World Health Organization

Second Face-to-Face Meeting Between the Global Certification Commission - Containment Working Group (GCC-CWG) and National Authorities for Containment (NAC)

10 – 11 October 2018

Geneva, Switzerland

Note for the Record

Table of Contents

List of abbreviations

AFP	Acute flaccid paralysis
CAG	Containment Advisory Group
CC	Certificate of Containment
CCS	Containment Certification Scheme to support the WHO Global Action Plan for Poliovirus Containment
CP	Certificate of participation
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 otherwise known as the WHO Global Action Plan for Poliovirus Containment (3rd edition; 2014)
GCC	Global Commission for the Certification of the Eradication of Poliomyelitis
GLP	Good laboratories practices
GMP	Good manufacturing practices
GPEI	Global Polio Eradication Initiative
ICC	Interim certificate of containment
IHR	International Health Regulations
IPV	Inactivated polio vaccine
MOH	Ministry of Health
NAC	National authority for containment
NCC	National Committee for the Certification of the Eradication of Poliomyelitis
NFP	National Focal Point
OPV	Oral polio vaccine
bOPV	Bivalent oral polio vaccine containing type 1 and type 3
mOPV2	Monovalent oral polio vaccine type 2
nOPV2	Novel oral polio vaccine type 2
PEF	Poliovirus-essential facility
PIM	Potentially infectious materials, poliovirus
PV	Poliovirus
PV1	Poliovirus serotype 1
PV2	Poliovirus serotype 2
PV3	Poliovirus serotype 3
RCC	Regional Commission for the Certification of the Eradication of Poliomyelitis
SAGE	Strategic Advisory Group of Experts on Immunization
VDPV	Vaccine-derived poliovirus
aVDPV	Ambiguous vaccine-derived poliovirus
aVDPV1	Ambiguous vaccine-derived poliovirus serotype 1
aVDPV2	Ambiguous vaccine-derived poliovirus serotype 2
aVDPV3	Ambiguous 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
iVDPV	Immunodeficiency-associated vaccine-derived poliovirus
iVDPV1	Immunodeficiency-associated vaccine-derived poliovirus serotype 1
iVDPV2	Immunodeficiency-associated vaccine-derived poliovirus serotype 2
iVDPV3	Immunodeficiency-associated 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

Executive Summary

This meeting has provided a very valuable opportunity for representatives of NACs to meet members of the GCC-CWG to discuss progress made, experience gained, and challenges faced[1]. Following on from resolution WHA71.16 (Poliomyelitis – Containment of Polioviruses) adopted by all WHO Member States in 2018, this meeting is a strong indication that GAPIII implementation is being taken seriously and discussion is no longer a general discourse about if and why containment should take place but detailed exchange on how and when it will happen.

Progress in implementing GAPIII requirements have been made; most of countries with potential PEFs have now established functional NACs, and one PEF has attained a GCC-endorsed CP. Training workshops for GAPIII auditors have been held and electronic information sharing mechanism has been established in the form of a mailing list. Guidance to minimize risks for facilities collecting, handling or storing materials potentially infectious for polioviruses (PIM guidance) have been published and the mechanism of communication between NACs and GCC-CWG is now operational as is the communication channels between the different groups supporting containment work i.e., GCC, GCC-CWG and CAG.

The meeting focused on the challenges faced by NACs in meeting the implementation of CCS. Meeting the requirements for suitably qualified auditors, particularly lead auditors, is a major challenge that will require an innovative approach. More training workshops, increased collaboration between NACs, creation of regional pool of auditors, more opportunities for trainee auditors to gain on-site experience, and greater flexibility in the GAPIII-CCS qualification requirements for auditors have all been discussed as potentially contributing to the solution.

Acquiring the necessary resources, both human and financial, to establish and maintain an effective NAC was discussed as a challenge for several countries. The legal authority of the NACs was also a topic of debate and discussion, with some countries establishing new legislative instruments to empower the NAC, while others are developing mechanisms to link NAC functions and authority with existing legal statutes. National requirements for data security and confidentiality, the nature and extent of information that can be shared with the GCC-CWG and the requirement to protect national security, were also challenging issues for some NACs.

Meeting the CCS timeline was a challenge for several NACs, particularly regarding submission of the CP application. At present the deadline for submission of CP applications is 31st December 2019, but a CP will only be valid for an initial period of 12 months with two possible extensions of 3 months each under extenuating circumstances. Under current recommendations, an ICC/CC will have to be achieved before the end of the validity of the CP. This provides little incentive for the PEFs to submit their CP applications before the deadline, and some

[1] The First Face-to-Face Meeting Between the Global Certification Commission - Containment Working Group (GCC-CWG) and National Authorities for Containment (NAC) was held on 27 October 2017 in Geneva, Switzerland.

revision to the current requirements such as to extend the validity of CPs acquired earlier than the end of 2019 may reduce the potential for a last-minute surge in applications as the deadline approaches.

There was a general request from the NACs to improve the mechanisms for exchange of information, particularly for NACs to gain easier access to key guidance and advice documentation, but also for informal exchange between NACs. Establishment of a NAC website or NAC-specific web-based collaborative platform was discussed as potential solutions to be explored by the WHO Secretariat.

Of continuing concern to the CWG was the number of proposed PEFs being considered solely for the storage only of WPV materials (no handling). All Member States should consider carefully their reasons for maintaining poliovirus repositories and weigh these against the financial and administrative burden of establishing and maintaining PEFs, including the inherent responsibility in meeting primary, secondary and tertiary safeguards described in GAPIII. Unless there are well developed and detailed plans for the productive use of poliovirus biorepository materials all Member States should consider either safely destroying poliovirus materials or transferring them to an international repository. Additional information for transfer to an international repository can be obtained by emailing containment@who.int.

Following discussions during the meeting it was apparent the GCC and WHO Secretariat should consider providing further clarity and guidance on several important areas. These include specific oversight roles and functions of the GCC and associated bodies, amendments to GAPIII, and additional guidance on implementation of PIM guidance and its oversight.

The meeting agenda and list of participants are included in Annexes 1 and 2.

Background

The Global Certification Commission (GCC) for the Eradication of Poliomyelitis acts as a global containment oversight body, approving and endorsing the issuance of containment certificates delivered by the National Authorities for Containment (NACs) and confirming the global containment of polioviruses. The Containment Working Group (CWG) of the GCC reviews the national containment certification of poliovirus-essential facilities (PEFs) and make recommendations to the GCC. The CWG aims to provide the required level of assurance that requirements of the *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* (GAPIII) are appropriately identified, implemented and monitored, according to the Containment Certification Scheme (CCS). PEFs are required to submit their applications to their respective NACs, and if approved by the CWG, the PEF will be issued a GCC-endorsed certificate as described in the CCS.

This meeting represented an opportunity for members of the GCC-CWG and representatives of NACs from Member States hosting facilities retaining polioviruses to review the current situation regarding poliovirus containment, exchange information and experience gained to date, debate procedures and methodologies and identify key challenges to further progress.

Objectives of the Meeting

- Update stakeholders on progress related to the implementation of CCS;
- Provide a forum for key containment certification stakeholders to synergize their efforts and to collaborate where needed; and

SESSION 1. Introduction

Opening remarks

Professor David Salisbury, Chair, Global Certification Commission for the Eradication of Poliomyelitis

The meeting was opened and chaired by Professor David Salisbury, Chair of the GCC. Dr Salisbury welcomed all participants to this second meeting of the established NACs with members of the CWG and underscored the importance of establishing and maintaining easy and effective communications between the CWG and the NACs.

Update on Polio Eradication and the Endgame Strategy

Dr Roland Sutter, Special Adviser on Research, Policy and Containment to the Director, Polio Eradication, WHO

An overview of the Global Polio Eradication programme was provided, with emphasis on the status, progress and challenges in the 2 remaining endemic countries facing ongoing transmission of wild poliovirus serotype 1 (WPV1). The last cases of WPV1 to date were reported in August 2018 in Afghanistan and Pakistan, with cases largely restricted to three major transmission corridors that span the border areas. AFP surveillance has been supplemented by environmental surveillance in both countries, demonstrating significant ongoing virus transmission in the absence of detected cases. Inaccessibility to many children, due primarily to security concerns, remains a significant challenge in this area.

