

PUBLIC HEALTH LABORATORY INFORMATICS AND THE LRN-C

APHL Report

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Electronic Data Transfer
Critical to LRN-C Success



The Association of Public Health Laboratories (APHL) is a national non-profit organization dedicated to working with members to strengthen governmental laboratories that perform testing of public health significance. By promoting effective programs and public policy, APHL strives to provide member laboratories with the resources and infrastructure needed to protect the health of US residents and to prevent and control disease globally.

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Executive Summary

Informatics is a critical component not only of public health laboratory operations, but also the success of the Chemical Laboratory Response Network (LRN-C).

At the October 2011 Level 1 LRN-C meeting, attendees discussed barriers to integrating laboratory information management systems (LIMS) with LRN-C reporting systems. Topics covered instrumentation output, data exchange, lack of IT support and interfering state IT requirements.

APHL, as the national membership association representing public health laboratories (PHLs), saw an opportunity to assist this group in understanding, navigating and sending electronic data to the LRN-C. Experience with PHLIP (Public Health Laboratory Informatics Project)¹ and LIMS² positions APHL to meet the needs of both members and CDC.

Example of an LRN-C LIMS Networking Implementation Workaround:

One PHL with instruments interfaced to its LIMS reported their IT department required networked computers to “time out” on a frequent basis. Since such networked computers control multiple instruments and require regular chemist interaction, this timing out compromised analytical activities. As an example of ingenuity and resourcefulness in the wake of calamity, the laboratory purchased many shaker tables and placed computer mice on these tables. Another state experienced the same problems, but was able to find a USB attachment to the mouse that also keeps the mouse moving.

<http://www.cdw.com/shop/products/WiebeTech-Mouse-Jiggler/1271126.aspx>

Information gathering occurred via visit, interviews, a detailed survey, conference calls, and interactions at the spring 2012 LRN-C technical conference. Research identified both gaps and bridges within level 1 and level 2 LRN-C laboratories’ informatics capabilities. The gaps included barriers to (a) LIMS implementations, (b) integration of laboratory instruments and collection devices, and (c) automated delivery of LRN-C data to the Centers for Disease Control (CDC). The bridges highlight success stories and potential solutions drawn from real-life experiences.

This paper discusses gaps and bridges associated with improving the flow of laboratory data from analytical instrumentation all the way to decision makers during a chemical threat incident. The audience includes public health laboratory directors, APHL and CDC.

Overall, findings reinforce that LIMS implementations and interoperable data exchange depend upon appropriate resources (both funding and staff), as well as competencies. However, other issues remain relevant, such as: provision of information technology (IT) services in an age of consolidation, networking, security, and laboratory participation in IT management. Recommendations for laboratories include:

1. Use a laboratory-wide “sub” network within the larger state or local IT-networked domain.
2. Automate data flow within the laboratory.
3. Develop and maintain the necessary informatics competencies within the laboratory.
4. Implement policies and practices to promote improved communication and service-level support between the laboratory and IT authority.
5. Configure your LIMS to adopt standardized electronic data outputs.

CDC can help laboratories by embracing recommendation number five and encouraging states to adopt a single, standardized electronic data deliverable (EDD), preferably the APHL EDD. This would lead to standardization not just within LRN-C, but also with EPA’s emergency response network and hopefully other federal networks moving forward.

¹<http://www.aphl.org/aphlprograms/informatics/collaborations/phlip/Pages/default.aspx>

Introduction

At the October 24-27, 2011 CDC LRN-C technical meeting in St. Paul Minnesota, staff from LRN-C level 1 laboratories as well as some level 2 laboratories met for roundtable discussions. Attendees discussed a range of issues regarding barriers to the successful integration of LIMS with LRN-C, covering instrumentation, data exchange, lack of IT support and interfering state IT requirements.

Attendees noted that LIMS implementations and interoperable data exchange between networked LRN-C laboratories depends upon appropriate funding, and staff with necessary competencies. However, other issues such as provision of IT services in the age of consolidation, networking, security, and laboratory participation in IT management also remain very relevant. Most agreed that informatics serves a critical component both of public health laboratory operations and of the delivery of services necessary for success with the LRN-C.

