Potential Contamination of Imported Samples with Poliovirus: Implications and Update

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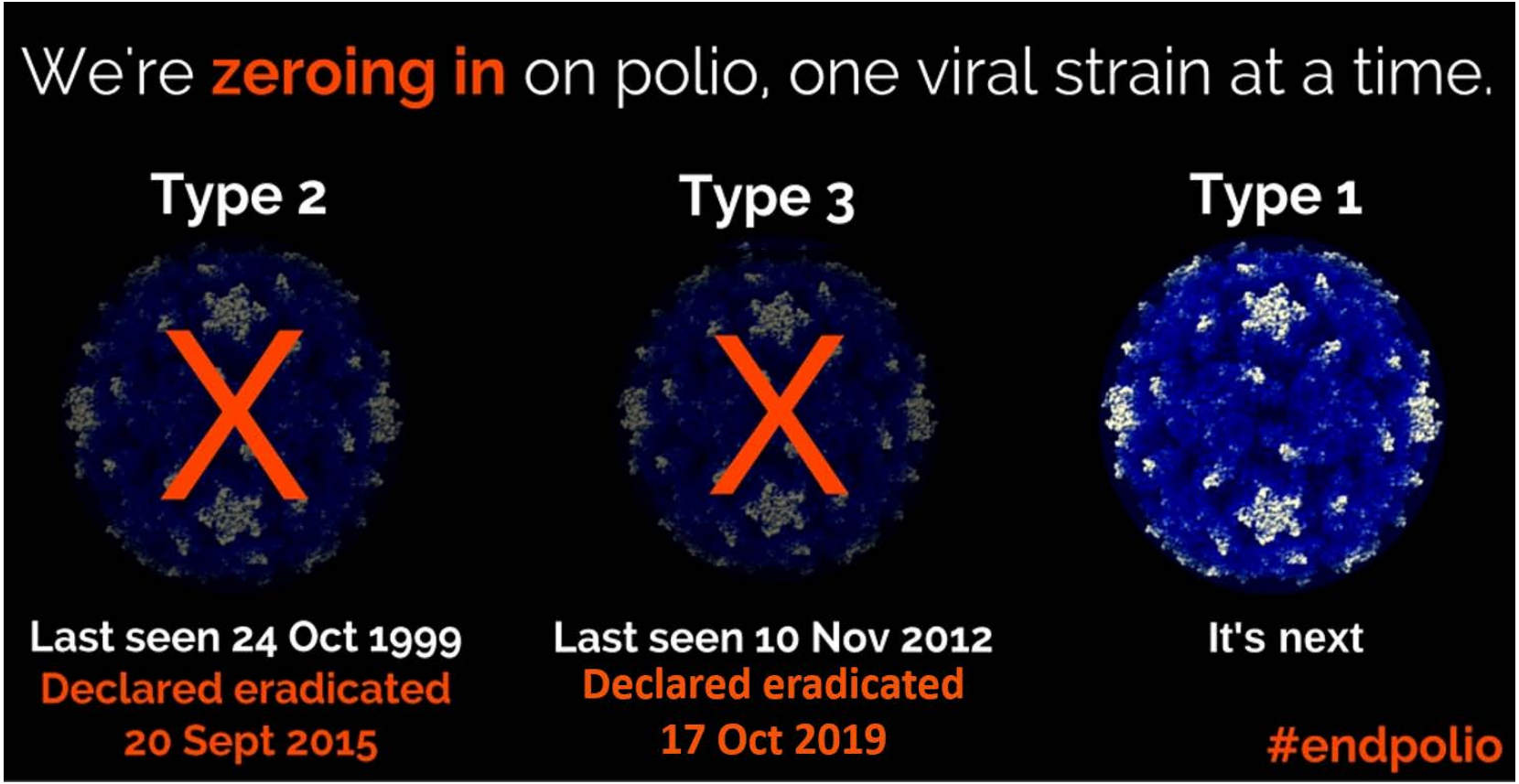
NAC
U.S. National Authority
for Containment of Poliovirus

