KEY POINTS ABOUT POLIOVIRUS CONTAINMENT

April 2025

Two out of three wild poliovirus types have been globally eradicated

- Wild poliovirus type 2 (WPV2) was certified eradicated by the Global Commission for the Certification of Eradication of Poliomyelitis (GCC) in September 2015, and in October 2019, the Commission certified the eradication of wild poliovirus type 3 (WPV3). Eradication of WPV2 and WPV3 means that these viruses are no longer found in communities or in the environment.
- Wild poliovirus type 1 (WPV1) is the only naturally occurring strain of poliovirus still circulating, in Afghanistan and Pakistan.
- Outbreaks of vaccine-derived poliovirus (VDPV) types 1, 2 and 3 continue to occur in some countries, and oral polio vaccines (OPVs) containing weakened, live poliovirus strains, because of their unique ability to stop person-to-person transmission of virus, continue to be needed for use in routine immunization or outbreak response.

All type 2 and types 1 and 3 wild and vaccine-derived poliovirus materials must be destroyed or appropriately contained

- The only way to eliminate the risk of accidental or malicious release of polioviruses from
 facilities, into communities, is to not retain any. WHO therefore urges countries to destroy <u>all
 poliovirus infectious or potentially infectious materials</u> unless they are needed for the
 continuation of critical functions such as vaccine production, research, or outbreak response
 activities.
- To minimize the risk of release of polioviruses from vaccine production or laboratory facilities, the retention and handling of all WPV, VDPV, OPV2¹ or Sabin2 infectious materials must be associated with the certified implementation of biorisk management or containment requirements.
- The destruction or containment of types 1 and 3 OPV/Sabin materials will come into effect once the use of oral polio vaccine consisting of these strains is stopped globally.

Safe and secure containment minimizes the risk of release of poliovirus into communities

- Containment is a key objective of the Polio Eradication Strategy 2022-2026 and will be critical for maintaining a polio-free world for the long-term.
- Certified containment is a prerequisite for the declaration of poliovirus eradication².

¹ Novel oral polio vaccine type 2 (nOPV2) currently benefits from a waiver from GAPIV containment requirements

² See: Report from the Seventeenth Meeting of the Global Commission for the Certification of Eradication of Poliomyelitis, February 2018

Any release of poliovirus from facilities retaining it could have major consequences

- If poliovirus strains are released into communities, person-to-person transmission could resume and potentially cause paralysis and death in populations. This is particularly a risk in areas where polio vaccination coverage is low and in areas with poor sanitation. However, even in countries with high levels of coverage and high sanitation levels, some people may not be vaccinated or fully protected against the virus, putting them at risk of infection if they are exposed.
- The consequences associated with the release of polioviruses into communities are expected to be amplified once the world stops routinely using OPV in the post-eradication era.
- A release of the only other eradicated human pathogen, variola virus causing smallpox, from
 a laboratory in the United Kingdom in 1978 resulted in a person dying from the disease. This
 triggered countries to reduce the number of facilities retaining variola virus to two official
 repositories that are regularly assessed to meet highest standards of biosafety and
 biosecurity. Learning from and building on the smallpox experience, the polio eradication
 programme is working with countries to minimize the number of sites retaining polioviruses,
 and to ensure that containment is appropriately implemented in these facilities.

WHO sets the requirements for facilities retaining polioviruses

- The WHO Global Action Plan for Poliovirus Containment (GAPIV), available in draft on the GPEI website, is the reference document for poliovirus containment. All countries holding poliovirus stocks are urged to follow the requirements in GAPIV to ensure risk associated with handling or storage of poliovirus materials is minimized.
- Countries hosting 'poliovirus-essential facilities' (PEFs) facilities designated by their host
 governments as serving functions deemed to warrant continued handling or storage of
 poliovirus understand the responsibilities inherent in complying with the crucial facility,
 immunization coverage and environmental safeguards described in GAPIV, and the need to
 provide evidence that all requirements are met.
- Both PEFs and their host countries are responsible for appropriate containment of
 polioviruses. PEFs must meet the requirements for safe and secure handling and storage of
 poliovirus, and host countries, in addition to ensuring the containment certification of PEFs,
 must ensure additional safeguards such as high population immunity levels and
 environmental safeguards around PEFs.
- Facilities that do not wish to destroy their poliovirus stocks nor implement containment measures may opt to safely transfer their needed materials to a PEF.

