WHO Regional Meeting on Poliovirus Containment Progress for National Poliovirus Containment Coordinators and National Authorities for Containment

26–27 September 2023
Copenhagen, Denmark
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Abstract

The WHO regional meeting on poliovirus containment progress for national poliovirus containment coordinators and national authorities for containment, held on 26–27 September 2023, provided technical support in the field of poliovirus containment implementation at the national level. The meeting addressed the role of national poliovirus containment coordinators in the implementation of the Global Action Plan for Poliovirus Containment and discussed the status and challenges of polio eradication and polio containment implementation in the WHO European Region based on the Regional overview and country experiences.

Keywords

POLIOMYELITIS
CONTAINMENT OF BIOHAZARDS
LABORATORY INFECTION
PROGRAMS, IMMUNIZATION
STRATEGIC PLANNING

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Abbreviations

CAG  Poliovirus Containment Advisory Group
CCS  Containment Certification Scheme
CP   Certificate of Participation
cVDPV circulating vaccine-derived poliovirus
cVDPV2 circulating vaccine-derived poliovirus type 2
cVDPV3 circulating vaccine-derived poliovirus type 3
CWG  Containment Working Group
eAPR Annual Progress Report on polio eradication activities
GAPIII Global Action Plan for Poliovirus Containment (third edition)
GAPIV Global Action Plan for Poliovirus Containment (fourth edition)
GCC  Global Certification Commission for Polio Eradication
GPEI  Global Polio Eradication Initiative
ICC  Interim Certificate of Containment
IM   infectious material
IPV  inactivated poliovirus vaccine
MOT  micro-organisms and toxins
NACs national authorities for containment
NCC  National Certification Committee
nOPV novel oral polio vaccine
nOPV2 novel oral polio vaccine monovalent type 2
NPCC National Poliovirus Containment Coordinator
OPV  oral polio vaccine
OPV2 oral polio vaccine type 2
PEF  poliovirus-essential facility
PIM potentially infectious material
<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>POSE</td>
<td>polio outbreak simulation exercise</td>
</tr>
<tr>
<td>PV</td>
<td>poliovirus</td>
</tr>
<tr>
<td>RCC</td>
<td>Regional Commission for Certification of Poliomyelitis Eradication</td>
</tr>
<tr>
<td>SAGE</td>
<td>Strategic Advisory Group of Experts on Immunization</td>
</tr>
<tr>
<td>SBB</td>
<td>Service Biosafety and Biotechnology unit of Sciensano</td>
</tr>
<tr>
<td>VDPV</td>
<td>vaccine-derived poliovirus</td>
</tr>
<tr>
<td>WPV1</td>
<td>wild poliovirus type 1</td>
</tr>
</tbody>
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Introduction

The WHO regional meeting on poliovirus containment progress for national poliovirus containment coordinators (NPCC) and national authorities for containment (NACs) was held on 26–27 September 2023 in a hybrid mode in Copenhagen, Denmark. The meeting was opened by Dr Jose Hagan, Team Lead for Disease Control and Elimination, Vaccine-preventable Diseases and Immunization Programme, WHO Regional Office for Europe, who welcomed the meeting participants. The list of participants is provided in Annex 1.

Scope and purpose of the meeting

The aim of the meeting was to provide technical support to NPCCs and NACs in the field of poliovirus (PV) containment implementation at the national level. The following aspects were addressed:

• the role of the NPCCs in the implementation of the Global Action Plan for Poliovirus Containment (fourth edition) (GAPIV);
• GAPIV and changes introduced in comparison with the previous edition, GAPIII;
• the requirements of the Containment Certification Scheme (CCS) and planned changes;
• the inventory process for facilities handling/storing PV infectious materials (IM)/potentially infectious materials (PIM);
• PV containment breach management; and
• common issues, potential challenges and best practices.

Session 1. Global and regional updates, polio eradication and PV containment status

Status of polio eradication and The Global Polio Eradication Initiative (GPEI) 2022–2026

The (GPEI) 2022–2026 (1) goals and strategy milestones were reviewed in this session. The 22nd report of the Independent Monitoring Board of the GPEI, Closing in on zero (2), has been released and outlines several risks and 15 recommended actions; the Independent Monitoring Board considers Goal 1 to be off-track and likely to be missed and also predicts that Goal 2 will be missed.

