

Public health management of

facility-related exposure to live polioviruses >>>

Guidance in managing exposed persons for countries hosting facilities that maintain live polioviruses

July 2020





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> Abbreviations

AFP	Acute flaccid paralysis
bOPV	Bivalent oral polio vaccine
GAPIII	Global Action Plan to minimize poliovirus facility-associated risk after type-specific
	eradication of wild polioviruses and sequential cessation of oral polio vaccine use
GCC	Global Commission for the Certification of the Eradication of Poliomyelitis
GPLN	Global Polio Laboratory Network
IHR	International Health Regulations (2005)
IPV	Inactivated polio vaccine
mOPV2	Monovalent oral polio vaccine type 2
NAC	National authority for containment
NFP	National IHR Focal Point
NPL	National Polio Laboratory
OPV	Oral polio vaccine
OPV2	Oral polio vaccine type 2
PEESP	Polio Eradication & Endgame Strategic Plan
PEF	Poliovirus-essential facility
PIM	Potentially infectious material for poliovirus
PPE	Personal protective equipment
PV	Poliovirus
PV1, 2, 3	Poliovirus types 1, 2, 3
RT-PCR	Reverse transcription polymerase chain reaction
SL	Sabin or Sabin-like poliovirus
SL1, 2, 3	Sabin or Sabin-like poliovirus types 1, 2, 3
UNICEF	United Nations Children's Fund
VDPV	Vaccine-derived poliovirus
VDPV2	Vaccine-derived poliovirus type 2
WHO	World Health Organization
WPV	Wild poliovirus
WPV1, 2, 3	Wild poliovirus types 1, 2, 3

Abbreviations

> Preface

The containment of polioviruses is an evolving area of work in polio eradication that has become particularly critical since the declaration in 2015 of the eradication of wild poliovirus type 2 (WPV2) and the global withdrawal of the oral polio vaccine type 2 (OPV2) component from routine polio immunization in 2016. Wild poliovirus type 3 (WPV3) was also declared eradicated, in 2019, and in the future so too will wild poliovirus type 1 (WPV1), meaning that the scope of poliovirus containment will expand. This guidance was developed by the Polio Eradication Department of the World Health Organization, Geneva, Switzerland, based on expert opinion and scientific principles. It aims to assist countries faced with a containment breach, but may be adapted according to the situation and country context, especially the legal context. As knowledge and experience may grow, this guidance may need to be reviewed and updated. Many experts provided input and feedback on this guidance, including experts from polio laboratories, national authorities for containment, public health agencies within WHO Member States and other stakeholders.

This guidance was endorsed by the Global Commission for the Certification of the Eradication of Poliomyelitis on 18 October 2019 following a six-month period of public consultation. The Global Commission for Certification consists of the chairpersons of the six WHO regional certification commissions and is the peak oversight body for the certification of poliovirus containment.

> 1. Background

The eradication of all wild polioviruses (WPV) is approaching. Wild poliovirus type 2 (WPV2) was declared eradicated in 2015 by the Global Commission for the Certification of the Eradication of Poliomyelitis (GCC), wild poliovirus type 3 (WPV3) was declared eradicated in October 2019, and wild poliovirus type 1 (WPV1) has only been detected in three countries since 2015: Afghanistan, Pakistan and Nigeria.

Under the Polio Eradication & Endgame Strategic Plan (PEESP) 2013–2018, endorsed by the World Health Assembly, once all WPV transmission has ceased, the use of oral polio vaccines (OPV) containing attenuated live Sabin viruses will cease. This is taking place in a staged manner, commencing with poliovirus type 2 (PV2). The eradication of WPV2 made it possible to withdraw the type 2 component from OPV from immunization programmes in 2016, to reduce the likelihood of vaccine-derived poliovirus (VDPV) emerging, particularly in areas of poor population immunity.

The safe containment of eradicated polioviruses (PVs) is a key objective of the PEESP 2019–2023. This objective aims to ensure that all unneeded PV stocks are destroyed. Where necessary for a critical national or international function,¹ such as vaccine production, surveillance and research, PVs must be safely and securely contained to minimize the risk of their reintroduction into the population and consequently of the re-emergence of poliomyelitis. 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)² describes the necessary conditions for the containment of needed stocks in poliovirus-essential facilities (PEFs)³.

³ A facility designated by the ministry of health or another designated national body or authority as serving critical national or international functions that involve the handling and storage of needed PV infectious materials or potentially infectious materials under conditions set out in GAPIII.



¹ Including Salk inactivated polio vaccine (IPV) and Sabin IPV production, the development and storage of OPV stockpiles, vaccine quality assurance, diagnostic reagent production, virus diagnostic and reference functions, and crucial research.

² GAPIII: WHO Global Action Plan to minimize poliovirus facility-associated risk after type-specific eradication of wild polioviruses and sequential cessation of oral polio vaccine use, Third edition. Geneva: World Health Organization; 2015 (http://polioeradication.org/wp-content/uploads/2016/12/GAPIII_2014.pdf, accessed 27 July 2020).

A facility-associated PV infection or release into the environment during the period following eradication use would be a significant public health event with international implications.

This guidance is based on a risk management approach for biological emergencies that recognizes that:

- a PV release or containment breach will occur infrequently;
- the potential public health impact may be very high;
- the evidence base for decision-making is limited and evolving; and
- community concern about a facility breach may be disproportionate to the level of risk.

> 2. Purpose of this guidance

This guidance has been prepared primarily for public health authorities in countries hosting a PEF, to provide direction for response to a human exposure or infection related to a known spill or breach of containment involving any PV, whether a WPV, VDPV or Sabin or Sabin-like poliovirus (SL), from any PEF. The paradigm assumed in the development of this guidance is that the recommended stringent measures are justified in relation to an eradicated or soon to be eradicated pathogen, insofar that every relevant public health measure should be taken to reduce the risk as far as possible that an exposure results in re-established community transmission. Given the very large financial and human resources (including deaths of polio vaccination workers) invested in WPV eradication, and the risk of reversal of progress caused by an accidental exposure or containment breach, the stringent isolation of exposed or infected individuals and the quarantine of at-risk contacts are considered justified and proportionate to this risk.

