Wednesday, 20 October 2021		Chair: Arlene KING
15:30-16:15	Questions and clarifications from NACs	Arlene KING
<b>Session: National Implementation and Certification of Poliovirus Containment</b>		
16:15-16:30	Country experience: PEF reduction	NAC Canada
16:30-17:15	Country experience: Containment certification	NAC Belgium NAC Denmark NAC USA
17:15-17:45	Discussion	All
<b>SESSION: Conclusions, recommendations and the way forward certification of poliovirus containment</b>		
17:45-18:00	The way forward	Mark PALLANSCH

## Annex 2: List of Participants

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