

Report from the Eighteenth Meeting

Global Commission for the Certification of Poliomyelitis Eradication

Amman, Jordan, 29 - 31 October 2018

Foreword:

The GCC met in October 2018 to review progress in interruption of transmission, to further develop Certification criteria and to note progress that has been made on containment. Whilst the GCC was encouraged by the continuing lack of identification of any Wild Polio Virus type 3 from humans or the environment in the face of improving surveillance quality, the GCC was concerned that progress in interrupting Wild Polio Virus type 1 transmission had stalled. The GCC believes that there are enough data to permit the certification of eradication of Wild Poliovirus type 3 and plans to make this a priority for 2019.

The GCC reviewed the options for timing of certification of wild polioviruses and definitions that could be used for absence of vaccine derived polioviruses. The GCC recommended that it would work towards sequential certification of wild polioviruses (type 3 as soon as possible and type 1 once eradication criteria have been fulfilled); absence of circulating vaccine derived polioviruses would be verified after an interval still to be determined.

The GCC noted the very high number of countries proposing to retain polioviruses and hoped that these numbers will fall as countries appreciate the responsibilities that accompany retention of polioviruses and potentially infectious materials in Polio Essential Facilities. Countries will need to be encouraged to include poliovirus 1 and 3 materials in the inventories that they have been completing for type 2 materials.

The GCC will meet in February 2019.

Abbreviations

Containment:

CAG	Containment Advisory Group
CMG	Containment management group
CC	Certificate of Containment - ICC Interim Certificate of Containment
CCS	Containment Certification Scheme to support GAPIII
CP	Certificate of Participation
CWG	Containment Working Group
GAPIII	Global Action Plan for Poliovirus Containment
NAC	National Authority for Containment
PEF	Poliovirus-Essential Facility
PIM	Potentially infectious material to poliovirus - PIM Guidance: Guidance to minimize risks for facilities collecting, handling or storing materials
ECBS	Expert Committee on Biologicals Standardization
POSE	Polio Outbreak Simulation Exercise

Certification

GCC	Global Commission for the Certification of the Eradication of Poliomyelitis
NCC	National Certification Committee
RCC	Regional Commission for the Certification of the Eradication of Poliomyelitis

Viruses and vaccines

IPV	Inactivated poliomyelitis vaccine
OPV	Oral poliomyelitis vaccine bOPV Bivalent oral poliomyelitis vaccine containing Sabin type 1 and type 3 mOPV2 Monovalent oral poliomyelitis vaccine Sabin type 2 nOPV Novel oral poliomyelitis vaccine
PV	Poliovirus (PV1 is PV type 1, PV2 is PV type 2, and so on)
VDPV	Vaccine-derived poliovirus aVDPV Ambiguous vaccine-derived poliovirus cVDPV Circulating vaccine-derived poliovirus iVDPV Immunodeficiency-associated vaccine-derived poliovirus
WPV	Wild poliovirus WPV1Wild poliovirus type 1 WPV2Wild poliovirus type 2 WPV3Wild poliovirus type 3

Others

AFP	Acute Flaccid Paralysis
CDC	Centers for Disease Control and Prevention (United States of America)
GPEI	Global Polio Eradication Initiative
IDP	Internally Displaced Persons
IHR EC	International Health Regulation Emergency Committee
IMB	Independent Monitoring Board
MMWR/WER	Morbidity and Mortality Weekly Record / Weekly Epidemiological Record
PEESP	Polio Eradication and Endgame Strategic Plan 2013-2018
SAGE	Strategic Advisory Group of Experts on immunization
SC	Strategy Committee
TAG	Technical Advisory Group
ToR's	Terms of Reference
WHA	World Health Assembly

WHO World Health Organization
AFR – African Region
AMR – Region of the Americas / PAHO
EMR – Eastern Mediterranean Region
EUR – European Region
SEAR – South East Asian Region
WPR – Western Pacific Region

Introduction and background

The 18th meeting of the Global Commission for the Certification of Poliomyelitis Eradication (GCC) took place in Amman, Jordan, on 29 – 31 October 2018, with the Chair of each of the six Regional Certification Commissions (RCC) in attendance:

Professor David Salisbury, Chair of the GCC and Chair European RCC,
Professor Yagoub Al-Mazrou, Chair Eastern Mediterranean RCC,
Dr Supamit Chunsuttiwat, Chair South-East Asian RCC,
Dr Arlene King, Chair American RCC, and Chair, CWG,
Professor Rose Leke, Chair African RCC, and
Dr Nobuhiko Okabe, Chair Western Pacific RCC.