This guidance could also be useful for public health authorities in any other country where a human has been exposed to a PV resulting from a spill in a laboratory or other setting where PVs are stored or handled. It is not intended to provide guidance to countries where natural exposure has occurred to a PV that is still circulating in the community in that country (or another country with a PV importation).

A country's application of these measures will depend heavily on its regulatory framework regarding biological hazards. As a matter of legal preparedness, countries that plan to host a PEF should review whether their public health legislation is sufficient to mandate the isolation of a person known or suspected to be infected with an eradicated organism to prevent them from transmitting the infection and thereby becoming a risk to public health. Another prerequisite is access to the recommended diagnostic testing, which should be in a Global Polio Laboratory Network (GPLN) accredited laboratory, preferably within the country, as, in the future, the international transport of eradicated PVs may become subject to stricter regulations. Where the arrangements for the implementation of this guidance are lacking, measures should be taken to address the gaps or, alternatively, to reconsider the wisdom or value of hosting a PEF. Furthermore, legal preparedness should include planning for instances of non-compliance, such as when an infected person refuses or evades proper isolation. Appropriate sanctions will need to be applied, proportionate to the risk involved.

PEFs may wish to consider including provisions in their terms of employment about the possible need for the isolation of employees exposed to PV and also consider including aspects of this guidance in staff orientation and training programmes.

> 3. Definitions

A PV exposure is considered to occur when a human comes into direct contact with a PV, through ingestion, inhalation or skin contact (skin contact that is limited and immediately identified and subject to appropriate washing may be considered not to be a PV exposure). For contained PV, this may result in a breach of containment if it causes the virus to no longer be confined within the defined, controlled space that is considered the containment zone. GAPIII requires primary safeguards (to prevent infection and the release of contaminated materials from a PEF), secondary safeguards (such as population immunity in the country hosting the facility) and tertiary safeguards (such as domestic and environmental hygiene standards) to be in place for containment.

The probability of recognizing that a PV exposure has occurred will depend on several key factors, such as:

- whether the virus is neuropathic (WPV and VDPV) and therefore paralysing or attenuated (SL);
- whether a known incident leading to PV exposure or a containment breach was identified at the time of its occurrence, or a presumed breach identified through either a human case or environmental isolation, implying delayed detection and response; and
- the volume and concentration of virus to which the person is exposed, with the highest potential risk being from facilities routinely working with larger volumes of viral material, such as vaccine manufacturers, to no or negligible risk in an exposure that involves, for example, potentially infectious material as defined in GAPIII.

In this document, a PV "exposure" is any facility accident that potentially exposes humans to any PV, whereas a PV "breach" refers specifically to a release from a PEF of a PV subject to containment, now or in the future, under GAPIII.

In keeping with the definitions used in the *International Health Regulations (2005)* (IHR),⁴ "isolation" in this document refers to the separation of infected or contaminated persons, i.e. the person who has been directly exposed to a PV, while "quarantine" refers to separation from their contacts, to preemptively remove the risk of further transmission. Notwithstanding the use of these terms, this document recognizes that some countries may have specific legal definitions and that the particular legal authority may be required to enforce isolation or quarantine.

⁴ International Health Regulations (2005), Third edition. Geneva: World Health Organization; 2016 (<u>https://apps.who.int/iris/</u> <u>bitstream/handle/10665/246107/9789241580496-eng.pdf?sequence=1</u>, accessed 28 July 2020).

> 4. Scope of the guidance

As stated earlier, the guidance is primarily aimed at countries hosting PEFs, but may be useful in other countries, depending on national regulations and the ability to implement the measures.

4.1 Scope of the event response

The scope of the response is limited to the initial public health management of a human exposure and/or infection due to a known accidental PV exposure, containment breach or intentional release, including the management of contacts. In some circumstances, the guidance may be applied where human infection is detected for which there is evidence that the infection occurred because of an unrecognized containment breach; for example, if WPV2 infection is detected in a worker at a PEF, even when no breach is known to have occurred, the response could follow this guidance if sustained transmission has not yet been identified.

In case of evidence or likelihood of sustained transmission, the relevant document is the standard operating procedures for outbreak management (see *Standard operating procedures: Responding to a poliovirus event or outbreak*)⁵.

For guidance on the diagnostic procedures to be used, the reference document is the GPLN Guidance Paper number 8 "Diagnostic procedures following accidental exposure to polioviruses", which can be found at <u>http://polioeradication.org/tools-and-library/policy-reports/gpln-publications</u>.

This guidance does not cover the environmental management or "clean-up" of a spill within a facility. However, at the country and facility levels, this guidance should be implemented and linked to the preparedness plan and emergency protocol set up by the facility in case of an accidental or intentional PV release that occurs inside the facility. This guidance elaborates on aspects of GAPIII biorisk management elements 9 (health care), 10 (emergency response and contingency planning) and 11 (accident/incident investigation) in GAPIII Annexes 2 and 3.

⁵ Standard operating procedures: Responding to a poliovirus event or outbreak, version 3.1. Geneva: World Health Organization; 2020, <u>http://polioeradication.org/wp-content/uploads/2020/04/POL-SOP-V3.1-20200424.pdf</u>, accessed 30 July 2020).



4.2 Virological scope

The measures in this guidance must be applied to all PVs that are required to be contained in a PEF according to the implementation phases of GAPIII. As of October 2019, this is limited to PV2 but in the future will also apply to poliovirus types 1 and 3 (PV1 and PV3). Nevertheless, depending on national policies, it is recommended that this guidance also be applied for exposures to other PVs, particularly WPVs and VDPVs, as outlined below.

