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## Supporting Containment Standards for Poliovirus after Eradication

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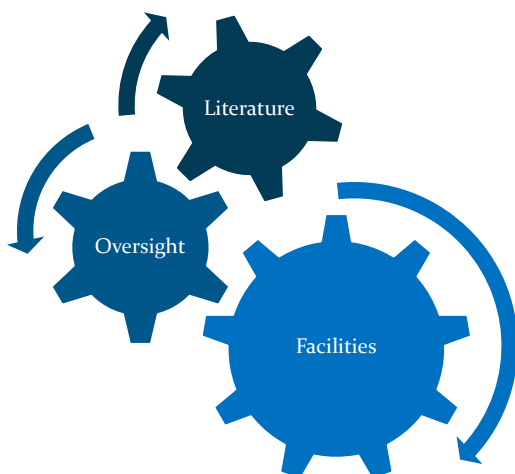


### Project Background

- **Purpose:**
  - Study currently-practiced **poliovirus risk assessment** and control measures
  - Set requirements for **a tool to support risk-based decision-making for poliovirus containment** activities under the WHO Global Action Plan III (GAPIII)
- **Team:** Sandia National Laboratories and Gryphon Scientific under the direction and funding of the CDC
- **Assumption:** Risk management of poliovirus will be aided by more rigorous and consistent risk assessment and risk-based decision-making.
  - Experience-based risk assessment is, by itself, inadequate to understand risk in a post-eradication world.



## Data Sources and Methods



- **Literature**
  - Reviewed >150 articles relevant to poliovirus public health, safety and risk, dating between 1940 and 2018
- **Oversight**
  - Reviewed WHO GAPIII and GAPIII-derived guidance for references to and expectation for risk assessment and facility-based risk assessment
- **Facilities**
  - Solicited input from all US laboratories that declared intent to maintain PV2
  - Facilitated discussions with personnel from seven facilities

## Findings: Practices & Oversight

Finding	Details
<b>GAPIII and other poliovirus guidance is limited</b>	<ul style="list-style-type: none"> <li>• GAPIII and GAPIII-derived guidance, by design, relies heavily on facilities to make their own decisions on risk and risk management.</li> <li>• Little poliovirus-specific information for choosing best practices is provided by GAPIII, GAPIII-derived guidance, or the literature.</li> </ul>
<b>Risk-based decision making varies</b>	<ul style="list-style-type: none"> <li>• Risk-based decision-making at facilities varies in content, contributors, and rigor.</li> <li>• All processes we observed are experience-based.</li> </ul>
<b>Silent infections create an unknowable risk</b>	<ul style="list-style-type: none"> <li>• Due to current widespread vaccination and the likelihood of silent infection among those vaccinated, the frequency of facility-acquired infections is unknowable today               <ul style="list-style-type: none"> <li>• This silent nature of laboratory-acquired infections likely skews experience-based perception of risk for poliovirus</li> </ul> </li> <li>• Disconnect between risks to worker safety and containment</li> </ul>
<b>Facilities are willing partners but face challenges</b>	<ul style="list-style-type: none"> <li>• Capacity to meet GAPIII infrastructure requirements is limited</li> <li>• Evolving oversight is confusing and can be frustrating</li> </ul>

## Findings: How a Tool Would be Used

- A more robust and standardized approach to risk-based decision making could provide several advantages:

<b>Reduce facility burden</b>	A tool could “prepackage” data and processes for conducting risk assessments
<b>Elevate risk assessment practices</b>	A tool could help facilities consider risks in a projected future no one has yet experienced
<b>Identify unrecognized risk factors</b>	By standardizing risk assessments, a tool could help facilities ensure they consider all relevant factors
<b>Quantify risks</b>	A tool could account for facility-specific differences in titers and volumes
<b>Prioritize risk reduction</b>	Due to the quantitative nature, a tool could also compute the risk reduction value of control measures and offer a prioritized list
<b>Provide an evidence basis</b>	Tool outputs could provide evidence for the necessity of control measures that may not be obvious

## Notional Tool--Inputs

- A risk assessment tool would take information about the types of experiments conducted in the lab
  - For example, their frequency, strains, volumes and titers

Inputs 1—Experiments Notional Dashboard					
Experiment Type	Frequency (#/mo)	Strain	Are Samples Titered?	Titer (CCID50/ml)	Total Volume (ml)
Neutralization Assay ▼	20	OPV1 ▼	NO, infant stool ▼		100
Serotyping Assay ▼	1	UNK ▼	NO, PIM- historic ▼		5,000
Neutralization Assay ▼	.5	WT3 ▼	YES ▼	1E7	100
Other—mouse study ▼	.1	WT2 ▼	YES ▼	5E5	1
Other—in vitro ▼	-	▼	▼		

## Notional Tool—Inputs 2

- A risk assessment tool would take information about the safety features of the laboratory
  - Including equipment, materials, processes, SOPs, training, etc.
  - Considering taking information about environment, utilities, etc.

