

# CDC's role as the U.S. National Authority for the Containment (NAC) of Poliovirus

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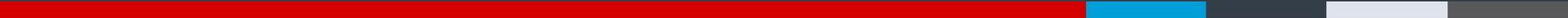
December 4, 2019



# Presentation Overview

1. Eradication and Global Context
2. Poliovirus Containment
3. About the U.S. NAC
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5. National survey/Inventory
6. Poliovirus infectious materials
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8. Importing poliovirus materials
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# **Eradication and Global Context**

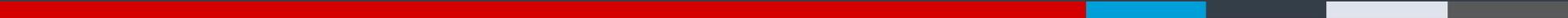


# Brief History of Poliovirus Eradication

- World Health Assembly passed a resolution in 1988 to eradicate all three poliovirus (PV) serotypes
  - World Health Organization (WHO) declared wild PV2 (WPV2) eradicated in 2015
  - WHO declared wild PV3 (WPV3) eradicated on October 17, 2019
  - Wild PV1 (WPV1) is still circulating in Afghanistan and Pakistan
- Oral polio vaccine (OPV) type 2 was removed from the live attenuated trivalent vaccine in 2016

# Poliovirus Containment

...the other half of eradication



# Introduction:

## Poliovirus Containment

- Certification of polio-free world requires containment
- Prevent reintroduction of polioviruses into community from labs or facilities
- Does your lab have polio?

### 4 PILLARS OF POLIOVIRUS CONTAINMENT



**Identify:** All countries survey their laboratories and other facilities to identify infectious and potentially infectious poliovirus materials



**Destroy:** All countries request that laboratories and facilities destroy all unneeded poliovirus materials



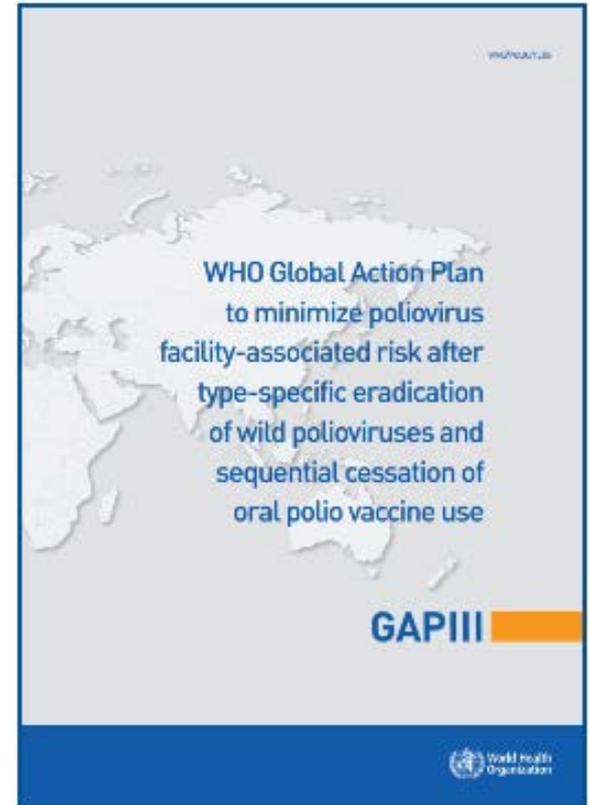
**Transfer:** Laboratories and facilities may choose to transfer needed poliovirus materials to designated poliovirus-essential facilities



**Contain:** Countries will designate poliovirus-essential facilities for continued work with poliovirus type 2. These facilities are expected to comply with the World Health Organization Global Action Plan requirements.