PV2

WPV2 and vaccine-derived poliovirus type 2 (VDPV2) are currently subject to containment in PEFs as agreed by the World Health Assembly. The most stringent measures in these guidelines are applied to exposures or infections, or containment breaches, involving any WPV2, as an eradicated organism. In most circumstances, exposures, infections or containment breaches involving VDPV2 will be considered the same as for WPV2, but further discussion might be necessary if the circulation of VDPV2 is already ongoing in the country. Similarly, in many countries, stringent measures should be applied to Sabin or Sabin-like poliovirus type 2 (SL2) as well, as global completion of Phase I (inventory, destruction and preparation for the containment of PV2) of GAPIII approaches. However, if monovalent oral polio vaccine type 2 (mOPV2) has been used in the country because of an outbreak of circulating vaccine-derived PV2, an event involving SL2 may not require implementation of this guidance, depending on the risk assessment that considers the geographic scope and time since the use of mOPV2.

Globally, as population intestinal immunity to PV2 wanes in previously OPV2-using countries where the inactivated polio vaccine (IPV) coverage is suboptimal, and as the size of the cohort of children born after the trivalent oral polio vaccine to bivalent oral polio vaccine (bOPV) switch increases, the risk of a rapidly evolving PV2 outbreak increases if a containment breach results in community transmission.

This guidance may also be applied to unexpected situations where exposure to PV2 has occurred outside a PEF, such as in a polio diagnostic lab, where a sample had leaked or been incorrectly packaged and opened outside of a biosafety cabinet and subsequently found to contain PV2.

PV1 and PV3

WPV1 and WPV3 will be required to be contained according to GAPIII once transmission has ceased and prior to global certification of WPV eradication. The measures in this guidance are recommended to be applied also during any spill or release that threatens global polio eradication. For example, as WPV3 was declared eradicated on 24 October 2019, any spill or release involving WPV3 also requires a vigorous response, as the re-establishment of WPV3 circulation would be a major setback to polio eradication. Similarly, releases involving WPV1 in non-endemic countries should also result in a vigorous response. These measures do not apply to spills or releases of Sabin or Sabin-like poliovirus types 1 or 3 (SL1 or SL3) at this time, as these viruses are common globally due to widespread use of bOPV; the measures will apply to these viruses after OPV cessation and the final containment of all PVs.

Potentially infectious material

Faecal, respiratory, concentrated sewage samples or derivatives of such samples may be potentially infectious for PV if they have been stored under conditions that maintain the viability of PV. If these samples were collected in a place and at a time when WPV or VDPV was in circulation, they are WPV/VDPV potentially infectious material (PIM) and are subject to the full containment described in GAPIII, Annex 2, and will need to be stored and handled in a PEF. If WPV/VDPV were not in circulation, but OPV was in use, these samples are OPV/Sabin PIM and may only be handled outside a PEF under certain conditions, described in the *Guidance for non-poliovirus facilities to minimize risk of sample collections potentially infectious for polioviruses.*⁶

⁶ Guidance for non-poliovirus facilities to minimize risk of sample collections potentially infectious for polioviruses. Geneva: World Health Organization; 2018 (<u>http://polioeradication.org/wp-content/uploads/2018/04/polio-containment-guidance-for-non-poliovirus-facilities-20180410-en.pdf</u>, accessed 30 July 2020).



4.3 Exclusions

The measures in this guidance may or may not apply to PV exposures in countries or subnational areas where the particular virus that has been released or spilled is already circulating or presumed to be circulating. The polio status of countries can be found on the WHO Global Polio Eradication Initiative website in the Outbreak Countries section (see http://polioeradication.org/where-we-work/polio-outbreak-countries).

For example, in Pakistan, which is WPV1 endemic, a hypothetical release of WPV2 (or WPV3 as mentioned above) from a PEF in the country would be managed according to this guidance, whereas a release of WPV1 would be managed according to existing national protocols.

A containment breach involving SL2 in any country that has used mOPV2 in the preceding 12 months may possibly be excluded from implementation of these measures, depending on the risk assessment that considers the geographic scope of the mOPV2 use.

Where a breach involves multiple PVs, the response should be according to the virus that has been assessed as the highest risk to public health (see section 8 below).

> 5. Roles and responsibilities

5.1 Target audience of this guidance

The target groups for this guidance are those who will implement the measures, including:

- national and subnational and/or local public health authorities, and any other health agency under their jurisdiction, including health centres, hospitals or quarantine centres;
- any facilities handling PV and their designated biosafety officer, management and occupational health staff;
- the national authority for containment (NAC) where one exists; and
- diagnostic laboratories aware of the guidance that apply the associated GPLN guidance on the same issue (refer to section 4.1).

Other audiences that may need to be aware of the guidance include:

- other government agencies, such as environmental management, laboratory regulators, etc.; and
- WHO regional offices and country offices.

5.2 Roles

The roles and responsibilities may vary according to the structure and legislative powers of the country but in general are the following:

- National public health authority: reporting to WHO (see below), national coordination of an event, declaration of national public health emergency (if required), PV event response planning (including ensuring the response to a containment breach is included in the polio outbreak response plan, testing the plan, and overseeing public health legislation in terms of isolation and quarantine powers);
- Subnational and/or local public health authority, in cooperation with the national public health authority: implementation of the measures (including isolating exposed and infected persons, quarantining contacts, incorporating a containment breach in the local response planning if a PEF is located in the area, and declaring a subnational public health emergency), and specimen collection and transport to a GPLN accredited laboratory according to WHO regulations for the transport of specimens and infectious substances⁷;



⁷ Guidance on regulations for the transport of infectious substances 2019–2020. Geneva: World Health Organization; 2019 (<u>https://apps.who.int/iris/bitstream/handle/10665/325884/WHO-WHE-CPI-2019.20-eng.pdf?ua=1</u>, accessed 29 July 2020).