In addition to WPV1 transmission, several large-scale outbreaks associated with cVDPVs have occurred and continue to occur. Outbreak response to large-scale transmission of cVDPV serotype 2 (cVDPV2) has included supplementary immunization using monovalent OPV type 2 (mOPV2) and evidence is accumulating that this action has resulted in the emergence of additional cVDPV2 transmission. Most of the cVDPV outbreaks have occurred in areas with persistently low immunization coverage, insecurity, and populations that are difficult to access.

In response to these challenges the GPEI has focused efforts on implementing action plans addressing ongoing transmission in the northern and southern corridors of Pakistan and Afghanistan and expanded community-based vaccination in key areas in Pakistan. Negotiations have also started into improving access to under-immunized populations in Afghanistan. High-level advocacy for political commitment to address the continuing cVDPV outbreaks has also been intensified, including deployment of high level WHO and partner agency staff to support field operations.

The programme's priorities for the coming 6 months include: (1) development of a new Endgame Strategic Plan 2019-2023 that will assume interruption of transmission in 2020, global certification in 2023 and cessation of OPV use one year after certification; (2) acceleration of interruption of virus transmission in remaining endemic countries (Nigeria, Pakistan, Afghanistan); (3) enhanced focus on stopping cVDPV2 outbreaks; (4) enhanced AFP surveillance to meet certification standards and expanded environmental surveillance; and (5) development of the mOPV stockpiles to respond to outbreaks post-OPV cessation.

Discussion

- Significant evidence of poliovirus-positive environmental samples with few recognised cases of poliomyelitis in Pakistan and the inference that there is continued widespread transmission that is being missed by AFP surveillance;
- The outbreak of cVDPV1 in Papua New Guinea, the high risk that the country has posed for several years, and the ability to mount an effective response to deal with the current outbreak and maintain polio-free status in future.

SESSION 2: Global update on poliovirus biocontainment

Global poliovirus containment update

Dr Arlene King [Chair, Global Commission for the Certification of the Eradication of Poliomyelitis - Containment Working Group (GCC-CWG) and Member, GCC]

The World Health Assembly (WHA) resolution 71.16 (2018)[2] urges all |WHO Member States to intensify efforts to accelerate the progress of poliovirus containment certification, complete inventories for type 2 polioviruses, destroy unneeded poliovirus type 2 materials and to begin inventories and destruction of unneeded poliovirus type 1 and 3 materials in accordance with the latest available published WHO guidance. The resolution also requires immediate reporting of any breach of poliovirus containment to the National IHR Focal Point. Member States retaining polioviruses are urged to reduce to a minimum the number of facilities designated for the retention of polioviruses, prioritizing facilities performing critical national or international functions and appoint a competent National Authority for Containment (NAC) by end-2018.All facilities designated to retain poliovirus type 2 are required to formally engage in the Containment Certification Scheme (CCS) by submitting to their NAC

[2] WHA71.16 Poliomyelitis – containment of polioviruses. Available at: http://apps.who.int/gb/ebwha/pdf_files/WHA71/A71_R16-en.pdf

their applications for participation (CP), which is the first step of the global certification process, as soon as possible and no later than 31 December 2019.

As of 7 October 2018, twenty-eight Member States have notified WHO of their intention to retain poliovirus type 2 (PV2) materials in a total of 89 designated poliovirus-essential facilities (PEF). Of these 28 Member States, only 22 have established NACs. To date, applications for CPs have been submitted by NACs to the Global Certification Commission (GCC) for six facilities. Of these applications, one has been endorsed by the GCC, two applications are on hold and three are under review.

The Containment Working Group of the GCC (GCC-CWG) was established in January 2017 with seven members charged with supporting GCC's role in global containment oversight by providing review of containment certification applications. There are plans to expand the GCC-CWG membership in 2018. Major challenges faced include ensuring the establishment of NACs in all countries hosting PEFs before the end of 2018 and accelerating the certification process for PEFs so that CPs can be issues by the end of 2019. To accomplish this, GAPIII auditing capacity of newly established NACs will need to be increased. Additional challenges include meeting the GCC deadline of April 2019 for implementing the Guidance to minimize risks for facilities collecting, handling or storing materials potentially infectious for polioviruses (PIM guidance), updating all national poliovirus inventories to include poliovirus types 1 and 3, and establishing a verification mechanism to ensure data quality of national inventories. There is an ongoing requirement to increase the awareness of all Member States of WHA resolution 71.16 (2018).

To meet these challenges, a communications/advocacy strategy has been developed and deployment of consultants to support implementation of the PIM guidance is in progress. A series of workshops on the implementation of the PIM guidance at WHO Regional level and training of auditors to strengthen the capacity of NACs is also being established.

Discussion

- There is a consensus that the GPEI containment webpages are difficult to navigate and there is a need to have in one place all containment related documents e.g., amendments to GAPIII and reports from the meeting of the GCC, Containment Advisory Group (CAG), and Strategic Advisory Group of Experts (SAGE) on immunization, and others useful documents.
- The CAG will address the issue of amendments to GAPIII and related administrative processes at the Third CAG Meeting in December 2018.

The Ideal NAC

Dr Harpal Singh, Technical Officer - Poliovirus Containment, Research, Policy and Containment, Polio Eradication, WHO

NACs are responsible for national GAPIII containment certification and oversight, charged with ensuring and documenting that the required primary, secondary and tertiary safeguards described in GAPIII are met. The NAC should ensure that containment certification activities are conducted in all facilities that retaining polioviruses post-eradication and provide adequate assurance that the requirements set out in GAPIII and the CCS are effectively implemented and maintained. All WHO Member States hosting such facilities must have an official authority or body functioning as a NAC to exercise its critical control functions in a competent and independent manner, ideally backed up with the ability to enforce their decisions and recommendations.

WHO Member States should nominate the appropriate division or section of the Ministry of Health or other established national authorities to perform the role of a NAC, and commit the necessary resources, both human and financial to permit the NAC to function effectively. Once NACs have been established, countries should assess the functioning of their NACs, and develop a systematic plan to indicate how any identified gaps will be filled, including targets, goals, milestones, and the costs for each step. This plan should include a plan for staff training and accessing necessary technical and financial inputs, and impact of implementing these plans should be monitored.

NACs are required to review and process applications for containment certification of designated PEFs in consultation with the GCC, ensuring only relevant facilities enter the containment certification process. The NACs should also ensure that containment certification activities are conducted to provide adequate assurance that the requirements set out in GAPIII and the CCS are effectively implemented and maintained. It is a role of the NAC to ensure that effective procedures are established to address relevant aspects of the containment certification cycle, and to verify that internal processes function appropriately. The NACs are expected to provide the PEFs, audit team members and the GCC with appropriate access to pertinent information which may be required during the review of containment certificate applications e.g., information demonstrating compliance with secondary and tertiary safeguards as described in GAPIII. The NAC will also issue, suspend or revoke certificates of containment, in consultation with the GCC.

Discussion

- The need for review and possible revision of existing generic terms of reference for NACs (Annex 3: TORs of the NAC as per CCS);
- There are different legal and administrative restrictions in WHO Member States to grant access of information by the GCC or for verification of containment under routine work or when breaches occur and the exact details of how each country works with the GCC in this specific area will need to be established on a country-by-country basis;
- The need for each NAC to be working to standards aligned to ISO/IEC 17021-1:2015 and be able to demonstrate compliance with this standard, but not necessarily be ISO/IEC 17021 accredited;

- Many countries with designated PEFs have national regulatory authorities that follow their own standards and procedures in their area of work, and the requirements of NACs in these countries should be compatible and consistent with the functions of existing regulatory authorities;
- The NAC should initiate the containment process with the facilities retaining polioviruses and to as the interface between the PEF and the GCC and should minimize delays in application for, and approval of, facility certification. Generic characteristics of a NAC have been provided as an ideal example (Annex 3: TORs of the NAC as per CCS) but each WHO Member State will need to ensure that the functions of a NAC are conducted as best suits their own regulatory and legislative environment and in line with the CCS.