# Global Action Plan (GAPIII) for Poliovirus Containment

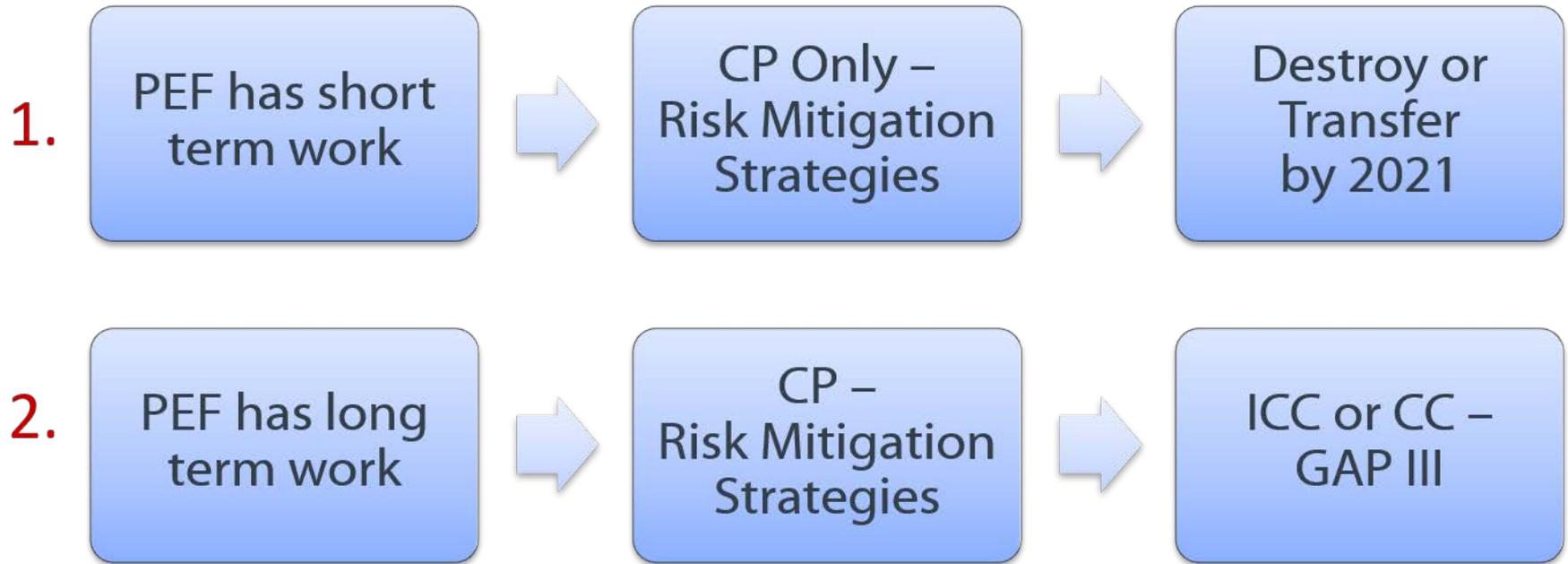
- GAPIII published by WHO in 2014
- Defines a strategy to minimize PV facility-associated risk after type-specific eradication of WPVs and cessation of OPV use
- 16 technical requirement categories for containment
- **Eradicated strains of poliovirus may only be handled & stored in certified poliovirus-essential facilities (PEFs)**



# GAPIII – Examples for PV2 Containment

- Work in laboratories with:
  - Inward directional airflow
  - Pass-through autoclave
  - Exit shower
  - Effluent decontamination
- Biorisk management system & conduct risk assessments
- Establish immunization policy
- Security provisions (*e.g., access controls, personnel reliability policy, inventory*)

