NATIONAL ACADEMIES Sciences Engineering Medicine

Future of the Nation's Laboratory Systems for Health Emergency Response: A Workshop

Meeting 44 of the Forum on Medical and Public Health Preparedness for Disasters and Emergencies

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Workshop Objectives

1. Summarize the nation's various laboratory systems and their perceived roles and responsibilities for public health emergency preparedness and response.
2. Identify the factors that influence how the nation's various laboratory systems and their component parts/players perform.
3. Identify potential strategies for improving the nation's various laboratory systems within the next three to five years.
4. Begin to articulate a model structure, characteristics, components, capabilities, and functions of a more integrated and coordinated national laboratory system that is prepared for current and future public health threats and emergencies

Summary of the Agenda

- Day 1 laid the foundation for the workshop and examined the current laboratory systems for public health emergency preparedness and responses and begin to understand the performance of the current systems—what is working and what is not working—and why that matters.
- Day 2 discussed short-term strategies and actions that can be taken now and in the next 3-5 years to enhance the capabilities, capacities, and coordination of the laboratory systems for public health emergency preparedness and response.
- The workshop concluded with a roundtable discussion envisioning the ideal structure, characteristics, components, capabilities, and functions of a more coordinated national laboratory system that is prepared to respond to future public health threats and emergencies.

Potential Short-Term Strategies Suggested to Improve Laboratory Preparedness and Testing Response

- **Capabilities and Capacity**
- Developing a surge plan to use the LRN more fully and to use other partners to mitigate sample overload (Kubin) and preposition testing materials (Binnicker, Stenzel)
- Creating reliable systems for specimen collection and transport (Kubin, Van Meter)
- Developing a radiological laboratory testing hub (Scott)
- Developing a repository for development and validation of materials and other inventory (Egan, Van Meter)
- Developing inactivation procedures that allow work at BSL-2 (Becker, Egan, Kubin)
- Leveraging the use of automatic and high throughput platforms and further updating existing protocols to modernize them for automatic and high throughput testing (Becker, Egan, Marlowe) and use of high-throughput platforms (Marlowe)

Potential Short-Term Strategies Suggested to Improve Laboratory Preparedness and Testing Response

- **Capabilities and Capacity cont…**
- Employing pathogen-agnostic testing / sequencing (Goldstein, Gundlapalli, Sauer, and Kraft)
- Developing multiplex assays on multiple platforms already in laboratories (Becker, Kubin, Stenzel)
- Developing assays that are designed with enough redundancy to cover for mutations and enhance coverage of the target pathogens (Kubin, Marlowe)
- Supporting the development of at home and OTC collection kits and/or testing with appropriating designed systems and adequate controls (Marlowe)
- Defining the “minimum data set” necessary to act (Scott, Becker, Taylor, Van Meter) and creating interoperable data systems for all local, state, and federal jurisdictions and partners (Kubin, Yassif)

Potential Short-Term Strategies Suggested to Improve Laboratory Preparedness and Testing Response