Overview

1. Eradication and Global Context
2. Poliovirus (PV) Containment
3. PV and Potentially Infectious Material
4. Importing PV Material
5. Work with and Storage of Potentially Infectious Material
6. Key Messages

Eradication and Global Context

Eradication Update



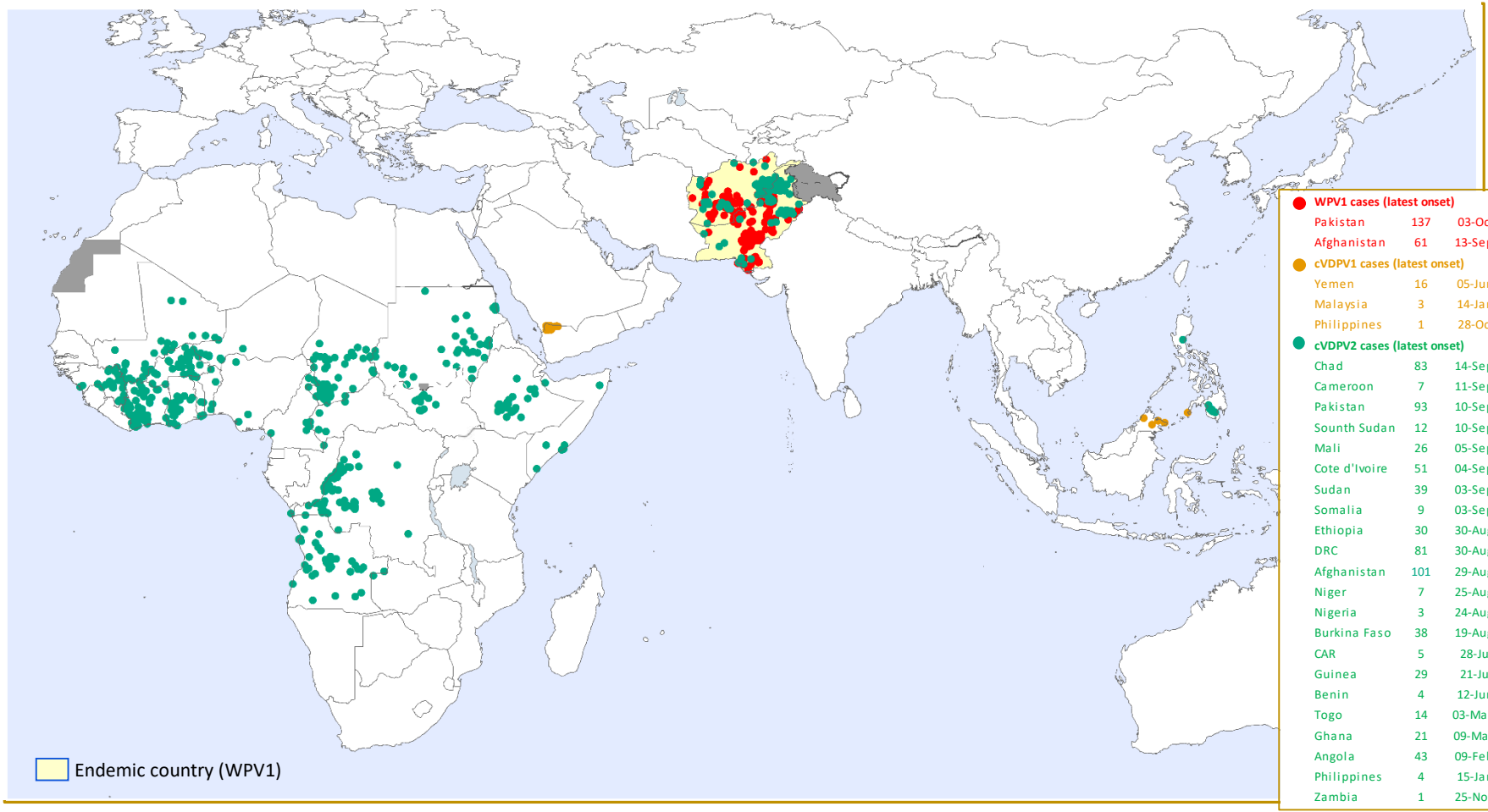
Source: Adapted from Global Polio Eradication Initiative (GPEI)