The success of the LRN-C involves the ability of public health laboratories to collect data locally and to send this data to CDC. Electronic transfer of PHL data to CDC can occur in three ways:

1. Instrument to CDC: Laboratory data can go directly and securely from the instrument to CDC via Results Messenger (RM). This option is perhaps the least complex option, as laboratories only provide instrument results. Case information and demographics associated with the specimen are stored at a CDC-central LIMS. The disadvantages associated with this option include:

- not storing demographics and metadata in the local LIMS makes this data unavailable to the testing laboratory or local PH authority;³
- not encouraging automatic interfacing between instruments and the local LIMS, which reduces transcription errors and improves turnaround times; and
- not utilizing a standardized electronic data deliverable.⁴

2. PHL LIMS to CDC: In this case, instrument data is entered into the PHL LIMS, and the LIMS manages the delivery of data to Results Messenger. In the most automated case, instruments electronically interface directly to the LIMS, and the LIMS automates the secure delivery of data to CDC via Results Messenger. While this route may not include specimen case information and demographics, this option offers advantages:

- serves as a first step in the process of automating data collection and delivery;
- allows the inclusion of accessioning and metadata with analytical results reporting; and
- can include multiple electronic data delivery formats.

²The Laboratory Information Management Systems Integration (LIMS_i) project supports ongoing efforts to optimize information flow and system interoperability between CDC and participating LRN facilities. The objective of the LIMS_i program is to leverage the LIMS capabilities existing at LRN facilities to support electronic data exchange among LRN partners using Public Health Information Network (PHIN) standards. Through the success of the LIMS_i initiative, participating LRN laboratories are able to maximize their IT capabilities and fully leverage the benefits of their investments. In addition, LRN laboratories can achieve PHIN interoperability, ultimately enhancing the LRN's capability to manage data in response to a public health emergency.

³During a large-scale incident, or even a local event managed by a local public health agency, a PHL may need to operate independently of a centralized CDC system. The PHL must include demographic and metadata in reporting and also be able to share this data with the local PH authority. Under method #1, sharing this data locally may require unique electronic or even paper reports.

⁴The report consists of an excel spreadsheet with only analytical data that may not be understood locally.

3. **LIMSi:** Utilizes the LIMS to automate the data exchange and looks to the future with a more standardized automated delivery of data. Advantages include:

- a more standardized approach to electronic data delivery that is more consistent with other public health data delivery, such as data messaging (e.g. HL7), vocabulary (e.g. codes, semantics), and transport (e.g. PHINMS)
- near-true, machine-to-machine data exchange potentially in real-time, with the ability to exchange data interoperably⁵
- potential future use of electronic test orders and results
- provides many of the features currently existing in LRN-B
- reduces (or eliminates) double-data entry into Results Messenger
- provides improved data volume and accuracy during an event
- builds on a laboratory's own systems and workflow
- leverages system automation, such as instrument interface to LIMS
- reduces training time
- facilitates interoperability with other public health partners.

While LIMSi offers the best option for PHLs to automate electronic data delivery and interoperability, it does present a significant challenge for some labs, which must configure their LIMS to ensure that the appropriate data elements and corresponding vocabulary will support messaging requirements.

The goal of this document remains to assist LRN-C labs in understanding, navigating and accomplishing the task of sending electronic data directly from instruments, through their LIMS, to CDC. This paper breaks down into two major sections: gaps and bridges. 'Gaps' identifies barriers to successful LIMS implementations, barriers to successful integration of laboratory instruments and collection devices, and barriers to automated delivery of LRN-C data to CDC and partners. 'Bridges' represents potential solutions based on success stories from real LRN-C laboratories. Sources of information include:

- *A comprehensive "LRN-C Informatics Survey" sent via Survey Monkey® on Feb 28th 2012 to Level 1 and Level 2 LRN-C laboratories;*
- *A presentation and discussion at the LRN-C Technical Conference on April 3rd 2012 entitled: "Informatics Gaps and Bridges, A Recent LRN-C Survey";*
- *An on-site visit to a Level 1 LRN-C laboratory to meet laboratorians, IT and informatics specialists;*
- *Seven conference calls with individual state laboratory and informatics teams;*
- *Discussions with APHL Environmental Health Committee, Environmental Laboratory Subcommittee, and Informatics Committee members;*
- *Discussions with CDC LIMSi staff and contractors;*
- *Individual discussions with PHL Directors at the 2012 APHL annual meeting in Seattle.*

Overall recommendations for LRN-C laboratories fall into the following categories, detailed below in 'Bridges':

1. Use a laboratory-wide "sub" network within the larger state or local IT-networked domain.
2. Automate data flow within the laboratory.
3. Develop and maintain the necessary informatics competencies within the laboratory.
4. Implement policies and practices to promote improved communication and service-level support between the laboratory and IT authority.
5. Configure the LIMS to adopt standardized electronic data outputs.

⁵ Interoperability refers to the ability of two or more systems or components to exchange information and to use the information that has been exchanged.

Gaps

APHL sent the 13-question “LRN-C Informatics Survey” via Survey Monkey© on Feb 28, 2012 to Level 1 and Level 2 LRN-C scientists and project managers. Prior to sending, the APHL Environmental Health Committee and the Environmental Laboratory Subcommittee pilot-tested the survey instrument.

