Guidance to minimize risks for facilities collecting, handling or storing materials potentially infectious for polioviruses

Second edition
Poliovirus containment: guidance to minimize risk for facilities collecting, handling or storing materials potentially infectious for polioviruses, second edition

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The Poliovirus containment: guidance to minimize risks for facilities collecting, handling or storing materials potentially infectious for polioviruses was first published in 2018.

This second edition was developed for application after the declaration of wild poliovirus type 3 eradication (October 2019). It was endorsed by the Containment Advisory Group (CAG) in November 2020.

This guidance intends to facilitate the identification of materials potentially infectious for polioviruses within laboratories that handle human stool specimens, respiratory samples or environmental sewage. Depending on the place and time of collection, these materials may contain infectious polioviruses that are eradicated (types 2 and 3) or nearly eradicated (type 1) in the wild. Identifying, eliminating the risk through destruction, or mitigating the risk of handling such materials is essential, not only to maintain the safety of laboratory workers and their communities, but also for the success of the global polio eradication effort.
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ABBREVIATIONS AND ACRONYMS

CCID  Cell culture infectious dose
CCID_{50}  Cell culture infectious dose, 50% endpoint
CCS  GAPIII Containment Certification Scheme
cDNA  Complementary DNA
ELISA  Enzyme-linked immunosorbent assay
GAPIII  Global Action Plan III for Poliovirus Containment
GCC  Global Commission for the Certification of the Eradication of Poliomyelitis
GPEI  Global Polio Eradication Initiative
IPV  Inactivated polio vaccine
NAC  National authority for containment
NCC  National Certification Committee for Poliomyelitis Eradication
nOPV  Novel oral polio vaccine
nOPV2  Novel oral polio vaccine type 2
OPV  Oral polio vaccine
bOPV  Bivalent oral polio vaccine (containing attenuated Sabin poliovirus type 1 and type 3)
mOPV  Monovalent oral polio vaccine (containing one type of attenuated Sabin poliovirus)
mOPV1  Monovalent oral polio vaccine type 1
mOPV2  Monovalent oral polio vaccine type 2
mOPV3  Monovalent oral polio vaccine type 3
OPV1  Oral polio vaccine type 1
OPV2  Oral polio vaccine type 2
OPV3  Oral polio vaccine type 3
tOPV  Trivalent oral polio vaccine (containing attenuated Sabin poliovirus type 1, type 2 and type 3)
PCR  Polymerase chain reaction
S19  A new attenuated poliovirus type 2 strain
VDPV  Vaccine-derived poliovirus
aVDPV  Ambiguous vaccine-derived poliovirus
cVDPV  Circulating vaccine-derived poliovirus
cVDPV1  Circulating vaccine-derived poliovirus type 1
cVDPV2  Circulating vaccine-derived poliovirus type 2
cVDPV3  Circulating vaccine-derived poliovirus type 3
iVDPV  Immunodeficiency-associated vaccine-derived poliovirus
VDPV1  Vaccine-derived poliovirus type 1
VDPV2  Vaccine-derived poliovirus type 2
VDPV3  Vaccine-derived poliovirus type 3
WHO  World Health Organization
WPV  Wild poliovirus
WPV1  Wild poliovirus type 1
WPV2  Wild poliovirus type 2
WPV3  Wild Poliovirus type 3
1. INTRODUCTION

The Global Polio Eradication Initiative, launched in 1988, has been the largest international public health effort ever undertaken (1). Billions of children have been immunized and millions of paralytic poliomyelitis cases have been prevented through donations from individuals and organizations, the dedicated efforts of governments at all levels, and countless volunteer hours (1).

The Global Commission for the Certification of the Eradication of Poliomyelitis (GCC) certified the eradication of wild poliovirus type 2 (WPV2) in 2015 (2) and the eradication of wild poliovirus type 3 (WPV3) in 2019 (3). The eradication of wild poliovirus type 1 (WPV1) and the elimination of circulating vaccine-derived polioviruses (cVDPVs) is anticipated in the near future (4), along with the gradual disappearance of immunodeficiency-associated vaccine-derived poliovirus (iVDPV). At that point, the only remaining poliovirus reservoirs will be the facilities retaining poliovirus infectious or potentially infectious materials (PIM) (5-8). Countries responsible for these facilities must assure the world that these reservoirs do not present a post-eradication risk of re-emerging paralytic disease due to PV that could undermine this extraordinary humanitarian achievement.

In May 2015, the World Health Assembly voted to provide risk reduction guidance for poliovirus facilities by endorsing the 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 (GAPIII; 5, 9). As these facilities work with PV, they have the advantage of being aware of the nature of the agents, the operational risks, and the effective containment measures to reduce those risks.

Facilities that collect, handle or store clinical or environmental samples for purposes other than polio-related work also present a PV transmission risk if the samples were collected where wild poliovirus (WPV) or vaccine-derived poliovirus (VDPV) was circulating, or oral polio vaccine (OPV) or novel oral polio vaccine (nOPV) was being used. These non-poliovirus facilities are at a disadvantage in that personnel may not suspect the potential presence of an infectious PV in such samples and may not be aware of the operational risks and the required containment measures to reduce those risks.

Facilities that may possess poliovirus potentially infectious materials include those working in diarrhoeal and respiratory disease research, nutritional research and other human research areas that involve using faecal and respiratory samples, and environmental research areas using concentrated raw sewage (6, 10-16). Facilities at particular risk include (but are not limited to) those working with enterovirus, rotavirus, norovirus, hepatitis A and E, other viral enteric agents, and enteric bacterial agents including E. coli, Shigella, as well as respiratory agents such as influenza, measles and other respiratory samples.
2. Purpose

The purpose of this guidance is to assist facilities in assessing the risk of release associated with retention and the handling and storage of poliovirus potentially infectious materials in their possession and to implement appropriate risk reduction consistent with GAPIII. Facilities that store or work with material known to contain PV must adhere to GAPIII.

Risk is defined in this guidance as the potential for release of poliovirus from the facility into a polio-free community.

At the time of this 2021 update, this guidance is in effect for all poliovirus type 2 potentially infectious materials¹ and for WPV3/vaccine-derived poliovirus type 3 (VDPV3) potentially infectious materials. Countries and facilities are also encouraged to identify and report poliovirus type 1 (PV1) and bivalent oral polio vaccine (bOPV) potentially infectious materials in anticipation of achieving WPV1 eradication and subsequent OPV cessation, at which time this guidance will apply to all poliovirus potentially infectious materials.