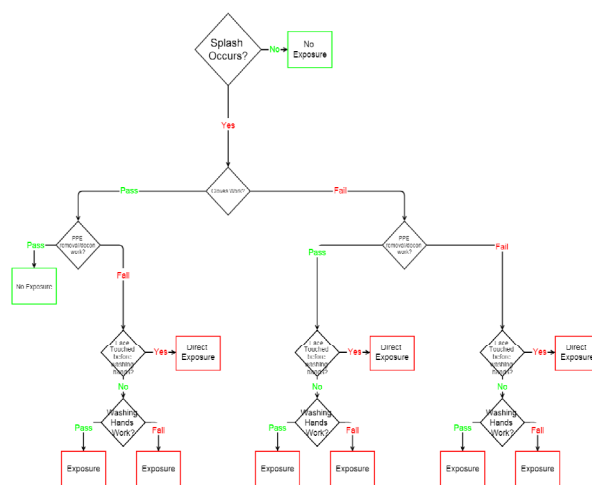
### Notional Dashboard

Inputs 2—Safety Features

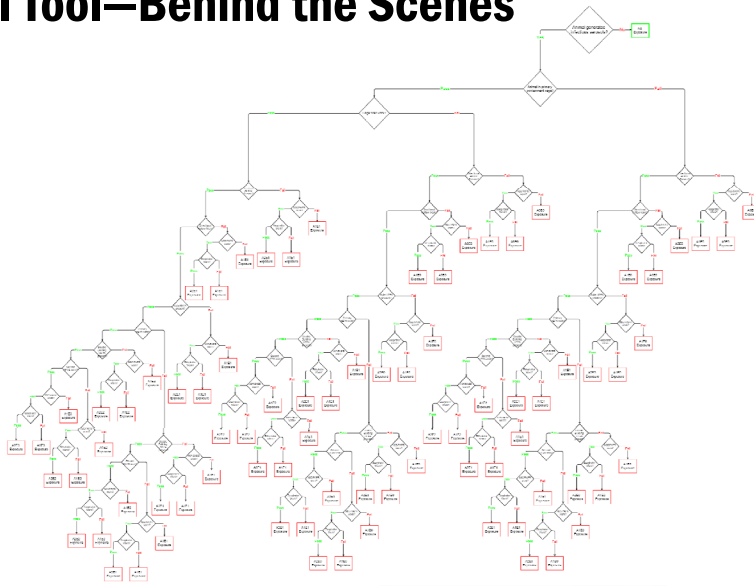
Centrifuge with seals <input checked="" type="checkbox"/>	Shower out <input type="checkbox"/>
Centrifuge in BSC <input type="checkbox"/>	Liquid waste decon <input type="checkbox"/>
Vortexer in BSC <input type="checkbox"/>	Secondary liq waste contain <input checked="" type="checkbox"/>
Class III BSC <input type="checkbox"/>	Liq waste overflow alarm <input checked="" type="checkbox"/>
Class I/II BSC <input checked="" type="checkbox"/>	Double gloving <input type="checkbox"/>
Disposable lab coats <input checked="" type="checkbox"/>	...
HEPA filtered exhaust <input type="checkbox"/>	...

## Notional Tool—Behind the Scenes

- The tool would be loaded with quantitative data
  - Dose-response, stability, decontamination, transfer, source-terms, human reliability, etc.
- The tool would be based on several probabilistic, fault-tree models
  - Events and cascading errors that could lead to a LOC would be considered



## Notional Tool—Behind the Scenes



## Notional Tool—Outputs 2

- A risk assessment tool would provide simple, actionable information to help identify unappreciated aspects of risk
  - To be used in conjunction with current BRM approaches

### Notional Dashboard—Final Tool will Have Graphical Output

#### Outputs 1—Risk Drivers

Click for mitigation measures to consider

1. Contaminated hands via glove and handwashing failure
2. Vortexing out of BSC
3. Improper inactivation
4. ....

## Notional Tool

- A risk assessment tool would provide simple, actionable information to help mitigate these risks
  - This information would allow stakeholders to consider additional investments to further reduce risk
  - Outputs would be considered in the context of the ground-truth in their laboratory

### Notional Dashboard—Final Tool will Have Graphical Output

#### Outputs 2—Potential Risk Mitigation Measures

1. **Contaminated hands via glove and handwashing failure**
  1. Consider training (and annual refresher training) on hand washing—potential 10x reduction in risk
  2. Consider double-gloving—potential 10x reduction in risk
  3. Consider shower out—potential 40x reduction in risk

## Next Steps

- We hope to receive funding to begin development of a prototype tool
- We would love your feedback on the features of the tool

# THANK YOU

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