- NACs in countries hosting PEFs: certification of a PEF, investigation of breaches, reassessment of PEF certification status, recertification of a PEF (if applicable and appropriate) and oversight of the re-establishment of containment;
- GPLN accredited laboratory, preferably within the country: sample receipt and testing;
- WHO: receipt of notification, communication with Member States as necessary, assessment of the risk of transmission and impact on the certification of polio-free status, where applicable, and technical assistance and support as required; and
- Regional certification commission/GCC: review of breach events and their consequences in light of the impact on the polio-free status of the WHO region concerned.

5.3 Reporting

The IHR provide the legal framework for reporting public health events involving PVs.

Cases or environmental detection (WPV, VDPV, SL2)

According to Annex 2 of the IHR, the National IHR Focal Point (NFP) must notify the WHO regional contact point under the IHR immediately of any case of polio due to WPV (normally no later than 24 hours after detection of the event). As per the IHR case definition,⁸ this requirement extends to any VDPV case or VDPV environmental detection and, since global OPV2 withdrawal in 2016, to any SL2 viruses in humans or the environment.

Spills, releases or breaches (without known or demonstrated human transmission or environmental contamination)

⁸ Case definitions for the four diseases requiring notification in all circumstances under the International Health Regulations (2005). Geneva: World Health Organization (<u>http://www.who.int/ihr/Case_Definitions.pdf, accessed 28 July 2020</u>).

PV2

Because WPV2 has been eradicated, OPV2 has been withdrawn and all PV2 is currently being targeted for destruction, transfer or containment in a secure PEF, any PV2 exposure or breach should also be regarded as a notifiable event that may constitute a public health emergency of international concern (PHEIC) according to Annex 2 of the IHR. It must therefore be notified by the NFP to the WHO regional contact.

PV1 and PV3

Spills or releases involving PV1 or PV3 should also be notified according to Annex 2 of the IHR, if the event meets at least two of the following criteria:

- 1) The event's public health impact is serious.
- 2) The event is unusual or unexpected.
- 3) The risk of international spread is significant.
- 4) The risk of international travel or trade restrictions is significant.

Annex 2 of the IHR provides further advice on the interpretation of these criteria. In general, any containment breach involving WPV/VDPV types 1 and 3 should also be notified to WHO.

When a facility identifies a breach at the time it is occurring, it is the facility management's responsibility to immediately (as soon as possible, and no later than 24 hours) inform the appropriate public health authority in the country of the breach event. The communication channel put in place should be clearly set out in the facility's emergency response and contingency plan and involve any relevant level of government or administrative authority. It is then the responsibility of the national public health authority to notify WHO via the NFP as per normal arrangements under the IHR.

The WHO secretariat will inform the GCC.

5.4 Event management and coordination

The formation of a single incident management team under the appropriate authority and with welldefined roles and responsibilities is strongly advised, as all parties must coordinate these efforts strongly to avoid overlap, gaps or conflicting efforts.

At the national level, this guide's overall implementation is the responsibility of the national public health authorities, including managing any cases, contacts or environmental contamination and enhanced surveillance. The national protocol should outline the role of local, regional and national public health authorities in each aspect of the investigation, response and control strategies.

The PEF management is responsible for the immediate institutional response to the breach, following its emergency response and contingency plan required under GAPIII, such as providing first aid or decontaminating exposed workers or visitors, and applying any longer-term rectification steps required, including corrective and preventative measures.

The NAC, where one is established, is primarily responsible for overseeing the investigation of root causes leading to the breach and deciding in collaboration with the GCC if the facility's certification should be suspended or withdrawn. If the event triggers an audit of the facility, the GCC may request that an independent auditor join the national audit team.

For any breach notifiable under the IHR, WHO must be informed and involved in the response as per the relevant articles of the IHR (IHR PART II – Information and public health response).

> 6. Overview of control strategies

Control strategies in this guidance are based on standard measures for polio cases, stratified by assessed risk level and augmented to take into account that WPV2 and WPV3 are eradicated pathogens, and that all PV2 is currently in the process of containment, destruction or transfer to containment facilities.

The main components or strategies used to respond to a breach of containment and prevent the potential establishment of further transmission include risk assessment, isolation of exposed persons and quarantine of their contacts, stool and throat sample analyses to assess PV shedding, infection control and disinfection, targeted vaccination and the intensification of surveillance. As previously stated in this document and consistent with the IHR, isolation refers to the management of exposed/infected persons, while quarantine applies to their contacts.

Critical factors affecting the success of the response will be the timeliness of:

- the recognition and reporting of the incident (section 5);
- a thorough but prompt risk assessment of the containment breach (section 8);
- the identification of the source or cause, a root cause analysis of the breach and its rectification, including the prevention of recurrence (GAPIII);
- the identification of all PV-exposed or infected persons and their isolation where indicated (section 9);
- contact tracing and quarantine where indicated (section 9); and
- testing⁹ for PV shedding and the vaccination of exposed persons and their contacts (section 9).

The Global Polio Eradication Initiative has supported the development of antiviral agents to clear prolonged or chronic PV infection among individuals with primary immunodeficiency disorders, for post-exposure prophylaxis, and potentially for outbreak control. An antiviral agent may also be available in the future for post-exposure prophylaxis for people exposed to PV, under an investigational new drug protocol.

⁹ In vaccinated persons, oral PV excretion is rare but should be included in testing because it has implications for the isolation and quarantine measures used (i.e. whether droplet precautions are also needed).

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> 7. Ethical considerations

Given the high cost of polio eradication, including considerable human resources and finances and the personal sacrifices and danger many workers and volunteers face in achieving eradication, the ethical imperative to maintain PV containment well into the future and to respond vigorously to any breaches is enormous. GAPIII and the Containment Certification Scheme aim to help prevent exposure to PVs after eradication, while this guidance aims to limit the consequences of any accidental exposure. Reducing the number of PEFs is a major path to reducing the risk of re-established transmission in the future.