After de-duplicating responses from the same entities, data from 48 labs were evaluated, representing some 96% of those surveyed. Appendix 1 tabulates the complete results. The following summarizes the findings:

1. Thirty percent (30%) of respondents stated that instrument computers are networked and must comply with their IT network standards. These laboratories already achieved integration between their instruments and LIMS; but that means 70% of respondents have not done this yet. Comments included:

- *“We have encountered instrument manufacturers who prohibited us from having anti-virus software on their workstation. This is an issue for computers that need to be networked.”*
- *“We tried [to network our instruments] initially, but every time IT worked on our system it crashed. Right now, we have ‘sneakernet’.”*
- *“Our computers are not allowed to be on the network, as they use “third-party” software that our department won’t support. Our IT group will also only support Windows 7 machines. Many of our instrument computers are still running XP, as the vendors have yet to release a software package for Windows 7.”*
- *“Definitely a sneakernet, and it works very well. We have Excel spreadsheets that we can cut and paste results into for inputting data to RM, and have had no significant problems with data entry, review and submission. This way, we can avoid the LIMS.”*

2. Sixty-four percent (64%) of laboratories reported that IT networking requirements compromise their instrument computer functions. Comments included:

- *“We have a separate instrument network server for secure back-up...[it is] local to the PHL and does not comply with IT standards. By the same token, it does not allow internet download, or reach-back from the instrument vendors.”*
- *“Laboratorians do not generally have administrative rights to laboratory computers. They can, under a maintenance mode, install updates as necessary.”*
- *“Our instrument computers are not networked... to avoid having conflicts with IT policies.”*
- *“We have the capability of networking our instruments, but when we initially tried to, the GC/MS operating system did not work correctly. We have not attempted to try since!”*
- *“50% of the instrument computers are on the network. As the computers age, they no longer meet the network requirements. Occasionally, the laboratory staff will have to request administrator rights to the instrument computers. If there is a problem with the computer, the service technicians voice their concern of the computer being on the department’s network due to all the updates, patches, etc. that is pushed out to all networked computers.”*
- *“IT can restart all computers as they see fit. This means that runs over a weekend can be stopped by IT.”*
- *“Our PCs on the network time-out.”*
- *“We used to have a ‘lab net’, but IT got wind of that and now it’s back to sneakernet. However, IT admin is in flux, and there is hope that we can re-establish a lab sub net.”*
- *“We run macros on our data from the instrument computers to convert them into a format suitable for upload to RM. This is then copied onto an encrypted USB drive provided by the IT group. This USB drive doesn’t work with a number of computers, as the encryption seems to have a conflict with the encryption on the hard drives. This is the only way we are ‘officially’ able to upload data.”*

⁹LRN-C LIMS that are not configured to mirror the vocabulary mapping established with LRN-C may face significant validation challenges as they attempt integrated messaging with CDC/LRN applications.

3. Twenty-three percent (23%) stated that their LIMS vendor or developer provides workgroups to assure LIMS support for their clinical chemistry laboratory. Comments suggested “that laboratorians are not aware of vendor/developer support or team activities.”

4. Thirty-nine percent (39%) stated that their LRN-C laboratory has a modern LIMS capable of managing and tracking clinical chemical laboratory activities. Comments included:

- “Technically, we [have a modern LIMS], but the reality is that Chemistry's LIMS differs from Micros', and ours is not what I would call robust.”
- “Our LIMS can do this, but as chemical terrorism does not receive ‘routine’ samples, we are last on the list for any integration into LIMS and any interfacing. It's taken to this past month to get some of our methods into LIMS and its just manual data entry and verification, only because we did a small-scale biomonitoring pilot.”
- “Our present LIMS can manage and track samples, but nothing else. When developing the requirements for the new LIMS, the 16 business practices above were included.”⁸
- “Yes to most, but note that currently the chemical threat program is not utilizing the LIMS.”
- “We accession, track, and designate as completed our clinical chemical samples, including PTs. However, none of our instruments are interfaced with the LIMS - this is by my (and my group's) intent.”

5. Fifty-two percent (52%) reported that their LIMS provides or supports data capture utilities (or interfaces) to automate the delivery of clinical chemistry instrument data to their LIMS. Comments included:

- “Currently, only our lab's ICP-MS instruments are interfaced. Our lab will interface our remaining instrumentation as funding becomes available and as the LRN-C tests are configured within the LIMS.”
- “All other laboratory instrumentation is prioritized above CT (no routine samples); there is the possibility to do so, but only if funding holds out and once all of the other areas are interfaced.”
- “The LIMS data capture utilities are not implemented for LRN-C activities.”
- “Any data capture utilities have to be configured for each specific instrument, even if they are the same type of instrument from the same manufacturer. The vendor (for the most part) has to be involved in the creation of the DCU.”
- “Yes, but it is considered customization and must be paid for.”
- “Not as far as I am aware unless you mean excel format upload, since we have to sneakernet all our data over to the Network side.”
- “The LRN-C lab does not use a LIMS system, but this support is available for other groups that do.”
- “The functionality is there, but because of ‘uber’ IT issues we load data from the instrument to a USB drive, then to the LIMS for analysis.”