SESSION 3: National updates on poliovirus biocontainment

Australia

Dr Gary Lum, National Authority for Containment, Australia

- Number of facilities designated for the retention of PV2 materials:
  - One (laboratory retaining WPV2/VDPV2 and OPV2/Sabin2 materials);
  - The facility has not applied for a CP, will apply but the time-frame has yet to be determined;
  - This facility has expressed an intention to retain PV1 and PV3 materials.
- The NAC is established and is functional:
  - The NAC is within the Office of Health Protection, Australian Government Department of Health;
  - This is effectively a virtual NAC within the Australian Government and has no direct authority over Australian states and territories;
  - The NAC composition is linked to official positions/designation but none of the NAC members is engaged in poliovirus containment full time;
  - The NAC was established in December 2015 and has 3 members with a professional background in policy, epidemiology and clinical microbiology/pathology and regulatory affairs.
- Challenges and constraints:
  - Risk of release of polioviruses from the proposed PEF is low and full compliance with GAPIII is expected, but as GAPIII continues to evolve and be amended it remains unclear what the cost implications of full compliance will be;
  - There are relatively few qualified GAPIII auditors available in the country.
- Website (if any): Not available

Belgium

Ms Anna Kubina, National Authority for Containment, Belgium

- The number of facilities designated for the retention of PV2 materials:
  - Five or six (1 facility includes 2 sites), with 2 classified as laboratories and 3 or 4 classified as vaccine producers;
  - Three are expected to retain OPV2/Sabin2 only; 2 or 3 are expected to retain WPV2/VDPV2 and OPV2/Sabin2;

  - None have applied for a CP but are expected to do so by the end of 2019, and all expect to pursue an ICC or CC;
  - It is not known how many facilities expect to retain PV1 and PV3 materials.
- The NAC is established and is functional:
  - The NAC is established at the Federal Public Service, Health, Food Chain Safety and Environment, Ministry of Social Affairs and Public Health
  - The NAC resides within the Ministry of Health and has close links to the Scientific Institute of Health and the audit of good manufacturing practices
  - The NAC was established in September 2017 after a period of debate over which national entities would be the most appropriate and how this body would collaborate with other national authorities.
- Challenges and constraints:
  - Identifying the most appropriate national entities to host the NAC, and distributing responsibilities among different national authorities and bodies;
  - Creation of a legal basis to empower the NAC to implement its responsibilities given the complex Federal and Regional governmental system;
  - Uncertainty over the expected role of the NAC in the national crisis response system in the event of containment breach;
  - Uncertainties over GAPIII containment requirements and risk assessment needs for development and clinical trials of novel poliovirus strains
- Website (if any): not available

Brazil

Dr André Luiz de Abreu, National Authority for Containment, Brazil

- The number of facilities designated for the retention of PV2 materials:
  - Four facilities have been designated, of which 3 are laboratories and 1 is a vaccine producer;
  - All 4 will retain WPV2/VDPV2 and OPV2/Sabin2
  - No applications have yet been made for CP;
  - There are at least 6 facilities that have expressed an intention to retain PV1 and PV3 materials.
- The NAC is established and is functional:
  - The NAC has been established in the General Coordination of Public Health Laboratories under the Ministry of Health and has legislative power;
  - The NAC was established in June 2015 comprised of 5 members with expertise in pharmaceuticals, biology, IT and engineering
  - NAC members have responsibilities in risk assessment, laboratories survey and data management.
- Challenges and constraints:
  - Difficulties in contacting all laboratories in the country for the national laboratory survey;
  - There is a lack of qualified auditors;
  - The generally low poliomyelitis vaccine coverage will make it difficult for PEFs to meet the secondary safeguard requirement.
- Website (if any): not available

Canada

Dr Mary Louise Graham, National Authority for Containment, Canada

- The number of facilities designated for the retention of PV2 materials:
  - Three, of which 2 are classified as laboratories and 1 is classified as a vaccine producer;
  - Two are expected to retain WPV2/VDPV2 and OPV2/Sabin2 materials; 1 is expected to retain OPV2/Sabin2 only;
  - Two are expected to retain PV1 and PV3 materials.
- The NAC is established and is functional:
  - The NAC is within the Centre for Biosecurity of the Public Health Agency of Canada and was established in September 2015;
  - The Centre for Biosecurity has 24 inspectors, none dedicated to poliovirus containment work, with expertise in microbiology, inspection, engineering, biosafety and biosecurity; representing the national authority for biosafety and biosecurity of human pathogens and toxins.
- Challenges and constraints:
  - The NAC operates under existing legislation but has no legislative authority to restrict a facility's possession of poliovirus materials nor to "force" these facilities to implement GAPIII requirements that exceed national containment requirements;
  - In Canada polioviruses are classified as a Risk Group 2 human pathogen and facilities need to meet the Containment Level (CL2) requirements described in the Canadian Biosafety Standards and Guidelines; there is a need to start discussions with other countries on changing the Risk Group classification of polioviruses post-eradication and the implications for national biosafety and biosecurity legislation;
  - Responsibilities to implement secondary and tertiary safeguards lie at the Provincial/Territorial and Municipal Government levels and the NAC does not have the authority nor the expertise to assess these;
  - Extensive coordination between the different levels of authority is required; this is resource intensive, costly and time consuming for the NAC;
  - There is a need for further discussion on the qualifications required for auditors. NACs should be able to justify to the GCC-CWG equivalent training, experience and competencies of audit team members;
  - GAPIII requirements are not commensurate with risks associated with different areas of vaccine manufacturing facilities, different types of activities with poliovirus materials, and different types of poliovirus materials;
  - Request that a risk- and evidence-based approach be undertaken for the application of GAPIII biocontainment requirements – both at the facility level, and within specialized areas of facilities;
  - The current timeline does not consider potential increase in number of PEFs possessing poliovirus potentially infectious material (WPV and VDPV2). NACs have until April 2019 to compete their national inventory and survey of PIM and any additional facilities will further increase workload for NACs and auditors.

- Website (if any): not available

China

Dr Cheng Liu, Senior Principal Staff Member, National Health and Family Planning Commission, China

- The number of facilities designated for the retention of PV2 materials:
  - Currently 8; one for WPV (national polio laboratory) and 7 for OPV2/Sabin2 only (vaccine producers);
  - There are also 16 facilities retaining VDPV2, including provincial polio laboratories.
- The NAC has not been established:
  - On 4 May 2018, an internal consultation proposed National Health and Family Planning Commission (NHFPC) and National Medical Products Administration (NMPA) formerly known as China Food and Drug Administration (CFDA) to be the acting-NACs for China; the NHFPC is for containment oversight of laboratories and the NMPA is for containment oversight of poliomyelitis vaccine production and control sites
- Challenges and constraints:
  - Given the size of China this is a huge undertaking requiring extensive resources and funding;
  - Each of the 31 provincial authorities in China has responsibility for containment and coordinating activities is a challenge;
  - VDPV2 materials held in provincial laboratories requires additional legal basis for transfer to the national polio laboratory;
  - A containment breach response strategy has not yet been developed; this will be discussed over the coming year and will feature in the NCC report for 2019.
- Website (if any): not available

Cuba

Ms Danay Mora Pascual, National Authority for Containment, Cuba

- The number of facilities designated for the retention of PV2 materials:
  - One laboratory has been designated but there are currently 10 laboratories retaining PV2;
  - No application for a CP has been made;
  - Nine of the 10 PV2-retaining laboratories are believed to retain Sabin2 PIMs only
  - There are no laboratories retaining WPV.
- The NAC is established but is not functional:
  - The Centro Nacional de seguridad Biologica (Cuba National Center for Biological Safety, CNSB) was designated as the NAC by the Ministry of Health in 2017, but has not been active and functional;
  - The Ministry of Health has now designated a new NAC, Centro para el Control Estatal de Me-di-ca-mentos, Equipos y Dispositivos Médicos (Center for State Control of Drugs, Equipment and Medical Devices, CECMED) which alos functions as the NRA in Cuba;
  - The new NAC is not yet functional but expects to be officially designated by the end of October 2018.
- Challenges and constraints:
  - No GAPIII auditing capacity has been established;

- Require capacity building on the NAC's certification and oversight preparatory activities and GAPIII auditing.

