EXPLORING CRITICAL GAPS AND SOLUTION STRATEGIES IN LABORATORY CAPACITY AND CAPABILITIES FOR PUBLIC HEALTH RESPONSE WORKSHOP

FINAL REPORT

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Funding Source Acknowledgment

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About SGNL Solutions

SGNL Solutions (SGNL), a service-disabled veteran-owned small business corporation, connects across research, policy, and practice communities to identify, understand, and solve complex health security challenges. We undertake collaborative projects involving stakeholder engagement, process facilitation, data collection, analysis, evaluation, scientific writing, and product development. Our team of experienced consultants provides cross disciplinary expertise and perspectives, which fosters better understanding and integrated solutions to address our nation's most pressing issues. We become issue experts and get excited about what matters to our clients. We sift through noisy data and distractions to get at the core of persistent problems to find the signal – the real information and approaches needed to finally address problems. We work across disciplines, think creatively, and break apart silos that oftentimes prevent progress. We then work with clients to make these important issues approachable and actionable.

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EXECUTIVE SUMMARY

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Executive Summary

Background

Through funding from the Centers for Disease Control and Prevention (CDC), Center for Preparedness and Response (CPR), the Association of Public Health Laboratories (APHL) collaborated with SGNL Solutions (SGNL) from August 2021 to September 2022 to design, implement, and document an information-gathering process to capture individual input from diverse stakeholders and subject matter experts (SMEs) to inform understanding of key public health laboratory capacity and capability gaps for chemical, biological, radiological and nuclear (CBRN) hazards and other emerging threats. Through this information-gathering process, SGNL sought to explore the following questions:

Primary:

1. How can we improve public health laboratory capacity/capabilities to respond to events, like COVID-19, in the next 1-3 years?
    - 1.1. What are the gaps in public health laboratory capacity/capabilities needed for CBRN and emerging threats?
        - 1.1.1. Why do the gaps in public health laboratory capacity/capabilities exist?
        - 1.1.2. What is the impact of addressing these gaps on public health laboratory capacity/capabilities?
            - 1.1.2.1. Do any of these gaps address multiple hazards?
    - 1.2. What are potential specific and near-term strategies to address the gaps?
        - 1.2.1. What resources are required to implement the strategy?
        - 1.2.2. Who is best positioned or responsible (whether public or private) for implementing the strategy?

Secondary:

1. What research might be needed to generate new knowledge or to evaluate a promising practice?

Methods

Information Gathering Activities

As part of the information-gathering process, SGNL conducted three invite only virtual workshops with governmental and private sector laboratory practitioners, academia, and federal stakeholders to explore gaps and solution strategies in public health laboratory capacity and capabilities. Workshops 1 and 2 were designed to identify gaps in laboratory capabilities to address CBRN hazards and explore their root causes

Though the objectives for Workshops 1 and 2 were the same, the participants were different. Workshop 1 included 26 active participants and Workshop 2 included 29 active participants. See the Information Gathering Activities Participant Overview sub-section of the final report for the distribution of participants by sector. SGNL analyzed the outputs (audio recordings, notes, white boards) from Workshop 1 and 2 to identify the themes and gaps in laboratory capabilities and capacity and organized them into five themes. See Appendix A and Appendix B of the full report for detailed documentation of identified gaps, solutions, and context derived from each workshop.

Upon receiving these outputs, CDC project team members generated a list of six final theme areas containing 32 high priority gaps essential to building national laboratory capacity for public health emergency response. The final theme areas were:

1) Proficient federal and state, tribal, local, and territorial (STLT) workforce,
2) Flexible, broadly applicable infrastructure and equipment,

3) Accurate, rapid detection and characterization of threats to inform decision making,
4) Flexible and extensible data exchange for CBRN and emerging threats,
5) Preemptive, sustainable public-private partnerships, and
6) Sustainable laboratory surge capacity and transition to whole-of-society response.

Workshop 3 included APHL and CDC project staff and 15 participants representing public health laboratory stakeholders from across the CDC and sought to review and rank the 32 high priority gaps. A document with the high priority gaps was shared with participants prior to the workshop. During the workshop, participants were provided an opportunity to reflect on and add to the list of high priority gaps. SGNL then facilitated two rounds of discussion and real- time ranking via an online poll. During each round of ranking, participants were asked to select and rank five of the provided high priority gaps that were within the CDC's scope and/or authority to address. Following round one, SGNL facilitators shared the results and asked participants to discuss the ranked items to see if the results arcuately reflected their perceptions and current or upcoming work in their area related to the gaps. Following round two, facilitators shared the revised ranking and asked participants to discuss how CDC could make an impact on the top tier of gaps the next few years and what next steps might be for each CDC Center, Institute or Office (CIO). See Appendix E of the full report for a detailed matrix of the results of both high priority gap ranking rounds.

Additionally, SGNL conducted two virtual focus groups with governmental and private sector stakeholders to further explore a selection of issues identified through the previous workshops. The first focus group explored a proposed model for the radiological laboratory response network (LRN-R), including how the LRN-R might fit into and leverage the existing public health laboratory capabilities, and to identify critical next steps for the implementation and sustainability of an LRN-R. See Appendix C of the full report for LRN-R, focus group proceedings. The second focus group explored the role of manufacturers in supporting laboratory response to public health threats. Eight discussants from manufacturing companies participated in the conversation. See Appendix D of the full report for manufacturers focus group proceedings.

Gap Tiering

The gap ranking results from Workshop 3 were used to prioritize gaps by placing them into three tiers (Tier 1 as the highest priority receiving the most votes, and Tier 3 as the lowest) by dividing the total number of gaps into thirds. Find the tiered results of Round 2 below and the results of Round 1 in Tiered High Priority Gaps sub-section of the final report.

Key Findings

Overview

The gaps identified through the Workshops 1 and 2 were in some cases refined, narrowed, and expanded through subsequent internal discussions between APHL and CDC. This approach resulted in some differences, exclusions, and additions to the gaps and themes identified by SGNL and the priority gaps included in the Workshop 3 ranking exercise. An overview of all the gaps identified by SGNL through Workshops 1 and 2, associated context, a determination of bearing on CBRN hazards/threats, and gap implications can be found in the Overview of All Identified Gaps final report sub-section. The gaps identified through the two focus groups can be found Additional Gaps Identified from Focus Groups final report sub-section.

Tiered High Priority Gaps

The following table details the tiered high priority gaps resulting from round two of the gap ranking exercise held during Workshop 3. See Appendix E of the final report for a detailed matrix of the results of both high priority gap ranking exercise rounds.

Table 1: Tiered High Priority Gaps

Tier	Priority Gap	Aligned Theme	C	B	R	N
1	Lack of interagency collaboration with FDA, BARDA, NIH, EPA, DOE, DOD, etc. on their roadmap for development and implementation next generation technologies	Sustainable laboratory surge capacity and transition to whole-of society response	×	×	×	×
	Insufficient federal and STLT workforce in general and during surge; and weakness in recruitment/retention, onboarding, and training.	Proficient federal and STLT workforce	×	×	×	×
	Lack of a LRN-R to be able to rapidly respond to a radiological or a nuclear incident.	Flexible, broadly applicable infrastructure and equipment			×	×
	Lack of threat agnostic biological, and chemical surveillance systems and methods (e.g., metagenomic sequencing of wastewater and clinical samples compared to amplicon and PCR assays or FluNet, which is influenza specific)	Accurate, rapid detection and characterization of threats to inform decision making	×	×		
	Lack of plan to support surge testing for agents with special considerations (e.g., select agents, RG3 and 4 pathogens)	Accurate, rapid detection and characterization of threats to inform decision making	×	×	×	×
	Aging and/or outdated IT infrastructure and data management systems in PHLs.	Flexible and extensible data exchange for CBRN and emerging threats	×	×	×	×
	Lack of collaboration and communication for coordinated development, quality control, manufacturing, dissemination, and adoption of diagnostic assays and platforms to PHLs and surge testing partners	Preemptive, sustainable public-private partnerships	×	×	×	×
2	Lack of critical expertise in federal and STLT workforce in bioinformatics, CLIA compliance, and radiological/nuclear.	Proficient federal and STLT workforce			×	×
	Lack of rapid characterization and detection of novel or emerging pathogens to identify changes in transmissibility or virulence	Accurate, rapid detection and characterization of threats to inform decision making	×	×		
	Inability to maintain or replace outdated/sunsetting equipment (including maintaining surge capacity equipment)	Flexible, broadly applicable infrastructure and equipment	×	×	×	×
	Lack of communications that effectively inform and motivate public action	Sustainable laboratory surge capacity and transition to whole-of society response	×	×	×	×
	Lack of coordinated, timely surge testing for response	Preemptive, sustainable public-private partnerships	×	×	×	×

	Lack of systems to promote rapid, parallel development of accurate laboratory assays on platforms that are already in use in laboratories	Accurate, rapid detection and characterization of threats to inform decision making	×	×	×	×
	Limited sustainable surge testing capacity within PHLs	Accurate, rapid detection and characterization of threats to inform decision making	×	×	×	×
	Lack of data sharing agreements between federal, state, and other partners	Flexible and extensible data exchange for CBRN and emerging threats	×	×	×	×
3	Lack of mechanism to harmonize equipment needs to facilitate assay development on equipment available to most	Flexible, broadly applicable infrastructure and equipment	×	×	×	×
	Lack of standardized, non-siloed, data sharing requirements to allow case-level surveillance.	Flexible and extensible data exchange for CBRN and emerging threats	×	×	×	×
	Lack of consistent laboratory quality management systems.	Flexible, broadly applicable infrastructure and equipment	×	×	×	×
	Lack of partnerships to facilitate effective communications to inform and motivate public action	Preemptive, sustainable public-private partnerships	×	×	×	×
	Lack of broadly applicable federal, state, and local supply chain management frameworks (e.g., access to specimens, reagents, materials, PPE, medical equipment, etc.), including reevaluation of equipment (e.g., reusable respirators vs. N95s).	Sustainable laboratory surge capacity and transition to whole-of society response	×	×	×	×
	Lack of mechanisms to develop, coordinate, and support rapid research during emergency response (e.g., routes of transmission, PPE, disinfectants).	Sustainable laboratory surge capacity and transition to whole-of society response	×	×	×	×
	Lack of rapid development, manufacture, and rollout of Point-of-Care and Point-of-Need assays that include reporting considerations	Accurate, rapid detection and characterization of threats to inform decision making	×	×		

Solution Strategies Identified Across Theme Areas

The following outlines the solutions strategies for all identified gaps across the six theme areas. Several solution strategies appear in more than one theme area. Repeated solution strategies are denoted with an asterisk. These could be considered for prioritized action, as gaps across multiple themes could be addressed simultaneously. See the Overview of All Identified Gaps sub-section of the final report for the specific gaps, context, and bearing on CBRN associated with these solutions strategies.

Proficient Federal and STLT Workforce

- Find and support sustainable funding solutions that make public health lab careers competitive with the private sector. Incentives include starting salary increases, pay raises, retirement benefits, flexible schedule and paid time-off options, tuition reimbursement, and student loan forgiveness
- Provide career development opportunities for current lab staff
- Improve marketing and recruitment strategies by learning from other areas of the government
- Collaborate with academic partners and invest in programs focused on expanding the laboratory workforce (e.g., graduate-level certificates in biosafety and biosecurity, laboratory response) as well as providing opportunities for students to receive hands-on internships/work experience in biosafety level 3 (BSL-3) suites in public health labs
- Increase exposure of public health laboratory career opportunities in undergraduate and high school programs (e.g., explore a public health laboratory STEM concentration)
- Continue to support and expand fellowship programs to reestablish the lab workforce
- Create a reserve workforce or available lab staff pool for public health emergencies (e.g., AmeriCorps and ASPR hospital staff programs)
- Ensure additional rapid staffing procurement mechanisms and enabled for emergencies (e.g., contract work and temporary staffing)
- Build academic partnerships for student recruitment during emergencies
- Support strategies to increase national recognition of lab professionals to improve morale
- Allow flexibility in grants for better staff retention strategies
- Support cross-training of staff (internal and external) to increase capabilities during an emergency
- Provide more specialized training for testing and protocol compliance to increase lab capabilities during different types of CBRN events
- Ensure training is available for specific aspects of lab work, such as using lab equipment, toxicology, emergency response, and technical skills required for working in a BSL-3 suite.
- Support specialized education or training programs to develop the radiological/nuclear workforce pipeline (e.g., establish pathway programs for radiochemistry students to get master's degrees)

Flexible, Broadly Applicable Infrastructure and Equipment

- Earmarking funds that could allow labs to make acquisitions of new instruments as well as maintenance/service agreements (e.g., Public Health Emergency Preparedness (PHEP) Cooperative Agreement)
- Provide support for additional staffing or training for staff on new technologies and equipment
- Provide support for labs to acquire scalable technologies for all hazards and capable of detecting novel pathogens (i.e., threat agnostic technologies)
- Support new technology developments and validation methods
- Expand capacity to meet fluctuating and high-volume testing needs during response, surge, and long-term recovery, including during radiological/nuclear decontamination and recovery
- Specify funding in grants for procuring and implementing new technology in labs, including expansion of physical lab space, construction of new facilities and workforce training for new technologies

- Utilize third parties such as foundations or non-profits to assist with equipment procurement and staffing
- Assist with the development and identification of validation materials for emerging technologies
- Earmarking funds that could allow labs to make acquisitions (e.g., PHEP)
- Support the rapid addition of more platforms (common systems in public health labs) to allow labs to be nimbler
- Assist with the development and identification of validation materials for emerging technologies.

Accurate, Rapid Detection and Characterization of Threats to Inform Decision Making

- Support new technology development and validation methods, and proactively share guidance to manufacturers about Food and Drug Administration (FDA) concerns and requirements for rapid solutions and new technologies
- Support advancements in sequencing to detect unknown pathogens and develop a regional pipeline for Whole Genome Sequencing (WGS)
- Support development and implementation of supplies and materials needed for rapid detection and characterization by addressing supply and demand challenges, improving stockpiling practices, and enabling multiple vendor partnerships for wider distribution in preparation for emergencies
- Better define metrics in grants to ensure laboratories have more input on budgets, provide funding flexibility, and earmarked funds
- Assist with navigating regulatory pathways during response or surge so labs have the ability to scale up for response or surge without regulatory burdens
- Engage diverse partners such as veterinary diagnostic laboratories and major commercial vendors to help build capacity across a jurisdiction*
- Educate hospital partners in the difference between lab types, and who to send certain specimens to for rapid identification or confirmation*
- Use the Laboratory Response Network (LRN) to work with professionals from multiple backgrounds to build partnerships and enhance rapid detection and characterization abilities
- Improve the regulatory approval process for industry bringing new products to market
- Increase flexibility and support for products with multiple potential uses to expand market and commercial value
- Support the development and implementation of supplies and materials needed for rapid detection and characterization
- Increase flexibility and support for products with multiple potential uses to expand market and commercial value
- Provide funding flexibility for rapid procurement of resources and staff during surge
- Consider decentralizing data and setting standards for data reporting that are uniform across states
- Conduct scientific studies to understand the performance of rapid tests in the real world. This will be critical to gaining confidence in these screening assays. If there is to be a shift away from WGS towards rapid systems, CDC should be involved in ensuring the new system does not have decreased performance (e.g., sensitivity and specificity)

Flexible and Extensible Data Exchange for CBRN and Emerging Threats

- Apply current biological/chemical data entry and sharing practices to radiological programs
- Provide clear data sharing rules and responsibilities
- Clearly define information that can be shared for true public health needs
- Develop and support training programs for IT expertise development
- Support data modernization and streamlining processes

- Create integrated lab consortium networks and facilitate consortium-level discussions among public health labs to discuss support, needs, and MOUs*
- Establish a standardized incident report and minimum data element report across all states that define critical variables

Preemptive, Sustainable, Public-Private Partnerships

- Support large-scale commercial availability of critical products, including better manufacturing capabilities during a surge
- Create integrated lab networks and facilitate consortium-level discussions among public health labs to discuss support, needs, and MOAs*
- Support training and exercises across agencies to develop workforce skills and opportunities to work through coordinated response activities
- Engage in more outreach with partners where public health provides training. This approach ensures that the right sample gets into the laboratory system
- Engage diverse partners such as veterinary diagnostic laboratories to help build capacity across a jurisdiction*
- Educate hospital partners in the difference between lab types, and who to send certain specimens to for identification or confirmation*
- Support improved partnerships across industries and agencies for better planning processes and response, including commercial lab partners
- Support training and exercises across agencies to prepare for and practice response and surge coordination
- Enable multiple vendor partnerships in preparation for emergencies
- Develop "tighter partnerships" between agencies and industry to help understand how to anticipate test volume, expectations, and public health needs (e.g., industry could be more reliable when looped into conversations before CDC and HHS places volume expectations on agent specific testing)
- Engage in a collaborative effort to strengthen the "path to scale" where the manufacturing and scaling up environment can apply to a variety of partners and pathogens, increasing confidence in methods for scaling up to meet demand across all agencies and vendors
- Utilize independent testing facilities, supply chains, and a variety of test types could increase flexibility (e.g., thinking beyond PCR and including antigen testing and serology so there are contingencies in place in the event of a shortage)
- Increase flexibility and support for products with multiple potential uses
- Engage in effective government partnerships during emergencies and steady states
- Improve agreement mechanisms for manufacturing and production
- Streamline processes and strengthen capabilities to quickly move to manufacturing and production when needed
- Provide funding flexibility and specify funding in grants for implementing new technology in labs
- Alignment of FDA and CMS Clinical Laboratory Improvement Amendment (CLIA) requirements will be critical for future responses
- License content from the CDC to extend their detection and characterization assays to the commercial sector (as opposed to developing something new) to help reduce the workload on public health labs.
- Build better relationships between responding entities involved in emergency response supply chains (FDA, CDC, CLIA, etc.) to address regulatory challenges that prevent labs from pivoting and acquiring specific items during events, or validating those items
- Support preparedness activities so labs have the ability to scale up for response or surge without

regulatory burdens

Sustainable Laboratory Surge Capacity and Transition to Whole-of-Society Response.

- Support the development of MOUs for planning between federal entities
- Support novel supply chain improvements
- Create a consistent allocation process that is based on communication, transparency, and legitimate metrics
- Revise procurement rules and grant language to provide more funding flexibility and allow for rapid deployment of funds, including approval of purchases for equipment and supplies that are over funding limits
- Strengthen public health lab partnerships to allow for product redistribution, and build space in cooperative agreements to allow jurisdictions to address their own priorities
- Collaborate across the federal government to invest in domestic manufacturing to create a resilient supply chain
- Engage laboratories in discussions to determine priority items for stockpiling and integrate critical lab supplies into the SNS
- Build relationships between public health laboratories and communities so each is aware of relevant work prior to an emergency
- Reintroduce industry into planning processes and explore ways to create a more collaborative approach
- Develop a structure/model for public health-focused Incident Command System to assist with partner integration

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Background

Through funding from the Centers for Disease Control and Prevention (CDC), Center for Preparedness and Response (CPR), the Association of Public Health Laboratories (APHL) collaborated with SGNL Solutions (SGNL) from August 2021 to September 2022 to design and implement an information-gathering process to capture individual input from diverse stakeholders and subject matter experts (SMEs) to inform understanding of key public health laboratory capacity and capability gaps for chemical, biological, radiological and nuclear (CBRN) hazards and other emerging threats.

Through this information-gathering process, SGNL sought to explore the following questions:

Primary:

2. How can we improve public health laboratory capacity/capabilities to respond to events, like COVID-19, in the next 1-3 years?
    - 2.1. What are the gaps in public health laboratory capacity/capabilities needed for CBRN and emerging threats?
        - 2.1.1. Why do the gaps in public health laboratory capacity/capabilities exist?
        - 2.1.2. What is the impact of addressing these gaps on public health laboratory capacity/capabilities?
            - 2.1.2.1. Do any of these gaps address multiple hazards?
    - 2.2. What are potential specific and near-term strategies to address the gaps?
        - 2.2.1. What resources are required to implement the strategy?
        - 2.2.2. Who is best positioned or responsible (whether public or private) for implementing the strategy?

Secondary:

2. What research might be needed to generate new knowledge or to evaluate a promising practice?

Constraints and Assumptions

Through scoping discussions with APHL and CPR, and after review of available background materials, SGNL observed the following constraints and assumptions in our work:

- Avoid actively looking at funding as a gap and solution strategy.
- Focus on overall national laboratory system, not a specific response network or limited to laboratory role in a response network

Methods

As part of the information-gathering process, SGNL conducted three virtual workshops with governmental and private sector laboratory practitioners, academia, and federal stakeholders to explore gaps and solution strategies in public health laboratory capacity and capabilities.