¹Including poliovirus type 2 potentially infectious material associated with the planned renewed use of trivalent oral polio vaccine (tOPV) or the introduction of a novel oral polio vaccine type 2 (nOPV2) in specific countries.
Transmission of the three serotypes of PV is maintained by the person-to-person infection of humans, with no evidence of an extra-human animal reservoir (17). Most PV infections are asymptomatic, with paralytic poliomyelitis occurring in less than 1% of WPV infections (17). A reported community outbreak of 10 paralytic poliomyelitis cases may be the result of 1000-10 000 asymptomatic infections (6). Any faecal, respiratory secretion or concentrated sewage samples collected in the community during that time and stored by a facility for whatever purpose are considered poliovirus potentially infectious materials, which include:

- faecal or respiratory secretion samples and their derivatives (e.g. stool suspensions, extracted nucleic acids, etc.) collected for any purpose in a geographic area where WPV/cVDVPV is present or OPV/nOPV is being used at the time of collection;
- products of such materials (above) from PV-permissive cells or experimentally infected polio-susceptible animals (18-20);
- uncharacterized enterovirus-like cell culture isolates derived from human specimens from countries known or suspected to have circulating WPV/VDPV or use of OPV/nOPV at the time of collection;
- respiratory and enteric virus stocks derived from poliovirus potentially infectious materials and handled under conditions conducive to maintaining the viability or enabling the replication of incidental PV; and
- environmental samples (i.e. concentrated sewage, waste water) collected from areas known or suspected to have circulating WPV/VDPV or use of OPV/nOPV at the time of collection.

Because no diagnostic test is 100% sensitive, and available tests may differ widely in their sensitivity and degree of validation, it is impossible to exclude the presence of PV in a given sample.

The non-poliovirus facility with poliovirus potentially infectious materials collections is similar to the poliovirus facility in that:

1. Both are possible sources of facility-associated transmission.
2. Both require facility-specific risk assessments, based on the type of potentially infectious material, the procedures used and facility safeguards.
3. Both must implement measures to reduce risks.

The non-poliovirus facility is different from the poliovirus facility in that:

1. Poliovirus is not its field of work.
2. Poliovirus may be encountered only as an incidental, undesirable agent.
3. Poliovirus may be present in clinical samples at varying rates and moderate titres.
4. Poliovirus titres are usually not enriched by agent-specific procedures.
5. Historic potentially infectious material collections are retained for special studies on agents other than polioviruses.

The inclusion of all facilities with poliovirus potentially infectious materials in global poliovirus containment efforts is crucial. Any possible advantage of a facility’s lower facility-transmission risk could be wholly offset by the facility worker who is uninformed, unaware or unconcerned about poliovirus potentially infectious materials risks, or untrained in procedures to reduce those risks (6, 21).

Whether originating from a poliovirus or non-poliovirus facility, the global health and economic consequences of facility-associated poliovirus transmission are the same.
4. **Strategy**

The global strategy for minimizing risks from the non-poliovirus facility is aligned to the one outlined for the poliovirus facility in GAPIII: 1) risk elimination by poliovirus potentially infectious materials destruction, inactivation or transfer to a poliovirus-essential facility (PEF) in the same or a different country/region; and 2) biorisk management by those facilities that retain poliovirus potentially infectious materials and meet the required safe-handling and containment requirements.

**Risk elimination:** The goal is no poliovirus potentially infectious materials. Facilities should carefully consider the required resources and set a high bar when deciding on whether to retain poliovirus potentially infectious materials collections, particularly those with WPV/VDPV potential. The scientific value of retaining a specific poliovirus potentially infectious materials sample collection should be carefully weighed against the public health value of its destruction. Often, the scientific value of poliovirus potentially infectious materials collections may be retained via inactivation, fixation or nucleic acid extraction.

**Biorisk management:** Facilities electing to retain scientifically valuable poliovirus potentially infectious materials collections should be familiar with and prepared to meet biorisk management standards adequate for risk mitigation, addressing accidental exposure and release, as well as the loss, theft, misuse, diversion, unauthorized access or malicious release of poliovirus potentially infectious materials.

For poliovirus potentially infectious materials collections with WPV/VDPV potential, the requirements are described in GAPIII, Annex 2, *Biorisk management standard for poliovirus-essential facilities holding wild poliovirus materials*. These are stringent standards as required for an eradicated agent and should be in place when working with these poliovirus potentially infectious collections. Alternatively, nucleic acids may be extracted from poliovirus potentially infectious materials or the materials may be inactivated using an appropriate method (59). However, these procedures must be performed within proper containment.

For potentially infectious materials collections with OPV/Sabin or nOPV potential, facilities must meet the biorisk management standards described in this publication.

Responsibility for compliance lies with the facility and its respective national authorities (e.g. the Ministry of Health), in coordination with National Certification Committees (NCCs), National Polio Containment Coordinators and other relevant stakeholders where applicable.

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2 nOPV meets the definition of poliovirus and must be included in inventories performed in Phase I of GAPIII.
5. IMPLEMENTATION

Containment timelines are described in detail in GAPIII and consist of three phases leading to the containment of all WPV/VDPV, OPV/Sabin strains, and OPV derivatives, which will occur when poliovirus eradication is achieved.

Poliovirus type 2 containment is already in progress and includes all WPV2 and oral polio vaccine type 2 (OPV2)/Sabin type 2 viruses (5). WPV2 was declared eradicated by the GCC in 2015. Trivalent oral polio vaccine (tOPV, active against poliovirus types 1, 2 and 3) was replaced with bOPV (active against poliovirus types 1 and 3) in 2016 to reduce the number of OPV2-associated paralytic poliomyelitis cases and the emergence of circulating vaccine-derived poliovirus type 2 (cVDPV2) outbreaks (5). At the time of tOPV withdrawal, inactivated poliovirus vaccine (IPV) was recommended for introduction in routine immunization (RI) programmes in all countries where the vaccine was not already in use to maintain immunity for poliovirus type 2 (22). Due to a global shortage, IPV was initially only newly introduced in selected high-risk countries, though all countries now have access to the vaccine. In May 2018, the World Health Assembly urged all Member States to begin inventories and the destruction of unneeded poliovirus type 1 and poliovirus type 3 materials (WHA71.16). Upon the GCC’s declaration of WPV3 eradication in October 2019, identification and containment of all WPV3/VDPV3 materials is now required.