- Website (if any): not available

Denmark

Ms Katja Nyholm Olsen, National Authority for Containment, Denmark

- The number of facilities designated for the retention of PV2 materials:
  - Two, of which one is a laboratory and one a vaccine producer;
  - One is expected to retain WPV2/VDPV2 and OPV2/Sabin2 materials
  - No applications for CP have been made but are expected by 2019.
- The NAC is not yet established:
  - Formal establishment is expected after October 2018;
  - The NAC is expected to be part of the Centre for Biosecurity and Bio-preparedness (CBB);
  - A legislative basis for establishment of a NAC is underway and a new bill of health will be presented to parliament in October 2018.
- Challenges and constraints:
  - The need to establish a legal framework for the NAC;
  - Issues of national security and confidentiality in connection to sharing information with the CWG;
  - Requirements for GAPIII and CCS audit team competencies and qualifications.
- Website (if any): not available

Belgium, Canada, the Netherlands and Denmark: Outcome of a meeting to identify mutual challenges in containment implementation

Ms Katja Nyholm Olsen, National Authority for Containment, Denmark

- Requirements essential for NACs:
  - Establishment of a website specifically for NACs would greatly aid exchange of information and experience sharing;
  - An accessible calendar of NAC-specific events and common deadlines would help the planning process.
- Uncertainties regarding decisions on CAG recommendations:
  - More transparency is needed on the process of decision making and recommendations from the CAG;
  - GAPIII continues to evolve and more information on amendments and revised requirements is needed
- Audits:
  - Many countries do not have the resources to conduct the required audits;
  - There needs to be flexibility regarding auditor competencies and qualifications;

- Requirements for auditors should be revised in collaboration with the NACs, and revisions should be reflected in the CCS.

- Approach to poliovirus-non-essential facilities retaining Sabin PIMs:
  - There needs to be greater clarity on how countries are expected to deal with poliovirus-non-essential facilities and on non-polio laboratories retaining Sabin PIMs;

France

Ms Marie-Anne Mortelette, Counsellor (Health), Permanent Mission of France to the United Nations and other international organizations in Geneva, Switzerland

- The number of facilities designated for the retention of PV2 materials:
  - Four, of which 2 are laboratories and 2 are vaccine producers;
  - All 4 are expected to apply for CPs in 2019;
- The NAC is established and is functional:
  - Established in the Direction Générale de la Santé (DGS), Ministry of Health, France;
  - This Directorate is also designated as IHR NFP and is directly under the supervision of the Director-General of Health.
  - The NAC was established in April 2017 and is made up of government policy makers supported by the expertise of the French National Agency for Medicines and Health Products Safety (ANSM), the competent authority for on the regulation of health products and GMP
- Challenges and constraints:
  - The need to establish a specific policy for GAPIII in the French legislation;
  - The need to identify qualified GAPIII-CCS auditors and to train them.
- Website (if any): not available

Hungary

Dr Mária Takács, National Public Health and Medical Officer Service, National Center of Epidemiology, Hungary

- The number of facilities designated for the retention of PV2 materials:
  - One laboratory has been identified, and expects to retain WPV2/VDPV2 and OPV2/Sabin2 together with WPV1 and WPV3 materials;
  - A CP application has not yet been initiated.
- The NAC is established and is functional:
  - The NAC was established within the National Public Health Center, Ministry of Human Capacity, in November 2015;
  - It has 3 members with expertise in virology, epidemiology and vaccine control.
- Challenges and constraints:
  - Frequent restructuring of the public health system presents a challenge;
  - Due to ongoing reorganization there are limited human and financial resources for containment activities.
- Website (if any): not available

India

Dr Shailesh D Pawar, National Authority for Containment, India

- The number of facilities designated for the retention of PV2 materials:
  - One laboratory has been designated to retain PV2, but prospective vaccine producers and at least one more research laboratory are also expected to be designated and will eventually apply for ICC/CC;
  - The CP application process has been initiated for the one facility but is pending for want of auditing expertise in India. WHO has been requested to provide onsite training to auditors to be able to accomplish the task.
- The NAC is established and is functional:
  - The NAC was established within the Ministry of Health and Family Welfare in August 2017;
  - It is composed of 8 members with a range of expertise;
  - The NAC can also draw upon the expertise of the National Laboratory Biosafety Assessment Board (NLBSAB) to provide qualified auditors.
- Challenges and constraints:
  - Challenges to CCS implementation, particularly regarding differences in interpretation of GAPIII requirements, are expected;
  - Identification of GAPIII-qualified lead auditor is a challenge until existing trained auditors qualify as lead auditors;
- Website (if any): Expected soon

Indonesia

Dr Siswanto, Chairperson, Indonesia-National Authority for Containment (i-NAC)

- The number of facilities designated for the retention of PV materials:
  - Two facilities; 1 biorepository and 1 vaccine producer.
  - Biorepository in Center for R&D of Biomedical and Basic Health Technology intend to retain WPV2/VDPV2. The biorepository has also indicated the intention to retain PV1 and PV3 materials
  - Vaccine producer (PT Biofarma) intend to retain OPV2/Sabin2. This PEF has started the CP application process;
- The NAC is established and is functional:
  - The NAC, Indonesia-NAC (i-NAC) has been established under the Ministry of Health by a Ministerial Order and has legal authority under the Ministry;
  - The NAC was established in February 2017 and is composed of 14 members together with 8 NAC auditors with expertise in epidemiology, microbiology, biorisk management and laboratory accreditation.
- Website (if any): not available

Iran

Dr Saeedeh Fakhrzadeh, National Authority for Containment, Iran

- The number of facilities designated for the retention of PV2 materials:
  - One facility has so far been designated – a vaccine producer intending to retain WPV2 and Sabin2;
  - A second vaccine producer is expected to produce poliomyelitis vaccine so will need to be a PEF;
  - No applications for CPs have been made.
- The NAC is established and is functional:
  - The NAC was established in 2016 under the Ministry of Health but due to potential conflict of interests was moved to the Food and Drug Administration of The Islamic Republic of Iran (FDA) in 2017;
  - The NAC has 8 members with expertise vaccine regulation and lot release, immunization and disease surveillance, audit and inspection, diagnostic and medical laboratories management and surveillance;
  - The head of NAC is head of the FDA with legal authority to inspect and certify facilities and issue or cancel licenses.
- Challenges and constraints:
  - There is a need for specific training for GAPIII auditing;
  - Improved communications with other countries NACs and WHO experts should be encouraged and facilitated.
- Website (if any): There is not a specific web site for NAC however Iran FDA has a website http://www.fda.gov.ir/ in which it may host the NAC, if the need be.

Italy

Dr Francesco Maraglino, Director, Office for Communicable Diseases Prevention, Directorate General of Health, Ministry of Health

- The number of facilities designated for the retention of PV2 materials:
  - Two facilities have expressed an intention to become PEFs, but a total of 8 facilities have indicated some intention of retaining poliovirus materials.
- The NAC is not established:
  - The NAC will be established after deciding whether to maintain the PEFs or not.
- Challenges and constraints:
  - Legal constraints in establishing new committees according to the decree 31-5-2010 no. 78 issued by the Ministry of Economy and Finance and the need to define the professionalisms to be included in the NAC
  - Uncertainties over the need for the NAC to be independent of the Ministry of Health;
  - Lack of resources for establishing and maintaining a NAC and the need for auditor training.
- Website (if any): not available

Japan

Dr Norifumi Shigemoto, National Authority for Containment, Japan

- The number of facilities designated for the retention of PV2 materials:
  - Five PEFs; of which 1 is a laboratory and 4 are vaccine producers, all retaining WPV2/VDPV2 and OPV2/Sabin2; it is expected that 5 will also retain PV1 and PV2 materials;
  - None have yet started the CP application process, but all are expected to pursue ICC/CC.
- The NAC is established and is functional:
  - The NAC is established under the
  - Infectious Disease Control Division, Health Service Bureau, Ministry of Health, Labour and Welfare, Japan
  - The NAC is composed of 3 members with expertise in legislation and inspections and audits
- Challenges and constraints:
  - Insufficient human resources to establish a sustainable NAC and is planning to be establish an advisory expert group that will provide guidance and support NAC.
  - There is a shortage of potential auditors due to conflict of interest issues of available experts;
  - Insufficient information has been provided on the expected functions of the NAC to establish a government budget plan
  - More information is required on the nature and extent of tertiary safeguards.
- Website (if any): not available

The Netherlands

Margreet van der Veer, National Authority for Containment Bureau of the Netherlands

- The number of facilities designated Dr for the retention of PV2 materials:
  - Currently 10, with 9 being classified as laboratories and one vaccine producer. 7, however retain WPV2/VDPV2 and OPV2/Sabin2;
  - Eight are expected to apply for CP and pursue ICC/CC.
- The NAC is not established:
  - It is expected that a NAC will be established in 2019.
- Challenges and constraints:
  - Lack of a legal status for the NAC – no authority to restrict a facility's possession of poliovirus materials. Together with the MoH are we working on adjusting the public health law, this will take approximately 2 years
  - The MoH approved the budget for 2019-2023;
  - Insufficient access to independent experts
  - The large number of potential PEFs and lack of qualified auditors makes it impossible to meet the CCS time-frame.
- Website: www.igj.nl/nac (active from January 2019)

