Report from the Twenty-second Meeting of the Global Commission for Certification of Poliomyelitis Eradication

Geneva, Switzerland, 28 - 29 June 2022
Members of the Global Commission for Certification of Poliomyelitis Eradication attend the virtual meeting held 28 July 2021

Left to Right,
*top row:* Professor David Salisbury, Professor Rose Leke, Dr Nobuhiko Okabe,
*lower row:* Professor Yagoub Al-Mazrou, Professor Mahmudur Rahman, Dr Arlene King,
Abbreviations

**Containment**

CAG  Containment Advisory Group  
CC  Certificate of Containment  
CCS  Containment Certification Scheme to support GAPIII  
CP  Certificate of Participation  
CWG  Containment Working Group of the GCC  
ICC  Interim Certificate of Containment  
NAC  National Authority for Containment  
PFE  Poliovirus-Essential Facility

**Certification**

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

**Viruses and vaccines**

IPV  Inactivated poliomyelitis vaccine  
OPV  Oral poliomyelitis vaccine  
bOPV  Bivalent oral poliomyelitis vaccine containing Sabin type 1 and 3  
mOPV2  Monovalent oral poliomyelitis vaccine Sabin type 2  
nOPV  Novel oral poliomyelitis vaccine  
PV  Poliovirus (PV1 is PV type 1 etc)  
VDPV  Vaccine-derived poliovirus  
aVDPV  Ambiguous vaccine-derived poliovirus  
cVDPV  Circulating vaccine-derived poliovirus  
iVDPV  Immunodeficiency-associated vaccine-derived poliovirus  
WPV  Wild poliovirus  
- WPV1  Wild poliovirus type 1  
- WPV2  Wild poliovirus type 2  
- WPV3  Wild poliovirus type 3

**Others**

AFP  Acute Flaccid Paralysis  
BMGF  Bill and Melinda Gates Foundation  
CDC  Centers for Disease Control (United States of America)  
ES  Environmental surveillance  
GPEI  Global Polio Eradication Initiative  
IDM  Institute Disease Modelling  
IDP  Internally Displaced Persons  
IMB  Independent Monitoring Board  
LQAS  Lot Quality Assurance Sampling  
LSHTM  London School of Hygiene and Tropical Medicine  
PPEESP  Polio Eradication and Endgame Strategic Plan 2013–2018  
SAGE  Strategic Advisory Group of Experts on immunization  
TAG  Technical Advisory Group  
ToR  Terms of Reference  
WHO  World Health Organization
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Introduction

The 22nd meeting of the Global Commission for Certification of Poliomyelitis Eradication (GCC) took place in Geneva on 28 and 29 June 2022, chaired by Professor David Salisbury. Commission Members are chairs of their respective Regional Commissions for Certification of Poliomyelitis Eradication (RCC), and five members were in attendance:

Professor David Salisbury - WHO European Region,
Professor Yagoub Al-Mazrou - WHO Eastern Mediterranean Region,
Dr Arlene King - WHO Region of the Americas, and Chair, GCC Containment Working Group,
Professor Rose Leke - WHO African Region,
Dr Nobuhiko Okabe - WHO Western Pacific Region.

Professor Mahmudur Rahman - WHO South-East Asian Region, was unable to attend.

Aim and Objectives

The aim of the meeting was to ensure global certification of poliovirus eradication takes place in a timely manner with transparent processes.

Specific objectives were:

• To review progress toward eradication of WPV, including the response to the outbreak of WPV1 in southern Africa;
• To review progress toward stopping and preventing outbreaks of cVPDV2;
• To make recommendations regarding the current criteria for certification of WPV eradication, and
• To review timelines of PV containment in view of ongoing use of type 2 polio vaccines in response to cVDPV2 outbreaks.