Type 2 is the most transmissible of the three OPV/Sabin strains (6). Monovalent oral polio vaccine type 2 (mOPV2) has been used in supplementary immunization activities (SIAs) in certain countries to prevent or interrupt cVDPV2 outbreaks (Annex 2) since the switch from tOPV to bOPV. To help solve the problem of ongoing cVDPV2 outbreaks, the GPEI plans to use novel oral polio vaccine type 2 (nOPV2) under WHO’s Emergency Use Listing. nOPVs are modified versions of the existing Sabin OPV vaccine strains that provide comparable protection while being more genetically stable. This increased genetic stability compared to OPV decreases the risk of OPV reverting to a form that could cause paralysis in areas of low immunization coverage. The Containment Advisory Group has granted a provisional waiver (60) for the use of nOPV2 outside of GAPIII containment requirements for the purposes of vaccine production, quality control testing, clinical trials, stockpile, outbreak response and laboratory diagnosis. This waiver will continue to be reviewed as new information becomes available from clinical trials and use in outbreak response. Regardless of the current waivers, nOPV and new attenuated poliovirus type 2 (S19) strains are considered poliovirus infectious materials by definition and must be included in the national poliovirus containment inventories reported to NCCs and Regional Certification Commissions. tOPV may be reintroduced in some countries continuing to experience cVDPV2 outbreaks, substituting for the need to provide mOPV2 and bOPV as separate vaccines during supplementary immunization activities. National poliovirus containment inventories must include mOPV2, nOPV2, and tOPV infectious material (IM) and potentially infectious materials.
6. CATEGORIZATION OF POLIOVIRUS POTENTIALLY INFECTIOUS MATERIAL ACCORDING TO RISK

The evidence-based rationale for categorizing sample collections according to relative risks is derived from data provided in this document under Rationale and Risk factors for the categorization of poliovirus potentially infectious material into risk groups and Annex 2 (Country- and area-specific poliovirus data).

The poliovirus transmission risk of poliovirus potentially infectious material collections is a product of multiple elements, including the nature of the sample collection (when, where and what was collected), the poliovirus that may be present (WPV/VDPV, OPV/nOPV/Sabin), the hazards related to the laboratory procedures being used, and worker/community susceptibility.

Poliovirus potentially infectious materials sample collections may be categorized into one of two divergent risk groups based on poliovirus virulence and transmissibility. Of greatest risk are collections with potential for WPV/VDPV, which are the target viruses of the GPEI. Of lower risk are collections with potential only for OPV/nOPV/Sabin poliovirus and related strains, which have been used or may be reintroduced in some countries to immunize untold numbers of children for more than 50 years.

Despite the safety record of OPV in routine immunization programmes, all three attenuated poliovirus types in the vaccine have been linked to rare vaccine-associated paralytic poliomyelitis. Further, under certain conditions of low immunization rates of populations in high-risk environments, the prolonged replication of OPV/Sabin poliovirus can lead to a loss of attenuation and the production of VDPV. cVDPVs pose a public health threat, as outbreaks of paralytic poliomyelitis that clinically are indistinguishable from WPV infection have occurred due to each poliovirus serotype, with more than 90% of cVDPV outbreaks associated with vaccine-derived poliovirus type 2 (VDPV2). cVDPVs pose a public health threat, as outbreaks of paralytic poliomyelitis that clinically are indistinguishable from WPV infection have occurred due to each poliovirus serotype, with more than 90% of cVDPV outbreaks associated with vaccine-derived poliovirus type 2 (VDPV2). People with primary B-cell immunodeficiencies exposed to OPV can develop a chronic poliovirus infection leading to iVDPV. While iVDPV has not been identified as the source of a poliovirus outbreak, the prolonged shedding of virulent strains of poliovirus represents a potential threat to the global eradication of poliovirus. Ambiguous vaccine-derived polioviruses (aVDPVs) are isolates from people without a known primary B-cell immunodeficiency or from environmental samples (e.g. concentrated sewage) with an unknown human source, neither of which is genetically linked to another VDPV. The introduction of nOPV, more attenuated and stable than OPV, is intended to stop the emergence of VDPVs. While the implementation of the requirements described in Annex 3 of GAPIII is currently not required for the handling of nOPV/S19 strains, inventory data on these strains, meeting the definition of polioviruses, will need to be collected once their use starts. The safe retention of nOPV/S19 strains is addressed below.

Full-length poliovirus nucleic acid is considered potentially infectious material, as under certain conditions it may develop into infectious poliovirus particles. The safe retention of poliovirus nucleic acid is described below.

Illustrative guidance to determine the presence of poliovirus potentially infectious materials is provided in Fig. 1.
Fig. 1. Determination process of poliovirus potentially infectious materials

* Conditions supporting poliovirus survival include long-term storage at temperatures below -20 °C.
** If a sample has a missing or damaged label or the type, country of origin or date of collection is unknown, the sample should be destroyed or inactivated using a method known to inactivate poliovirus.
The transmission risk of poliovirus in potentially infectious material collections is a product of multiple elements, including the conditions under which the samples were stored, the nature of the sample collection (what, who, when and where), the poliovirus(es) that may be present (WPV/VDPV or OPV/nOPV/Sabin), the hazards related to the laboratory procedures, and worker/community susceptibility (6).

Potentially infectious material risk divides naturally into two widely divergent risk groups based on poliovirus virulence and transmissibility. Collections with potential for WPV/VDPV are highest risk and are required to be stored and handled only within poliovirus-essential facilities. Collections with potential only for OPV/nOPV/Sabin poliovirus and related strains present lower risks and may be handled under specific conditions within non-poliovirus-essential facilities. These groups do not overlap. However, within each group, factors may raise or lower the risk of facility-associated transmission. All facilities that propose to retain poliovirus potentially infectious material collections should prepare a thorough risk assessment, with the objective of minimizing the risks of poliovirus release back into polio-free communities.

After WPV eradication and cVDPV elimination, susceptibility may change as immunization policies and coverage change.

What samples were collected

Infection of humans with WPV is predominantly via the faecal-oral route (17). OPV is administered orally. Ingestion of either form of poliovirus by a non-immune person leads to an initial brief infection in the throat followed by a more prolonged infection of the gut epithelium (6). A short period of viraemia may occur during the early phase of infection (6). In rare instances, the virus may cross the blood-brain barrier and lead to meningitis or paralytic poliomyelitis, depending on the site of virus replication (6). Poliovirus may replicate in the gut without an initial throat infection (6). The following describes the relative risk of different sample types.

**Faeces**: Poliovirus isolation rates vary widely in samples collected from asymptomatic subjects in a time and place where WPV/VDPV or OPV-derived viruses were in circulation or where OPV was in use. A stool survey of asymptomatic children in Cartagena, Colombia in 1989 reported a WPV isolation rate of 8% (27), while the highest rate reported in a similar survey was 19% in Mumbai, India in 1994 (28). A survey of asymptomatic persons of all ages in index households and neighbouring households in Uttar Pradesh, India in 2009 found 4.8% were shedding WPV. The same study reported a 2.4% stool-positive rate for any poliovirus in Bihar, India (29).

