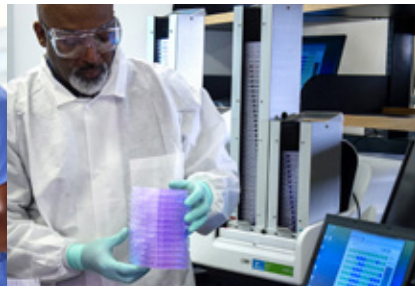
Interim Guidance for Non-Laboratory Facilities that Collect, Handle, Store, and Transport Potentially Infectious Materials in Areas Where Ongoing Poliovirus Positive Samples are Being Detected

EFFECTIVE NOVEMBER 22, 2022



NAC
U.S. NATIONAL AUTHORITY
FOR CONTAINMENT OF POLIOVIRUS

U.S. DEPARTMENT OF
HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE
CONTROL AND PREVENTION

Office of Readiness and Response

NAC.AUDIT.EXT.006.01

Definitions

Non-laboratory facilities: For the purposes of this document, non-laboratory facilities are defined as facilities that treat wastewater, provide healthcare (*i.e.,* hospitals), and other facilities and service providers that collect, handle, store and/or transport poliovirus potentially infectious material (PIM). Non-laboratory facilities are distinct from laboratory facilities, with the latter including research, university, clinical, and public health laboratories.

Vaccine-derived poliovirus (VDPV) PIM: The WHO GAPIV VDPV PIM definition includes but is not limited to:

- "Environmental samples (*i.e.* concentrated sewage, wastewater) collected from areas known or suspected to have circulating wild poliovirus (WPV) or VDPV at the time of collection." [i]
- Fecal "or respiratory secretion samples and their derivatives (*e.g.* stool suspensions, extracted nucleic acids, etc.) collected for any purpose in a time and geographic area where wild poliovirus (including VDPV) circulation" [i] is identified or confirmed.
- "Uncharacterized enterovirus-like cell culture isolates derived from countries known or suspected to have circulating wild poliovirus or VDPV at the time of collection." [i]

Sewershed: The Centers for Disease Control and Prevention (CDC) defines a sewershed as "the community area served by a wastewater collection system." [ii]

Wastewater: For the purposes of this document, wastewater is defined as used water that contains human fecal waste. Wastewater may include septage (*i.e.*, at wastewater treatment plants that accept hauled septage), and may be referred to as "municipal wastewater". The human waste component of wastewater may be referred to as "domestic sewage" or "sanitary sewage."

VDPV PIM Geographic Area: The CDC defines VDPV PIM [1] geographic areas as:

- Two or more CDC confirmed, VDPV -positive wastewater (WW) samples from one sewershed more than two months apart [2], or non-overlapping sewersheds with more than one CDC confirmed, genetically related VDPV-positive WW sample. [3] Further consideration will be given to establish upstream wastewater sampling sites to narrow a multi-county sewershed. [4]
- A county with two CDC confirmed genetically linked VDPV-positive clinical specimens from two unrelated (do not share same household) patients.

[1] Applies to VPDV type 2 (≥6 nucleotide changes in VP1), VDPV type 1 or type 3 (>10 nucleotide changes in VP1).
[2] Two genetically linked PV positives more than months (approximate shedding period is 4-8 weeks) apart from one sewershed suggests at least two different people shedding and community-level transmission.
[3] More than one genetically linked PV positives in separate sewersheds suggests at least two different people shedding and community-level transmission
[4] Global Polio Eradication Initiative, Standard Operating Procedure "Responding to A Poliovirus Event or Outbreak", March 2022, version 4, page 8. Standard-Operating-Procedures-For-Responding-to-a-Poliovirus-Event-Or-Outbreak-20220905-V4-EN.pdf (polioeradication.org)

Purpose and Scope

The U.S. National Authority for the Containment of Poliovirus (NAC) *Interim Guidance for Non-Laboratories that Collect, Handle, Store, and Transport Potentially Infectious Materials in Areas Where Ongoing Positive Poliovirus Samples are Being Detected* applies to U.S. non-laboratory facilities and personnel performing these activities with VDPV PIM. Vaccine-derived poliovirus PIM includes materials and samples collected at a time and place where VDPV is known or suspected to be circulating and may contain poliovirus (See definition). Activities addressed in this guidance include specimen collecting (*e.g.,* obtaining wastewater samples at a treatment plant), handling (*e.g.,* carrying or processing samples post-collection), storing (*e.g.,* keeping samples in storage units such as refrigerators and freezers), and transporting (*e.g.,* transferring samples to other locations within or outside the non-laboratory facility).