Additionally, SGNL conducted two virtual focus groups with governmental and private sector stakeholders to further explore:

1) a proposed model for the Radiological Laboratory Response Network (LRN-R)
2) the role of manufacturers in supporting laboratory response to public health threats.

Workshop 1

On Friday, January 21, 2022, SGNL and APHL hosted a 3.5-hour, invite-only workshop for 26 participants representing Federal, state, territorial, local, and tribal (FSTLT) public health laboratories, commercial laboratories, and foundations. Observers from CDC and APHL also attended the workshop. The workshop was designed to meet the following objectives:

1) Identify the gaps in laboratory capabilities and capacity to support a response to public health threats from CBRN hazards;
2) Explore the root causes of gaps in laboratory capabilities and capacity to support response to public health threats from CBRN hazards; and
3) Generate potential specific and near-term strategies to address the gaps in laboratory capabilities and capacity to support a response to public health threats from CBRN hazards.

In the first activity, participants described gaps in laboratory capabilities and capacity. Participants were distributed across three breakout rooms, each focused on a different threat (biological, chemical, and radiological/nuclear). In each breakout room, a facilitator shared a brief threat-based scenario and asked participants to list gaps across following categories: equipment/supplies, facilities, personnel/training, safety/security, procedures/communications, partnering, and data exchange.

In the second activity, during a closed session, facilitators solicited gaps of interest from CDC observers through a series of solution sprints. Due to time limitations, not all provided gaps of interest were discussed during solutions sprints. During each solution sprint, a facilitator named a gap and asked participants to reflect on how this gap showed up in their work. Next participants were prompted to identify potential root causes of the gap. Finally, participants offered specific solutions they thought CDC could support in the next three to five years to close the gaps.

Following the workshop, SGNL analyzed the workshop outputs (audio recordings, notes, white boards) to identify the themes and gaps in laboratory capabilities and capacity to support a response to public health threats from CBRN hazards. The gaps identified were organized by the following five themes:

1) Proficient federal, state, and local public health laboratory workforce;
2) Infrastructure and equipment that meets capability and capacity needs for multiple threats;
3) Accurate, rapid detection and characterization of threats to inform decision-making;
4) Flexible and extensible data exchange for CBRN and emerging threats; and
5) Coordinated federal, state, and local public health response networks, frameworks, best practices and partnerships during all emergency response phases.

See Appendix A for workshop proceedings with detailed documentation of identified gaps, solutions, and context.

Workshop 2

On Friday, February 18, 2022, SGNL and APHL hosted a 3.5-hour, invite-only workshop for 28 participants representing FSTLT public health laboratories, commercial laboratories, and foundations. Observers from the CDC and APHL also attended the workshop. The workshop was designed to meet the following objectives[1]:

1) Identify the gaps in laboratory capabilities and capacity to support a response to public health threats from CBRN hazards;
2) Explore the root causes of gaps in laboratory capabilities and capacity to support a response to public health threats from CBRN hazards; and
3) Generate potential specific and near-term strategies to address the gaps in laboratory capabilities and capacity to support a response to public health threats from CBRN hazards.

SGNL facilitated three discussion activities, each focused on a specific theme area identified during the previously held workshop in January 2022. These theme areas included:

- Accurate, rapid detection and characterization of threats to inform decision making,
- Proficient federal, state, and local public health laboratory workforce, and
- Coordinated federal, state, and local public health response networks, frameworks, best practices, and partnerships during all emergency response phases

Each activity consisted of a brief small group discussion followed by a larger group discussion. Participants were distributed across six breakout rooms for an unfacilitated ten-minute discussion. Then participants reconvened for a longer facilitated discussion. At the end of each activity, participants were offered an opportunity to provide final thoughts via an anonymous survey.

Following the workshop, SGNL analyzed the workshop outputs (audio recordings, notes, white boards) to identify and document findings within the three prescribed themes observed during workshop 1.

See Appendix B for workshop proceedings with detailed documentation of identified gaps, solutions, and context.

Workshop 3

On Friday, May 13, 2022, SGNL and APHL hosted a 3-hour, invite-only workshop with APHL and CDC project staff and 15 participants representing public health laboratory stakeholders from across the CDC. The workshop was designed to meet the following objectives:

1) Describe what we've learned about laboratory-related gaps in preparedness and response;
2) Understand current efforts to address laboratory-related gaps in preparedness and response across the CDC; and
3) Consider and prioritize gaps in laboratory-related gaps in preparedness and response.

Prior to the CDC Internal Stakeholder Workshop, CDC project team members reviewed outputs from the previous workshops to generate a list of six final theme areas containing 32 high priority gaps essential to building national laboratory capacity for public health emergency response. A document with the themes and gaps was shared with participants prior to the workshop. The final theme areas were:

1. Proficient federal and STLT workforce,
2. Flexible, broadly applicable infrastructure and equipment,
3. Accurate, rapid detection and characterization of threats to inform decision making,
4. Flexible and extensible data exchange for CBRN and emerging threats,

[1] The objectives for workshop 1 and 2 were the same, however different participants and facilitation exercises were involved.

5. Preemptive, sustainable public-private partnerships, and
6. Sustainable laboratory surge capacity and transition to whole-of-society response.

During the workshop, SGNL facilitated a modified Delphi process (i.e., real-time ranking and discussion) to further explore the gaps and the role of the CDC in closing the gaps. First, participants were provided an opportunity to reflect on and add to the list of priorities. Then, the facilitators asked participants to select five gaps and challenges that were within the CDC's scope or authority to address via an online poll (Round one). After a break, the facilitators shared the results and asked participants to discuss the ranked items to see if the results arcuately reflected their perceptions and current or upcoming work in their area related to the gaps and challenges.

Following the discussion, the participants were again asked to select five gaps and challenges that were within the CDC's scope or authority to address via an online poll (Round two). The facilitators shared the revised ranking and asked participants to discuss how CDC could make an impact on the top tier of gaps and challenges in the next few years and what next steps might be for each CDC Center, Institute or Office (CIO).

See Appendix E for a detailed matrix of the results of the high priority gap ranking rounds.

Gap Tiering Process

Gap ranking results from the CDC Workshop held on May 13, 2022, were used to prioritize gaps by placing them into three tiers (Tier 1 as the highest priority receiving the most votes, and Tier 3 as the lowest) by dividing the total number of gaps into thirds. Find the tiered results of round one and round two in Tiered High Priority Gaps sub-section of this report.

Focus Group – LRN-R

On June 28, 2022, SGNL and APHL hosted a 90-minute focus group to discuss a proposed model for the LRN-R, including how the LRN-R might fit into and leverage the existing public health laboratory capabilities, and to identify critical next steps for the implementation and sustainability of an LRN-R. Five discussants from state laboratories and federal agencies were invited to participate. After a brief overview of a proposed LRN-R model, a facilitator posed questions to explore the barriers and facilitators from both a systems and an implementor perspective.

See Appendix C for focus group proceedings.

Focus Group – Manufacturers

On July 11, 2022, SGNL and APHL hosted a two-hour focus group to discuss the role of manufacturers in supporting laboratory response to public health threats. Eight discussants from manufacturing companies participated in the conversation. A facilitator posed questions about the enablers of and barriers to developing, manufacturing, and producing assays, platforms, and reagents.

See Appendix D for focus group proceedings.

Information Gathering Activities Participant Overview

Information-gathering activities included participants from government, private, non-profit, and academic organizations. Participant distribution across organization types was as follows:

Organization Type	Number Of Participants
Government	55
Private	14
Non-profit	4
Academia	4
Total	77

Gap Analysis and Implication Generation

SGNL synthesized the outputs from the information gathering activities to match each identified gap with a thematic area created by the CDC, assess applicability to CBRN threat/hazards, and consider implications for future CDC prioritization. To develop implication statements for each gap, a primary SME reviewer considered the following questions:

1) What is the importance of this gap? Why should it potentially be a priority for the CDC?
2) Who benefits from efforts to close the gap and why/how?
3) What are some anticipated/possible complications to taking action on this gap?

Following primary review, a secondary SME reviewer expanded upon each implication statement, as needed. Lastly, APHL staff reviewed the implication statements and contributed additions, as necessary.

Gaps in Public Health Laboratory Capacity and Capabilities

The gaps identified in this section result from numerous information-gathering activities and review periods involving nearly 100 participants, observers, and staff. The gaps and themes identified through Workshops 1 and 2 were in some cases refined, narrowed, and expanded through subsequent internal discussions with APHL and CDC. This approach resulted in some differences, exclusions, and additions to the gaps and themes documented throughout this section.

To best document the evolution of the gaps, this section begins with an overview of all the gaps identified by SGNL through Workshops 1 and 2. In these tables, the six final themes provided by CDC prior to Workshop 3 are used to organize the identified gaps. Next, the gaps identified through the two focus groups are provided. High level implications of all identified gaps are then provided.

Lastly, tiered high priority gaps, which resulted from the ranking exercise conducted during Workshop 3, are provided. The 32 priority gaps included in the ranking exercise were provided by the CDC project team members following their review of SGNL's outputs from Workshops 1 and 2 and include some changes from the gaps identified by SGNL. At the start of the Workshop 3, participants were asked to offer alterations and additions to the gaps, which resulted in some additional changes from SGNL's and CDC's versions of the identified gaps.

Overview of All Identified Gaps

The following tables contain all gaps and possible solution strategies across the six final themes identified through workshops 1 and 2, as well as a SGNL's determination of bearing on CBRN hazards/threats. The implications of each gap are also noted. In some cases, gaps were identified during information gathering activities, but not sufficiently discussed. In those cases, context, solution strategies, bearing on CBRN threats/hazards, and consequent implications may not be provided and it is noted as such.

Theme 1: Proficient federal and STLT workforce

Gap 1: Workforce recruitment challenges			
Context	Solution Strategies	CBRN	Implications of Gaps
• A lack of incentives makes it difficult to hire and retain new staff, especially when salaries are not competitive for positions with unfavorable hours/schedules and high levels of stress • Challenges also exist around federal funding allocation to support lab positions, state hiring freezes, and long hiring wait times	• Find and support sustainable funding solutions that make public health lab careers competitive with the private sector. Incentives include starting salary increases, pay raises, retirement benefits, flexible schedule and paid time-off options, tuition reimbursement, and student loan forgiveness • Provide career development opportunities for current lab staff • Improve marketing and recruitment strategies by learning from other areas of the government	All	Prior to the coronavirus disease (COVID-19) pandemic, public health laboratories were already struggling with recruiting new staff. The pandemic worsened existing public health laboratory workforce challenges. Further, the pool of potential recruits is shallow as public health laboratories struggle to compete with employers who can offer more competitive compensation, access to newer technologies and infrastructure, and less bureaucratic hiring experiences Without a robust and knowledgeable workforce, it is difficult for public health to stay ahead of threats – surveillance programs are threatened, development and evaluation of new diagnostics tools are delayed – and ultimately, the nation has a reduced ability to quickly detect threats.
Gap 2: Need for workforce development pipeline			
Context	Solution Strategies	CBRN	Implications of Gaps
• A lack of training and education opportunities exist nationwide to prepare new	• Collaborate with academic partners and invest in programs focused on	All	As many in the laboratory workforce look to retire, younger professionals are not taking their place, which means the institutional knowledge

applicants for laboratory work • Enrollment is low in education and training programs that prepare applicants for entering the workforce, such as dwindling nationwide Medical Laboratory Technology (MLT)/Medical Laboratory Sciences (MLS) programs • There are no campaigns aimed at raising awareness of available career paths and increasing interest for students to enter programs applicable to lab work (e.g., microbiology) • A robust workforce pipeline is needed to build a cadre of highly trained lab professionals to embed in STLT labs with the goal of assisting with technology evaluation and implementation	expanding the laboratory workforce (e.g., graduate-level certificates in biosafety and biosecurity, laboratory response) as well as providing opportunities for students to receive hands-on internships/work experience in biosafety level 3 (BSL-3) suites in public health labs • Increase exposure of public health laboratory career opportunities in undergraduate and high school programs (e.g., explore a public health laboratory STEM concentration) • Continue to support and expand fellowship programs to reestablish the lab workforce		gained over years may be lost, and future capacity for laboratory needs is in jeopardy. This gap can be addressed in part by increasing exposure of the field, career paths, and opportunities to a wider array of students and new graduates. Investing in education and training programs, including fellowships, can also provide a return on investment for public health laboratories interested in building a strong workforce.
Gap 3: Difficulty meeting surge workforce needs during incident(s)			
Context	Solution Strategies	CBRN	Implications of Gaps
• Challenges for staffing up for surge including hiring, retaining on-call workers, licensure requirements in some jurisdictions, and adequate training for volunteers and surge workers to respond to	• Create a reserve workforce or available lab staff pool for public health emergencies (e.g., AmeriCorps and ASPR hospital staff programs) • Ensure additional rapid staffing procurement	All	This gap in meeting surge needs was further exposed throughout the COVID-19 pandemic and remains difficult to address because these positions are skilled and require specific training. Making progress toward closing it can take the burden off existing staff, allowing them to perform their jobs better and be less likely to burn out. Because of the diversity of needs in a

different threat types • There are currently insufficient strategies in place to balance surge capacity and workforce hiring, and building a reserve workforce for public health emergencies is not prioritized • Labs have benefited from recruiting students during the pandemic by partnering with universities, especially those with clinical lab training programs and clinical science preceptorships or internships	mechanisms and enabled for emergencies (e.g., contract work and temporary staffing) • Build academic partnerships for student recruitment during emergencies		laboratory, it will take time and work to engage schools and other workforce pools to build an adequate reserve and the right mechanisms to address these needs. STLT agencies may find it challenging to work around their policies and authorities to build in this type of hiring flexibility in systems that have typically not been nimble and innovative. Federal support for a laboratory reserve corps would help to ensure a ready, trained and skilled surge workforce.
Gap 4: Workforce retention issues			
Context	Solution Strategies	CBRN	Implications of Gaps
• High turnover due to burnout or fatigue results in a significant loss of knowledge and expertise in the workforce, with no formal way to capture knowledge and mentorship for new generations. This has led to a loss of institutional knowledge in the lab workforce.	• Support strategies to increase national recognition of lab professionals to improve morale • Allow flexibility in grants for better staff retention strategies	All	Related to Gaps 2 and 3, this issue of retention will further slow turnaround time during testing and in public health responses because of loss of staff and knowledge. Sustaining the existing workforce and the lessons that have been learned during the last few years could be hugely beneficial to new recruits as well as the overall public health system in future events. Because of the rigidity of some STLT level policies and funding, solutions may need to be creative and pilot-tested before being implemented on a wider scale.
Gap 5: Workforce training inefficiencies (e.g., some trainings of limited utility, other needed trainings not available – issues with bandwidth, funding, and incentives for needed broadly applicable trainings: emergency preparedness, interagency coordination, cross-training)			
Context	Solution Strategies	CBRN	Implications of Gaps
• There are challenges around training staff on new technology including staff	• Support cross-training of staff (internal and external) to increase capabilities	All	This weakness in training inefficiency becomes

availability (and shortages) and existing level of knowledge and proficiencies on equipment ● There is a lack of training and exercise opportunities for disaster events, including collaborative training between agencies ● Better training is needed for responders who feed samples from a site (e.g., use of state/local HAZMAT or use of National Guard Bureau Civil Support Teams) to support rapid detection (Radiological/Nuclear)	during an emergency ● Provide more specialized training for testing and protocol compliance to increase lab capabilities during different types of CBRN events ● Ensure training is available for specific aspects of lab work, such as using lab equipment, toxicology, emergency response, and technical skills required for working in a BSL-3 suite.		magnified during a surge event as laboratories can experience longer turnaround times, thus delaying test results. While every staff member cannot be trained on all instrumentation and CBRN hazards, increased opportunities for training across departments and leveraging partners can increase capabilities during surge and provide more all-hazards preparedness for laboratory staff. This will require increased funding for technology, trainers, and staff time, but can provide return on investment not only for more rapid and accurate emergency response, but also more incentives for workforce retention and collaboration across agencies.
Gap 6: Pipeline of radiological/nuclear SMEs declining			
Context	Solution Strategies	CBRN	Implications of Gaps
● There are significant gaps in the radiochemist workforce and a diminishing supply of well-trained staff who understand the technology, as well as the extensive radiological methods and instrument training that would be required for existing public health lab professionals. ● Some public health labs may be familiar with the environmental matrices but presenting them with	● Support specialized education or training programs to develop the radiological/nuclear workforce pipeline (e.g., establish pathway programs for radiochemistry students to get master's degrees)	Radiological/Nuclear	This challenge with the radiological/nuclear SME pipeline has been growing for years and is now a clear concern as there are very few incoming students or young professionals in this career path. In the event of a radiological or nuclear emergency, communities and states would be left with large gaps in understanding available best courses of action for their population and who might be most at risk. Because these are low likelihood/high impact events, they often get less attention in academia and funded positions, this gap will be difficult to address without dedicated efforts and specialized programs and training. This puts all communities at risk in the event of this type of disaster.

a different matrix would require a significant amount of training ● With significant turnover and attrition, finding the next generation of radiochemists is already very difficult.			

Theme 2: Flexible, broadly applicable infrastructure and equipment

Gap 1: Inability to replace outdated / sunsetting equipment (including maintaining surge capacity instrumentation and equipment)			
Context	Solutions	CBRN	Implications of Gaps
• Labs need the capability to shift between testing environmental and clinical samples during different response phases. Scalable technologies are needed in hospital and clinical lab settings to ensure adequate lab response to all hazard types, as most are currently unable to scale up for radiological/nuclear and chemical threats (Chem, Radiological/Nuclear)[2] • While there has been growth in technologies, tools, and instruments that have expanded lab capabilities for detection, diagnostic testing, and sequencing, not all labs have been able to acquire and implement new equipment. • Procurement processes can be difficult and time-consuming. Often, funding must be specified in a grant for the purchase of an instrument, otherwise the laboratory has no way of using or requesting funds for instruments,	• Earmarking funds that could allow labs to make acquisitions of new instruments as well as maintenance/service agreements (e.g., Public Health Emergency Preparedness (PHEP) Cooperative Agreement) • Provide support for additional staffing or training for staff on new technologies and equipment • Provide support for labs to acquire scalable technologies for all hazards and capable of detecting novel pathogens (e.g., threat agnostic technologies) • Support new technology developments and validation methods	All	Labs need the capability to adapt to changing testing needs (environmental vs clinical) and the ability to update and maintain scalable technologies, tools, and instruments can help expand lab capabilities. Encouraging and supporting laboratories with a shift to automation would significantly enhance capacity. Allowing labs to expand capabilities to quickly adapt to different magnitudes of testing needs across all hazard types could lead to improved turnaround times, which ultimately benefits decision makers and the public. However, not all labs have the resources needed to acquire and implement new equipment, including funding flexibility, the ability to train staff on new equipment, or administrative support. Those that may have the resources, may find procurement and implementation processes cumbersome or time-consuming, presenting barriers to acquisition.

[1] This context reflects the workshop discussion as it occurred, but it is important to note that some of the workshop/focus group participants may be unaware of the clinical/environmental testing issue within hospitals/clinical labs.

especially given competing priorities.			
Gap 2: Difficulty implementing new technologies into laboratories for various reasons (funding, staff training needs, physical space, staff bandwidth, regulatory concerns)			
Context	Solution Strategies	CBRN	Implications of Gaps (Significance and Impact)
• Facilities need the physical space and equipment to expand for high volume samples, including expanding secure storage space and freezers (Chemical, Biological). There is currently low or nonexistent storage availability for certain specimen types or surge testing. Facilities also need the ability to store large quantities of sequencing data. • Support is needed for labs to become equipped and authorized (e.g., CLIA) to handle specialized testing capabilities for different CBRN samples • There are administrative aspects of new technology implementation to consider with high complexity systems, which can determine if a lab is even able to implement after considering factors such as overhead, licensing and staffing • Often, funding must be specified in a grant for the purchase of an instrument, otherwise the laboratory has	• Expand capacity to meet fluctuating and high-volume testing needs during response, surge and long-term recovery, including during radiological/nuclear decontamination and recovery (Radiological/Nuclear) • Specify funding in grants for procuring and implementing new technology in labs, including expansion of physical lab space, construction of new facilities and workforce training for new technologies • Utilize third parties such as foundations or non-profits to assist with equipment procurement and staffing. • Assist with the development and identification of	All	There have been many developments in lab technology that have the potential to extend the reach of public health labs to assist with pathogen detection and characterization in-house, which could result in more efficient sample collection, analysis, and decision-making during an incident. Even with the availability of new technologies and funding, there are various barriers to implementation that would need to be addressed. Many labs would require support in expanding physical space or constructing new facilities to accommodate new technology and the ability to process a high volume of samples as well as maintain a trained workforce capable of working with new technologies across threat types, including managing surge capacity. Additional support may be required in navigating regulatory requirements and validation methods. Without pre-response action on the noted solutions, increased/improved capacity and capabilities will be difficult to achieve.

no way of using or requesting funds for instruments, especially given competing priorities ● There are also challenges around training staff on new technology, including staff availability and existing level of knowledge and proficiencies on equipment. ● If standing up an LRN-R, there would likely be significant staffing needs to address up front if a lab does not already have staff with a strong background in radiological methods (Radiological/Nuclear)	validation materials for emerging technologies ● Earmark funds that could allow labs to make acquisitions (e.g., PHEP) ● Support the rapid addition of more platforms (common systems in public health labs) to allow labs to be nimbler		
Gap 3: Limited infrastructure / operational planning for BSL-3 pandemic response			
Context	Solution Strategies	CBRN	
● Not addressed in discussions	● No specific solution strategies discussed	Biological	BSL-3 labs are designed to prevent release of pathogens into the environment and provide a safe setting to protect those working with these pathogens. In addition to technical and funding challenges, there are biosecurity and dual-use risks, and local community issues to contend with in order to sustain operations. Without adequate infrastructure and operational planning for pandemic response (to include adequately trained and scalable staff), labs are at risk of being overwhelmed and failing to meet need during pandemics. Exploring and implementing pathogen inactivation methods would greatly reduce the need for BSL-3 suites.