Wild poliovirus type 1 (WPV1) cases increased in Afghanistan and Pakistan in 2022 and continue to occur. There was an increase in circulating vaccine-derived poliovirus (cVDPV) cases in 2022, mainly in southeast African countries. The number of cases of circulating vaccine-derived poliovirus type 2 (cVDPV2) was high globally in 2020, but has decreased over the last three years. An effective immunization campaign response (2+1 campaign strategy) has stopped outbreaks in 20 of 28 African countries; however, this strategy has not worked in the countries with the greatest risk of virus circulation – Democratic Republic of the Congo, Nigeria, Somalia and Yemen. Advocacy continues for the 28 countries globally that still faced virus circulation in 2022 to introduce a second dose of inactivated poliovirus vaccine (IPV), and many countries need to conduct catch-up activities for dose 1 of IPV.
Discussion

- There have been challenges in interrupting PV circulation in Afghanistan during the current humanitarian emergency. The Taliban is collaborating with public health officials to allow door-to-door vaccination and to offer vaccinations bundled with other services at mosques; these activities are ongoing.
- Robust environmental surveillance in Afghanistan and Pakistan has allowed rapid identification of PVs; continued work is needed in the Democratic Republic of the Congo, Nigeria, Somalia and Yemen.
- Production of novel oral polio vaccine monovalent type 2 (nOPV2) is now on a scale to meet demand and the goal is to continue to use nOPV2 globally to respond to cVDPV2 outbreaks; the Strategic Advisory Group of Experts on Immunization (SAGE) will determine if additional recommendations should be made around this issue. The longer live polio vaccines are in use, which creates transmission risks to additional countries, the longer it will take to end the containment of PV. Any area with under-immunized pockets of individuals is susceptible to the importation of PV.
- When PV outbreaks are declared, the International Health Regulations committee issues temporary recommendations for the vaccination of travellers before leaving the country, but implementation of this recommendation has been limited. The International Health Regulations recommendation provides opportunities to set up vaccination points in areas with migration/transit between countries; it is hoped that countries will better implement this recommendation in the future.

Polio eradication status and cVDPV outbreaks in the European Region. The thirty-seventh meeting of the RCC – outcomes and recommendations

There were increased PV detections of concern in the European Region in 2022 and fewer but more significant PV detections in 2023. Polio outbreaks occurred in 2021–2023 in Israel (cVDPV2 and circulating vaccine-derived poliovirus type 3 (cVDPV3)), Ukraine (cVDPV2) and the United Kingdom (cVDPV2). The response to the 2021 cVDPV2 outbreak in Ukraine was robust amid many challenges during the conflict. An outbreak response assessment was conducted in May 2023 and recommended that the Regional Office consider closing the outbreak. An expanded risk assessment in neighbouring countries regarding Ukrainian refugees was conducted to review actions taken to prevent, detect and respond to vaccine-preventable diseases and provide recommendations. As regards Israel’s cVDPV outbreaks in 2021–2023, the last cVDPV3 detection was in May 2022 and the last cVDPV2 detection was in May 2023. The response included a nationwide vaccination campaign. cVDPV2 related to the virus isolated in Israel was detected in London, United Kingdom, between February and November 2022 and the United Kingdom implemented intensified surveillance and increased vaccination of targeted communities in response.

In 2019, the Regional Commission for Certification of Poliomyelitis Eradication (RCC) and the European Technical Advisory Group of Experts on Immunization recommended an increase in IPV use and a gradual reduction in the use of oral polio vaccine (OPV) doses in their schedules, and in 2022, SAGE concluded that an IPV-only schedule may be considered in countries in polio-free regions with very low risk of importation and high routine immunization coverage. During the RCC meeting in October 2022, the Region celebrated 20 years of polio-free status; however, Bosnia and Herzegovina, Montenegro, Romania and Ukraine were assessed to be at a high risk of sustained transmission in the event of PV importation or emergence of a vaccine-derived poliovirus (VDPV). In September 2023, the RCC again assessed Bosnia and Herzegovina and Ukraine to be at a high risk due to low population immunity.
The role of PV containment and the global status of its implementation

GAPIV (3) represents an update of the Global Action Plan for Poliovirus Containment (third edition) (GAPIII) and contains revisions made in line with the latest research in facility biorisk management and international standards, and allows for local risk management strategies guided by local risk assessment. The Containment Strategy (4) and its Action Plan (5), aligned with the GPEI global strategy, are focused specifically on containment, with related objectives and timelines, map existing gaps, and detail required resources.