Incidental poliovirus in potentially infectious material has been found in stool samples stored for more than 20 years in a gastroenteritis laboratory. In the first collection of 82 samples, viable WPVs were recovered from six samples and Sabin poliovirus was recovered from one sample (9% in total) (30). In the second collection, six Sabin poliovirus s were recovered from 183 samples (3%) (30). Because of extensive immunization campaigns, Sabin poliovirus s may be incidentally detected in stool samples of acute flaccid paralysis cases, even though the Sabin poliovirus may not be the cause of the paralysis (6). In 2019, for example, Sabin poliovirus was detected in 2.4% of 219 049 stool samples collected globally for acute flaccid paralysis surveillance (31).

WPV strains present the greatest transmission risk, with an estimated human minimum infectious dose of 100-fold less than for OPV strains (~10 CCID50 for WPV vs ~10³ CCID50 for OPV strains) (6). Epidemiologic models and field studies estimate the transmissibility for WPV/VDPV to be more than 10-fold greater than for OPV (6). The secondary spread of WPV was reported to approach 90% among
susceptible contacts in family and institutional settings, with the secondary spread of OPV strains less than half that (6).

OPV circulation in the community rarely exceeds three months after an immunization campaign (32-34). Immunologically naïve subjects may shed WPV/VDPV, OPV or OPV-derived viruses over a range of cell culture infectious doses (CCIDs) up to $10^6$ CCID$_{50}$/g stool (mean $\sim 10^4$ CCID$_{50}$/g stool) for six weeks to three months, although shedding duration may sometimes be less for OPV/Sabin strains (6). Poliovirus reinfecions of the gut may occur, depending on the virus challenge dose and the length of time since the receipt of OPV or natural infection. The virus concentration and duration of faecal shedding is generally lower on reinfection (6). IPV immunization has little or no effect on the susceptibility of the gut to poliovirus infection (6, 35). nOPV has not been used for outbreak response activities yet and no data exist currently on nOPV circulation in the community after an immunization campaign. Vaccine recipients, administered one of two versions of nOPV2 as part of a clinical trial, shed virus up to 23 or 36 days depending on the strain received (36).

**Nasopharyngeal, oropharyngeal and other upper respiratory tract secretions:** Similarly, WPV/VDPV and OPV/Sabin viruses may be recovered from respiratory secretions of naïve subjects at equivalent concentrations for a period of 2-6 days post-infection (6). Virus shedding wanes and usually disappears at 7-10 days post-infection, coinciding with the appearance of serum antibodies (6). The virus is rarely recovered from respiratory secretions after a WPV or OPV challenge of persons with measurable serum antibody, including IPV recipients (6). Based on the limited duration of post-infection virus shedding and the absence of shedding on reinfection, the probability of recovering poliovirus from respiratory secretions in surveys is estimated to be less than 1%, or at least 10-fold less than from stool samples (6). During a community survey in Bihar, India in 2009, poliovirus -positive rates for respiratory samples were 0.1%, ~20-fold less than for stool samples (2.4%) (29). No data exist currently on nOPV shedding in nasopharyngeal, oropharyngeal and other upper respiratory tract secretions.

**Sewage:** Poliovirus recovery from raw sewage usually involves some form of sample concentration (e.g. filtration, centrifugation or phase separation). The recovery of WPV or OPV/Sabin has been reported from raw sewage samples, but the concentration of infectious virus is usually <1 CCID$_{50}$/ml, well below the estimated infectious dose for either OPV strains or WPV (6, 14, 35, 37-39). The poliovirus content of sewage concentrates may be several logs higher, depending on the method employed (6). No data exist currently on nOPV recovery from raw sewage.

**Cerebrospinal fluid, serum and blood:** Poliovirus is rarely recovered from cerebrospinal fluid (6, 40). Blood samples yield WPV in less than 25% of infected persons with levels usually low (<50 CCID$_{50}$/ml) (6). A similar low-level viraemia pattern in OPV recipients has been observed for Sabin type 2, but no viraemia has been reported for Sabin types 1 and 3 (6). Consequently, collections of cerebrospinal fluid, serum and blood samples are not considered poliovirus potentially infectious material. No data exist currently on nOPV recovery from cerebrospinal fluid, serum and blood.

**Who were samples collected from**

**Age of subjects:** Children aged under 5 years are the group most often infected during a WPV epidemic and are the target population for routine immunization programmes and multiple OPV campaigns. Children aged 6-15 years are rarely included in OPV campaigns but may be infected or reinfected by WPV or OPV-derived viruses circulating in the family or community (6). The reinfection of immunologically experienced adults and older children is less likely, but appears to be a function of virus dosage (6). Reinfecions of older children or adults rarely result in virus recovery from throat samples, and faecal shedding may be greatly reduced in virus content and duration (6).

**When, where and from where samples were collected**
The “when, where and from where” of the collection indicates the likelihood of poliovirus being present. Annex 2 provides country-specific poliovirus data for the time of the last estimated presence of
WPV, the time of the last estimated presence of VDPV, and the last use of OPV/nOPV/Sabin, by poliovirus type, for any given country or area. Data on WPV/VDPV outbreaks and use of mOPV2, bOPV, tOPV and nOPV will be provided and Annex 2/Web Annex A updated regularly.

Sample storage conditions
Poliovirus in clinical or environmental specimens survive indefinitely in the laboratory freezer (<-20 °C), for many months in the refrigerator, and for hours to days on the bench top (6).

Laboratory hazards
Inoculating/harvesting poliovirus -permissive cells: Attempts to isolate infectious agents other than poliovirus from poliovirus potentially infectious material collections using poliovirus-permissive cell cultures (Annex 1) may result in an enhanced poliovirus content of up to $10^8$ CCID$_{50}$/ml (6, 41). This possible greater than $10^5$ increase in virus concentration over the original clinical sample greatly increases the risk to the laboratory worker, particularly if the identity of the amplified incidental poliovirus is unrecognized.

Full-length poliovirus ribonucleic acid (RNA) can infect permissive cell lines, facilitated by using transfection reagents (42, 43). The extraction of nucleic acid from poliovirus potentially infectious material could coincidentally co-purify poliovirus RNA. The transfection of poliovirus RNA into poliovirus -permissive cells may generate infectious poliovirus particles, possibly at high titres (43).

Laboratory procedures generating aerosols: Procedures that may create aerosols through the release of liquids under pressure (sprays), dropping or breaking containers, the mixing of suspensions, mechanical blending, shaking or pouring constitute a high risk (6). The survival of poliovirus in the laboratory environment is favoured by higher initial titre, lower temperatures, a moist environment, and the presence of stabilizing material such as organic matter (6). The laboratory worker may be infected directly through ingestion of droplets or indirectly through contaminated work surfaces or clothing (6). High-content poliovirus materials (high titre and/or high volume) represent the highest risk.