Gap 4: Infrastructure and equipment are often specialized and not able to quickly pivot to respond to new threats (silos, agent-specific, etc.)			
Context	Solution Strategies	CBRN	Implications of Gaps
• Labs need the capability to shift between testing environmental and clinical samples during different response phases. Scalable technologies are needed in hospital and clinical lab settings to ensure adequate lab response to all hazard types, as most are currently unable to scale up for radiological/nuclear and chemical threats (Chem, Radiological/Nuclear).[3] • Adequate testing, collection, and reference materials are needed for a variety of hazards across all response phases. If an organism or pathogen substrain is found, guidance is needed to help make decisions, verify the finding is a genuine anomaly, rapidly share the findings, and make appropriate decision	• Assist with the development and identification of validation materials for emerging technologies.	All	Public health labs lacking the ability to rapidly shift between testing needs during emergency or surge events can result in significant delays in specimen processing and reporting results to inform decision making. Without existing infrastructure capable of processing different types of samples across hazards, STLT public health labs and commercial labs often rely on the CDC to receive, test, and report results back from Atlanta before any response can be initiated. Investing in lab equipment, as well as the knowledgeable workforce needed to use the equipment, may not be feasible for some jurisdictions, especially without flexible funding or federal support.
Gap 5: Lack of consistent laboratory quality management systems			
Context	Solution Strategies	CBRN	Implications of Gaps
• Not addressed in discussions	• No specific solution strategies discussed	All	*Gap not addressed in discussions; cannot conclude implications without more data.*

[3] This context reflects workshop discussion as it occurred, but it is important to note that some of the workshop/focus group participants may be unaware of the clinical/environmental testing issue within hospitals/clinical labs.

Theme 3: Accurate, rapid detection and characterization of threats to inform decision making

Gap 1: Lack of threat agnostic biological and chemical surveillance systems and methods (wastewater and metagenomic sequencing or wastewater and clinical samples compared to amplicon and PCR assays or FluNet, which is influenza specific)			
Context	Solutions	CBRN	Implications of Gaps
• Threat-agnostic and scalable technologies that are capable of detecting novel pathogens are needed. • Most labs have whole genome sequencing (WGS), but the pipeline analysis looking for different organisms is still a limitation. • If an organism or pathogen substrain is found, guidance is needed to help make decisions, verifying the finding is a genuine anomaly, rapidly share the findings, and make appropriate decisions	• Support new technology development and validation methods, and proactively share guidance to manufacturers about FDA concerns and requirements for rapid solutions and new technologies • Support advancements in sequencing to detect unknown pathogens and develop a regional pipeline for WGS	Biological/ Chemical	The ability to rapidly detect and characterize novel pathogens can assist in timely initiation of disease mitigation and containment strategies, allowing for a more proactive response. The COVID-19 pandemic highlighted the potential for novel methods (e.g., wastewater surveillance) in predicting disease incidence and trends more quickly than traditional surveillance methods which rely on the collection of clinical samples. It has also illustrated the significance of lab capabilities to conduct WGS for variant detection and spread. Support in developing and implementing new technologies that would expand capabilities to detect unknown pathogens would enhance awareness and preparedness for biological and chemical threats. Standardization of practices, guidance, and validation methods would likely require significant time and resources for development as well as implementation in labs. Furthermore, operationalizing detection, reporting and other related guidance at STLT levels would need to be considered.
Gap 2: Need for rapid characterization and detection of novel or emerging pathogens			
Context	Solution Strategies	CBRN	Implications of Gaps
• Infrastructure development in labs from an analytical standpoint needs support so all state labs can expand capacity and broaden methods to	• Support development and implementation of supplies and materials needed for rapid detection and characterization by addressing supply and	All	The ability to rapidly detect and characterize novel pathogens can assist in timely initiation of disease mitigation and containment strategies, allowing for a more proactive response. Currently, most STLT and commercial labs rely on the CDC to deploy technologies to detect

look at more chemical threats and faster sample preparation (Chemical) • There is a desire for the ability to detect novel pathogens, i.e., develop and implement pathogen agnostic assays. Infrastructure development in labs from an analytical standpoint needs support so all state labs can expand capacity (e.g., broaden methods to look at more threats and faster sample preparation) (Biological, Chemical) • There is currently a reliance on CDC labs for specialized testing and detection due to limited tests and surge capabilities at STLT labs. Limited resources are not always readily available locally for sample collection, transport, testing, and detection of threats that require rapid distribution of testing kits and other supplies. Geographically isolated locations responding to events may also wait longer periods of time for supplies to arrive.	demand challenges, improving stockpiling practices, and enabling multiple vendor partnerships for wider distribution in preparation for emergencies • Better define metrics in grants to ensure laboratories have more input on budgets, provide funding flexibility, and earmarked funds • Assist with navigating regulatory pathways during response or surge so labs have the ability to scale up for response or surge without regulatory burdens • Engage diverse partners such as veterinary diagnostic laboratories and major commercial vendors to help build capacity across a jurisdiction (Biological) • Educate hospital partners in the difference between lab types, and who to send certain specimens to for rapid identification or confirmation (Biological) • Use the Laboratory Response Network (LRN) to work with professionals from multiple backgrounds to build partnerships and		novel or emerging pathogens, as well confirmation and characterization of pathogens during containment and response phases. When labs seek to detect, test, and confirm the presence and type of pathogen in their community, the ability to rapidly obtain results is critical in implementing timely disease mitigation strategies, but is strained when needing to send samples to CDC and await results. The challenges associated with navigating logistics appropriate for the pathogen type (e.g., courier services and sample transport regulations) as well as the turnaround time for testing and reporting back to STLT labs can be problematic and hinder decision making at local levels. While a significant initial investment would be required to expand physical, technological, and administrative capabilities, STLT and commercial labs, as well those responsible for managing necessary response activities, would greatly benefit from the ability to detect and characterize novel and emerging pathogens on-site.

• There is a lack of capability for radiological testing with many laboratories unable to measure human radiation contamination / perform radiobioassay in clinical samples. Radiological or nuclear response in public health is the largest gap that still remains, specifically in the sense that there are no lab networks that can do radiological analysis on clinical samples, "which is a significant omission in protecting public health." (Radiological/Nuclear) • Support is needed for labs to become equipped and authorized (e.g., CLIA) to handle specialized testing capabilities for different CBRN samples • PHLs are often bound to a single vendor's technology due to the amount of work associated with validations and training on multiple platforms. Modern technology can make enabling multiple vendors	enhance rapid detection and characterization abilities • Support advancements in sequencing to detect unknown pathogens and develop a regional pipeline for WGS		

easier during emergencies			
Gap 3: Need for systems to promote rapid development of laboratory assays			
Context	Solution Strategies	CBRN	Implications of Gaps
• FDA approval process can be limiting for rapidly addressing testing needs • The market is the primary driver of industry decisions in developing products. Industry will likely continue to look to develop platforms that are capable "of more open development, but not specific platforms developed in response to a given pathogen." Expanding on or creating an additional market can be an opportunity to develop new assays (e.g., influenza typing is already on the market, and adding subtyping for H5N1 was an opportunity to expand)	• Improve the regulatory approval process for industry bringing new products to market • Increase flexibility and support for products with multiple potential uses to expand market and commercial value	All	Clinical testing remains to be one of the primary methods used for detecting the emergence of novel pathogens and increases in disease prevalence. When existing testing mechanisms cannot be used for novel pathogens, the public and private sectors need the ability to rapidly develop, manufacture, distribute, and utilize new assays in order to respond in a timely manner. If such assays are developed on platforms that are currently used in public health labs, it would eliminate the challenges around platform incompatibility and incentivize industry to support development considering the potential use across different markets. Prior to developing new assays, federal agencies and others should have data on available extraction and testing platforms in STLT and commercial labs.
Gap 4: Need for rapid development and rollout of Point-of-Need (PON)/Point-of-Care (POC) assays			
Context	Solution Strategies	CBRN	Implications of Gaps
• An important need is developing more rapid PCR assays (e.g., Abbott ID Now) which, if the same technology could be made more high-throughput, would be	• Support the development and implementation of supplies and materials needed for rapid detection and characterization • Increase flexibility and support for products with	All	Clinical testing remains to be one of the primary methods used for detecting the emergence of novel pathogens and increases in disease prevalence. When existing testing mechanisms cannot be used for novel pathogens, the public and private sectors need the ability to rapidly develop, manufacture, distribute, and utilize new

useful for expanding lab capacity. ● If there is a commercial value, then an industry partner would likely develop a novel assay. The larger the industry partner, the less likely to develop a novel assay for a small market	multiple potential uses to expand market and commercial value		assays in order to respond in a timely manner. PON or POC tests are valuable in providing efficient testing mechanisms in clinical settings, and even in individual homes. This capability could greatly improve responses in communities and reduce the burden on public health labs. However, use of at home tests needs to be simple for the end user and should have a reporting connection to public health. Without an understanding of who is testing and the results of such tests, it is difficult for public health to implement measures that protect the community.
Gap 5: Limited sustainable surge testing capacity within public health laboratories			
Context	Solution Strategies	CBRN	Implications of Gaps
● There is a lack of capacity to meet fluctuating and high-volume testing needs during response, surge, and long-term recovery, including during Radiological/Nuclear decontamination and recovery ● If a surge of testing is expected upon identification, STLT labs will need to be able to communicate with external lab partners to assist with capacity needs. External partners (e.g., hospitals) need to be educated in the difference between lab types and who to send certain	● Provide funding flexibility for rapid procurement of resources and staff during surge ● Support development and implementation of supplies and materials needed for rapid detection and characterization by addressing supply and demand challenges, improving stockpiling practices, and enabling multiple vendor partnerships for wider distribution in preparation for emergencies ● Assist with navigating regulatory pathways during response or surge so labs have the ability to scale up	All	Public health labs need to be prepared for events that would require high-volume testing for extended periods of time, including novel pandemics, surge, and concurrent biological, chemical, or radiological emergencies requiring expanded testing capacity. When lab testing surge capacity is overwhelmed, this can create a backlog of data, sometimes resulting in outdated or incomplete information being disseminated to both the public and those responsible for making decisions during an infectious disease emergency.

specimens to for identification or confirmation	for response or surge without regulatory burdens • Educate hospital partners in the difference between lab types, and who to send certain specimens to for rapid identification or confirmation (Biological)		
Gap 6: Need for improved reporting (results and metadata) for PON/POC assays			
Context	Solution Strategies	CBRN	Implications of Gaps
• Data modernization should include improved reporting mechanisms (e.g., reduce the number of platforms and increase interoperability) • Reporting and data systems were unable to keep up with testing volume during the pandemic. Better integration with reporting rapid test results to public health would allow for enhanced surveillance	• Consider decentralizing data and setting standards for data reporting that are uniform across states	All	There is an urgent need for modernization of the nation's reporting infrastructure. There are multiple pipelines or mechanisms for reporting results and often new systems are created for new threats. Building a system that is fully electronic (electronic test orders and results) and allows data to flow to multiple partners will great enhance the ability to identify and respond to threats. While there are PON/POC assays that can be more widely distributed and may not require testing to be proctored for public benefit, this can result in data collection and accuracy challenges (e.g., calculating disease incidence only using data from reported results from home tests does not necessarily account for all positive or negative home tests completed). To give an accurate picture of disease prevalence, data collection and analysis would need to account for the likelihood that not all test results are reported to public health.
Gap 7: Need to translate genomic sequences into phenotypic traits			
Context	Solution Strategies	CBRN	Implications of Gaps
• Most labs have WGS, but the pipeline analysis looking for different organisms is still a	• Support advancements in sequencing to detect unknown pathogens, and develop a regional pipeline	Biological	The ability to examine phenotypic traits provides a more in-depth understanding of pathogens, how they interact with other organisms, and what their consequences may

limitation.	for WGS		be on population health. The ability to quickly understand characteristics of any given pathogen or predict the effects of their variants (e.g., changes in virulence) is crucial in determining appropriate response actions. Continuous support for advancing fundamental understanding of the genetic expressions of various pathogens and their substrains contributes to a knowledge base that can help in both preparedness and response decision-making and activities as more novel pathogens emerge. If the scientific community and public health labs are able to better understand, translate, and make predictions from genomic sequences and pathogenic traits prior to or during an outbreak or pandemic, they are in a better position to quickly make decisions than if this knowledge or capability goes unexplored.
Gap 8: Need for ongoing evaluation of tests against new variant/strains			
Context	Solution Strategies	CBRN	Implications of Gaps
• Rapid tests do not have the same sensitivity or specificity as other traditional tests, so there are concerns about the validity of these tests in becoming the new "gold standard."	• Conduct scientific studies to understand the performance of rapid tests in the real world. This will be critical to gaining confidence in these screening assays. If there is to be a shift away from WGS towards rapid systems, CDC should be involved in ensuring the new system does not have decreased performance (e.g., sensitivity and specificity)	Biological/ Chemical	Sensitivity and specificity of tests should always be considered when introducing novel tests as well as reevaluating existing tests for novel pathogens and their variants. This increases accuracy of data collection used to support decision making, and actions taken based on accurate surveillance data can help lead to rebuilding public trust and buy-in. This can be especially important if testing relies on conducting and reporting home tests.

Theme 4: Flexible and extensible data exchange for CBRN and emerging threats

Gap 1: Lack of standardized, non-siloed, data sharing requirements to allow case-level surveillance			
Context	Solution Strategies	CBRN	Implications of Gaps
• There are major differences in informatics capability between jurisdictions, and separate accounts are needed for data sharing between states • There is a need for cross-jurisdictional data sharing and exchange capabilities, including unified database systems and structures across entities and labs • There are political considerations now involved in releasing protected health information • There is a need for improvements to methods for sharing data on specimen collection, instruments, and stockpile distribution as well as communicating test results between labs and partners, especially during emergencies. The CDC already has a system in place where environmental data is entered in a large database by various entities (e.g., DOE, EPA, local departments) which the CDC can pull from. From a Radiological/Nuclear perspective, entering results into a large database would help to determine where the hottest samples are,	• Apply current biological/chemical data entry and sharing practices to radiological programs • Provide clear data sharing rules and responsibilities • Clearly define information that can be shared for true public health needs	All	Accurate and accessible lab information/data enhance effective public health interventions by supporting a more healthcare-integrated, data-driven decision-making interface for public health professionals to direct resources and to provide guidance. With the rapid movement of people across jurisdictions, having a platform to obtain needed data or established methods for data sharing can accelerate more accurate reporting and surveillance. MOUs for data sharing across state systems may be difficult to set up as blanket agreements. All data are not the same and system owners/end users may not be willing to agree to share their data wholesale. It is difficult to prescribe an architecture that abides by regulation in every locality across the nation while maintaining utility. It is possible that a lab focused information exchange may not be able to share information with a public health entity because of protections to proprietary information or restrictions by individuals to sharing their public health information (PHI). Electronic data systems exclusively within government public health entities face similar challenges in regulation and standards associated with localities.

which areas indicate the greatest risk of exposure and contamination, and where epidemiologists need to concentrate human sampling and prioritize samples (Radiological/Nuclear).			Existing public health data systems have varying capability to transmit secure data to systems outside their associated enterprise. Considerations will need to be made for integration of public health data streams into health information exchange platforms as well as the protections needed for that data. Increasing the interoperability of health data systems broadens the attack surface for exfiltration of PHI. System owners and data service providers will need to consider the cybersecurity implications of integrating data.
Gap 2: Aging and/or outdated IT infrastructure and data management systems in PHLs.			
Context	Solution Strategies	CBRN	Implications of Gaps
• Current technology is outdated or incompatible and does not support sharing capabilities. The differences in information technology and data infrastructure results in incompatibility between systems which impacts the capability for information transfer (e.g., laboratory information management systems) • Existing systems are not able to support high testing periods • The shared cost of data sharing and information exchange is cost prohibitive • There is a lack of expertise in government information technology, especially with specialized knowledge of data exchange between labs and data sharing needs, without an adequate	• Develop and support training programs for IT expertise development • Support data modernization and streamlining processes • Create integrated lab consortium networks and facilitate consortium-level discussions among public health labs to discuss support, needs, and MOAs	All	Current systems are a patchwork of outdated and poorly integrated infrastructure. This impacts data sharing, integrity, and scaling during high testing periods. Standards vary from state to state (in some cases jurisdiction to jurisdiction) and system upgrades that are made are not coordinated between jurisdictions, which limits compatibility. System upgrades and acquisition are also costly, which requires coordination with political powers.

training model to address the workforce gap			
Gap 3: Lack of standardized clinical data reporting requirements (from private clinical labs to PH entities and from STLTS to federal)			
Context	Solution Strategies	CBRN	Implications of Gaps
• Labs demand different data elements from various reports	• Establish a standardized incident report and minimum data element report across all states that define critical variables	All	Developing standardized metrics for clinical data will contribute to a more cohesive approach to decision making. This will require support from national health associations supporting the STLT levels. Data standards and infrastructure varies from state to state, which makes establishing clinic data reporting requirements difficult.