The biorisk management of facilities designated for the retention of PV post-eradication (poliovirus-essential facilities (PEFs)) is achieved through the implementation of facility, environmental and immunization coverage safeguards, as described in GAPIV. For immunization safeguards, SAGE recommends all countries implement a two-dose IPV schedule, maintain coverage rates for the second dose of IPV of 90%, and ensure high vaccination coverage among infants in areas around PEFs. The geographical extent of coverage should be determined through a risk assessment by the NAC.

World Health Assembly Resolution 71.16 (6) urges Member States to: intensify efforts to accelerate the progress of PV containment certification; inventory and destroy unneeded PV materials; and ensure any breach in PV containment is immediately reported. All Member States retaining PVs are urged to reduce to a minimum the number of PEFs, appoint a competent NAC, and request facilities retaining PV type 2 to submit applications for a Certificate of Participation (CP) to their NAC. As of September 2023, of the 22 countries with facilities retaining PVs globally, 20 have established an NAC.

Pending issues include the extensive use of type 2 live oral polio vaccine (OPV) to address VDPV outbreaks, which creates a containment risk as it generates additional PV IM and PIM. The COVID-19 pandemic had an impact on the implementation of the World Health Assembly resolution on PV containment, and progress on facility certification has been suboptimal in several countries. The majority of countries are missing legal frameworks to enforce containment policies and there are risks associated with containment breaches. Containment, survey and inventory activities and containment certification are integral components of the global eradication programme. Strong national and international collaboration is needed between regulatory authorities and progress needs to be accelerated.

Discussion

• The delays in the progress of certification of PEFs in accordance with PV containment requirements were highlighted for certain countries. Possible approaches to address this issue were discussed, including continuation of high-level diplomatic discussions between WHO and the leaders of governments, as well as possible regulatory mechanisms that would oblige PEFs to be certified before being able to perform their activities (e.g. under the framework of the WHO prequalification mechanism for funding for research).

• There is no global PV biorisk-related oversight framework under the GPEI, similar to that which exists for smallpox; if such a framework is not established this would require moving the containment issue from the GPEI umbrella to another WHO working area where such a mechanism is already properly functioning.

• Currently, there is a need for certain facilities to retain PV materials due to the critical functions they perform (e.g. polio vaccine production and quality control, research and development, etc.). As we get closer to PV eradication, this demand will decline and there will need to be a cost–benefit analysis for facilities that want to continue retaining PV materials, and Member States will need to ensure they are meeting the global requirements for PV containment.

• The problem was raised that it is relatively easy to synthesize live PV in vitro nowadays, which has implications for biosecurity as well as global PV containment implementation. The most tangible work
from WHO on the subject is the 2015 report of the Independent Advisory Group on Public Health Implications of Synthetic Biology Technology Related to Smallpox, summarizing the challenge (7).

• The report states: “...With the development of these technologies, public health agencies have to be aware that henceforth there will always be the potential to recreate variola virus, and therefore the risk of smallpox re-emerging can never be fully eliminated”.

During the plenary discussion on global PV containment implementation progress, it was noted that due to the continued presence of PV in some areas in the world and the existence of PIM, PV containment implementation could be compromised. There is the need for further advocacy to get commitment from those countries where there are still challenges with PV containment implementation. It was mentioned that the containment verification process should be standardized and implemented across countries and stakeholders.

**Status of PV containment implementation in the European Region**

The PV containment inventory procedure in the Region started with pre-certification in 2001, and continued to verification in 2001–2006, data standardization in 2006–2015, and an emphasis on risk from 2016 to date.

The PV inventory by countries and sites in the Region was reviewed in this session. In 2022 there were 32 PEFs in 11 countries, 29 applications for CPs had been submitted to the Containment Working Group (CWG), and 20 CPs had been issued. The countries with the greatest number facilities were France, Netherlands (Kingdom of the) and the Russian Federation.

The WHO European Regional Polio Laboratory Network is a member of the Global Polio Laboratory Network encompassing 47 national and subnational laboratories in 37 countries. These laboratories provide services to all 53 Member States and represent both PEF and non-PEF.