Facility effluents
The risk of community exposure through liquid effluents generated within the facility requires a facility-by-facility assessment and will depend on potential poliovirus content, the nature of the sewage system and the potential for human consumption (6). However, if the laboratory works with only OPV/nOPV/Sabin potentially infectious material without further replication of incidental poliovirus and adheres to good laboratory practices, the community risk is very low (6).

Worker/community susceptibility
The facility/laboratory worker: For OPV recipients, reinfection of the gut is a function of the time between OPV or natural infection and the challenge virus dosage (6). IPV provides a high level of pharyngeal protection but little or no immunity to gut infection (6). IPV recipients are not at risk of paralytic poliomyelitis, but could be at risk of transmitting WPV or OPV/OPV-derived viruses to their family and community through poliovirus-contaminated skin or clothing, silent infections of the gut, or work practices that may contribute to contamination of facility effluents (6).

Community vaccine coverage: The risk of outbreaks from laboratory-associated transmission is inversely proportional to population immunity. Risk may be assessed by percent vaccine coverage of children aged under 5 years (6).

Facility location: Facility location should be taken into consideration if the facility is situated near high-risk populations with a potentially elevated force of infection (high population density, inadequate hygiene standards, high birth rate and suboptimal immunity) (6).
8. BIORISK MANAGEMENT OF POLIOVIRUS POTENTIALLY INFECTIOUS MATERIAL

Faecal, respiratory, concentrated sewage samples or derivatives of such samples stored under conditions that maintain poliovirus viability may be potentially infectious (6). If these samples were collected in/from a place and at a time when WPV or VDPV was in circulation (Annex 2), they are WPV/VDPV potentially infectious material, and are subject to the full containment described in GAPIII and must be stored and handled in a poliovirus-essential facility certified by a national authority for containment (NAC), as outlined in section A below. If WPV/VDPV were not in circulation, but OPV was in use (Annex 2), these samples are OPV/nOPV/Sabin potentially infectious material and may be handled outside a poliovirus-essential facility only under the conditions described in section B. If nOPV was in use, samples are nOPV potentially infectious material and are subject to the same conditions that apply to OPV/Sabin potentially infectious material.

Samples that are unlabelled, mislabelled or for which the origin, type, date of collection or ownership are unknown, should be inactivated or destroyed following procedures effective against poliovirus.

The retention of poliovirus potentially infectious materials, including poliovirus nucleic acid, is subject to declaration to and the agreement of the responsible national authorities (e.g. Ministry of Health), who should inform the national authority for containment or consider establishing a national authority for containment where necessary.

8.1 Collections with potential for WPV/VDPV

Facilities with WPV/VDPV potentially infectious material that do not plan to qualify as a poliovirus-essential facility must destroy, inactivate or transfer the materials to a poliovirus-essential facility. All countries/facilities that have participated in the response to cVDPV outbreaks must update poliovirus inventories after the outbreak is declared over and the use of OPV/nOPV is discontinued. The retention of samples potentially infectious for WPV/VDPV (Table 1) subjects the facility to the approval of the responsible national authority, containment certification by the national authority for containment and final approval by the GCC (44). Poliovirus-essential facility certification requires the following:

1. The responsible national authority (e.g. Ministry of Health) agrees to the retention of these materials.
2. The facility engages in the certification process against GAPIII requirements and applies to the national authority for containment for a certificate of participation as described in the GAPIII Containment Certification Scheme (CCS).
3. The facility granted a certificate of participation may continue to retain relevant materials during the certification process.
4. The facility granted a certificate of participation for the retention of WPV/VDPV materials must demonstrate compliance with GAPIII, Annex 2, and apply to the national authority for containment for a certificate of containment (CC). During the poliovirus type 2 containment period, an interim certificate of containment (ICC) will be issued if the national authority for containment determines the facility does not meet all requirements for full containment certification but has the ability to address the non-conformities.
   Once an interim certificate of containment or a certificate of containment is obtained, the facility is certified as a poliovirus-essential facility.
5. A facility not designated to retain poliovirus materials post-eradication has the option to destroy, inactivate or transfer the relevant materials to a poliovirus-essential facility.
6. The validity of a certificate of participation / interim certificate of containment / certificate of containment is of limited duration and subject to regular reassessments, as described in the CCS.
**Nucleic acid** extracted from WPV/VDPV infectious or potentially infectious material using methods demonstrated to inactivate poliovirus, or synthesized RNA, or complementary DNA (cDNA) can be handled outside of poliovirus containment under the condition that these materials will not be introduced into poliovirus-permissive cells or animals with or without a transfection agent, except under appropriate containment conditions as recommended by the Containment Advisory Group in November 2017 (61).

All facilities that plan to retain WPV/VDPV nucleic acid must declare their holdings to the national authority (e.g. Ministry of Health) in the national poliovirus survey and maintain an accurate inventory of materials in their possession.

Facilities that intend to retain WPV/VDPV potentially infectious material for a limited period (e.g. to complete research studies) may wish to consider applying for certificate of participation/interim certificate of containment only, as described in the CCS, and transfer to a certificate of containment-certified poliovirus-essential facility or destroy their materials before their certificate of participation/interim certificate of containment expires. Note that stringent requirements still apply during this period. Facilities that intend to retain WPV/VDPV potentially infectious material long term are expected to demonstrate full compliance with all GAPIII requirements and be granted a certificate of containment.

WPV2 and WPV3 are eradicated agents, with WPV1 soon to follow. **Facilities are now (as of 2020) required to apply this guidance to poliovirus type 2 and WPV3/VDPV3 potentially infectious material.** The GCC set the deadline for completion of the identification, destruction, transfer or containment for WPV1 materials by the time of complete poliovirus eradication.