6. Thirty-five percent (35%) stated that their LRN-C LIMS provides the capability to automatically review their clinical analytical data, associated quality control data, and tracking information prior to reporting out of the laboratory. Comments included:

- “Sort of, but not really. We can see QC data and analytical data, but not tracking information or final reports. We do manually review the data; there is no automatic QC evaluation.”
- “These capabilities are not implemented for LRN-C activities.”
- “This is in the deliverables for the new LIMS.”
- “The LRN-C lab does not use a LIMS system, but this support is available for other groups that have a LIMS.”
- “The quality control would be done on instrument PC as the LIMS do not have a QC module.”

⁷Sneakernet is an informal term describing the transfer of electronic information, especially computer files, by physically moving removable media such as magnetic tape, floppy disks, compact discs, USB flash drives, or external hard drives from one computer to another. This is usually in lieu of transferring the information over a computer network. (<http://en.wikipedia.org/wiki/Sneakernet>).

⁸<http://www.aphl.org/aphlprograms/informatics/Pages/requirementslims.aspx>

7. Sixty-two percent (62%) stated that their LIMS is capable of storing instrument results and quality control data. Comments included:

- *“Electronic data can be reported in the form of ASCII flat files. We do not do clinical data on this LIMS.”*
- *“Our LIMS is flexible enough to accommodate those features though we have not fully implemented them.”*
- *“Yes, electronic data deliverable capability exists, but [it is] not used for the chemical threat program. [We need] guidance from CDC on format.”*
- *“This is in the deliverables for the new LIMS.”*
- *“Features are not functioning at the present time. They were built in originally, but there are issues.”*
- *“This applies only to LRN-B testing and other biological clinical testing performed in the laboratory. Currently, our LRN-C and environmental testing is not in a LIMS.”*

8. Twenty-four (24%) stated that their LIMS is able to automate electronic data exchange with the LRN-C and send required data elements/results directly to Result Messenger (RM). Comments included:

- *“Capability is in development.”*
- *“Data is manually entered into LIMS, and manually entered from LIMS to RM.”*
- *“I do not believe that CDC's Results Messenger has the ability to directly accept an EDD from a LIMS.”*
- *“At least not without a lot of investment in customization.”*
- *“This is in the deliverables for the new LIMS.”*
- *“Our LIMS may be able to. We have not tried to send data to Results Messenger at this time.”*
- *“Steps are in place that facilitate upload into RM, but it isn't automatic. This is the goal we are working towards.”*
- *“We use Excel for most all of our work and avoid the LIMS.”*
- *“Currently, our LIMS generates an Excel file which has to be copied into a new Excel file to be uploaded into [Results] Messenger.”*

9. This is a multi-part question regarding the IT department support of the PHL:

- a. 41% stated that their IT department can provide 24 x7 IT staff available for emergency support of their laboratory.*
- b. 49% stated that there is partnering with the IT department and laboratory staff to manage vendors.*
- c. 51% stated that there is dedicated application-level LIMS support.*
- d. 20% stated that there are defined partnerships with high visibility agencies within their state and/or local government to assure that the laboratory has a role in IT governance.*
- e. 59% stated that there is oversight and project management at the laboratory level.*

Comments included:

- *“Our state ‘IT department’ provides none of these features without extreme costs. Our internal IT staff provides instrumental and LIMS administration and support.”*
- *“There is a disconnect between the people that work directly with us in the IT department and their superiors.”*
- *“We have one person to support our LIMS system. We have managerial rights in the LIMS, but not administrative rights.”*
- *“We have a part-time IT application specialist who is available on-site (perhaps two days of the week) and on-line (3 days/wk).”*
- *“We have our own LIMS Administrator (a microbiologist by training). IT does not interact with LIMS if they can avoid it as it is not ‘their’ application.”*
- *“They do not work to facilitate the lab needs but to maintain the state requirements.”*
- *“Funding has been extremely difficult for dedicated application level LIMS support.”*
- *“They are on grant money. Last year, funding for the next contract year only became available the day before their current contract ended.”*

10. Twenty-three percent (23%) state that their laboratory leadership has a signed memorandum of agreement (MOU) or a service level agreement (SLA) with their jurisdiction's IT leadership that specifically defines support for IT functions. Comments included:

- *"Our state 'IT Department' does not sign MOUs or SLAs with other state agencies under most circumstances."*
- *"Not to my knowledge. If one is there, it is not being wisely used, in my opinion."*
- *"Because of budget considerations, IT management is being moved to another Department of the state government. It is unknown at this time what form service agreements will take in the near future."*
- *"Not sure."*
- *"The IT support comes within the agency from another group."*

11. Fifty-four percent (54%) believe that their LRN-C laboratory will have access to LRN-B laboratory modern broker tools (e.g. Orion Rhapsody, MIRTH etc.) and staff trained to use these tools to map LIMS data elements, provide vocabulary harmonization, and transport messages.

