

# Current Status of Data Exchange in the Laboratory Response Network (LRN)

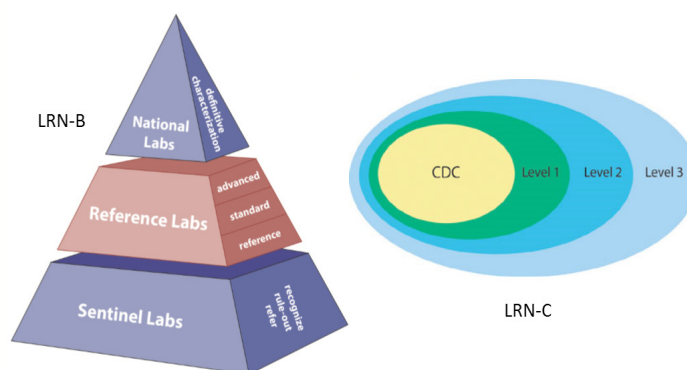
## SUMMARY

To assist the US Centers for Disease Control and Prevention (CDC) with planning for the future of data exchange in the Laboratory Response Network (LRN), the Association of Public Health Laboratories (APHL) included a suite of data messaging questions in its Annual All-Hazards Laboratory Preparedness Survey in September 2015 to determine the status of electronic data messaging in 54 public health LRN member laboratories across the United States. The assessment demonstrated that state and local public health LRN member laboratories are utilizing multiple systems for electronic data exchange. Following are data analysis and recommendations for data exchange in the LRN.

## INTRODUCTION

In 1999, through a collaborative effort with CDC, the Federal Bureau of Investigation (FBI) and APHL, the LRN was founded primarily to respond to biological threats. Today, the LRN is charged with the task of maintaining an integrated network of state and local public health, federal, military, and international laboratories that can respond to biological, chemical and other public health threats. The LRN for Biological Threats Preparedness (LRN-B) and the LRN for Chemical Threats Preparedness (LRN-C) are unique assets, linking clinical, state and local public health laboratories, veterinary, agriculture, military, water- and food-testing laboratories, and federal laboratories (See Figure 1). The LRN has expanded greatly since 1999 and remains a strong system capable of responding to a variety of public health threats, including emerging infectious diseases such as Ebola and Zika viruses.

Maintaining this extensive laboratory network is critical to the nation's biological and chemical threat preparedness. A cornerstone of the LRN is its ability to produce rapid and actionable test results. To do this, the LRN employs two methods for electronic data exchange, LRN Results Messenger (RM) and Laboratory Information Management System integration (LIMS). LRN RM was created to provide LRN laboratories with the ability to manage and share standard laboratory results data securely with CDC. LRN RM represented the first step in an



**Figure 1.** Structures of the LRN for Biological Threats Preparedness (LRN-B) and LRN for Chemical Threats Preparedness (LRN-C)

incremental approach to providing full standards-based electronic data exchange for the LRN. LIMS<sub>i</sub> is a parallel effort to LRN RM, representing the next generation of data exchange in the LRN. Its purpose is to enable laboratories to rapidly exchange data with CDC using their existing Laboratory Information Management System (LIMS) and reducing the burden of duplicate data entry.

LIMS<sub>i</sub> was launched in 2010 by CDC, in partnership with APHL, and its goal is to speed data exchange by integrating software that LRN laboratories use to store their internal records with an automated messaging service that sends critical results directly to CDC, sample submitters and other critical partners. Note that LIMS<sub>i</sub> is not currently available for implementation in LRN-C laboratories. Currently, some LRN-B laboratories still use LRN RM in addition to LIMS<sub>i</sub> to transmit results to CDC. The LRN-B program is still utilizing LRN RM for a variety of reasons including:

- For the Department of Defense (DoD) LRN-B member laboratories, LRN RM is the mechanism for data messaging to CDC.
- For state and local public health LRN-B member laboratories which also participate in the Department of Homeland Security (DHS) BioWatch Program, LRN RM is the only mechanism for data messaging to CDC.
- For response to emerging threats, CDC is able to manage data exchange by updating RM and ensure ability to collect results from each lab during the emergency.

LRN RM requires time-consuming manual double data entry, an extra step that LIMS<sub>i</sub> eliminates. In addition to reducing errors and simplifying electronic data messaging, LIMS<sub>i</sub> delivers high consequence and critical test results to the CDC much faster, enabling efficient preparedness and response efforts while reducing the burden for LRN PHL labs.