With regard to PV containment, implementation gaps and challenges exist in some countries, both with and without PEFs. Some countries still have not destroyed PV IM/PIM in their non-PEFs and further follow-up is needed to ensure that no such materials are handled/stored without safe and secure containment conditions. Some countries with PEFs still face challenges in proceeding with the certification of their designated PEFs due to the absence of an NAC or due to no decision being made as to whether the PEF should be designated, or PV materials should finally be transferred/destroyed. The WHO Regional Office for Europe is working closely with country offices to reach agreement with respective governments regarding this matter.

There is a robust mechanism of inventory revision for IM/PIM in the Region, and good dialogue with NPCCs is the best way to ensure the continued improvement of inventories. Challenges to containment exist; all guidance documents on PV containment are currently under revision, one country’s containment strategy requires clarity, several countries that do not have a PEF need to review stored PV IMs/PIMs generated during diagnostic and surveillance activities in 2021–2023 and dispose of those IMs/PIMs that are subject to containment, and several countries need to expedite their PEF audits.

**Discussion**

• WHO headquarters is making final edits to GAP IV. The Poliovirus Containment Advisory Group (CAG) has not recommended any significant changes to the main text; however, some changes have been requested to enhance guidance to facilities on how to meet the requirements described in the main
text. This will be presented at the 8th meeting of the CAG in December 2023 for consensus among members.

**Session 2. Insights into global PV containment requirements**

**Overview of the key roles/responsibilities and key documents on PV containment; completed and planned revisions**

The GPEI Polio Eradication Strategy 2022–2026 (1) was developed due to the dual emergencies of WPV1 transmission and cVDPV outbreaks, and introduced transformations in the eradication workstream, which impacted containment processes; containment is featured under the section “Preparing for a post-certification world” and the activities are in line with GAPIV. The Global Polioivirus Containment Action Plan 2022–2024 (5) was developed to support GPEI partners and Member States with commitments to achieve containment amid changes to the polio eradication effort and presents distinct goals and objectives for safe and secure PV containment in facilities retaining PV; it aligns with fundamental principles of the Strategy for Global Poliovirus Containment (4) and the overall Polio Eradication Strategy 2022–2026 (1). The global strategy for the implementation of GAPIV (i.e. risk elimination and biorisk management) also aligns with these documents.

Implementing containment timelines linked to eradication milestones is challenging because GPEI continues to face ongoing WPV1 endemic circulation, widespread cVDPV2 circulation, continued use of OPV type 2 (OPV2), and uncertainty concerning OPV cessation. These factors also challenge the internally consistent logic of PV containment, according to which eradicated PV should not be in use elsewhere, but only in a PEF. However, this is currently not the case because eradication, certification and cessation processes are not fully synchronized and containment implementation is dependent on all three. Inventories cannot be considered final while there is still WPV, cVDPV and OPV in the world. Therefore, continuous inventory process is required to maintain monitoring and timely disposal of IMs/PIMs appearing in facilities that continue performing laboratory investigations in support of epidemiological surveillance for PV.

Various PV containment guidance documents have been revised or are under revision – these revisions were necessary due to improved understanding of biorisk management, the availability of new evidence for containment requirements, and lessons learned on requirements that were not attainable following the implementation of GAPIII. GAPIV, utilizes a risk- and evidence-based approach for the implementation of the biorisk management strategies for facilities retaining PVs. GAPIV reflects the current approaches to biorisk management and improved clarity of risk management. The Containment Certification Scheme (CCS), currently undergoing revision, is also expected to reflect containment certification progress despite its dependence on eradication, certification, and cessation of OPV, empowering countries (specifically NACs) to perform and sustain their national oversight function.

The roles and responsibilities of the different containment stakeholders, which are harmonized across the different containment documents, are described in Annex B of the Global Poliovirus Containment Action Plan 2022–2024 (5), GAPIV (Chapter: Roles and activities of the different poliovirus containment stakeholders) (3), and the current version of the CCS, and are expected to be included in the revised CCS.
General overview of GAPIV, comparison with GAPIII

Revisions of GAPIII were needed due to the dynamic nature of polio eradication and increased understanding of biosafety practice. GAPIV utilizes a risk- and evidence-based approach for the implementation of biorisk management requirements for facilities retaining PVs, and these are described in biorisk management elements 1–14 of Annex 1 of GAPIV. In addition to structural changes and reorganization of the annexes, other technical revisions were also made in line with recommendations from the CAG. Safeguards were renamed from “primary”, “secondary” and “tertiary” to “facility”, “immunization coverage” and “environmental safeguards”, respectively. A new section on the containment requirements for the handling of novel PV strains was added based on the criteria for the evaluation of improved “safety” of novel PV strains developed by the CAG (8).