Vaccines

SABIN	SALK
Live, attenuated oral polio vaccine (OPV)	Inactivated polio vaccine
Trivalent until April 2016 switch to bivalent (types 1 and 3 only	Trivalent (types 1, 2 and 3)
Oral (drops)	Intramuscular (injection)
Very rarely reverts to polio – vaccine-derived poliovirus (VDPV)	Can't cause VDPV
Reduces transmission via mucosal immunity	Can't stop transmission

Global wild PV1 (WPV1) & circulating VDPV Cases[1], Previous 12 Months[2]

World Health Organization



WPV1 cases (latest onset)		
Pakistan	137	03-Oct-20
Afghanistan	61	13-Sep-20
cVDPV1 cases (latest onset)		
Yemen	16	05-Jun-20
Malaysia	3	14-Jan-20
Philippines	1	28-Oct-19
cVDPV2 cases (latest onset)		
Chad	83	14-Sep-20
Cameroon	7	11-Sep-20
Pakistan	93	10-Sep-20
Sounth Sudan	12	10-Sep-20
Mali	26	05-Sep-20
Cote d'Ivoire	51	04-Sep-20
Sudan	39	03-Sep-20
Somalia	9	03-Sep-20
Ethiopia	30	30-Aug-20
DRC	81	30-Aug-20
Afghanistan	101	29-Aug-20
Niger	7	25-Aug-20
Nigeria	3	24-Aug-20
Burkina Faso	38	19-Aug-20
CAR	5	28-Jul-20
Guinea	29	21-Jul-20
Benin	4	12-Jun-20
Togo	14	03-May-20
Ghana	21	09-Mar-20
Angola	43	09-Feb-20
Philippines	4	15-Jan-20
Zambia	1	25-Nov-19

[1]Excludes viruses detected from environmental surveillance; [2]Onset of paralysis 28 Oct. 2019 – 27 Oct . 2020