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

Aims and objectives

The aim of the meeting was to ensure global certification of poliovirus eradication takes place in a timely manner with credible and transparent processes. Specific objectives were:

- To review current progress toward WPV eradication, including the feasibility of certifying the eradication of WPV3;
- To approve a finalized harmonized global risk assessment tool that can be used to promote a risk based approach to global certification;
- To consider the appraisal of options with respect to WPV certification with or without consideration of VDPV verification / certification, and
- To review progress in developing certification standards that should apply with respect to AFP, environmental and enteroviral and other supplementary surveillance systems, including in conflict and access compromised areas.
- To review the WHA 2018 resolution on poliovirus containment, including progress with completion of GAPIII phase 1 and implementation of the Guidance to minimize risks for facilities collecting, handling or storing materials (known as PIM guidance)
- To review progress in accelerating and implementing the Containment Certification Scheme (CCS);
- To discuss establishment of a verification mechanism to ensure quality of data collected at national level during surveys and inventories of Phase I.

Session 1 Review of Global Progress and Surveillance

Global update

WPV epidemiology: The year 2018 has seen an increase in the number of WPV cases reported compared to 2017, but with only two countries reporting detection of WPV1, namely Afghanistan and Pakistan. Furthermore, there has been an increase in environmental specimens that have tested positive.

Afghanistan

There is ongoing transmission in the Southern and Eastern regions due to access and security challenges, bans on house to house campaigns in the Southern region and increasing inaccessibility in the Eastern region. There are challenges in accessing all children in highly mobile populations.

Pakistan

Challenges include accessing all children in highly mobile populations, persistent resistance to vaccination (both overt and covert), and systemic weaknesses in EPI throughout many parts of the country. Widespread transmission appears to continue, based on environmental surveillance.

Nigeria

Currently there are about 102,000 children who remain unreached, compared to over 600,000 in 2016, thanks to the innovative strategies: *Reach Every Settlement (RES)* and *Reach Inaccessible Children (RIC)*.

cVDPV

There are eight ongoing outbreaks: two in Nigeria and three in the Democratic Republic of Congo (all type 2), Papua New Guinea (type 1), and Somalia (both type 2 and type 3).

IPV supply

Supply has improved so that all countries have had access to IPV since mid-2018, and the global demand (for one dose in 87 countries) is being met for the first time since OPV2 withdrawal in 2016. However, there is now a large cohort of missed children, 43 million globally.

Containment

There has been a decrease in the number of proposed poliovirus essential facilities (PEF); there are now 27 countries which plan to retain poliovirus type 2 materials in 79 facilities.

Certification

'Electronic Annual Progress Report' project is a web application being developed in the European Region and created with the purpose of streamlining submission of annual polio updates by NCCs to the RCC. It is currently operational in English and Russian and will be rolled out to all 53 member states following pilot testing undertaken in 2018.

Transition

A dedicated polio transition team has been established at WHO/HQ to support implementation of the WHA polio transition strategic action plan. Country visits are being undertaken in up to 20 priority countries to review polio transition plans and identify next steps for implementation.

WPV circulation will not be interrupted in 2018

Revision of the current GPEI strategy is underway to cover the period from now until certification, at which point the Post-Certification Strategy will begin. The three main themes are "Eradication, Certification, Integration". The strategy will describe the path to achieving eradication and

certification, activities that work, need to be altered or discontinued, specific work with immunization and emergency programs and innovative updates to the program.

Surveillance in inaccessible and conflict affected area

Multiple modalities to increase the sensitivity of polio surveillance are being employed in such areas, including enhancing environmental surveillance, community based surveillance, healthy child surveys and active case searching during vaccination activities. Except for parts of Borno state, Nigeria and the Lake Chad countries, inaccessibility is not hindering AFP reporting. In Nigeria and Lake Chad countries, much has been achieved to address the issue. However, considering continued inaccessibility, further in-depth technical review is needed to ensure there is no missed circulation in the remaining small pockets of inaccessible population. The quality of surveillance is affected by the capacity of senior staff to conduct field visits for monitoring and supervision in these areas and additional work is needed to assess the impact of this. Attention is needed to mitigate risk associated with conflicts in eastern CAR, West Africa (tri-border area), Mozambique and Yemen.

