POLIOVIRUS CONTAINMENT

61st Annual Biological Safety Conference

October 12-17, 2018 Charleston, SC.

Poliovirus Containment for Non-Polio Facilities

Daphne Moffett, PhD
(on behalf of the Polio Containment Team: J. Fournier-Caruana, N. Previsani, H. Singh, and L. Boualam)
Department of Polio Eradication,
WHO HQ,
Geneva, Switzerland

POLIO GLOBAL ERADICATION INITIATIVE

EVERY LAST CHILD

POLIOVIRUS CONTAINMENT

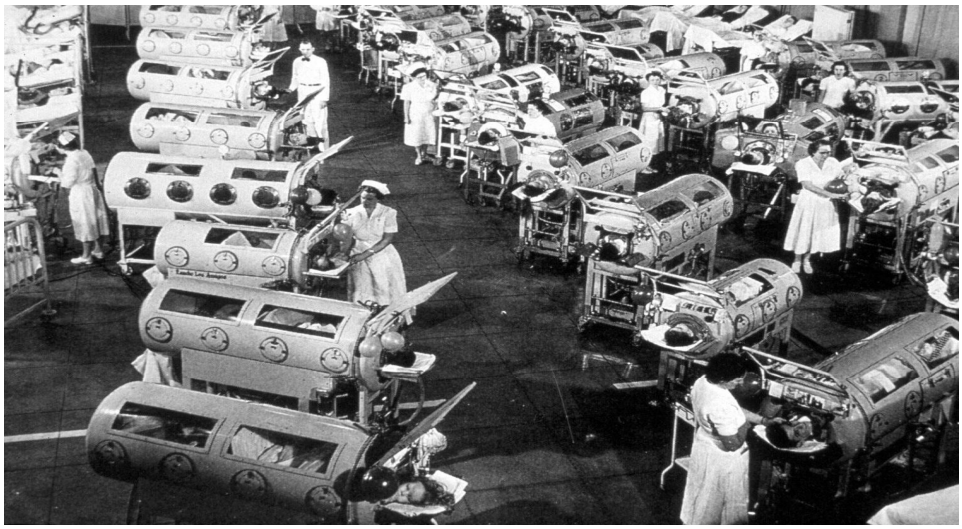
Topics

- 3 Types of Polio Virus
- Polio eradication effort
- Infectious materials versus potentially infectious materials (PIMs)
- Risk associated with PIMs
- GAP III -Global Plan of Action for Poliovirus Containment
- PIM Guidance including risk mitigation strategies

