POLIO GLOBAL ERADICATION INITIATIVE

GLOBAL POLIOVIRUS CONTAINMENT ACTION PLAN 2022–2024

UN Foundation / Christine McNab

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ACRONYMS AND ABBREVIATIONS

bOPV	Bivalent oral polio vaccine
CAG	Containment Advisory Group
CC	Certificate of containment
CCS	Containment Certification Scheme
CDC	U.S. Centers for Disease Control and Prevention
CMG	Containment Management Group
CNT	Containment Team (WHO headquarters)
COVID-19	Coronavirus disease 2019
CP	Certificate of participation
cVDPV	Circulating vaccine-derived poliovirus
cVDPV2	Circulating vaccine-derived poliovirus type 2
DG-WHO	Director-General (WHO)
dPEF	Designated poliovirus-essential facility
ECBS	Expert Committee on Biological Standardization
GAP	Global Action Plan for containment (all editions)
GAPIII	Global Action Plan to minimize poliovirus facility-associated risk, third edition
GAPIV	Global Action Plan for Poliovirus Containment, fourth edition
GCC	Global Commission for the Certification of the Eradication of Poliomyelitis
GCC-CWG	Containment Working Group of the Global Commission for the Certification of the Eradication of Poliomyelitis
GPCAP	Global Poliovirus Containment Action Plan
GPEI	Global Polio Eradication Initiative
GPLN	Global Polio Laboratory Network
ICC	Interim certificate of containment
IM	Infectious materials
IPV	Inactivated polio vaccine
KPI	Key performance indicator
M&E	Monitoring and evaluation
MoH	Ministry of Health
mOPV2	Monovalent oral polio vaccine type 2
NAC	National authority for containment
NCC	National Committee for the Certification of the Eradication of Poliomyelitis
nOPV	Novel oral polio vaccine
nOPV2	Novel oral polio vaccine type 2
NPCC	National poliovirus containment coordinator
NPCTF	National Poliovirus Containment Task Force
NTF	National Task Force for Poliovirus Containment (applicable whenever NPCTF is cited)
OPV	Oral polio vaccine
OPV2	Oral polio vaccine type 2
PCS	Polio Post-Certification Strategy
PEF	Poliovirus-essential facility
PIM	Potentially infectious materials
PRSEAH	Preventing and responding to sexual exploitation, abuse and harassment
PV	Poliovirus
PV2	Poliovirus type 2
RCC	Regional Commission for the Certification of the Eradication of Poliomyelitis
S19 strain	Hyper-attenuated (weakened), very genetically stable strain
Sabin strain	Sabin vaccine poliovirus strain
SAGE	Strategic Advisory Group of Experts on Immunization
SAGE WG	SAGE Working Group on Polio
SOPs	Standard operating procedures
tOPV	Trivalent oral polio vaccine
ToRs	Terms of reference
UNICEF	United Nations Children’s Fund
VDPV	Vaccine-derived poliovirus
VLP	Vaccine-like particle
WHA	World Health Assembly
WHO	World Health Organization
WPV	Wild poliovirus
WPV1	Wild poliovirus type 1
WPV2	Wild poliovirus type 2
WPV3	Wild poliovirus type 3

INTRODUCTION

PURPOSE

In 2018, Member States of the World Health Organization (WHO) at the Seventy-first World Health Assembly unanimously passed a resolution prioritizing global poliovirus containment.[1] The resolution urged international commitment to expedite full implementation of containment requirements, as described in the *WHO Global Action Plan* (GAP) *to minimize poliovirus facility-associated risks*.[2] Adoption of the resolution committed all countries to complete inventories of facilities in possession of poliovirus type 2 (PV2) materials, to destroy or transfer all unneeded PV2 materials to a poliovirus-essential facility (PEF), and to begin inventories for facilities with types 1 and 3 wild poliovirus (WPV1 and WPV3) materials in accordance with WHO guidance. The resolution prioritized these activities as critical to achieving an ultimate milestone for poliovirus containment: that all designated PEFs should be certified as compliant with GAP by the time global wild poliovirus (WPV) eradication is certified.

Progress on these international commitments, however, has been impacted both by delays in achieving polio eradication and by challenges in reaching containment-related milestones.

In 2022, the Global Polio Eradication Initiative (GPEI) defined a new eradication strategy to address the dual emergency of WPV1 transmission and circulating vaccine-derived poliovirus (cVDPV) outbreaks.[3] The GPEI Strategy introduced transformations in eradication workstreams that impacted containment processes, particularly through the expanded use of type 2-containing vaccines. It also outlined new efforts to increase country ownership of polio eradication as part of transition planning for the eventual closure of the GPEI at the certification of WPV eradication.

To support GPEI partners and Member States with commitments to achieve poliovirus containment amid changes to the polio eradication effort, this **Global Poliovirus Containment Action Plan (GPCAP) 2022–2024** presents distinct goals and objectives for poliovirus containment as outlined in the *Strategy for Global Poliovirus Containment*.[4] As the eradication effort has adjusted to the long tail of WPV1 transmission and cVDPV outbreaks, containment milestones and policies have also been impacted. The GPCAP is intended to **clear the way for country-level implementation of poliovirus containment.** It connects national, regional and global containment efforts and provides a framework to coordinate the efforts of all stakeholders engaged in poliovirus containment.

Underlying this action plan, the ***Strategy for Global Poliovirus Containment*** provides a blueprint to understand the goals and objectives around which polio eradication stakeholders must organize their efforts to safely contain poliovirus. The strategy is intended broadly for the GPEI partnership and particularly for national political and health leaders and heads of facilities retaining poliovirus.

Above all, the *Strategy for Global Poliovirus Containment* and its companion, this GPCAP 2022–2024, are intended to bring urgency to internationally-endorsed commitments to poliovirus containment as a critical means to safeguard the historic achievement of polio eradication.

[1] Resolution WHA71.16. Poliomyelitis – containment of polioviruses. In: Seventy-first World Health Assembly, Geneva, 26 May 2018. Geneva: World Health Organization; 2018 (https://apps.who.int/gb/ebwha/pdf_files/WHA71/A71_R16-en.pdf).
[2] As a GAPIV will soon be published, but GAPIII criteria may stay in effect for three years after GAPIV publication, this action plan refers to both GAPIII and GAPIV as "GAP guidelines." GAPIII: WHO Global Action Plan to minimize poliovirus facility-associated risk after type-specific eradication of wild polioviruses and sequential cessation of oral polio vaccine use, third edition. Geneva: World Health Organization; 2015 (http://polioeradication.org/wp-content/uploads/2016/12/GAPIII_2014.pdf).
[3] Global Polio Eradication Initiative (GPEI). Polio Eradication Strategy 2022–2026: Delivering on a promise. Geneva: World Health Organization; 2021 (https://apps.who.int/iris/bitstream/handle/10665/345967/9789240031937-eng.pdf).
[4] Global Polio Eradication Initiative (GPEI). Strategy for Global Poliovirus Containment. Geneva: World Health Organization; 2022 (https://polioeradication.org/wp-content/uploads/2022/07/Strategy-Global-Poliovirus-Containment.pdf).

CONTEXT

Containment efforts, as overseen by the Global Commission for the Certification of Poliomyelitis Eradication (GCC), with support and advice from its Containment Working Group (GCC-CWG) and the Containment Advisory Group (CAG), have achieved marked progress in recent years.

Since the eradication of wild poliovirus type 2 (WPV2) was declared in 2015, followed by the 2016 cessation of routine Sabin type 2 oral polio vaccine (OPV2) use, containment has largely focused on PV2 materials. Beginning in 2016, national and international governance structures for implementing and overseeing containment have been created. Additionally, inventories of facilities holding PV2 materials have been mostly completed, and national authorities for containment (NACs) have been established in many countries planning to retain poliovirus materials. Furthermore, diagnostic laboratories have been instructed by the Global Polio Laboratory Network (GPLN) on the safe handling and storage of PV2 materials as part of their role in diagnostic testing to support poliovirus surveillance efforts.[5]

Poliovirus containment responsibilities	
Countries	✓ Containment implementation ✓ National policy
WHO & GPEI	✓ Technical guidance ✓ Technical support and expertise ✓ Monitoring and evaluation
Advisory bodies	✓ Policy and technical guidance ✓ Certification oversight

Progress has also been made toward identifying and establishing PEFs. Training sessions have been conducted in all six WHO regions on principles and practices of poliovirus containment, including courses to strengthen national capacity (NACs and PEFs) for GAP implementation. Many PEFs designated by countries have been enrolled in the Containment Certification Scheme (CCS).[6] The WHO has been informed that some PEFs will soon apply for the interim certificate of containment (ICC), the next step towards formal certification, after each facility undergoes detailed audits for compliance with GAP. As anticipated, communicating the longer-term requirements and resources for retaining poliovirus after global certification has continued to decrease the number of designated PEFs over the last four years.