For the purposes of this document, non-laboratory facilities include, but are not limited to, facilities that treat wastewater, provide healthcare (*i.e.,* hospitals), and other facilities and service providers that collect, handle, store and/or transport PIM. This guidance document is limited to non-laboratory facilities located in geographical areas where VDPV positive samples have been detected. Please contact the U.S. NAC for guidance for non-laboratory facilities performing these activities outside of this scope.

Based on the World Health Organization (WHO) Global Action Plan, 4th edition (GAPIV) and PIM Guidance documents, this U.S. NAC PIM interim guidance document outlines measures to mitigate the risks that VDPV PIM poses to personnel, environment, public health, and the global eradication of poliovirus. While not all PIM will contain poliovirus, WHO considers the possibility that PIM could contain PV to be a significant risk to the environment and community, if not addressed properly. The U.S. NAC recommends the measures described here to be implemented at a minimum to be protective of human health. The U.S. NAC will continue to revise and update this document as additional information becomes available.

The U.S. NAC understands that some guidance elements will not apply to all non-laboratory facilities. The U.S. NAC recommends that non-laboratory facilities perform a site-specific risk assessment or job-specific analysis to 1) identify personnel involved with PIM activities, 2) identify risks associated with PIM activities, and 3) develop procedures to mitigate risks associated with PIM to protect personnel, environment, and public health. Risk mitigation approaches for VDPV PIM are described below.

Please contact the U.S. NAC for additional guidance and assistance.

Background

Poliovirus is an enteric virus that may cause poliomyelitis, a disabling and life-threatening disease that can infect the spinal cord and cause paralysis, in some individuals. Most infected individuals are asymptomatic and will not experience disease; however, these persons can still transmit the virus to individuals or contaminate the local wastewater collection and treatment systems. The virus is spread through person-to-person contact, most frequently through the oral route resulting from ineffective handwashing following contact with feces [iii].

The WHO declared eradication of wild poliovirus (WPV) types 2 and 3 in 2015 and 2019, respectively. **U.S. non-laboratory facilities that collect, handle, store and/or transport VDPV PIM are not required to be a poliovirus-essential facility (PEF) or implement additional containment requirements not outlined in this document at this time. However, non-laboratory facilities that retain stool, upper respiratory secretions, untreated wastewater (*e.g.*, grab or composite influent samples), primary sludge and primary effluent, and derivatives (*e.g.,* wastewater solids retained on filter media, concentrated sewage, stool suspensions, extracted nucleic acid) collected in VDPV PIM geographic areas for thirty (30) days or more must report PIM possession to the U.S. NAC by submitting a U.S. NAC Poliovirus Inventory Survey, maintain an accurate inventory, and notify the U.S. NAC of PIM samples transferred to other facilities. If poliovirus is detected in a PIM sample, the material will be considered poliovirus infectious material and may be subject to enhanced containment requirements.**

A U.S. non-facility associated paralytic VDPV type 2 case was identified in a person in Rockland County, New York in July 2022. Vaccine-derived poliovirus type 2 has been detected in subsequent local wastewater samples from multiple counties in the surrounding geographical area. The polioviruses identified from the New York paralytic VDPV type 2 case and wastewater samples meet WHO's criteria for circulating VDPV. This U.S. NAC document 1) provides guidance for non-laboratory facilities tasked with collecting, handling, storing, and transporting VDPV PIM and 2) outlines risk mitigations to contain and protect non-laboratory facilities and personnel, environment, and public from infection, contamination, and transmission. The risk mitigations should be employed while the non-laboratory facility is in possession of PIM.

Risk Mitigations

Non-laboratory facilities in the U.S. should implement the following measures, as appropriate, to mitigate the risks to personnel collecting, handling, storing and/or transporting VDPV PIM. This includes wastewater workers exposed to wastewater at the treatment facility during routine treatment operations and maintenance activities, workers exposed to wastewater during routing collections system operations and maintenance, and septage haulers exposed to septage during collection, hauling, and dumping.