Facilities must be certified to handle or store polioviruses

- Only facilities holding containment certifications approved by their respective National Authority for Containment (NAC) and endorsed by the Global Commission for the Certification of Eradication of Poliomyelitis (GCC), are permitted to handle or store eradicated polioviruses.
- The Containment Certification Scheme (CCS) helps countries put in place the appropriate mechanisms to enable national certification against the requirements in GAPIV with global oversight.

- The CCS offers three stages of containment certification: (1) certificate of participation (CP) is awarded to facilities in countries that have demonstrated compliance with the required population immunity and environmental safeguards described in GAPIV and are recognized by their NACs and the GCC as being suitable to engage in the CCS process; (2) an interim containment certification (ICC), which allows facilities broadly compliant with GAPIV to continue conducting activities such as vaccine production and research, provided they have effective alternative control measures in place; and (3) certificate of containment (CC) is awarded when the facility is fully compliant with GAPIV.
- The implementation of GAPIV requirements at PEFs must be certified by competent NACs by end-2026³. Compliance will continue to be regularly reassessed, and certificates can be suspended or revoked if facilities fail to comply with requirements or experience containment breaches resulting in human exposure or infection.

Many samples held by facilities may potentially be infected with poliovirus

- Samples (e.g. stool, respiratory secretion or concentrated sewage samples) collected at times and in geographic areas where wild or vaccine-derived poliovirus was in circulation, or oral polio vaccine was in use, may harbour viruses requiring particular attention.
- 'Non-poliovirus facilities' may inadvertently be handling or storing samples infected with polioviruses. Examples include facilities working with stool, respiratory or concentrated sewage samples to carry out rotavirus, hepatitis, influenza, measles, diarrhoeal disease or nutrition research.
- Tailored guidance (PIM Guidance) has been developed by WHO to help these 'non-polio facilities' identify samples potentially infected with polioviruses, and to implement appropriate measures for their safe and secure retention.

Universal intent to accelerate poliovirus containment action

- At the 71st World Health Assembly in May 2018, through a WHA resolution, WHO Member States committed to accelerating containment progress globally.
- Progress has been made since 2018, however, it has not been universal nor fast enough. Countries and PEFs are strongly urged to enhance efforts to ensure containment of polioviruses in line with the GCC-recommended timelines³.

More information

Global Polio Eradication Initiative (GPEI) - poliovirus containment

³ See: Report from the Twenty-Fourth Meeting of the Global Commission for the Certification of Eradication of Poliomyelitis, November 2023

FREQUENTLY ASKED QUESTIONS ON POLIOVIRUS CONTAINMENT

This document is intended as a resource for National Authorities for Containment. It will be updated periodically.

April 2025

When is wild poliovirus type 3 (WPV3) required to be under containment?

All facilities retaining wild, or vaccine-derived (VDPV) polioviruses (all types) are expected to implement the containment requirements in accordance with the WHO Global Action Plan for poliovirus containment (GAPIV) and achieve the required containment certification by end-2026, except for facilities holding WPV1/VDPV1 in Afghanistan and Pakistan¹.

Why is it important that wild poliovirus type 1 (WPV1) containment start now, when the virus is not yet eradicated like wild types 2 and 3? Isn't this putting the horse before the cart?

WPV1 still circulates in Pakistan and Afghanistan but has been eliminated in all other WHO regions.