POLIO GLOBAL ERADICATION INITIATIVE

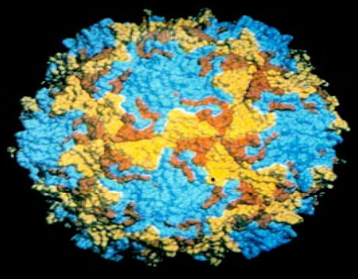
EVERY LAST CHILD

Polio once paralyzed >1000 children/day



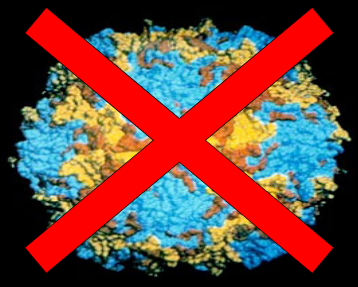
POLIO GLOBAL ERADICATION INITIATIVE

EVERY LAST CHILD



WILD
POLIO TYPE 1

- Endemic in certain parts of **Pakistan**, **Afghanistan** and **Nigeria**



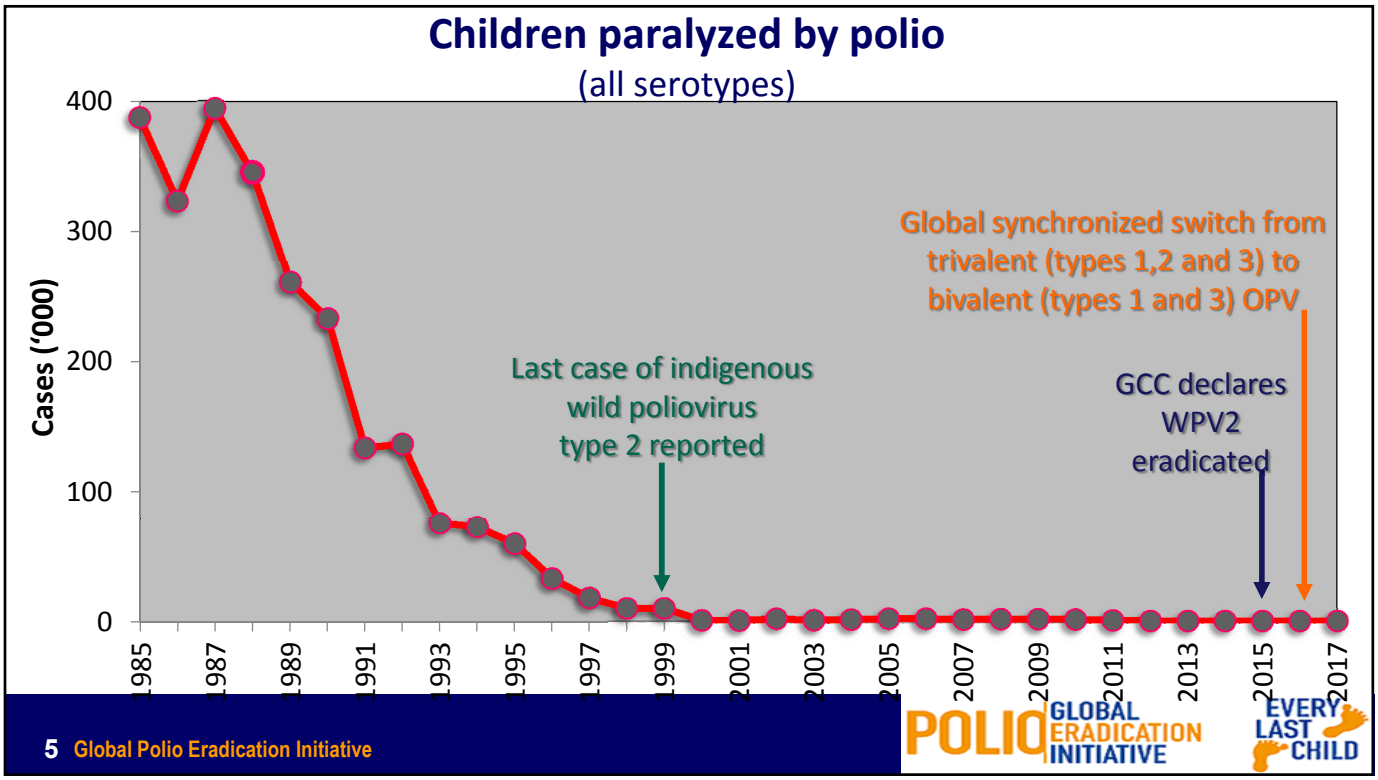
WILD
POLIO TYPE 2

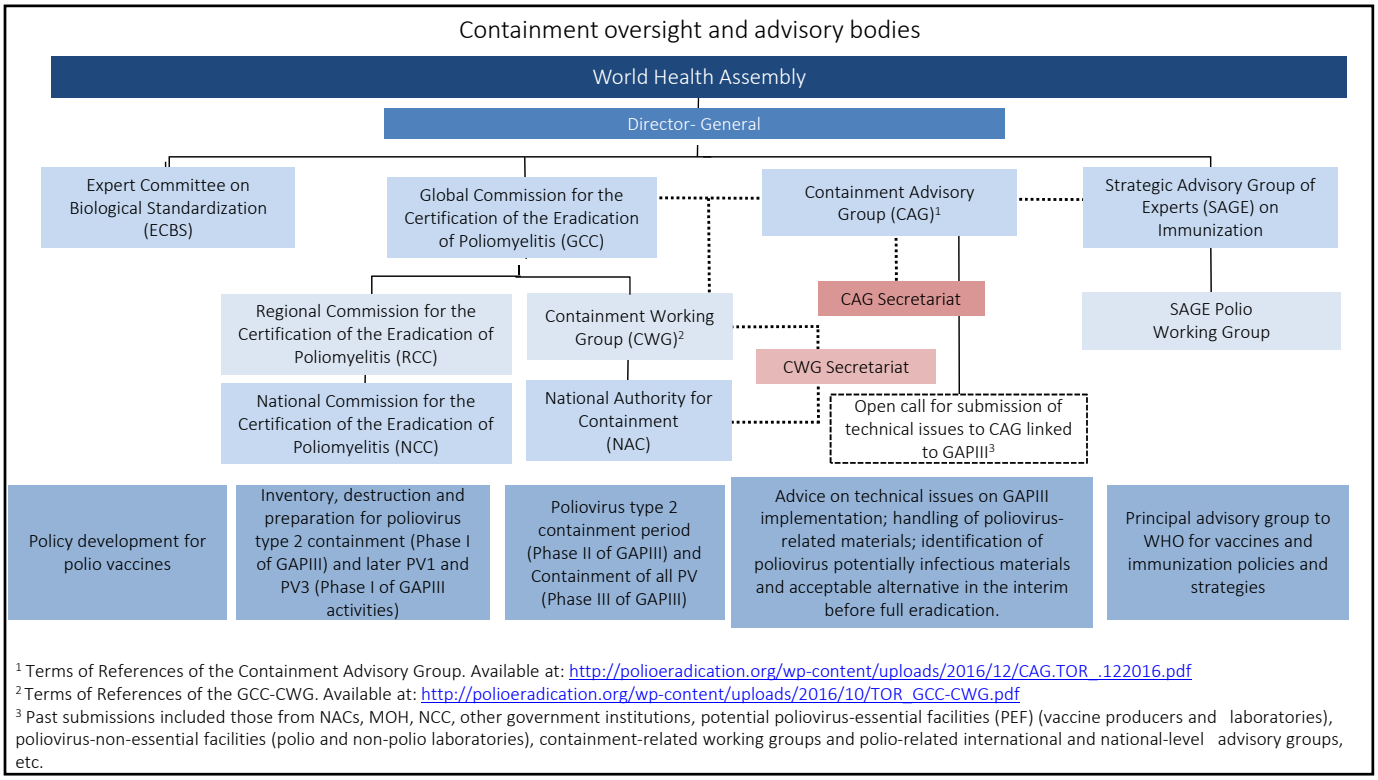
- October 1999: **India** reported the last indigenous case globally
- September 2015: Declared eradicated by the GCC*

