Sample Collections and Poliovirus Containment: What’s the Connection

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Christy Myrick, PhD, RBP
What’s in Your Institution’s Freezers?

- Poliovirus that hasn’t been declared?
- Human specimens or sewage samples that could be contaminated with poliovirus?
- Historical domestic or international human sample collections?
Agenda

1. Risks of continued work with poliovirus (PV)
2. Introduction to the US NAC
3. PV Infectious materials (IM) in the US
4. PV Potentially infectious materials (PIM) in the US
5. National surveys
6. Questions
Risks of continued work with poliovirus
Accidents happen

April 2017 WPV2 spill inside vaccine manufacturer $^1$
- 2 vaccinated workers exposed
- 1 worker tested positive for PV on day 4, as did sewage
- Worker isolated at home with no additional transmission

Sept 2014 vaccine manufacturer released 45 L of concentrated WPV3 ($10^{13}$) $^2$
- Facility to treatment plant and then into river
- River flowed into areas of lower vaccine coverage
- No PV detected in river

References provided at end of presentation
Silent outbreak of WPV1 in Israel

- Israel polio free since 1988
- Inactivated polio vaccine (IPV) only used since 2005, > 95% coverage rate
- Environmental surveillance detected WPV1 in 2013 at multiple locations
- Reintroduction of virus and “silent” circulation w/o acute flaccid paralysis (AFP)
- Vaccination campaigns using oral polio vaccine (OPV), again certified free in April 2015
Asymptomatic Laboratory Acquired Infections (LAI) and Shedding

- Both vaccines protect against disease but not infection
- Vaccinated worker – no symptoms
- If worker was infected in the laboratory
  - Poliovirus shed in stool
  - Potential silent transmission in community
  - Possible polio disease in unvaccinated individuals

- If worker becomes infected, you won’t know.
Secondary transmission from unidentified LAIs

- WPV1 (Mahoney) used in IPV production detected in a 19 mo old during a WPV3 epidemic in the Netherlands (1992)\(^4\)
  - Father worked at PV vaccine production facility and accidentally exposed to high amount of Mahoney

- WPV3 (Saukett) used in IPV production outside the Netherlands detected in a 5 yo in the Netherlands (1993)\(^4\)
  - Source not identified

- WPV2 (MEF-1) detected in 10 patients in India with paralytic polio (2000, 2002-2003)\(^5\)
  - Source not identified, no evidence of extensive transmission
Additional risk mitigation is needed for PV2

- To protect eradication efforts
- Primary route of infection for immunized worker = ingestion
- Likely to occur via inadvertent touch of mouth with contaminated hands or gloves
- Recommend focus on:
  - hand hygiene
  - PPE use
  - training
  - adherence to protocols
  - non-punitive incident reporting
Introduction to the US National Authority for Containment (NAC) of Poliovirus
Getting started

- Poliovirus Containment Activity stood up Jan 2017
- Designated as NAC Jan 2018
- Located at CDC due to expertise in poliovirus, eradication, and laboratory containment
- No regulation in the US compelling facilities to adopt WHO GAP III containment measures
U.S. National Authority for Containment of Polioviruses
Office of Public Health Preparedness and Response

Director and National Poliovirus Containment Coordinator
Lia Haynes Smith, PhD

Executive Assistant

Public Health Advisor
Christye Brown, PhD, MPH

Lead Auditor
Christy Myrick, PhD

Auditor
Christy Ottendorfer, PhD

Auditor
Bryan Shelby, PhD

Public Health Analyst
Cecelia Sanders, MPA

Database Support
Responsibilities

- Implement the Containment Certification Scheme for GAP III = application and audit process to become a Poliovirus Essential Facility (PEF)
  - Assist US facilities working with PV materials in understanding containment needs
  - Where needed, develop policies that interpret WHO GAP III elements for US circumstances
  - Seek WHO endorsement for PEF applications
  - Conduct audits to assess implementation of GAP III containment elements
- Complete national inventory
Approach

- Collaborative approach to containment
  - Engage affected facilities
  - Seek input on NAC documents and policies
- Encourage a community of practice
  - NAC-PEF Webinars
  - Voluntary sharing of contact information
PV Infectious Materials (IM) in the US
PV2 Infectious Materials

- Starting here – PV2 eradicated, IM highest risk
- NAC engagement began in Jan 2018 with introductory visits
- 12 facilities intend to retain PV2 IM
- NAC currently receiving Certificate of Participation (CP) applications from facilities with PV2 IM
  - 1st step in Containment Certification Scheme
  - Formal engagement in the process
Risk Mitigation Strategies for Work with PV2 During the Transition Period

- Now and while working under a CP
- Addition of BSL3 practices in BSL2 laboratory, such as work in primary containment and PPE to protect worker
- Minimum mitigation measures for work with PV2 IM
- Not a substitute for WHO GAP III
- Starting point for enhanced practices
PV1 and 3 Infectious Materials

- Containment not required until final eradication
- At least 3 years away
- No lead-in period for implementation as with PV2
- All GAP III elements implemented at time of final eradication
- Initial outreach now to keep PV1 and 3 IM facilities informed and help them prepare
PV Potentially Infectious Materials (PIM) in the US
Are sample collections at your institution potentially contaminated with poliovirus?