- Comments included: *"LRN-C development is more complex than LRN-B."*

Bridges

The same survey identified many positive activities and examples of innovative bridging options related to successful LRN-C informatics practices. Examples include:

1. Eighty percent (80%) of respondents reported that laboratorians have the necessary independence and support to assure instrument computers can operate according to the instrument manufacturers' needs.

2. Ninety percent (90%) reported that laboratorians have authority to work directly with instrument vendors to maintain instrument computers. Comments included:

- *“Our instruments are on the network, however, updates are first tested on a test machine and downloads occur at a time determined by the bench chemist. Because the lab is secure, timing out is not necessary. Our IT group works with us.”*

3. Eighty (80%) reported that instrument computers can utilize the operating systems supported by the instrument manufacturer.

4. Sixty-nine percent (69%) reported that laboratorians have administrative rights to the laboratory to manage key LIMS operations.

5. Other positive comments provide examples of individual successes (but do not represent majority statements):

- *“This survey came at the right time and helped us refine the goals for our IT system for LRN-C. Thanks.”*
- *“All our LRN-C instruments are networked internally within the lab. We would be able to put LIMS on that network.”*
- *“Our laboratory implements a buffer network. Primary Network Interface Controller (NIC) connects to state network with 2nd NIC. Creates a private network between the buffer network and the instrument computer. Communication is limited within the private network.”*
- *“Our Instrument Network at the PHL is separate from the DOH Network. This prevents the automatic upgrades that cause the older instrument software to crash, and allows maintenance of the software systems that were sold with, and work with, the instruments. Files are transferred between the two by mobile memory device.”*
- *“Our IT department is part of the laboratory.”*
- *“IT and the PHL are separate departments but are both part of the DOH and are both under the direction of the state health officer. Both department directors are members of the governance council.”*
- *“We have our own LIMS Administrator (a microbiologist by training). IT does not interact with LIMS if they can avoid it as it is not ‘their’ application. Our IT staff provides technical support on computer hardware and some software issues. Laboratory staff routinely works to resolve software issues.”*
- *“Our laboratory is in the process of installing a new LIMS with advanced capabilities to meet needs described in this survey.”*
- *“Electronic data messages can be released through Orion Rhapsody, where it is parsed to the correct public health partners.”*
- *“The LIMS vendor has an annual meeting.”*
- *“Data is automatically uploaded to our LIMS from our instruments.”*

Thematically, research and discussions with states suggests that successful bridges fall into the following five areas:

1. Use of an independent laboratory-wide “sub” network within the larger state or local IT-networked domain.
2. Automate data flow within the laboratory.
3. Develop and maintain the necessary informatics competencies within the laboratory.
4. Implement policies and practices to promote improved communication and service-level support between the laboratory and IT authority.
5. Configure your LIMS to adopt standardized electronic data outputs.

A Laboratory-Wide “Sub” Network

Several states indicated that LRN-C implementation benefits from the use of a laboratory-wide “sub” network within the larger domain of the state or local IT authority. For many, this means placement of both instruments, and interfaces to their LIMS, on a network domain separate from the jurisdiction-wide area network domain. In some cases, the laboratory’s LRN-C and LRN-B have similar implementation paths to automatically collect and transmit data electronically. The use of sub networks allows the laboratory to take ownership of an important component of IT services. Instruments and LIMS (which to many is an extension of analytical processes and instruments) remain in an area that many IT departments have little interest in physically attending.

To better understand this idea of separate network domains for the laboratory and IT authority, APHL interviewed several laboratories. Two state labs were chosen as examples for this paper because of their successful integration of laboratory and IT, and because of their systematic approach to networking multiple laboratory systems (e.g., LRN-B, LRN-C and other public health testing). The states used different approaches to address their needs, but both used holistic approaches to develop their domains.

State #1:

In this state, two separate domains exist: one for “in-scope” networks (managed through the state-wide area IT authority) and another for “out-of-scope” networks (managed at least partly by laboratory informaticians). Each domain maintains separate policies, e.g., patch-and-release cycles. The firewalls for each domain are configured differently.