In a situation where there are differences between requirements in GAPIV and national legislation, facilities must satisfy the more rigorous requirement. The definition of environmental safeguards has been expanded to include “local context” (local site-specific environmental parameters) that hinder the transmissibility of PV should there be a facility-associated release of PV, and takes a risk-based approach tailored to the local situation in the area around the facility. Several prescriptive facility safeguard requirements in GAPIII were shifted to a risk-based approach (e.g. exit showers, PV dedicated facilities, etc.).

GAPIV was endorsed by the CAG in June 2023 and entered into force on 1 July 2023. Global and national tolerance for minimal risk of release of PV from a facility is unaltered from GAPIII to GAPIV.

Survey, inventory and biorisk management requirements and the compliance verification mechanism for retention of the different PV material types have been updated in line with GAPIV, the CCS, PIM guidance and applicable CAG recommendations.

The PIM guidance provides advice for facilities to minimize the risk of sample collections potentially infectious for PV. During the sixth meeting of the CAG in January 2023, recommendations were issued on revisions to the PIM guidance (9).

Discussion

• GAPIV incorporates recommendations from the CAG. Moving forward, GAPIV will be a living document on the GPEI website. An expedited publication process within WHO will be used to inform stakeholders of CAG recommendations that constitute a change in the text in GAPIV, with relevant changes tracked.
• For environmental safeguards, GAPIII included several parameters on water treatment but was not prescriptive. GAPIV maintains these parameters but also provides the opportunity for the inclusion of other environmental safeguards for facilities, such as sewage treatment and location of the facility in areas of low population density, which minimizes the risk of re-establishing the circulation of highly transmissible PV.
• The globally harmonized compliance verification mechanism for facilities implementing GAPIII or GAPIV is described in the CCS.
• In accordance with CAG recommendations on the transition period from GAPIII to GAPIV, the initial interim certificate of containment (ICC) audits carried out against the requirements of GAPIII must be completed by 31 December 2023. From 1 January 2024, all ICC audits must be performed against GAPIV.
Overview of the CCS and recommendations made by the Global Certification Commission for Polio Eradication on the certification process and timeframe

The key document describing the CCS, *Containment Certification Scheme to support the WHO Global Action Plan for Poliovirus Containment (10)*, outlines the compliance verification process for facilities implementing the PV containment requirements developed by the CAG; global oversight of compliance verification is under the Global Certification Commission for Polio Eradication (GCC). The current recommendations for CCS activities and timelines, some of which are no longer applicable, are being reviewed (e.g. the deadline for the submission of ICC). Deviations from the CCS were also made, for example, additional documentation not described in the CCS was requested, such as a description of the current containment conditions during the CP application; an ICC plan, which includes a timeframe; a list of audit team composition and experience; and a detailed audit plan. The quarterly review cycle of CCS applications is also expected to interrupt the current CCS timelines and processes, which will be taken into consideration during the revision of the CCS. The CCS process should be revised, and additional CCS chapters may be needed. The CCS should not be tied to a specific version of the GAP and visuals will simplify the containment certification and audit processes. The roles and responsibilities should have a standalone section and the role of WHO in the review process should be clarified. Calibration of the CCS could be facilitated during annual WHO–NAC–GCC meetings. Auditor qualifying activities (demonstration of competence in an applied setting) is likely to be the most challenging aspect of revising the CCS. Updating the CCS is an opportunity to integrate lessons learned and this document should be regularly revised.

**Discussion**

- After receiving a PEF certificate of containment, audits will continue to occur every three years. In the current version of the CCS, the standards set out for auditor experience may not be realistic for many countries to achieve, given resource limitations; however requirements for auditor qualifications do need to be established to avoid significant divergence between countries. Likewise, the CWG must have established standards by which to assess audit teams to ensure that the quality of certification is consistent.
  - For countries moving forward with the current CCS, WHO will honour the current document and countries should use the current criteria. The revised document will build upon the current CCS.