WILD
POLIO TYPE 3

- November 2012: **Nigeria** reported the (hopefully) last case globally
- Has not been declared eradicated by the GCC

*GCC – Global Certification Commission for the Eradication of Poliomyelitis.





[1] Terms of References of the Containment Advisory Group. Available at: http://polioeradication.org/wp-content/uploads/2016/12/CAG.TOR_.122016.pdf
[2] Terms of References of the GCC-CWG. Available at: http://polioeradication.org/wp-content/uploads/2016/10/TOR_GCC-CWG.pdf
[3] Past submissions included those from NACs, MOH, NCC, other government institutions, potential poliovirus-essential facilities (PEF) (vaccine producers and laboratories), poliovirus-non-essential facilities (polio and non-polio laboratories), containment-related working groups and polio-related international and national-level advisory groups, etc.

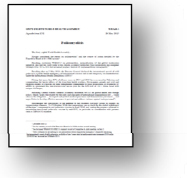
What is poliovirus containment?

A system for confining polioviruses within a defined space

Global agreement:

WHA resolution 68.3:

- The May 2015 resolution urges countries to implement GAPIII



Global Plan of Action for Poliovirus Containment (GAPIII)

- Based around a 'modern' biorisk management philosophy
- Annex requirements are generic and apply regardless of:
  - Type
  - Size
- Risk-based approach and is not focused upon biological agent risk groups or containment levels
- If exclusions proposed, claims of conformity are not acceptable unless detailed and shown to be justified
- Compliance with national and local requirements of primary importance

WHA resolution 71-16

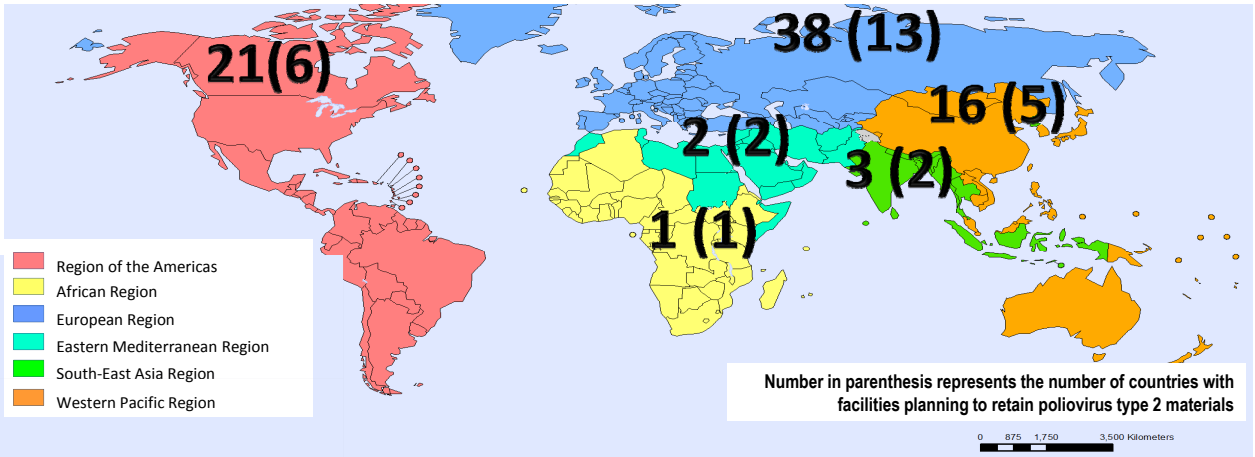
Urges all MS:

- to intensify efforts to accelerate the progress of poliovirus containment certification
- to complete inventories for type 2 polioviruses, destroy unneeded type 2 materials and to begin inventories and destruction of unneeded type 1 and 3 materials in accordance with the latest available published WHO guidance;
- to ensure that any confirmed event associated with a breach in poliovirus containment is immediately reported to the National IHR Focal Point

URGES all Member States retaining polioviruses:

- to reduce to a minimum the number of facilities designated for the retention of polioviruses, prioritizing facilities performing critical national or international functions
- to appoint, as soon as possible and no later than the end of 2018, a competent National Authority for Containment
- to request facilities designated to retain poliovirus type 2 to formally engage in the Containment Certification Scheme by submitting to their NAC their applications for participation, which is the first step of the global certification process, as soon as possible and no later than 31 December 2019

29 countries plan to retain poliovirus type 2 materials* in 81 designated PEFs



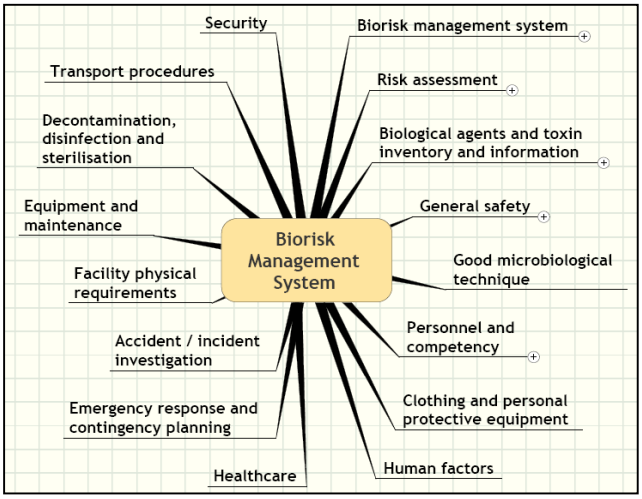
*Includes WPV/cVDPV and OPV/Sabin type 2
Data reported by WHO Regional Offices as of 3 September 2018 and subject to change

The boundaries and names shown and the designations used on this map do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted and dashed lines on maps represent approximate border lines for which there may not yet be full agreement.

- NACs: 22 of 30 NACs 'nominated'
- PEFs: Applications submitted to GCC 3; CPs delivered: 1

Annexes – Facility (primary) safeguards

- Annex 2 – Poliovirus-essential facilities holding wild polioviruses
- Annex 3 – Poliovirus-essential facilities holding only OPV/Sabin
- Annex 2 – is identical to Annex 3 except for certain facility containment-specific areas applying in Phase III for containment of all wild poliovirus
- Annex 6 – Poliovirus-non-essential facilities if they suspect they will handle new poliovirus samples



Population immunity (secondary) safeguards

Revised population immunity (secondary safeguards) to reduce the consequences of a poliovirus release from a facility based on current recommendations by SAGE for countries hosting PEFs (to align GAPIII and SAGE recommendations on IPV immunization schedules):

	Poliovirus type 2 containment period	Final poliovirus containment period	
2° safeguards: Population immunity in country hosting the facility	All type 2 polioviruses	All OPV/Sabin polioviruses	All wild polioviruses
IPV doses	≥ 2	≥ 2	≥ 2
IPV2 coverage	≥ 90%*	≥ 90%*	≥ 90%*