Republic of Korea

Dr Haesun Yun, National Authority for Containment, Republic of Korea

- The number of facilities designated for the retention of PV2 materials:
  - One PEF is expected – a vaccine producer that is expected to start the CP application soon;
  - Two facilities have expressed an interest in retaining PV1 and three facilities have expressed an interest in retaining PV3.
- The NAC is established and is functional:
  - The NAC was established in September 2018 within the Korean Centers for Disease Control & Prevention (KCDC) under the Ministry of Health
  - The NAC has 6 members with expertise in virology, biosafety and biorisk management, immunization, GMP and immunology.
  - The Korean CDC is the national authority for biosafety and biosecurity of human pathogens and biorisk management with legal authority under the Infectious Disease Control and Prevention Act of the Republic of Korea
- Website (if any): Not available

Romania

Dr Anda Baicus, National Poliovirus Containment Taskforce for Romania

- The number of facilities designated for the retention of PV2 materials:
  - It is intended that 1 facility will be designated for the retention of all poliovirus types including WPV;
- The NAC is not established:
  - There are plans to establish a NAC under the Ministry of Public Health and the Ministry of National Defense
- Website (if any): not available

Serbia

Dr Aleksandra Knežević, National Poliovirus Containment Taskforce for Serbia

- The number of facilities designated for the retention of PV2 materials:
  - One PEF retaining all types of polioviruses including WPV
  - The CP application process has not yet begun;
- The NAC is established and is functional:
  - The NAC was established under the Ministry of Health in August 2018;
  - The NAC is composed of 3 members with expertise in microbiology and epidemiology;
  - Legal authority is defined by government decree.
- Challenges and constraints:
  - Adherence to the CCS timeline is expected to be challenging;
  - There is a lack of human and financial resources for the audit and certification processes.
- Website (if any): Not available

South Africa

Dr Corena de Beer, Chairperson, National Authority for Containment Committee, South Africa

- The number of facilities designated for the retention of PV2 materials:
  - One facility has been designated for retention of WPV2/VDPV2 and OPV2/Sabin2 materials;
- The NAC is established and is functional:
  - The NAC was established in June 2017 under the Department of Health, which provides secretariat and administrative support;
  - The NAC is composed of 4 named members appointed by the Minister of Health for a 3-year term. The members are experts in medical and clinical virology from the academic sector (independent from MOH);
  - All 4 members of the NAC has successfully completed the GAP III Auditor's training
- Challenges and constraints:
  - The 4 members of the NAC are from different provinces in South Africa and meetings can only be held once every 3-4 months for one day;
  - No additional auditors are available or have been identified;
  - The CP application has been placed on hold by the GCC due to the need for more information on the poliovirus surveillance and immunization coverage.
- Website (if any): Not available

Sweden

Dr Åsa Szekely Björndal, Chairperson, National Authority for Containment, Sweden

- The number of facilities designated for the retention of PV2 materials:
  - One facility has been designated for the retention of PV2 materials – a vaccine producer;
  - In April 2018, the facility was awarded a GCC-endorsed CP
- The NAC is established and is functional:
  - The NAC was established in February 2017 at the Public Health Agency of Sweden (PHAS);
  - The NAC is composed of 6 members with expertise in poliovirus virology, GLP, GMP, poliovirus surveillance, research and diagnostic activities, auditing and biorisk management;
  - GAPIII auditing will predominately be managed using a team from PHAS;
  - There is a high degree of collaboration between different agencies, related to the containment of PV, in Sweden.
- Challenges and constraints:
  - Lack of experts with relevant experience as auditors, particularly lead auditors and containment engineering;
  - Uncertainties exist over requirements for national oversight of Sabin PIM
- Website: under construction in November - December 2018

United Kingdom of Great Britain and Northern Ireland

Dr Ruth Parry, Secretariat to the Joint Committee on Vaccination and Immunisation, Hepatitis, Blood Safety and Countermeasures Response, National Infection Service, Public Health England

- The number of facilities designated for the retention of PV2 materials:
  - There are currently 8 facilities that have been identified– all are classified as laboratories.
- The NAC is not established:
  - There is currently a 'shadow NAC' which is the Secretariat to the Joint Committee on Vaccination and Immunisation, Immunisation, Hepatitis, Blood Safety and Countermeasures Response, National Infections Service, Public Health England
  - The Department of Health and Social Care (DHSC), England has prepared a Memorandum of Understanding between the four countries and await final agreement from all Devolved Administrations. Once agreed, DHSC will invite the core members of the 'shadow NAC' to form the UK-NAC with the addition of the nominees from the Devolved Administrations.
- Challenges and constraints:
  - Meeting the timeline for CCS
- Website (if any): please add the URL to your NAC website

United States of America

Dr Lia Haynes Smith, Director, US National Authority for Containment

Disclaimer: The findings and conclusions in this report are those of the author(s) and do not necessarily represent the official position of the Centers for Disease Control and Prevention, the Department of Health and Human Services, or the United States government.

- The number of facilities designated for the retention of PV2 infectious materials:
  - There are currently 12 facilities retaining PV2 infectious materials – all laboratories;
  - Seven are expected to apply for CPs and cease work; 5 are expected to pursue ICC/CC; 3 have currently applied for CP;
  - At present, 17 facilities have expressed an intention to retain PV1 and PV3 infectious materials post-eradication. This number may decrease as the US NAC increases engagement with these facilities and as the facilities awareness of GAPIII requirements improves.
- The NAC is established and is functional:
  - The NAC was established in January 2017 under the US Department of Health and Human Services and resides within the CDC;
  - In January 2017, Office of Public Health Preparedness and Response (OPHPR) of CDC established Poliovirus Containment Activity (PCA). On 31 January 2018, Department of Health Human Services designated CDC's PCA as the US NAC. Key responsibilities include managing the design and implementation of adequate and appropriate oversight measures and issuing certificates of containment to facilities authorized to store and handle poliovirus (PEFs). The NAC is responsible for implementing the containment plan in the U.S., which includes completing all three phases of GAPIII.

- The NAC is composed of 6 members (plus 2 contractors) with expertise in molecular virology and/or immunology, BSL-3 experience and training, biosafety, security, auditing and, regulatory compliance.

- Challenges and constraints:
  - The lack of statutory authority for the NAC;
  - The large number of designated PV2 infectious material PEFs;
  - Translating GAPIII requirements into policies that can be applied to US facilities;
  - Facilities retaining PV2 infectious material are aware of the need for additional containment measures, but none are currently operating under full GAPIII containment;
  - Establishing CP application and certification processes;
  - Limited human resources with WHO GAPIII auditor training and meeting CCS requirements for auditors;
  - WPV2/VDPV2 PIM requirements still presents challenges for outreach and future implementation of containment.
- Website: https://www.cdc.gov/cpr/polioviruscontainment/index.htm

Viet Nam

Ms Varja Grabovac, Scientist, Expanded Programme on Immunization, WHO WPRO

[on behalf of Dr Nguyen Thi Thu Thuy, Drug Administration of Vietnam (DAV)]

- The number of facilities designated for the retention of PV2 materials:
  - One facility has been designated – a vaccine producer;
  - The CP application process has not yet been started and there is uncertainty over the need;
  - If the decision is taken to increase national poliomyelitis vaccine production capacity it is possible a second PEF will be required.
- The NAC is established and is functional:
  - The NAC was established in April 2014 under the Drug Administration of Vietnam (DAV) which is responsible for GMP and GLP inspection of pharmaceutical manufacturers/laboratories including vaccine manufacturers or biological laboratories;
  - The NAC members are all GMP/GLP inspectors of the DAV.
- Challenges and constraints:
  - There is no specific legislative authority for the NAC;
  - There is a lack of expertise in BSL3 inspection and auditing.
- Website (if any): not available

SESSION 4: Mitigating activities to handle identified challenges

Acceleration of GAPIII-CCS implementation

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

At the Special Meeting of the GCC on Poliovirus Containment[3] held in October 2017 it was decided that only facilities performing critical national or international functions[4] in countries complying with secondary and tertiary safeguards should enter the CCS process. This requirement has been communicated to all WHO Member States together with the recommendation that competent NACs should be appointed by 31t December 2018 and that all CP applications should be processed no later than 31 December 2019. To meet the demands for oversight this timeframe imposes the GCC has requested WHO to expand the CWG membership.