Theme 5: Preemptive, sustainable public-private partnerships

Gap 1: Need for improved, coordinated, timely surge testing for response			
Context	Solution Strategies	CBRN	Implications of Gaps
• There is a need for more proactive planning, timely communication, and coordination between responding entities during a surge. If a surge of testing is expected upon identification of a threat, state labs will need to be able to communicate with external lab partners to assist with capacity needs (Biological). • During a response, sample collection processes need to be in place that support rapid, effective communication and partnerships among those responding in the field and the lab	• Support large-scale commercial availability of critical products, including better manufacturing capabilities during a surge • Create integrated lab networks and facilitate consortium-level discussions among public health labs to discuss support, needs, and MOAs • Support training and exercises across agencies to develop workforce skills and opportunities to work through coordinated response activities • Engage in more outreach with partners where public health provides training. This approach ensures that the right sample gets into the laboratory system • Engage diverse partners such as veterinary diagnostic laboratories to help build capacity across a jurisdiction • Educate hospital partners in the difference between lab types, and who to send certain specimens to for	All	Related to the theme on workforce, the gaps in recruitment, retention, and training at the STLT level for laboratories demand other solutions and creative strategies in order to meet the demand during surge events. If strong partnerships with the private sector and other fields (e.g., veterinary laboratories) were developed, the capability for rapid testing could be improved. However, as partnerships cannot be built overnight, improving the ability for coordinated and rapid testing will require dedicated personnel for outreach and potentially new policy development and regulation for things like data sharing and specimen handling.

	identification or confirmation (Biological) • Support improved partnerships across industries and agencies for better planning processes and response, including commercial lab partners • Support training and exercises across agencies to prepare for and practice response and surge coordination		
Gap 2: Need for improved collaboration for coordinated development, quality control, manufacturing, and dissemination of diagnostic assays to surge testing partners			
Context	Solution Strategies	CBRN	Implications of Gaps
• The market is the number one factor industry looks at to develop a product. Companies need to continuously confirm the market needs and that the income that would justify the investment to ensure that the direction they take is "the right thing to do commercially" • Some products are already being manufactured and distributed for certain pathogens (e.g., influenza), which companies have previously licensed with the CDC that could be repurposed when companies need to "ramp	• Enable multiple vendor partnerships in preparation for emergencies • Develop "tighter partnerships" between agencies and industry to help understand how to anticipate test volume, expectations, and public health needs (e.g., industry could be more reliable when looped into conversations before CDC and HHS place volume expectations on agent specific testing) • Engage in a collaborative effort to strengthen the "path to scale" where the manufacturing and scaling	All	While the private sector can be a helpful ally in increasing the development of needed assays, they are inherently more risk-adverse and have limitations when it comes to prioritizing assay development for pathogens before investing in products that may never be used. More collaboration at earlier stages of the process can identify strengths and weaknesses of each partner and areas for opportunity at various stages of product development. Additionally, stronger partnerships could assist in addressing gaps in information needed by industry to better anticipate test manufacturing and dissemination needs during all phases of a pandemic/epidemic curve, as well as during different types of chemical or radiological/nuclear incidents. Differences in priorities between public health and industry, such as market value or regulatory pathways

up" production • Building collaborative partnerships across agencies and industries for test or platform development can lessen the risk felt by industry. This may allow industry to assist in expanding public health's reach by commercializing assays developed by public health agencies • A difference exists between products fully available for commercial sale (e.g., regular shelf products) and products with a smaller market that could involve more of a custom pipeline for lower scale. • More specific requirements and plans built into agreement structures can result in a more strategic response for recognizing and addressing needs • Industry looks to public health surveillance and labs to guide decisions of which pathogens or assays should be the priority to develop and have on hand when and if they are needed • The earlier test scalability can be scoped to "look at all the contingencies" in	up environment can apply to a variety of partners and pathogens, increasing confidence in methods for scaling up to meet demand across all agencies and vendors • Utilize independent testing facilities, supply chains, and a variety of test types could increase flexibility (e.g., thinking beyond PCR and including antigen testing and serology so there are contingencies in place in the event of a shortage) • Increase flexibility and support for products with multiple potential uses • Engage in effective government partnerships during emergencies and steady states • Improve agreement mechanisms for manufacturing and production • Streamline processes and strengthen capabilities to quickly move to manufacturing and production when needed		may present as a barrier, but could also be an opportunity to find actionable solutions through strong communication and partnership.

developing a test for global use or shift developments as needed, the better industry can understand and react appropriately • It is easier for industry to scale up if multiple vendors are participating			
Gap 3: Lack of designated research and development dollars in public health and need for partners			
Context	Solution Strategies	CBRN	Implications of Gaps
• Not addressed in discussions	• Provide funding flexibility and specify funding in grants for implementing new technology in labs	All	Gap not addressed in discussions; cannot conclude implications without more data.
Gap 4: Need for improved emergency regulatory pathways			
Context	Solution Strategies	CBRN	Implications of Gaps
• FDA approval process can be limiting for testing needs. • The pandemic has "revealed to industry that public health can demobilize quickly, which should allow for more evidence generation that would provide justification for greater FDA approvals on other testing needs" • Regulatory opportunities and routes (e.g., emergency use authorizations (EUAs) need to exist in order for industry to bring a test to market • "The regulatory apparatus tends to force requirements in areas where it does not	• Alignment of FDA and CMS CLIA requirements will be critical for future responses • Licensing content from the CDC to extend their detection and characterization assays to the commercial sector as opposed to developing something new could help in reducing the workload on public health labs. • Build better relationships between responding entities involved in emergency response supply chains (FDA, CDC, CLIA, etc.) to address	All	Given the vast number of viruses and pathogens that could become threats, assays for diagnostic testing may not be developed until a threat is present. Having a more streamlined and rapid regulatory process in emergencies, bolstered by better relationships across responding agencies, can help bring products to market faster at a scale necessary for surge demands.

fit," illustrating a need for "sensible regulatory requirements that account for the uniqueness of the technology and differences across labs" (Radiological/Nuclear) ● Clinical Laboratory Improvement Amendment (CLIA) requirements and compliance can be challenging to navigate.	regulatory challenges that prevent labs from pivoting and acquiring specific items during events, or validating those items ● Support preparedness activities so labs have the ability to scale up for response or surge without regulatory burdens		

Theme 6: Sustainable laboratory surge capacity and transition to whole-of-society response

Gap 1: Need for improved, broadly applicable federal, state, and local supply chain management frameworks (e.g., access to specimens, reagents, materials, personal protective equipment (PPE), etc.)			
Context	Solution Strategies	CBRN	Implications of Gaps
• Supply chain challenges can limit ability to respond, especially when specific items are only manufactured by one company (Radiological/Nuclear) • Supply chains face challenges in maintaining quality standards among diverse suppliers EUA situations, providing transparency in allocation processes by manufacturers, providing a manageable procurement process, ensuring sufficient distribution of supplies to where they are needed, and negotiating with supply chain contracts and competition • Federal agencies have separate caches and equipment and do not always partner well together	• Support the development of memorandum of understanding (MOUs) for planning between federal entities • Support novel supply chain improvements • Create a consistent allocation process that is based on communication, transparency, and legitimate metrics • Revise procurement rules and grant language to provide more funding flexibility and allow for rapid deployment of funds, including approval of purchases for equipment and supplies that are over funding limits • Strengthen public health lab partnerships to allow	All	The pandemic exacerbated existing challenges related to supply chain resilience, as noted by a recent National Academies consensus study, Building Resilience into the Nation's Medical Product Supply Chains. Simply put, laboratories cannot adequately respond to threats to the public's health if they do not have access to the materials, supplies, and equipment they need to perform testing for surveillance. Resolving supply chain issues brings a number of challenges. End users have complex responses to perceived and actual resource shortages, including hoarding behaviors, which can be difficult to manage. Allocation programs are often met with resistance from end users. Manufacturers and distributors might resist sharing detailed inventory data or other proprietary information in an effort to protect competitiveness. Updating administrative policy, including procurement rules, at the local, state, and federal levels can be a cumbersome process.

	for product redistribution, and build space in cooperative agreements to allow jurisdictions to address their own priorities ● Collaborate across the federal government to invest in domestic manufacturing to create a resilient supply chain ● Engage laboratories in discussions to determine priority items for stockpiling and integrate critical lab supplies into the SNS		
Gap 2: Need for mechanisms to develop, coordinate, and support rapid research during emergency response (e.g., routes of transmission, PPE, disinfections)			
Context	Solution Strategies	CBRN	Implications of Gaps
● Not addressed in discussions	● No specific solution strategies discussed	All	While not focused on rapid research related to science, the Action Collaborative on Disaster Research may serve as a mechanism for rapid research on response-related activities. ● Gap not addressed in discussions; cannot conclude implications without more data.
Gap 3: Need for interagency collaboration with FDA, BARDA, NIH, etc. on their roadmap for development and implementation next generation technologies			
Context	Solution Strategies	CBRN	Implications of Gaps

• COVID-19 has sparked collaboration and partnerships in federal agencies that should be continued (e.g., NIH Rapid Acceleration for Diagnostics (RADx), BARDA for point of care tests, or between the USDA and FDA networks)	• No specific solution strategies discussed	All	There are a number of federal initiatives to improve national laboratory, epidemiology, and bioinformatics capacity and capabilities. If federal agencies do not coordinate and communicate their efforts, they risk ineffective and inefficient implementation of innovative platforms and technologies at the state and local levels. Public health practitioners have expressed a desire to understand what improvements and changes are coming in order to gain buy-in from leaders and plan for adoption.
Gap 4: Need for improved communications to effectively inform and motivate public action			
Context	Solution Strategies	CBRN	Implications of Gaps
• There is a need for targeted messaging to communities about the importance of getting tested and communicating results is vital in providing the public with education and situational awareness	• Engage with communities so public health laboratories and community organizations are each aware of relevant work prior to an emergency	All	The pandemic put public health surveillance in the spotlight. Like much of the public health workforce, laboratories might benefit from campaigns to familiarize the public with the role of testing in surveillance to improve compliance with public health recommendations. The CDC AMD Scientific Superheros is an example of such a campaign, which has the added benefit of attracting potential workforce members.
Gap 5: Need for lower barrier to entry for potential partners interested in collaborating with CDC on surveillance, research, sample sharing			
Context	Solution Strategies	CBRN	Implications of Gaps
• APHL partnerships with the LRN, ACLA, ACLA member labs, ASM, CAP as well as other partnerships have allowed for multicenter evaluation studies, implementation of electronic laboratory reporting, development and maintenance of microbiology protocols,	• No specific solution strategies discussed	All	The more difficult it is to collaborate, the harder it is to ensure sufficient emergency response and surge capacity, or even ongoing research to add to the knowledge base. When novel pathogens emerge, or when the presence of a known pathogen is detected (e.g., monkeypox, polio), epidemiology and emergency response rely on rapid, evidence-based data, resources, and recommendations to protect the public and contain the threat. If these do not exist, or are only accessible by the CDC, then valuable time is spent waiting for accurate and complete information to act upon, assay development and validation,

exercises and networking among laboratory professionals ● Sequencing partnerships between CDC, commercial vendors, and clinical labs have been helpful in gathering data during the COVID-19 pandemic			guidance, and shared data. When developing solutions, stakeholders must consider data sharing agreements, system interoperability, differences in pace (public vs private sector), and data privacy and public trust.
Gap 6: Need for improved public/private planning and coordination			
Context	Solution Strategies	CBRN	Implications of Gaps
● Industry is often a neglected partner in planning, and partners may not understand lab-specific practice requirements with materials or like-surrogates ● Communication around jurisdictional issues regarding incident command is not always clear	● Reintroduce industry into planning processes and explore ways to create a more collaborative approach ● Develop a structure/model for public health-focused Incident Command System to assist with partner integration	All	Public-private partnerships are essential to ensuring surge capacity. In order to have effective and efficient communication and coordination during disruptions, stakeholders must develop familiarity with one another well in advance of an event, specify expected roles and responsibilities during events, and identify how to hold one another accountable. Through planning and practice (e.g., exercises), public and private stakeholders can enhance the foundation for response.

Additional Gaps Identified from Focus Groups

The following tables contain the gaps and supporting context identified during the LRN-R and Manufacturers focus groups. These focus groups did not build directly upon the process and results of Workshops 1 and 2 and occurred after the Workshop 3 high priority gap ranking exercise. These gaps were not analyzed for bearing on CBRN threats/hazards, nor considered for gap level implications. These gaps were, however, considered in the development of the high-level implications of all identified gaps in the next sub-section of this report.

LRN-R Focus Group	
Gaps Identified	Context
Need for addressing workforce and training challenges to stand up an LRN-R	• LRN-R model would be starting off well behind the LRN for Chemical Threats Preparedness (LRN-C) model if labs are not already staffed with professionals who have a strong background in radiological methods. There would be significant training needs up front. • Supplemental personnel would be needed to maintain capability and expertise across different methods, as well as manage activities such as running proficiency testing, instrument comparisons, and maintaining CLIA requirements. • Some public health labs may be familiar with the environmental matrices but presenting them with a different matrix would require a significant amount of training. • There are concerns about the diminishing supply of well-trained staff who understand the technology, as well as the extensive radiological methods and instrument training that would be required for existing public health lab professionals.
Need for considering administrative burdens that would be placed on LRN-R labs	• Radioactive materials licenses are going to be needed but can be difficult to obtain if a lab does not already have one. The terms of the license also need to be managed at the facility level. • The additional burden on labs standing up an LRN-R would need to be considered, such as the addition of radiation safety officers, audits, licensing, accreditation, and waste disposal plans or practices, which require funding, personnel, and time. • Labs that have some existing radiological infrastructure may not find additional requirements or activities burdensome, but it could be a significant challenge for labs that do not have any existing radiological infrastructure.
Need for addressing differences in capacity between laboratories leading to resource competition	• Public health labs may not have the capacity that DOE or commercial labs have, however, DOE tests are "not fit for public health" and commercial labs are largely environmental. • Commercial labs may also have inconsistent capacity to provide support when needed, depending on their own client needs and volume. • If an incident occurs when a lab has additional priorities to consider, there is a lot of competition for a limited pool of resources, personnel, and funding.

Need for addressing challenging regulatory requirements and accreditation	• Bureaucracy "gets in the way" of clinical and environmental accreditation. • Labs may have the technical abilities to run many of the same analyses DOE labs do, but there are accreditation or contract challenges that do not allow for it. Procedures may need to be amended to ensure that they meet the clinical requirements from the CDC. • CLIA requirements and compliance can be challenging to navigate. One example includes labs trying to become a part of an LRN-R but were not able to because their lab directors couldn't qualify as CLIA-qualified lab directors. • In addition to federal regulatory oversight, there are some states that have regulatory oversight of their clinical labs, which is "another level of bureaucracy to deal with." • "The regulatory apparatus tends to force requirements in areas where it does not fit," illustrating a need for "sensible regulatory requirements that account for the uniqueness of the technology and differences across labs", which APHL could help coordinate and develop.
Need for navigating licensure agreements	• Select agent labs have limits on how much of a select agent can be stored long-term. The same would be true for radioactive materials, but proper disposal would be more difficult. • In most regulations, there is a blanket license allowing possession of small amounts of specific radioactive materials (e.g., if an unknown sample is received and tests positive as a radioactive material) but possessing larger quantities for longer periods of time would require going through a process to obtain a radio materials license. • Without a radio materials license, a "workaround" process would be needed for labs to possess a defined amount for reference standards and quality control materials in order to avoid violating licensure agreements. Maintaining a system for these samples to go to labs that already have a program and license in place or strengthening partnerships with DOE labs are more reasonable solutions.
Need for improved agreement mechanisms and contracts with DOE labs	• DOE labs do not staff federal employees, and have very complex contracts requiring staff to account for their time down to 15- or 30-minute intervals • DOE contracts can restrict activities. If a task is not within the scope of the contract, they can be asked to stop work • Preparedness planning should be prioritized and coordinated with DOE labs. Public health labs should be proactive in managing contracts dictating how assistance could be provided through the DOE system. • DOE labs have the regulatory frameworks and infrastructure in place (e.g., waste disposal, licensing) to support the CDC. The interagency agreements and contractual funding mechanisms can be challenging when DOE labs are asked to pivot in order to prioritize incident support.

Manufacturer Focus Group	
Gaps Identified	Context
Need for increased flexibility and support	• The market is the primary driver of industry decisions • Expanding on or creating an additional market can be an opportunity to develop new assays (e.g., influenza

for products with multiple uses	typing is already on the market, and adding subtyping for H5N1 was an opportunity to expand) ● "Influenza is a threat business, so there's always the opportunity that Research Use Only (RUO) could expand into a pathogen involved in an outbreak or pandemic, which could create a future market and significant return later on" ● Utilizing independent testing facilities, supply chains, and a variety of test types could increase flexibility (e.g., thinking beyond PCR and including antigen testing and serology so there are contingencies in place in the event of a shortage) ● Some products are already being manufactured and distributed for certain pathogens (e.g., influenza) which companies have previously licensed with the CDC that could be repurposed or utilized when companies need to "ramp up" production ● Industry will likely continue to look to develop platforms that are capable "of more open development, but not specific platforms developed in response to a given pathogen"
Need for stronger collaborative partnerships between agencies and industry in emergencies and steady states	● Engage in a collaborative effort to strengthen the "path to scale" where the manufacturing and scaling up environment can apply to a variety of partners and pathogens, increasing confidence in methods for scaling up to meet demand across all agencies and vendors ● Develop "tighter partnerships" between agencies and industry to help understand how to anticipate test volume, expectations, and public health needs (e.g., industry could be more reliable when looped into conversations before CDC and HHS place volume expectations on monkeypox testing) ● Creating a more collaborative approach between public health and industry for test or platform development can lessen the risk felt by industry. This may allow industry to assist in "expanding public health's reach by commercializing assays developed by public health agencies"
Need for expanding platforms and products for improved vendor participation	● Broadly define requirements to allow for multiple vendors to open up platforms and participate in order to fill gaps and ensure industry has the ability to scale up when required ● It is easier for industry to scale up if multiple vendors are participating
Need for improved agreement mechanisms for manufacturing and production	● More specific requirements and plans built into agreement structures can result in a more strategic response for recognizing and addressing needs ● There may not be agreements in place without a particular need, which can be challenging
Need for a streamlined process and strengthening of capabilities to quickly move to	● Develop a "package" that provides the ability to move quickly from manufacturing and production ● Develop a generic pipeline for systematically increasing manufacturing for previously developed tests or assays when needs arise ● Companies can conduct exercises that include the full pathway to better anticipate gaps and needs that may come up during an event that require scaling up

manufacturing and production when needed	• The government can proactively identify potential bottlenecks in future scenarios (e.g., bottleneck analysis during COVID-19 identified challenges that were addressed so scaling up was possible)
Need for improved communication of pathogen information and guidance to industry partners to assist in decision making	• Assist industry in understanding targets within a given pathogen, and what would differentiate a target for various strains that could help guide the development process • Industry looks to public health surveillance and labs to guide decisions on which pathogens or assays should be the priority to develop and have on hand when and if they are needed
Need for improved communication of product scalability guidance and manufacturing expectations to industry partners to assist in decision making	• The government has the desire to partner with multiple manufacturers to avoid the risks associated with reliance on a single company. Companies need an understanding of how the development pipeline feeds into the manufacturing pipeline • Determining who is going to be performing the testing also determines what kind of lab partnerships may be needed, how many labs are going to be involved, and what scale tests need to be manufactured • Information on product scalability. The earlier test scalability can be scoped to "look at all the contingencies" in developing a test for global use or shift developments as needed, the better industry can understand and react appropriately • During an outbreak companies need to determine how to rapidly increase manufacturing and distribution. A variety of approaches should be considered when thinking about how manufacturers can ensure an ability to scale up when needed • Partners would benefit from information on scale-up needs and expectations. Determining ways to match testing capacity to meet demand but remain flexible and adaptable can provide some of this insight. • Helpful to determine how capacities can be best leveraged to respond to outbreaks effectively and prepare for worst case scenarios
Need for available and feasible regulatory approval pathways	• The length and complexity of the approval process to get products out to market quickly can be challenging (e.g., EUA). • There is always a risk that a new product will not approved. Tighter regulations mean greater risk and less participation from companies and vendors
Need for data modernization	• Data modernization should include improved reporting mechanisms (e.g., reduce the number of platforms increase interoperability) • Consider decentralizing data and setting standards for data reporting that are uniform across states

High Level Implications of All Identified Gaps

Across the various workshops and discussions held during this project, several themes emerged in terms of gaps that still exist, the implications of those gaps, and potential solution strategies. This section summarizes the implications of gaps across all identified themes.

While previous disasters and emergencies have resulted in many lessons learned for public health laboratories around the country, the COVID-19 pandemic became a "pressure test" that exposed the shortcomings of U.S. laboratory system when responding to emerging public health threats. This became especially clear in four key areas: workforce capacity, infrastructure, public private partnership, and supply chain. Workforce is critical because it requires specific knowledge, skills, and training for a range of threat types, pathogens, and systems. The current lab infrastructure is often single purpose, does not allow for rapidly scaling up across events, and lacks data interoperability. This also contributes to challenges with public private partnership, as data sharing is difficult, the roles are unclear, and relationships are often not established until the emergency occurs. Lastly, the supply chain, often set up as a "just in time" system, is easily disrupted and affected by many other upstream manufacturing factors beyond the scope of a single laboratory's visibility.

Public health emergencies require whole system preparedness planning and response. While the testing, workforce, and procurement of supplies are at the forefront of necessary roles for a laboratory in an emergency response, there are numerous actions and responsibilities that happen behind the scenes but are no less critical in ensuring success. For example, questions remain about what strategies are best for making decisions about whether to expand in house capacity or outsource all hazards capabilities, and how and when to establish pathways for public private partnerships to rapidly scale testing or bring products to market faster. Where and how much to invest also remains an area that lacks clarity, and for many labs, there is also a shortage of the resources to invest. Investment in scalable technologies, tools, and instruments in order to keep public health laboratories up to date and optimize efficiencies is also needed, as well as scaling new and innovative surveillance methods (e.g., wastewater surveillance, WGS) that can more rapidly detect and characterize pathogens. These strategies are still in their infancy in many places but would be able to enhance mitigation and containment strategies, resulting in a strong return on investment.

Finally, it has become clear in several scenarios that laboratories are critical in contributing to the integrity of and trust in the public health system. They are relied on to generate accurate, timely, and useful data that can help inform critical actions such as treatment of patients and public health departments actions, and it is challenging for labs to produce real-time data without adequate infrastructure, workforce, and supplies. They also need secure data collection and exchange that can be trusted to ensure privacy and security of information. But to address all of these challenges, many systems and aspects of laboratories will need to change, which is difficult because U.S. governmental agencies are inherently complex and slow to change. They are not known for agility and innovation, often offer lower pay scales and opportunity compared to the private sector, lack transparency in communication and coordination, and have older technology and infrastructure requiring significant investment. On the administrative side, it's difficult to convince leaders to invest in improvements, as their funding is not always clear and budget cycles require very advanced notice for changes, and procurement policies are complex.

Tiered High Priority Gaps

The following sub-section provides the tiered high priority gaps resulting from round one and round two of the ranking exercise held during Workshop 3. Gap ranking exercise results were used to prioritize gaps by placing them into three tiers (Tier 1 as the highest priority, and Tier 3 as the lowest). The tiered gaps are accompanied by the aligned theme and its bearing on CBRN threats/hazards.

