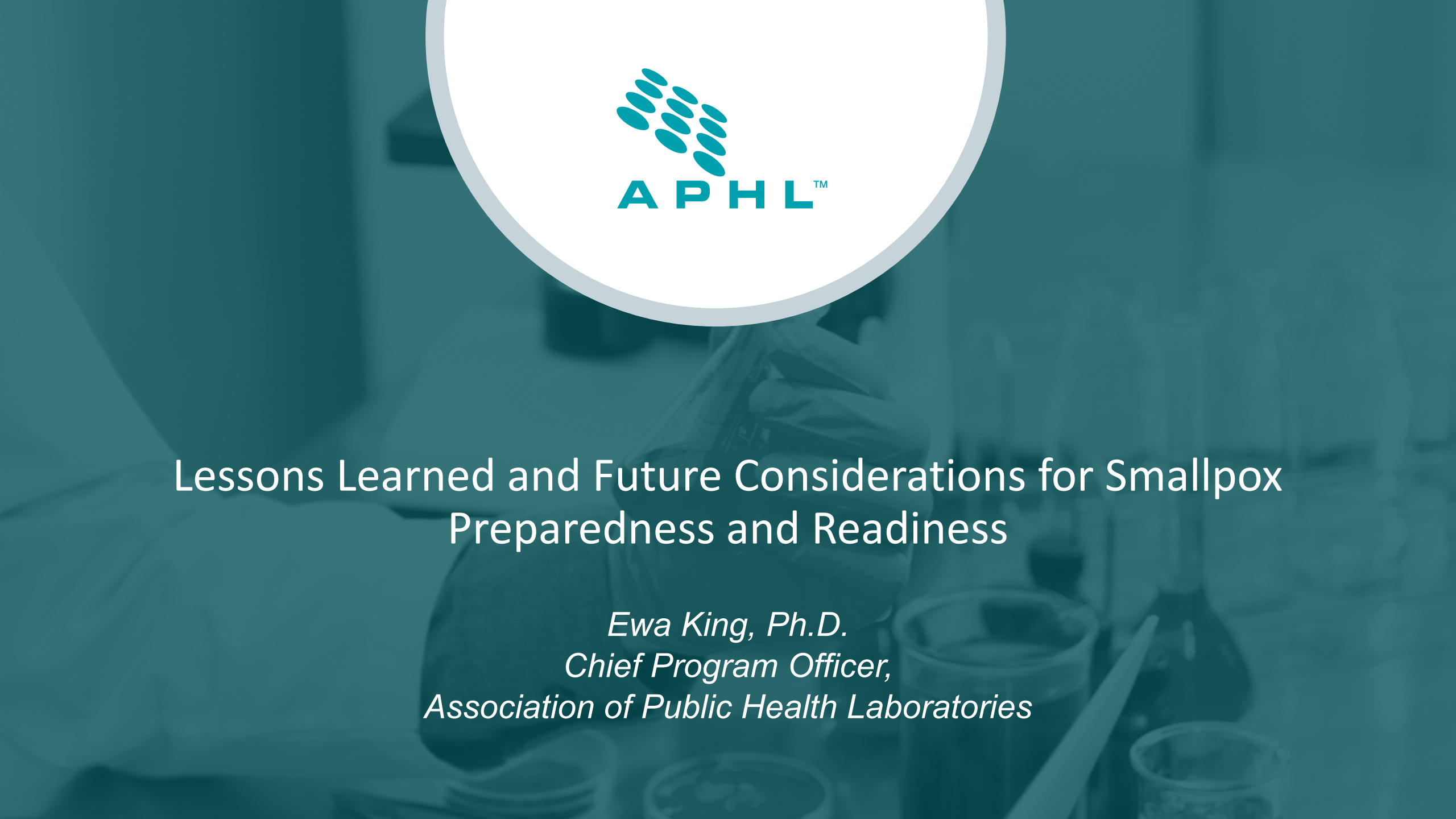

Lessons Learned and Future Considerations for Smallpox Preparedness and Readiness

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Diagnostic challenges in previous public health emergencies

- **Logistics**
  - Inefficient sample transport from collection site to public health laboratories
  - Supply chain shortages
- **Test technology**
  - Faulty test design and lack of redundancy in test development system
  - Outdated and manual laboratory methods
  - Complex and lengthy new test regulatory approval process
- **Information exchange**
  - Complex process for HCP to obtain approval for testing at PHL
  - Non-standardized data collection systems

LRN high-risk smallpox specimen testing is outdated

- Requires enhanced BSL-3 facility with up-to-date vaccinated personnel
- 19 LRN laboratories in the US with variola testing capability
- Protocol currently requires three different PCR reactions on three different instruments
- Electron microscopy is rarely available
- Positives require confirmation at CDC

Multiplexing the three orthopox-specific PCR reactions would provide a faster and more efficient approach. Additionally, performing a comprehensive rash PCR panel in parallel would provide rule-in/rule-out information.