- Do you have human respiratory secretion, stool, or sewage samples?
  - Yes
    - Are these samples stored at -20°C or colder?
      - Yes
        - All samples collected within the U.S.?
          - Yes
            - Not PIM
          - No
            - Not PIM
      - No
        - Not PIM
  - No
    - Not PIM

Contact the NAC
Email: poliocontainment@cdc.gov
Phone: 404-718-5760
You will be asked to complete a survey to determine if you have PIM.*
# Domestic samples

<table>
<thead>
<tr>
<th>Date collected, within the US</th>
<th>Sample potentially contains</th>
<th>Indicate on survey</th>
<th>Subject to containment now?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Before 1966</td>
<td>WPV1,2,3; OPV</td>
<td>WPV2 PIM</td>
<td>Yes– GAP III</td>
</tr>
<tr>
<td>1966–1968</td>
<td>WPV1,3; OPV</td>
<td>WPV3 PIM</td>
<td>No(^2)</td>
</tr>
<tr>
<td>1969-1972,1979(^1)</td>
<td>WPV1; OPV</td>
<td>WPV1 PIM</td>
<td>No(^2)</td>
</tr>
<tr>
<td>April 2000 - present</td>
<td>N/A</td>
<td>N/A</td>
<td>No</td>
</tr>
</tbody>
</table>

1 = WPV1 outbreak in 1979  
2 = subject to GAP III at time of final eradication
## International samples

- WHO table with dates for each country
  - WPV last present (by type)
  - OPV use ceased

### Table A2.1. Country- and territory-specific poliovirus data

<table>
<thead>
<tr>
<th>No.</th>
<th>Country or territory</th>
<th>Province, district, local area</th>
<th>Poliovirus potentially infectious materials</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>WPV2</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Rest of the country</td>
<td>Until 31 Dec 1997</td>
</tr>
</tbody>
</table>
Samples potentially contaminated with wild poliovirus WPV PIM

- Subject to GAP III containment
- Current US recommendations for these materials
  - Storage: secure samples in locked freezer or laboratory, limit access
  - Work: contact the US NAC
Samples potentially contaminated w/ oral polio vaccine
OPV PIM

- Not subject to GAP III containment
- Subject to WHO Guidance to minimize risk for facilities collecting, handling or storing materials potentially infectious for poliovirus (PIM Guidance)
  - Risk classification based on material 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 include risk assessment, good laboratory practices, validation of methods, and immunization of staff
US National Surveys
2015 Survey

- Conducted 2015-2017
- All 3 types
- Asked about IM and PIM
- Targeted PV and enterovirus laboratories (n > 250)
- National inventory not complete
  - outreach needed to labs that may have PIM
2018 Survey

- To be released in 2018
- Will target laboratories with PIM, especially respiratory laboratories
- Will be available on NAC website and direct email
- Advertise
  - NAC website
  - Distribution through professional societies
  - Conference talks and expos
  - Future MMWR, Applied Biosafety articles
Actions Needed by Laboratories

- **ALL**
  - Assess historical domestic and international sample collections for PIM
  - Destroy all non-essential PV materials, IM and PIM
  - Ensure all retained materials are declared in the national survey

- **PV2 IM**
  - Implement additional containment measures for PV2 IM and PIM now
  - Submit CP application

- **PV1 and PV3 IM**
  - Determine whether crucial work with PV1 and PV3 will need to continue after eradication/ability to meet GAP III
  - Participate in conference call with NAC
Key Messages for Biosafety

- Asking for your help to
  - Share information with your PIs
  - Identify PV materials at your institution
  - Encourage destruction of non-essential PV materials
  - Contact NAC to declare/complete survey
  - Foster good material accountability/inventory practices
Resources

- US NAC website
  - [www.cdc.gov/phpr/polioviruscontainment](http://www.cdc.gov/phpr/polioviruscontainment)
  - [poliocontainment@cdc.gov](mailto:poliocontainment@cdc.gov)

- 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 (GAP III)
    - Guidance to minimize risk for facilities collecting, handling or storing materials potentially infectious for poliovirus (PIM Guidance)
    - Country table for identifying PIM
1. Duizer E, Ruijs WL, van der Weijden CP, Timen A. Response to a wild poliovirus type 2 (WPV2)-shedding event following accidental exposure to WPV2, the Netherlands, April 2017. Euro Surveill. 2017;22(21)


Questions?

For more information, contact the US NAC at
404-718-5160
poliocontainment@cdc.gov
www.cdc.gov/phpr/polioviruscontainment

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.