Framework for certification of polio eradication in the African Region

The African Region has made progress towards certification of polio eradication, and it is more than two years since the latest WPV1 case (August 2016) and confirmed healthy WPV1 positive contact (September 2016). Surveillance gaps, localized inaccessibility due to insecurity and population immunity challenges pose a risk of delaying certification of the Region. Therefore, there was a need to alert governments of the risks for timely actions to be implemented to meet the set criteria for certification of the Region.

The Framework for Certification of Polio Eradication in the African Region articulates the priority interventions / actions for ensuring certification in a timely manner. The Framework was presented, deliberated and endorsed at the 68th Session of the WHO Regional Committee of Health Ministers in the African Region, Senegal, on 29 August 2018. The Chairperson of the ARCC presented the risks that would delay certification of the Region. The WHO Director General, WHO African Regional Director, WHO Director Polio and Senior GPEI partners participated in the discussion and advocated for government leadership and ownership. Based on the agreed ranking with Ministers of Health on country performance and progress, feedback will be shared and ARCC advocacy visits will be conducted to selected priority countries.

Conclusions and Recommendations concerning epidemiology and surveillance

The GCC concluded that it required a regular, deeper analysis of WPV1 epidemiology prior to each meeting, including data on surveillance coverage in the remaining endemic countries to distinguish sub national areas which are consistently free of WPV in the presence of good surveillance from

those areas where there is no or inadequate surveillance and therefore a risk of missed transmission.

The GCC concluded that the approach presented by the secretariat regarding polio surveillance in conflict affected and inaccessible areas was appropriate and very useful for the purposes of global certification. These special surveillance activities should continue in full until global certification.

The GCC expressed its appreciation of the work done by EMRO in stopping transmission of cVDPV2 in Syria. However, other outbreaks of cVDPV, particularly type 2, were of concern and there is a need for urgent effort to control these outbreaks, including accelerating the availability of nOPV2.

The GCC noted other regional certification developments and commended the regional certification committees involved:

- the electronic submission of annual reports by NCCs in the European Region was a step forward and should be adopted by all six regions.
- the 'Framework for polio certification in Africa' was a welcome advocacy tool with governments in the Region.

Recommendation 1.1

GCC recommended that an in-depth analysis of WPV1 epidemiology and surveillance in endemic countries be provided ahead of the next meeting in February 2019, and be regularly updated by the secretariat prior to each GCC meeting; in addition data on the quality of surveillance in key non-endemic conflict affected and inaccessible areas should be provided. The approach to surveillance should be supplemented by modelling, to provide the level of confidence the GCC can have in the absence of WPV in such areas.

Recommendation 1.2

GCC recommended all regions work towards adoption of electronic submission of annual reports by NCCs.

Session2: Options for Certification

Appraisal of options for cVDPV in global certification.

The GCC had requested an appraisal of options for dealing with cVDPV during the global certification process. The question of how to verify that cVDPV has been eradicated has not been previously addressed by the GCC. Given the increasing amount of attention being made to preventing and controlling cVDPV, this gap in the certification process needs to be addressed.

Concepts

Certification: implies a high degree of certainty that specific criteria have been met; requires strict procedures (e.g. documentation process by every country, oversight and vetting by regions, and

then oversight and vetting globally) which could provide high confidence that transmission has stopped.

Verification of absence: implies a lower level of certainty due to unknowns about transmission and/or substantial challenges to meeting certain criteria. Procedures are not yet determined but would be expected to be less rigorous than those required for certification.

The GCC considered the Options Appraisal paper that had been developed as a result of a meeting of polio-relevant committees and that had been presented earlier to the SAGE Polio Working group. The options discussed included certification of WPVs (1 and 3), with or without verification of the absence of cVDPVs, and an option to certify both WPVs and cVDPVs. The GCC held back their conclusions on the options until discussion had been held on WPV3 and Sequential Certification (see below).