However, progress has slowed. Beginning in 2020, as might be expected, containment activities were disrupted by the COVID-19 pandemic. Furthermore, the large-scale use of OPV2-containing vaccines to respond to widespread circulating vaccine-derived poliovirus type 2 (cVDPV2) outbreaks generated new PV2 materials in countries affected by outbreaks, which required updating national facility inventories.

The ***Strategy for Global Polio Containment*** and this ***GPCAP 2022–2024*** were developed to address these challenges and accelerate progress on containment. Progress toward containment will be further measured through a forthcoming monitoring & evaluation (M&E) framework and achieved through distinct GPEI agency containment workplans that define specific, measurable activities and related timetables.

Annex A details key poliovirus containment programmatic and policy guidance, including:

- the Global Action Plan (GAP) for Poliovirus Containment,
- the Containment Certification Scheme (CCS),
- guidance for potentially infectious materials (PIMs), and
- other technical guidance.

[5] Global Polio Eradication Initiative (GPEI), Global Polio Laboratory Network (GPLN). Guidance Paper 1: For safe handling and storage of type 2 poliovirus (PV2) in GPLN laboratories, third version. Geneva: World Health Organization; 2018 (https://polioeradication.org/wp-content/uploads/2020/01/GP1-Handling-and-Storing-PV2-version3.pdf).

[6] Facilities are not officially referred to as PEFs until they reach final containment certification. When they are designated by countries for entry into the certification process, they are referred to as "designated PEFs" (dPEFs). For ease of reference, this action plan refers to all dPEFs as PEFs. See Containment Certification Scheme to support the WHO Global Action Plan for Poliovirus Containment. Geneva: WHO; 2017 (http://polioeradication.org/wp-content/uploads/2017/02/CCS_2016EN.pdf).

GOALS

Both the *Strategy for Global Poliovirus Containment* and this companion GPCAP 2022–2024 draw on the Seventy-first World Health Assembly (2018) resolution on poliovirus containment and the GPEI *Polio Eradication Strategy 2022–2026* to define overarching goals and strategic objectives for poliovirus containment (**Table 1**), to be pursued in parallel to polio eradication and beyond in the post-certification era.[7]

The **three main strategic goals** are:

1. to reduce to a minimum the number of facilities retaining poliovirus materials;
2. to ensure that all eradicated poliovirus materials remaining in PEFs are stored and handled according to agreed-upon international biosafety and biosecurity standards; and
3. to strengthen and support national and international organizations and programmes to ensure the sustainability and continuity of poliovirus containment in the post-certification era.

For each major goal, this GPCAP 2022–2024 discusses in detail the current state and the way forward. It provides actionable guidance for national containment stakeholders and supportive actions on the part of regional and global containment stakeholders. The GPCAP also discusses main functions and factors enabling progress in containment.

Poliovirus containment can only be achieved through timely country implementation and compliance.

— *Strategy for Global Poliovirus Containment*

Table 1. Goals, objectives, and country focus for the *Strategy for Global Poliovirus Containment*

Goals		Objectives	Country focus
1	Reduce to a minimum the number of facilities retaining poliovirus materials	1A. Establish and maintain inventories for all facilities retaining poliovirus materials – and destroy or transfer unneeded material	All countries
		1B. Keep the number of poliovirus-essential facilities (PEFs) to a minimum	
2	Ensure retained polio materials are handled according to international standards to maintain appropriate long-term containment	2A. Establish national authorities for containment (NACs) in all countries retaining poliovirus in PEFs	Countries designating PEFs
		2B. Achieve certification of all facilities continuing to work with poliovirus materials after WPV eradication, as compliant with global standards	
3	Strengthen and support national and international programmes to ensure sustainability and continuity of poliovirus containment in the post-certification era	3A. Strengthen continued national ownership of polio containment activities and ensure regular review and recertification of all PEFs	All countries
		3B. Maintain sufficient technical support capacity within the WHO and through external stakeholders for post-certification containment	

NAC = national authority for containment; PEF = poliovirus-essential facility; WHO = World Health Organization; WPV = wild poliovirus

[7] Resolution WHA71.16. Poliomyelitis – containment of polioviruses. In: Seventy-first World Health Assembly, Geneva, 26 May 2018. Geneva: World Health Organization; 2018. (https://apps.who.int/gb/ebwha/pdf_files/WHA71/A71_R16-en.pdf). Global Polio Eradication Initiative (GPEI). *Polio Eradication Strategy 2022–2026: Delivering on a promise.* Geneva: World Health Organization; 2021 (https://apps.who.int/iris/bitstream/handle/10665/345967/9789240031937-eng.pdf).

AUDIENCE

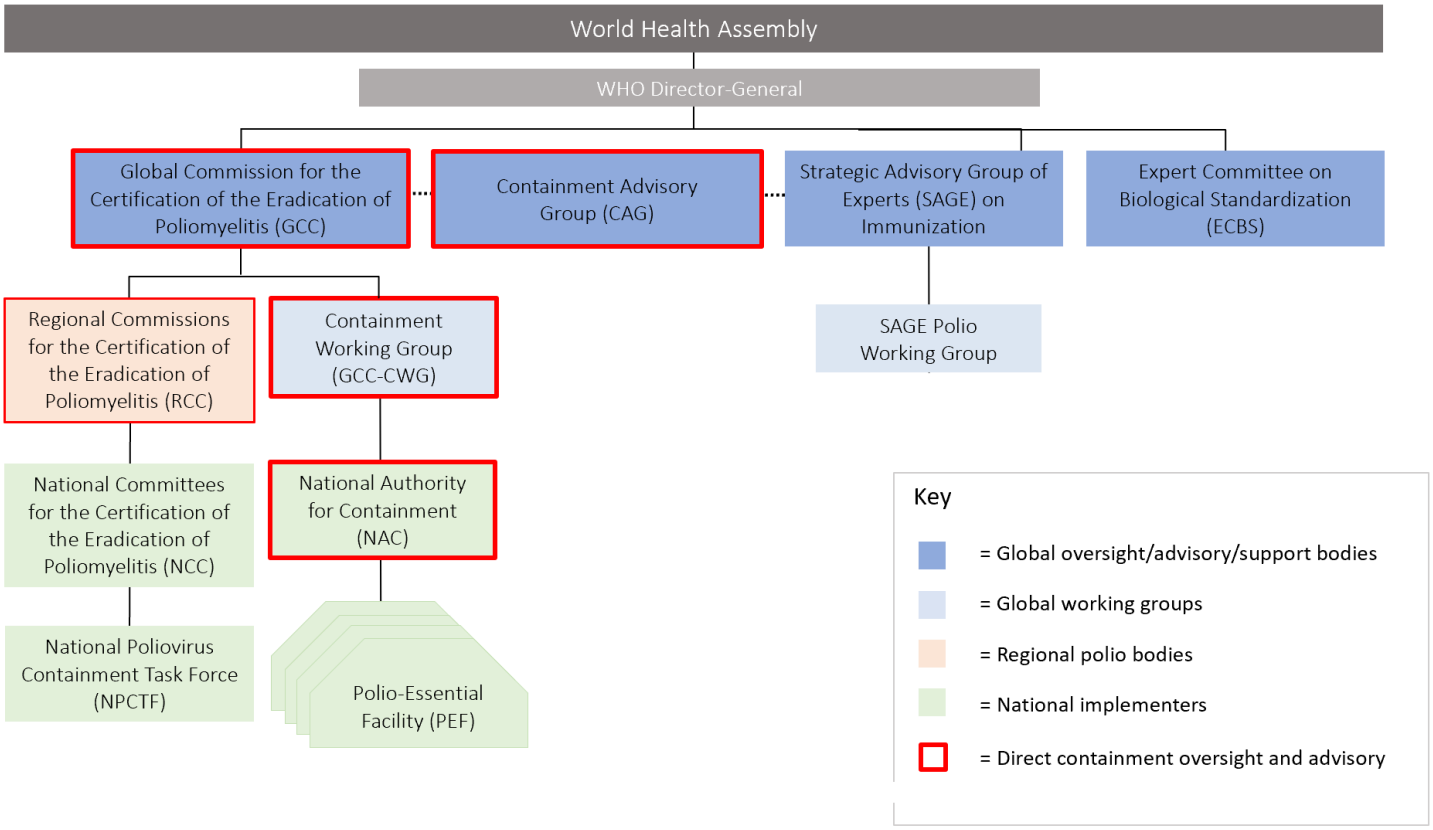
The GPCAP 2022–2024 is directed to existing groups and stakeholders that are key contributors to the implementation of poliovirus containment in and beyond the GPEI, including critical roles that fulfill Member State commitments to containment. It offers a course of action for broad alignment on poliovirus containment. More detailed containment-related activities can be found in the containment workplans of GPEI partners that are tasked with spearheading containment.