Polio Immunization

Non-laboratory facilities should assess the polio vaccination status of personnel collecting and handling PIM and offer vaccination or adult boosters in accordance with Advisory Committee on Immunization Practice recommendations, when indicated.

Safety Precautions

Non-laboratory facilities should employ safety precautions (*e.g.,* PPE, training, handwashing, waste disposal) for all activities associated with PIM collection, handling, storage, and transport. Each non-laboratory facility should determine the necessary precautions, based on the facility type (*e.g,* healthcare, wastewater) or sample type *(e.g.,* respiratory). Personnel should receive training on non-laboratory facility precautions per their institutional policy.

Personal Protective Equipment (PPE)

In addition to the PPE recommendations included in the facility and sample type precautions, non-laboratory facilities should consider the following PPE recommendations below.

Gloves

Personnel should wear gloves to protect hands and reduce exposure to fluid leakage while handling PIM. Personnel should change gloves when the gloves are suspected or known to be contaminated, glove integrity is compromised, or when otherwise necessary. Non-laboratory facilities should consider waterproof gloves for specific PIM collection (e.g., untreated wastewater).

Surgical Mask

Personnel should wear surgical masks to provide oral mucous membrane protection when handling poliovirus PIM to mitigate oral transmission, the most common pathway to transmit PV. Surgical masks are not necessary if personnel are wearing face shields.

Clothing

Personnel should wear protective clothing when collecting, handling, or working with PIM to prevent personal clothes from contamination. Non-laboratory facilities should consider the following options to wear over street clothes.

- Liquid-repellent coveralls (*e.g.,* Tyvek® [5]) (*i.e.,* wastewater setting)
- Liquid-repellent solid front gown (*e.g.,* disposable wrap-around gown) (*i.e.*, healthcare setting)

Foot Protection

Personnel should wear specialized footwear (*e.g.,* safety shoes, rubber boots) or shoe covers to prevent

[5] Use of trade names and commercial sources is for identification only and does not imply endorsement by the Centers for Disease Control and Prevention, the Public Health Service, or the U.S. Department of Health and Human Services.

shoe contamination, depending on facility risk assessment to determine foot protection need.

Eye and Face Protection

Personnel should wear eye and face protection (*e.g.,* goggles, mask, face shield or other splatter guard) for anticipated splashes or sprays.

Putting On and Removing PPE

Non-laboratory facilities should put on (*i.e.,* donning) and remove (*i.e.,* doffing) PPE in an order that minimizes the transfer of poliovirus. Each facility should determine their sequence, depending on the PPE used by personnel. The U.S. NAC has provided an example of each below.

Example order for putting on PPE:

1. Coverall/gown and booties
2. Surgical mask
3. Eye protection
4. Gloves

Example order for removing PPE

1. Disinfect PPE surfaces, including gloves, using a validated method (e.g., 20% bleach final concentration [6] [iv]). To prevent potential corrosion of sensitive surfaces (*i.e.* stainless steel) and/or equipment, non-laboratory facilities should consider wiping the bleached area with water afterward [7].
2. Remove body PPE (coverall/gown and shoe covers) and discard into biohazardous solid waste
3. Remove disposable face shield/safety glasses and discard into biohazardous solid waste. Reusable face shield/safety glasses should be decontaminated using a validated method (*e.g.* 20% bleach final concentration).
4. Remove surgical mask and discard into biohazardous solid waste
5. Remove gloves and discard into biohazardous solid waste
6. Wash hands with soap and water

PPE Decontamination and Disposal

Non-laboratory facilities should dispose of used disposable PPE as biohazardous solid waste, if available. If not, non-laboratory facilities should chemically treat PPE using a validated method before disposal (*e.g.,* 20% bleach final concentration [iv]). Reusable PPE should be decontaminated using a validated method (*e.g.,* 20% bleach final concentration [iv]) before storage and reuse. The U.S. NAC recommends the use of an autoclave to inactivate waste for disposal, if available and necessary.