All instrumentation and instrument servers reside on the “out-of-scope” domain. Laboratory informatics staff and IT staff work together to manage these servers and instrument systems: updating and patching them on the third Sunday of each month, after pilot testing. Lab staff manage instrument PCs in accordance with recommended vendor practices and (along with instrument servers) which must have required anti-virus software installed prior to being placed on the network.

Instrument PCs and servers do not have to comply with the state IT (in-scope) device-management policies or operating-system standards; however, they do have to comply with state IT security policies for password management and display time-outs.

This state employed a Domain Controller to authenticate users on the out-of-scope network, and to communicate with the in-scope domain. A firewall exists between the two domains and a one-way trust allows in-scope access to the out-of-scope domain, but blocks the reverse. This adds another layer of security and protection for the in-scope domain.

A signed service level agreement exists between the laboratory (the agency) and the state IT infrastructure provider. It clearly defines the roles and responsibilities of all parties regarding out-of-scope equipment. Parties revisit the agreement annually and make adjustments accordingly.

State #2

This approach more specifically integrates the LRN-C LIMS with all other laboratory informatics activities, leading to a single laboratory-wide network. Here, the state’s ability to collect and interface instrument data with a LIMS, and to transfer this data to a laboratory-wide network, are clearly defined and supported by the IT authority and laboratory management. The LIMS for the LRN-C differs from the LIMS for LRN-B; however, both LIMS occur within an enterprise system.

The state laboratory information system provides a test station and environment on which to test all patches to:

- prevent conflicts with laboratory software and hardware,
- allow software and updates to remain consistent with network requirements,
- assure compatibility with the OS,
- and maintain security.

Laboratory workspaces remain highly secure with limited access, assuring HIPAA compliance without the need to mandate automatic:

- restarts of the operating system after an update,⁹
- or time outs on the workstations.

Automated Data Flow

In addition to states having an IT domain under their control, APHL recommends a planned automated approach to linking instruments with their LIMS. Within state #2, laboratory data flows electronically from the LIMS to the LRN-C as follows: after entering the event ID at a console, the data (as a csv file) goes to a personal desktop with a fixed IP address, and from there it can be sent to the LRN-C.

- A standalone system for the chemistry lab, the LIMS was originally designed for environmental specimens over 2 years ago. Now it is configured for both clinical and environmental specimens.¹⁰
- The LIMS handles all aspects of sample tracking as well as collection of data from instruments, and reporting of data electronically.
- Staff understand and use a detailed “help” file on the LIMS.
- Custom data capture utilities (developed for all instruments) provide:
 - o sample results automatically to the LIMS,
 - o the ability to upload files,
 - o reports on stages of sample collection, and
 - o the ability to review final reporting to Results Messenger.
- A detailed Sample Receipt Checklist for tracking all aspects of sample receipt, data folders, sample storage, and staff notification and secondary review by assigned analysts.
- A login Batch Report for sharing samples—white powders, environmental, and clinical specimens.
- A detailed checklist for Chemical Threat Response Tracking, including LC/MS and test specific sample PT data review checklists.
- A summary Data Review Sheet is automatically produced that summarizes run date, run cycle, sample ID, CDC ID, analyte, and results.
- A Progress Report summarizes the LIMS id, test name, logged in date, analysis start time, load time to LIMS, validation dates, reported dates, and turnaround time to prioritize sample analysis.
- Printed results of LRN-C specified data elements. Note, additional data elements can be output from the LIMS, such that the lab can meet APHL EDD data elements.
- The procedure for sending results to Results Messenger is clear, and staff are trained.