The agenda is included in appendix 1.
Session 1: Review of global progress on goal one: WPV eradication

WPV1 epidemiology overview
In 2021, there were only six cases of WPV1 worldwide, with four occurring in Afghanistan, one in Pakistan and a case in Malawi, the first case detected in Africa since the Region was certified polio free. Cases have risen in 2022, with eleven cases in Pakistan, one in Afghanistan, and one in Mozambique. The cases in Malawi and Mozambique appear to be due to a single importation, leading to at least two chains of transmission. The eleven cases in Pakistan have all occurred in a single district, North Waziristan which is part of the South Khyber Pakhtunkhwa (KP) province and central cross-border epidemiological corridor between Pakistan and Afghanistan.
Conversely, the isolation WPV1 from environmental samples has continued to become less frequent, with only four positive samples in 2022 compared to 66 in 2021. Of the four positive samples, three were in Pakistan and one in Afghanistan. In Afghanistan, all environmental sites were negative for WPV since the first quarter in 2021 until the May 2022 positive sample found in Nangarhar province. In Pakistan, all sites in both Peshawar and Quetta have been negative since the second quarter of 2021, with a single detection in Karachi since May 2021.

Performance of polio vaccination campaigns
In Pakistan, LQAS data indicates sub-optimal coverage in North Waziristan and neighboring districts of South KP during some SIAs conducted in 2022, with recent improvement in the March 2022 vaccination round. In Afghanistan, the proportion of districts where house to house campaigns are possible has risen since August 2021, but gaps remain in epidemiologically important regions.

In response to the southern Africa WPV1 outbreak, two multi country immunization rounds have taken place, involving Malawi, Mozambique, Zambia and Tanzania. While independent monitoring shows satisfactory results in the latter three countries, coverage was very low in Malawi in both rounds. LQAS showed even lower quality in Malawi, and unsatisfactory coverage in Mozambique and Zambia.

Two further rounds are being conducted which will also involve Zimbabwe, and target over 30 million children aged under five years. Mozambique is conducting two novel OPV2 rounds in response to concurrent detections of cVDPV2. Campaign quality improvement plans have been made also.

Challenges in the outbreak response have included:

- lack of experience in the outbreak zone with house to house approaches and microplanning,
- lack of high quality supervision,
- problems with population data,
- shortage of vaccines and vaccine carriers in many districts
- delays in the funding mechanism to the sub national level, including delays in paying personnel,
- competing priorities such as COVID vaccination and responding to other
emergencies,
• security issues in northern Mozambique, and
• vaccine refusals related to local religious and other groups.

As part of the outbreak response, AFP and environmental surveillance are being strengthened, including expansion of ES sites. Routine immunization is also being improved.

Surveillance in Pakistan and Afghanistan
A review of surveillance was carried out in Pakistan in two phases, first in October 2021 and second in February 2022. The review found that a sound AFP surveillance structure was in place, with active and zero reporting sites well distributed, thus showing presence of a sensitive surveillance system. The AFP surveillance is complemented by environmental surveillance.

The overall conclusion was that the current epidemiological situation in the reviewed districts most likely is accurate. However, persistent evidence of low-level transmission represents high likelihood of sustained transmission in the high-risk/underserved populations, particularly living in Union Councils along the border with Afghanistan and special groups of seasonal migrants where reach of surveillance and vaccination system seems limited. Targeted and tailored surveillance and vaccination strategies for these sub-groups of populations will be crucial for early detection and stopping transmission.

Surveillance has also been formally reviewed in Afghanistan in June 2022, where it was concluded that the AFP surveillance system is sound, and well complemented by environmental surveillance. Most of the AFP surveillance indicators meet the desired global standards indicating presence of overall sensitive surveillance.

In the South, South-east and East Regions, particularly districts along the border of Pakistan, are at high risk, given the high proportion of zero-dose children and inconsistent vaccination quality during polio SIAs. It is a priority to maintain close coordination with Pakistan PEI to reach these border population groups. Systematic mapping and tracking of these sub-populations remain a challenge, as are insecurity and inability to conduct house-to-house vaccination everywhere in Afghanistan.