### Table 1. Risk mitigation strategies for handling or storing WPV/VDPV potentially infectious material

<table>
<thead>
<tr>
<th>WPV/VDPV potentially infectious material</th>
<th>Risk mitigation strategy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Faecal, respiratory, concentrated sewage samples or derivatives of such samples stored under conditions that maintain the viability of poliovirus</td>
<td>Destroy, inactivate or transfer materials to a poliovirus-essential facility</td>
</tr>
<tr>
<td></td>
<td>Receive retention approval from the responsible national authority (e.g. Ministry of Health) and undergo containment certification</td>
</tr>
<tr>
<td></td>
<td>Only handle or store materials in a poliovirus-essential facility certified by the national authority for containment against GAPIII, following the CCS</td>
</tr>
<tr>
<td>Extracted nucleic acid from WPV/VDPV infectious or potentially infectious material</td>
<td>Declare holdings to the national authority (e.g. Ministry of Health) in the national poliovirus survey and maintain an accurate inventory</td>
</tr>
<tr>
<td></td>
<td>Only perform transfections into poliovirus-permissive cells or animals under GAPIII containment</td>
</tr>
<tr>
<td></td>
<td>Handle outside of GAPIII containment except for transfections into poliovirus-permissive cells or animals</td>
</tr>
</tbody>
</table>

---

8.2 Collections with potential only for OPV/nOPV/Sabin and related strains

Facilities with OPV/nOPV/Sabin potentially infectious material do not need to become poliovirus-essential facilities to retain such materials, as long as the conditions described in this section are followed. OPV/nOPV/Sabin potentially infectious material can be subcategorized into three risk levels, depending on the type of sample and laboratory procedures being used with these materials (Table 2). The risk level is determined by associating the type of poliovirus potentially infectious materials retained with the procedures to be performed using the poliovirus potentially infectious materials. In general, procedures introducing potentially infectious material into poliovirus-permissive cells (Annex 1) will have a higher risk level than other laboratory procedures (6). For example, inoculation of these materials into poliovirus-non-permissive cells, bacterial cultures, polymerase chain reactions (PCRs) (DNA or RNA), mass spectrometry or enzyme-linked immunosorbent assays (ELISAs) would be considered lower risk procedures.

As OPV2 is no longer present in routine immunization worldwide, **facilities are required to apply this guidance to OPV2/nOPV2/Sabin2 potentially infectious material now.** Countries that have used mOPV2, will use nOPV2 or are planning to reintroduce tOPV since the switch from tOPV to bOPV in April 2016 are required to repeat their inventories after the use of mOPV2/nOPV2/tOPV has ceased. This guidance will apply to all OPV/nOPV/Sabin strains after the cessation of OPV/nOPV use.

Countries planning to use nOPV2 are expected to start collecting and reporting inventory data as soon as nOPV2 is introduced.

All facilities that plan to retain OPV/nOPV/Sabin poliovirus potentially infectious materials or OPV/nOPV/Sabin/S19 nucleic acid must declare their holdings to the national authority (e.g. Ministry of Health) in the national poliovirus survey and maintain an accurate inventory of materials in their possession. All OPV/nOPV/Sabin poliovirus potentially infectious materials and derived materials should be stored securely, with access restricted to staff who are eligible and competent to work with such materials. Responsibility for compliance with these measures, summarized in Table 3, lies with the facility and its respective national authorities (e.g. Ministry of Health).

Risk mitigation strategies for handling OPV/nOPV/Sabin potentially infectious material are described in Table 3.
Table 2. Risk classification of OPV/nOPV/Sabin poliovirus potentially infectious materials

<table>
<thead>
<tr>
<th>Type of OPV/nOPV/Sabin potentially infectious material*</th>
<th>Procedure used with potentially infectious material</th>
<th>Risk level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Faecal samples or concentrated sewage</td>
<td>Inoculation into poliovirus-permissive cells</td>
<td>Moderate</td>
</tr>
<tr>
<td></td>
<td>Other laboratory procedures**</td>
<td>Low</td>
</tr>
<tr>
<td></td>
<td>Transfection into PV-permissive cells</td>
<td>Moderate</td>
</tr>
<tr>
<td></td>
<td>Other laboratory procedures**</td>
<td>Lowest</td>
</tr>
<tr>
<td>Extracted nucleic acid from faecal samples or concentrated sewage</td>
<td>Inoculation into poliovirus-permissive cells</td>
<td>Low</td>
</tr>
<tr>
<td></td>
<td>Other laboratory procedures**</td>
<td>Lowest</td>
</tr>
<tr>
<td>Respiratory tract samples</td>
<td>Inoculation into poliovirus-permissive cells</td>
<td>Low</td>
</tr>
<tr>
<td></td>
<td>Other laboratory procedures**</td>
<td>Lowest</td>
</tr>
<tr>
<td>Extracted nucleic acid from respiratory tract samples</td>
<td>Transfection into poliovirus-permissive cells</td>
<td>Low</td>
</tr>
<tr>
<td></td>
<td>Other laboratory procedures**</td>
<td>Lowest</td>
</tr>
<tr>
<td>Inactivated OPV/nOPV/Sabin potentially infectious material***</td>
<td>Any</td>
<td>Not potentially infectious material</td>
</tr>
</tbody>
</table>

* Cerebrospinal fluid, serum/blood and other clinical materials not listed in this table are not considered poliovirus potentially infectious materials.
** May include, but not limited to, inoculation into poliovirus-non-permissive cells, bacterial cultures, PCRs (DNA or RNA), mass spectrometry or ELISAs.
*** Must be inactivated using a validated method (45).

Table 3. Risk mitigation strategies for handling OPV/nOPV/Sabin poliovirus potentially infectious materials

<table>
<thead>
<tr>
<th>Risk mitigation strategy</th>
<th>Moderate</th>
<th>Low</th>
<th>Lowest</th>
<th>Storage only^2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Declare OPV/nOPV/Sabin potentially infectious material in national poliovirus survey and maintain accurate inventory</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Biosecurity (including, for example, locked freezers, limited access, staff training)</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Biosafety (including, for example, good laboratory/microbiological practices, and documentation and validation of methods/standard operating procedures, as described in GAP III, Annex 6)</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>n/a</td>
</tr>
<tr>
<td>Risk assessment for specific procedures being used</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Required polio immunization of staff</td>
<td>✓</td>
<td>✓</td>
<td>n/a^3</td>
<td>n/a</td>
</tr>
<tr>
<td>Certification to a national or international standard that includes biosafety and biosecurity components</td>
<td>✓</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
</tr>
</tbody>
</table>

^1 ✓: must comply with the risk mitigation strategy; n/a: not applicable.
^2 If “stored” samples are to be handled, the risk mitigation strategies for moderate, low and lowest risk levels must be applied as appropriate for the sample type and procedure (Table 2).
^3 Polio immunization of staff is recommended.
Guidance for facilities with collections in the MODERATE risk level

In a facility handling OPV/nOPV/Sabin poliovirus potentially infectious materials, the inoculation of faecal samples or sewage concentrates, or the transfection of nucleic acid derived from such material into poliovirus-permissive cells (Annex 1) represents the greatest potential risk of inadvertent poliovirus release (6). The inoculation or transfection of poliovirus potentially infectious materials into poliovirus-permissive cells could result in unintentional poliovirus amplification, greatly increasing the risk of release from the facility if the production of poliovirus was undetected (6).

