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Surge Capacity Planning Tool for the Laboratory Response Network for Biological Threats Preparedness (LRN-B)

This tool is designed to help laboratory leaders plan for and estimate their surge capacity for responding to all-hazard threats, including naturally emerging infectious diseases. Laboratory leaders should review this information on an annual basis or whenever major changes occur in space allocation, instruments, staff or other factors that could affect surge capacity.

Definitions of Laboratory Emergency Preparedness Capacity for LRN Reference Laboratories

Standing Capacity

Standing capacity is the total volume of testing that an LRN reference laboratory can perform or absorb with no or minimal operational changes, within normal hours of operation, using existing staff and without curtailing other routine laboratory activities. Standing capacity includes routine modifications to daily work assignments and/or staffing changes due to reagent shortages, equipment failures and personnel shortages (e.g., absences due to illness or vacation). Standing capacity also includes routine absorbable capacity, which is the additional volume of testing that a laboratory can perform with minimal operational changes, such as during a small-scale natural disease outbreak, small-scale suspicious event or short-term planned events, such as a major political conference or sporting event.

Internal Surge Capacity

Internal surge capacity is the sudden and sustained increase in the volume of testing that a LRN reference laboratory can perform in an emergency situation, implementing substantial operational changes as defined in laboratory emergency response plans and using all resources available within the laboratory. Internal surge capacity may require movement of staff to support surge activities, including reassigning technical staff, assigning support staff to cover administrative tasks and the addition of extra shifts.

Overall Surge Capacity

Overall surge capacity is the sudden and sustained increase in the volume of testing that an LRN reference laboratory can perform in an emergency situation, implementing substantial operational changes as defined in laboratory emergency response plans and using all resources available, including resources internal and external to the state public health or military or environmental laboratory system such as personnel, equipment or facilities. Overall surge capacity may require the actual transfer of personnel, equipment and/or specimens from or to a local facility that has been previously determined to meet technical requirements and for which appropriate Memoranda of Understanding/Agreement have already been established. Overall surge would also include "inter-state" surge agreements, especially with bordering states.

Factors Affecting Surge Capacity

Infrastructure Factors

- BSL-2 and BSL-3 facilities and total laboratory bench space
- Biological safety cabinets and chemical fume hoods
- Reagent supply (amount, type, expiration date) and access to additional/different reagents
- Analytical equipment (PCR, MALDI-TOF, GC/MS, LC/MS, ICP/MS, etc.)
- Space for intake, processing and storage of samples
- Versatility/capacity of instruments/equipment (single vs. multiple use; tests per hour/shift)
- Standardized instrumentation in multiple lab areas (allows for reallocation of testing)
- Robotic technologies to enhance throughput processing
- Electrical capacity/emergency power supply
- Personal protective equipment
- Biosafety and biosecurity (containment)
- Disposable lab supplies
- Autoclave/incinerator (for "terminal decontamination")
- Ventilation capacity

Staffing Factors

- Adequately trained, cross-trained and competent staff to perform assays
- · Auxiliary/surge staff
- Staff vaccinations and agent-specific prophylaxis
- Staff with appropriate clearances/licensure (e.g., DOJ Select Agent Registration)
- Support staff (answer phones, data entry, etc.)
- Support for staff during an incident (e.g., psychological/behavioral support; food, comfort and rest during prolonged shifts; family care; transportation to and from work)
- LRN sentinel laboratories appropriately trained and drilled
- Information Technology (IT) staff to assist with IT issues during or after an incident
- Capability of staff to implement new technologies for new threats
- Stability of staffing (absenteeism due to incident, illness, family emergencies, rate of turnover)
- Capability to hire rapidly
- Staff sharing agreements (staff from outside LRN lab, familiarity with laboratory and policies)

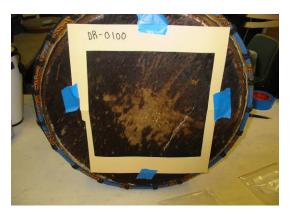
Operations Factors

- Type of sample (unknown vs. targeted request; clinical vs. environmental)
- Screening, triage and processing of routine and emergency samples
- Ability to reassign staff to new tasks
- Quality assurance and quality control
- · Test sharing ability with other LRN reference laboratories

