

Laboratory Containment of Poliovirus Materials: Risks and Risk Mitigation

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Background: Polio Vaccines

- **Oral polio vaccine (OPV; Sabin)**
 - Live-attenuated (Sabin strains)
 - Inexpensive, easy to deliver
 - Trivalent (tOPV) and bivalent (bOPV; types 1 and 3)
- **Inactivated polio vaccine (IPV; Salk)**
 - Formalin-inactivated, uses wild polio strains
 - Delivered by IM injection
 - Trivalent formulation, sometimes in combination with other antigens

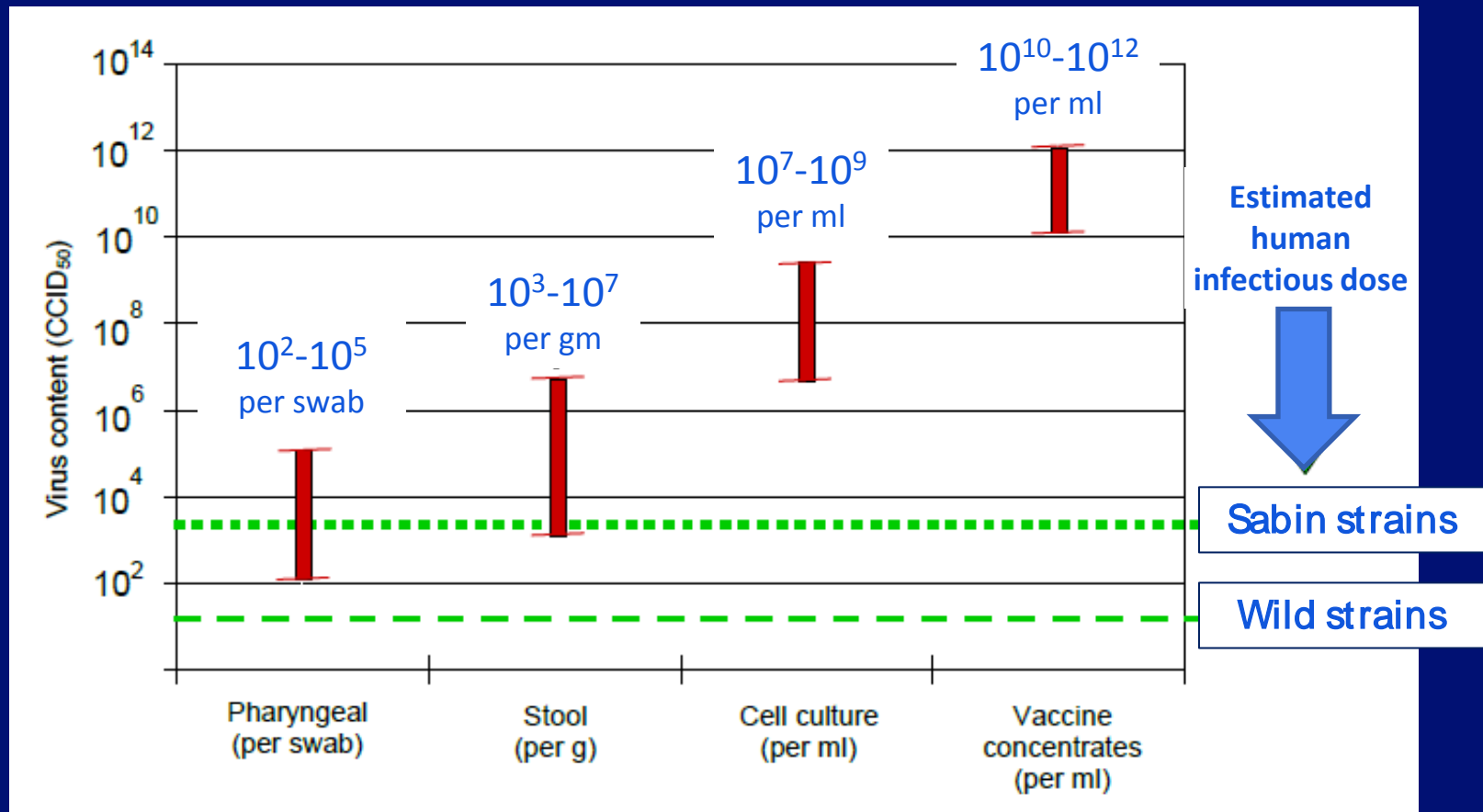
Background: Status of Polio Eradication

- **Wild poliovirus**
 - WPV1: Ongoing (AFG, PAK)—48 cases to date in 2015
 - Last case in Africa in Aug 2014
 - WPV2: **Declared eradicated, Sep 2015** (last case: India, 1999)
 - WPV3: Eradicated? (last case: Nigeria, Nov 2012)
- **Vaccine-derived poliovirus (VDPV; reversion of Sabin strains)**
 - VDPV1: (2015) Madagascar (9 cases); 2 cases in Ukraine
 - VDPV2: (2015) 2 cases (Guinea, Nigeria); **Highest emergence risk**
 - VDPV3: (No cases since 2013) Relatively rare