Several independent bodies, advisory groups, coordinators, and other stakeholders exist to implement, support and oversee poliovirus containment activities across the national, regional and global levels (**Fig. 1**). **Annex B** and **Annex C** introduce these stakeholders, their main terms of reference (ToRs), and their roles and responsibilities for progress on poliovirus containment.

Annex B defines the roles of key groups at the national level: National Certification Committees (NCCs), national authorities for containment (NACs), National Poliovirus Containment Task Forces (NPCTFs) and national poliovirus containment coordinators (NPCC).[8]

Annex C details the global bodies, advisory groups and organizations that oversee containment, including the GCC, the GCC-CWG, and the CAG. These groups provide guidance and technical support to help facilities at the country level, such as laboratories and vaccine manufacturers, to manage risks related to poliovirus containment. They are also invested with defining containment priorities and policies in the post-certification era.

Fig. 1. Polio containment groups



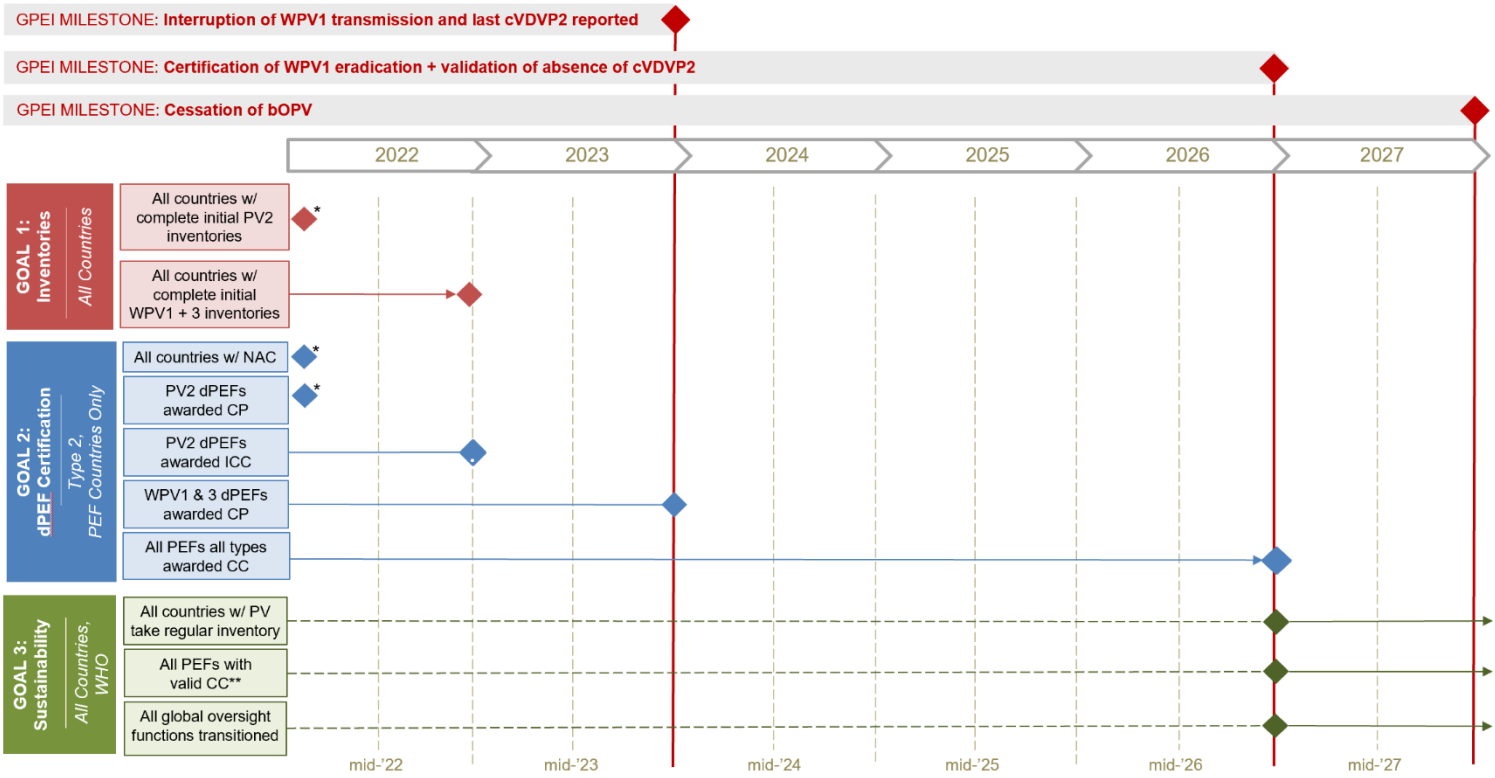
Source: GPEI.

[8] NPCTFs are sometimes referred to as National Task Forces (NTFs) for Poliovirus Containment in different country or regional contexts. As their functions are equivalent, NTFs are referred to as NPCTFs throughout this action plan.

TIMELINE

While the *Strategy for Global Poliovirus Containment* defines fundamental principles for poliovirus containment, the GPCAP 2022–2024 define activities within a limited timeframe that is aligned with the overall GPEI *Polio Eradication Strategy* (**Fig. 2**).

Fig. 2. Global poliovirus containment progress timeline and milestones, 2022–2027



* WHA71.16 deadlines: PV2 inventories end-2016; NAC designation end-2018; and CP completion by end-2019.
** All CCs have to be reviewed and re-certified on regular basis by NAC, as per CCS guidelines.

Notes:

- Progress towards PV containment is closely linked to and dependant upon progress towards certification of WPV eradication, validation of absence of cVDPV, and cessation of all OPV use.
- These milestones are aligned with the timeline towards WPV eradication, VDPV validation and OPV cessation, as envisioned in the GPEI's *Polio Eradication Strategy 2022–2026*. They might require adjustments if interruption of WPV1 transmission is delayed.
- WPV3 and WPV1 date of inventory completion should be confirmed by the GCC.

bOPV = bivalent oral polio vaccine; CC = certificate of containment; CCS = Containment Certification Scheme; CNT = WHO Containment Team; CP = certificate of participation; cVDPV = circulating vaccine-derived poliovirus; cVDPV2 = circulating vaccine-derived poliovirus type 2; dPEF = designated poliovirus-essential facility; GCC = Global Commission for the Certification of the Eradication of Poliomyelitis; GPEI = Global Polio Eradication Initiative; ICC = interim certificate of containment; NAC = national authority for containment; OPV = oral polio vaccine; PV = poliovirus; PV2 = poliovirus type 2; VDPV = vaccine-derived poliovirus; WPV = wild poliovirus; WPV1 = wild poliovirus type 1; WP3 = wild poliovirus type 3

Source: GPEI.

NEXT STEPS

In coordination with the regular review of GPEI agency containment workplans, this GPCAP will be reviewed every two years to strictly observe progress toward achieving each goal, with ad hoc adjustments to be made as required. An M&E framework, to be developed by the end of 2022, will build upon this action plan by defining criteria against which containment implementation will be assessed to inform timely decision-making and course correction, where needed. Future versions of the GPCAP will integrate this M&E framework as a tool for communicating the way forward for the many roles upon which poliovirus containment depends for its ultimate success.

GOAL ONE

Reduce to a minimum the number of facilities retaining poliovirus materials

OBJECTIVE 1A

Establish and maintain inventories for all facilities retaining poliovirus materials – and destroy or transfer unneeded material

Conducting surveys and establishing and maintaining inventories of facilities holding both infectious and potentially infectious materials (IM and PIM) are critical baseline activities required in all countries. This work is conducted by National Poliovirus Containment Task Forces (NPCTFs), led by a national poliovirus containment coordinator (NPCC), with support from the independent National Certification Committees (NCCs).

Annex A guidance

- GAP
- PIM guidance
- GPLN guidance

These baseline activities are almost completed in all WHO Member States for facilities retaining any poliovirus type 2 (PV2) materials. Upon declaration of wild poliovirus type 3 (WPV3) eradication in 2019, poliovirus type 3 (PV3) materials from WPV3 and circulating vaccine-derived poliovirus type 3 (cVDPV3) became subject to the same survey and inventory requirements as those for PV2. Most Member States have also already reported on their inventories of facilities holding wild type 1 and 3 materials. The Global Commission for the Certification of the Eradication of Poliomyelitis (GCC) decided at its June 2022 meeting that both WPV1 and WPV3 should now enter into containment immediately and moving forward. Only facilities retaining WPV1 or WPV3 will need to complete this process; facilities which already attained a certificate of participation (CP) for type 2 materials should not reapply.

