

Containment of Polioviruses

What is containment?

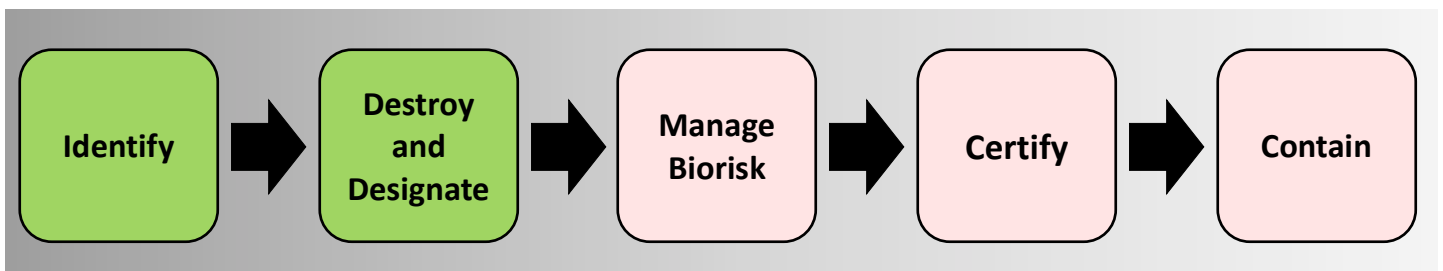
Poliovirus (PV) containment is a system for confining PV within a defined space.

Why must PV be contained?

Once polio is eradicated, laboratories and polio vaccine production sites handling or storing must minimize the risk of PV reintroduction into the community.

What must countries do to contain PV before the switch?

Poliovirus containment requirements are detailed in the WHO Global Action Plan III (GAPIII).



Identify

All countries survey all biomedical facilities to identify infectious or potentially infectious WPV2 materials and develop a national inventory of facilities that handle and/or store WPV2 materials.

Destroy and Designate

Countries request facilities to destroy all unneeded WPV2 material, and designate poliovirus-essential facilities (PEFs) that will store needed WPV2 materials following the requirements described in GAPIII.

Countries submit a report on the inventory, destruction and designation of PEFs to WHO through their Regional Certification Commission (RCC).

It is expected that most countries and facilities worldwide will destroy PV materials, and only a limited number of facilities in a limited number of countries will be designated as PEF.

Manage biorisk

Countries request facilities that store PV2 to implement Annex 2/3 of GAPIII. Countries request facilities that are likely to investigate new PV2 isolates to implement a non-retention policy for PV2, and Annex 6 of GAPIII.

Certify

National authorities for containment (NACs) apply the WHO GAPIII Containment Certification Scheme (CCS) to certify PEFs against GAPIII. Countries seek approval of certification from the global oversight body for containment (Global Certification Commission, GCC).

Contain

Certified PEFs handling and storing PV must implement and be regularly (e.g. annually) reassessed against GAPIII.

How will the GAPIII be implemented?

The global strategy for minimizing poliovirus (PV) facility-associated risk is implemented in 3 phases:

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|------------------|---|
| Phase I | Reduce the number of facilities containing PV2 before (WPV2) or shortly after (OPV2/Sabin2) OPV2 withdrawal |
| Phase II | Ensure appropriate containment of PV2 in PEFs until certification of eradication of all WPV |
| Phase III | Ensure appropriate containment of all types of PV after certification of eradication of all WPV |

What is the progress towards Phase I completion?

AMRO, EURO, SEARO, WPRO

- All countries completed WPV inventories in the past
→ WPV2 inventory updates and PV-essential facility designations due by end-Sept (SEARO, WPRO), end-Nov (EURO) and end-Jan (AMRO)
- Considering PV-essential facility designations for laboratories, IPV or s-IPV producers: **42** estimated

AFRO & EMRO

- 15/47 (AFRO) and 18/21 (EMRO) countries completed inventories in the past
→ WPV2 inventories and PV-essential facility designations due by end-November
- Considering PV-essential facilities designations for s-IPV producers: **1** estimated

How does WHO support the timely completion of Phase I?

- **Global Work Plan:** a global work plan has been developed to accelerate the implementation of Phase I that includes specific activities, priorities, timelines for progress monitoring, and the identification of additional resources. Under this plan, human resources have already been increased in HQ, EURO, EMRO, and AFRO in support of containment implementation activities.
- **Communications:** a communications' strategy and work plan is being prepared to roll out a major communication drive immediately after SAGE to inform and engage all stakeholders.
- **Advocacy:** an advocacy work plan is being prepared that includes high-level engagement with countries at risk of not meeting the expected deadlines.

What has slowed down preparations for implementation of containment in Phase II?

- At national level:
 - In many concerned countries, national authorities for containment (NACs) with responsibility to certify containment against GAPIII still need to be designated
 - Most concerned countries still need to develop appropriate national containment regulations that are aligned with GAPIII
 - Technical expertise to support activities needs to be developed
- At laboratory or manufacturing facility level:
 - The implementation of GAPIII is not a regulatory requirement
 - Technical expertise, financial resources and time still need to be identified to support the appropriate implementation of GAPIII requirements

How does WHO support the implementation of containment in Phase II?

- **Advocacy:** An advocacy plan that targets the countries planning to host PV-essential facilities is being developed. The advocacy will target all relevant sectors of government (beyond health) to ensure buy-in and implementation;
- **Risk Management:** The Containment Certification Scheme (CSS) for the certification of PEFs was endorsed by the Global Commission for the Certification of Poliomyelitis Eradication (GCC) in September 2015. In order to effectively manage risks until full implementation of containment is completed, interim certification of containment is proposed.
- **Consultation and Training:** Consultations with IPV manufacturers and the NACs of their hosting countries are planned to address next steps. GAPIII implementation training for candidate PEFs and NACs will continue.
- **Verification of certified PV-Essential Facilities:** A Global Containment Advisory Group (GCAG) will be established to advise GCC on approving national certification against GAPIII provisions, as well as to ensure effective procedures are established and maintained for certification processes to function appropriately across sectors and geographies.