Post-Eradication withdrawal of Type 2 from OPV

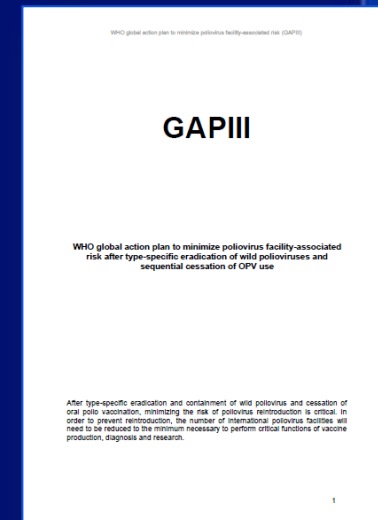
- Reduce risk of VDPV2 emergence
- Synchronized global Switch from tOPV to bOPV, **Apr 2016**
 - At least one dose of IPV in all countries to confer type 2 immunity
- **Post-eradication, poliovirus becomes “exotic”**
 - Risk of accidental or intentional reintroduction
 - Type 2 is immediate priority

Risk: Poliovirus Content in Specimens and Cultures



Global Action Plan (“GAP III”)

- **WHO global action plan to minimize poliovirus facility-associated risk after type-specific eradication of wild polioviruses and sequential cessation of OPV use**
 - Based on risk assessment and risk mitigation
 - Endorsed by World Health Assembly, May 2015
- **Inventory of materials**
 - Type-specific, starting with type 2
 - But all “infectious” and “potentially infectious” polio materials must be inventoried by end 2015
 - Virus-specific: Wild/VDPV vs OPV/Sabin



http://www.polioeradication.org/Portals/0/Document/Resources/PostEradication/GAPIII_2014.pdf

Or google “gap iii polio”

Survey of Facilities/Laboratories

▪ **Original 2004 survey**

- Asked only about wild polio materials
 - Did not ask about Sabin materials
- Not differentiated by serotype

▪ **2015 survey**

- Emphasis on WPV2 (and VDPV2) and OPV2/Sabin2
 - Identify WPV2/VDPV2 and OPV2/Sabin2, “infectious” and “potentially infectious” materials
- Will also capture inventory of type 1 and type 3 materials

Definition: Poliovirus “Infectious Materials”

- **Presence of poliovirus confirmed and storage consistent with maintaining infectivity (stored at $<20^{\circ}\text{C}$)**
- **Virus isolates identified as poliovirus, e.g. by antigenic typing, rRT-PCR, or sequencing**
 - Specimens from person/animal known to be infected, e.g. stool from which a poliovirus isolate was obtained

Definition: Poliovirus “Potentially Infectious Materials”

- Presence of poliovirus unknown but collected in a place and time where poliovirus was circulating or OPV was used (starting with type 2), and storage consistent with maintaining infectivity (stored at $<20^{\circ}\text{C}^*$)
- Fecal, sewage, or respiratory samples, extracted nucleic acid
 - Working on risk assessment/management/mitigation language to minimize disruption in non-polio labs, especially for respiratory samples and extracted nucleic acid

**Containment applies to all laboratories, not just polio labs
(and not just virology/microbiology labs)**

*Or stored at 4°C for less than 1 year

Importance of Place and Time

- **WPV2**
 - WHO developing a list of last year of WPV2 for each country (pre-2000)
- **VDPV2**
 - More complicated—may be specific range(s) of years
 - Confirmed cases/outbreaks in at least 15 countries
 - Emergence always possible with continued tOPV use
- **OPV2/Sabin2**
 - 1961-Apr 2016 for ~150 countries
 - USA: pre-2001

What Does “Containment” Mean?

- **Destroy (and document):** Autoclave, incinerate
- **Transfer:** To an “essential” laboratory facility
- **Contain:** *Become* an “essential” laboratory facility
 - Work with materials in appropriate containment space

“Essential” vs “Non-Essential” Facilities

- **Essential:** It is *essential* that facility retains live poliovirus materials
 - Vaccine (IPV) manufacturers
 - Key reference laboratories
 - Key laboratories performing essential research to directly inform endgame and post-eradication decision-making
- **Non-essential:** It is *not essential* that facility retains live poliovirus materials
 - Diagnostic labs—can perform diagnostics regardless of specimen source, but procedures must prevent generation of live polio
 - If “containable” virus detected, materials must be forwarded to an essential facility