Outbreaks of cVDPV2 and the use of several type-2-containing vaccines, specifically monovalent oral polio vaccine type 2 (mOPV2), trivalent oral polio vaccine (tOPV), and novel oral polio vaccine type 2 (nOPV2) for outbreak response, have important implications, particularly for updating national inventories of facilities holding PV2-infectious materials.

WAY FORWARD FOR OBJECTIVE 1A

- ✓ Country-level containment stakeholders should continue to ensure that inventories of poliovirus-retaining facilities are complete and updated in alignment with progress towards WPV certification (see **Fig. 2, Introduction**). Such inventories must be updated whenever and wherever type 2-containing vaccines are used for cVDPV2 outbreak response.
- ✓ All countries and supporting GPEI stakeholders involved in cVDPV2 outbreak response should collaborate to ensure that the risks associated with the handling, transport and possible storage of cVDPV2 outbreak virus isolates (and with the use of vaccines containing OPV2, such as mOPV2, tOPV and nOPV2) are fully addressed. Relevant containment issues should be included in both outbreak response plans and outbreak response assessments.
- ✓ Ongoing work to complete and maintain surveys and inventories (for both poliovirus IM and PIM) should be intensified to include wild, Sabin and vaccine-derived PVs of all three types, even if only the currently required PV types are included in the annual report from the country to the Regional Certification Commissions (RCCs).

→ **National entities responsible:** Expanded Programme on Immunization (EPI) managers, NPCCs, NPCTFs

→ **Support from:** UNICEF, WHO, NCCs, RCCs, GPLN

OBJECTIVE 1B

Keep the number of poliovirus-essential facilities to a minimum

All facility-associated poliovirus risk can be addressed through the destruction of all poliovirus materials known to be infectious or potentially infectious. However, important national and international functions require the continued maintenance and handling of poliovirus materials beyond the certification of WPV eradication in poliovirus-essential facilities (PEFs). PEFs designated by Member States need to be certified by meeting stringent biorisk and biosafety control measures, as defined by GAP. These designated PEFs represent a wide variety of facilities, from vaccine manufacturers to large quality control or diagnostic laboratories. However, there are also other, smaller research facilities that have been designated, the importance of which in the international context is not obvious.

Although the number of candidate PEFs designated by WHO Member States has already decreased over time since the publication of GAPIII in 2015, there are still 67 designated PEFs (for PV2) at the start of 2022. It is hoped that a further reduction of designated PEFs, particularly of high-level diagnostic labs in the GPLN, may occur once safer, genetically stable PV strains become available.

A further reduction of the number of designated PEFs appears both urgent and possible. Despite the time-intensive nature of this work, strengthened and systematic advocacy on the part of the WHO and other GPEI partners must become a strategic priority to reduce to a minimum the number of PEF designations and to support the goal of global poliovirus containment.

Annex A guidance

- GAP
- PIM guidance
- GPLN guidance

WAY FORWARD FOR OBJECTIVE 1B

- ✓ A strategy with short- and medium- to long-term components should be developed and implemented to systematically reduce to a minimum the number of PEFs and further avoid over-designation of new PEFs. This should be based on a prioritization of designated PEFs according to feasibility for achieving and maintaining global poliovirus containment functions, as well as a risk assessment related to a possible containment breach that may reseed poliovirus into a community.
- ✓ Countries with facilities that retain PV materials for low-priority and possibly non-essential activities for polio eradication should be targeted with systematic communication and advocacy efforts. Country-level decision-makers should also be fully aware and informed about the considerable managerial and resource implications of moving ahead with certification of the facility.
- ✓ In coordination with experts from the GPLN and other poliovirus researchers, global poliovirus containment stakeholders should ensure that work is pursued on safer, hyper-attenuated poliovirus strains, such as the S19 type 2 strain, to be made available as soon as possible.

→ **Agencies or groups responsible:** WHO Containment Team (CNT), regional offices

→ **Support from:** Containment Management Group (CMG), global and regional polio lab networks, other GPEI partners

GOAL TWO

Ensure retained polio materials are stored and handled according to international standards to maintain appropriate long-term containment

According to GAP, all designated poliovirus-essential facilities (PEFs) must be certified as compliant with containment requirements by the time global WPV eradication is certified. However, delays in establishing national authorities of containment (NACs) and implementing the Containment Certification Scheme (CCS) carries the risk of shifting an increasing part of the work to implement GAP into the era after WPV eradication.

Contributing to these delays, country-level containment activities were considerably disrupted by the COVID-19 pandemic, as WHO containment teams at all levels were given additional COVID-19-related assignments and as international travel disruptions negatively impacted containment training activities for NACs and auditors at several levels. Turnaround times for the GCC-CWG's considerable workload have also impacted national containment timelines. Furthermore, revising GAP was also delayed – and even after GAPIV has been published, the criteria of GAPIII could still apply for a transition period of three years. These delays leave some uncertainty among NACs and PEFs about the exact application of criteria against which facilities will be audited and at what time in the near future.

Taken altogether, these delays could negatively impact poliovirus containment, as awareness of and support for all polio-related activities at the country level are likely to further decrease following WPV certification and the closure of the GPEI. The stakes are high: potential containment breaches and reintroduction of poliovirus into susceptible populations may jeopardize the substantial investments of the GPEI and countries to secure a polio-free world.

OBJECTIVE 2A

Establish national authorities for containment in all countries retaining poliovirus in poliovirus-essential facilities

In any country intending to retain live PV materials, the establishment of a functional, competent and empowered NAC is the main prerequisite to begin activities towards certifying one or more facilities as a PEF. At the start of 2022, there are still gaps in planning by Member States to retain PV materials in designated PEFs. Some countries which have announced their intention to designate one or more PEFs still do not have an established NAC. This includes countries with relatively large numbers of candidate PEFs. Of the established NACs, some appearing far more functional, competent and well-resourced than others.

Annex A guidance

- GAP
- CCS

The lack of a functioning NAC is one of the main reasons for delays in implementing the CCS: for the first step of enrolling the facility in the CCS, as of 2022, there are still no applications for a certificate of participation (CP) for nearly a quarter of PEFs designated by Member States.

WAY FORWARD FOR OBJECTIVE 2A

- ✓ GCC and RCC chairs, supported by the WHO secretariat, should continue to work with WHO and GPEI leaders to remind countries without a functional NAC that they are non-compliant with the 2018 resolution (WHA71.16), which they endorsed, and that establishing a competent NAC is urgent if the country wants to retain PV material.
- ✓ The WHO will update the Executive Board and World Health Assembly with the global status of progress toward the implementation of the 2018 resolution (**Fig 1**, **Introduction**).

→ **National entities responsible:** NAC, NCC, NPCC/NPCTF

→ **Support from:** WHO CNT, WHO regional offices, other GPEI partners

OBJECTIVE 2B

Achieve certification of all facilities continuing to work with poliovirus materials after WPV eradication, as compliant with global standards

Annex A guidance

- GAP
- CCS
- GPLN

While progress was initially made toward implementing the CCS, and most (but not all) designated PEFs have applied for and received a CP, full implementation has been considerably delayed. Some countries have failed to apply for a CP, and none of the candidate PEFs which do hold a CP has yet submitted an application (as of this writing) for an interim certificate of containment (ICC), which allows the designated PEF to retain and work with PV for up to three years until the facility is fully compliant with GAP and can apply for a final certificate of containment (CC). Contributing to the delays, no GAP auditors have yet been trained and qualified to conduct audits of candidate PEFs.

Overall, preparedness of countries for CCS implementation has remained variable. The implementation of the CCS, which was first developed in 2017, has demonstrated noted challenges: some CCS requirements are not compatible with existing legal frameworks within countries; expected external capacity building has also not materialized; and the COVID-19 pandemic created disruptions. Facility certification has significantly been delayed, triggering two extensions of the CP certificate validity. Some mitigation options were offered by the GCC, and the revision of the CCS in 2022 will reflect the adjustments already implemented based on lessons learned.

Adding to this urgency, as part of its role in procuring polio vaccine for the GPEI, the United Nations Children's Fund (UNICEF) has recently begun to require that all manufacturers of WHO-prequalified polio vaccines should have entered into the CCS prior to negotiation of tender with UNICEF.

On the importance of containment in vaccine manufacturing sites

While GAP requirements are essential everywhere, regardless of facility type, polio vaccine production sites have a high importance for poliovirus containment both because of the known levels of risk associated with vaccine production, given the large amount of infectious material, and because vaccine production will have to continue into the post-certification era.