WPV3 Options: Sequential Certification of Polio Eradication

WPV3 transmission has not been detected anywhere since November 2012:

- Latest WPV3 in EMR was isolated from a child aged 1 year in the Federally Administered Tribal Area of Pakistan who had onset of AFP on April 18, 2012
- The latest environmental WPV3 isolate in EMR was from a sample collected in Karachi, Pakistan, on October 7, 2010.
- The latest WPV3 in the African Region was isolated from an 11 month old infant in Yobe, Nigeria, who had onset of paralysis on November 10, 2012
- The latest environmental WPV3 isolate in the African Region was from a sample collected in Lagos, Nigeria, on November 11, 2012.

Since these last detected WPV3 cases and environmental positive samples, over 150,000 AFP cases have tested negative for WPV3 across the African Region and over 92,000 AFP cases have tested negative for WPV3 across the Eastern Mediterranean Region. Furthermore, AFP surveillance in these two regions has continued to detect WPV, with nearly 1000 WPV cases (895 EMR, 103 AFR) found and all of these were serotype 1. This is strongly suggestive that WPV3 is no longer circulating.

Certification of WPV3 eradication would send a clear measure of progress and would demonstrate again the feasibility of WPV eradication. This may provide added motivation for the polio program including resource mobilization from partners and donors. The interval between WPV3 and WPV1 certification could be used to verify the absence of cVDPV2 while the current certification structures are still in place.

Cessation of OPV3 use also may become possible, thereby reducing the risk of VAPP due to type 3 (~67% of VAPP cases after OPV2 cessation), reducing the risk of emergence and circulation of VDPV3 and the creation of iVDPV3 cases. This in turn opens the possibility of verifying the absence of cVDPV3 (interval to be defined).

There are alternative pathways to certification:

1. Certify WPV1 and WPV3 simultaneously: This would fulfil the original promise of polio eradication but the present circumstances were not anticipated by GPEI, WHA, or donors in 1988 as it was then assumed all three serotypes would be eradicated more or less at the same time. This approach will take until at least 2022 -23 for the certification of eradication. In the meantime, there will continue to be paralysis from serotype 3 VAPP and/or cVDPV3 will continue and creation

of new cases of serotype 3 iVDPVs; this raises ethical concerns as these circumstances could, in principle, be avoided.

2. **Certify WPV3 now:** This may reinvigorate WPV eradication and provide motivation for the final steps. If followed by withdrawal of OPV3 (or discontinuation of bOPV in some countries or regions at lowest risk), it would increase the effective vaccine capacity for production of mOPV1, which may be important as OPV manufacturers leave the market. It resolves the ethical issue above. Certification of WPV1 would follow and could be coupled with verification of the absence of cVDPV2 and cVDPV3. It would only remain then to verify the absence of cVDPV1 after mOPV1 cessation (interval to be agreed).

Three options were considered by the GCC:

- **Sequential Certification:** Certification of WPV3 in 2019, followed by certification of WPV1 three years after the last case or environmental detection of WPV1. The absence of Circulating Vaccine Derived Polioviruses would be verified or 'confirmed' after appropriate lengths of time (to be defined).
- **Joint Certification** of WPV3 and WPV1 three years after the last WPV1 case or environmental positive, with verification of the absence of cVDPV 2, 3 and 1 either together or sequentially after appropriate lengths of time (to be defined).
- **Single Certification** of all polioviruses (WPV3, WPV1, cVDPV 2, 3 and 1) after an appropriate length of time (to be defined) following the last cVDPV case or environmental virus identification of any of the vaccine derived strains.

Conclusions and Recommendations concerning certification options

The GCC concluded that based on the data available (as above) with the last WPV3 detected in 2012, it appears that it may already be possible to certify the eradication of WPV3 and that a process to do so should now commence.

Recommendation 2.1

The GCC recommended that a sequential approach to global certification be adopted, with WPV3 certification to take place as soon as appropriate in 2019, and independently of WPV1 certification. Between WPV3 and WPV1 global certification, the absence of cVDPV could be verified after an interval to be determined by modelling and surveillance data, and definition of procedures to achieve this.

Recommendation 2.2

The GCC recommended that the secretariat conduct a comprehensive review of the programmatic implications of sequential certification, and report back to the next GCC meeting.