The IHR in Article 3, Principles, states that "The implementation of these Regulations shall be with full respect for the dignity, human rights and fundamental freedoms of persons." Restrictions on the freedom of movement, such as isolation and quarantine, can impose a significant burden on individuals and communities, causing stress or tension. According to the WHO Guidance¹⁰, in the event of infectious disease outbreaks, these measures can be justified by the ethical value of protecting the community and public health, but should not be implemented without careful attention to the following considerations (reflected in Tables 1 and 2 in section 9):

- a) a justifiable evidence base for imposing restrictions;
- b) implementation in a manner that imposes the fewest constraints possible to reach the public health goal;
- c) humane conditions, e.g. access to basic necessities;
- d) the financial and social consequences for individuals;
- e) due process protections, with complaint and review mechanisms in place;
- f) an equitable and non-arbitrary application; and
- g) communication and transparency to enhance public trust and compliance.

The identity of the concerned individuals should only be shared on a need-to-know basis, i.e. it should not be released to the public, to avoid stigma and discrimination.

¹⁰ Guidance for managing ethical issues in infectious disease outbreaks. Geneva: World Health Organization; 2016 (<u>https://apps.who.int/iris/bitstream/handle/10665/250580/9789241549837-eng.pdf?sequence=1&isAllowed=y</u>, accessed 28 July 2020).

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7. Ethical considerations

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> 8. Risk assessment of the PV exposure

Recognizing that the risks of transmission and re-established circulation vary significantly according to the context and that the response needs to be proportionate and tailored according to the risk and potential impact, the following event risk stratification has been established. The stratification that places PV2 exposures at the highest level is based on the following facts:

- WPV2 and WPV3 are the only PVs that have been officially eradicated.
- Since OPV2 was withdrawn in 2016, type 2 population intestinal immunity is lower than for PV1 or PV3.
- IPV provides protection against polio disease but is less effective against intestinal infection, excretion, and therefore transmission.
- While WPV1 has been eliminated in most countries and WPV3 in all countries, the availability of bOPV means that population immunity is likely higher for PV1 and PV3 compared to PV2.

A risk assessment should be conducted by the relevant public health authority and ideally completed within 48 hours of a breach, to identify, for example, the following:

- characteristics of the breach (volume, concentration, potential or confirmed exposure of staff, site in facility or whether release outside the facility has occurred);
- the pathway of exposure (ingestion would be higher risk than dermal exposure);
- the use of adequate personal protective equipment (PPE) at the time of the breach, gowning and de-gowning and decontamination procedures;
- the time elapsed since the breach (if known);
- the immunization history of the exposed person(s) and their contacts;
- any travel history of the exposed person after the exposure, including within the local community;
- the immunity profile of the local population and areas of suboptimal vaccination coverage;
- any history of PV transmission in the community;
- any subpopulations at high risk, such as unimmunized close contacts or local under-immunized communities; and
- environmental risks that would heighten the concern for transmission.

Key facts about poliomyelitis are available in Arabic, Chinese, English, French, Russian and Spanish on the WHO website (<u>http://www.who.int/en/news-room/fact-sheets/detail/poliomyelitis</u>).

Very high risk

• Any containment breach or exposure anywhere involving WPV2 or VDPV2.

High risk

- Any exposure involving WPV1/VDPV type 1 or WPV3/VDPV type 3;
- Any exposure involving SL2, in a country or surrounding area (within a radius of 100 km) with inadequate type 2 immunity (less than 90% IPV coverage according to the respective national schedule¹¹) OR with lower access to basic or safely managed sanitation (less than 95% of the population as per WHO/UNICEF JMP data¹²).

Low risk

- Any exposure involving SL2 in a country and the surrounding area with adequate type 2 immunity (more than 90% IPV coverage) AND higher access to basic or safely managed sanitation (the converse of high risk described above);
- Any exposure involving WPV2/VDPV2 PIM.

Minimal risk

- Any exposure involving SL1 or SL3 material that is considered minimal risk and that is not considered within the scope of this guidance currently but that, following OPV cessation in the future, will need to be addressed in a future revision;
- Any exposure involving SL2 PIM.

¹¹ at the national level as per the most recent WHO–UNICEF estimates.

¹² World Health Organization/UNICEF: Joint Monitoring Programme (JMP) Data [website] (<u>https://washdata.org/data</u>, accessed 28 July 2020).

> 9. Management of PV-exposed persons and their at-risk contacts, including quarantine and isolation

9.1 Contact tracing

To limit the potential spread of PV, which is characterized by many asymptomatic infections, contact tracing undertaken by public health authorities is important to identify potentially infected individuals. Six categories of people must be urgently traced and tested as they may have had contact with the exposed persons (or their stools) and therefore may also be at risk of PV infection or transmitting the virus:

- a) Household contacts: people who lived with the exposed person and shared a toilet during the infectious period. These people, particularly children and the unimmunized, are at greatest risk as they may have had contact with the potentially infected person prior to the detection of the virus. Sexual contacts should be considered as a similar risk.
- b) Toilet contacts: other people (non-household contacts) who have shared a toilet with the exposed person during the infectious period, before the toilet was cleaned or disinfected, such as those sharing a toilet at the workplace and visitors to the home. These are especially relevant when the isolation of the exposed individual is delayed.
- c) Food consumer contacts: people who ate food prepared by the PV-exposed person.
- d) Facility first-aid workers or first responders: individuals who rendered assistance to the exposed person, without using PPE. Any personnel directly exposed should be regarded as potentially infected exposed persons, and managed accordingly.
- e) Health care workers: individuals who cared for the exposed person during the infectious period.
- f) Sewerage workers: although at very low risk, individuals who may also need to be considered in situations of proven infection, where a PV2-infected person was excreting into the general sewerage system prior to isolation and collection and incineration/inactivation of stools.