If the inoculation of faecal samples or sewage concentrates, or the transfection of nucleic acid from OPV/nOPV/Sabin poliovirus potentially infectious materials into poliovirus-permissive cells is deemed essential (e.g. to isolate other viruses of public health importance that replicate in the same cell lines as poliovirus), the laboratory and staff should meet stringent standards of biosafety and biosecurity (Table 3). These include adherence to accepted standards of good laboratory and microbiological practices, supported by the validation/documentation of methods and the implementation of written standard operating procedures, and certification to a national or international biorisk management standard (e.g. GAPIII, Annex 6). Rigorous risk assessments should be conducted and documented for all procedures that will be used with poliovirus potentially infectious materials faecal samples or sewage concentrates to identify strategies to minimize the risks of inadvertent release.

Laboratory staff should provide proof of poliovirus immunization according to the national schedule. Any individuals who cannot produce proof of polio immunization should be immunized according to national or international recommendations for persons with potential occupational exposure to poliovirus.

Guidance for facilities with collections in the LOW risk level

Poliovirus potentially infectious material faecal samples or sewage concentrates that will not be inoculated into poliovirus-permissive cells (e.g. samples that will be handled only for nucleic acid extraction or fixation, or inoculation only into poliovirus-non-permissive cells) pose a lower risk, as these procedures will not enable live virus to grow (6). The inoculation of respiratory tract specimens, or the transfection of nucleic acid derived from such material into poliovirus-permissive cells is also of lower risk, largely because of the lower poliovirus incidence and titres in these sample types (6).

However, the laboratory is expected to adhere to nationally or internationally accepted standards of good laboratory and microbiological practices, supported by the validation/documentation of methods and the implementation of written standard operating procedures (Table 3). Similar to the moderate risk level, facilities should conduct and document risk assessments to identify strategies to minimize the risks of inadvertent exposure or release.

As above, laboratory staff should provide proof of poliovirus immunization according to the national schedule. Any individuals who cannot produce proof of polio immunization should be immunized according to national or international recommendations for persons with potential occupational exposure to poliovirus.

Guidance for facilities with collections in the LOWEST risk level

Respiratory tract samples that will not be inoculated into poliovirus-permissive cells (e.g. samples that will be handled only for nucleic acid extraction or fixation, or inoculation only into poliovirus-non-permissive cells) pose the lowest risk, as the poliovirus incidence and titres in respiratory materials are low (6). Nucleic acid extracted from OPV/nOPV/Sabin poliovirus potentially infectious materials that will not be transfected into poliovirus-permissive cells is also of the lowest risk (6). The laboratory is expected to adhere to accepted standards of good laboratory and microbiological practices, supported by the validation/documentation of methods and the implementation of written standard operating
procedures, and facilities should conduct and document risk assessments to identify strategies to minimize and mitigate the risks of inadvertent release (Table 3).

Polio immunization for relevant staff is recommended.

8.3 Guidance for the short-term retention of historical collections with potential for poliovirus while final disposition is being determined

Facilities that require a brief period of storage of valuable poliovirus potentially infectious materials collections while their final disposition is being determined should declare the materials in their national poliovirus survey and maintain an accurate inventory of materials in their possession (Table 3). Poliovirus potentially infectious materials must be segregated from other materials and stored in locked freezers, with access limited to specifically trained and competent staff. It must be emphasized that this is a short-term measure only, while the final disposition of the collection is being considered. During this time, the facility is still subject to oversight by the national authority (e.g. Ministry of Health) and should eventually destroy, inactivate or transfer the materials, adopt the biorisk management strategies described above if the potentially infectious material collection is OPV/nOPV/Sabin material, or begin the process to become a poliovirus-essential facility and apply for Certificate of Participation if the poliovirus potentially infectious materials collection is categorized as WPV/VDPV and the facility is designated to become a poliovirus-essential facility.
REFERENCES


**Annex 1: Poliovirus-permissive cell lines**

Poliovirus grows in nearly all human and monkey cell lines, in addition to mouse L cells (L20B, Lα) that were engineered to express the human poliovirus receptor (CD155) \((18)\). **Table A1.1 highlights some, but not all cell lines susceptible to poliovirus infection.**

Extracts of faecal specimens, rectal swabs, respiratory specimens or concentrated sewage that are inoculated onto the poliovirus-susceptible cells listed below will enable growth of any polioviruses present.

**Table A1.1. Examples of cell lines susceptible to poliovirus infection**

<table>
<thead>
<tr>
<th>Poliovirus-permissive cell lines</th>
<th>Origin</th>
</tr>
</thead>
<tbody>
<tr>
<td>AS49 ((46))</td>
<td>Human</td>
</tr>
<tr>
<td>CaCo-2 ((47))</td>
<td>Human</td>
</tr>
<tr>
<td>HeLa ((46))</td>
<td>Human</td>
</tr>
<tr>
<td>HEp-2 ((48))</td>
<td>Human</td>
</tr>
<tr>
<td>HEK ((49))</td>
<td>Human</td>
</tr>
<tr>
<td>MRC-5 ((50))</td>
<td>Human</td>
</tr>
<tr>
<td>PERC-6 ((51))</td>
<td>Human</td>
</tr>
<tr>
<td>RD ((48))</td>
<td>Human</td>
</tr>
<tr>
<td>WI-38 ((52))</td>
<td>Human</td>
</tr>
<tr>
<td>Various neuroblastoma (e.g. IMR-32, SK-N-MC) ((53))</td>
<td>Human</td>
</tr>
<tr>
<td>BGMK (sometimes referred to as BGM or GMK) ((20))</td>
<td>Non-human primate</td>
</tr>
<tr>
<td>LLC-MK2 ((54))</td>
<td>Non-human primate</td>
</tr>
<tr>
<td>MA-104 (Vero derivative) ((46))</td>
<td>Non-human primate</td>
</tr>
<tr>
<td>Primary monkey kidney cells(^1) ((50))</td>
<td>Non-human primate</td>
</tr>
<tr>
<td>Vero ((46))</td>
<td>Non-human primate</td>
</tr>
<tr>
<td>L20B ((55))</td>
<td>Mouse(^2)</td>
</tr>
<tr>
<td>Lα ((56))</td>
<td>Mouse(^2)</td>
</tr>
<tr>
<td>Super E-Mix ((57))</td>
<td>Hybrid; mixture of cell lines</td>
</tr>
<tr>
<td>R-Mix ((58))</td>
<td>Hybrid; mixture of cell lines</td>
</tr>
</tbody>
</table>

\(^1\) Old World monkeys.