Global Certification Commission Global Risk Assessment (GCC RA) Tool

In July 2017, the GCC recommended that a global risk assessment be developed and tailored to assess risks for global certification. Consequently, the Inter-Regional Risk Assessment Working Group (IRRAWG), a semi-formal working group consisting of regional polio focal points, and facilitated by CDC on behalf of the GPEI, developed a draft certification specific risk assessment using a single set of

globally defined indicators to assess certification risks in countries using existing data sources; there would be no additional data required from regions or countries.

Currently, the six WHO regions conduct their own regional risk assessments. All of these are individualized and non-standardized, with variance between models used. This makes comparison of risk across regions difficult, and as the world moves towards global eradication it becomes increasingly important for the GCC to assess risk in a standardized fashion in order to best prepare for global certification.

The objective of the GCC Risk Assessment is to create a single tool that can rank all countries in terms of overall risk, while also assessing risk within subcategories (see below) to offer guidance on where mitigations to prepare for certification must occur.

Assessing global risk is a difficult task that will inevitably be imperfect. One such example includes countries with vast populations in which national assessments of risk do not accurately portray the wide variation in risk that exists within each country. Such examples include India and Indonesia, among others. The current GCC RA does not analyze risk at a subnational level, which remains the job of the regional assessments.

This risk assessment does not replace regional RAs but rather complements them and allows for better comparison of risk across countries around the entire world.

The following categories were established based on consensus of the IRRAWG as well as members of various partner agencies in GPEI. Each of these categories comprise a component of a country's risk profile that could predispose to a re-introduction of polio into the general population.

- **Population immunity** indicates the susceptibility of the nation to having cases of polio should the virus be reintroduced into the community and is a composite of WUENIC POL3 coverage estimates, uniformity across the country, and previous outbreaks of WPV and cVDPV.
- **Surveillance** strives to capture the ability of a country to be able to detect cases of polio should they arise from an outbreak, such as non-polio AFP rate and stool adequacy, necessary to detecting and controlling outbreaks swiftly.
- **Preparedness** assesses countries' potential to respond quickly and decisively to any outbreaks, should they occur.
- **Containment** characterizes the ability of countries to contain poliovirus and ensure that it is not reintroduced into either the environment or the community.
- Lastly, the category related to **health systems** assesses the overall state of a nation's healthcare system and is a surrogate marker meant to characterize its likelihood of having an outbreak with the assumption that improved healthcare systems will lead to lower risk of polio outbreaks.

Considerable discussions ensued regarding the need to clarify the implementation of the global risk assessment tool, the main issue being explaining its use in relation to the regional risk assessments, given the possibility that the two may not always reach the same conclusion.

Conclusions and Recommendations concerning the global certification risk assessment

The GCC concluded that the risk assessment tool was a valuable tool to assist the GCC in its mandate to monitor risks to global certification, and endorsed the tool as presented. However, the GCC recognized the concerns of some regions that there needed to be clearer information on how the tool would be used and implemented.

Recommendation 2.3

GCC recommended that a paper on the implementation of the proposed certification RA tool explaining rationale, methods development, use and rollout of GCC Certification Risk Assessment be developed by the IRRAWG in its next meeting in Jan – Feb 2019, and be presented to the GCC in Feb 2019.

Session 3: Progress on poliovirus containment

Reduction in the number of PEFs

Reducing the number of PEFs was supported by a WHA Resolution (71.16), endorsed by all member states in May 2018 which urged Member States to reduce to a minimum the number of facilities designated for the retention of polioviruses, prioritizing facilities performing critical national or international functions. Other measures included letters from WHO DG to RDs and from RDs to countries, regional advocacy, advocacy visits to key countries (such as Italy, UK, and planned for Romania). There is an ongoing cost analysis by PATH, commissioned by the CMG, to provide information on the costs related to establishment of a PEF and a NAC in PEF hosting countries.

Completion of Phase I (Preparation for containment of poliovirus type 2) of GAPIII

Activities include:

- Establishment of a standardized data collection process (harmonized reporting forms, SOPs, development of an 'e-tool' and an Global/Regional database) are ongoing.
- Verification mechanisms of data quality are still being developed.
- NCC/RCC ToRs are being changed and annual reports indicate or will indicate completion of Phase I.
- Current deadline for completion of Phase I for all PV2 is set at April 2019 but some regions feel this is not realistic due to ongoing use of mOPV2 in some countries.
- EURO and PAHO have already included WPV1 and WPV3 inventories in their Phase I survey.
- Although many countries reported not having legislation to compel the destruction of PV materials, early engagement with these facilities through any appropriate means (visit, e-mail, call) to explain the inherent responsibility in complying with GAPIII requirements has proven to be effective in discouraging retention.