See Appendix E for a detailed matrix of the results of both gap ranking exercise rounds.

Tiered High Priority Gaps Following the Round One Ranking Exercise During Workshop 3

Tier	Ranked Gap	Aligned Theme	C	B	R	N
1	Lack of interagency collaboration with FDA, BARDA, NIH, EPA, DOE, DOD, etc. on their roadmap for development and implementation next generation technologies	Sustainable laboratory surge capacity and transition to whole-of society response	×	×	×	×
	Lack of collaboration and communication for coordinated development, quality control, manufacturing, dissemination, and adoption of diagnostic assays and platforms to PHLs and surge testing partners	Preemptive, sustainable public-private partnerships	×	×	×	×
	Lack of rapid characterization and detection of novel or emerging pathogens to identify changes in transmissibility or virulence	Accurate, rapid detection and characterization of threats to inform decision making	×	×		
	Aging and/or outdated IT infrastructure and data management systems in PHLs.	Flexible and extensible data exchange for CBRN and emerging threats	×	×	×	×
	Insufficient federal and STLT workforce in general and during surge; and weakness in recruitment/retention, onboarding, and training.	Proficient federal and STLT workforce	×	×	×	×
	Lack of threat agnostic biological, and chemical surveillance systems and methods (e.g., metagenomic sequencing of wastewater and clinical samples compared to amplicon and PCR assays or FluNet, which is influenza specific)	Accurate, rapid detection and characterization of threats to inform decision making	×	×		
	Lack of data sharing agreements between federal, state, and other partners	Flexible and extensible data exchange for CBRN and emerging threats	×	×	×	×
2	Lack of mechanisms to develop, coordinate, and support rapid research during emergency response (e.g., routes of transmission, PPE, disinfectants).	Sustainable laboratory surge capacity and transition to whole-of society response	×	×	×	×
	Lack of standardized, non-siloed, data sharing requirements to allow case-level surveillance.	Flexible and extensible data exchange for CBRN and emerging threats	×	×	×	×
	Lack of critical expertise in federal and STLT workforce in bioinformatics, CLIA compliance, and radiological/nuclear.	Proficient federal and STLT workforce			×	×
	Lack of systems to promote rapid, parallel development of accurate laboratory assays on platforms that are already in use in laboratories	Accurate, rapid detection and characterization of threats to inform decision making	×	×	×	×
	Lack of a LRN-R to be able to rapidly respond to a radiological or a nuclear incident.	Flexible and extensible data exchange for CBRN and emerging threats	×	×	×	×

	Lack of plan to support surge testing for agents with special considerations (e.g., select agents, RG3 and 4 pathogens)	Accurate, rapid detection and characterization of threats to inform decision making	×	×	×	×
	Lack of mechanism to harmonize equipment needs to facilitate assay development on equipment available to most	Flexible, broadly applicable infrastructure and equipment	×	×	×	×
	Inability to maintain or replace outdated/sunsetting equipment (including maintaining surge capacity equipment)	Flexible, broadly applicable infrastructure and equipment	×	×	×	×
3	Lack of consistent laboratory quality management systems.	Flexible, broadly applicable infrastructure and equipment	×	×	×	×
	Lack of broadly applicable federal, state, and local supply chain management frameworks (e.g., access to specimens, reagents, materials, PPE, medical equipment, etc.), including reevaluation of equipment (e.g., reusable respirators vs. N95s).	Sustainable laboratory surge capacity and transition to whole-of society response	×	×	×	×
	Lack of partnerships to facilitate effective communications to inform and motivate public action	Preemptive, sustainable public-private partnerships	×	×	×	×
	Lack of rapid development, manufacture, and rollout of Point-of-Care and Point-of-Need assays that include reporting considerations	Accurate, rapid detection and characterization of threats to inform decision making	×	×		
	Limited sustainable surge testing capacity within PHLs	Accurate, rapid detection and characterization of threats to inform decision making	×	×	×	×
	Lack of communications that effectively inform and motivate public action	Sustainable laboratory surge capacity and transition to whole-of society response	×	×	×	×
	Lack of coordinated, timely, surge testing for response	Preemptive, sustainable public-private partnerships	×	×	×	×

Tiered High Priority Gaps Following the Round Two Ranking Exercise During Workshop 3

Tier	Priority Gap	Aligned Theme	C	B	R	N
1	Lack of interagency collaboration with FDA, BARDA, NIH, EPA, DOE, DOD, etc. on their roadmap for development and implementation next generation technologies	Sustainable laboratory surge capacity and transition to whole-of society response	×	×	×	×
	Insufficient federal and STLT workforce in general and during surge; and weakness in recruitment/retention, onboarding, and training.	Proficient federal and STLT workforce	×	×	×	×
	Lack of a LRN-R to be able to rapidly respond to a radiological or a nuclear incident.	Flexible, broadly applicable infrastructure and equipment			×	×
	Lack of threat agnostic biological, and chemical surveillance systems and methods (e.g., metagenomic sequencing of wastewater and clinical samples compared to amplicon and PCR assays or FluNet, which is influenza specific)	Accurate, rapid detection and characterization of threats to inform decision making	×	×		
	Lack of plan to support surge testing for agents with special considerations (e.g., select agents, RG3 and 4 pathogens)	Accurate, rapid detection and characterization of threats to inform decision making	×	×	×	×
	Aging and/or outdated IT infrastructure and data management systems in PHLs.	Flexible and extensible data exchange for CBRN and emerging threats	×	×	×	×
	Lack of collaboration and communication for coordinated development, quality control, manufacturing, dissemination, and adoption of diagnostic assays and platforms to PHLs and surge testing partners	Preemptive, sustainable public-private partnerships	×	×	×	×
2	Lack of critical expertise in federal and STLT workforce in bioinformatics, CLIA compliance, and radiological/nuclear.	Proficient federal and STLT workforce			×	×
	Lack of rapid characterization and detection of novel or emerging pathogens to identify changes in transmissibility or virulence	Accurate, rapid detection and characterization of threats to inform decision making	×	×		
	Inability to maintain or replace outdated/sunsetting equipment (including maintaining surge capacity equipment)	Flexible, broadly applicable infrastructure and equipment	×	×	×	×
	Lack of communications that effectively inform and motivate public action	Sustainable laboratory surge capacity and transition to whole-of society response	×	×	×	×

	Lack of coordinated, timely surge testing for response	Preemptive, sustainable public-private partnerships	×	×	×	×
	Lack of systems to promote rapid, parallel development of accurate laboratory assays on platforms that are already in use in laboratories	Accurate, rapid detection and characterization of threats to inform decision making	×	×	×	×
	Limited sustainable surge testing capacity within PHLs	Accurate, rapid detection and characterization of threats to inform decision making	×	×	×	×
	Lack of data sharing agreements between federal, state, and other partners	Flexible and extensible data exchange for CBRN and emerging threats	×	×	×	×
3	Lack of mechanism to harmonize equipment needs to facilitate assay development on equipment available to most	Flexible, broadly applicable infrastructure and equipment	×	×	×	×
	Lack of standardized, non-siloed, data sharing requirements to allow case-level surveillance.	Flexible and extensible data exchange for CBRN and emerging threats	×	×	×	×
	Lack of consistent laboratory quality management systems.	Flexible, broadly applicable infrastructure and equipment	×	×	×	×
	Lack of partnerships to facilitate effective communications to inform and motivate public action	Preemptive, sustainable public-private partnerships	×	×	×	×
	Lack of broadly applicable federal, state, and local supply chain management frameworks (e.g., access to specimens, reagents, materials, PPE, medical equipment, etc.), including reevaluation of equipment (e.g., reusable respirators vs. N95s).	Sustainable laboratory surge capacity and transition to whole-of society response	×	×	×	×
	Lack of mechanisms to develop, coordinate, and support rapid research during emergency response (e.g., routes of transmission, PPE, disinfectants).	Sustainable laboratory surge capacity and transition to whole-of society response	×	×	×	×
	Lack of rapid development, manufacture, and rollout of Point-of-Care and Point-of-Need assays that include reporting considerations	Accurate, rapid detection and characterization of threats to inform decision making	×	×		

Appendices

- Appendix A: Workshop 1 Proceedings
- Appendix B: Workshop 2 Proceedings
- Appendix C: Radiological Laboratory Response Network Focus Group Proceedings
- Appendix D: Manufacturers Focus Group Proceedings
- Appendix E: Tiered High Priority Gaps Ranking Results Matrix

Appendix A: Workshop 1 Proceedings

EXPLORING CRITICAL GAPS AND SOLUTION STRATEGIES IN LABORATORY CAPACITY AND CAPABILITIES FOR PUBLIC HEALTH RESPONSE

WORKSHOP I
PROCEEDINGS

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On Friday, January 21, 2022, SGNL Solutions (SGNL) and Association of Public Health Laboratories (APHL) hosted a 3.5-hour, invite-only workshop for 28 participants representing federal, state, territorial, local, and tribal (FSTLT) public health laboratories, commercial laboratories, and foundations. Observers from Centers for Disease Control and Prevention (CDC) and APHL also attended the workshop. The workshop was designed to meet the following objectives:

1. Identify the gaps in laboratory capabilities and capacity to support a response to public health threats from chemical, biological, radiological, and nuclear (CBRN) hazards;
2. Explore the root causes of gaps in laboratory capabilities and capacity to support a response to public health threats from CBRN hazards; and
3. Generate potential specific and near-term strategies to address the gaps in laboratory capabilities and capacity to support a response to public health threats from chemical, biological, radiological, and nuclear hazards.

Justin Snair (SGNL) and Chris Mangal (APHL) offered opening remarks to orient participants to the initiative and the workshop agenda, objectives, and activities. Then, Joanne Andreadis (CDC) provided a brief commentary on the goals of the project and importance of the workshop discussion. Next, Justin Snair (SGNL) defined key terms (Box 1) and assumptions to establish shared language and understanding of concepts that would be explored during the workshop.

Box 1- Key Terms

- Threats to public health are incidents involving CBRN agents whose scale, timing, or unpredictability results in health consequences that have the potential to overwhelm routine community capabilities to address them.
- Laboratory capabilities is defined as the ability of a unit or a system to perform a specific set of actions or achieve a specified set of outcomes, in this case to detect and respond to a threat.
- Laboratory capacity is defined as the quantity of something (e.g., number of tests, number of projects, number of runs or total working volume) that can be produced by a given unit or system.
- Laboratories have a vital role providing support for public health emergencies, including (1) rapidly identifying and investigating analyses of CBRN agents, regardless of the source of exposure (i.e., unintentional, terrorist, or natural disaster); (2) ensuring the capacity to quickly and accurately handle a substantial volume of tests during an emergency situation; and (3) providing a rapid response system for hazardous contaminants.
- Laboratory support for CBRN events comes from a fragmented system of public and private units, with varying degrees of capacity and capabilities. The system involves a complex supply chain of instrumentation, reagents, and other consumables.

In the first activity, participants described gaps in laboratory capabilities and capacity. Participants were distributed across three breakout rooms, each focused on a different threat (biological, chemical, and radiological/nuclear). In each breakout room, a facilitator shared a brief threat-based scenario and asked participants to list gaps across following categories: equipment/supplies, facilities, personnel/training, safety/security, procedures/communications, partnering, and data exchange. Facilitators documented the group discussion using virtual whiteboards. The white boards from each breakout room were consolidated and presented to all participants.

Following the workshop, SGNL analyzed the workshop outputs (audio recordings, notes, white

boards) to identify themes in the gaps in laboratory capabilities and capacity to support a response to public health threats from chemical, biological, radiological, and nuclear hazards (Box 2). Detailed documentation of the gaps is provided in Appendix A.

Box 2 – Major Themes in Gaps in Laboratory Capabilities and Capacity

1. Proficient federal, state, and local public health laboratory workforce
2. Infrastructure and equipment that meets capability and capacity needs for multiple threats
3. Accurate, rapid detection and characterization of threats to inform decision making
4. Flexible and extensible data exchange for CBRN and emerging threats
5. Coordinated federal, state, and local public health response networks, frameworks, best practices and partnerships during all emergency response phases

During a closed session, facilitators solicited gaps of interest from CDC observers (Box 3) for the second activity, a series of solution sprints. Due to time limitations, not all provided gaps of interest were discussed during solutions sprints.

Box 3 – Gaps of Interest Provided by CDC Observers

- Aging or outdated infrastructure (IT, lab equipment, storage, physical buildings)
- Automation/streamlining for scaling
- Communication and notification of stakeholders
- Communication between first responders and labs
- Cross jurisdictional data sharing
- Environmental clean up
- Exercising for incidents
- Lack of expertise for specific threats (e.g., radiation/nuclear)
- Maintaining chain of custody from sample collection to sample return
- Proactive planning
- Recruitment and retention of new laboratory staff
- Resistance from entrenched staff (IT, lab, leaders, informatics)
- Staff shortages/burnout/fatigue
- Rate limiting effect of supply chain issues
- Transport of specimens

During each solution sprint, a facilitator named a gap and asked participants to reflect on how this gap showed up in their work. Next participants were prompted to identify potential root causes of the gap. Finally, participants offered specific solutions they thought CDC could support in the next three to five years to close the gaps. The discussion was captured on a virtual whiteboard during this session. The solutions are summarized in Box 4. Appendix B provides a detailed documentation of the solution sprints.

Box 4 – Summary of Solutions Generated by Participants

Workforce Management

- Improve hiring and onboarding processes within government agencies

- Offer incentives that attract and retain lab workers (e.g., fellowships, loan forgiveness, competitive salaries)
- Promote lab profession in secondary and higher education
- Develop lab recruitment strategies based on successful campaigns in other government entities (e.g., armed forces)
- Increase recognition of contribution of lab professionals to public health efforts
- Launch national service program of easily activated/deployable lab workforce

Resource Management

- Identify and monitor suppliers and manufacturers of unique and critical lab resources to better predict and prevent supply chain issues
- Expand International Reagent Resource (IRR), a CDC resource to provide registered users with reagents, test kits and other information, support capacity
- Develop network of just-in-time suppliers and manufacturers that can be activated during periods of surge
- Create a national resource allocation process that is consistent, transparent, and data-driven
- Develop cross-jurisdictional and cross-sector partnerships for redistribution of lab supplies
- Allow flexibility in public health laboratory grants and contracts for rapid deployment of funds (e.g., procurement approvals)
- Enhance lab capabilities for negotiating prices with distributors and manufacturers
- Perform relevant studies to extend expiration dates for common consumables to prolong use
- Support labs in acquiring 3D printing capabilities
- Encourage research into alternatives for bottleneck supplies

Performance Management

- Improve federal interagency planning processes
- Develop a structure/model public health Incident Command System
- Require laboratory response planning processes to include commercial labs and industry (i.e., suppliers, manufacturers)

Information Management

- Establish a standard, minimum data element report for all hazards to facilitate cross-jurisdictional data exchange

The workshop concluded with a reflection and closing remarks by SGNL and APHL.

This project was supported through Cooperative Agreement Number U60OE000104 between the U.S. Centers for Disease Control and Prevention (CDC) and the Association of Public Health Laboratories, Inc. The contents of this report are solely the responsibility of the authors and neither represent the official views of CDC nor reflect CDC's endorsement of a product or procedure.

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Appendix A – Description of Gaps in Laboratory Capabilities and Capacity Organized by Theme

Theme: Proficient federal, state, and local public health laboratory workforce		
Gaps	Context	Hazards (CBRN)
Recruiting and retaining laboratory workforce	• Challenges around federal funding allocation to fund lab positions, state hiring freezes, and long hiring wait times • Lack of incentives to hire and retain new staff, including lack of competitive salaries for positions with unfavorable hours/schedules, and high stress. • Lack of training and education opportunities exist nationwide to prepare applicants for laboratory work	Crosscutting
Turnover and attrition of experienced laboratory staff	• Turnover due to burnout or fatigue results in loss of knowledge and expertise in the workforce, with no formal way to capture knowledge and mentorship for new generations	Crosscutting
Workforce emergency preparedness	• Lack of training and exercises for disaster events, including collaborative training between agencies • Specialized training for testing and protocol compliance is needed to increase lab capabilities during different types of CBRN events • Cross-training of staff (internal and external) to increase capabilities during an emergency is not well supported	Crosscutting
Workforce mobilization and surge staffing	• Challenges staffing up for surge including hiring, retaining on-call workers, and adequate training for volunteers and surge workers to respond to different threat types. • Reserve workforce for public health emergencies is not prioritized	Crosscutting
Theme: Infrastructure and equipment that meets capability and capacity needs for multiple threats		
Gaps	Context	Hazards (CBRN)
Infrastructure and equipment improvements	• Support is needed for labs to become equipped and authorized (e.g., CLIA) to handle specialized testing capabilities for different biological, chemical, radioactive or nuclear samples • Labs need capability to shift between testing environmental and clinical samples during different response phases	Crosscutting

	• Expanded capacity needed to meet fluctuating and high-volume testing needs during response, surge and long-term recovery, including during Radiological/Nuclear decontamination and recovery (Radiological/Nuclear) • Facilities need the physical space and equipment to expand for high volume samples, including expanding secure storage space and freezers (Chemical, Biological)	
Materials and supplies	• Adequate testing, collection, and reference materials are needed for a variety of hazards across all response phases • Appropriate PPE for staff and responders is not always on hand • Supply chain challenges can limit ability to respond, especially when specific items are only manufactured by one company (Radiological/Nuclear) • Supply chains need to be secured for rapid response distribution	Crosscutting
Theme: Accurate, rapid detection and characterization of threats to inform decision making		
Gaps	Context	Hazards (CBRN)
Materials and resources	• Reliance on CDC labs for specialized testing and detection due to limited detection and surge capabilities for local labs • Limited resources are not always readily available locally for sample collection, testing and detection of threats that require rapid distribution of testing kits and other supplies • Geographically isolated locations responding to events would be waiting a longer period of time for supplies and equipment to arrive • Type of sample collection (e.g., blood, urine, environmental) should be considered when deploying resources and planning collection, transport, and testing	Crosscutting
Timely communication and coordination between responding entities	• If a surge of testing is expected upon identification, state labs will need to be able to communicate with external lab partners to assist with capacity needs (Biological) • Hospitals need to be educated in the differences between lab types, and who to send certain specimens to for identification or confirmation (Biological) • Clinical and environmental laboratories may need to collaborate quickly depending on the threat and phrase of response	Crosscutting

	• During response, sample collection processes need to be in place that support rapid, effective communication and establishment of partnerships between those responding in the field and the lab • Communication strategies are needed to quickly get a hold of people who may have been contaminated or exposed (Radiological/Nuclear)	
Logistics and chain of custody	• Plan is needed for efficient transportation of specimens while maintaining full chain of custody and accurate specimen tracking • Process is needed for ensuring appropriate temperature conditions for specimen integrity through transport • Logistics challenges for transport, packaging, and shipping hazardous samples, especially when detecting Radiological/Nuclear threats	Crosscutting
Theme: Flexible and extensible data exchange for CBRN and emerging threats		
Gaps	Context	Hazards (CBRN)
Cross-jurisdictional data exchange	• Need for cross-jurisdictional data sharing and exchange capabilities, including unified database systems and structures across entities and labs • Sharing and communication of testing results between labs and partners is needed, especially during emergencies • Need for sharing data on specimen collection, instruments, and stockpile distribution	Crosscutting
Information Technology	• Current technology is outdated or incompatible, and does not support sharing capabilities • Current lack of experienced government IT personnel who understand data sharing needs, without adequate training to develop workforce	Crosscutting
Theme: Coordinated federal, state, and local public health response networks, frameworks, best practices and partnerships during all emergency response phases		
Gaps	Context	Hazards (CBRN)
Proactive planning between entities	• Established, coordinated timelines for transitioning roles and responsibilities between emergency response phases is needed, including defining shifts between clinical and environmental sampling needs (Biological) • Improved preparedness planning for coordination between entities to ensure a timely response to events	Crosscutting

	• Support is needed for improved partnerships across industries and agencies for better planning processes and response, including commercial lab partners	
Incident Management and communication across responding entities	• Timely communication of incident management plans and responsibilities between federal, state, and local partners during an event, including communicating lead agencies and ensuring adequate information sharing between federal entities and labs • Improved communication between incident command, labs, first responders and health care facilities, especially regarding potential exposure for field personnel and collecting and transporting samples from event	Crosscutting
Public information and messaging	• Managing public information dissemination during an event is critical for educating the public, building trust, and addressing worried well challenges in surge testing • Communication strategies are needed to provide accurate updates to the public, including explanation of risks to decrease potential exposure, especially during Radiological/Nuclear events • Information dissemination to the public should consider the potential impacts it can have on worried well and surge testing	Crosscutting
Capacity for environmental clean-up during containment and recovery	• Environmental clean-up can require be a significant undertaking and require long-term efforts to test and sample large areas, which has implications for the workforce and lab capacity	Crosscutting