Data in WHO HQ as of 27 Oct 2020

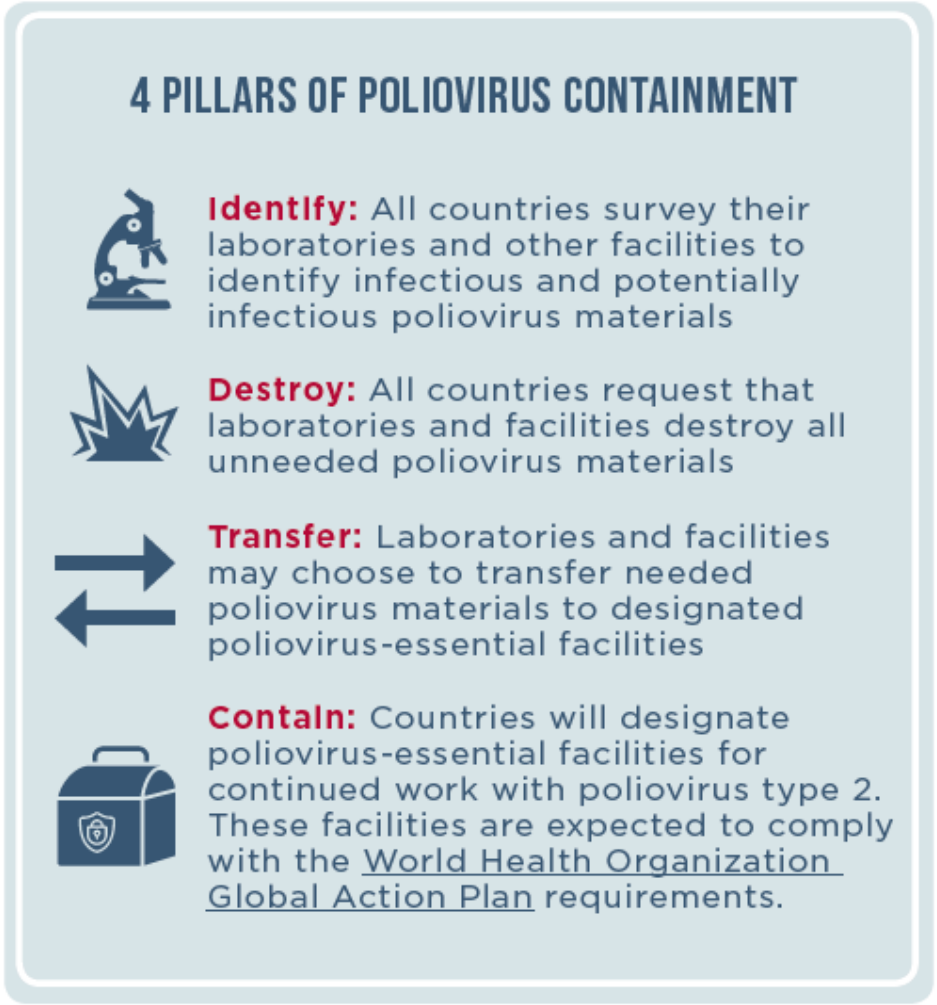
Impact of COVID-19

- Special immunization activities in high-risk countries ceased
- Routine immunization interrupted
- Increase
  - Number of susceptible children
  - Cases of polio caused by WPV1 and VDPVs
- Global delays in PV surveys, containment activities, completion of PV work
  - Laboratories and personnel diverted to COVID-19 work

Poliovirus Containment
… the other half of eradication

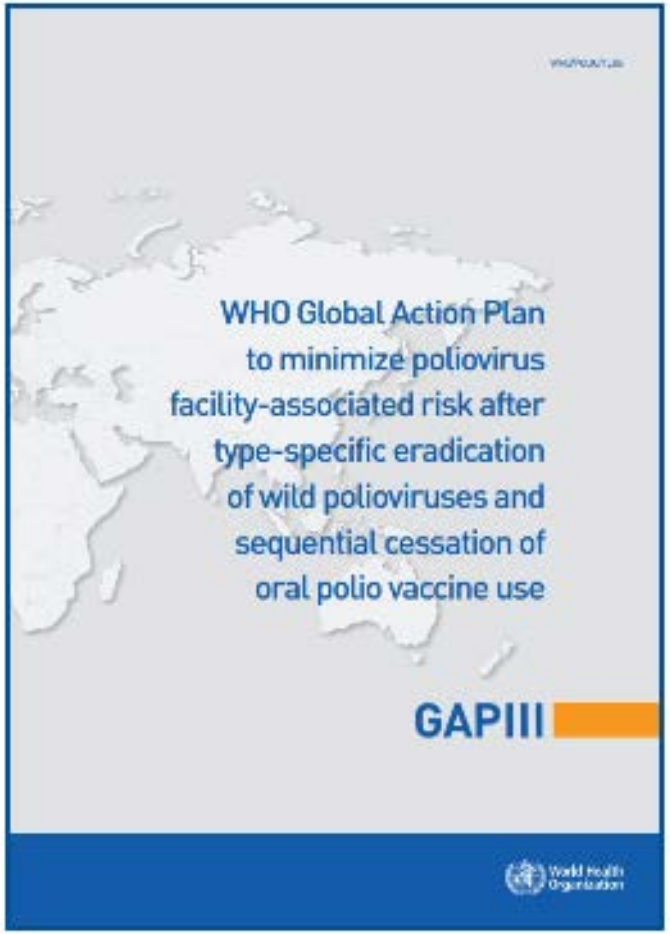
Introduction to Containment

- Certification of polio-free world requires containment
- Prevent reintroduction of polioviruses into community from laboratories or vaccine manufacturers



Global Action Plan (GAPIII)

- WHO's plan for global containment
- Objective: reduce risk of PV release from a facility to as close to zero as possible
- 16 technical requirement categories for containment
- Eradicated strains of PV may only be handled & stored in certified poliovirus-essential facilities



What PV Material is Subject to Containment?