Since inception, the CDC and APHL have been heavily involved in ensuring the success of LIMS<sub>i</sub>, both in an administrative capacity and with hands-on efforts. The CDC LIMS<sub>i</sub> implementation team works closely with laboratories throughout the process ensuring that laboratories are meeting standards and have the support they need to achieve full compatibility. Conference calls, test messages, and multiple site visits by implementation teams are all part of the process. LIMS<sub>i</sub> operability generally takes several months to complete, as laboratories (and their software) need to fit within certain parameters before implementation is possible. One of the biggest challenges in implementing LIMS<sub>i</sub> has been the wide range of LIMS that LRN member laboratories employ. Due to factors such as difference in budgets, and types of test performed, a LIMS that works perfectly in one laboratory may be inappropriate choice for another. Those that use the same software may use different modules or versions. Coping with these differences requires extensive involvement and cooperation with the software manufacturers, which can further extend the timeline for implementation of LIMS<sub>i</sub>. However, these hurdles are outweighed by the benefits in particular, the time-saving advantages and reduced double-data entry burden.

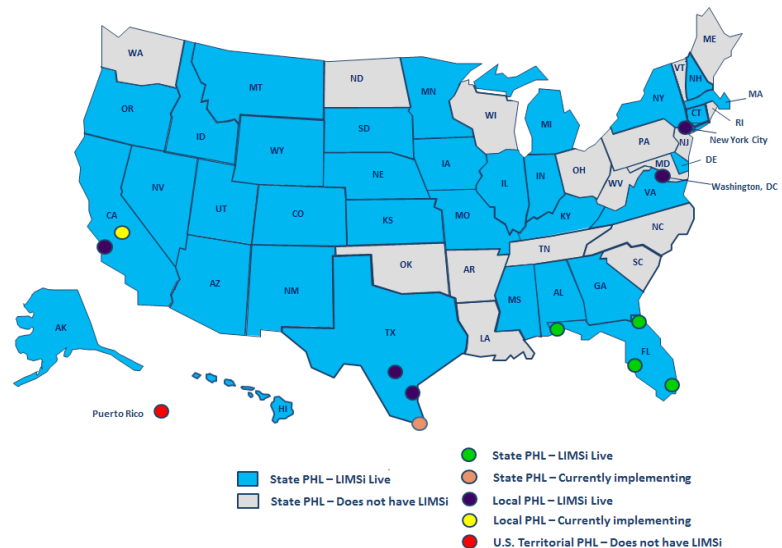
To date, CDC has provided \$2.2 million in funding to APHL which was used towards 37 LIMS<sub>i</sub> completions (See Figure 2). Public health laboratories also utilize CDC Public Health Emergency Preparedness (PHEP) funding and other resources to implement LIMS<sub>i</sub> without assistance from APHL. An additional eight laboratories have completed LIMS<sub>i</sub> in this capacity.

## METHODS

APHL fielded the Ninth Annual All-Hazards Laboratory Preparedness Survey to assess public health laboratories capability and capacity to respond to biological, chemical, radiological and other public health threats. The 2015 survey included, for the first time, questions related to electronic data messaging in the LRN.

The purpose of these questions was to assess the current state of electronic data messaging for LRN-B and LRN-C member laboratories. Administered between September and

November 2015, the survey had a 100% response rate from public health laboratories in 50 states, Puerto Rico, the District of Columbia, Los Angeles and New York City.



**Figure 2.** Laboratory Information Management System integration (LIMS) implementation in US state and local public health laboratories

## LIMITATIONS

The survey was designed to take a cross sectional snapshot of current data exchange in state and large local public health LRN member laboratories. The survey was not distributed to all LRN member laboratories, primarily local public health laboratories and DoD laboratories, which may use LRN RM or LIMS to message results to CDC. Further, LIMS applies to state and local public health LRN-B member laboratories and is not in place in LRN-C laboratories.

LIMS funding assistance is a competitive process and depends highly on available resources. Laboratories that have expressed interest in LIMS but have not implemented the system may lack resources for implementation that is out of their control.

## DISCUSSION OF FINDINGS

Findings pertaining to the data exchange questions are discussed below. Note that the responses below are for 54 public health laboratories which are also members of the LRN.

- 52 (96.3%) public health LRN member laboratories are familiar with LRN-B Policy Statement on Notification of Officials of Significant Laboratory Results. These 52 laboratories have a good or excellent understanding of the notification policy.
- 51 (94.4%) public health LRN member laboratories are familiar with the Policy Statement on Data Messaging of Testing Results for Biological Threat Agents by Members of the LRN. 47 (92.2%) of these laboratories have a good or excellent understanding of the data messaging policy.
- 53 (98.1%) public health LRN member laboratories are familiar with the LIMS project.