Appendix B – Description of Solution Strategies in Laboratory Capabilities and Capacity Organized by Theme

Theme: Proficient federal, state, and local public health laboratory workforce		
Gaps	Root Causes	Solutions Strategies
Recruiting and retaining laboratory workforce	• Insufficient political will and federal budget proportion allocated to public health to support staffing • Generational norms of moving on in positions creates difficulties in continually training new staff • Lack of incentives to recruit and retain workforce: Entry-level technicians work extreme hours with limited flexibility in high-stress environments for a salary that does not compete with larger corporate or clinical labs. • Lack of enrollment in education and training programs that prepare applicants for entering the workforce, including dwindling MLT/MLS programs nationwide or campaigns aimed at raising awareness of available career paths and increasing interest for students to enter programs applicable to lab work (e.g., microbiology)	• Improved hiring and onboarding processes • Support incentives that help attract and retain lab workers: Support of fellowships that have attracted scientists into the field of public health science and keep them in state labs; Highlight commissions at the state level for improving salaries; Facilitate public-private partnerships for private sector partners to fund, support and highlight these issues; Regional and locally embedded fellowships; Provide loan forgiveness programs • Create programs for all education levels that increase student interest in lab work • Improve marketing by learning from other areas of the government with recruitment strategies (e.g., military recruitment campaigns)
Turnover and attrition of experienced laboratory staff	• Lab workers are invisible in national recognition	• Support strategies to increase national recognition of lab professionals
Workforce emergency preparedness	• Training isn't always provided for staying up to date for all new products and tools, or for demonstrating competency handling special agents in lab settings • Invitations from lab partners for to participate in their training is nonexistent	*No solutions were provided*
Workforce mobilization and surge staffing	• Insufficient strategies to balance surge capacity and workforce hiring	• Create available lab staff pool similar to AmeriCorps and ASPR hospital staff programs
Theme: Infrastructure and equipment that meets capability and capacity needs for multiple threats		

Gaps	Root Causes	Solutions Strategies
Infrastructure and equipment improvements	• Low or nonexistent storage availability for certain specimen types or surge testing	*No solutions were provided*
Materials and supplies	• Supply chains face challenges in maintaining quality standards among diverse suppliers in emergency use authorization (EUA) situations, providing transparency in allocation processes by manufacturers, providing a manageable procurement process, ensuring sufficient distribution of supplies to where they are needed, and negotiating with supply chain contracts and competition	• Unique and critical items should be identified and inventoried in terms of suppliers and manufacturer • Expand IRR practices and capacity, or expand network of Just-in-Time suppliers to decrease reliance on IRR (e.g., Amazon) • Create a consistent allocation process that is based on communication, transparency, and legitimate metrics • Strengthen public health lab partnerships to allow for product redistribution, and build space in cooperative agreements to allow jurisdictions to address their own priorities • Revise procurement rules and grant language to provide more funding flexibility and allow for rapid deployment of funds, including approval of purchases for equipment and supplies that are over funding limits • Provide assistance or flexibility in negotiating pricing with distributors vs manufacturers • Extend expiration dates for common consumables to prolong use when possible • Acquiring more 3D printing capabilities • Use grants to encourage research into alternatives for bottleneck supplies
Theme: Accurate, rapid detection and characterization of threats to inform decision making		
Gaps	Root Causes	Solutions Strategies
Materials and resources	*No root causes were discussed*	*No solutions were provided*
Timely communication and	*No root causes were discussed*	*No solutions were provided*

coordination between responding entities		
Logistics and chain of custody	*No root causes were discussed*	*No solutions were provided*
Theme: Flexible and extensible data exchange for CBRN and emerging threats		
Gaps	Root Causes	Solutions Strategies
Cross-jurisdictional data exchange	• There are major differences in capability and informatics structures between jurisdictions, and separate accounts are needed for data sharing between states • Labs demand different data elements from various reports • Political nature of data security issues and releasing protected health information (PHI)	• Creation of an integrated lab consortium network • Established a standardized incident report and minimum data element report across all states that define critical variables • Clearly define information that can be shared for true public health needs
Information Technology	• There are differences in information technology and data infrastructure which result in incompatible systems and capability for information transfer (e.g., laboratory information management systems (LIMS)) • Existing systems are not able to support high testing periods • Shared cost of data sharing and information exchange is cost prohibitive • There is a lack of expertise in government information technology, especially with specialized knowledge of data exchange between labs, without an adequate training model to address workforce gap	• Develop and support training programs for IT expertise development
Theme: Coordinated federal, state, local public health response networks, frameworks, best practices and partnerships during all emergency response phases		
Gaps	Root Causes	Solutions Strategies
Proactive planning between entities	• Difficult to obtain buy-in and funding for activities that are not prioritized • Industry is often a neglected partner in planning, and partners may not understand lab-specific practice requirements with materials or like-surrogates	• Support the development of memorandum of understanding (MOUs) for planning between federal entities

	• Federal agencies have separate caches and equipment and do not always partner well together	• Reintroduce industry into planning processes and explore ways to create a more collaborative approach as a unified nation
Incident Management and communication across responding entities	• Communication around jurisdictional issues regarding incident command is not always clear	• Develop a structure/model for a public health-focused Incident Command System to assist with partner integration
Public information and messaging	*No root causes were discussed*	*No solutions were provided*
Capacity for environmental clean-up during containment and recovery	*No root causes were discussed*	*No solutions were provided*

Appendix B: Workshop 2 Proceedings

EXPLORING CRITICAL GAPS AND SOLUTION STRATEGIES IN LABORATORY CAPACITY AND CAPABILITIES FOR PUBLIC HEALTH RESPONSE

WORKSHOP 2
PROCEEDINGS

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About SGNL Solutions

SGNL Solutions (SGNL), a service-disabled veteran-owned small business corporation, connects across research, policy, and practice communities to identify, understand, and solve complex health security challenges. We undertake collaborative projects involving stakeholder engagement, process facilitation, data collection, analysis, evaluation, scientific writing, and product development. Our team of experienced consultants provides cross disciplinary expertise and perspectives, which fosters better understanding and integrated solutions to address our nation's most pressing issues. We become issue experts and get excited about what matters to our clients. We sift through noisy data and distractions to get at the core of persistent problems to find the signal – the real information and approaches needed to finally address problems. We work across disciplines, think creatively, and break apart silos that oftentimes prevent progress. We then work with clients to make these important issues approachable and actionable.

Activity Overview

On Friday, February 18, 2022, SGNL Solutions (SGNL) and Association of Public Health Laboratories (APHL) hosted a 3.5-hour, invite-only workshop for 28 participants representing federal, state, territorial, local, and tribal (FSTLT) public health laboratories, commercial laboratories, and foundations. Observers from the Centers for Disease Control and Prevention (CDC) and APHL also attended the workshop. The workshop was designed to meet the following objectives:

4. Identify the gaps in laboratory capabilities and capacity to support a response to public health threats from chemical, biological, radiological, and nuclear (CBRN) hazards;
5. Explore the root causes of gaps in laboratory capabilities and capacity to support a response to public health threats from CBRN hazards; and
6. Generate potential specific and near-term strategies to address the gaps in laboratory capabilities and capacity to support a response to public health threats from chemical, biological, radiological, and nuclear hazards.

Justin Snair (SGNL) and Chris Mangal (APHL) offered opening remarks to orient participants to the initiative and the workshop agenda, objectives, and activities. Matt Mauldin (CDC) provided a brief commentary on the goals of the project and importance of the workshop discussion. To establish shared language and understanding of concepts that would be explored during the workshop, Justin Snair (SGNL) defined key terms (Box 1).

Box 1 – Key Terms
• **Threats to public health** are incidents involving CBRN agents whose scale, timing, or unpredictability results in health consequences that have the potential to overwhelm routine community capabilities to address them. • **Laboratory capabilities** is defined as the ability of a unit or a system to perform a specific set of actions or achieve a specified set of outcomes, in this case to detect and respond to a threat. • **Laboratory capacity** is defined as the quantity of something (e.g., number of tests, number of projects, number of runs or total working volume) that can be produced by a given unit or system. • **Laboratories have a vital role providing support for public health emergencies**, including (1) rapidly identifying and investigating analyses of CBRN agents, regardless of the source of exposure (i.e., unintentional, terrorist, or natural disaster); (2) ensuring the capacity to quickly and accurately handle a substantial volume of tests during an emergency situation; and (3) providing a rapid response system for hazardous contaminants. • **Laboratory support for CBRN events** comes from a fragmented system of public and private units, with varying degrees of capacity and capabilities. The system involves a complex supply chain of instrumentation, reagents, and other consumables.

SGNL facilitated three activities, each focused on a specific theme area identified during a previously held workshop in January 2022. These theme areas included:

- Detection and characterization of threats,
- Proficient laboratory workforce, and
- Coordinated laboratory response.

Each activity consisted of a brief small group discussion followed by a longer group discussion. Participants were distributed across six breakout rooms for an unfacilitated ten-minute discussion. Then participants reconvened for a longer facilitated discussion. At the end of each activity, participants were offered an opportunity to provide final thoughts via an anonymous survey.

Following the workshop, SGNL analyzed the workshop outputs (audio recordings, notes, white boards) to identify findings within the themes.

Detailed documentation of the findings generated from workshop discussions is provided in the Findings section below, which is organized into three tables:

- Table 1: Detection and Characterization of Threats
- Table 2: Proficient Laboratory Workforce
- Table 3: Coordinated Laboratory Response

These tables are further organized by improvements observed and opportunities to improve, partnerships that were or could be helpful, and gaps and possible solutions, accompanied by contextual statements paraphrased from workshop participants.

Findings

Table 1: Detection and Characterization of Threats

Improvements observed in rapid detection and characterization	
Improvement	Context
Quick development, manufacturing, and distribution of rapid antigen tests	• Many new products have been brought to market to ensure rapid antigen testing supply is meeting demand • Rapid antigen development, manufacturing and distribution since the pandemic has been useful in improving detection
Growth in technologies, tools and instruments that have expanded lab capabilities for detection, diagnostic testing, and sequencing	• There has been tremendous growth in direct-to-consumer services, new instrument development for COVID-19, and application of nucleic acid technologies to detect assays of agents that increase the ability to detect multiple pathogens faster (e.g., multiplex PCR). In addition to multiplex PCR, matrix-assisted laser desorption/ionization time of flight (MALDI-TOF) and sequencing are now more widely implemented technologies. • Improvements in rapid sequencing have been helpful in increasing lab sequencing capabilities (e.g., "ability to report about 30 sequences every day, at a minimum, some days as high as 60") as well as ability for detection of novel pathogens and emerging variants. • Moving to longer read sequencing technology is more affordable, quicker, and more efficient.
Advancements in partnerships	• Having partnerships in place assisted with surge capacity. For example, during COVID-19, a public health lab utilized a veterinary diagnostic lab to start processing tests, which expanded capacity and took burden off public health labs (vet diagnostic labs have high throughput).
Expansion of surveillance systems	• There has been a shift away from an insular perspective in health care systems, and wider syndromic surveillance programs have improved.
Opportunities to improve rapid detection and characterization	
Opportunity	Context
Address limitations of genetic sequencing	• "Genetic sequencing could be a valuable tool, but there are limitations, such as changing taxonomy." Further, next generation sequencing (NGS) in its present state is not a rapid solution. • Advancements in sequencing to detect unknown pathogens would be beneficial.
Improve the regulatory process	• FDA approval process can be limiting for testing needs. • The pandemic has "revealed to industry that public health can demobilize quickly, which should allow for more evidence generation that would provide justification for greater FDA approvals on other testing needs"

	• Alignment of FDA and CMS Clinical Laboratory Improvement Amendment (CLIA) requirements will be critical for future responses.
Address limitations and concerns regarding a potential shift towards rapid testing systems	• Rapid tests do not have the same sensitivity or specificity as other testing mechanisms, so there are concerns about the validity of these tests in becoming the new "gold standard." Conducting scientific studies to understand the performance of these rapid tests in the real world will be critical to gaining confidence in these screening assays. • Reporting and data systems were unable to keep up with testing volume during the pandemic. Better integration with reporting rapid test results to public health would allow for enhanced surveillance. • An important need is developing more rapid PCR assays (e.g., Abbott ID Now) which, if the same technology could be made more high-throughput, would be useful for expanding lab capacity.
Maintain improvements to communication across lab partners for early detection	• The One Health model requiring interactions between all agencies assists with the ability to respond (e.g., vet labs reporting anthrax cases in cows that could link to human exposures). Keeping a One Health approach would increase collaboration and ensure open communication capacity with partners.
Invest in workforce pipeline and training programs	• Severe staffing shortages create workforce challenges • There are significant gaps in radiochemist workforce • Better training is needed for responders who feed samples from a site (e.g., use of state/local HAZMAT or use of National Guard Bureau Civil Support Teams)
Expand lab capabilities for all hazards (CBRN)	• There is a lack of capability for radiological testing with many laboratories unable to measure human radiation contamination/perform radiobioassay in clinical samples.
Important partnerships opportunities for enhancing rapid detection and characterization	
Partnership	Context
Public Health Laboratories/Laboratory Professionals	• Use the Laboratory Response Network (LRN) of working with professionals from multiple backgrounds, such as chemical engineers, poison control center representatives, etc. • Engage in more community outreach where public health provides training. This approach ensures that the right sample gets into the laboratory system. • Engage diverse partners such as veterinary diagnostic laboratories to help build capacity across a jurisdiction.
Commercial partnerships	• Establishing contracts with major commercial vendors during the COVID -19 pandemic to sequence around 2000 positive samples per week from different regions has been useful. • Supporting partnerships between commercial entities can be beneficial (e.g., Quest partnered with Walmart to deliver COVID-19 collection kits by drone).

	• Licensing content from the CDC to extend their detection and characterization assays to commercial sector as opposed to developing something new could help in reducing the workload on public health labs.
Academic partnerships	• Partnering with academic institutions is helpful for workforce development and special trainings.
Government partnerships	• COVID-19 has sparked collaboration and partnerships in federal agencies that should be continued (e.g., NIH Rapid Acceleration for Diagnostics (RADx), BARDA for point of care tests, or between the USDA and FDA networks). • Partnering with the DoD, similar to Ebola assay deployment, is another good approach to developing pre-EUA assays/pre-positioned tests. • At the state and local level, LRN laboratories have established partnerships with rural volunteer fire departments and EMTs (e.g., HAZMAT), which has been beneficial.
Partnerships with community-based organizations, foundations, and other private sector companies	• Targeted messaging to communities about the importance of getting tested and communicating results is vital in providing the public with education and situational awareness. • Public health laboratories should engage more with communities so they are aware of their work (don't wait for an emergency). • More basic messaging on testing (why, how) will be important to connect with the public.

Gaps: Technologies needed for threat-agnostic or threat-agile screening of biological and chemical threats	
Gap	Context
Technologies capable of detecting novel pathogens	• There is a desire for the ability to detect novel pathogens, i.e., develop and implement pathogen agnostic assays. • If an organism or pathogen substrain is found, guidance is needed to help make decisions, verify the finding is a genuine anomaly, rapidly share the findings, and make appropriate decisions.
Scalable technologies and capabilities for all hazard types	• Most clinical labs and hospitals are currently unable to scale up for radiological/nuclear and chemical threats. Scalable technology is needed in these in these settings to ensure adequate lab response to all hazard types.
Solutions: How the CDC can support emerging technology	
Solution	Context
Form and support partnerships	• Need to invest in a robust workforce pipeline to build a cadre of highly training laboratory professionals. Embed these scientists and other laboratory professionals in state, local and territorial laboratories with the goal to assist with technology evaluation and implementation.

	• Partnerships could facilitate more scientific discussions among academic, clinical, and public health laboratories.
Support expansion and wider distribution of testing supplies	• Taking a proactive approach to develop and send kits on a larger scale and support novel innovations (e.g., wastewater surveillance) can make tests more widely available to communities. • Engaging in preparedness activities can bolster supply availability prior to an event. If the market drives decisions, then public health won't be prepared, so "CDC should help drive decisions to boost preparedness and make sure adequate supply exists up front"
Support new technology development and validation methods	• CDC can assist with the development and identification of validation materials for emerging technologies. • Infrastructure development in labs from an analytical standpoint needs support so all state labs can expand capacity (e.g., broaden methods to look at more chemical threats and faster sample preparation). • CDC could "proactively share guidance to manufacturers about FDA concerns and requirements for rapid solutions and new technologies" • Communicate needs with vendors so they have an understanding of market requirements, functions, and content when developing technology solutions (e.g., expected turnaround times).
Assist in addressing Whole Genome Sequencing (WGS) system limitations and changes	• Most labs have whole genome sequencing (WGS), but the pipeline analysis looking for different organisms is still a limitation. CDC can help think through how to develop the use of a regional pipeline. • Storage of sequencing data will be a significant need – examining infrastructure options for data storage would be beneficial. • If there is to be a shift away from WGS towards rapid systems, CDC "should be involved in ensuring the new system does not have decreased sensitivity and specificity."
Gaps: Factors hindering implementation of new technology in Public Health Laboratory (PHL)	
Gap	Context
Funding	• Often, funding must be specified in a grant for the purchase of an instrument, otherwise the laboratory has no way of using or requesting funds for instruments, especially given competing priorities. • Earmarking CDC funds (e.g., Public Health Emergency Preparedness (PHEP) Cooperative Agreement) could allow labs to make acquisitions. • "Costs need to be justified, which is easier to speak to if a new instrument has multiple uses."
Staff availability, knowledge and training	• There are challenges around training staff on new technology including staff availability (and shortages) and existing level of knowledge and proficiencies on equipment.

Administrative challenges	• "Procurement processes can be difficult and time-consuming" • There are administrative aspects of new technology implementation to consider with high complexity systems, which can determine "if a lab is even able to implement these after considering factors such as overhead, licensing and staffing."
Solution: How the CDC can help implement technology in PHL	
Solution	Context
Utilize third parties such as foundations or non-profits for procurement and staffing	• Consider a third party to manage fellowships or other workforce development programs and procurement. For example, CDC-Foundation, APHL and other partners supported these activities in response to the 2017 Hurricanes.
Specified funding	• Specify funding in grants for implementing new technology in labs.
System and protocol improvements	• "Support the rapid addition of more platforms (common systems that could go into a public health lab)." This would allow for labs to be nimbler.
Gaps: Availability of supplies and other materials for rapid detection and characterization	
Gap	Context
Lack of awareness of laboratory supply and consumable needs	• Limited information on laboratory needs • Limited engagement of laboratories in the Strategic National Stockpile (SNS)
Solution: How the CDC can support development and implementation of the supplies and materials needed for rapid detection and characterization	
Solution	Context
Provide funding flexibility	• Earmark funds for specified activities. This is the only way some states have been able to obtain funds from the grant for supplies and materials. • Better define metrics in grants to ensure laboratories have more input on budgets.
Support novel supply chain improvements	• Consider novel solutions for supply chain issues, such as 3D printing technology. This approach would "help state labs become more self-sufficient in terms of supplies."
Assist with navigating regulatory burdens during response or surge	• Support preparedness activities so labs have the ability to scale up for response or surge without regulatory burdens. • Build better relationships between responding entities involved in emergency response supply chains (FDA, CDC, CLIA, etc.) to address regulatory challenges that prevent labs from pivoting and acquiring specific items during events, or validating those items
Address supply and demand	• Ensure adequate supply of medications and stockpiles.

challenges and improve stockpiling practices	• Consider strategies for supply chain support while reducing waste, such as providing lot numbers with extended expirations or partnering with commercial entities to build local stockpiles. • Engage laboratories in discussions to determine priority items for stockpiling and integrate critical lab supplies into the SNS. • Collaborate across the federal government to invest in domestic manufacturing to create a resilient supply chain.
Enable multiple vendor partnerships in preparation for emergencies	• PHLs are often bound to a single vendor's technology due to the amount of work associated with validations and training on multiple platforms. "Closed systems require more effort to enable multiple vendors, but modern technology can make enabling multiple vendors easier" during emergencies. • Examples of current partnerships could serve as model for expanding vendor relationships (Thermo Fisher provides reagents to Cepheid, they package them into cartridges and sends onto Northrop Grumman for operation use).