- WPV2, VDPV2, OPV2 and WPV3, VDPV3
  - Infectious material (IM)
  - Potentially infectious material (PIM)

- NOT subject to global containment measures
  - OPV3, WPV1, VDPV1, OPV1 IM and PIM
  - Nucleic acids
    - Required to be reported on national survey

PV and Potentially Infectious Materials

Poliovirus IM Include:

- Cell culture isolates, seeds stocks
- Clinical samples from confirmed PV infections
- Fecal or respiratory secretion samples from recent oral polio vaccine (OPV) recipients
- Samples (human or environmental) that have tested positive for PV
- Infected animals or samples
- Derivatives that contain PV capsid sequence

Poliovirus PIM

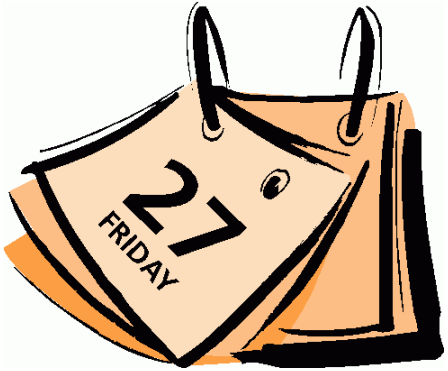
- Samples collected for different purpose that are potentially contaminated with PV
  - Presence of PV is both unknown and unwanted
- Collected in a time and place where WPV is circulating (WPV PIM) or OPV is in use (OPV PIM)
- Presence of PV cannot be ruled out by testing (per WHO)
- Samples imported for COVID-19 work may be PIM

Poliovirus PIM, Sample Types

- Include
  - Fecal samples
  - Respiratory secretion samples
    - Nasal and nasopharyngeal swabs
  - Environmental samples (*i.e.*, concentrated sewage, wastewater)
- Do not include
  - Saliva
  - Blood
- Laboratories performing COVID-19 (or other) work may import some of these sample types

Poliovirus PIM, Time and Place

- Contemporary samples – countries with:
  - Endemic WPV transmission
  - VDPV outbreaks
  - Use of OPV for immunization



- Historic collections – at time:
  - WPV was endemic
  - OPV was in use
  - Includes the US prior to 2000

Poliovirus PIM, Countries with Current Transmission

- VDPV outbreaks are creating more PIM
  - Report all PIM to US NAC
  - VDPV2 PIM (in green) subject to containment now

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Data in WHO HQ as of 27 Oct 2020

WHO *PIM Guidance* Country Table

ANNEX 2: COUNTRY OR AREA-SPECIFIC POLIOVIRUS DATA

Facilities are encouraged to use Table 1 of Annex 2, in conjunction with the *Guidance to minimize risks for facilities collecting, handling or storing materials potentially infectious for polioviruses*, to assess the risk of sample collections potentially infectious for poliovirus.

Identifying all laboratory samples at risk for containing poliovirus is essential for securing a polio-free world. Presence of poliovirus in a given country can only be ruled out with active AFP surveillance. The data and information shown in Table 1 was collected from multiple sources using the following algorithm for

No.	Country or area	1. WPV PIM dates			2. OPV2/Sabin2 PIM dates (Must mitigate now)
		WPV1/cVDPV1	WPV2/cVDPV2 (Must contain now)	WPV3/cVDPV3	
208.	Turks and Caicos Islands[1]	Until Dec 1978 (11)	Until Dec 1978 (11)	Until Dec 1978 (11)	Jan 1979 – Jul 2016
209.	United Republic of Tanzania[1]	Until Dec 1996 (6)	Until Dec 1981[2] (14)	Until Dec 1981[2] (14)	Jan 1982 – Jul 2016
210.	United States of America[9]	• Until Dec 1971 (11) • Jan 1979 – Dec 1979 (40)	Until Dec 1965 (11)	Until Dec 1968 (11)	Jan 1966 – Mar 2000
211.	American Samoa[10]	Until Dec 1959[2] (12)	Until Dec 1959[2] (12)	Until Dec 1959[2] (12)	• Jan 1960 – Dec 1960[8] • Jan 1961 – Mar 2005