All vaccine production sites and the countries that host them must meet not only facility safeguards, but also immunity and environmental safeguards to protect against the risk of a possible breach reseeding poliovirus in vulnerable communities.

WAY FORWARD FOR OBJECTIVE 2B

CCS implementation to assess and eventually certify all designated PEFs as fully compliant with GAP should have the highest priority for global poliovirus containment.

- ✓ Countries with incomplete CP applications should expedite their completion in coordination with the GCC-CWG. Countries with already-awarded CPs should urgently move forward with ICC applications for the selected facilities they wish to certify.
- ✓ Recognizing that the workload of the GCC-CWG will be significantly increased, an in-depth assessment of support options will ensure adequate qualitative and quantitative expertise support in the ICC audit assessment phase.
- ✓ UNICEF and the WHO, including the vaccine prequalification departments, will work with polio vaccine manufacturers to ensure that both OPV and inactivated polio vaccine (IPV) is procured only from manufacturers who have demonstrated compliance with global standards by entering into the CCS. Containment criteria should also be considered by the WHO in prequalifying polio vaccines for procurement by UNICEF.

- ✓ Acceleration of CCS implementation should be coordinated and aligned with the GPEI *Polio Eradication Strategy 2022–2026* to ensure that as many of the remaining PEFs as possible will be certified as GAP-compliant by the time WPV eradication is certified.

→ **Agencies or groups responsible:** NACs and designated PEFs, WHO CNT, UNICEF

→ **Support from:** GCC-CWG, CAG

GOAL THREE

Strengthen and support national and international programmes to ensure sustainability and continuity of poliovirus containment in the post-certification era

Once global WPV eradication has been certified, the GPEI partnership will dissolve, and the polio eradication department at WHO headquarters and polio teams in WHO regional offices will also be discontinued. However, all polio eradication and containment stakeholders, particularly at country level, should be aware that the importance of poliovirus containment will increase after certification, particularly in countries hosting poliovirus-essential facilities (PEFs).

OBJECTIVE 3A

Strengthen continued national ownership of polio containment activities and ensure regular review and recertification of all PEFs

A critical component of post-certification containment will be to ensure that Member States with designated and certified PEFs take full ownership of conducting and resourcing the work of national authorities for containment (NACs) or successor authorities, independent of the GPEI, to monitor progress towards final certification of a PEF and to ensure that certified PEFs continue to maintain compliance with international regulations for as long as they handle, retain and store PV materials.

Annex A guidance

- GAP
- PCS

WAY FORWARD FOR OBJECTIVE 3A

- ✓ Countries that decided to retain polioviruses in designated PEFs will have to ensure long-term containment beyond the post-certification era. Member states designating PEFs will have to secure the required costs and dedicated expertise to ensure global GAP compliance.
- ✓ All countries hosting or considering to host PEFs should be made aware that, before and after WPV certification, they are solely responsible for all activities and resources needed to achieve and maintain final containment certification of the PEF. Their responsibility to closely monitor the PEFs compliance with international standards will not end as long as poliovirus materials are retained in the PEF.

→ **National entities responsible:** NACs, PEFs

→ **Support from:** Member State Ministries of Health (MoHs), WHO CNT, GCC-CWG

OBJECTIVE 3B

Maintain sufficient technical support capacity within the WHO and through external stakeholders for post-certification containment

To sustain a polio-free world, transition planning is already underway to ensure that core polio functions, such as surveillance, laboratory support and technical support for containment, will continue post-certification at both WHO headquarters and in regional offices. Discussions are ongoing to consider how polio containment functions will be sustained post-WPV eradication with WHO technical guidance, drawing upon lessons learned from smallpox eradication.

Annex A guidance

- GAP
- PCS

In addition to the central role of the WHO in providing technical support, independent containment oversight and advisory groups, such as the Global Commission for the Certification of the Eradication of Poliomyelitis (GCC), its Containment Working Group (GCC-CWG) and the Containment Advisory Group (CAG), supported by their corresponding WHO secretariat teams providing independent expertise, have been critically important to advancing poliovirus containment. However, their continued existence following the certification of WPV eradication and the dissolution of the GPEI is not yet clear.

Depending on the timeline for achieving the goals of the *Polio Eradication Strategy 2022–2026*, decisions about maintaining the polio certification infrastructure, including the GCC, Regional Certification Commissions (RCCs) and National Certification Committees (NCCs), will be critical for achieving and sustaining long-term poliovirus containment. Similarly, considerations about maintaining poliovirus containment as part of a broader biosafety or health security entity at the WHO will also be critical as a means to provide expert technical guidance on poliovirus containment standards beyond eradication and into the post-certification era. These decisions should be addressed with the *Post-Certification Strategy* (PCS), which will soon be revised.[9]

WAY FORWARD FOR OBJECTIVE 3B

- ✓ Preparations for transitioning key polio functions to other WHO departments following WPV certification must ensure that essential WHO technical support for poliovirus containment remains available to all Member States, and especially to those countries with designated PEFs, even as financial resources required to maintain PEFs are the responsibility of Member States.
- ✓ Similarly, planning for continued containment activities post-certification should, as much as possible, allow for maintaining the current structure of independent containment oversight and advisory groups, or a new one tailored for the post-certification era, to ensure their guidance and support for containment work of NACs, PEFs and other national stakeholders.

→ **Agencies or groups responsible:** WHO headquarters and regional offices

→ **Support from:** GCC, GCC-CWG, CAG, RCCs

[9] Polio Post-Certification Strategy: A risk mitigation strategy for a polio-free world. Geneva: World Health Organization; 2018 (http://polioeradication.org/wp-content/uploads/2018/04/polio-post-certification-strategy-20180424-2.pdf).

ENABLING ENVIRONMENT

Progress towards poliovirus containment will depend on effective support through several enabling functions delivered through the WHO and with support from other GPEI partners. These include monitoring and evaluation (M&E), communication and advocacy, gender equality efforts and resource mobilization.

MONITORING AND EVALUATION

Over more than three decades, the GPEI has built impressive systems for M&E to collect data, assess performance, inform decision-making, make course corrections where needed, and measure overall progress.

While not as extensive as the global surveillance system for acute flaccid paralysis (AFP), the global poliovirus containment programme does generate a considerable amount of data on the maintenance of facility surveys and inventories and on progress towards certifying facilities as meeting GAP requirements. Detailed country-level data related to facility surveys and inventories is largely collected at the regional level, where several WHO regions have established databases to support monitoring survey and inventory activities.

Containment performance indicators currently in use include:

- the completeness of initial inventories of facilities holding infectious or potentially infectious material (IM or PIM) by PV type and by country;
- the number of countries designating one or more poliovirus-essential facility (PEF);
- the total number of designated, planned PEFs; and
- the progress towards certification of PEFs against GAP requirements (i.e., the proportion of PEFs which have applied for and received a certificate of participation [CP] or interim certificate of containment [ICC]).

While much of this data is broadly available, its analysis and use through reporting is still incomplete and irregular. Furthermore, no systematic, centralized global-level M&E framework currently exists for poliovirus containment, which makes it difficult for GPEI partners, national programme managers and technical leads, and global containment advisory groups to make appropriate, timely decisions followed by corrective action.

Agreement on key performance indicators (KPIs) and an M&E framework to monitor containment, parallel to the timeline towards certification of WPV eradication, will make monitoring more effective as a tool to drive progress on poliovirus containment.

WAY FORWARD FOR MONITORING AND EVALUATION

To facilitate progress in containment from 2022 to 2024 and beyond, containment M&E activities should be strengthened as soon as possible.

- ✓ Coordinated by the Containment Management Group (CMG), GPEI partners and other containment stakeholders will review the existing containment monitoring mechanisms, including available data and current indicators, with the objective to create a standardized M&E framework that will make better use of available containment data for progress review and decision-making.
- ✓ The WHO should identify and agree on a set of KPIs which will be most useful for monitoring, as well as key milestones and deadlines for project deliverables
- ✓ Performance against containment milestones should be reviewed and published on a regular basis. Routine review will allow milestones to be adjusted, if and when necessary.

- ✓ Agreement on key data and indicators on survey and facility inventory activities should be part of the M&E framework. Efforts should be made to harmonize scope and quality of available national- and regional-level containment data across WHO regions.
- ✓ Suggested milestones included in this GPCAP 2022–2024 should be discussed by all containment stakeholders and adjusted as necessary (see **Introduction: Timeline**).