The working agreement between the CWG and NACs should include a mechanism for the GWG to verify compliance with GAPIII requirements under routine circumstances and in the event of a containment breach, and for the CWG to determine the impact of a containment breach on the certification status of the facility. The nature of the verification process and impact assessment will differ from country to country and be partially determined by national legislative structures and confidentiality requirements. These processes may form part of the agreement between the CWG and the PEF or may rely on the on the International Health Regulations (2005) (IHR) reporting and notification framework. While the CWG is the obvious conduit for information exchange and assessment, further discussion on the details of how the CWG will verify and assess national information is required.

CP-holding facilities should within the period of validity of the CP (1 year) achieve a Containment Certificate(CC). If absolutely necessary, facilities may apply for an Interim Containment Certificate (ICC) for the shortest possible duration. At the time of the declaration of WPV eradication, all facilities retaining WPVs and Sabin type 2 materials should have a CC, and if not, have a time-limited ICC, with a clear end point for obtaining a CC agreed with the GCC. The long-term prospect is for very few facilities in the world retaining polioviruses, and the certification and verification activities of these facilities will become institutionalized at the national and global level.

PEFs are expected to be responsible for performing national and international critical functions, and while the definitions for are reasonably clear[4], it is not clear what constitutes critical research. Further discussion maybe needed on providing suggestions as to what constitutes critical research and further guidance from the GCC and the Secretariat would be helpful.

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[3] Special Meeting of the Global Commission for the Certification of the Eradication of Poliomyelitis on Poliovirus Containment, 23-25 October 2017, Geneva, Switzerland. Available at: http://polioeradication.org/wp-content/uploads/2018/03/polio-global-certification-commission-report-2017-10-20180314-en.pdf

[4] Critical national or international functions includes IPV and Sabin-IPV production, production and storage of mOPV stockpiles, vaccine quality assurance, diagnostic reagent production, virus diagnostic and reference functions, together with crucial research.

SAGE recently recommended that to align GAPIII and SAGE recommendations on IPV immunization schedules, countries with PEFs using a single dose of IPV should adjust their IPV schedule, coverage targets and geographical scope. These adjustments should be made as soon as possible, and no later than at the time of all OPV cessation, and include[5]:

- At least 2 IPV doses included in the routine immunization schedule, with the first dose at 4 months and the second dose at least 4 months after that (full or fractional, standalone or in combination vaccines);
- ≥90% coverage with 2 doses of IPV in infants within a 100 km radius of the PEF.

Meeting the recommendation for high coverage with IPV within a given radius of the PEF is recognised as being an administratively complex requirement in small countries and where the PEF is located close to national borders, as this will require multi-national collaboration. It should also be recognised that the requirement for ≥90% coverage with IPV will be a continuing requirement for the foreseeable future. Many national immunization and surveillance systems do not currently collect data on IPV2 coverage rates, but this will become essential data for all countries hosting PEFs at the time of OPV withdrawal, and national governments need to be informed of this requirement.

Following the experience of having one WHO Member State go through the CP application process it is apparent that the application form needs revision. Further discussions will be held between the NACs and the CWG to define the revisions needed and update the form. The ICC and CC applications forms are currently under development and the NACs will be requested to participate in their creation. Standard operating procedures (SOPs) for the CWG are in various stages of development and implementation, together with a range of forms and instructions, including guidance for PEF applicants. A one-page summary of the CCS, developed by CMG, has been published on the containment website.

Current membership of the CWG is limited and there are concerns that the requirement for designated PEFs to submit their CP applications no later than 31st December 2019 may overstretch the capacity of the CWG to review all applications in a timely manner. The CP is currently limited to a single year duration, after which it will expire, and PEFs are expected to be awarded a GCC-endorsed ICC or CC during that period. There are no incentives for PEFs or NACs to submit applications in advance of the December 2019 deadline, which may result in an expected last-minute influx of applications that would overwhelm the capacity of the CWG to respond. Further discussion is required on the time-expiry of CPs and the 31st December 2019 deadline to develop incentives for earlier submission of applications, well in advance of the deadline.

[5] Meeting of the Strategic Advisory Group of Experts on immunization, April 2018 – conclusions and recommendations. Available at: http://apps.who.int/iris/bitstream/handle/10665/272782/WER9323.pdf?ua=1

Update on the CCS Application Collaborative Platform and Process

Ms Liliane Boualam, Technical Officer, Research, Policy and Containment, Polio Eradication, WHO

The CCS Application Collaborative Platform has been created to enable the CWG to review documents submitted by the NACs in full confidentiality. Authorization is maintained by the WHO Secretariat, who also have responsibility for maintaining the site. This is a dedicated platform for containment certification and includes relevant information on the WHO Member States implementing the CCS, the NAC, the designated PEFs, details of the CP, ICC or CC, essential contact information and monitoring of timelines of the different tasks in the different stages of the CCS application process

The process for CP application is currently as follows: (the following should be read in conjunction with Chapter 2 (Containment certification process), of the GAPIII-Containment Certification Scheme (CCS) available at http://polioeradication.org/wp-content/uploads/2017/03/CCS_19022017-EN.pdf

- An application for a CP[6] is submitted by the candidate facility to the NAC. The submission should include relevant documentation e,g., rationale for retaining poliovirus material post-eradication, outline of a time-bound action plan for achieving ICC/CC status or cease work, description of conditions for containment of poliovirus material during CP validity (PEF)
- The NAC reviews the application, to ensure the facility is potentially capable of meeting the requirements of GAPIII.
- The NAC then submits satisfactory applications to the GCC for review by e-mail containmentcertification@workspace.who.int. The submission should include relevant documentation e,g., evidence for secondary and tertiary safeguards fulfilment and overview of any proposed evaluation and monitoring activities, designed to ensure work relating to the CP will be conducted appropriately.
- The CWG Secretariat receives and acknowledges receipt of the emails, screen the applications for completeness and informs the GCC and CWG Chairs. The CWG secretariat also keeps the NAC informed on the progress with the application;
- Primary and secondary CWG reviewers are assigned to review the CP application and all relevant documentation by the CWG Chair.
- A TC is scheduled for the CWG to discuss their conclusions and arrive at a final decision;
- The CWG Chair signs the CP application, with final decision and comments, if any. The GCC Chair signs the CP application to acknowledge the process and to endorse the CP.

Discussion

- A lot of containment information and data are collected and reported by NCCs annually to their RCCs. These reports form supplementary information or for verification purposes and should be used in the CP

[6] Application form for Certificate of Participation (CP). Available at: http://polioeradication.org/wp-content/uploads/2018/01/cp-application-form-20180111-en.docx

application process. Mechanisms should be developed to allow the exchange of this information e.g., it should be part of the CP application package or via CWG-RCC Secretariats.

- The NACs do not currently have the responsibility in the implementation of secondary and tertiary safeguards as such they do not have a verification or an assessment role in this area. This is expected to evolve as progress is made with the implementation of GAPIII and CCS where stronger involvement of the NACs on issues related to containment are required.

Collaboration between NACs

The Swedish Experience – Dr Åsa Szekely Björndal, Chair, NAC Sweden and M. Sc. Anna-Maria Jonsson, Analyst, NAC Sweden

There are four main areas for discussion on collaboration:

1. The main role and mandate of NACs is in ensuring the requirements set out in GAPIII are effectively implemented and maintained in the PEFs or the country-hosting the PEF. Areas for potential discussions: national oversight responsibility for the implementation of the biorisk management for Sabin PIM in facilities retaining Sabin PIM, functional relationships between the NACs, NCC and NPCC (or their regional equivalent)
2. Collaborative platform for information sharing – which may include for example terms of reference, cost-expectations, cost-benefit analyses, etc. A common platform for use by NACs, such as a NAC website or similar site would provide a valuable resource to share knowledge and experience.
3. Auditor training and qualification activity– the training (e.g., classroom, opportunities to observe and mock-audits) and qualifying requirements (e.g., opportunities to demonstrate competence in an applied-setting) for GAPIII auditors are described in the CCS. There is a need to establish a specific qualification for WHO-trained auditors as GAPIII CCS. These different training and qualifying activities are being planned by WHO and opportunities for collaboration between NACs e.g., allowing PEF sites to be used for non-host country NAC auditors to become qualified would be appreciated.
4. Global or Regional Pool of Auditors - the creation of pool of auditors would allow several NACs to tap into this pool to make auditors available for the implementation of their certification processes

The Canadian Experience

Dr Mary Louise Graham, Chair, NAC Canada

Bilateral discussions with representatives of the US-NAC has revealed the need for effective information sharing and the necessity of developing effective tools or platforms to make this possible. A platform for exchange of information between NACs, both within and between Regions, should be developed and maintained by WHO. Shared information should be extended to audit data, to encourage a consistency of approach that will become a necessity as the programme advances.