Poliovirus PIM: Storage conditions

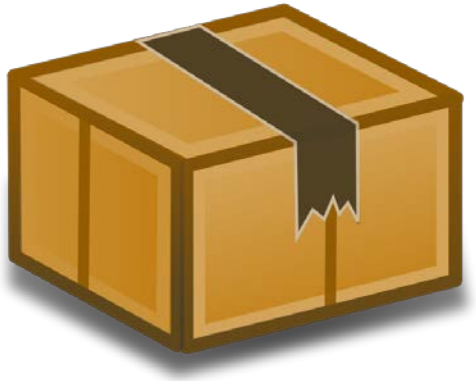
- Preserve infectivity of PV
- Freezer (-20°C or colder)
- Samples not stored at freezing temperatures are not considered PIM

Poliovirus PIM also includes

- Products collected from poliovirus permissive cells or animals that were infected with PIM
- Uncharacterized enterovirus-like cell culture isolates from countries known or suspected to have circulating wild poliovirus at the time of collection
- Respiratory and enteric virus stocks handled under conditions where poliovirus contamination is possible

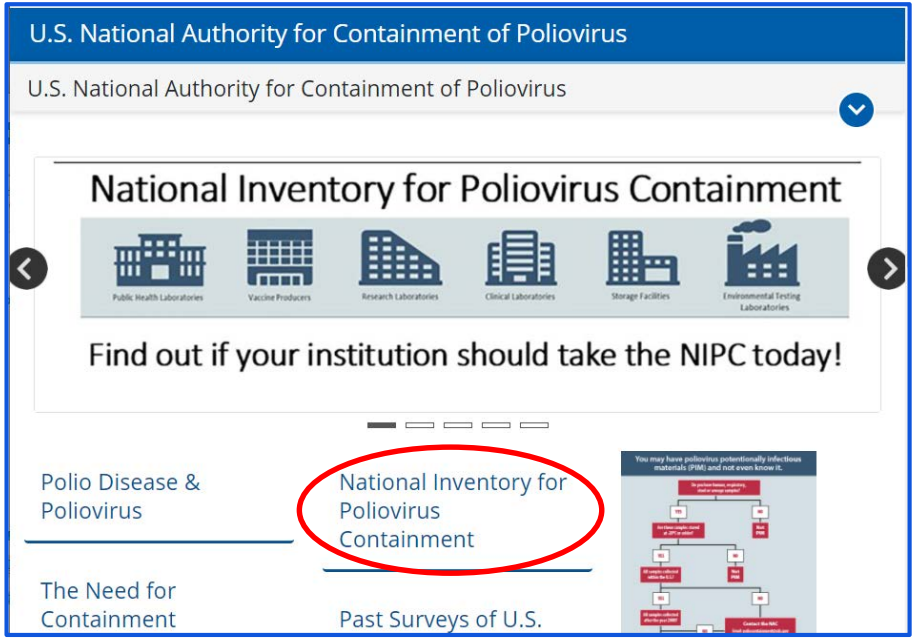
Importing PV Material

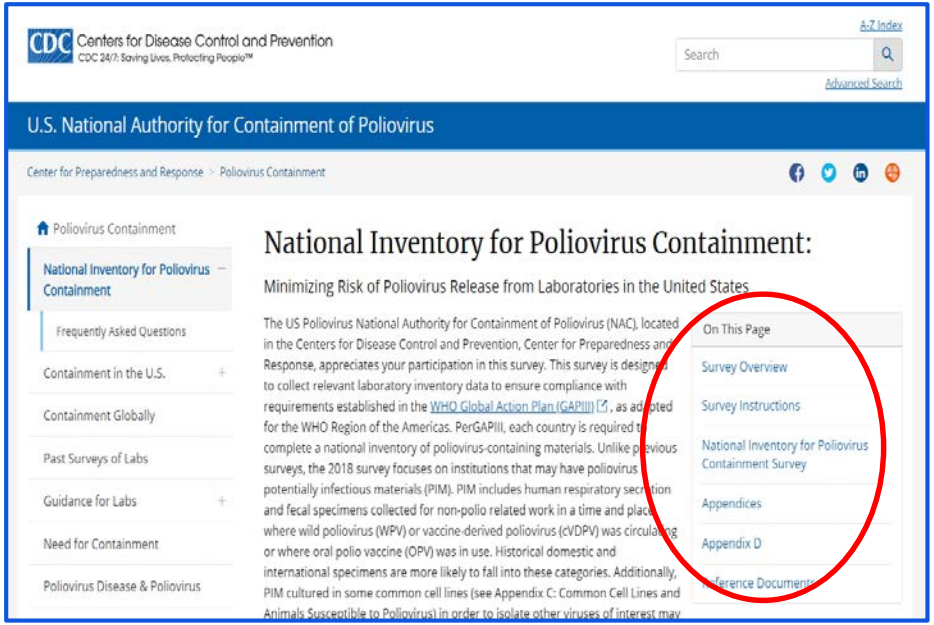
Importing Material



- Determine if PV PIM or IM
- Indicate on Import Permit Program (IPP) application
  - IM as “known” PV
  - PIM as “suspected to contain” PV
- Make institution/biosafety officer aware
- Complete survey or update current inventory with US NAC
- Contact the US NAC prior to importing WPV2, VDPV2, OPV2, WPV3, VDPV3 IM
  - Institutions with these materials need to apply to become a Poliovirus Essential Facility and comply with stringent global containment measures

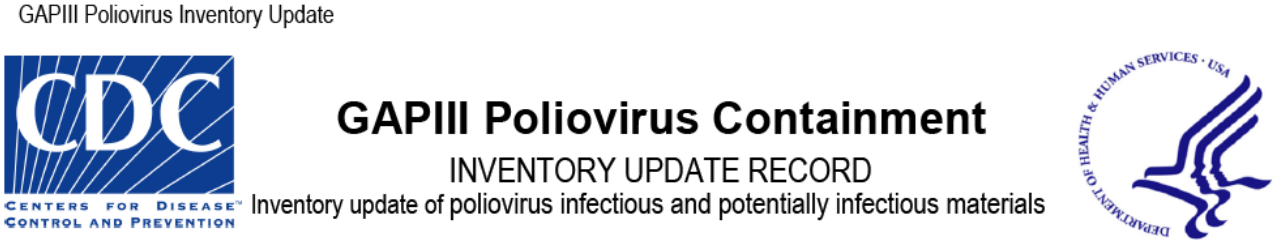
U.S. NAC Website – Survey Webpage





https://www.cdc.gov/cpr/polioviruscontainment/surveys_laboratories.htm