There remains limited availability of proper environmental surveillance sites in high risk areas and among high risk populations. There needs to be a more focused search for adhoc sites to improve detection in key populations. The likelihood of undetected poliovirus transmission in Afghanistan is low. However, surveillance for polioviruses must be upscaled for further improving the ability to detect any low-level transmission, particularly in the South-East and South.

Global Surveillance
Globally, surveillance indicators appear to be rebounding from the decline seen during the pandemic, but significant gaps remain particularly at sub-national level.

There are two priorities for Acute Flaccid Paralysis and Environmental surveillance,
enhancing quality at subnational level and improving the timeliness of detection, especially in priority countries. This will be achieved by facilitating a skilled workforce and promoting integration of AFP surveillance with other health programmes. For environmental surveillance, which is still being expanded there need to be activities to improve the quality of ES in underperforming countries.

Both the Global AFP Surveillance Guidelines and Field Guidance for Environmental Surveillance are being updated and associated training materials are being developed and made available online.

Sample transport and shipment remains a challenge, especially in the WHO African Region, where an on-line monitoring tool is being used to follow up with countries among other initiatives.

Sub-national surveillance gaps in several priority countries pose a risk to the programme as a whole. Although environmental surveillance continues to be expanded, in many priority countries it can be difficult to consistently select good sites, thus limiting the benefits of expansion of ES, in terms of improved surveillance sensitivity and timeliness of detection.

Review of the Certification Criteria by the expert working group

The Region of the Americas was the first Region to undertake certification of interruption of transmission. Other Regions and the GCC followed the PAHO criteria. The three year period of non-detection was chosen based on experiences with the certification of smallpox eradication, allowing for non-paralytic polio infections. There was little scientific basis for the three year period although post hoc modelling indicated that the period was likely to be correct. The essential criterion for certification was compliance with AFP indicators at national level for PAHO countries. The indicators were AFP rate at a minimum of 1/100,000 individuals less than 15 years; timeliness of collection of faecal samples and completeness of laboratory testing. There was no environmental surveillance.

The three years interval was not tested against the appropriate period for WPV1/2/3, given their different infection to paralysis rates.

The process to review the three year period of non detection started in 2021 following the GCC’s 21st meeting and continued into 2022.

An Expert Working Group was appointed. The task for the Group was to
1) review the period needed to certify the interruption of transmission of WPV1, and
2) review/propose the criteria for validation of absence of cVDPVs.

The Group completed the first task and provided its advice to GCC; subject to the support of GCC, the Group will move onto the second task.

Members of the Group were GCC Chair (Professor Salisbury), EMR RCC Chair (Professor Al-Mazrou), Chair AFG/PAK TAG (Jean Marc Olivé), Dr Elizabeth Miller, Dr Mark Pallansch, Professor John Edmunds, Dr Jay Wenger (Director BMGF Polio team), and Dr Hamid Jafari (Director Polio, EMR).
Three groups of modellers were invited to provide their inputs (Kid Risk, BMGF/IDM, LSHTM). The modellers had access to data from GPEI and EMRO and worked independently of each other. Summary papers of the work of the modellers were provided to the GCC and full details of the models were available, including published papers12.

At its third meeting, the group discussed the two options put forward by the chair, to advise the Regional and Global Certification Commissions to:

- Maintain the current criterion, or
- Alter the existing certification criteria to remove a fixed three year period of non-detection of WPV.

There was unanimous support for the second option above.

Modelling supported the idea that the ‘three year rule’ was not absolute, and shorter periods could be justified, noting that this was highly dependent on the quality of surveillance. Surveillance has changed since the first WHO Region was certified, especially with the widespread use of environmental surveillance. The modelling reviewed pertained to the Afghanistan and Pakistan epidemiological situation, and did not apply to the risk of missed importation and transmission elsewhere, and as such did not consider the recent southern African cases. Such outbreaks would be assessed according to the normal process of an outbreak response assessment as per GPEI standard operating procedures.

With the benefit of hindsight, the certification of five WHO Regions already certified was correctly done, and much experience in certification has thus been gained. Only in the WHO African Region did ‘the clock’ have to be reset once the three year period had started.

