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

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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](https://www.who.int/).
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

1. PEF has short term work → CP Only – Risk Mitigation Strategies → Destroy or Transfer by 2021
2. PEF has long term work → CP – Risk Mitigation Strategies → ICC or CC – GAP III

*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 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)
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)
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 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 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)
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
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

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

### 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

<table>
<thead>
<tr>
<th>No.</th>
<th>Country or area</th>
<th>1. WPV PIM dates</th>
<th>2. OPV2/Sabin2 PIM dates (Must mitigate now)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>WPV1/cVDPV1</td>
<td>WPV2/cVDPV2 (Must contain now) WPV3/cVDPV3</td>
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\(^1\) Data from http://www.wpro.who.int/disease-polio/afp-who-office/policies-guidelines/en/

\(^2\) Data from http://www.who.int/rural/afp-office/en/

\(^3\) Data from http://www.cdc.gov/ncidod/dvbd/polio/policy/guidance.htm

\(^4\) Data from http://www.cdc.gov/ncidod/dvbd/polio/policy/afp-data.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
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)

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.