Table 2: Proficient Laboratory Workforce

Successes in building a proficient laboratory workforce	
Successes	Context
Investing in training programs and cross training	• Fellowship programs and workgroups developed in partnership with CDC and APHL have been a tremendous resource throughout the years. • Establishing government lab workgroup meetings with the state has been helpful in finding experts to help train new staff. • Cross training has been important in building redundancies, so labs are better prepared for surge (e.g., training non-molecular testing staff for COVID-19). • Setting up new employees with a structured, comprehensive training process to help retain some institutionalized knowledge from experienced staff. • Maintaining detailed training records for staff, even as individuals transfer between labs, can be helpful in understanding what level of knowledge staff possess.
Establishing academic partnerships	• Labs have benefited from recruiting students during the pandemic by partnering with universities, especially those with clinical lab training programs and clinical science preceptorships or internships.
Enabling contract work and temporary staffing	• Employing individuals from external temporary staffing agencies has been critical for response and surge capacity during the COVID-19 pandemic. • Epidemiology and Laboratory Capacity for Prevention and Control of Emerging Infectious Diseases (ELC) for public health in some states (e.g., NY) allows for a faster hiring process for temporary workers than for permanent staff.
Rapid scale up and down of staffing	• Labs have been able to quickly identify gaps in the workforce, but they can be difficult to fill depending on the location and salary offered. • Labs have been able to bring on large quantities of full-time and part-time staff for surge.
Opportunities for building a proficient laboratory workforce	
Opportunities	Context
Incentivize the workforce	• Find and support sustainable funding solutions that make public health lab careers competitive with the private sector and CDC Foundation compensation packages. • Provide career development options for lab staff (e.g., providing new laboratory professionals with a clear path towards career advancement).

Find sustainable solutions for a surge workforce	• Allow for the creation of dedicated positions that are focused on surge, such as permanent volunteer positions for trained individuals able to respond to emergencies. • Consider a "first class deployment plan," to maintain a pool of knowledgeable response or surge staff who are currently trained in emergency preparedness and response. • The inability to advertise for positions until its funding is received results in onboarding delays.
Expand internal lab training programs	• Ensure training is available for specific aspects of lab work, such as using lab equipment, toxicology, emergency response, and technical skills required for working in a biosafety level (BLS)-3 lab. • Continue funding internships from industry and fellowship programs.
Invest in academic programs focused on expanding the laboratory workforce	• Utilize universities and graduate schools for education and training, as well as partnering to develop special certificate programs (e.g., Biosafety and Security Certificate program with a lab internship) for graduate students to assist with workforce development as well as staffing up during surge. • Invest in programs focused on reaching out to high schools, (e.g., Project Lead the Way or other S.T.E.M. programs) to increase early exposure of potential lab careers to science students. "We get so focused on people who are already professionals and are missing the potential for a new pipeline."
Define workforce skills and proficiencies	• Characterize the workforce beyond bench-level work (e.g., informatics) and determine how to best utilize staff skill sets (e.g., not having skilled lab staff performing data entry in their job descriptions). • Define what "proficiency" looks like for different roles.
Important partnerships for building a proficient laboratory workforce	
Partnerships	Context
Academic partnerships	• Partner with academic institutions (graduate, undergraduate, and medical programs) to recruit students who want research and lab experience. • Partner with universities and entities to support building academic programs focused on addressing specialized knowledge and experience needs (e.g., radiation and chemical). • Labs have benefited from recruiting students during the pandemic by partnering with universities, especially those with clinical lab training programs and clinical science preceptorships or internships.
Partnerships between government agencies and public health lab associations	• Lab staff who have participated in CDC projects (e.g., Surge Project) have benefited from expertise and helped staff (including microbiologists) learn from the CDC. • Partnerships between CDC and APHL expand opportunities for increasing visibility of career prospects to students.

	• Collaborative partnerships between a variety of organizations can be beneficial for recruitment, knowledge sharing and training (e.g., CDC, American Society for Clinical Pathology (ASCP), American Society for Microbiology (ASM), American Clinical Laboratory (ACLA), CAP). • Partnerships between CDC and lab associations (e.g., ABSA International, ASM) that could provide certification of laboratorians and assist with lab technology trainings.

Solutions: What the CDC can do to support a functional talent pipeline for the PHL workforce	
Solution	Context
Support public health lab education programs and fellowships	• Use pandemic funds for fellowship programs to reestablish the lab workforce. • Promote the need for sustained funding for fellowship programs. • Universities with graduate and undergraduate students are a valuable resource for rapid recruitment of staff with background knowledge. • Increase exposure of PHL career opportunities in undergraduate and high school programs (e.g., post-bachelor microbiology certification program through the CDC).
Advocate for strategies to generate new interest in subject areas related to lab work	• Invest in marketing strategies to increase visibility and interest in PHL work (e.g., leveraging social media and popularity of television shows or podcasts). • Support programs reaching out to high schools to present information about PHL work and allow students to tour facilities.
Solutions: What the CDC can do to support the recruitment and retention of the PHL workforce	
Solution	Context
Advocate for pay increases, benefits, and other incentives for staff	• Incentives include starting salary increases, pay raises, retirement benefits, flexible schedule and leave options, tuition reimbursement and student loan forgiveness.
Provide professional development opportunities	• Provide paths for professional development, including free certification trainings to work towards advancement (e.g., using the APHL network for trainings and networking). • Outline competency guidelines for PHL professionals to motivate them to expand their skills sets and "move up levels." • Additional fellowships could also turn PHLs into "training grounds for people who get training before moving on to the private industry for better pay," which could be resolved with agreements in place to train workers who agree to work for PHLs (e.g., fellows have to commit to a certain time period in public health labs).

Allow flexibility in grants for staff retention strategies	• Staff funding is largely grant funded, and there is often a lack of flexibility built in for permanent staffing or staff promotions. • Grant funding is temporary, which does not provide incentives or job security to contract, temporary or term-limited employees. Labs should communicate that grant-funded positions do not necessarily mean job instability.
Improve morale and staff recognition	• Improve methods for sharing information with PHL workers that reinforce feelings of purpose and achievement in their work on a large scale.
Support specialized education or training programs	• Include private sector support in recruitment and retention to assist with staffing positions that are difficult to fill and create positions appropriate for early career professionals. • Collaborate with academia to establish certificate programs in graduate schools (e.g., biosafety and biosecurity, laboratory response) and provide hands-on internships/work experience in BSL-3 labs. • Establish pathway programs for radiochemistry students to get master's degrees.
Solutions: How can the CDC support automation or streamlining tasks to redirect staff time	
Solution	Context
Advocate for consistency in systems with automated workflows	• CDC can provide worksheet aids for LRN labs, quality control charts, etc. to save time for labs, and streamline and improve compliance processes (similar to what CDC provided for Zika response). • Develop systems that can "accommodate multiple workstreams, not just one large one." • Establish IT support, as "systems are only beneficial if there is an IT structure to utilize it."

Table 3: Coordinated Laboratory Response

Example partnerships that have worked well for laboratory response:	
Partnerships	Context
Commercial vendors	• Sequencing partnerships between CDC, commercial vendors and clinical labs have been helpful in gathering data during the COVID-19 pandemic. • Establishing and maintaining strong communication strategies between labs and supply chain vendors to share real-time data, supply chain status, and manage reconciliations as needed.
Public health lab associations	• Public-private partnerships with APHL and CDC have been successful in the past when roles are clearly defined, (e.g., using quantitative polymerase chain reaction (QPCR) platforms to clear flu assays during H1N1). • APHL partnerships with the LRN, ACLA, ACLA member labs, ASM, CAP as well as other partnerships have allowed for multicenter evaluation studies, implementation of electronic laboratory reporting, development and maintenance of microbiology protocols, exercises and networking among laboratory professionals.
Government partnerships	• In New York State, the development and coordination with the state agencies for messaging, procedures and test procurement was beneficial during the COVID-19 pandemic. • Internal CDC partnerships with pandemic response labs and surveillance allowed for discussions around testing, standards, and sequencing. • CDC Zika Tri-Agency task force established conditions of authorizations for labs and outlined clear roles and responsibilities for an emergency use of diagnostic tests. • "CDC, Quest, and Labcorp partnership was beneficial for determining where people were developing COVID-19 antibodies though population disease surveillance." • The federal government has "good internal partnerships, and functional relationships with state and local agencies." • Pre-existing relationships with CMS/CLIA regional offices during COVID-19 were helpful in navigating compliance and waivers.
Academic partnerships	• Pre-established relationships with academic institutions that include data sharing agreements.
Hospitals and healthcare partners	• Some public health agencies leveraged contact tracing work with hospitals and were able to do so successfully due to open dialogue and efficient coordination. • Sentinel labs, hospital labs, and clinics can be successful in getting together for wet lab workshops and trainings. • Clinicians are working together with labs to develop reporting mechanisms for all opioid related cases being sent to the poison control center, and are also working on adding state lab testing for expanded opioid panels.

Public health colleagues	• Labs have benefited from working with environmental health and epidemiology partners obtaining samples and linking cases to exposures during Legionella and other foodborne outbreaks in North Carolina.
Multi-sectoral partnerships	• During Hurricane Sandy in New Jersey, public health labs partnered with the National Guard Bureau and state police for sample transportation and flood mitigation assistance in the laboratory facilities. • LRN laboratories have established monthly meetings involving stakeholders from different public health labs, law enforcement, EMS and HAZMAT, and healthcare to share resources, develop training opportunities and provide monthly clinical analytical toxicology rounds. • Annual conference planning with multi-sectoral stakeholders (e.g., EMS, hospitals, labs, emergency management, law enforcement) include trainings and refreshers on how to work together to respond to emergencies. • Partnerships with National Guard Bureau Civil Support Teams were valuable in the beginning of the COVID-19 response due to their close proximity and response time, ability to leverage mobile labs, and military background. • Partnerships with FBI Weapons of Mass Destruction (WMD) also valuable for threat assessments and chain of custody of samples during a suspect criminal case.

Solutions: How the CDC can promote laboratory partnerships and capabilities ahead of time that can be rapidly activated	
Solution	Context
Support commercial needs	• Support large-scale commercial availability of critical products, including better manufacturing capabilities during a surge.
Support consortium-level discussions	• Public health lab consortiums allow for discussions around "how to provide support between partners, needs, establish Memorandum of Agreements (MOAs), and address barriers."
Support training and exercises across agencies	• Practice and familiarity are helpful in developing the workforce skills as well as forming professional partnerships • Conducting exercises (table-top exercises (TTX) and full-scale exercises) for different types of events forms connections and familiarity with other professionals in different roles.
Gaps: Obstacles to partnerships	
Gap	Context
Lack of ongoing communication	• There is a need for ongoing interactions between individuals in different roles, fields, and specializations in order to easily initiate communication during events. • "Relationships should be productive, not just a present formality."
Lack of time to maintain meaningful professional	• In the last few years (due to COVID-19) there has been little time to conduct regular exercises with partners. • Interactions are hard to maintain due to time constraints.

relationships	
Information security and sharing requirements are burdensome	• Data Use Agreement (DUA) navigation can be difficult and time-consuming. • Internal offices of information security determining the ability to share and receive external data means decisions are being made by staff without a lab background, which can result in communication challenges and delays. • Bureaucracy creates challenges in forming connections and relationships (e.g., local labs wanting to become reference labs and partner with state wastewater systems but are hindered by bureaucratic processes).
Goals between partners do not always align	• State and local agency priorities do not always align with the goals of a university.
Solutions: Incentives for implementing sustainable, pre-emptive partnerships	
Solution	Context
Workforce development support	• Investing in building up local and state lab staff and pipeline is in the CDC's best interest, so responsibility does not shift to them when local capacity is exceeded.
Communicate financial benefits	• Allowing partners to take advantage of pre-funded and developed scenario exercises (e.g., involve local HAZMAT, EMT, law enforcement and others) is well received by organizations when they do not have to fund or organize events. • Communicating a potential business case around a partnership incentivizes collaboration with the private sector.
Improve information sharing and transparency	• Transparency helps form partnerships. • Allowing others to access data incentivizes partnerships.
Solutions: Sustaining public private partnerships between public health emergencies	
Solution	Context
Maintain formal communication methods and support partner activities	• Support exercise activities (e.g., TTX, drills, full scale) that maintain connections and provide opportunities for professional engagement from different agencies. • Establish regular communication strategies between labs and agencies to maintain relationships and connections, even through staff turnover. • The CDC Laboratory Outreach and Communication System (LOCS) was established a few years ago but has been better utilized since 2020 when CDC activated its Emergency Operations Center for COVID-19. LOCS has been "very useful communication system around relevant topics such as EUAs, approved methods, and supply chain shortages. This created a partnership that has remained active and should continue to evolve as the pandemic shifts into recovery and preparedness."

Appendix C: Radiological Laboratory Response Network Focus Group Proceedings

EXPLORING CRITICAL GAPS AND SOLUTION STRATEGIES IN LABORATORY CAPACITY AND CAPABILITIES FOR PUBLIC HEALTH RESPONSE

RADIOLOGICAL LABORATORY RESPONSE NETWORK FOCUS GROUP PROCEEDINGS

July 9, 2021

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About SGNL Solutions

SGNL Solutions (SGNL), a service-disabled veteran-owned small business corporation, connects across research, policy, and practice communities to identify, understand, and solve complex health security challenges. We undertake collaborative projects involving stakeholder engagement, process facilitation, data collection, analysis, evaluation, scientific writing, and product development. Our team of experienced consultants provides cross disciplinary expertise and perspectives, which fosters better understanding and integrated solutions to address our nation's most pressing issues. We become issue experts and get excited about what matters to our clients. We sift through noisy data and distractions to get at the core of persistent problems to find the signal – the real information and approaches needed to finally address problems. We work across disciplines, think creatively, and break apart silos that oftentimes prevent progress. We then work with clients to make these important issues approachable and actionable.

Activity Overview

On June 28, 2022, APHL hosted a 90-minute focus group to discuss a proposed model for the Radiological Laboratory Response Network (LRN-R), including how the LRN-R might fit into and leverage the existing public health laboratory capabilities, and to identify critical next steps for the implementation and sustainability of an LRN-R. Five discussants from state laboratories and federal agencies were invited to participate. After a brief overview of a proposed LRN-R model, a facilitator posed questions to explore the barriers and facilitators from both a systems and an implementor perspective. Following the focus group, SGNL analyzed the outputs (audio recordings, notes, white boards) to identify findings

Detailed documentation of the findings and contextual statements paraphrased from focus group discussions is provided in the Findings section below, which is organized into the following theme areas:

- How the proposed LRN-R fits within the public health system
- Challenges for the proposed LRN-R to fit within the public health system
- Adaptations that would be needed for the LRN-R model
- Integrating LRN-R with existing radiological programs across local/state jurisdictions within or outside the public health system
- Challenges or barriers to entry for labs interested in the proposed LRN-R
- Regulatory requirements
- Data sharing infrastructure

Findings

How the proposed LRN-R fits within the public health system	
Finding	Context
There is a natural fit for LRN-R in public health labs and systems due to existing experience, methods, and relationships between sectors	• LRN-R fits naturally into public health labs that already have expertise in radiological measurements, participate in FERN Rad grants, and have some experience in emergency response for radiological contamination of food. • There are some complimentary chemical LRN (LRN-C) capabilities that could be expanded for radiological, namely for some radionuclides spectrometer methods. • New instruments used for radiological analysis could also be utilized for tasks some labs are already performing and be more efficient (higher throughput and lower LODs for labs running nuclear power plant compliance samples or EPA drinking water analysis). • Many public health labs are already working with radiation control programs, epidemiologists, and those responsible for public health interventions. • When considering LRN-R reporting clinical test results, under the current regulatory apparatus a lab would have to hold a CLIA permit. Most public health labs are familiar with and do hold CLIA permits in other areas.
The inclusion of LRN-R in the public health system could assist in bridging the gap between public health and Radiological/Nuclear labs	• Radiological or nuclear response in public health is the largest gap that still remains, specifically in the sense that there are no lab networks that can do radiological analysis on clinical samples, "which is a significant omission in protecting public health." • Public health needs more data on people in addition to the data on environmental and food matrices.
Challenges for the proposed LRN-R to fit within the public health system	
Finding	Context
Managing laboratory accreditation processes and maintenance	• Public health labs may tend to be accredited to process clinical samples, but samples being tested must remain under the scope of that accreditation. There are very few public health labs that have radiological methods under the scope of their CLIA accreditation. • A lot of time, money, and manpower is needed to manage lab accreditation requirements, and this would only increase when adding radiological accreditation for labs.
Navigating differences in radiological models and methods	• Traditional models of quality assurance and quality control in a clinical laboratory may be challenging if staff do not have strong backgrounds in radiological counting methods. • Analytical chemistry models, regulations, and standards can't be forced on a radiological lab. • The labs that generally have experience conducting radiological measurements are likely to be environmental, so adding another matrix could introduce another challenge that labs are not used to.
Addressing workforce	• With significant turnover and attrition, finding the next generation of radiochemists is already very difficult.

attrition and training challenges	• Some public health labs may be familiar with the environmental matrices but presenting them with a different matrix would require a significant amount of training. • There are concerns about the survival of public health labs due to a diminishing supply of well-trained staff who understand the technology, as well as the extensive radiological methods and instrument training that would be required for existing public health lab professionals. • Additional awareness and training are needed around the consequences of radiological incidents and what types of incidents can occur in the broader public health community.
Adaptations that would be needed for the LRN-R model	
Finding	Context
Ensure the model considers the current level of LRN-R expertise within labs	• The current LRN-C nested model (level one, two, and three labs) would likely need to be adapted for an LRN-R model. • The CDC will likely need to be the coordinating lab, then have a select number of "level one" labs that have prior experience of radiological analyses and have demonstrated expertise in those methods.
Consider the workforce and training components that would be required for standing up an LRN-R	• The basic model would be appropriate to follow and could be very successful, however the LRN-R model is starting off well behind the LRN-C model if labs are not already staffed with professionals who have a strong background in radiological methods. There would be significant training needs upfront. • Supplemental personnel would be needed to maintain capability and expertise across difference methods, as well as manage activities such as running proficiency testing, instrument comparisons, and maintaining CLIA requirements.
Consider the administrative burdens that would be placed on LRN-R labs	• Radioactive materials licenses are going to be needed but can be difficult to obtain if a lab does not already have one. The terms of the license also need to be managed at the facility level. • The additional burden on labs standing up an LRN-R would need to be considered, such as the addition of radiation safety officers, audits, licensing, accreditation, and waste disposal plans or practices, which require funding, personnel, and time. • Labs that have some existing radiological infrastructure may not find additional requirements or activities burdensome, but it could be a significant challenge for labs that do not have any existing radiological infrastructure.
Integrating LRN-R with existing radiological programs across local/state jurisdictions within or outside the public health system	
Finding	Context
Leveraging existing processes and relationships between labs and the public health system	• Integration could follow similar types of activities that are already in place for environmental monitoring, where labs are working closely with bureau radiation protection and conduct joint drills with them. • Integration could occur with environmental epidemiologists within the departments of health. These relationships are already in place and could be strengthened. • Communication between epidemiologists and health physicists or between states has historically been challenging, and integration of this program could provide an opportunity to improve.

Utilizing the benefits of lab networks and partnerships	• States receive funding and the benefits that come with being a part of a lab network. DOE labs are partners, and they could play a role in training and swapping samples that do not require regulatory oversight as a good planning practice. • Laboratory Response Network for Chemical Threats (LRN-C) networks are beneficial in sharing expertise and lessons learned. Strengthening partnerships with DOE labs could expand these practices. • There is uncertainty about whether or not there are sufficient numbers of public health labs with existing radiological capabilities to form a network within or outside the public health system.
Challenges or barriers to entry for labs interested in the proposed LRN-R	
Finding	Context
Differences in capacity between laboratories leading to competing for resources	• Public health labs may not have the capacity that DOE or commercial labs have, however, DOE tests are "not fit for public health" and commercial labs are largely environmental. • Commercial labs may also have inconsistent capacity to provide support when needed, depending on their own client needs and volume. • If an incident occurs when a lab has additional priorities to consider, there is a lot of competition for a limited pool of resources, personnel, and funding.
Regulatory requirements and accreditation	• Bureaucracy "gets in the way" of clinical and environmental accreditation. • Labs may have the technical abilities to run many of the same analyses DOE labs do, but there are accreditation or contract challenges that do not allow for it. Procedures may need to be amended to ensure that they meet the clinical requirements from the CDC.
Agreement mechanisms and contracts with DOE labs	• DOE labs do not staff federal employees, and have very complex contracts requiring staff to account for their time down to 15- or 30-minute intervals • DOE contracts can restrict activities. If a task is not within the scope of the contract, they can be asked to stop work • Preparedness planning should be prioritized and coordinated with DOE labs. Public health labs should be proactive in managing contracts dictating how assistance could be provided through the DOE system. • DOE labs have the regulatory frameworks and infrastructure in place (e.g., waste disposal, licensing) to support the CDC. The interagency agreements and contractual funding mechanisms can be challenging when DOE labs are asked to pivot in order to prioritize incident support.
Challenges: Regulatory requirements	
Finding	Context
CLIA requirements	• CLIA requirements and compliance can be challenging to navigate. One example includes labs trying to become a part of an LRN-R but were not able to because their lab directors couldn't qualify as CLIA-qualified lab directors. • In addition to federal regulatory oversight, there are some states that have regulatory oversight of their clinical labs, which is "another level of bureaucracy to deal with."