- Currently, 42 (77.8%) public health LRN member laboratories utilize LRN RM while 28 laboratories (51.9%) use LRN LIMS<sub>i</sub> to electronically message data. (Note: While a total of 45 laboratories have completed LIMS<sub>i</sub> implementation, not all LIMS<sub>i</sub> laboratories were represented in the survey. Additionally, some laboratories utilize both LRN RM and LIMS<sub>i</sub> depending on the response and sample being tested, and some laboratories have LIMS<sub>i</sub> implemented but don't use it for various reasons). Of the laboratories that implemented LIMS<sub>i</sub>, the majority indicated funding and IT support were the major barriers to maintaining adequate LIMS<sub>i</sub> infrastructure for data messaging in the LRN.
- Of the 28 laboratories that indicated they use LIMS<sub>i</sub> for data exchange, 25 (89.3%) continue to routinely use LIMS<sub>i</sub> after implementation. Laboratories that did not continue to routinely utilize LIMS<sub>i</sub> for data exchange indicated lack of dedicated IT staff to troubleshoot software issues and maintain system updates. LIMS<sub>i</sub> and LRN RM require periodic updates as new requirements for biological and chemical threat agent reporting are determined.
- 32 (59.3%) public health LRN member laboratories indicated they have dedicated information technology (IT) staff while 22 (40.7%) do not. Laboratories that do not have dedicated IT staff may share IT staff with the entire health department or contract to third party companies. The lack of dedicated IT staff can increase the time it takes to resolve software issues and update systems, rendering the system unusable for certain data messaging.
- During a large scale event, public health LRN member laboratories indicate they would use the following systems to electronically message data to CDC (see Table 1):

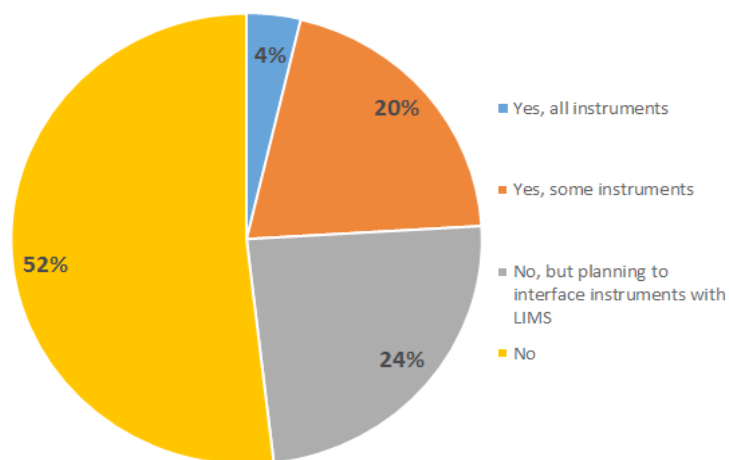
System Used to Report During Large Scale Event	Number and Percentage of Public Health LRN Member Laboratories (n = 54)
RM Only	27 (50.0%)
LIMS <sub>i</sub> and RM	17 (31.5%)
LIMS <sub>i</sub> Only	10 (18.5%)

**Table 1.** Result Reported During Large Scale Events

Some laboratories continue to utilize both LRN RM and LIMS<sub>i</sub> to message results to CDC. This can occur if a laboratory has not updated their LIMS<sub>i</sub> infrastructure for a specific threat agent or in the case of an emerging infectious diseases, like Ebola or Zika, where the LIMS<sub>i</sub> reporting requirements are unknown at the time testing capability is implemented. The requirements and ability to report emerging infectious disease results can more rapidly be implemented in LRN RM remotely by CDC. Updating LIMS<sub>i</sub> may take longer as it is the responsibility of the laboratory to perform these functions.

During an emergency surge event (i.e., a sudden and sustained increase in the number of samples being tested), an LRN member laboratory is responsible for messaging large batches of sample results. LRN RM has a special surge mode, requiring less data input, and allows the laboratory to input a large number of results at one time. For this reason, half of survey respondents indicated they would use LRN RM in a surge situation. However, LRN RM surge mode still requires double data entry and increases the chance of data messaging errors, issues that are minimized by LIMS<sub>i</sub>.