# Two Paths for Certification<sup>+</sup>



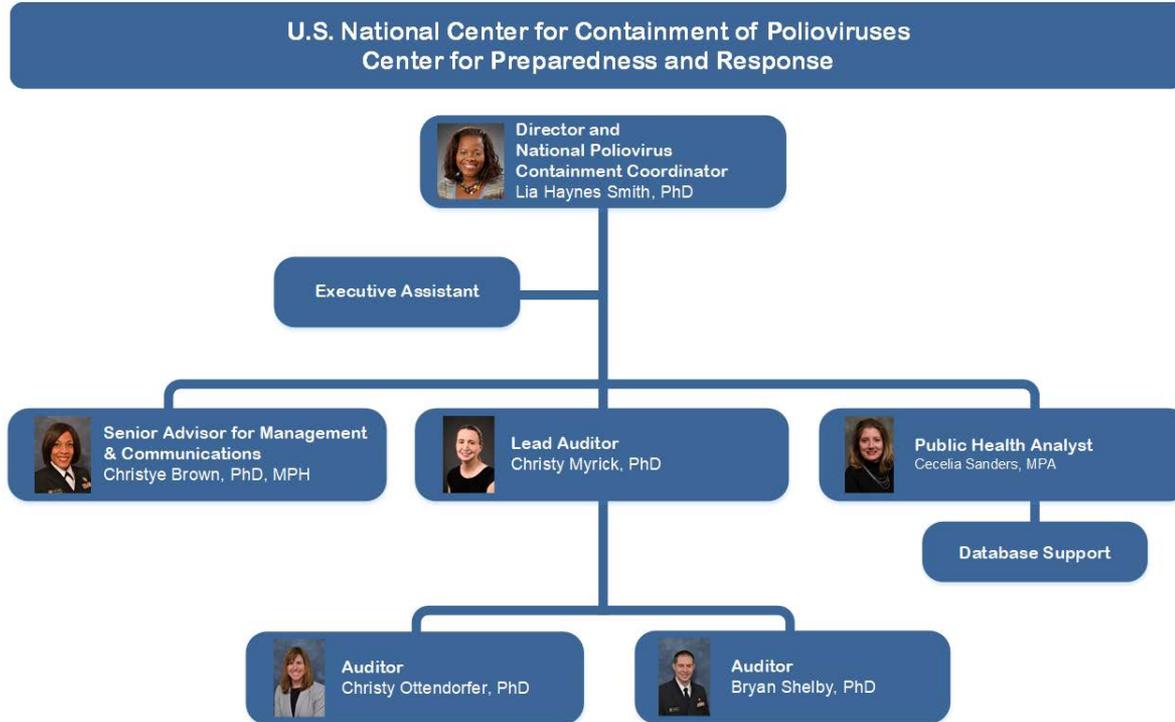
<sup>+</sup>CP = Certificate of Participation, ICC = Interim Certificate of Containment, CC = Certificate of Containment

# About the U.S. NAC

# Brief history of U.S. NAC

- Poliovirus Containment Activity stood up Jan 2017
- Designated as U.S. NAC Jan 2018
- Located at the Centers for Disease Control and Prevention, Center for Preparedness and Response, based on expertise in poliovirus, eradication, and laboratory containment
- There is no regulation in place in the U.S. compelling PEFs to adopt WHO GAPIII containment measures
- [www.cdc.gov/cpr/polioviruscontainment](http://www.cdc.gov/cpr/polioviruscontainment)

# U.S. NAC Organizational Chart



# U.S. NAC Responsibilities

- National Survey/Inventory of PV material implementation
- Implement the Containment Certification Scheme for GAPIII = application and audit process to become a PEF
  - Assist U.S. PEFs working with poliovirus materials in understanding containment needs
  - Where needed, develop policies that interpret WHO GAPIII elements for national circumstances
  - Seek WHO endorsement for PEF applications
  - Conduct audits to assess implementation of GAPIII containment elements