	• "The regulatory apparatus tends to force requirements in areas where it does not fit," illustrating a need for "sensible regulatory requirements that take into account the uniqueness of the technology and differences across labs" which APHL could help coordinate and develop.
Transportation regulations	• Transportation issues can exist if materials are declared a biohazard, chemical hazard, or radioactive and need to comply with International Air Transport Association (IATA) transport regulations. • Different entities regulate transport procedures depending on mode of transport (e.g., the Coast Guard regulates if materials are transported by boat, IATA regulates if materials are transported by air, and state departments of transportation regulates if materials are transported by vehicle). Adequate planning can assist with navigating these challenges during an incident.
Special licensures	• Select agent labs have limits on how much of a select agent can be stored long-term. The same would be true for radioactive materials, but proper disposal would be more difficult. • In most regulations, there is a blanket license allowing possession of small amounts of specific radioactive materials (e.g., if an unknown sample is received and tests positive as a radioactive material) but possessing larger quantities for longer periods of time would require going through a process to obtain a radio materials license. • Without a radio materials license, a "workaround" process would be needed for labs to possess a defined amount for reference standards and quality control materials in order to avoid violating licensure agreements. Maintaining a system for these samples to go to labs that already have a program and license in place or strengthening partnerships with DOE labs are more reasonable solutions.
Challenges: Data sharing infrastructure	
Finding	Context
Applying current biological/chemical practices to radiological programs	• The CDC already has a system in place where environmental data is entered in a large database by various entities (e.g., DOE, EPA, local departments) which the CDC can pull from. • Entering results into a large database helps to determine where the hottest samples are, which areas indicate the greatest risk of exposure and contamination, and where epidemiologists need to concentrate human sampling and prioritize samples.
Need to provide clear data sharing rules and responsibilities	• Clear communication of roles would be needed. For example, the CDC would need to clearly state in a contract that a lab will only report data to them unless they give permission to share with others. Reporting rules need to be clearly defined.
Supporting data modernization and streamlining processes	• Technical aspects of entering LRN-C data should be considered, such as the "amount of typing required which can lead to more mistakes." • Data infrastructure is currently being modernized to ensure that data streams and pipelines can be "reported in a modern way" (e.g., web portals).

Appendix D: Manufacturers Focus Group Proceedings

EXPLORING CRITICAL GAPS AND SOLUTION STRATEGIES IN LABORATORY CAPACITY AND CAPABILITIES FOR PUBLIC HEALTH RESPONSE

MANUFACTURERS FOCUS GROUP PROCEEDINGS

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About SGNL Solutions

SGNL Solutions, LLC (SGNL), a service-disabled veteran-owned small business, connects across research, policy, and practice communities to identify, understand, and solve complex health security challenges. We undertake collaborative projects involving stakeholder engagement, process facilitation, data collection, analysis, evaluation, scientific writing, and product development. Our team of experienced consultants provides cross disciplinary expertise and perspectives, which fosters better understanding and integrated solutions to address our nation's most pressing issues. We become issue experts and get excited about what matters to our clients. We sift through noisy data and distractions to get at the core of persistent problems to find the signal – the real information and approaches needed to finally address problems. We work across disciplines, think creatively, and break apart silos that oftentimes prevent progress. We then work with clients to make these important issues approachable and actionable.

Activity Overview

On July 11, 2022, APHL hosted a two-hour focus group to discuss the role of manufacturers in supporting laboratory response to public health threats. Eight discussants from manufacturing companies and government participated in the conversation. A facilitator posed questions about the facilitators of and barriers to developing, manufacturing, and producing assays, platforms, and reagents. Following the focus group, SGNL analyzed the outputs (audio recordings, notes, white boards) to identify findings

Detailed documentation of the findings and contextual statements paraphrased from focus group discussions is provided in the Findings section below, which is organized by the following questions:

- Who develops new diagnostic assays, and under what circumstances?
- What motivates or facilitates development, manufacturing, and production?
- What discourages or hinders development, manufacturing, and production?
- What could help encourage development and manufacturing, and mitigate challenges?
- What information would be helpful in deciding to develop or manufacture products?

Findings

Who develops new diagnostic assays, and under what circumstances?	
Findings	Context
Industry	• If there is commercial value, then an industry partner would likely develop a novel assay. The larger the industry partner, the less likely to develop a novel assay for a small market • Industry may develop research use tests depending on the research questions at hand (e.g., the Abbot Research and Development Pandemic Defense Coalition developed research, use tests, and published research on viruses or other pathogens) • Industry may provide the mechanisms for those tests to be developed, whether that be individual components or the platforms
Public Health	• The CDC or an individual public health lab "may utilize or develop a novel test, but most novel assays are catalyzed outside of industry and then incorporated later" • If a large market is not available, public health agencies would be more likely to develop rather than a larger company
What motivates or facilitates development, manufacturing, and production?	
Findings	Context
Realizing potential markets and commercial values, especially for products with potential multiple uses	• The market is the primary driver of industry decisions • Expanding on or creating an additional market can be an opportunity to develop new assays (e.g., influenza typing is already on the market, and adding subtyping for H5N1 was an opportunity to expand) • "Influenza is a threat business, so there's always the opportunity that research use only development could expand into a pathogen involved in an outbreak or pandemic which could create a future market and significant return later on"
Available regulatory approval pathways	• Regulatory opportunities and routes (e.g., EUAs) needs to exist in order to bring a test to market • Previously authorized CDC assays or protocols can be "exponentially grown out into public health and commercial areas" and become more viable
What discourages or hinders development, manufacturing, and production?	
Findings	Context
Timeline requirements and changes in priorities to move from development to manufacturing and production	• The development and manufacturing phases both require time and resources, but the manufacturing processes can be lengthy (e.g., allowing time to manufacture to scale, considering return on investment, ensuring product is not going to waste) • From a practical standpoint, it can take a year to plan what is going to be manufactured, when it will be manufactured, and to what scale. Any changes to this plan could result in additional time and resources, or require a change in priorities

	• Commercial entities have a development process that require meeting milestones prior to releasing a product into the commercial space. • It can take years to build a new platform, from concept development to production to commercial availability
Regulatory and approval processes	• The length and complexity of the approval process to get products out to market quickly can be challenging (e.g., EUA). • There is always a risk that a new product will not approved. Tighter regulations mean greater risk and less participation from companies and vendors
Compatibility of basic product components needed for development	• Some platforms are easy to validate and obtain regulatory approval for but are still not open. Therefore, "the companies themselves have to complete the development work to bring an assay onto that platform, and in some cases, it has to go back to the basics to make it compatible (e.g., fundamental primer probe selection from a molecular test to run on a particular amplification backbone) • Sample types often indicate capabilities, and a lack of samples for test validation slows down development
Smaller markets or commercial value	• A difference exists between products fully available for commercial sale (e.g., regular shelf products) and products with a smaller market that could involve more of a custom pipeline for lower scale.
What could help encourage development and manufacturing, and mitigate challenges?	
Findings	Context
Increase flexibility and support for products with multiple potential uses	• Utilizing independent testing facilities, supply chains, and a variety of test types could increase flexibility (e.g., thinking beyond PCR and including antigen testing and serology so there are contingencies in place in the event of a shortage) • Some products are already being manufactured and distributed for certain pathogens (e.g., influenza) which companies have previously licensed with the CDC that could be repurposed or utilized when companies need to "ramp up" production • Industry will likely continue to look to develop platforms that are "capable of more open development, but not specific platforms developed in response to a given pathogen"
Work towards a "common environment" and build collaborative partnerships	• Engage in a collaborative effort to strengthen the "path to scale" where the manufacturing and scaling up environment can apply to a variety of partners and pathogens, increasing confidence in methods for scaling up to meet demand across all agencies and vendors • Develop "tighter partnerships" between agencies and industry to help understand how to anticipate test volume, expectations, and public health needs (e.g., industry could be more reliable when looped into conversations before CDC and HHS place volume expectations on monkeypox testing) • Creating a more collaborative approach between public health and industry for test or platform development can lessen the risk felt by industry. This may allow industry to assist in "expanding public health's reach by commercializing assays developed by public health agencies"
Data modernization	• Data modernization should include improved reporting mechanisms (e.g., reduce the number of platforms increase interoperability)

	• Consider decentralizing data and setting standards for data reporting that are uniform across states
Expand platforms and products for improved vendor participation	• Broadly define requirements to allow for multiple vendors to open up platforms and participate in order to fill gaps and ensure industry has the ability to scale up when required • It is easier for industry to scale up if multiple vendors are participating
Improve agreement mechanisms for manufacturing and production	• More specific requirements and plans built into agreement structures can result in a more strategic response for recognizing and addressing needs • There may not be agreements in place without a particular need, which can be challenging
Engage in effective government partnerships during emergencies and steady states	• Designating someone within a task force to communicate with government and acts as a liaison. This was practiced during the pandemic and has continued since, assisting with streamlining communications • There is sometimes a split between public health, and animal and food safety which can be challenging to reconcile at different levels of government • Leveraging platforms and technologies that companies already had, or funding small entities to create new technologies, "paid off during COVID-19" • Stockpiling reagents is not feasible due to their short shelf lives. There is a hope to establish agreements between the government and manufacturers to have the ability to rapidly produce reagents for certain threats • There is concern that the manufacturing capacity created during COVID-19 cannot be sustained, even though COVID-19 has illustrated how important that capacity is during a public health emergency • Some government relationships have been formed through personal connections or networking (e.g., former CDC employees making connections). Communication and relationships have grown and improved recently • Relationships with government agencies often focus on programmatic opportunities rather than developmental. If there is a market, they can develop their own products • If there is an urgent requirement, manufacturing a design could be completed quickly if a relationship with CDC is in place
Streamline processes and strengthen capabilities to quickly move to manufacturing and production when needed	• Develop a "package" that provides the ability to move quickly from manufacturing and production • Develop a generic pipeline for systematically increasing manufacturing for previously developed tests or assays when needs arise • Companies can conduct exercises that include the full pathway to better anticipate gaps and needs that may come up during an event that require scaling up • The government can proactively identify potential bottlenecks in future scenarios (e.g., bottleneck analysis during COVID-19 identified challenges that were addressed so scaling up was possible)
What information would be helpful in deciding to develop or manufacture products?	
Findings	Context
Information on pathogen characteristics and	• Assist industry in understanding targets within a given pathogen, and what would differentiate a target for various strains that could help guide the development process

prioritization	• Industry looks to public health surveillance and labs to guide decisions of which pathogens or assays should be the priority to develop and have on hand when and if they are needed
Information on the global market value, including the potential for product adaptability or expansion for multiple uses	• The market is the number one factor industry looks at to develop a product. Companies need to continuously confirm the market needs, that the income would justify the investment, and ensure that the direction they take is "the right thing to do commercially" • Public health globally is often not a big enough market, so companies need to "build a bigger market" to support commercial development (e.g., product is able to serve a purpose beyond the public health community) • Building a program or a tool (e.g., point of care device) that "doesn't have a global market or get a company global distribution or market" can be very complex, especially for smaller companies, and if there is not a market a company may decide to "kill the program"
Information on the role of various partnerships in development and manufacturing	• The government has the desire to partner with multiple manufactures to avoid the risks associated with reliance on a single company. Companies need an understanding of how the development pipeline feeds into the manufacturing pipeline which leads to production • Determining who is going to be performing the testing also determines what kind of lab partnerships may be needed, how many labs are going to be involved, and what scale tests need to be manufactured
Information on product scalability and the needs, requirements, and expectations for scaling up	• The earlier test scalability can be scoped to "look at all the contingencies" in developing a test for global use or shift developments as needed, the better industry can understand and react appropriately • During an outbreak companies need to determine how to rapidly increase manufacturing and distribution. A variety of approaches should be considered when thinking about how manufacturers can ensure an ability to scale up when needed • Determine ways to match testing capacity to meet demand but remain flexible and adaptable • Determine how capacities can be best leveraged to respond to outbreaks effectively and prepare for worst case scenarios

Appendix E: Tiered High Priority Gaps Ranking Results Matrix

Ranking Round 1

	Votes (N=19)	Gap Ref.	Position	Ranked Gap	Aligned Theme	C	B	R	N
Tier 1	10	a	1	Lack of interagency collaboration with FDA, BARDA, NIH, EPA, DOE, DOD, etc. on their roadmap for development & implementation next generation technologies	Sustainable laboratory surge capacity & transition to whole-of society response	x	x	x	x
	9	b	2	Lack of collaboration and communication for coordinated development, QC, manufacturing, dissemination, and adoption of diagnostic assays and platforms to PHLs and surge testing	Preemptive, sustainable public-private partnerships	x	x	x	x
	8	c	3	Lack of rapid characterization and detection of novel or emerging pathogens to identify changes in transmissibility or virulence	Accurate, rapid detection and characterization of threats to inform decision making	x	x		
	7	d	4	Aging and/or outdated IT infrastructure and data management systems in PHLs.	Flexible and extensible data exchange for CBRN and emerging threats	x	x	x	x
	7	e	5	Insufficient federal and STLT workforce in general and during surge; and weakness in recruitment/retention, onboarding, and training.	Proficient federal and STLT workforce	x	x	x	x
	7	f	6	Lack of threat agnostic biological, and chemical surveillance systems and methods (e.g., metagenomic sequencing of wastewater and clinical samples compared to amplicon and PCR	Accurate, rapid detection and characterization of threats to	x	x		
	6	g	7	Lack of data sharing agreements between federal, state, and other partners	Flexible and extensible data exchange for CBRN and emerging threats	x	x	x	x
Tier 2	6	h	8	Lack of mechanisms to develop, coordinate, and support rapid research during emergency response (e.g., routes of transmission, PPE, disinfectants).	Sustainable laboratory surge capacity & transition to whole-of society response	x	x	x	x
	6	i	9	Lack of standardized, non-siloed, data sharing requirements to allow case-level surveillance.	Flexible and extensible data exchange for CBRN and emerging	x	x	x	x
	5	j	10	Lack of critical expertise in federal and STLT workforce in bioinformatics, CLIA compliance, and radiological/nuclear.	Proficient federal and STLT workforce			x	x
	5	k	11	Lack of systems to promote rapid, parallel development of accurate laboratory assays on platforms that are already in use in laboratories	Accurate, rapid detection and characterization of threats to inform decision making	x	x	x	x
	4	l	12	Lack of a Laboratory Response Network – Radiological (LRN-R) to be able to rapidly respond to a radiological or a nuclear incident.	Flexible and extensible data exchange for CBRN and emerging threats	x	x	x	x
	4	m	13	Lack of plan to support surge testing for agents with special considerations (e.g., select agents, RG3 & 4 pathogens)	Accurate, rapid detection and characterization of threats to inform decision making	x	x	x	x
	3	n	14	Lack of mechanism to harmonize equipment needs to facilitate assay development on equipment available to most	Flexible, broadly applicable infrastructure & equipment	x	x	x	x
	2	o	15	Inability to maintain or replace outdated/sunsetting equipment (including maintaining surge capacity equipment)	Flexible, broadly applicable infrastructure & equipment	x	x	x	x
Tier 3	2	p	16	Lack of consistent laboratory quality management systems.	Flexible, broadly applicable infrastructure & equipment	x	x	x	x
	1	q	17	Lack of broadly applicable federal, state, and local supply chain management frameworks (e.g., access to specimens, reagents, materials, PPE, medical equipment, etc.), including reevaluation of equipment (e.g., reusable respirators vs. n95s).	Sustainable laboratory surge capacity & transition to whole-of society response	x	x	x	x
	1	r	18	Lack of partnerships to facilitate effective communications to inform and motivate public action	Preemptive, sustainable public-private partnerships	x	x	x	x
	1	s	19	Lack of rapid development, manufacture, and rollout of Point-of-Care and Point-of-Need assays that include reporting considerations	Accurate, rapid detection and characterization of threats to inform decision making	x	x		
	1	t	20	Limited sustainable surge testing capacity within PHLs	Accurate, rapid detection and characterization of threats to	x	x	x	x
	0	u	21	Lack of communications that effectively inform and motivate public action	Sustainable laboratory surge capacity & transition to whole-of society response	x	x	x	x
	0	v	22	Lack of coordinated, timely surge testing for response	Preemptive, sustainable public-private partnerships	x	x	x	x

Ranking Round 2

	Votes (N=14)	Gap Ref.	Position	Change from 1st Round		Ranked Gap	Aligned Theme	C	B	R	N
Tier 1	8	a	1	None	0	Lack of interagency collaboration with FDA, BARDA, NIH, EPA, DOE, DOD, etc. on their roadmap for development & implementation next generation technologies	Sustainable laboratory surge capacity & transition to whole-of society response	x	x	x	x
	6	e	2	Up	3	Insufficient federal and STLT workforce in general and during surge; and weakness in recruitment/retention, onboarding, and training.	Proficient federal and STLT workforce	x	x	x	x
	6	l	3	Up	9	Lack of a Laboratory Response Network – Radiological (LRN-R) to be able to rapidly respond to a radiological or a nuclear incident.	Flexible, broadly applicable infrastructure & equipment			x	x
	6	f`	4	Up	2	Lack of threat agnostic biological, and chemical surveillance systems and methods (e.g., metagenomic sequencing of wastewater and clinical samples compared to amplicon and PCR assays or FluNet, which is influenza specific)	Accurate, rapid detection and characterization of threats to inform decision making	x	x		
	5	m	5	Up	8	Lack of plan to support surge testing for agents with special considerations (e.g., select agents, RG3 & 4 pathogens)	Accurate, rapid detection and characterization of threats to inform	x	x	x	x
	4	d	6	Down	-2	Aging and/or outdated IT infrastructure and data management systems in PHLs.	Flexible and extensible data exchange for	x	x	x	x
	4	b	7	Down	-5	Lack of collaboration and communication for coordinated development, QC, manufacturing, dissemination, and adoption of diagnostic assays and platforms to PHLs and surge testing partners	Preemptive, sustainable public-private partnerships	x	x	x	x
Tier 2	4	j	8	Up	2	Lack of critical expertise in federal and STLT workforce in bioinformatics, CLIA compliance, and radiological/nuclear.	Proficient federal and STLT workforce			x	x
	4	c	9	Down	-6	Lack of rapid characterization and detection of novel or emerging pathogens to identify changes in transmissibility or virulence	Accurate, rapid detection and characterization of threats to inform decision making	x	x		
	3	o	10	Up	5	Inability to maintain or replace outdated/sunsetting equipment (including maintaining surge capacity equipment)	Flexible, broadly applicable infrastructure & equipment	x	x	x	x
	3	u	11	Up	10	Lack of communications that effectively inform and motivate public action	Sustainable laboratory surge capacity &	x	x	x	x
	3	v	12	Up	10	Lack of coordinated, timely surge testing for response	Preemptive, sustainable public-private partnerships	x	x	x	x
	3	k	13	Down	-2	Lack of systems to promote rapid, parallel development of accurate laboratory assays on platforms that are already in use in laboratories	Accurate, rapid detection and characterization of threats to inform decision making	x	x	x	x
	3	t	14	Up	6	Limited sustainable surge testing capacity within PHLs	Accurate, rapid detection and characterization of threats to inform decision making	x	x	x	x
	2	g	15	Up	2	Lack of data sharing agreements between federal, state, and other partners	Flexible and extensible data exchange for CBRN and emerging threats	x	x	x	x
Tier 3	2	n	16	Down	-2	Lack of mechanism to harmonize equipment needs to facilitate assay development on equipment available to most	Flexible, broadly applicable infrastructure & equipment	x	x	x	x
	2	i	17	Down	-8	Lack of standardized, non-siloed, data sharing requirements to allow case-level surveillance.	Flexible and extensible data exchange for CBRN and emerging threats	x	x	x	x
	1	p	18	Down	-2	Lack of consistent laboratory quality management systems.	Flexible, broadly applicable infrastructure & equipment	x	x	x	x
	1	r	19	Down	-1	Lack of partnerships to facilitate effective communications to inform and motivate public action	Preemptive, sustainable public-private partnerships	x	x	x	x
	0	q	20	Down	-3	Lack of broadly applicable federal, state, and local supply chain management frameworks (e.g., access to specimens, reagents, materials, PPE, medical equipment, etc.), including reevaluation of	Sustainable laboratory surge capacity & transition to whole-of society response	x	x	x	x
	0	h	21	Down	-13	Lack of mechanisms to develop, coordinate, and support rapid research during emergency response (e.g., routes of transmission, PPE, disinfectants).	Sustainable laboratory surge capacity & transition to whole-of society response	x	x	x	x
	0	s	22	Down	-3	Lack of rapid development, manufacture, and rollout of Point-of-Care and Point-of-Need assays that include reporting considerations	Accurate, rapid detection and characterization of threats to inform	x	x		