Acceleration of the implementation of the CCS process

- This is also supported by WHA Resolution 71.16.
- 24/26 NACs have been established, with two pending (Romania and Serbia).
- Six CP applications were submitted in 2018 (one granted, three on hold and two under review)
- A second meeting with NACs and GCC-CWG members to address the remaining challenges and accelerate the certification process was held 10 - 11 October 2018.
- Revised TRS 926 on safe production and control of polio vaccines was endorsed by ECBS in October 2018.

Coordination and Oversight

- Coordination of information exchanges between the ECBS, CAG, CWG, SAGE, IHR EC, CMG, SC and the GCC was discussed in April 2018.
- Advice to CWG on requirements associated with secondary and tertiary safeguards was provided by SAGE and CAG.
- A mechanism to be established for the CWG to obtain more frequent technical support from CAG for clarifications on the operationalization of GAPIII was discussed at the CAG meeting 13 - 14 December 2018.

Containment Working Group

- The CWG membership has been expanded from six to seven and was to be further expanded to 10 members including the Chair through a call for candidates in October 2018.

Communications

A communication officer is supporting both certification and containment. Together with partnership colleagues, a proactive strategy has been drafted outlining communication implications of the various certification options and suggested communication approaches. A communications strategy addressing certification and containment was developed in March with the goal to raise awareness and promote implementation of GAPIII and increase understanding of the certification process. Wherever possible, communication material stresses destruction/transfer over retention, and the risks and costs associated with PV containment. Activities include:

- An MMWR/WER article on containment progress
- A document about key points on containment
- A document of frequently asked questions on PIM guidance and a video on PIM guidance with CDC lab expert on polio
- A media interview with the WHO Director of Polio on STAT news
- A biannual newsletter called 'Containment Corner'
- A story about Sweden's NAC being the first to obtain a CP, with accompanying social media
- Coffee with Polio Experts video with GCC members David Salisbury and Arlene King
- Reports – GCC, GPEI annual/semi-annual

Other planned activities include:

- Potential outreach depending on certification path chosen
- Containment animated video for lay audiences
- Advocacy statement from senior virologists on the need for containment
- Scientific magazine article on destruction of PV in comparison to retention
- Containment webpage restructure
- NAC information sharing platform
- Infographics on the containment process
- Brochure – 'So you want to be a PEF?'
- Stories/interviews, e.g. with labs, progress updates
- Speaking engagements, e.g. regional biosafety conferences

Priorities 2018/2019

1. Continued development of the Communication/Advocacy strategy
2. Implementation of the PIM guidance and update of inventories including PV types 1 and 3
3. Establishment of the global/regional database to collect all containment data
4. Development of the verification mechanism for monitoring the data quality of inventories and surveys
5. Acceleration of implementation of GAPIII-Containment Certification Scheme
6. Implementation of the training plan to strengthen the auditing capacity of the NACs and establish a roster of international auditors
7. Planning regional containment breach simulation exercises based on experience gained during the European Region 'POSE'
8. Reach out to OIC/FAO to draw on experiences and lessons learned regarding containment of rinderpest following its eradication.

PIM Guidance Implementation

Most of the surveys and inventories performed in the past have been limited to only polio laboratories, but other stakeholders include:

- Global Rotavirus Laboratory Network: As of January 2016, the network included 115 laboratories including 68 sentinel hospital laboratories (SHL), 37 national and provincial laboratories, nine regional reference laboratories (RRL) and one Global Reference Laboratory (GRL).
- Measles and Rubella Network: 696 laboratories have been established in 164 countries
- influenza: Established in 1952, the network currently comprises 143 institutions in 113 WHO Member States, which are recognized by WHO as National Influenza Centres; six WHO Collaborating Centres, four WHO Essential Regulatory Laboratories, 13 WHO H5 reference laboratories; and ad hoc groups established to address specific emerging issues.
- GPLN: 146 labs (a third of these are proposed to be PEFs)

The purpose of the 'Guidance to minimize risks for facilities collecting, handling or storing materials potentially infectious for polioviruses' is to assist facilities in assessing the risk of PV PIM in their possession and to implement appropriate risk reduction consistent with GAPIII. Risk mitigation strategies include:

- Declare PIM in National Survey and maintain working inventory
- Biosecurity (locked freezers, limit access)
- Good laboratory/microbiological practices, including documentation and validation of methods/SOPs
- Risk assessment for specific procedures being used
- Polio immunization for staff
- Accreditation to a national or international biorisk management standard

Conclusions and Recommendations concerning PV Containment

The GCC concluded that substantial progress on Phase I was reported by the Regions and HQ in implementing previous GCC recommendations. However, GCC noted some pending issues that should be addressed in a reasonable timeframe.