\(^2\) Transgenic mouse cell lines.
Facilities are encouraged to assess the risk of poliovirus potentially infectious materials in their collections using the data provided in this Annex. The data address the following parameters:

1. year of last detection of each type of WPV
2. period of detection of VDPV

Currently, poliovirus type 2 and WPV3 potentially infectious material are required to be contained in a poliovirus-essential facility. The last detection of WPV2 worldwide was in India in October 1999. WPV3 was last detected in Nigeria in November 2012. However, the month and year of the last detection were not accurately recorded for all countries. Table A2.1 of Annex 2 systematically refers to December as the month of last detection of WPV2 for specimens collected during a specific year and assigns 31 October 1999 as the date of last detection in any country or territory where uncertainty surrounds the last reported case of WPV2. Samples collected up to the indicated dates for each type of WPV/VDPV are considered WPV potentially infectious material for that type. A sample may be WPV/VDPV potentially infectious material for more than one type of virus, depending on what types of poliovirus were in circulation in a given country at the time of collection.

Surveillance activities have detected cVDPVs, iVDPVs and aVDPVs. This guidance refers to the date of any first and last detected VDPV2/VDPV3 with evidence of circulation for each country or area.

Samples are considered VDPV2/VDPV3 potentially infectious material if collected between the time of the first reported VDPV2/VDPV3 and the close of the outbreak in any given country or area.

As indicated in Table A2.1 of Annex 2, the inventories and destruction of unneeded cVDPV2/circulating vaccine-derived poliovirus type 3 (cVDPV3) potentially infectious material must be completed after a VDPV2/VDPV3 outbreak is declared closed.

The following information in Table A2.1 of Annex 2 can help determine whether a facility has OPV2/nOPV2/Sabin2 potentially infectious material:

1. tOPV use in RI
   a. year of tOPV introduction
   b. month and year of last tOPV use

---

4 Source of virus: acute flaccid paralysis, environmental sampling (i.e. waste water, sewage), enterovirus surveillance or any other source, including contact sampling, healthy children and special studies.

5 VDPV: OPV virus strains that are >1% divergent (or ≥10 nucleotide changes for types 1 and 3) or >0.6% divergent (≥6 nucleotide changes for type 2) from the corresponding OPV strain in the complete VP1 genomic region. See Classification and reporting of vaccine-derived polioviruses (VDPV), GPEI guidelines. Geneva: World Health Organization; August 2016 (http://polioeradication.org/wp-content/uploads/2016/09/Reporting-and-Classification-of-VDPVs_Aug2016_EN.pdf, accessed 7 December 2020).

6 The year of tOPV introduction is generally not known. For this reason, the table assumes that materials collected between the last listed WPV2 case and three months after the last use of tOPV, excluding periods with VDPVs, would fall under the category of OPV2/nOPV2/Sabin2 potentially infectious material.

7 In countries and territories where only the year is known, the date of the last tOPV use was arbitrarily set at 31 December.
2. post-tOPV-cessation supplementary immunization activity using mOPV2/tOPV/nOPV2 in countries responding to, or at risk of, a poliovirus type 2 event or outbreak
   a. Supplementary immunization activity start and end dates.

In countries showing evidence of continued use of tOPV post-switch, the last date of tOPV use was adjusted to the latest detection. In the absence of evidence showing otherwise, samples collected as of three months after the reported last use of tOPV/mOPV2/nOPV2 are no longer considered OPV2/nOPV2/Sabin2 potentially infectious material.

Countries using mOPV2/tOPV/nOPV2 are expected to repeat and submit their inventories for OPV2/Sabin2 materials once the use of mOPV2/tOPV/nOPV2 is discontinued.

The identification of oral polio vaccine type 1 (OPV1)/oral polio vaccine type 3 (OPV3) or Sabin1/Sabin3 potentially infectious material is currently not required, as bOPV is still in use in routine immunization.

Table A2.1 of Annex 2 of this Poliovirus containment: guidance to minimize risks for facilities collecting, handling or storing materials potentially infectious for polioviruses, second edition is available in Web Annex A: Country- and area-specific poliovirus data.
The Global Polio Eradication Initiative, launched in 1988, has been the largest international public health effort ever undertaken. Billions of children have been immunized and millions of paralytic poliomyelitis cases have been prevented through donations from individuals and organizations, the dedicated efforts of governments at all levels, and countless volunteer hours.

The Global Commission for the Certification of the Eradication of Poliomyelitis certified the eradication of wild poliovirus type 2 (WPV2) in 2015 and the eradication of wild poliovirus type 3 (WPV3) in 2019. The eradication of wild poliovirus type 1 (WPV1) and the elimination of circulating vaccine-derived polioviruses are anticipated in the near future, along with the gradual disappearance of immunodeficiency-associated vaccine-derived poliovirus. At that point, the only remaining poliovirus reservoirs will be the facilities retaining poliovirus infectious or potentially infectious materials. Countries responsible for these facilities must assure the world that these reservoirs do not present a post-eradication risk of re-emerging paralytic disease due to poliovirus that could undermine this extraordinary humanitarian achievement.

This guidance aims to facilitate the identification of materials potentially infectious for polioviruses within laboratories that handle human stool specimens, respiratory samples or environmental sewage. Depending on the place and time of collection, these materials may contain infectious polioviruses that are eradicated (WPV2 and WPV3), nearly eradicated (WPV1) or originating from oral polio vaccines. Identifying, eliminating the risk through destruction, or mitigating the risk of handling such materials is essential, not only to maintain the safety of laboratory workers and their communities, but also for the success of the global polio eradication effort.

Facilities are encouraged to use Table A2.1 (Country- and area-specific poliovirus data) to assess the risk of sample collections potentially infectious for poliovirus. The data and information were collected from multiple sources using algorithms for each country. Table A2.1 is revised and updated regularly. It forms part of the Poliovirus containment: guidance to minimize risks for facilities collecting, handling or storing materials potentially infectious for polioviruses, second edition and is available in Web Annex A: Country- and area-specific poliovirus data.

Web Annex B outlines the standard operating procedure to identify, destroy or prepare the containment of poliovirus infectious or potentially infectious materials. The procedure helps all facilities, whether or not they knowingly work with polioviruses, to identify this material and eliminate or minimize the risks associated with handling and storing them. It also provides information on completing the facility reporting form (FORM 1), available as Web Annex C. This updated form should be used to report the identification, destruction or retention of poliovirus infectious or potentially infectious materials. Web Annex D helps National Poliovirus Containment Coordinators, National Task Forces for containment Chairs and other focal persons to complete the progress reporting form (FORM 2) describing their preparations for poliovirus containment and the completion of Phase I of the WHO Global Action Plan for Poliovirus Containment (GAPIII).

As the world works to eradicate polio, all precautions must be taken to minimize the risk of eradicated polioviruses being released from the laboratories and facilities that retain them. These documents taken together will help to reduce that risk and to ensure the virus can no longer get into the environment and cause harm.