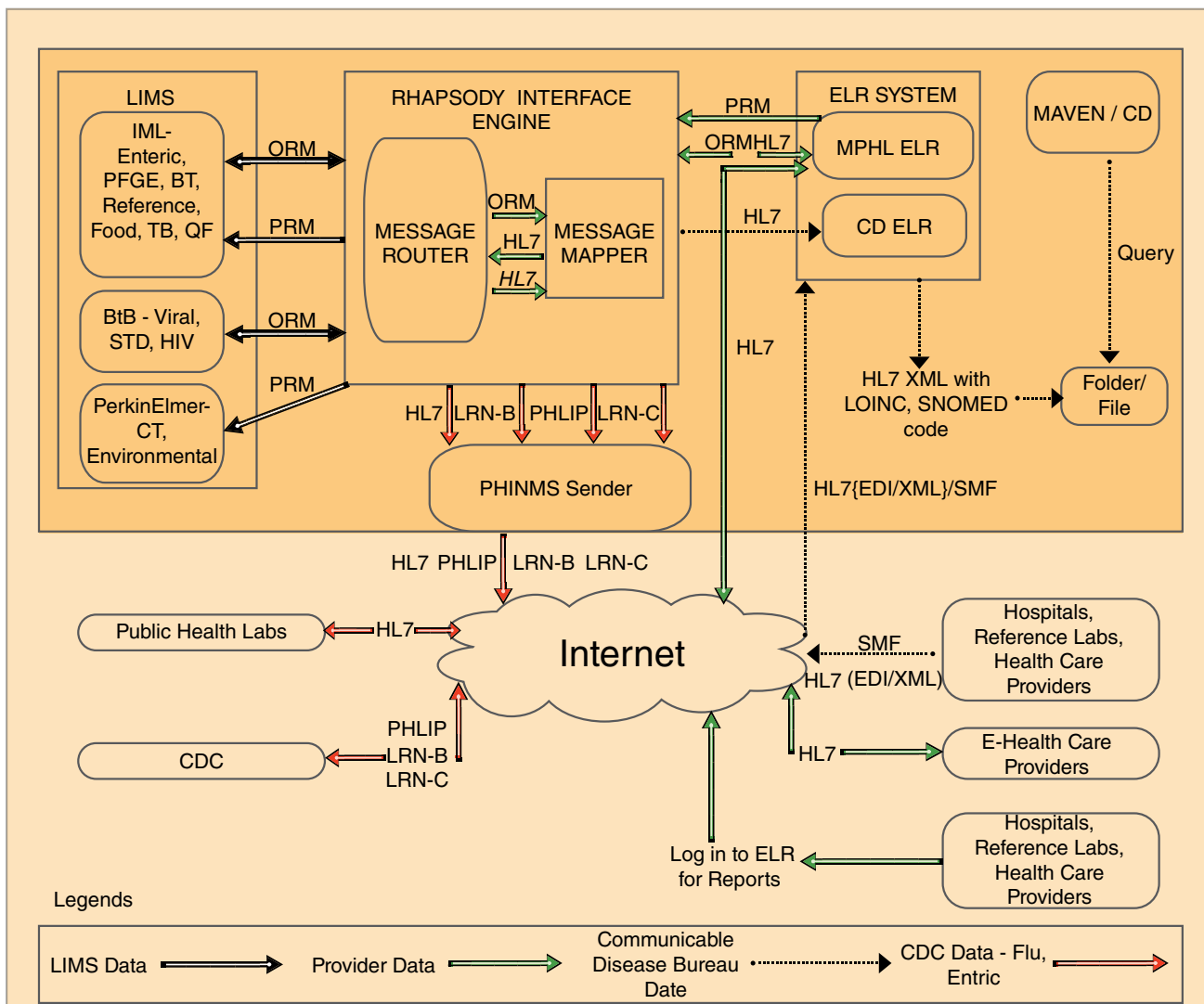
⁹Because updates have been tested already, laboratory staff can perform the restart at a convenient time.

¹⁰One advantage of having trained laboratory analysts involved at the system admin level is the ability to configure the LIMS to meet laboratory needs. The learning curve may be steep and require a serious time commitment, but will likely pay off in the end with a highly-functional system.

Other Notes:

1. Data entry occurs in batches, so outputs can be ordered by batch and include QC data such as sample type (blank, spike, duplicate, etc.), expected values can be entered to allow a percent recovery to be calculated for spikes, analysis end time and preparation times can be reported to the second. Reporting should be able to meet APHL requirements for EDDs.
2. QC samples have unique test codes, not sample numbers. The associated number relates to the data back to the QC batch.
3. The Department automates all current LRN-C messaging directly from their LIMS.
4. The Department uses Crystal Reports¹¹ to map data from the instrument and LIMS to the LRN message.
5. The IT Department prefers to move the LRN-C out of RM and use Rhapsody to create an LRN-C HL7 message, and send it to the CDC using PHINMS¹². Alternatively, LRN-C data is delivered to CDC using PHINMS in csv format. LIMS LRN-C data can be located through BatchID and EventID and sent like LRN-B. The fact that LRN-C has such few data elements makes this task even more manageable.

Figure 1: An Example of Data Flow for a State System that Integrates LRN-C, LRN-B, and Infectious Disease Reporting



¹¹Crystal Reports is a business intelligence application used to design and generate reports from a wide range of data sources

¹²Public Health Information Network Messaging System

Informatics Competencies and the Laboratory

Informatics competencies and capabilities remain distinct components of a laboratory's ability to meet current challenges, and to participate effectively in a changing environment. Modern-day competencies of laboratorians and IT partners describe a growing and diverse set of skills. Without training in informatics, laboratories cannot meet current and future needs in public health.

To achieve appropriate functional requirements, the modern-day laboratory may need to draw support from multiple sources. These can be within the laboratory, departmental IT resources, dedicated IT resources within the laboratory, a consolidated/shared pool of IT resources, vendors and private/public sector support groups. Regardless of the source, resources fit into five core groups (see Table 1).