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To successfully prevent further spread, the tracing of contacts needs to be more rapid than the spread of the virus. Beyond household contacts, who may be at highest risk due to the extent and duration of exposure to an infected person, priority should be given to tracing and managing high-risk contacts, such as health care workers, food handlers and childcare workers, who have the potential to spread infection to many people. At-risk contacts need to be evaluated for immunization status, and educated on symptoms of PV infection and personal hygiene.

Contact tracing does not prevent a contact from becoming infected with PV, but stool sampling of household and incompletely vaccinated health care worker contacts (as outlined in Table 1) and increased surveillance for clinical symptoms such as acute flaccid paralysis (AFP) will identify the spread of the virus and prevent further transmission.

Contact tracing should be carried out while respecting the involved persons' confidentiality, and must be done equitably, avoiding actual or perceived discrimination.

9.2 Management of exposed and infected persons and their contacts

The management of exposed persons and their contacts is set out in Table 1. If testing detects infection during management activities listed in Table 1, then Table 2 applies, requiring the broader use of quarantine of at-risk contacts.

Activity	Low-risk event	Very-high-risk or high-risk event	
>>> Exposed person			
Isolation – location	At home	If possible and supported by a national/local legal framework, a hospital isolation room with a single bathroom if available should be considered for very- high-risk events, particularly if compliance with other control measures is likely to be low.	
		Otherwise, home isolation may be used. Public health workers should frequently monitor compliance to ensure strict isolation from household contacts, including separate toileting and bathroom, and stringent cleaning, disinfection and waste disposal. Stools must be collected and incinerated.	
Isolation – duration	Seven days if testing is negat	ive	
Specimen collection and transport to a	Stool specimens and throat swabs should be collected daily for the presence of PV for at least seven days.		
GPLN accredited laboratory	A baseline blood sample should be collected on the day of exposure and 15-21 days later, as per the GPLN guidance (see section 4.1).		
Management of faeces	General sewerage	Very-high-risk: Collected and incinerated or otherwise inactivated (see also section 10).	
		High-risk: Collected and incinerated or otherwise inactivated if the toilet is not connected to adequate wastewater management.	
Health care workers	Promote handwashing and good hygiene.	Appropriate barrier practices: enteric precautions using gowns and gloves;	
		Respiratory precautions may be required, if the person is unvaccinated, until throat specimens are shown to be negative.	
Cleaning and disinfection	Use household bleach or an appropriate equivalent (see section 11).	Enhanced cleaning and disinfection (see section 11).	
Waste disposal, including laboratory samples	Encourage good practices.	Should be treated as infectious.	
Food handling (for other people)	Not permitted.	Not permitted.	
Childcare (non- household)	Not permitted.	Not permitted.	
Visitors	Limit to close family/ friends/care providers with proven PV immunity or vaccination history; educate visitors regarding handwashing.	Limited to close family/friends/care providers with proven PV immunity or vaccination history, and monitored compliance. Visitors must take enteric precautions, so gloves and gowns should be provided for home visitors; droplet precautions may also be needed if the exposed person was unvaccinated.	

Table 1. Management of PV-exposed persons and their contacts



Activity	Low-risk event	Very-high-risk or high-risk event
>>> Contacts		
Household contacts	 No quarantine. Provide hygiene advice. Take two stool samples, 24 to 48 hours apart, starting three days after the contact's first exposure. Consider contacts to be negative only when two stool samples taken 24 to 48 hours apart are shown to be negative for PV. 	 Quarantine at home, using separate sanitation. Take two stool samples, 24 to 48 hours apart, starting three days after the contact's first exposure. Release contacts from quarantine only when two stool samples taken 24 to 48 hours apart are shown to be negative for PV.
Toilet contacts; Food consumer contacts; First-aid workers who did not use PPE	 No quarantine. Provide hygiene advice. Take two stool samples, 24 to 48 hours apart, starting three days after the contact's first exposure. Consider contacts to be negative only when two stool samples taken 24 to 48 hours apart are shown to be negative for PV. 	 Quarantine at home. Take two stool samples, 24 to 48 hours apart, starting three days after the contact's first exposure. Release contacts from quarantine only when two stool samples taken 24 to 48 hours apart are shown to be negative for PV.
Vaccination – all at- risk contactsTake and test a baseline serum sample prior to vaccination with a booster dos IPV or, if the vaccination status is unknown, offer a full course of IPV. Vaccination should not be delayed while waiting for the result of the antibody test.Vaccination –Encourage an assessment of community immunization coverage and enhancer		
community	j. IPV).	

If the testing of the exposed person and contacts results in the detection of proven PV infection, certain management activities are required and set out in Table 2. In essence, when PV infection is proven, quarantine may need to be employed more broadly.

Table 2. Subsequent management when testing of exposed persons or their contactsdemonstrate PV infection (not including SL1 or SL3)

Activity	SL2	WPV, VDPV	
>>> Case management			
Isolation – location	Home isolation with frequent monitoring is necessary to ensure that compliance with the control measures of the SL2-infected person and household contacts is high. Public health workers should check compliance with strict isolation from household contacts, including separate toileting and bathroom, and stringent cleaning, disinfection and waste disposal. Stools should be collected and incinerated or otherwise inactivated.	A hospital isolation room with a single bathroom and appropriate waste management is recommended.	
Isolation – duration	Until three negative stool samples are collected on three consecutive days		
Health care contacts	Appropriate barrier practices: enteric precautions using gowns and gloves; PPE should be properly disposed after use. In cases of individuals with proven WPV/VDPV infection who are symptomatic, or whose throat swabs are positive, droplet precautions should also be employed.		
Management of faeces	Faeces should be collected and incinerate section 10).	ed or otherwise inactivated (see also	
Cleaning and disinfection	Enhanced cleaning and disinfection are required (see section 11).		
Waste disposal	Waste should be treated as infectious.		
Food handling (for other people)	The handling of food is not permitted.		
Childcare (non- household)	The care of children is not permitted.		
Visitors	Visitors must be limited and, if allowed, restricted to close family/friends/care providers; only those with proven PV immunity or vaccination history may visit, but must take enteric precautions. If throat swabs are positive, droplet precautions are also required.		