The reference group recommended that the retrospective application of a three year period of non-detection be replaced by a flexible interactive prospective review of the quality of surveillance at around six monthly intervals until a high level of confidence that the absence of detection did indeed indicate the WPV1 transmission had ceased in Afghanistan and Pakistan.

EMR RCC may therefore be able to certify the Region in less than three years. The GCC needs to review data from all six regions to be satisfied that global eradication has been achieved.

Conclusion

The GCC accepted the advice of the Expert Working Group.

Recommendations

1.1 The GCC recommended that the fixed three year period of non-detection as a criterion for certification of eradication of endemic transmission be replaced with a flexible period, but not less than two years, of non-detection which takes into account the quality of surveillance in endemic countries, the risk in sub-population groups poorly or not reached by surveillance, and other data such as molecular analysis of the last chains of transmission.

1.2 GCC recommends that until there is cessation of WPV1 transmission, GPEI provides the GCC six monthly in-depth reviews of WPV1 epidemiology, genomic analysis and other data regarding countries and population groups where there is proven or possible transmission, and following apparent cessation of transmission that it also receives regular (six monthly) briefings on the status of implementation of the global surveillance action plan and in-depth surveillance analyses in the endemic countries.
Session 2: Developing the criteria for validation of the absence of cVDPV

cVDPV2 overview
Cases of cVDPV2 continue to fall in 2022, having peaked in September 2020. A cumulative total of 42 countries have now reported cVDPV2 since 2016, peaking in 2021 when 31 countries were infected. As at the date of the meeting, 13 countries had reported cVDPV2 in 2022. Geographical spread as indicated by the number of infected districts has dropped from 581 in 2020 to 427 in 2021, and 124 in 2022. The number of new emergences peaked in 2019, with 40 in 2019, 14 in 2020, nine in 2021, and none thus far in 2022.

There are four critical geographies identified where most transmission is occurring, namely northern Nigeria, eastern DR Congo, northern Yemen, as well as persistent transmission in the South Central Zone of Somalia. Analysis clearly shows a link between poor routine immunization coverage and the number of cVDPV2 cases. In Nigeria, over 80% of cVDPV2 cases are found in states predominantly in the north of the country with poor routine immunization, where less than 40% of children have received a dose of IPV, according to available AFP data; conversely states with high IPV routine coverage have a much lower number of cases of cVPDV2. Improving IPV routine coverage in the northern states will boost type 2 immunity.

Novel OPV2 rollout

Over 360m doses of novel OPV2 have been administered in 21 countries. There is no evidence of any increase in general safety risk compared with monovalent Sabin OPV2. Novel OPV2 demonstrates comparable immune response to monovalent Sabin OPV2 in infants, children, and adults (seroconversion rates). Assessment of viral excretion indicates that:

- novel OPV2 is unlikely to be shed in a greater amount or at a greater rate than Sabin OPV2
- The cessation of shedding in infants may occur earlier with novel OPV2

Data support the view that novel OPV2 is more genetically stable than Sabin OPV2 and has a lower risk of reverting to a form that could cause paralysis.

Global OPV Strategy 2022-26

Risks and assumptions include:

- Low usage of Sabin OPV2 puts the supply of polio vaccines and the effectiveness of outbreak responses to Type 2 PV at risk.
- Low diversification of the supplier base due to financing and political/regulatory barriers.
- Uncertainties in polio epidemiology and outbreak response quality (in the context of limited resources and low supplier diversification).
• Low diversification of financing/donor base.
• The strategy assumes no significant delays in the development and prequalification of novel OPV 1,2, and 3.
• The strategy assumes that the cVDPV2 outbreak will be successfully contained; thus, no preparation for OPV2 reintroduction in routine immunization is planned.