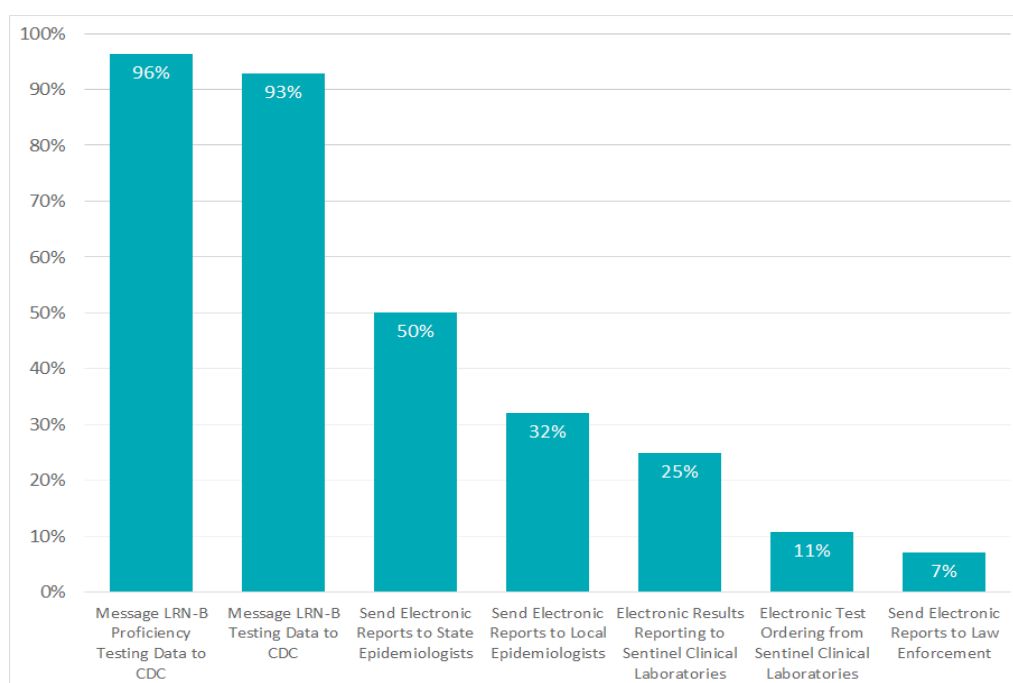
To further reduce messaging errors that may arise from manual data entry, either through LRN RM or LIMS, some laboratories have expanded their LIMS capabilities with instrument interfacing (see Figure 3). By interfacing an instrument with LIMS, results are transferred directly from the instrument to the LIMS, completely eliminating manual result entry. Unfortunately, instrument interfacing may not be available for all instruments, LIMS, or specific LRN-B tests.



**Figure 3.** Instrument interfacing capabilities with LIMS

Another significant benefit of LIMS is the ability to modify the system beyond data messaging to CDC, to include capabilities such as electronic test ordering and result reporting to law enforcement and epidemiologists (see Figure 4). Unfortunately, these modifications require significant IT infrastructure, additional funding, and laboratory staff time. For this reason, many laboratories lack advanced LIMS capabilities noted below.

Based on this assessment, it is clear that LRN laboratories face multiple issues pertaining to implementation and maintenance of data exchange systems. What works in one laboratory may not be effective in another; however, a strategic and standardized approach for the future of data exchange in the LRN is necessary.



**Figure 4.** LIMS capabilities

## RECOMMENDATIONS

Based on the findings of this assessment, APHL recommends the following steps to address the future of electronic data exchange in the LRN:

- Strategic planning for data exchange involving all stakeholders to address the current status of LRN data exchange, standardization of messaging systems, and the needs of both LRN-B and LRN-C as well as sample submitters and other key partners.
- A more in-depth analysis of current systems in place in all LRN member laboratories as well as a market scan of existing systems and planned software upgrades.
- A cost-benefit analysis to determine appropriate and secure system for LRN member laboratories. The analysis should encompass a detailed budget for development, implementation and maintenance of the recommended system.
- Sustained and dedicated federal funding to support the ongoing needs of data exchange in the LRN.

CDC has been vital in advancing public health laboratory infrastructure, enhancing laboratory technologies and improving the preparedness and response capacity by providing technical and operational support to LRN member laboratories. Despite the significant accomplishments of the LRN, obstacles such as electronic data messaging still remain and could potentially threaten its ability to quickly detect and respond to public health threats and emergencies. In order to maintain the strides in emergency preparedness achieved by the LRN, an efficient and sustainable strategy for electronic data messaging must be developed and implemented.

## Association of Public Health Laboratories

The Association of Public Health Laboratories (APHL) works to strengthen laboratory systems serving the public's health in the US and globally. APHL's member laboratories protect the public's health by monitoring and detecting infectious and foodborne diseases, environmental contaminants, terrorist agents, genetic disorders in newborns and other diverse health threats.

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