The USA Experience

Dr Lia Haynes Smith, Director, US National Authority for Containment

In an environment with no regulations to enforce GAPIII requirements, the US is taking a collaborative and proactive approach to engaging potential PEFs. There is a need to qualify US auditors and making use of every opportunity for auditors to gain on-site experience through collaboration with other NACs will be important. A series of documents related to implementation of GAPIII in the US have been developed and can be shared with other NACs upon request to the US NAC or may be posted on a future GCC-sponsored NAC specific website.

There is a general acceptance among poliovirus laboratories of the need for containment of all poliovirus, including Sabin-related viruses. There is, however, lower acceptance among non-poliovirus laboratories of the need to contain materials that are potentially infectious, particularly those that may contain only Sabin-related viruses. This area needs further discussion by the Secretariat and the CWG.

The South East Asia Regional Experience

Dr Sigrun Roesel, Technical Officer, Vaccine Preventable Diseases,
WHO Regional Office for South East Asia

Collaboration between the only two NACs in the WHO South East Asia Region comes in various forms - the Region has been engaged in a capacity-building programme in GAPIII implementation since 2015, with workshops for vaccine manufacturers, NACs and potential PEFs in 2016. Auditor training was conducted in 2017 that included experts from India, Indonesia, Australia and the Republic of Korea. Regional review meetings have also discussed implementation of the CCS by NACs and advised on terms of reference and technical support requirements for NACs.

The National Containment Taskforce is still regarded as the main authority for activities associated with the inventory, survey and destruction of PV materials.

There is a need for additional auditor training and development of a mechanism for collaborative sharing between NACs. There also needs to be an information sharing mechanism and data repository that NACs can access to share information more effectively.

SESSION 5: Conclusions

Challenges and the way forward

Dr Jacqueline Fournier-Caruana, Team Lead, *a.i.*, Containment, Research, Policy and Containment, Polio Eradication, WHO

Discussions with the NACs have identified several common concerns and challenges. These include:

- Lack of appropriately qualified auditors, particularly lead auditors, for the containment certification process;
    - Further training for auditors and qualifying activities for lead auditors is planned by WHO over 2019 and 2010;
    - The implementation of qualifying lead auditors is expected to create a regional pool of qualified lead auditors who not only have demonstrated the competencies and personal attributes but are passionate and most especially willing to qualify other auditors or lead auditors

- Data confidentiality and biosecurity challenges to sharing sensitive information;
    - This is not a new problem faced by WHO but require further discussion with the relevant NACs to result in country-specific solutions.

- Difficulties in navigating the containment webpages and accessing all relevant containment information;
    - Options for reorganization of the containment webpages are being planned. The Secretariat will also discuss the possibility to establish a collaborative platform for the NACs to exchange information or experience and to access all relevant containment related documentation in one place (Annex 4: List of containment-related documentation and their URLs)

- Visibility of poliovirus containment on national health agenda;
    - The adoption of resolution WHA71.16 (Poliomyelitis – Containment of Polioviruses) by all WHO Member States in 2018 describes national responsibilities and required resources for poliovirus containment.

- Lack of a legislative framework to restrict the retention of polioviruses and to empower the NAC.
    - WHA71.16 (Poliomyelitis – Containment of Polioviruses) is also a commitment from WHO Member States to either align national regulation with GAPIII or to adopt GAPIII its amendments.

- In other countries that also lack legislative authority i.e., USA, a more consultative and engaging process (e.g., phone, e-mail and visits) was used by the NAC to discourage retention of polioviruses at facilities that previously expressed intention to retain. This approach was useful in reducing the number of potential PEFs in the

- Implementation of the 'Guidance to minimize risks for facilities collecting, handling or storing materials potentially infectious for polioviruses'
  - An electronic version of this guidance (e-tool) is currently being developed, several accompanying forms to support the data collection and reporting process have been developed.
  - Challenges remain in the identification of an appropriate authority to play the national oversight role for facilities retaining Sabin PIM as well as the implementation of such an oversight role

- Meeting the recommended deadline of April 2019 for the completion of all survey and inventory activities related to PV2 including implementation of the PIM guidance is a challenge
  - This will be further discussed to consider a potential flexibility in meeting this deadline.

- High resource requirements (personnel and funding) for NAC activities;
  - Costs of the certification process should be borne by the PEFs on a cost-recovery basis, laboratory-type PEFs should include cost for certification in their grant applications, while other countries may not even charge for the performance of audits. A cost-analysis study is currently being undertaken to develop models that can be used to estimate the cost associated with the implementation of containment requirements and supporting activities e.g., cost associated with the certification process
  - Stronger advocacy and engagement is required to reduce the number of facilities retaining polioviruses, and hence reduce the workload associated with certification process.
  - More discussion is required on a risk of poliovirus release ranking of facilities retaining polioviruses as this could be used to identify facilities that should urgently be enrolled in the CCS process.

- lack of guidance on responding to breaches in poliovirus containment;
  - WHO is developing the 'Public Health Management of Facility-Based Exposure to Live Polioviruses: Guidance in managing exposed persons for countries hosting facilities that maintain live polioviruses' which will be published for public comments by end-2018 and published by the end of Q3/2019

- Management of potential or real conflict of interest issues in implementation and verification of compliance of GAPIII i.e., lack of independence of the NAC from the PEF;
    - The CWG may request additional information from the NACs on their national containment certification processes if potential flaws are identified in the review process.
    - This may be addressed through the composition and legal status of the NAC. NAC will also have the responsibility to demonstrate appropriate audit team composition failing which it may jeopardize the GCC's approval of an ICC/CC under the CCS.

- Lack of clarity, purpose and intent of secondary and tertiary safeguards;
    - SAGE's recommendation on GAPIII secondary safeguard of population immunity (IPV doses and coverage) for countries hosting PEFs is available at http://apps.who.int/iris/bitstream/handle/10665/272782/WER9323.pdf?ua=1 (Feedback on the implementation of this recommendation can be made to the Containment Advisory Group using the CAG submission form, and by e-mail to containment@who.int
    - Discussions are planned for the CAG to discuss at their 3rd meeting and provide a clearer definition, purpose and intent of tertiary safeguards of facility location and associated environmental controls

- GAPIII is continuing to evolve, having implications for national legal authority implementation and planning;
    - Amendments to GAPIII were based on issues that were submitted by containment stakeholders and are meant to give flexibility in GAPIII implementation yet have appropriate controls in place to manage those risks. The evolution of GAPIII into a living document would allow more timely amendments to be published. The amendments to GAPII will be discussed by CAG their third meeting end-2018.