**Session 3. PV containment implementation: certification process, current experience and challenges**

**Containment audit of a PEF – country experience, Netherlands (Kingdom of the)**

In 2014, the Dutch National Institute for Public Health and the Environment made a decision to become a PEF. They updated their biorisk management policy, implemented a committee, expanded and updated the biorisk management manual, improved and intensified the internal audit system, and produced 30 GAPIII/IV-specific risk assessments. Pre-audit activities began in 2018, the GAPIII phase 1 initial ICC audit occurred in 2021, a partial ICC certification audit took place in 2022 and the second part of the Phase 2 compliance audit against GAPIV happened in 2023. This was a significant effort by the NAC and PEF and
improvements were made on many levels, mostly in paperwork and some in practical work and personal protective equipment.

**Containment breach management – country experience, Netherlands (Kingdom of the)**

Netherlands (Kingdom of the) shared experiences with containment breaches. PV can be discovered through clinical enterovirus or acute flaccid paralysis surveillance, environmental surveillance, a facility reporting an incident, or PV isolation from a PEF wastewater sample. When a facility reports a possible exposure to PV, there are WHO guidelines (11) and national guidelines to follow. Based on the lessons learned from the response to PV containment breaches from a facility in 2017, 2022 and 2023, communication is important and public health services should collaborate in producing a press release, including the PEF and NAC. The country team emphasized that in managing such containment breaches, the NAC should work with the PEF to obtain information and samples and always follow up on PV detections; the PEF should collaborate with the NAC when undertaking root-cause analysis and implementing appropriate corrective measures.

**Discussion**

- It was highlighted that environmental surveillance around a PEF could be of value since it proved to be an informative way to detect containment breaches.

**Containment breaches in the European Region**

Facility-associated releases of PV into communities in the Region since 1990 were reviewed in this session. Eradicated PVs should be properly contained, and containment breaches should be properly managed; risk should be mitigated to the maximum extent possible. Guidance available includes the *Public health management of facility-related exposure to live poliovirus* (11), *Responding to a poliovirus event or outbreak* (12) and GAPIV (3).

The RCC has made recommendations on polio outbreak simulation exercises (POSE); in 2014 they recommended all preparedness plans be tested using a POSE, and in 2018 recommended that Member States consider their highest-priority risks (i.e. risk of importation, risk of VDPV circulation and risk of facility containment breach from a PEF) when conducting a POSE. In 2018, 12 countries in the Region participated in a POSE, with three to five representatives from each country. The POSE was designed as a two-day table-top exercise using a scenario based on a real previous breach. Lessons learned from the POSE were reviewed. In summary, risk mitigation measures for PV containment breach should be considered by PEF and non-PEF countries; PV containment breach readiness should be strengthened through further development of national action plans; and regular POSE-like tests of plans should be conducted and plans updated.

**Containment audit of a PEF – country experience, Netherlands (Kingdom of the)**

The Dutch NAC is within the Health Care Inspectorate and has a quality management system. There are five PEFs in the country; four have CPs and one is pending. Audits were changed to gap assessments using GAPIV guidelines; a template is used to gather necessary information and documents. The process takes one to two weeks onsite, is followed by a report and follow-up on non-conformities and ends with an application for ICC. The NAC conducts an annual inventory of PEFs, issues mandatory notifications and permits, and monitors sewage surveillance around the PEFs. Challenges include the lack of a certified lead auditor.
**Discussion**

- The audit process should be harmonized worldwide so that requirements for PV containment implementation and audit procedures are as similar in different countries as possible. It should be ensured that the audit process in one country is not easier or harder than in another.
- To address threats of impartiality, Netherlands (Kingdom of the) has a policy for a one-year waiting period before someone who has left a facility can begin conducting audits.
- Sewage surveillance is conducted at all facilities in Netherlands (Kingdom of the). There were different causes for PV in sewage, including the infection of workers, procedures not being followed, unclear procedures and human error.
- The most challenging elements of GAPIII and GAP IV are the risk assessments.
- Audits are time-intensive and complex. The NAC is expecting to certify facilities during the first audit; the next audit should be easier as it will mainly involve follow-up activities.