Recommendation 3.1

The GCC recommended that a verification mechanism for the quality of data collected during inventories be developed for endorsement by the next GCC containment meeting.

Recommendation 3.2

The GCC recommended that validation of the inventory and destruction of unneeded PV1 and PV3 materials be initiated, and accelerated in the context of the imminent certification of WPV type 3 eradication.

The GCC commended the effort made to reduce the number of PEFs but expressed concern about the decision of certain countries to keep collections of PV with no real clear plans for critical research to justify the possible risks associated with retention.

GCC recognized the value of the cost analysis commissioned by the Containment Management Group to clarify the cost implications of hosting a PEF. This could be used as a tool to raise awareness of countries of the costs involved of hosting a PEF, thereby reducing the number of PEFs.

Recommendation 3.3

GCC recommended that further efforts be made to reduce the number of PEFs, including:

- **advocacy meetings and visits to PEF hosting country to propose alternatives to retaining polioviruses;**
- **requesting RDs to write to the MoH of the PEF hosting countries to increase awareness of the implications of PV containment, and additionally to clarify to other countries without NACs (i.e. those that are not hosting a PEF but which may have PIM) that the MoH should be responsible for PV containment;**
- **using the cost analysis commissioned by the Containment Management Group to clarify the cost implications of hosting a PEF; the costing exercise should include various types of PEFs.**

Session 4 Progress in implementing the Containment Certification Scheme (CCS)

In 2018, the World Health Assembly passed Resolution 71.16 urging Member States to reduce to a minimum the number of facilities designated for the retention of polioviruses, prioritizing facilities performing critical national or international functions; and to appoint no later than the end of 2018,

a competent National Authority for Containment (NAC); and for prospective PEFs to submit to their NAC their CP applications for participation in the CCS no later than 31 December 2019.

Translation of the Resolution into other UN specific languages caused some ambiguity and misunderstanding e.g. what was meant by 'unneeded material' was ambiguous and led to countries expressing serious reservations on the grounds that it was beyond the mandate of the NACs, the CWG or WHO to tell a lab that its retention of material is unnecessary.

At the time of the meeting, 27 countries planned to retain poliovirus type 2 materials in 79 designated PEFs (subsequently reduced to 26 countries).

Issues requiring attention to advance implementation of the CCS include:

1. Standard procedures required for completion of CP, ICC and CC application forms
2. Issues around secondary and tertiary safeguards
3. Continuing to reduce the number of PEFs by promoting common understanding of critical functions such as IPV and Sabin-IPV production, production and storage of mOPV stockpiles, vaccine quality assurance, diagnostic reagent production, virus diagnostic and reference functions and critical research.

Conclusions and Recommendations concerning the CCS

The GCC expressed concern with the workload generated by 'last minute' CP applications that may be received just before the deadline of December 2019 and also future ICC/CC applications. The work involved is time consuming and requires considerable commitment.

The GCC welcomed the suggestion for a global NAC website/platform to be set up as soon as possible and no later than the next GCC containment meeting, and the development of guidance for NACs to prepare applications to the CWG.

Recommendation 4.1

The GCC recommended that the CWG secretariat expand the number of reviewers available to assess CCS applications and to consider providing additional support.

Recommendation 4.2

The GCC urged WHO to implement urgently the training programme established for strengthening the auditing capacity of NACs, including mentorship and development of a roster of lead auditors who can build capacity of CCS auditors.

Recommendation 4.3

GCC recommended completion of work mapping PEFs and surrounding areas that fall within the 100 km radius/distance to better understand the potential issues related to the SAGE April 2017 recommendations regarding application of secondary safeguards for the next GCC meeting.