Activity	SL2	WPV, VDPV		
>>> Contacts of the PV-infected person				
Household contacts	 Quarantine at home. Take two further stool samples, 24 to 48 hours apart, at least three days after the contact's most recent exposure. Release contacts from quarantine only when two stool samples taken 24 to 48 hours apart are shown to be negative for PV. 	 Quarantine at home, if not already implemented. Take two further stool samples, 24 to 48 hours apart, at least three days after the contact's most recent exposure. Release contacts from quarantine only when two stool samples taken 24 to 48 hours apart are shown to be negative for PV. 		
Toilet contacts; Food consumer contacts	 Quarantine at home. Take two further stool samples, 24 to 48 hours apart, at least three days after the contact's <u>most recent</u> exposure. Release contacts from quarantine only when two stool samples taken 24 to 48 hours apart are shown to be negative for PV. 	 Quarantine at home, if not already implemented. Take two further stool samples, 24 to 48 hours apart, at least three days after the contact's most recent exposure. Release contacts from quarantine only when two stool samples taken 24 to 48 hours apart are shown to be negative for PV. 		
Exposed sewage workers Vaccination – all at- risk contacts	 No quarantine. Take two stool samples, 24 to 48 hours apart, at least three days after the contact's most recent exposure. Considered the workers to be negative only when two stool samples taken 24 to 48 hours apart are shown to be negative for PV. Take and test a baseline serum sample prior to vaccination with a booster dose of IPV or, if the vaccination status is unknown, offer a full course of IPV. Vaccination should not be delayed while waiting for the result of the antibody test 			
Vaccination – community	Encourage a community assessment and enhancement of the routine immunization schedule (e.g. IPV).			

9.3 Avoiding and managing negative consequences

Every effort should be made to avoid causing financial or material loss to persons subject to quarantine and isolation and, where such loss is unavoidable, compensation should be awarded to the extent practicable.

A careful explanation of the rationale for isolation/quarantine should be given. Access to counselling should be made available.

Public health authorities should make every effort to prevent stigma that could be associated with quarantine and isolation. This might include avoiding donning PPE in front of the person's housing, avoiding using vehicles that are likely to draw attention to the fact that residents of the housing are subject to isolation/quarantine, and so on.

> 10. Sanitation

Faeces should be collected and incinerated or inactivated as per Tables 1 and 2.

An alternative in some situations may be the use of separate flush toilets or latrines that are not used by other individuals, provided that standard procedures for wastewater treatment are followed, including, at a minimum, on-site septic tank treatment with later controlled removal for further treatment.¹³ Containing the wastewater for a period of time prior to secondary biological treatment will allow the PV to die off naturally and will significantly reduce the concentration of virus, along with other pathogens, that may be found in the wastewater.

For subsequent wastewater management, all direct human contact with excreta should be avoided and full PPE should be worn by all workers. Such equipment includes heavy-duty rubber gloves, impermeable gowns, impermeable aprons, closed shoes (e.g. boots), facial protection (masks and goggles or face shields) and ideally a head cover. Workers should be properly trained in putting on, using and removing PPE so these protective barriers are maintained and not breached.

Regarding greywater or water from washing PPE, surfaces and other potentially contaminated objects, it is recommended to use chlorinated water (0.5% hypochlorite) to wash any reusable PPE, as well as surfaces that may have had contact with body fluids. This concentration of chlorine is sufficient to inactivate the PV in water that is relatively free of solids (less than 10 mg/L).

¹³ Environmental health in emergencies and disasters: A practical guide. Geneva: World Health Organization; 2002 (<u>http://www.who.int/water_sanitation_health/emergencies/emergencies2002/en</u>, accessed 27 July 2020).

11. Cleaning and disinfection at the hospital/home

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> 11. Cleaning and disinfection at the hospital/home

The proper cleaning and disinfecting of areas in contact with an infected individual are required to prevent onward transmission.¹⁴ The aim of cleaning is to remove soiling that may harbour and protect viral particles from disinfection. Effective disinfectants are those that contain free chlorine, such as sodium hypochlorite or bleach, glutaraldehyde solutions, formaldehyde solutions and iodophors. Contact time is also important in inactivating the virus.

Soiled linen should be safely disposed of, and any other laundry should be soaked in chlorine bleach (diluted according to the manufacturer's instructions) for at least 15 minutes.

Some common disinfectants such as 70% ethanol, isopropanol, Lysol and quaternary ammonium compounds are not effective against PV. The virus is also resistant to lipid solvents (such as Dettol) and is stable in many detergents at room temperature. For thermal inactivation, a temperature of 60°C for one hour, or 70°C for 10 minutes is required.

¹⁴ Lower temperatures and a high moisture content favour the survival of PV. Once excreted, the virus can survive outside the human body for weeks at room temperature. Laboratory studies have shown that PV survival in the environment is enhanced at high relative humidity. Interpolating data from various studies, Dowdle and Birmingham estimated PV infectivity to decrease by "90% every 20 days in winter and every 1.5 days in summer ... in sewage every 26 days at 23°C, in fresh water every 5.5 days at ambient temperatures, and in seawater every 2.5 days under the same conditions" (see Dowdle W, Birmingham M. The Biologic Principles of Poliovirus Eradication. J Infect Dis. 1997; 175(Suppl 1): S286–S292. doi: 10.1093/ infdis/175.Supplement_1.S286). PV survived on cotton fabric with minimal loss for 24 to 48 hours at ambient temperatures and 35% relative humidity, with rapid loss after 48 hours. PV survived longer on woollen fabrics with recovery after 20 weeks at the same humidity level.