# Collaborative Approach

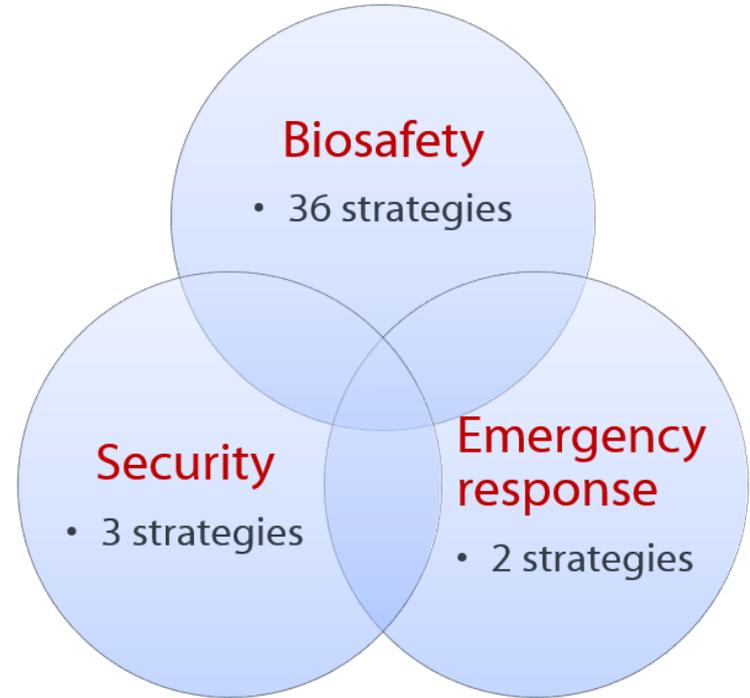
- Engage facilities possessing PV materials
  - Some may apply to become a PEF
- Seek input on U.S. NAC documents and policies
- Encourage a community of practice
  - U.S. NAC-PEF Webinars
  - Voluntary sharing of contact information

# U.S. NAC Risk Mitigation Strategies (RMS)



# U.S. NAC RMS Overview

- 41 containment strategies in 3 categories
  - Eradicated strains – improve routine laboratory practices now
  - Emphasize biosafety to mitigate risk of accidental release
- Can implement in BSL2 facilities
- Not a substitute for WHO GAPIII, Annex 2 or Annex 3



# U.S. NAC RMS - Biosafety

- 36 biosafety strategies
  - Dedicate or separate PV2 materials from other areas (4)
  - Primary containment (3)
  - Occupational health/immunization policy (2)
  - Personal protective equipment [PPE] (8)
  - Hand washing/hand hygiene (2)
  - Training/competency (3)
  - Prevent cross-contamination or misidentification (2)
  - Decontamination (10)
  - Destroy unneeded materials or inactivate materials when able (2)

# U.S. NAC RMS - Security and Emergency Response

- Security strategies (3)
  - Identify essential personnel
  - Control access to laboratory
  - Control access to freezer
- Emergency response strategies (2)
  - Plan for release of PV2
  - Incident reporting

# Poliovirus Infectious Materials (IM)



## 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

# PV2 IM

- Includes wild, vaccine derived, and oral polio vaccine type 2
- U.S. NAC is working to improve containment with PEFs that are retaining PV2
  - All are working to incorporate the mitigations outlined in the U.S. NAC RMS
  - Some PEFs will cease work soon and withdraw from the CCS
  - Others will work toward GAPIII containment

# WPV3 IM

- WPV3 eradication was declared on October 17, 2019
- U.S. NAC will perform phone calls and/or introductory visits in 2020 to discuss work and plans to meet GAPIII containment
  - Visits will not be an audit or verification
- WHO has not provided guidance on how WPV3 facilities should proceed at this time
- U.S. NAC recommends beginning to implement the U.S. NAC RMS

# PV1 IM

- WPV1 still circulating in two endemic countries
- U.S. NAC will continue to perform follow up calls to discuss work and plans to meet GAPIII containment
- U.S. NAC recommends securing and limiting access to material
- **WHO-Global Certification Commission expects PV1 to be in GAPIII containment at final eradication**

# Poliovirus Potentially Infectious Materials (PIM)



# Poliovirus PIM

- Samples collected for any purpose in a time and place where wild poliovirus was circulating or OPV was used
- Examples may include:
  - Human stool
  - Environmental
  - Sewage
  - Respiratory

## Poliovirus PIM (cont'd.)

- Products collected from poliovirus permissive cells or animals
- 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

# WPV PIM in the U.S.

- Subject to GAPIII
- U.S. NAC recommendations
  - **Work:** Implement U.S. NAC RMS
    - Contact the U.S. NAC for guidance
  - **Storage:** Secure samples in locked freezer or laboratory, limit access