Technical Requirements for Containment

- Biorisk Management
- Poliovirus inventory and information
- General safety
- Personnel and competency
- Good microbiological technique
- Clothing and personal protective equipment
- Human factors
- Healthcare
- Emergency response and contingency planning
- Accident/incident investigation
- **Facility physical requirements**
- Certification
- Decontamination, disinfection, and sterilization
- Transport procedures
- Security

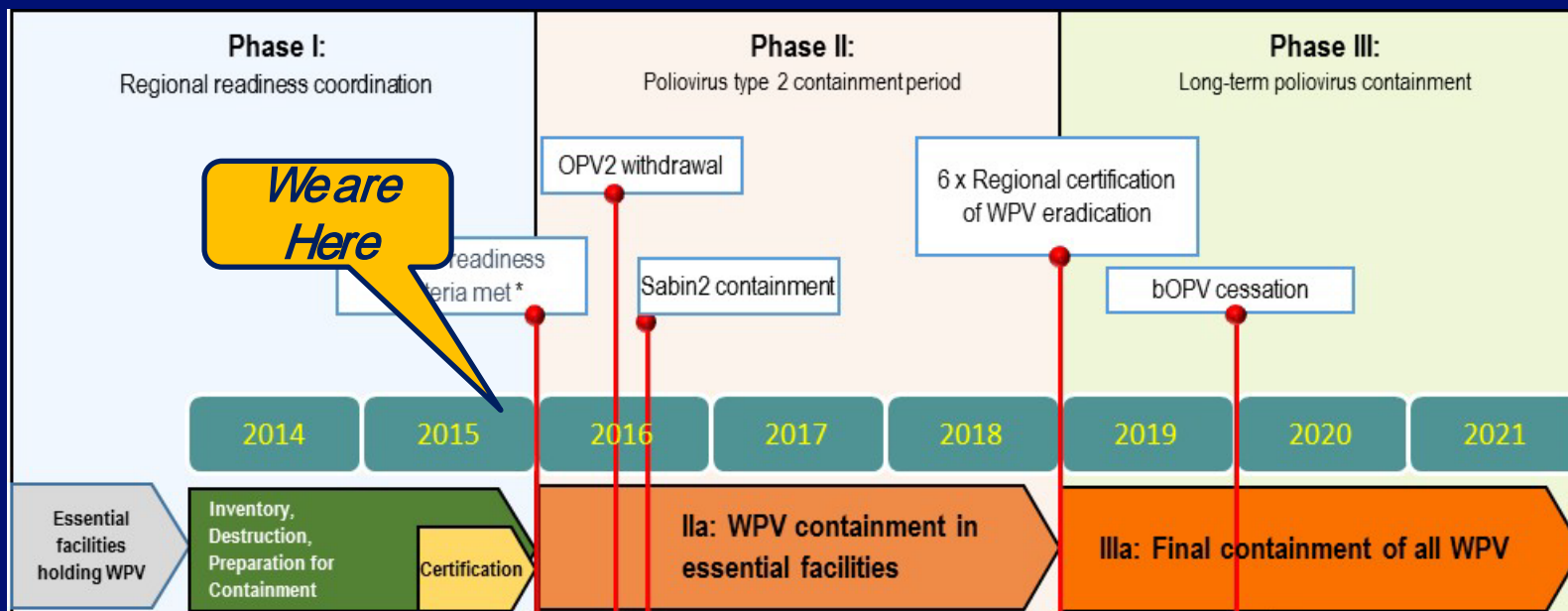
Facility Physical Requirements

- **Located in area with high polio vaccine coverage**
 - Immunization of staff
- **Controlled entry to lab, through double doors**
- **Decontamination**
 - Pass-through autoclave, airlock/decon chamber, dunk tank
- **Animal facility requirements**
- **HEPA-filtered exhaust (post-eradication)**
- **Effluent waste treatment (post-eradication)**
- **Controlled exit, mandatory shower-out**
 - Shower not required if using Class III BSCs

Basically, BSL-3 plus shower-out

Containment Implementation 2015 – 2019

- Contain WPV2 and VDPV2 by 31 Dec 2015
- Contain Sabin2 3 mo after OPV2 withdrawal (by 31 Jul 2016)
- Countries must certify compliance; WHO to audit
- Types 1 and 3 to follow after complete eradication (~2019)



Infrastructure to Support US National Containment

- **National Polio Containment Coordinator: Dr. Olen Kew**
 - Technical POC
 - Responsible for US national survey of poliovirus materials
 - Planning online survey: expect to see it soon
 - Developing an MMWR article to communicate containment issues
 - Reports to National Certification Committee
- **National Certification Committee**
 - Assures absence of polio in US and compliance with containment guidelines
 - Reports to Assistant Secretary for Health, DHHS, through NVPO

CDC contacts for polio containment questions:

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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.