To prepare for WPV1 eradication, the GCC recommended in November 2023¹ that all facilities move to ensure that all WPV, VDPV, and all type 2 poliovirus materials (with the exception of novel oral polio vaccine type 2 (nOPV2)², are safely and securely contained by end-2026 – the time originally planned for the certification of WPV eradication – i.e., fully compliant with the requirements described in GAPIV. This requires facilities retaining the viruses and their hosting countries putting in place the safeguards as per GAPIV and achieving full certification through the Containment Certification Scheme (CCS) by end-2026.

As appropriate facility containment requires significant resources and time, the GCC recommends urgency in this work.

Retaining a highly infectious and dangerous pathogen, that has been or is slated for eradication is a serious responsibility, especially when most countries have already interrupted transmission. Rather than wait until declaration of eradication which occurs years after the detection of the last positive virus isolate, the GCC is urging that countries move now to put measures in place to allow for strong containment by end-2026.

¹ See: Report from the Twenty-Fourth Meeting of the Global Commission for the Certification of Eradication of Poliomyelitis, November 2023

² Novel oral polio vaccine type 2 (nOPV2) currently benefits from a waiver from GAPIV containment requirements

What happens if WPV1 transmission is not stopped by the end of 2026? Will the GCC's recommendation for containment of WPV1 still hold?

Regardless of whether WPV1 eradication is achieved by end-2026, the GCC's recommendation regarding containment criteria for WPV eradication, i.e., containment certification for facilities holding the virus (outside Afghanistan and Pakistan) by end-2026, will remain in place. This is to ensure risks of facility-associated release of poliovirus are minimized by the time eradication is declared. Most of the facilities retaining poliovirus are located in geographic areas where no poliovirus circulation is observed.

Does this mean that all facilities are required to have full certificates of containment by the end of 2026?

The GCC has specified that by end-2026, all facilities retaining WPVs and VDPVs, and all type 2 poliovirus infectious materials with the exception of nOPV2, should have a Certificate of Containment (CC), or a time-limited Interim Certificate of Containment (ICC), with a clear end-point for obtaining a CC agreed with the GCC.

What about functions such as polio diagnostics and polio vaccine research and production? Is there some leeway for facilities carrying out these?

While polio diagnostics, development of new polio vaccines and other products as well as clinical research related to safety and immunogenicity of polio vaccines, antivirals and monoclonal antibodies are essential to accelerate and sustain poliovirus eradication, it is important that all facilities opting to retain infectious polioviruses (all types) ensure proper containment following GAPIV so that risks of release of these viruses are minimized.

Why do some laboratories of the Global Polio Laboratory Network (GPLN) not need to become PEFs?

The GPLN performs poliovirus surveillance work essential to polio eradication and is expected to continue this function following WPV eradication and OPV withdrawal. A number of GPLN diagnostic laboratories retain poliovirus for the short term only (less than three months), and samples are destroyed following the availability of genetic sequencing results. GPLN laboratories requiring long-term retention of polioviruses (mainly Regional Reference and Global Specialized Laboratories) must achieve containment certification, as PEFs. Laboratories are required to implement GPLN practices and policies for the safe handling and storage of polioviruses and follow the PIM Guidance³.

What are the containment requirements for novel oral polio vaccines, and for S19 strains?

Through temporary waivers issued by the Containment Advisory Group (CAG), novel oral polio vaccines and hyper-attenuated Sabin strains known as S19 strains, which are designed to be more genetically stable than Sabin strains, are currently exempt from containment requirements for

³ See: https://polioeradication.org/what-we-do-2/containment/containment-guidance-and-tools/

specific usages. These waivers are revisited periodically and are based on CAG's assessment of available data on the strains⁴.

How could availability of virus-like particles (VLPs) impact containment?

Non-infectious virus-like particles (VLPs) based on viruses such as poliovirus are being explored for several medical and scientific applications. VLPs mimic real viruses but lack genetic material, meaning they cannot replicate. This makes them a safe alternative to working with live viruses. Poliovirus VLPs are still in development and are not expected to be available for use until 2029. It is anticipated that their availability will decrease the need for many PEFs to retain and ensure certified containment of live polioviruses.

⁴ See: Report from the Sixth Meeting of the Polio Containment Advisory Group, January 2023