# OPV PIM in the U.S.

- Subject to WHO *Guidance to minimize risk for facilities collecting, handling or storing materials potentially infectious for poliovirus*
- U.S. NAC recommends facilities consider implementing U.S. NAC RMS
  - **Work:** mitigations include risk assessment, good laboratory practices, validation of methods, and immunization of staff
  - **Storage:** secure samples in locked freezer or laboratory, limit access
  - **Risk classification** based on material type (stool/sewage, respiratory, nucleic acid) and work (use with poliovirus permissive cells)

# National Survey/Inventory



# Previous National Surveys

2002-2003

- All wild type poliovirus (WPV) IM and PIM
- 32,429 institutions surveyed (>100,000 laboratories)
- 180 laboratories identified IM and PIM of all three serotypes

2015

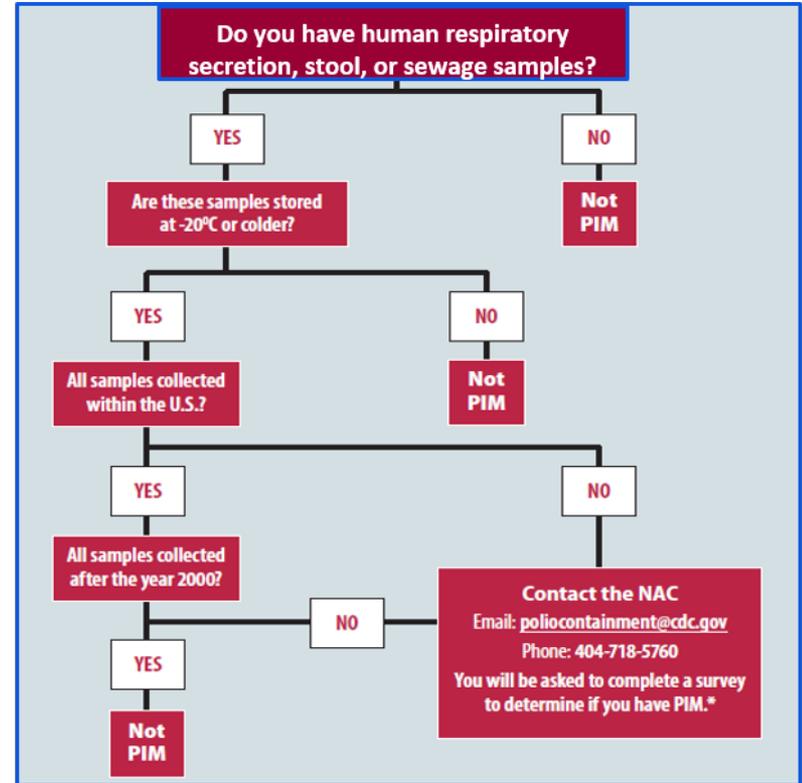
- Targeted poliovirus and enterovirus labs
- 398 surveys received/401 sent – response rate 99.3%
- 20 potential PEFs
- National inventory not complete

# Current U.S. NAC Survey (2018 Survey)

- Launched in December 2018
- Will target laboratories with PIM, especially respiratory laboratories
- Outreach
  - NAC website
  - Biosafety officers and IBC chairs
  - Distribution through professional societies
  - Conference talks and exhibits
  - Social media

# What's in your freezer?

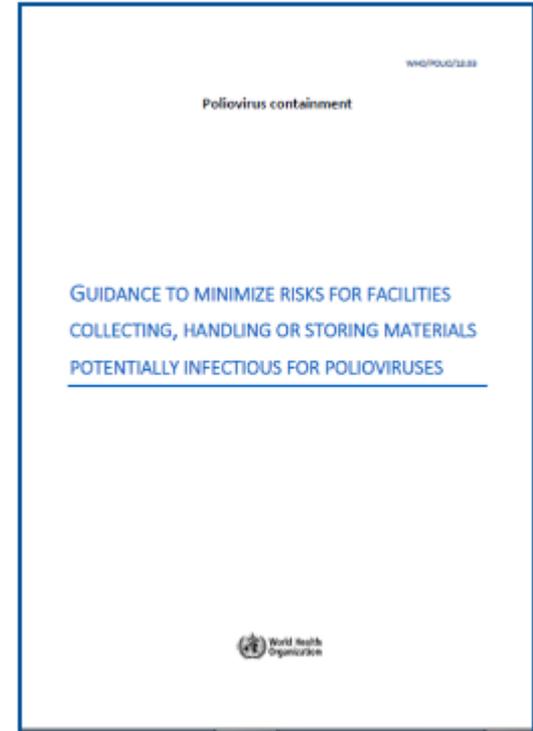
- Materials collected in U.S. after April 2000
  - YES = Not PIM
  - NO = PIM
- Materials collected internationally
  - MAYBE = Compare sample origin information with WHO country tables