**Containment audit of a PEF – country experience, France**

The French National Agency for the Safety of Medicines and Health Products is responsible for licensing of all health products in France and is in charge of conducting inspections and audits in the public health sector, including GAP audits. It works closely with the Ministry of Health, which serves as the NAC. There are two regulations on PEF surveillance in France related to vaccine production and regulation of microorganisms and toxins (MOT). The French MOT regulations and GAP have many of the same core requirements, which is advantageous. France has eight PEFs and three have CPs; one has an ICC and two are pending an ICC. Three audits were conducted in 2022 and early 2023. Preparation for the audit includes serology or vaccination of auditors and requests for necessary materials from the PEFs. An audit took one full week to conduct with two auditors and involved 50–100 people from the PEF. PEFs that previously conducted a GAP compliance test had already identified gaps. The audit process through the final audit report takes about six months to complete and the ICC application process takes up to eight months. France needs to audit the five remaining PEFs for ICC.

**Discussion**

- The MOT inspection is useful in terms of findings, and reports can be used to prepare for the GAP audit, but additional information must also be gathered.
- Having a country regulatory agency helps with the GAP assessment. The NACs in other countries have a similar structure for auditor team composition and plans to conduct audits. Regulators encourage PEFs to conduct an internal gap analysis prior to audits to identify possible gaps.

**Applications for CP and ICC – the experience of the Secretariat of the CWG**

The information flow between PEFs, NACs, the CWG and the GCC were reviewed in this session along with the terms of reference for the CWG. The GCC-CWG is comprised of a chair and seven members who represent a broad range of disciplines relevant to PV containment. The CWG holds monthly calls to review CPs and any time-sensitive issues, and quarterly meetings are held to plan and review applications. Additional CWG members are being recruited, and additional Secretariat support for the CWG is needed. The CCS is currently under revision, and there is a need for improved communication timeliness and
comprehensiveness and improved clarity and consistency when engaging with the GCC and CWG on critical decisions and providing technical guidance.

Discussion

- Four new GCC-CWG members and an alternate are needed; the duration of membership is three years. Most members are retired; people with NAC experience are desirable but cannot be currently serving on an NAC and members cannot be current PEF employees.
- SharePoint is used for secure sharing of documents between the NACs and the CWG; documents are not shared via email.

Session 4. PV containment implementation: inventory of PV IM and PIM, current experiences and challenges

Inventory of PV IM – Regional overview

A historical overview of activities in 2000–2023 and regional progress toward PV containment implementation was provided in this session. Stakeholder roles and responsibilities with regard to inventory, destruction and containment in line with GAPIV were outlined. The containment section of the electronic Annual Progress Report on polio eradication activities (eAPR), which all Member States submit on an annual basis for review by the RCC, gathers necessary information from countries and represents an official communication channel. This eAPR section includes questions from the WHO headquarters templates to reduce reporting workload. There are plans to add a new e-inventory section to the eAPR, which will include information about PEFs and biomedical facilities in the country, the strategy used to identify facilities with PV IM/PIM, and the national inventory.

In 2023, there were 42 countries in the Region without a PEF. The differences between PV IM and PIM were reviewed. There are many different types of facilities that may handle PV PIM including laboratories and industrial facilities; the number of such facilities could be very high. Challenges exist with the PV PIM inventory in the Region and the facility survey is a continuous process. There is a clear distinction between revision/verification and validation for IM/PIM, and true validation may never be attainable; however, risks could be mitigated. Proper training and building good technical dialogue with the NPCCs take time but are the best way to ensure systematic perennial improvement of inventories.

Inventory of PV IM – country experience, Belgium

The Service Biosafety and Biotechnology (SBB) unit of Sciensano (Belgian Public Health Institute) acts as the technical expert for matters of biosafety in Belgium, and the SBB serves as the NPCC. In 2002, a survey was conducted with 411 facilities retaining WPV and/or PIM, which identified five facilities holding WPV materials. In 2004–2014 the national inventory of facilities retaining WPV and/or PIM was updated annually. In 2014, four facilities were handling or storing WPV materials. In 2015, GAPIII was implemented, the national survey was updated and broadened, and 15 facilities retaining WPV materials and/or OPV2/Sabin2 materials were identified. In 2017, the NAC was designated, and GAPIII was implemented through legislation
in 2019. In 2020, four PEFs were designated by the NAC, and CP applications were issued for three active PEFs in 2022. In 2023, audits were performed according to GAPIV requirements.