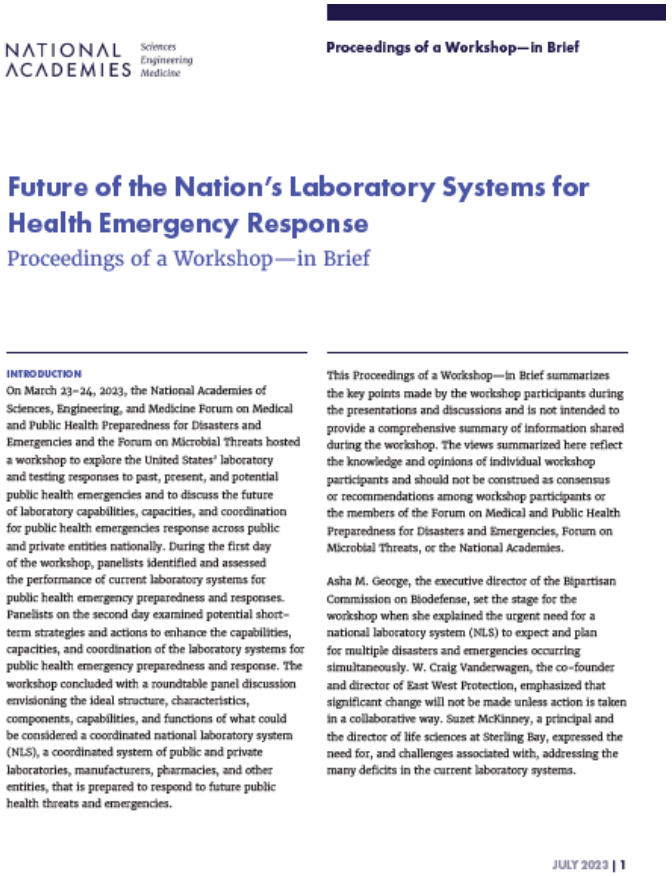
- **Capabilities and Capacity cont…**
- Enhancing regulatory flexibilities and including allowing high-complexity CLIA-certified laboratories to immediately deploy testing ahead of any regulatory submission and to streamline the EUA review process for in vitro diagnostic manufacturers to enable authorization within four weeks of submission (Konnick)
- Considering consistent and predictable reimbursement for clinical testing including the provision of adequate and predictable pathways to reimbursement for clinical testing to ensure laboratory solvency when responding to an emergency (Konnick) and de-risking the market for private, commercial entities through the establishment of pre-event contracting and predictable and robust reimbursements, coding, coverage, payment, etc. (Binnicker, Konnick, Van Meter)

Potential Short-Term Strategies Suggested to Improve Laboratory Preparedness and Testing Response

- **Coordination**
- Establishing permanent forum and mechanism to ensure public–private relationships with diverse entities and taking advantage of their assets (Aspinall, Becker, Binnicker, Gronvall, Gundlapalli, Konnick, Kubin, Marlowe, Patel, Shone, Van Meter)
- Educating stakeholders/physicians (Aspinall, Konnick, Stenzel) and providing federal, clinical guidance on use cases for testing for the public and providers (Van Meter)
- Applying a holistic, One Health concept to identify partners and strengthen systems (Annelli, Goldstein)

Workshop Products

- **Proceedings of a Workshop-In Brief** that summarizes workshop presentations and discussions.
- To be published this week – July 13, 2023.



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Proceedings of a Workshop—in Brief

Future of the Nation's Laboratory Systems for Health Emergency Response

Proceedings of a Workshop—in Brief

INTRODUCTION

On March 23–24, 2023, the National Academies of Sciences, Engineering, and Medicine Forum on Medical and Public Health Preparedness for Disasters and Emergencies and the Forum on Microbial Threats hosted a workshop to explore the United States' laboratory and testing responses to past, present, and potential public health emergencies and to discuss the future of laboratory capabilities, capacities, and coordination for public health emergencies response across public and private entities nationally. During the first day of the workshop, panelists identified and assessed the performance of current laboratory systems for public health emergency preparedness and responses. Panelists on the second day examined potential short-term strategies and actions to enhance the capabilities, capacities, and coordination of the laboratory systems for public health emergency preparedness and response. The workshop concluded with a roundtable panel discussion envisioning the ideal structure, characteristics, components, capabilities, and functions of what could be considered a coordinated national laboratory system (NLS), a coordinated system of public and private laboratories, manufacturers, pharmacies, and other entities, that is prepared to respond to future public health threats and emergencies.

This Proceedings of a Workshop—in Brief summarizes the key points made by the workshop participants during the presentations and discussions and is not intended to provide a comprehensive summary of information shared during the workshop. The views summarized here reflect the knowledge and opinions of individual workshop participants and should not be construed as consensus or recommendations among workshop participants or the members of the Forum on Medical and Public Health Preparedness for Disasters and Emergencies, Forum on Microbial Threats, or the National Academies.

Asha M. George, the executive director of the Bipartisan Commission on Biodefense, set the stage for the workshop when she explained the urgent need for a national laboratory system (NLS) to expect and plan for multiple disasters and emergencies occurring simultaneously. W. Craig Vanderwagen, the co-founder and director of East West Protection, emphasized that significant change will not be made unless action is taken in a collaborative way. Suzet McKinney, a principal and the director of life sciences at Sterling Bay, expressed the need for, and challenges associated with, addressing the many deficits in the current laboratory systems.

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