U.S. NAC Inventory Update Record



GAPIII Poliovirus Inventory Update

CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

GAPIII Poliovirus Containment

INVENTORY UPDATE RECORD

Inventory update of poliovirus infectious and potentially infectious materials

DEPARTMENT OF HEALTH & HUMAN SERVICES · USA

Facilities are strongly encouraged to destroy all unneeded materials. Facilities retaining poliovirus materials must report the inventory to the U.S. National Authority for Containment (NAC) of Poliovirus. Facilities that retain PV2 material (except OPV2/Sabin PIM) must meet the criteria for an poliovirus essential facility as outlined in the World Health Organization (WHO) Global Action Plan (GAP) III. Compliance with GAPIII is the responsibility of the institution.

A. FACILITY INFORMATION

Facility Name:

Department:

Address:

City: State: Zip:

Contact name: Title:

Phone: Email:

B. DESTROYED POLIOVIRUS MATERIAL AND METHOD

☐ No infectious and/or potentially infectious poliovirus material was destroyed (skip to Section C)

Work with and Storage of Potentially Infectious Material (PIM)

US Guidance– Does your laboratory need PIM?

- **DON'T IMPORT** if not essential
- **INACTIVATE** for future needs, using methods that are effective against poliovirus (*e.g.*, formaldehyde)
- **EXTRACT** nucleic acids