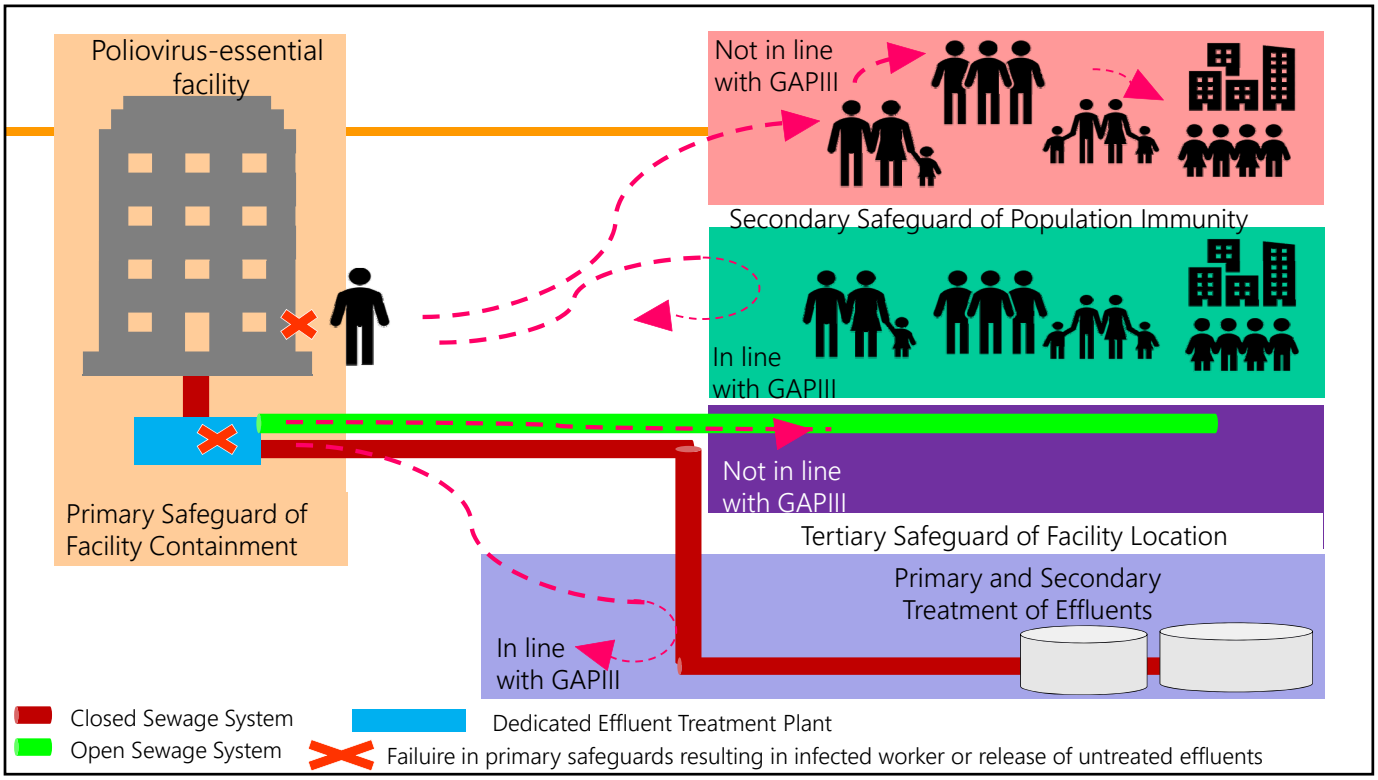
*≥90% of IPV2 coverage in infants within a 100 km of the PEF

(Source: Meeting of the Strategic Advisory Group of Experts on immunization, April 2018 – conclusions and recommendations. Weekly Epidemiological Record 2018;93:329–44)

Environment & location (tertiary safeguards)

Environment & location (tertiary safeguards) reduce the consequences of a poliovirus release from a facility

	Poliovirus type 2 containment period	Final poliovirus containment period	
3° safeguards: Environment & location	All type 2 polioviruses	All OPV/Sabin polioviruses	All wild polioviruses
Siting of facilities in areas with low transmission potential (R_o) for wild polioviruses	No	No	Yes



Relevant GCC recommendations on the implementation of the guidance document

SPECIAL MEETING OF THE

GLOBAL COMMISSION FOR THE CERTIFICATION OF THE ERADICATION OF POLIOMYELITIS

ON POLIOVIRUS CONTAINMENT

GENEVA, SWITZERLAND
23 – 25 OCTOBER 2017

World Health Organization

3 ISSUES, CONCLUSIONS AND RECOMMENDATIONS

3. Completion of Phase I (Preparation for containment of poliovirus type 2) of GAPIII

GCC conclusions:

- GCC noted the lack of consistent, standardized and harmonized data collection mechanisms to finalize preparations for PV containment phase in the six regions.
- GCC recognized the need for CAG to endorse the *Guidance for non-poliovirus facilities to minimize risk of sample collections potentially infectious for PV in order to support the completion of inventories for PV materials in polio and non-polio facilities.*

3 ISSUES, CONCLUSIONS AND RECOMMENDATIONS

Completion of Phase I (Preparation for containment of poliovirus type 2) of GAPIII

GCC recommendations:

- GCC encourages the establishment of a standardized data collection and verification mechanism.
- NCC/RCC reports need to clearly indicate where and when activities in Phase I have been completed, based on a standardized data collection and verification mechanism, so that, on the basis of equivalent data quality between regions, the GCC can declare global completion of Phase I.
- The deadline for completion of Phase I for all PV2 is set at one year after the publication of the Guidance for non-poliovirus facilities to minimize risk of sample collections potentially infectious for polioviruses

3 ISSUES, CONCLUSIONS AND RECOMMENDATIONS

Completion of Phase I (Preparation for containment of poliovirus type 2) of GAPIII

GCC recommendations:

- GCC urges countries affected by ongoing transmission of cVDPV2 to repeat their inventories and destroy, transfer or contain PV2 materials after the outbreak is declared closed.
- GCC requests RCCs to urge countries to complete the identification, destruction, transfer or containment (Phase I) of WPV1 and WPV3 materials by the end of Phase II.
- GCC urges countries planning to designate facilities for the retention of WPV1 and WPV3 materials to weigh the risks and benefits of having such facilities and the commitments that will be required to comply with the primary (facility), secondary (population immunity) and tertiary (sanitation and hygiene) safeguards.
- GCC requests a letter be prepared and distributed via Regional Offices formally acknowledging countries for the completion of Phase I of GAPIII.

Poliovirus Materials Defined in GAPIII

WPV2 and cVDPV2 Infectious Materials

WPV2 and cVDPV2 Potentially Infectious Materials

OPV2 and Sabin2 Infectious Materials

OPV2 and Sabin2 Potentially Infectious Materials

What differentiates IM and PIM is the known or unknown presence of poliovirus

(+) Samples that have tested positive for the presence of PV.

- These would usually be found in poliovirus laboratories and not non-polio labs.

WPV2 and cVDPV2
Infectious Materials

(+)

OPV2 and Sabin2
Infectious Materials

- Testing is NOT needed.

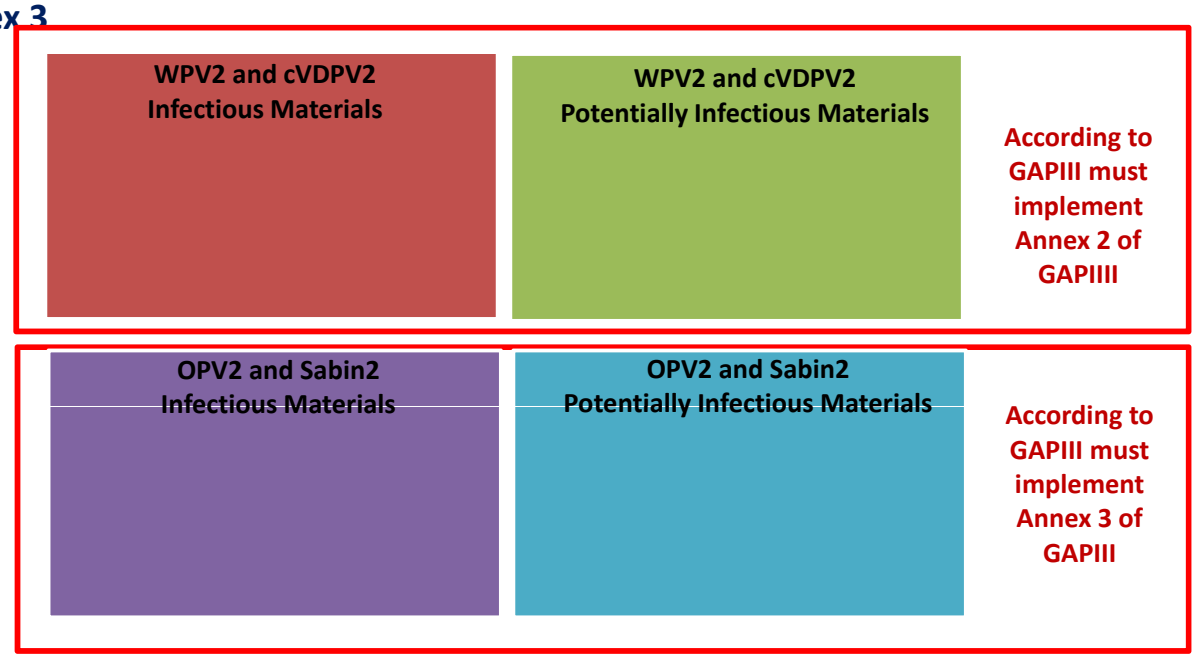
WPV2 and cVDPV2
Potentially Infectious Materials

- These are samples that have been collected from person from areas where WPV2 and cVDPV2 were in circulation