Recommendation 4.4

GCC recommended that the GPEI develop an international mechanism to review justifiable research to facilitate the identification of "critical" research areas that PEFs should consider doing.

Public Health Management of Facility-Based Exposure to Live Polioviruses

The need for guidance on managing PV-exposed persons for countries hosting facilities that maintain live polioviruses became apparent following a WPV2 containment breach at a vaccine manufacture plant in the Netherlands in 2016. In that incident, the worker was confirmed as infected with WPV2 and WPV2 was subsequently detected in sewage close to the worker's home. Inadequate initial management of the case and home contacts opened the possibility of further community spread although this did not eventuate. Furthermore, faecal waste going into general sewerage also raised a risk of further spread, albeit very small.

The proposed guidance was developed based on a review of national protocols for public health management of polio cases, with the control measures made more stringent, based on the rationale that WPV2 is eradicated, and other serotypes close to eradication. Principally, this means more vigorous use of isolation of exposed and infected persons, and, similarly, more stringent quarantine of contacts. There is scant scientific evidence in this area, so the approach developed in the guidance was based largely on expert opinion.

The guidance is primarily aimed at PEF hosting countries but may be useful for any country with a facility that has polioviruses not yet subject to containment. It is not a protocol that must be followed, but rather guidance to assist PEF hosting countries during a response. These countries need to consider whether the public health measures can be implemented with their existing national regulations for managing infectious hazards and quarantine laws.

In the guidance, a distinction is made between PV2 and PV 1 / 3:

- PV2 should be contained according to GAPIII as mandated by international agreement (WHA), and WHO therefore has a clearer mandate to recommend measures.
- PV 1 and 3 are not yet subject to the CCS and implementation of the measures depends on national laws and regulations.

A risk assessment is made so that the response can be proportionate to the risk:

1. Very high risk: exposure involving WPV2 or VDPV2
2. High risk:
 - exposure involving WPV1 / VDPV1 or WPV3 / VDPV3
 - exposure involving SL2, in a country or surrounding area with inadequate type 2 immunity OR has lower access to basic or safely managed sanitation
3. Low risk
 - exposure involving SL2 in a country and the surrounding area with adequate type 2 immunity AND higher access to basic or safely managed sanitation
 - Any exposure involving WPV2 / VDPV2 PIM
4. Minimal risk
 - Any exposure involving SL1 or SL3 material.
 - Any exposure involving SL2 PIM

In summary, exposed persons and their contacts are managed according to the risk:

- Very high risk: hospital isolation is recommended, especially if the person is non-compliant. Home isolation is an acceptable alternative provided monitoring by public health authorities

is in place to ensure compliance with control measures. Disposal of faeces is either through incineration or chemical destruction; and household contacts are quarantined.

- High risk: Home isolation with monitoring, household contacts and faeces managed as for very high risk.
- Low risk: Home isolation; contacts not quarantined, faeces go to standard sewerage.

Conclusions and Recommendations concerning containment breaches

The GCC concluded that the draft guidance on public health management of a facility related PV exposure presented was appropriate as a draft for consultation on the GPEI web site with a view to obtaining wider comment before April 2019.

The GCC concluded that containment breaches of eradicated PVs should be notified as an event that may constitute a public health emergency of international concern under the IHR 2005.

Recommendation 4.5

The GCC recommended that the NAC of countries planning to host a PEF facilitate a national review of available public health measures such as isolation of exposed PEF workers and quarantine of their contacts to manage containment breaches that have resulted in human exposure. The review should determine whether the national measures available are sufficient to manage a PV containment breach consistent with this guidance, and if not, what risk mitigation can be employed. The review should be assessed by the NCC and RCC and reported to the GCC. If a potential breach cannot be appropriately managed to prevent transmission, the containment certification status of the PEF may need to be reconsidered.

Recommendation 4.6

The GCC recommended that any country that is retaining type 1 and type 3 WPV/VDPV or WPV / VDPV PIM in facilities (including GPLN surveillance labs, research labs) be made aware of this guidance document, and report to its NCC on the measures available to effect management of exposed persons and their contacts should a containment breach occur.

Recommendation 4.7

The GCC recommend that facility related PV exposures should be considered in national preparedness and emergency response plans, using this guidance as a basis for the measures in the plan. Regions should consider holding a POSE based on a containment breach as soon as possible.