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12. Enhanced surveillance

> 12. Enhanced surveillance

Surveillance needs to be intensified in the local area surrounding the facility where the breach occurred, and near the exposed person's residence, workplace or other epidemiologically important location.

- a) Alert diagnostic laboratories in the area to the possibility of PV being detected, and plan for referral of specimens to facilities with appropriate containment.
- b) Alert paediatricians and other clinicians about the need to participate in intensified surveillance for cases of AFP or clinical surveillance for suspected polio. Hospital records may need to be checked for AFP cases if the appropriate management of exposed persons and contacts has been delayed.
- c) Consider ad hoc limited duration environment surveillance around the exposed person's home and the PEF, in consultation with the WHO regional office. The selection of possible sampling points around a PEF should be carried out when planning the establishment of a PEF.

A laboratory surge plan may need to be activated. The number of specimens to be tested from contacts of the exposed persons can quickly increase. Nucleic acid amplification tests (reverse transcription polymerase chain reaction, RT-PCR) are more amenable to high throughput testing than virus culture, but these are not yet fully validated and implemented for direct stool testing. The National Polio Laboratory (NPL) should be in a position to provide public health authorities with test results, either at the NPL or by referral to a regional/global reference laboratory, keeping in mind that only designated PEFs can work with PV2 at this time, and this will also apply to PV1 and PV3 in the future. In consultation with key stakeholders, the public health response could be based on the RT-PCR testing of patient specimens with the timing of confirmatory virus culture dependent on the number of cases involved.

Ethical aspects of enhancing surveillance include:

- Protecting the confidentiality of personal information The unauthorized disclosure of personal information collected during an event (including name, address, diagnosis, family history, etc.) can expose individuals to significant risk. Countries should ensure that adequate protection exists against these risks, including laws that safeguard the confidentiality of information generated through surveillance activities and that strictly limit the circumstances in which such information may be used or disclosed for purposes different from those for which it was initially collected.
- Assessing the importance of universal participation Public health surveillance is typically conducted on a mandatory basis, without the possibility of individual refusal. Collecting surveillance information on a mandatory basis is ethically appropriate on the grounds of public interest if an accountable governmental authority has determined that universal participation is necessary to achieve compelling public health objectives. However, it should not be assumed that surveillance activities must always be carried out on a mandatory basis.
- Disclosing information to individuals and communities Regardless of whether individuals are given the choice to opt out of surveillance activities, the process of surveillance should be conducted on a transparent basis. At a minimum, individuals and communities should be aware of the type of information that will be gathered about them, the purposes for which this information will be used, and any circumstances under which the information collected may be shared with third parties. In addition, information about the outcome of the surveillance activity should be made available as soon as reasonably possible. Careful attention should be given to the manner in which this information is communicated, in order to minimize the risk that subjects of surveillance may face stigmatization or discrimination.

> 13. Education of health care workers and cleaning staff

As part of the control strategy, education will be essential. Health care workers need to be reminded of appropriate contact precautions, testing and immunization. Cleaning staff will need to be educated on appropriate cleaning agents and contact times as well as appropriate precautions, and will need to work closely with health care staff to ensure cleaning is effective.

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> 14. Communication strategy

A breach from a facility handling PV with exposure of persons or populations to an eradicated organism is likely to attract a great deal of media interest. A communication expert from the public health authority should be involved at the earliest stages of the response and spokespersons should be identified.

The communication strategy should ensure that accurate information is provided to the media and the community, as the release of inaccurate or premature information may have serious repercussions for the affected individual, their family, health care workers and their community. The potential for social media to spread rumours must be countered by the communication strategy. The identity of the exposed individual should be kept confidential as far as possible. The media may also be important to educate the public on the assessed risk, and the role of sanitation, handwashing and immunization in the response to the incident.

It is important for the media to be presented with up-to-date and factual information to minimize speculation and public concern. It is important for key stakeholders to have agreed on a national notification and communication strategy, and for ongoing coordination between parties to ensure consistency in messaging and approach.

Efforts should be made prior to the occurrence of any incident to engage the community in the risks associated with hosting a PEF. However, this engagement should be proportionate to the risks pertaining to the PEF and should avoid unnecessarily raising alarm or disquiet in the community. The following documents provide information on effective media communications during public health emergencies:

- Communicating risk in public health emergencies: A WHO guideline for emergency risk communication (ERC) policy and practice. Geneva: World Health Organization; 2017 (<u>http://www.who.int/risk-communication/guidance/download/en</u>);
- Effective Media Communication during Public Health Emergencies: WHO Field Guide. Geneva: World Health Organization; 2005

(http://www.who.int/csr/resources/publications/WHO_CDS_2005_31a/en).

> 15. Outbreak management and immunization campaigns

Where ongoing transmission of WPV/VDPV is occurring, i.e. when a breach event becomes an outbreak, an immunization campaign will need to be implemented urgently as per the standard operating procedures for outbreak management (see Standard operating procedures: Responding to a poliovirus event or outbreak).¹⁵

¹⁵ Standard operating procedures: Responding to a poliovirus event or outbreak, version 3.1. Geneva: World Health Organization; 2020, <u>http://polioeradication.org/wp-content/uploads/2020/04/POL-SOP-V3.1-20200424.pdf</u>, accessed 30 July 2020).

16. Post-action debrief and guidance revision

Public health management of facility-related exposure to live polioviruses

> 16. Post-action debrief and guidance revision

After each event, it is necessary to rapidly undertake and complete a collaborative post-action review of response measures implemented at each level and recommend improvements of the guidance and emergency plan. The communication of lessons learned to relevant stakeholders should be carried out. Relevant authorities should monitor the implementation of the corrective and preventive action plan set up by the facility and local and national public health authorities. This guidance will be reviewed as required after each event of significance to benefit from the lessons learned.

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