OPV2 and Sabin2
Potentially Infectious Materials

- These are samples that have been collected from person from areas where OPV was in use

GAPIII REQUIRES that these materials can only be stored and handled if facilities that are designated by the governments fulfill the standards of GAPIII - Annex 2 and Annex 3

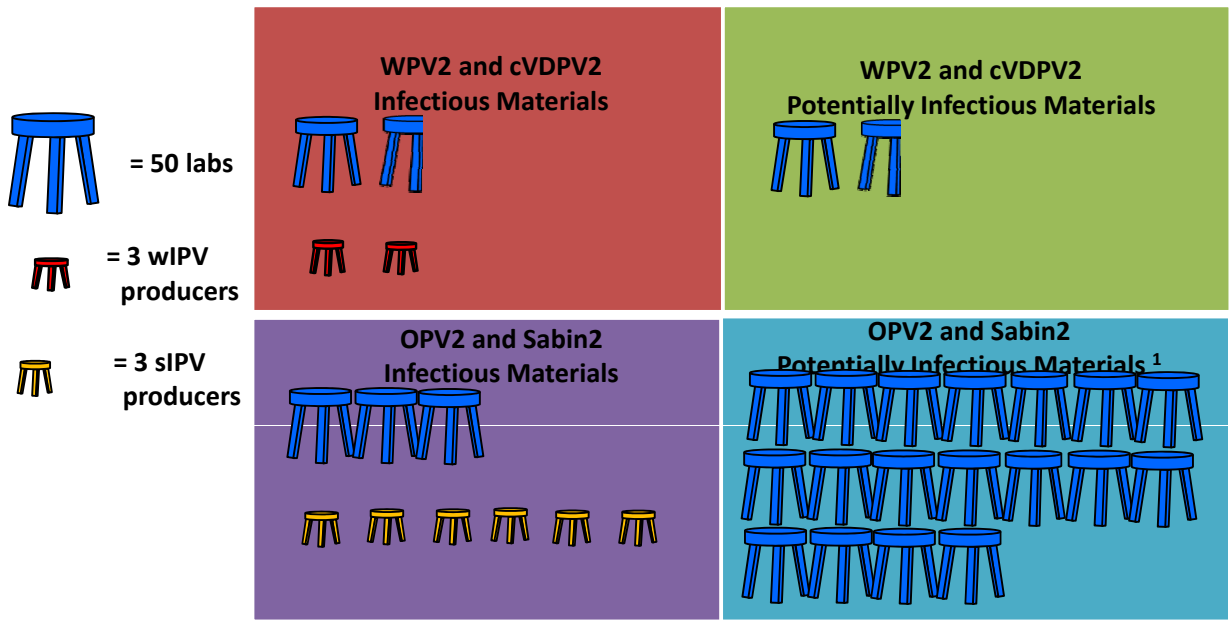


Why is Guidance for non-poliovirus facilities to minimize risk of sample collections potentially infectious for polioviruses needed?

Most of the surveys and inventories performed in the past have been limited to only polio laboratories . But we have stakeholders that we MUST collaborate with.

- Global Rotavirus Lab: As of January 2016, the network included 115 laboratories including 68 sentinel hospital laboratories (SHL), 37 national and provincial laboratories, 9 regional reference laboratories (RRL) and one Global Reference Laboratory (GRL).
- Measles and Rubella Network: 696 laboratories have been established in 164 countries
- Flu: Established in 1952, the network currently comprises 143 institutions in 113 WHO Member States, which are recognized by WHO as National Influenza Centres, 6 WHO Collaborating Centres, 4 WHO Essential Regulatory Laboratories, 13 WHO H5 reference laboratories, and ad hoc groups established to address specific emerging issues.
- GPLN: 146 labs (1/3 are PEFs)

Guidance for non-poliovirus facilities to minimize risk of sample collections potentially infectious for polioviruses



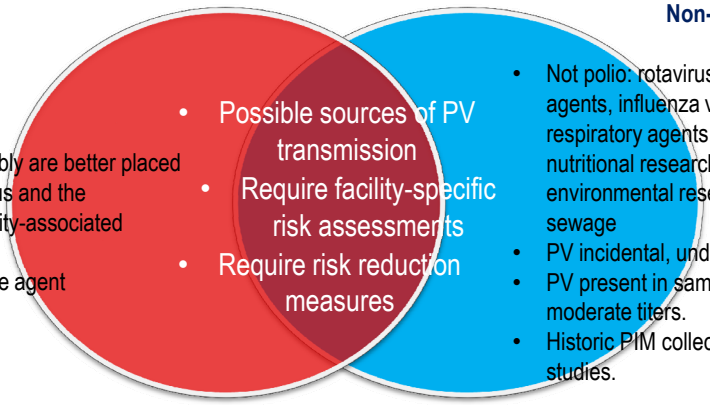
[1] Approximate number of facilities is based on **WHO** Global Rotavirus Lab (115 labs), WHO Measles and Rubella Network (696 labs) and WHO Flu Network (143 labs) and Polio-non-essential-facilities of GPLN : 146 labs (1/3 are PEFs)