→ **Agencies or groups responsible:** GPEI, WHO, WHO CNT, CMG

→ **Support from:** GCC, GCC-CWG, RCCs

COMMUNICATION AND ADVOCACY

From the beginning of poliovirus containment efforts, communication and advocacy expertise was valued as essential to raise awareness of, promote and accelerate poliovirus containment. Communication expertise translates complex technical requirements, specialized processes and precise biorisk management standards into a language easily understood by different stakeholders. Such effective communication is critical to successful advocacy interactions between the WHO, GPEI partners, and national-level decision-makers, particularly in facilities.

The WHO Containment Team (CNT) formerly received communication support, and considerable progress was made on communication projects and activities as part of a detailed containment communication plan. Key communication tools and materials included a twice-yearly containment newsletter, various documents with frequently asked questions (FAQs), fact sheets for donor governments and other audiences, and videos explaining containment and its role in polio eradication. A closed online networking platform for national authorities for containment (NACs) was also established to facilitate peer information exchange.

To support advocacy, several international WHO gatherings were leveraged to remind Member States of the priority that should be given to containment. This included the Seventy-first World Health Assembly in 2018, when a resolution that contained detailed content on poliovirus containment passed unanimously. WHO advocacy efforts also included CNT country visits for technical support.

However, since 2019, re-prioritization within the GPEI resulted in redirecting this technical resource to other workstreams.

Key objectives to strengthen containment communication and advocacy during the period covered by this action plan are to:

- identify and leverage opportunities to highlight the importance of poliovirus containment within the WHO and among GPEI partners and other key stakeholders and provide progress updates on GAP implementation;
- clarify to NACs and all containment stakeholders in Member States that, while the WHO will provide training and some technical support, countries are fully responsible to carry out and identify technical and financial resources for all containment activities;
- provide timely, informative and actionable materials to Ministries of Health (MoHs) and NACs in Member States and to WHO regions to support GAP implementation and PEF certification; and
- share information with donors and the public about the critical importance of poliovirus containment, as part of the process to secure a polio-free world, and about progress towards reaching containment goals.

WAY FORWARD FOR COMMUNICATION AND ADVOCACY

Special communication and advocacy support remains essential for progress in poliovirus containment until the certification of WPV eradication and well into the post-certification era.

- ✓ Coordinated by the CMG and in collaboration with WHO staff at all levels, the scope of current communication and advocacy needs for the poliovirus containment programme will be defined, and a specific containment communication and advocacy strategy and corresponding workplan will be developed.
- ✓ To develop and guide implementation of the *Strategy for Global Poliovirus Containment*, the WHO and all GPEI partners will collaborate to identify and make available the appropriate technical communication expertise and support.
- ✓ In defining the communication requirements of the containment programme, the overlap of communication and M&E activities should be taken into account.

→ **Agencies or groups responsible:** WHO

→ **Support from:** GPEI

GENDER EQUALITY

Gender equality and equity are core values for the GPEI. By taking a systematic approach to gender mainstreaming, the programme addresses gender-related barriers to vaccination, improves immunization outcomes, and increases women's meaningful participation in decision-making, leadership, demand creation, and health service delivery. In line with the GPEI *Gender Equality Strategy 2019–2023*,[10] the *Polio Eradication Strategy 2022–2026* recognizes that gender-responsive approaches further strengthen polio eradication interventions.[11]

This GPCAP 2022–2024 also commits to promote gender equality in containment-related work, including in the promotion of gender parity in national, regional and global containment advisory bodies and coordination groups and in the promotion of a safe work environment free from harassment and abuse in relevant facilities, as defined by WHO and UNICEF policies on preventing and responding to sexual exploitation, abuse and harassment (PRSEAH).

WAY FORWARD FOR GENDER EQUALITY

- ✓ Ensure that a safe work environment is guaranteed in poliovirus-retaining facilities in line with WHO and UNICEF PRSEAH policies
- ✓ Assess a baseline for the gender distribution of the containment advisory bodies and coordination groups leading and chairing across the national, regional and global levels. Set a target to achieve gender parity among chairing positions by the end of 2024.

→ **Agencies or groups responsible:** NAC and PEF

→ **Support from:** GPEI

[10] Global Polio Eradication Initiative (GPEI). Gender Equality Strategy 2019–2023. Geneva: World Health Organization; 2019 (https://polioeradication.org/wp-content/uploads/2020/10/Gender-Strategy.pdf). See also Gender [website]. Geneva: World Health Organization; 2021 (https://polioeradication.org/gender-and-polio/gender-and-polio-eradication).
[11] Global Polio Eradication Initiative (GPEI). Polio Eradication Strategy 2022–2026: Delivering on a promise. Geneva: World Health Organization; 2021 (https://apps.who.int/iris/bitstream/handle/10665/345967/9789240031937-eng.pdf).

RESOURCE MOBILIZATION

Containment activities at all levels need to be adequately resourced to achieve set objectives. The CMG is tasked to work with GPEI partners to ensure that WHO containment technical support activities at the global and regional level (e.g., technical support, secretariat support to advisory groups) are sufficiently resourced.

However, aside from some technical support from the WHO, all Member States must provide their own resources for containment activities in their country. Indeed, Member States wishing to retain poliovirus materials in one or more PEFs must evaluate and secure considerable resources that will be required for as many years as such materials are retained in order to assess and certify the PEF as compliant with global standards (GAP) and to maintain the required oversight to ensure that PEFs remain compliant.

WAY FORWARD FOR RESOURCE MOBILIZATION

The following activities are suggested to ensure the availability of sufficient funding and resources to achieve and sustain poliovirus containment:

- ✓ During the period of the GPEI *Polio Eradication Strategy 2022–2026*, each GPEI agency will develop annual containment budgets which are approved in each organization prior to joint GPEI validation. If additional requirements are identified, the CMG will submit ad hoc budgetary requests to the Strategy Committee through the Executive Management Unit.
- ✓ In the post-certification era, the WHO will provide the financial and human resources for all WHO technical support to countries, for secretariat support for global containment advisory bodies, and for M&E and communication and advocacy efforts.
- ✓ Both before and after WPV certification, countries hosting PEFs are solely responsible for all resources needed to achieve and maintain PEF certification, as well as to support NACs, NPCCs and NPCTFs, and NCCs. Ownership of containment will be in perpetuity for as long as countries wish to retain polioviruses. To ensure capacity to meet this threshold, countries should perform a “deep dive” of their poliovirus containment infrastructure, national policies for immunization, and any legal frameworks that may impact their ability to meet GAP containment requirements. Furthermore, in the post-certification era, countries must possess national competence in poliovirus containment, as global requirements to mitigate containment-related risks will become ever more evolved and more restrictive in a polio-free world.

→ **Agencies or groups responsible:** NACs**,** WHO, U.S. Centers for Disease Control and Prevention (CDC), Bill & Melinda Gates Foundation

→ **Support from:** GPEI

ANNEXES

ANNEX A.

Containment strategy and policy guidance

Strategic poliovirus containment guidance

❖ ***Strategy for Global Poliovirus Containment***: The containment strategy provides a blueprint for all countries and partners to understand the goals around which polio eradication stakeholders must organize their efforts to contain poliovirus. It is intended broadly for the Global Polio Eradication Initiative (GPEI) partnership – and particularly for national political and health leaders and heads of facilities retaining poliovirus.	Containment Strategy online
❖ ***Monitoring & Evaluation (M&E) Framework:*** A containment M&E framework will be developed by the World Health Organization (WHO) and the GPEI to track progress toward key performance indicators (KPIs) and milestones for national, regional and global containment stakeholders.	In development
❖ ***GPEI agency containment workplans***: Annual containment workplans direct the efforts of the WHO, the U.S. Centers for Disease Control and Prevention (CDC), and the Bill & Melinda Gates Foundation toward the coordination, assistance, and global M&E efforts needed to support global certification and ensure containment in the post-certification era.	N/A Internal guidance
❖ ***Polio Post-Certification Strategy (PCS)***: The PCS defines activities and functions that will be needed to sustain a polio-free world once certification criteria for global wild poliovirus (WPV) eradication are met. Revisions are forthcoming to provide updated frameworks to support the transition of core polio functions to countries and other future owners after the closure of the GPEI.	PCS online with revisions underway