Issues to consider in the validation of the absence of cVDPV:
1. The quality of AFP surveillance and geographical coverage of ES, particularly in conflict affected geographies and countries with high IPV coverage.
3. Primary Immuno-Deficiency Surveillance and modelling on the role of long term iVDPV2 excretors with the possibility, albeit low, of community transmission
4. Time since last use of Sabin OPV2 and increasing use of novel OPV2 which affects the likelihood of seeding.

GCC conclusions

The GCC concluded that building on the success of the process for deliberating on the criteria for WPV1 certification, that constitution of a second expert working group would be desirable to support the GCC in formulating the criteria for validation of the absence of cVDPV2. In doing this, the GCC will:
• discuss and finalize the composition of the group
• finalize the Terms of Reference of the group, which will decide what additional analyses and modeling is required
• based on the advice of the expert working group, the GCC will deliberate and define the criteria for validation of the absence of cVDPV2.

GCC recommendations

2.1 GCC recommends that validation of the absence of VDPV2 across all regions should involve a globally uniform process, coordinated by GCC and RCCs through an agreed framework, with thorough engagement of NCCs.

2.2 GCC recommends that the Terms of Reference of the GCC, RCCs and NCCs be revised to include validating the absence of cVDPV2.
Session 3: Progress towards global poliovirus containment for certification of eradication

Progress since the last meeting of the GCC in July 2021 was presented, including progress at country level, challenges, and most recent development of guidance and tools. Specific questions were formulated seeking the advice of the GCC for their recommendations.

Progress on Containment Certification

The WHO Seventy-first World Health Assembly (WHA) resolution 71.16 (WHA 71.16)\(^3\) adopted by all WHO Member States aims to accelerate progress in poliovirus containment and provides a timeline for the completion of national inventories of poliovirus materials and for the certification of facilities retaining poliovirus materials.

As of 28 June 2022, eight Member States are yet to complete their initial inventories for poliovirus type 2 materials, an activity which was due for completion in July 2016.

Of the 25 countries reporting a total of 65 facilities retaining poliovirus type 2 material, five are still pending the designation of their National Authority for Containment which was due by the end of 2019. Since 2018, 19 countries have initiated the certification of their facilities from which 14 countries have completed the first level of the certification of their facilities with 41 facilities awarded countersigned Certificates of Participation. Ten out of 21 countries have communicated their plans for their Interim certificate of containment providing visibility on the next certification phase of their respective facilities.

The GCC was presented the latest containment documents that have been produced, including

i) GAP-IV last stage content prior its endorsement by CAG, and

ii) the Containment Strategy and the Global Action Plan 2022-2026 which was recently endorsed by the GPEI Strategy Committee.

Mitigations measures taken by the containment programme in 2022 to adjust to identified challenges were discussed.

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\(^3\) WHO. Seventy-first World Health Assembly resolution 71.16 (WHA71.16), Poliomyelitis: Containment of Polioviruses, 2018 (https://apps.who.int/gb/ebwha/pdf_files/WHA71/A71_R16-en.pdf, accessed 15 August 2022)
The current and ongoing poliovirus containment programme priorities are:

- implementation of the GPEI Containment Strategy and the associated action plan for Global Poliovirus Containment (from July 2022), and
- the completion of the revision process of GAPIII (expected: July 2022) and dissemination for country implementation.

Other priorities for 2022 include:

- completion of the certification of facilities retaining PV as per the recommended timelines;
- the implementation of the GCC’s 2021 recommendation on progressing with the ICC phase of containment certification;
- expediting the establishment of NACs in the five remaining WHO Member States;
- strengthening advocacy to decrease the global number of PEFs;
- revision of other containment reference documents such as the Containment Certification scheme, Potentially Infectious Materials Guidance;
- reinforce high level advocacy efforts at country and organizational levels to promote country compliance with the requirements in WHA 71.16.