Annexes

Annex 1: Agenda
Annex 2: List of participants
Annex 3: Terms of Reference for NACs as per CCS
Annex 4: List of containment-related documentation and their URLs

Annex 1: Agenda

World Health Organization

Second Face to Face meeting between GCC-CWG members and National Authorities for Containment
10-11 October 2018,
Geneva, Switzerland

Rapporteur: Dr Ray Sanders

Wednesday 10 October 2018		Chair: David Salisbury
08:30	Registration	
SESSION 1:	Introduction	
08:45	Welcome, opening remarks	D. Salisbury
09:00	Update on Polio Eradication & Endgame Strategy	R. Sutter
SESSION 2: Global update on PV biocontainment		
09:30	Global poliovirus containment update	A. King
10:00	What the ideal NAC should be?	H. Singh
10:30	*Coffee Break*	
SESSION 3: National updates on PV biocontainment		
11:00	NACs update (using the WHO slide template)	NAC (10 min each)
12:30	*Lunch*	
14:00	NACs update (continued)	NAC (10 min each)
16:00	*Coffee Break*	
16:30	NACs update (continued)	NAC (10 min each)
18:00	Discussion and Wrap up Day 1 Meeting	Chair
Thursday 11 October 2018		Chair: David Salisbury
SESSION 4: Mitigations activities to handle identified challenges		
09:00	Acceleration of the GAPIII- CCS implementation • CP/iCC/CC forms • Quality assurance (SOPs, forms, instructions) • Extension of the CWG membership • Management of the estimated workload	A. King
09:30	Update on the CP application Containment Share point process	L. Boualam
10:00	WHO technical assistance 2019/2020	J. Fournier- Caruana
10:30	*Coffee Break*	
11:00	Collaboration between NACs • Sweden experience • Canada experience • USA experience • SEARO experience	Å. Björndal M.L. Graham L. Haynes S. Roesel
12:00	Discussion	All
12:30	Wrap up meeting and closing remarks	Chair
13:00	*Lunch*	

Annex 2: List of Participants

No	Title	First Name	Last Name	Position and Affiliation	Country	Email
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46.	Dr	Jeff	Partridge	Chair, Containment Management Group and Senior Program Officer, Bill & Melinda Gates Foundation	USA	Jeff.Partridge@gatesfoundation.org
Rapporteur						
47.	Dr	Ray	Sanders	Independent Consultant	UK	Ray @raysanders.co.uk

* Unable to attend

Annex 3: Terms of reference for national authorities for containment (NACs) as described in the CCS[7]

The NAC:[8]

1. Ensures and demonstrates that the required primary, secondary and tertiary safeguards described in GAPIII are met;
2. Establishes national mechanisms aligned with the CCS to ensure PEFs are appropriately assessed and comply with GAPIII requirements;
3. Reviews and processes applications for containment certification in consultation with the GCC, ensuring only relevant facilities enter the containment certification process;
4. Ensures containment certification activities are conducted so as to provide adequate assurance that the requirements set out in GAPIII and the CCS are effectively implemented and maintained;
5. Ensures effective procedures are established and maintained to address relevant aspects of the containment certification cycle, including:
   - application and acceptance
   - contract/agreement with the PEF applying for a certificate of containment (CC) or interim certificate of containment (ICC)
   - planning of audits
   - review of applications and other documents
   - initial and periodic audits
   - resolution of findings
   - certificate issuance
   - certificate maintenance
   - certificate renewal;
6. Ensures effective procedures are established and maintained to verify that internal processes function appropriately, including:
   - definition of roles, responsibilities and authorities
   - control of documents and records
   - confirmation of auditor competence, qualification and team composition
   - definition of audit scope and associated costs (see the GAPIII Containment Certification Cost (Man-day) Calculation Guidance)
   - reporting and follow-up of findings
   - use of certificates and logos
   - conduct of internal audit and review
   - confirmation of independence, impartiality and confidentiality;
7. Provides relevant parties (PEFs, audit team members, GCC) with appropriate access to pertinent information required for containment certification activities;
8. Provides relevant parties (e.g. GCC) with appropriate access to pertinent information demonstrating that secondary and tertiary safeguard requirements are appropriately met;
9. Adheres to the principles and practices as set out in ISO/IEC 17021-1:2015 (5) Conformity assessment – Requirements for bodies providing audit and certification of management systems – Part 1: Requirements; and
10. Issues, suspends or revokes certificates of containment, in consultation with the GCC.

[7] Excerpts taken from the Chapter 1, Subsection 1.6 of the GAPIII- Containment Certification Scheme (CCS) available at http://polioeradication.org/wp-content/uploads/2017/03/CCS_19022017-EN.pdf

[8] For reasons of potential conflict of interest, the NAC cannot be the national reference laboratory that functions as a facility dedicated to such activities as surveillance. Under some circumstances the national reference laboratory may also apply to become a PEF.

Annex 4: List of containment-related documentation and their URLs

Containment Homepage

http://polioeradication.org/polio-today/preparing-for-a-polio-free-world/containment/

Containment resources

http://polioeradication.org/polio-today/preparing-for-a-polio-free-world/containment/containment-resources/

GAPIII and GAPIII-CCS

The WHO Global Action Plan (GAPIII) was endorsed by the WHO Strategic Advisory Group of Experts on Immunization in October 2014 and the World Health Assembly resolution WHA68.3 in May 2015. The GAPIII Containment Certification Scheme (CCS) was endorsed by the WHO Strategic Advisory Group of Experts on Immunization in October 2016

GAPIII	عرب	中文	English	Français	Русский	Español
GAPII-CCS	عرب	中文	English	Français	Русский	Español
CCS, 1-pager			English			

The following Containment Certification Scheme forms and templates are available to support National Authorities for Containment in the roll-out and implementation of the certification process. All submissions to the Global Certification Commission for the Eradication of Poliomyelitis (GCC) must be made in English.

Cost (man-day) calculation guidance
Application form for Certificate of Participation (CP)
Audit findings and corrective action plan (CAP)
Auditor monitoring report
Auditor application form
Register of GAPIII auditors, technical experts and trainers
Document request form
Sample audit plan
Audit attendance sheet
Audit report template
CCS feedback form
All CCS forms

Containment Advisory Group (CAG)

http://polioeradication.org/tools-and-library/policy-reports/advisory-reports/containment-advisory-group/

- First meeting of the Containment Advisory Group
- Second meeting of the Containment Advisory Group
- Teleconference of the Containment Advisory Group (CAG TC1) on Showers
- Teleconference of the Containment Advisory Group (CAG TC2) on Novel Poliovirus Strains
- Teleconference of the Containment Advisory Group (CAG TC3) on nOPV2 candidate vaccines and S19 – poliovirus type 2 strains
- Criteria for the evaluation of improved 'safety' of novel poliovirus strains to determine the containment requirements for their storage and handling
- Ad hoc Teleconference of the Containment Advisory Group (CAG TC4) on Tertiary Safeguards

Submissions on issues for the consideration of the Containment Advisory Group can be made using the CAG submission form, and should be emailed to containment@who.int

Global Certification Commission (GCC)

http://polioeradication.org/tools-and-library/policy-reports/certification-reports/global-certification-commission/

Strategic Advisory Group of Experts (SAGE) on immunization reports

http://www.who.int/immunization/sage_conclusions/en/

SAGE's recommendation on GAPIII secondary safeguard of population immunity (IPV doses and coverage) for countries hosting PEFs. See: Meeting of the Strategic Advisory Group of Experts on immunization, April 2018 – conclusions and recommendations. Available at: http://apps.who.int/iris/bitstream/handle/10665/272782/WER9323.pdf?ua=1

Guidance to minimize risks for facilities collecting, handling or storing materials potentially infectious for polioviruses

- Main document http://polioeradication.org/wp-content/uploads/2018/06/polio-containment-guidance-for-non-poliovirus-facilities-20180614-en.pdf
- Annex 2 Country- and Territory-specific poliovirus data http://polioeradication.org/wp-content/uploads/2018/06/polio-containment-guidance-for-non-poliovirus-facilities-annex-2-20180614-2-en.pdf
- FAQs http://polioeradication.org/wp-content/uploads/2018/06/polio-containment-guidance-for-non-poliovirus-facilities-frequently-asked-questions-20180619-en.pdf
- Video https://www.youtube.com/watch?v=gFCoXncAqDk

Resolution WHA71.16 Poliomyelitis – containment of polioviruses (2018)

http://apps.who.int/gb/ebwha/pdf_files/WHA71/A71_R16-en.pdf

Poliovirus containment in large-scale polio vaccine production and quality control facilities

Guidelines for the safe production and quality control of poliomyelitis vaccines

The Containment Corner newsletter

The Containment Corner – Poliovirus Containment News is a GPEI publication to update stakeholders on key developments in global poliovirus containment. The e-newsletter replaces Polio Pipeline and will be biannual in frequency.

Issue No 1: May 2018

Subscribe to receive the publication by email.

Coffee with polio experts: Containment of polioviruses with Dr Arlene King

https://www.youtube.com/watch?v=WAfGmm65-sE

Sweden takes important first step to demonstrate containment of type-2 poliovirus

http://polioeradication.org/news-post/sweden-takes-important-first-step-to-demonstrate-containment-of-type-2-poliovirus/

If you would like to be added to the Containment E-mailing List, please e-mail: containment@who.int

Second Face-to-Face Meeting Between the Containment Working Group of the Global Certification Commission (GCC-CWG) and National Authorities for Containment (NAC)

10 – 11 October 2018

Geneva. Switzerland