Technical poliovirus containment policy guidance

❖ **GAPIII and GAPIV**: Since 2015, the *WHO Global Action Plan (GAPIII) to minimize poliovirus facility-associated risk after type-specific eradication of wild polioviruses and sequential cessation of oral polio vaccine use, third edition*, has been the chief guidance document. GAPIV, launched in 2022, provides guidance, details strain-specific containment requirements, clarifies the basis of facility safeguards, and emphasizes approaches for risk control for a range of poliovirus-essential facilities (PEFs).	Link to GAP online with revisions underway
❖ **CCS**: The *Containment Certification Scheme to support the WHO Global Action Plan for Poliovirus Containment* (CCS) outlines steps that facilities must take to become a PEF, a process which is overseen by national authorities for containment (NACs) that are established within Ministries of Health (MoHs). A second edition is planned in 2022, and regular updates will be provided in alignment with global epidemiology evolution.	CCS online with revisions underway
❖ **PIM Guidance**: *Guidance to minimize risks for facilities collecting, handling or storing materials potentially infectious for polioviruses, second edition,* aims to facilitate the identification of potentially infectious materials (PIMs) for polioviruses within laboratories that handle human stool specimens, respiratory samples or environmental sewage. A third edition is planned in 2022, and regular updates will be provided in alignment with global epidemiology evolution.	PIM guidance online with revisions underway

❖ **Public Health Management of Facility-Related Exposure to Live Polioviruses:** *Guidance in managing exposed persons for countries hosting facilities that maintain live polioviruses* provides direction for response to a human exposure or infection related to a known spill or breach of containment involving any poliovirus (PV), whether a WPV, vaccine-derived poliovirus (VDPV) or Sabin or Sabin-like poliovirus (SL) from any PEF.	Guidance online
❖ **Standard Operating Procedures (SOPs): Responding to a poliovirus event or outbreak**: A potential containment breach, for example from a laboratory or vaccine manufacturer, constitute one type of poliovirus event that requires coordinated outbreak response. Furthermore, because the intentional or unintentional release of poliovirus from a facility is a factor in outbreak risk assessments, the Outbreak SOPs provide useful guidance for containment.	Updated SOPs online
❖ **Global Polio Laboratory Network (GPLN) Guidance Paper 1:** *For safe handling and storage of type 2 poliovirus (PV2) in GPLN laboratories* describes changes in the handling and storage of PV2 materials, with specific measures to minimize polio laboratory-associated risk and to avoid unintentional release of poliovirus in the environment.	Guidance online

ANNEX B.

National poliovirus containment stakeholders

Poliovirus-essential facility (PEF)

A poliovirus-essential facility (PEF) is a facility that achieves and maintains the ability to handle and store poliovirus-infectious or potentially infectious materials (IM or PIM) after the global certification of wild poliovirus (WPV) eradication. PEF status is achieved by successfully undergoing the process of certification in compliance with *Global Action Plan for Poliovirus Containment* (GAP) requirements. PEFs are responsible for the implementation of facility safeguards. Along with national authorities for containment (NACs), PEFs share documentation to support a country's certification with the World Health Organization (WHO) and the Global Commission for the Certification of the Eradication of Poliomyelitis (GCC) through its Containment Working Group (GCC-CWG).

To achieve and maintain containment certification of the facility, each PEF will:

- establish, implement and maintain a biorisk management system aligned with GAP requirements;
- provide relevant groups (NAC, auditors, GCC) with access to all information and facilities relevant to containment certification activities;
- achieve and maintain containment certification and operate within the terms of the certificate throughout the certification cycle; and
- report to the NAC and other relevant parties on any event, process change, or other issue that could jeopardize the status of a certificate under the Containment Certification Scheme (CCS).

National authority for containment (NAC)

For any Member State that chooses to host facilities retaining poliovirus materials, a competent NAC must be established. NACs are nominated, established and supported with the required resources by the Ministry of Health (MoH) or other designated national authorities.

As a main containment stakeholder, NACs provide oversight and coordinate with designated PEFs to ensure PEFs meet the necessary safeguards to retain live poliovirus materials, according to GAP and CCS. NACs should conduct their work on PEF certification in close coordination with the GCC-CWG.

National Poliovirus Containment Task Force (NPCTF) *and*
National Poliovirus Containment Coordinator (NPCC)

Sometimes referred to at the country or regional level as National Task Forces (NTFs) for Poliovirus Containment, National Poliovirus Containment Task Forces (NPCTFs) are responsible for all national-level containment activities in each WHO Member State. This includes: conducting surveys to identify all facilities with infectious or potentially infectious poliovirus materials; establishing national inventories of such facilities; ensuring all identified infectious or potentially infectious materials are either destroyed or moved to a PEF; supporting facility visits and audits by containment experts; and reporting on containment progress to National Certification Committees (NCCs). NPCCs and NPCTFs remain active in all WHO Member States, including in certified regions, and coordinate their work closely with the NCCs. NTFs/NPCTFs are led by national poliovirus containment coordinators (NPCCs).

National Committee for the Certification of the Eradication of Poliomyelitis (NCCs)

NCCs are groups of independent experts in disciplines relevant for the certification of polio eradication, such as public health, immunization, epidemiology, paediatrics, infectious diseases, neurology and virology. NCCs are appointed by the national government in consultation with the

WHO regional office. NCC members act in a personal capacity only and cannot have responsibility for any activities to implement polio eradication in the country.

NCCs are responsible for assessing and verifying national documentation on polio-free status, which is assembled by the MoH with WHO support. NCCs cannot certify polio eradication in their country, which is the role of the Regional Commission for the Certification of the Eradication of Poliomyelitis (RCC) and the GCC in review of NCC supporting documentation on the polio-free status of the country.

In WHO regions not yet certified as WPV-free and for Member States where no WPV has been detected from any source for at least three years under conditions of “certification-standard” surveillance, NCCs provide the RCC with initial detailed documentation on all aspects of polio eradication, including immunization activities, the quality of surveillance (including environmental surveillance of PEF wastewater), laboratory support, risk assessment and PV containment. Once the RCC formally accepts this documentation, signaling their agreement with the NCCs claim that WPV transmission in the country has been interrupted, the NCC will continue to provide annual reports to the RCC on the maintenance of polio-free status in the country.

Their main involvement in poliovirus containment is to collaborate with NPCCs and NPCTFs, along with RCCs, to ensure that inventories of facilities holding infectious or potentially infectious materials are complete and regularly updated. In countries designating one or more PEFs, NCCs and RCCs are not directly involved in working with NACs towards certification of the PEFs.

Lastly, each NCC in their role also conveys recommendations on how to improve polio activities from the RCC to their national government.

ANNEX C.

Regional and global poliovirus containment stakeholders

Regional Commissions for the Certification of the Eradication of Poliomyelitis (RCCs)

RCCs are independent panels of international public health experts advising the World Health Organization (WHO) on all issues related to the certification of wild poliovirus (WPV) eradication at the regional level.

In WHO regions not yet certified as WPV-free, RCCs monitor progress towards interrupting WPV transmission and will eventually certify the WHO region as free of wild WPV, provided that a period of at least three years have passed without identification of WPV.

In WHO regions already certified as WPV-free, RCCs annually review updated documentation from each Member State on the maintenance of WPV-free status, i.e., on immunization, surveillance, polio laboratory support and poliovirus containment. RCCs then report conclusions on risk assessment and any risk mitigation measures to the respective country and WHO regional director. Related to poliovirus (PV) containment, RCCs in certified regions work with National Certification Committees (NCCs) to review national reports and documentation, specifically updating and maintaining complete inventories of facilities which previously hosted WPV or any other infectious or potentially infectious poliovirus materials.

Neither RCCs nor NCCs are directly involved in overseeing the process of certifying poliovirus-essential facilities (PEFs), as the direct oversight for this activity lies with the Global Commission for the Certification of the Eradication of Poliomyelitis (GCC) and its Containment Working Group (GCC-CWG) through the respective national authority for containment (NAC) and supported by the global and regional WHO secretariats.

Global Commission for the Certification of the Eradication of Poliomyelitis (GCC)

The GCC is the independent global oversight body which will issue, if and when appropriate, a final report to the Director-General of the WHO (DG-WHO) to certify that the global eradication of WPV has been achieved. The GCC also oversees global poliovirus containment. It receives annual reports from RCCs on poliovirus survey and inventory activities in all six WHO regions, as reported by NCCs in their annual reports to the RCCs on the achievement or maintenance of WPV-free status.

The GCC also directly oversees the implementation of the Containment Certification Scheme (CCS), the process of certifying PEFs as complying with Global Action Plan (GAP) requirements in countries retaining PV materials. Supported by the GCC-CWG (see below), the GCC reviews applications for containment certificates from PEFs through the respective NACs and, if the application is successful, endorses the issuance of containment certificates delivered to the respective PEF by their NAC.

The GCC is expected to eventually certify that global containment of all retained live poliovirus materials—including WPV, Sabin and vaccine-derived poliovirus (VDPV) of all types—has been achieved and maintained. It is still yet to be decided whether the GCC will exist by the time containment of all poliovirus materials (WPV, Sabin and VDPV) will be achieved. As of this writing, the mandate to the GCC from the DG-WHO remains to certify WPV eradication.[12]

[12] Expanded Programme on Immunization and Global Programme for Vaccines and Immunization. Report of the 1st Meeting of the Global Commission for the Certification of the Eradication of Poliomyelitis (16-17 February 1995). Geneva: World Health Organization; 1995 (https://polioeradication.org/wp-content/uploads/2016/07/10Report.pdf).