US Guidance – If you import PIM

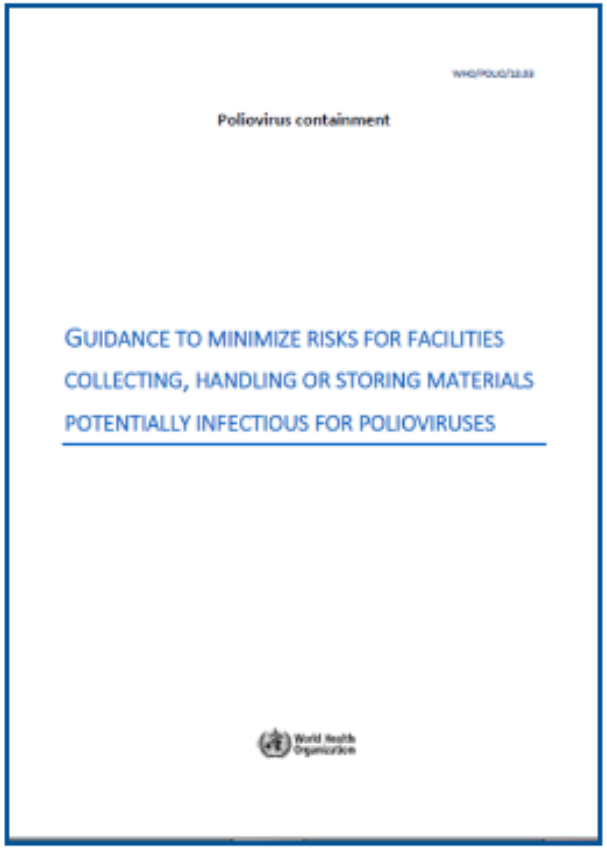
Strategies for Retained PIM

N/A	Wild PV (WPV) or vaccine-derived PV (VDPV) PIM	Oral polio vaccine (OPV) PIM
Definition*	At risk of containing WPV or VDPV	At risk of containing OPV
Storage	Segregate from non-PIM Secure samples in locked freezer or laboratory, limit access	Segregate from non-PIM Secure samples in locked freezer or laboratory, limit access
Work	Contact US NAC for work with WPV PIM at poliocontainment@cdc.gov	Follow risk mitigations as detailed in PIM Guidance
When	WPV2 and WPV3 PIM now WPV1 PIM in the future	tOPV[i] and mOPV2[ii] PIM now bOPV[iii] PIM in the future

*Includes derivatives of these samples (e.g., stool suspensions, extracted nucleic acids)
itOPV = trivalent containing OPV1, 2 and 3; iimOPV = monovalent containing only OPV2; iiibOPV = bivalent containing OPV1 and 3

WHO *PIM Guidance* for work with OPV PIM

- Risk classification
  - Based on sample type (stool/sewage, respiratory, nucleic acid) and work (use with PV permissive cells)
- Storage
  - Secure samples in locked freezer or laboratory
  - Limit access
- Work
  - Mitigations dependent on risk and include risk assessment, good laboratory practices, validation of methods, immunization of staff



US Guidance – What to do with PIM when work is complete

- Once work is completed with PIM, determine if material is still essential
- If essential, continue to **CONTAIN**
- If non-essential
  - **DESTROY** material by autoclave or incinerator
  - **CONTACT** U.S. NAC for required documentation
  - **TRANSFER** material to an approved laboratory
    - Contact U.S. NAC first

Key Messages

Summary

- Identify material to be imported as “known” PV or “suspected to contain” PV as applicable
- Make institution/biosafety officer aware
- Report to US NAC for national inventory
- Contact the US NAC prior to
  - Importing WPV2, VDPV2, OPV2, WPV3, VDPV3 IM
  - Work with WPV PIM
- If subject to containment now, follow US NAC guidance
- Destroy when (if) you no longer need material

Poliovirus and Potentially infectious material (PIM)

Global Poliovirus Eradication Initiative

polioeradication.org/polio-today/preparing-for-a-polio-free-world/containment/containment-resources/

- *Guidance to minimize risk for facilities collecting, handling or storing materials potentially infectious for poliovirus* (PIM Guidance)
- Country table for identifying PIM
- Global Action Plan III (GAPIII)

Contact the US NAC

- poliocontainment@cdc.gov
- 404-718-5160
- www.cdc.gov/cpr/polioviruscontainment/index.htm
  - Survey

THANK YOU!

For more information, contact the U.S. NAC at

404-718-5160
poliocontainment@cdc.gov
www.cdc.gov/cpr/polioviruscontainment/index.htm

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.