Guidance for non-poliovirus facilities to minimize risk of sample collections potentially infectious for polioviruses

The purpose of this guidance is to assist facilities in assessing the risk of PV PIM in their possession and to implement appropriate risk reduction consistent with GAPIII.

Polio Facilities

- Polio focus: Presumably are better placed to recognize poliovirus and the implications of a facility-associated release of PV
- PV is often a desirable agent



Non-Polio Facilities with PIMs

- Not polio: rotavirus, HAV, HEV, or other enteric agents, influenza viruses, measles virus, other respiratory agents, diarrhoeal disease and nutritional research using fecal samples, environmental research using concentrated raw sewage
- PV incidental, undesirable agent.
- PV present in samples at varying rates and moderate titers.
- Historic PIM collections are retained for special studies.

Guidance for non-poliovirus facilities to minimize risk of sample collections potentially infectious for polioviruses

Strategy to minimize the risk from non-polio facilities is consistent with GAPIII

1 **Risk elimination**

- Destruction
- Inactivation
- Transfer to a PEF

2 **Biorisk management**

WPV2/VDPV2 PIM retention requires the implementation of Annex 2 of GAPIIII and CCS

Moderate

Low

Lowest

OPV2/Sabin2 PIM retention requires the implementation of the risk-appropriate management standard described in the guidance. Compliance verification is the responsibility of the national authority e.g., MOH.

Collections with potential for only OPV/Sabin

	Type of PIM	Accepted procedures
Moderate	Faecal samples or concentrated sewage	Inoculation into poliovirus-permissive cells
	Extracted nucleic acid from faecal samples or concentrated sewage	Transfection into poliovirus-permissive cells
Low	Faecal samples or concentrated sewage	No cell culture inoculation
	Respiratory tract samples	Inoculation into polio-permissive cells
	Extracted nucleic acid from respiratory tract samples	Transfection into poliovirus-permissive cells
Lowest	Respiratory tract samples	No cell culture inoculation
	Extracted nucleic acid from faecal samples, concentrated sewage or respiratory tract samples	No transfection into polio-permissive cells
Non-PIM	CSF, serum/blood and other clinical material, materials inactivated by a validated method (e.g. formalin)	Not applicable

Risk mitigation strategies

Risk Mitigation Strategies	Moderate	Low	Lowest	Storage only
Declare PIM in National Survey and maintain working inventory	X	X	X	X
Biosecurity (locked freezers, limited access	X	X	X	X
Good laboratory/microbiological practices, including documentation and validation of methods/SOPs	X	X	X	n/a
Risk assessment for specific procedures being used	X	X	X	n/a
~~Polio immunization for staff:~~ Required Recommended	 X -	 X -	 - X	n/a
Accreditation to a national or international biorisk management standard	X	n/a	n/a	n/a

Poliovirus Containment Resources

Containment resources (GAPIII, CCS, CCS forms, non-polio guidance)
http://polioeradication.org/polio-today/preparing-for-a-polio-free-world/containment/containment-resources/

Containment supporting groups (Information on CAG, GCC, CWG e.g., TORs)
http://polioeradication.org/who-we-are/governance-and-structure/

CAG meeting reports
http://polioeradication.org/tools-and-library/policy-reports/advisory-reports/containment-advisory-group/

GCC meeting reports (certification and containment reports)
http://polioeradication.org/tools-and-library/policy-reports/certification-reports/global-certification-commission/

E-mail address to submit CCS applications (CCS SharePoint)
containmentcertification@workspace.who.int

POLIOVIRUS CONTAINMENT

- The Containment Corner, a new GPEI publication to update stakeholders on key developments in global poliovirus containment. The e-newsletter replaces Polio Pipeline and will be biannual in frequency.

POLIO GLOBAL ERADICATION INITIATIVE

EVERY LAST CHILD

POLIOVIRUS CONTAINMENT

Thank you

For any questions or suggestions on poliovirus containment and GAPIII please contact:

moffettd@who.int

POLIO GLOBAL ERADICATION INITIATIVE

EVERY LAST CHILD