**Inventory of PV IM – country experience, Italy**

National inventory surveys were conducted in Italy in 2001, 2005 and 2015. A decision was made by the Ministry of Health in 2018 not to have PEFs. Regional departments of health were delegated by the ministry to conduct the inventories using questionnaires. During the three surveys, more than 3000 facilities were contacted and 88 did not respond; most non-responders were private laboratories that do not store samples long-term. Only 16 laboratories declared possession of PIMs and most had high containment levels. The inventory activities were supported by the National Institute of Health, the Polio Working Group and the National Certification Committee (NCC). Annual national inventories were conducted in 2017/2018 and annually from 2019 to the present. Challenges include that not all laboratories respond to the questionnaire, the national survey focused mainly on IMs so there are issues with laboratories’ accuracy in identifying PIMs, and there is a newly appointed NPCC for the country.

**Inventory of PV IM – country experience, Slovenia**

Three national PV inventories were conducted in Slovenia – in 2002, 2015 and 2016. In 2002, all identified WPV were destroyed, and two laboratories retained PV materials. The 2015 survey checked for PV and PIM and two laboratories were identified; one destroyed PV materials and the other (the National Polio Laboratory) retained PV materials. Legislation on PV containment is under development in Slovenia.

**PIM guidance, second edition, 2021 overview**

The principles of the *Guidance to minimize risks for facilities collecting, handling or storing materials potentially infectious for poliovirus* (second edition) (13) were presented in this session. The strategy to maintain eradication status requires countries to identify all IM/PIM, destroy all unneeded PV materials, transfer needed PV materials to a PEF, and ensure PEFs are certified to meet the GAPIII/GAPIV requirements. Faecal samples are considered to be of high risk for possible PV contamination; respiratory tract secretions are of moderate risk; concentrated sewage samples are of the low risk, but are still considered to be PIM. PV is rarely recovered from cerebrospinal fluid, serum or blood samples and, therefore, these types of materials are not considered as PIM. The location and time when samples were collected are crucial to determine whether samples are PV PIM. The *Risk-based strategies for poliovirus containment in facilities* online training course is available (14), and relevant containment documents can be found on WHO’s *Containment guidance and tools* website (15). The PIM guidance is currently under revision in line with recommendations made by the CAG at its sixth meeting in January 2023 (16).

The NPCC plays a critical role in the establishing an exhaustive and comprehensive list of all facilities that may retain IM/PIM in the country, collecting information from these facilities, and analysing and compiling their responses. Facilities should be listed according to the retained type of material, and information on the designation and certification of PEFs should be provided along with an updated list of NAC members. The NPCC’s role is to inform the NAC of the retention of PV IM/PIM in facilities requiring certification. Facilities
are responsible for complying with the PIM guidance and national requirements in coordination with NPCCs, NCCs and other relevant stakeholders.

The ultimate goal of PV containment activities is to minimize the risk of release of PV from facilities. Facilities, therefore, should evaluate their sample collections and identify all PV IM/PIM; facilities retaining PV IM/PIM have to receive national authority approval. Facilities retaining WPV/VPV IM or PIM or OPV/novel oral polio vaccine (nOPV)/Sabin IM must implement full containment and be certified. Facilities retaining OPV/nOPV/Sabin PIM should implement risk reduction measures described in the PIM guidance.

**PIM survey in the European Region – country experience, Sweden**

The PV PIM inventory process in Sweden began in June 2022 and is nearly finalized. Facilities were identified and questionnaires were sent to more than 100 of them, with a completion rate of 65–100%. The questionnaire aimed to identify all PV PIM materials included in the PIM guidance and an additional question about IM was added after the first round. An extended inventory was conducted to check for samples obtained from patients who visited areas where cVDPV or WPV was present or where OPV2 is used (20% of the population was born outside of Sweden, some from areas where WPV or cVDPV are still detected or OPV is in use).

**Discussion**

- For countries in the European Region with recent cVDPV detections, the NAC should decide what area should be considered a circulation area based on these detections and review their PV IM/PIM inventories accordingly.
- According to one country experience, the PIM identification tool is challenging to use. The tool has not been updated yet to reflect the current list of countries with VDPV circulation. Depending on the date span, countries may have different choices and may not know what applies to the country and its samples; results may need interpretation.
- There was a request for all WHO documents and guidelines to be made available in additional languages.
References


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