Potential solutions for testing issues……

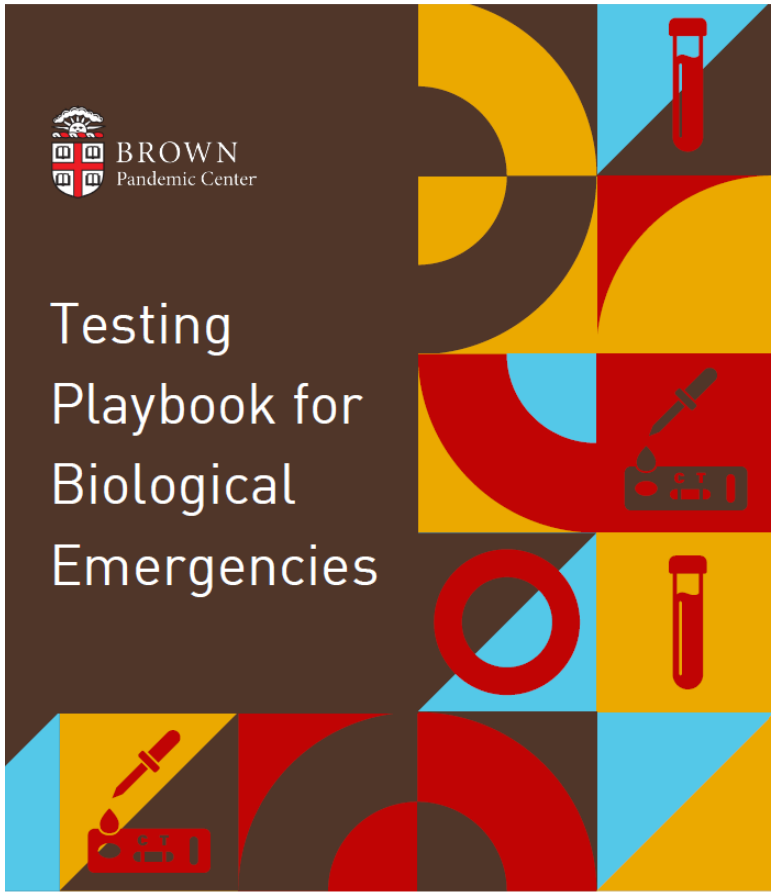
- Collaborate with commercial laboratories for specimen transport during public health emergencies
- Pro-actively develop government contracts with test manufacturers for supplies.
- Provide redundancy in the initial test development process using advanced public health laboratories.
- Update current LRN assays by multiplexing and adapting to high throughput
- Develop a minimum data set for the test request process and case definition
- Work with the FDA to develop a portfolio of pre-vetted test protocols to speed regulatory test approval in an emerging biological crisis

The COVID and mpox responses demonstrated a need for more coordination and connection between laboratory sectors as well as the determination of national roles and responsibilities.

How can this be achieved?

- Strengthen the concept of the National Laboratory System
- Maintain the laboratory infrastructure in a Ready State

The Playbook



- How the Playbook was envisaged
- Playbook structure
- Playbook evolution
- Next steps: Version 2

- Better Testing Now
- Testing-Playbook-Biological-Emergencies.pdf (aphl.org)

The Playbook was developed collaboratively

- Pandemic Center at Brown University School of Public Health
- STAT Public Health Network at Brown University
- Association of Public Health Laboratories
- Arizona State University's College of Health Solutions

- Informed by interviews from public health experts across the US

Funding from the Peter G. Peterson Foundation Pandemic Response Policy Research Fund

Why was the Playbook developed?

The goal of this Testing Playbook is to provide US decision-makers predominately at the federal level with a clear and evidence-based guide for making rapid and effective decisions regarding the development, implementation, and scale-up of diagnostic testing in an infectious disease emergency.

The Playbook focuses on actions that should be taken to support universal availability of testing in six sequential phases of a biological emergency

How is the Playbook structured?

- Explains the essential nature of diagnostic testing in mitigating the impact of a biological emergency.
- Describes the capability and capacity of the different sectors of the laboratory “industry” in the US and their roles during a biological emergency: National Laboratory System.
- Provides a phase-specific series of questions, the answers to which will be essential information to drive public health action in biological emergencies
- Defines the Calls-to-Action necessary to maintain a “Ready State”

Next steps...

Version 2 of the Playbook will focus on guidance for leaders at the state and local level.

Questions?