<https://www.cdc.gov/cpr/polioviruscontainment/index.htm>

# Evaluating Sample Collections for PIM

- Historical domestic or international samples
- Factors in identifying PIM
  - Sample type (human stool or respiratory, environmental, sewage)
  - Storage (-20°C or colder)
  - Country where collected
  - Date of collection
- Tables with dates when poliovirus was last present in each country



<http://polioeradication.org/wp-content/uploads/2018/11/PIM-Annex-2-16-Nov-18.pdf>

# 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 <sup>1</sup>	Until Dec 1978 (11)	Until Dec 1978 (11)	Until Dec 1978 (11)	Jan 1979 – Jul 2016
209.	United Republic of Tanzania <sup>1</sup>	Until Dec 1996 (6)	Until Dec 1981 <sup>2</sup> (14)	Until Dec 1981 <sup>2</sup> (14)	Jan 1982 – Jul 2016
210.	United States of America <sup>9</sup>	<ul style="list-style-type: none"> <li>• Until Dec 1971 (11)</li> <li>• Jan 1979 – Dec 1979 (40)</li> </ul>	Until Dec 1965 (11)	Until Dec 1968 (11)	Jan 1966 – Mar 2000
211.	American Samoa <sup>10</sup>	Until Dec 1959 <sup>2</sup> (12)	Until Dec 1959 <sup>2</sup> (12)	Until Dec 1959 <sup>2</sup> (12)	<ul style="list-style-type: none"> <li>• Jan 1960 – Dec 1960<sup>8</sup></li> <li>• Jan 1961 – Mar 2005</li> </ul>

# U.S. NAC Website- Survey Webpage

The screenshot shows the homepage of the National Inventory for Poliovirus Containment. At the top, there is a navigation bar with the title "National Inventory for Poliovirus Containment" and a search bar. Below the title, there is a horizontal menu with icons for Public Health Laboratories, Vaccine Products, Research Laboratories, Clinical Laboratories, Storage Facilities, and Environmental Testing Laboratories. A large banner below the menu reads "Find out if your institution should take the NIPC today!". On the left side, there are several menu items: "POLIO DISEASE & POLIOVIRUS", "POLIOVIRUS CONTAINMENT IN THE U.S.", "GUIDANCE FOR LABORATORIES", "NAC REFERENCE DOCUMENTS", "THE NEED FOR CONTAINMENT", "IMPLEMENTING POLIOVIRUS CONTAINMENT GLOBALLY", "POLIOVIRUS SURVEYS OF U.S. LABS", and "MEET THE NAC". On the right side, there is a "What's in Your Freezer?" flowchart. The flowchart starts with the question "Do you have human, veterinary, stool or sewage samples?". If "Yes", it asks "Are these samples stored at -20°C or colder?". If "No", it says "NOT PIM". If "Yes", it asks "All samples collected within last 12 months?". If "No", it says "NOT PIM". If "Yes", it asks "All samples collected after the year...". If "No", it says "NOT PIM". If "Yes", it says "Complete the National Inventory for Poliovirus Containment form". At the bottom of the flowchart, there are "Containment Resources" and "CDC" logos.