Pending issues requiring guidance or recommendations from GCC at this meeting included:

1. Containment certification requirements for facilities handling novel poliovirus strains granted ‘temporary waiver’ from the containment requirements of GAPIII.
2. Some WHO Member States’ lack of compliance with WHA 71.16, such as:
   a. Member States which still have not completed initial PV2 inventories;
   b. the urgent need to establish NACs in the five remaining WHO Member States retaining PV2 that have not yet established one;
   c. Compliance with the requirements for containment certification (CP-extension, initiation of ICC phase)
3. Commencement of the PV1 and PV3 containment phase;
4. Progress on the establishment of a standardized data collection and verification mechanism for poliovirus survey and inventory activities as a follow-up to a 2017 GCC recommendation.

Proposed indicators to monitor survey performance

To support regular and close GCC monitoring and oversight regarding containment certification, the WHO Secretariat has identified an NCC reported minimum data set to ensure consistent global reporting through Regional Offices. Selected qualitative process indicators for this global monitoring include:

**Participation:** Expected responses to the national survey as a proportion of forms sent out;
Representativeness: measuring the country specific mix of the various sectors involved in the survey including public, private and intergovernmental institutions;

Completeness: all information requirements are available in the annual report (based on PIM guidance Form 1 & 2 data requirements);

Timeliness: the country report is provided to the NCC as its meeting in the requested timeline.

GCC Conclusions

The GCC remains concerned that compliance with the timelines for containment as set out in WHA 71.16 is ‘off track’ in terms of an incomplete global initial inventory of PV2 and retention of PV2 materials in some countries without a NAC, or incomplete CPs or lack of information provided to WHO on planning to obtain an ICC.

GCC acknowledges that initial inventories of VDPV (all serotypes) may need to be updated. National inventories should be updated in ‘real time’ when there is a known change in a country with VDPV and presented to the relevant RCC for its annual report. VDPV (all serotypes) are subject to the same containment requirements as WPV (all serotypes).

The GCC endorsed the Containment Strategy as well as the related Containment Action Plan (2022-2024) and supported its implementation at all levels as per the expected timelines and expected outcomes.

The GCC noted some common inventory data exist and are already collected by the National Polio Containment Coordinator/ National Polio Containment Task Force and included in National Certification Committees reports.

GCC Recommendations

3.1 The GCC recommended that countries that are not in compliance with WHA 71.16 be informed or reminded of this fact, and that they be strongly urged to take action to address such non compliance.

3.2 GCC recommends that WHO maintains an inventory of facilities retaining novel poliovirus strains, with the collection of the same information as that which is provided in the Certificate of Participation (CP). This information should be provided by the facility to its National Authority for Containment (NAC) where one exists, or to its National Polio Containment Coordinator and processed onwards to the CWG Secretariat.

3.3 The GCC recommended that containment for WPV1 and WPV3 should be initiated now, resulting in the awarding of a GCC-countersigned CP to new facilities by latest end-2023. For facilities that plan to retain other polioviruses (e.g., VDPV3, VDPV1) the containment of these strains should occur as soon as possible.

3.4 The GCC endorsed the process survey performance indicators as above (ie participation, representativeness, completeness, and timeliness). GCC recommended these data be made available as a cross regional standardized dashboard on an annual basis.
Annex 1: Agenda

Global Commission for the Certification of Poliomyelitis Eradication
28 - 29 June 2022

AGENDA

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<td>Reviews of Surveillance in Afghanistan and Pakistan and future directions</td>
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<td>Outcomes of the GCC reference group and changes to certification criteria</td>
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<td>Progress on roll out of novel OPV2, plans for novel OPV1 and 3, note on iVDPV</td>
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<td>Vaccine supply for outbreak control</td>
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<td>Status of northern Nigeria, eastern DR Congo, SC Somalia, northern Yemen - are we on track for Goal 2</td>
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<td>16.05</td>
<td>Status of north Yemen outbreak, including spread to Djibouti, and SC Somalia - are we on track for Goal 2</td>
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Thursday 10th June - WHO HQ

10.00 | Coordination meeting of WHO regional and global certification focal points in Room L14 at WHO HQ |

WHO staff only
Report from the Seventeenth Meeting of the GCC, Geneva, Switzerland, 26-27 February 2018