GCC Containment Working Group (GCC-CWG)

The GCC-CWG, a small group of international experts led by a member of the GCC, supports the GCC in the verification and endorsement of the CCS-based certification process for PEFs meeting GAP requirements. On behalf of the GCC, the group reviews applications for containment certification for PEFs, as submitted by the respective NAC, to assess whether the application fulfills the requirements as laid out in GAP and the CCS. If approved by the GCC-CWG, the PEF will obtain a GCC-endorsed certificate through its NAC, as described in the CCS.

Since it was established in 2015, the GCC-CWG has overseen the first phase of the implementation of the CCS by assisting in establishing NACs, reviewing applications for certificates of participation (CPs), and facilitating the awarding of these certificates through the GCC to a large majority of designated PEFs.

Regardless of when WPV eradication will be certified, the functions performed by the GCC-CWG will need to continue beyond WPV certification. To ensure continuity of containment support and to plan for possible alternative mechanisms to monitor containment, it will be important to decide whether the currently existing certification groups, including the GCC and the GCC-CWG, will remain in existence beyond global WPV certification.

Containment Advisory Group (CAG)

The CAG is an independent global technical containment advisory body that reports directly to the DG-WHO. The CAG advises and provides recommendations to the WHO on key technical issues arising from the implementation of GAP and the CCS. It also provides guidance on the containment requirements associated with handling poliovirus-related materials for diagnosis and testing, research and production (including vaccine-like particle [VLP] production, pseudo viruses, etc.). The CAG provides further technical advice on national containment efforts. The CAG also plays an important role in finalizing and updating of global technical guidelines, such as GAP.

Recent important technical issues on which the CAG advised include questions of how novel oral polio vaccine (nOPV) virus strains, such as nOPV2 or the planned nOPV1 and nOPV3, should be considered for the purpose of containment regulations, and whether these nOPV viruses are indeed suitable for handling outside GAP containment requirements for the purposes of production, quality control testing and clinical trials.

The CAG is also involved in assessing the containment relevance of new approaches to polio vaccines. For the post-eradication era, when polio immunization will still be needed, vaccines that use live virus for production will pose a containment risk of potential release to the environment. Polio vaccines that do not use live virus for manufacturing, such as VLPs, could meet that challenge. These poliovirus empty particles lack the viral genome but have the appropriate antigenic characteristics to be useful as vaccines and are essentially equivalent to current inactivated polio vaccines (IPVs).

Containment Management Group (CMG)

Composed of containment representatives from all GPEI partners, the CMG manages and coordinates the poliovirus containment activities of partner agencies and stakeholders. In so doing, the CMG ensures that containment activities, policy and guidance are well aligned.

The CMG also facilitates the identification and resolution of key policy issues affecting containment. Included in its terms of reference (ToRs), the CMG ensures that resource needs for poliovirus containment are met by GPEI partners or through advocacy efforts in support of containment, at the global, regional and country level.

Furthermore, the CMG assists with the monitoring and evaluation (M&E) of progress toward containment per established GPEI and/or GAP timelines to ensure accountability of all containment stakeholders. The group routinely reports to GPEI leadership on progress in containment and on any impending risks to achieving milestones.

World Health Organization (WHO) *and*
WHO Containment Team (CNT)

The WHO is the GPEI partner that provides main technical support for poliovirus containment at all levels of the organization, as well as secretariat support to all containment advisory committees. The central coordinating group on the WHO side is the Containment Team (CNT). The CNT provided global leadership for the development of GAP, the chief guidance document for poliovirus containment which was endorsed by the Sixty-eighth World Health Assembly through resolution WHA68.3 in May 2015.[13]

WHO CNT has worked in coordination with WHO teams in all regions to assist Member States in designating one or more PEFs to meet containment certification requirements. The CNT also provides secretariat support for all independent polio containment advisory groups at the global level, including the GCC, GCC-CWG, and CAG.

The WHO's work on the regulation and standardization of biologicals, including vaccines, has an impact on poliovirus containment. Advised by the Expert Committee on Biological Standardization (ECBS, below), the WHO establishes recommendations and guidelines related to the manufacturing and control of diagnostic tests and of vaccines, including all types of polio vaccines. These regulations form the basis for 'prequalification' of vaccines, which is a service provided by the WHO to UNICEF and other UN agencies that procure vaccines.

United Nations Children's Fund (UNICEF)

UNICEF is the GPEI partner with responsibility for the worldwide procurement of all types of polio vaccines. Among other areas of work, UNICEF procures childhood vaccines and immunization supplies for around 100 countries annually, supplying over 2 billion doses of all types of vaccines and reaching an estimated 45% of the world's children in support of essential immunization programmes, vaccination campaigns, and outbreak and emergency response activities. With national immunization partners, UNICEF country teams are responsible for the management of type-2 containing vaccines (including monovalent oral polio vaccine type 2 [mOPV2], trivalent oral polio vaccine [tOPV], and novel oral polio vaccine type 2 [nOPV2]) used for circulating vaccine-derived poliovirus type 2 (cVDPV2) outbreak response, ensuring that all vaccine vials are accounted for, and that used and unused vials are collected and returned from the field to be inactivated or destroyed.

Expert Committee on Biological Standardization (ECBS)

The ECBS advises the WHO on setting standards for vaccine production and control to meet the quality standards and requirements for procurement by UN agencies. Specifically, the ECBS Technical Report Series 1016 (Annex 4) addresses the production and control of inactivated polio vaccines (IPV); this document has been revised recently to be closely aligned with the need for vaccine production sites to adhere to GAP.[14] Compliance of vaccine producers with ECBS guidelines and GAP requirements facilitate prequalification by WHO.

[13] Resolution WHA68.3. Poliomyelitis. In: Sixty-eighth World Health Assembly, Geneva, 26 May 2015. Geneva: World Health Organization; 2015. (https://apps.who.int/gb/ebwha/pdf_files/WHA68/A68_R3-en.pdf).
[14] World Health Organization (WHO). Guidelines for the safe production and quality control of poliomyelitis vaccines, Annex 4, TRS No 1016. Geneva: World Health Organization; 2019 (www.who.int/publications/m/item/poliomyelitis-vaccines-annex-4-trs-no-1016).

Strategic Advisory Group of Experts on immunization (SAGE)

SAGE is the principal advisory group for vaccines and immunization. Meeting twice annually, SAGE is charged with advising the WHO on overall global vaccination policies and strategies, ranging from vaccines and technology, research and development, to delivery of vaccination and its linkages with other health interventions. The remit of SAGE includes providing overall technical advice and recommendations on global polio eradication to WHO.

SAGE Working Group on Polio (SAGE WG)

Meeting twice annually ahead of SAGE meetings, the SAGE Working Group on Polio (SAGE WG) reviews in detail all available scientific evidence related to the implementation of polio eradication strategies, in order to assist with and prepare for SAGE conclusions and recommendations to advise on progress of the GPEI.

Main areas of work for the SAGE WG include to elaborate proposed SAGE guidance for the WHO and the GPEI on the development and finalization of the overall polio eradication strategy towards accelerating progress to interrupt WPV transmission and reducing the long-term risks associated with OPV use.

The Global Polio Laboratory Network (GPLN)

The Global Polio Laboratory Network (GPLN) was established in 1990 by WHO and national governments. Its primary responsibility is to assist national surveillance programs in detecting polioviruses wherever they should still be circulating.

The GPLN consists of 146 WHO accredited polio laboratories in 92 countries across all six WHO regions. The laboratories follow standardized protocols to isolate poliovirus, identify WPV or screen for Sabin (vaccine) poliovirus and VDPV, and conduct genomic sequencing. Sequencing results help to monitor how poliovirus is spreading by comparing the nucleotide sequences of poliovirus isolates. In addition to surveillance, the GPLN carries out a research agenda aimed at improving laboratory diagnostics, which is carried out at higher-level specialized GPLN labs.

The diagnostic services of the GPLN will be needed up to and beyond the certification of WPV eradication. Since the work of these labs involves handling and storing live polioviruses, it is expected some GPLN labs will need to be certified as PEFs. However, it is hoped that safer, genetically stable PV strains, such as the attenuated S19 strain, will become available in the near future. Polio labs working with these strains may be able to meet full GAP biosafety containment requirements for the near future. This may offer the opportunity to considerably reduce the number of designated PEFs, since many of the high-level diagnostic labs in the GPLN may no longer need to achieve PEF status at this time.