[6] Undiluted bleach contains 52,500-61,500 ppm sodium hypochlorite. Facilities should make a solution of 1-part bleach to 4-parts water to ensure 10,000 ppm is the final concentration. Due to poliovirus resistance to decontamination methods, the percentage of bleach is double the amount used traditionally by many laboratory and non-laboratory facilities. Please see reference for additional information.

[7] For situations requiring rapid surface drying, non-laboratory facilities may wipe down the area with 70% ethanol following the water wipe down.

Handwashing

Following removal and disposal of PPE, and before and after eating, drinking, smoking, and toileting, personnel should wash their hands with soap and water at the nearest sink. If a sink is unavailable, personnel can disinfect their hands using an alcohol-based sanitizer before washing hands at the next available sink. Note that hand sanitizer is not completely effective against poliovirus and should not be considered a substitute to handwashing [v,vi,vii].

Sample Handling and Processing

Sample collection

Personnel at non-laboratory facilities should collect samples while wearing PPE needed to perform the assigned task. Personnel should follow procedures to prevent splashes or spills that could contaminate the outside of the container, work surfaces, transport packages, individuals, or environment. Facilities should decontaminate the surface of all sample containers, packaging, and work surfaces using a validated method (*e.g.,* 20% bleach final concentration [iv]) after completing collection. Non-laboratory facilities collecting respiratory samples should review the CDC guidelines for collecting COVID-19 samples.

Primary containment

If available, personnel at non-laboratory facilities should use primary containment (*i.e.,* certified biosafety cabinet (BSC)) to open sample containers and process PIM samples, especially damaged or improperly sealed containers and while performing procedures with samples that could produce sprays or splashes. Regardless of BSC availability, personnel should wear PPE identified by the non-laboratory facility, as determined by risk assessment, and decontaminate the work area after work is complete.

Centrifugation

If available, non-laboratory facilities should use safety cups or sealed rotors when using a centrifuge to concentrate or filtrate collected material (*e.g.,* unconcentrated sewage). Splashes, spills, and leaks that occur when centrifuging PIM could contaminate the environment and potentially expose individuals to poliovirus. Personnel should decontaminate the work area after work is complete. Safety cups and sealed rotors should be opened in primary containment, if possible, or ensure additional PPE is provided based on risk assessment.

Filtration

If a non-laboratory facility filtrates PIM by vacuum or syringe, personnel should wear PPE in anticipation of splashes or spills. After work is complete, personnel should decontaminate the work area, equipment (*e.g.,* vacuum manifold) and either destroy or dispose waste and unneeded PIM, as described below.

Decontaminate work surfaces and waste using validated methods

Non-laboratory facilities should decontaminate work surfaces, materials, and equipment used for PIM handling and processing, using methods validated to inactivate poliovirus (*e.g.,* 20% bleach final concentration [iv]). Additionally, non-laboratory facilities should chemically treat liquid and solid (*e.g.,* contaminated containers, vials, PPE) PIM waste using a validated method (*e.g.,* 20% bleach final concentration [iv]) prior to disposal or return to the treatment train.

Segregate PIM from other materials

To prevent cross-contamination or misidentification, non-laboratory facilities should segregate PIM from other materials when storing PIM in refrigerators and freezers. Facilities can segregate PIM by storing PIM in separate clearly labeled boxes, racks, or shelves.

Transport

Procedures for transport within a facility should include leak-proof secondary containers (if possible), gloves and handwashing. Procedures for transports outside the facility should be in accordance with applicable local, state, federal, and international shipping laws (*i.e.,* Category B for PIM). Facilities must notify the U.S. NAC of a transfer prior to a shipment and complete the U.S. NAC Transfer form after the transfer is complete. (Refer to U.S. NAC *Policy for U.S. Facilities to Transfer Poliovirus*) Non-laboratory facilities should follow CDC guidelines when submitting samples to CDC for testing.

Destruction

Non-laboratory facilities should destroy unneeded or nonessential PIM using a validated method (*e.g.,* 20% bleach final concentration [iv] or return to start of the wastewater treatment train). Once destroyed, solid PIM can be disposed of in conventional trash and liquid PIM can be flushed down the sink, allowing the faucet to run for several minutes to dilute the bleach.