The screenshot shows the CDC website page for the National Inventory for Poliovirus Containment survey. At the top, there is the CDC logo and the text "Centers for Disease Control and Prevention" and "CDC 24/7: Saving Lives, Protecting People™". There is a search bar and a "CDC A-Z INDEX" dropdown menu. Below the search bar, there is a blue header with the text "U.S. National Authority for Containment of Poliovirus". On the left side, there is a navigation menu with items: "Poliovirus Containment", "Poliovirus Disease & Poliovirus", "Need for Containment", "Containment in the U.S.", "Containment Globally", "Surveys of Labs", "Guidance for Labs", and "Meet the NAC". Below the menu, there is a "Get Email Updates" section with a text input field and a "Submit" button. On the right side, there is a section titled "National Inventory for Poliovirus Containment: Minimizing Risk of Poliovirus Release from Laboratories in the United States". Below this, there are social media icons for Facebook, Twitter, and YouTube. There is a large logo for "NAC U.S. National Authority for Containment of Poliovirus". Below the logo, there is a paragraph of text: "The US Poliovirus National Authority for Containment of Poliovirus (NAC), located in the Centers for Disease Control and Prevention, Center for Preparedness and Response, appreciates your participation in this survey. This survey is designed to collect relevant laboratory inventory data to ensure compliance with requirements established in the WHO Global Action Plan (GAP) of an adapted for the WHO Region of the Americas. Per GAP, each country is required to complete a national inventory of poliovirus-containing materials. Unlike previous surveys, the 2018 survey focuses on institutions that may have poliovirus potentially infectious materials (PIM). PIM includes human respiratory secretions and fecal specimens collected for non-polio related work in a time and place where wild poliovirus (WPV)". At the bottom right, there is a "On This Page" section with a list of links: "Survey Guidance Document", "Survey Instructions", "National Inventory for Poliovirus Containment Survey", and "Appendix".

[https://www.cdc.gov/cpr/polioviruscontainment/surveys\\_laboratories.htm](https://www.cdc.gov/cpr/polioviruscontainment/surveys_laboratories.htm)

# Importing Poliovirus Materials



# Importing PV2/WPV3 IM

- Follow the guidance to identify PV2/WPV3 IM
  - Take the survey if you have not done so already
- If not a PEF, do not import PV2 or WPV3 IM without contacting the U.S. NAC for assistance and guidance
  - Facilities must be engaged with U.S. NAC to become a PEF in order to import PV2 and WPV3 IM, or
  - Facilities has been identified as a PEF
- Indicate on Import Permit Program (IPP) application that material is PV2 or WPV3 IM

# Importing other PV materials

- Includes:
  - IM (PV1 and OPV3)
  - PIM (all serotypes)
- Determine if the material is PIM
  - Take the survey if you have not done so already
- Indicate on IPP application that shipment includes PIM
- U.S. NAC may contact you for additional information

# Key Messages



## You should .....

- Follow U.S. NAC recommendations for IM and PIM
- Encourage destruction of non-essential PV materials
- Take the survey if you have not done so already
- Contact U.S. NAC to declare inventory changes, material destruction and/or material transfers to another facility

## You should ..... (cont'd.)

- Share information with your colleagues on how to identify PV IM and PIM and encourage them to declare PV materials (survey)
- Verify whether imported material is IM or PIM and take appropriate action

# Resources

- U.S. NAC website
  - [www.cdc.gov/cpr/polioviruscontainment](http://www.cdc.gov/cpr/polioviruscontainment)
- Global Poliovirus Eradication Initiative website
  - [polioeradication.org/polio-today/preparing-for-a-polio-free-world/containment/containment-resources/](http://polioeradication.org/polio-today/preparing-for-a-polio-free-world/containment/containment-resources/)
    - Global Action Plan III (GAPIII)
    - *Guidance to minimize risk for facilities collecting, handling or storing materials potentially infectious for poliovirus (PIM Guidance)*
    - Country table for identifying PIM

For more information, contact CDC  
1-800-CDC-INFO (232-4636)  
TTY: 1-888-232-6348 [www.cdc.gov](http://www.cdc.gov)

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.