Real-life Laboratory Experiences with Surge Capacity

Surge Capacity Partners and an Unexpected Call

The New Hampshire Public Health Laboratory (NH PHL) faced a real-life test of its surge capacity in 2009 when a 24-year-old New Hampshire woman was diagnosed with gastrointestinal anthrax. This extremely rare manifestation of *Bacillus anthracis* prompted a multiagency response to locate and address the source of infection and prevent further spread. By working with partner agencies such as the New Hampshire Department of Health and Human Services, the New Hampshire National Guard Civil Support Team, and partner laboratories in the LRN, the NH PHL was able to trace the patient's infection to a community center drumming circle event. *B. anthracis* spores are naturally present



Anthrax drum

in animal hides. The patient had inhaled the spores while drumming on a hide-covered drum. By drawing on support from partner agencies, the NH PHL and its partners were able to collect, test and confirm 145 samples in about five weeks, first confirming patient diagnosis to permit life-saving treatment and then assessing the community center to prevent further infection.

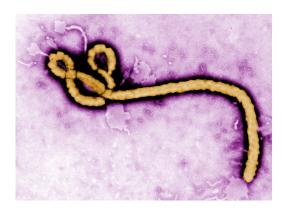


Erin Swaney reviews a flowchart for sample inactivation while training Biothreat Team members Wanda Songy, Garrick Gillispie and Mark Mergen (Texas Department of State Health Services, Laboratory Services Section Staff.)

Preparing for the Worst: Surge Capacity Planning and Ebola Response

As Ebola Virus Disease unfolded in the West African countries of Sierra Leone, Liberia and Guinea, the US Centers for Disease Control and Prevention quickly began distributing its testing capabilities to selected members of the LRN-B to ensure that domestic laboratories were prepared for this threat. Many of the LRN-B facilities were state and local public health laboratories with highly trained personnel, molecular diagnostic technologies, appropriate biosafety facilities and a demonstrated ability to respond to real threats.

Once contacted by CDC, state and local public health LRN reference laboratory directors communicated with their leadership and staff; collaborated with APHL to develop risk assessment tools, conducted risk assessments, made necessary biosafety changes and implemented the US Army Medical Research Institute of Infectious Diseases (USAMRIID) developed and CDC LRN-B deployed assay for the Zaire strain of Ebola. Between August and December 2014, CDC deployed this Ebola assay to over 50 state and local public health laboratories and selected Department of Defense laboratories. The testing capabilities for Ebola rapidly expanded to ensure coverage in every region of the US.



Ebola virus

This distributed testing capability enabled the Laboratory Services Section of the Texas Department of State Health Services in Austin, TX (TX State Public Health Laboratory) along with the CDC to confirm the first case of Ebola in the US. Dr. Grace Kubin, Director of the TX State Public Health Laboratory stated: "we had the necessary instrumentation, four highly skilled biothreat staff well-versed in handling select agents and a biothreat laboratory located in a separate building from the rest of the laboratory to ensure proper containment of threat agents." Kubin noted that because of the nature of the LRN, her staff was used to getting calls at three AM saying there is a specimen that needs immediate testing. The state lab coordinated with the local public health lab in Dallas, hospitals, federal and other partners to ensure that Ebola was contained and did not spread further in the communities.

Though most US patients have tested negative for the Ebola virus, a small number of positive cases have been identified allowing for rapid medical attention, contact tracing and increased surveillance to control the spread of the virus. While the potential for a widespread outbreak in the US remains low, a surge event would require a coordinated and high-level laboratory response that is only possible with a strong and well-organized network such as the LRN.

The ability of state and local public health LRN-B reference laboratories to respond to all-hazard threats including Ebola was developed primarily via the Public Health Emergency Preparedness (PHEP) Cooperative Agreement. This funding source has allowed states and locals to hire qualified personnel, procure and implement modern technologies, update biosafety facilities and perform outreach to sentinel clinical laboratories to ensure a strong public-private laboratory linkage.

Reference

1. Association of Public Health Laboratories, RAND Corporation, Centers for Disease Control and Prevention. (2008) Determining Surge Capacity in the Laboratory Response Network, Guidance for Conducting Assessments.

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National Center for Immunization and Respiratory Diseases (IP)

Office of Surveillance, Epidemiology and Laboratory Services (OSELS)

National Center for HIV, Viral Hepatitis, STDs and TB Prevention (PS)

National Center for Zoonotic, Vector-borne, and Enteric Diseases (CK)

National Center for Environmental Health (NCEH)

Coordinating Office for Terrorism Preparedness and Emergency Response (CTPER)

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