Limit access to PIM

Non-laboratory facilities should implement measures to ensure access to VDPV PIM is limited only personnel needing to access PIM. These facilities may limit access to PIM work, storage areas and units through various security measures (*e.g.,* passwords, keys, security badges). If available, facilities can lock storage units containing PIM (*e.g.,* refrigerators, freezers) using a padlock, combination lock or other unique means to lock the unit.

Inventory

Non-laboratory facilities should maintain current inventories and report all PIM samples possessed for 30 or more days to the U.S. NAC as described above. Inventory records should include material characteristics such as date of collection, current location, and date and method of final disposition (*e.g.,* transfer, destruction, consumption). Once samples have been processed or tested, non-laboratory facilities should destroy unneeded samples using a validated method (*e.g.*, 20% bleach final concentration [iv], autoclave, or return to start of wastewater treatment train), as applicable, or transfer medically important samples to a PEF. Please contact the U.S. NAC for assistance in transferring materials to a PEF.

Training

Non-laboratory facilities should train personnel on the procedures designed to mitigate risks associated with collecting, storing, handling, and transporting VDPV PIM including PPE, specimen handling and processing, decontamination and disposal, and storage.

Inactivate PIM for Experimental Use Using Validated Methods

U.S. non-laboratory facilities using PIM in experimental procedures (*e.g.,* polymerase chain reaction) should implement methods known to inactivate PV to prepare PIM samples for use. Non-laboratory facilities may find validated inactivation methods in peer-reviewed journals or protocols (*e.g.,* Global Poliovirus Laboratory Network protocols).

Nucleic Acids

As some nucleic acid extraction kits do not inactivate poliovirus effectively,
U.S. non-laboratory facility procedures for extracting nucleic acids from PIM should include these applications validated to inactivate PV. [viii]

- Use at least 4M guanidine thiocyanate (GuSCN) and a 20% final ethanol (ETOH) concentration for a 30-minute incubation following the lysis buffer step for kits using GuSCN.
- Incubate the nucleic acid preparation using a final concentration of at least 90% ETOH for 30 minutes, if the nucleic acids have been extracted already.

For a list of nucleic acid extraction kits tested and additional information on poliovirus inactivation, please see the U.S. NAC *Policy for U.S. Facilities to Inactivate Poliovirus Materials* or contact the U.S. NAC.

Resources

Non-laboratory facilities handling human waste or sewage should consult the EPA Wastewater Sampling and CDC Guidance for Reducing Health Risks to Workers Handling Human Waste or Sewage documents to supplement the guidance provided herein. Non-laboratory facilities collecting respiratory samples should review the CDC Interim Guidelines for Collecting and Handling of Clinical Specimens for COVID-19 Testing.

References

[i] WHO-Global-Action-Plan-for-Poliovirus-Containment-GAPIV.pdf (polioeradication.org)

[ii] National Wastewater Surveillance System (cdc.gov)

[iii] What is Polio? (cdc.gov)

[iv] Chiossone C, Fanuel S, Gedge LM, Nims RW, Suchmann DB, Zhou SS. Inactivation and Disinfection of Poliovirus Type 1 on Nonporous Carriers. Adv Biotech & Micro. 2018 Jul;9(5): 555773.

[v] Mbithi JN, Springthorpe VS, Sattar SA. Comparative in vivo efficiencies of hand-washing agents against hepatitis A virus (HM-175) and poliovirus type 1 (Sabin). Appl Environ Microbiol. 1993 Oct;59(10):3463-9.

[vi] Schürmann W, Eggers HJ. An experimental study on the epidemiology of enteroviruses: water and soap washing of poliovirus 1--contaminated hands, its effectiveness and kinetics. Med Microbiol Immunol. 1985;174(5):221-36.

[vii] Yuxin Su, Jie Han, Jie Li, Zhe Ren, Liuyu Huang, Binjie Xu, Qiuhua Wei. Resistance of poliovirus 1 and enterovirus A71 against alcohol and other disinfectants. J Virol Methods. 2021 Dec;298:114292.

[viii] Honeywood, MJ, Jeffries-Miles S, Wong K, Harrington C, Burns CC, Oberste MS, Bowen MD, Vega E. Use of guanidine thiocyanate-based nucleic acid extraction buffers to inactivate poliovirus in potentially infectious materials. J Virol Methods. 2021 Nov;297:114262.