Table 1: Laboratory Informatics - Functional Requirements - Core Groups

1. LIMS Business Processes
2. Software Support (in addition to LIMS)
3. Hardware Support
4. Data Exchange
5. IT Governance and IT Laboratory Support

Addressing each of these functional groups requires personnel with unique informatics capabilities. Actual personnel classifications remain diverse and cover a large range of technical specialties. For example, a CSTE Electronic Laboratory Reporting (ELR) Workgroup¹³ recently identified IT specialties required to assist in ELR implementation.¹⁴ Such classifications reside both within and outside the laboratory, although typically they reside outside the laboratory, in IT 'shops'.

Informal discussions with the APHL Informatics Committee suggest that success in meeting functional requirements strongly increases as IT staff better understands laboratory operations. For example, many laboratories achieve informatics capability through staff scientists transitioning to informaticians. Consequently, in many laboratories, a new classification is emerging, the hybrid Laboratorian/Informatics Specialist.

Laboratory informatics competencies can be grouped into four distinct classifications, with the last two considered full-time informaticians (see Table 2).

Table 2: Laboratory Informatics Personnel Classifications

1. Informatics-Scientist I (<50% FTE)
2. Informatics-Scientist II (<50% FTE)
3. Informatics Specialists (>50% FTE)
4. Informatics Manager/Laboratory Informatician (>50% FTE)

Some IT departments may consider certain duties beyond the reach of a laboratory hybrid. The APHL Workforce Development Committee is developing a comprehensive listing of specific competencies associated with laboratory informatics within existing laboratory classifications. Included in this listing of laboratory classifications are those listed in Table 2.

¹³Developed by the Council of State and Territorial Epidemiologists (CSTE) and the Centers for Disease Control and Prevention (CDC) Electronic Laboratory Reporting (ELR) Task Force, 2011.

¹⁴ELR-specific specialty titles include: Project manager / director, Program Sponsor, Program Manager, Info Systems Support Specialist, Systems Analyst, Programmers, Business Analyst, Data Analyst, Database Administrator (DBA), Integration Analyst, IT Program Manager, Developer (IT), Informaticist, NEDSS Coordinator, Data Modeler, ELR Coordinator, Network Security, Quality Assurance Tester, Surveillance System Manager, and Trainer.

Policies and Practices

In many jurisdictions, laboratory participation in informatics may be changing as centralized (or shared) IT services become more common. IT centralization may increase efficiency in some areas, reduce costs, and enable the laboratory to access equipment or services that were previously unaffordable. However, caution remains important because informatics requirements in a laboratory are often not well understood by traditional IT departments. While a clear path to success does not exist, laboratories remain cautious that when undergoing such a change the following risks await: poor implementation choices, insufficient communication among partners, and weak management structures (all of which can increase costs and have disastrous effects on a laboratory's ability to fulfill its mission).

The APHL white paper "The Brave New World of Consolidated and Shared IT Services: A Guide for Laboratories"¹⁵ provides guidance to identify, distinguish, and negotiate components of operational agreements to successfully employ consolidated IT services. It equips laboratory leaders to serve as effective advocates for their organization to maximize the upside, and minimize the downside, of IT centralization.

One noteworthy tool presented in the white paper, **data governance**,¹⁶ relies on continuous business analysis to improve IT operations. Just as assays change more quickly than testing platforms, data systems analysis models change more quickly than installed software.

Another tool, **shared IT services arrangements**, can take many forms. One approach involves focusing first on the totality of the laboratory IT infrastructure (more than just the LIMS). No matter the approach, before any IT negotiations begin, the following activities should occur:

- Identify IT leaders and their priorities
- Plan to explain the work of the laboratory
- Document the laboratory business case
- Identify costs
- Segregate services that must be managed locally
- Identify risks
- Plan for handoffs
- Participate in IT governance

Memoranda of understanding (MOUs) and service level agreements (SLAs) serve as the two major forms of shared service arrangements. They document the IT activities necessary for successful laboratory operations. IT and laboratory leaders use these to communicate and document the costs, risks and metrics of laboratory IT services. Such documents must convey the importance and functions of laboratory services, and be written in the language of the IT professional, with clear business case models.

The MOU, discussed on the next page, remains the more general of the two and defines the role of each of the governmental partners. The SLA, which is not addressed in depth in this document, remains more granular and presents the details of IT delivery, including a funding model for laboratory technology initiatives and infrastructure. The SLA also generally includes metrics to define acceptable outcomes, as well as the risks associated with failure to comply with the terms of the agreement. A critical component of both the MOU and SLA remains the approval page, which must be signed by high-ranking organization representatives.

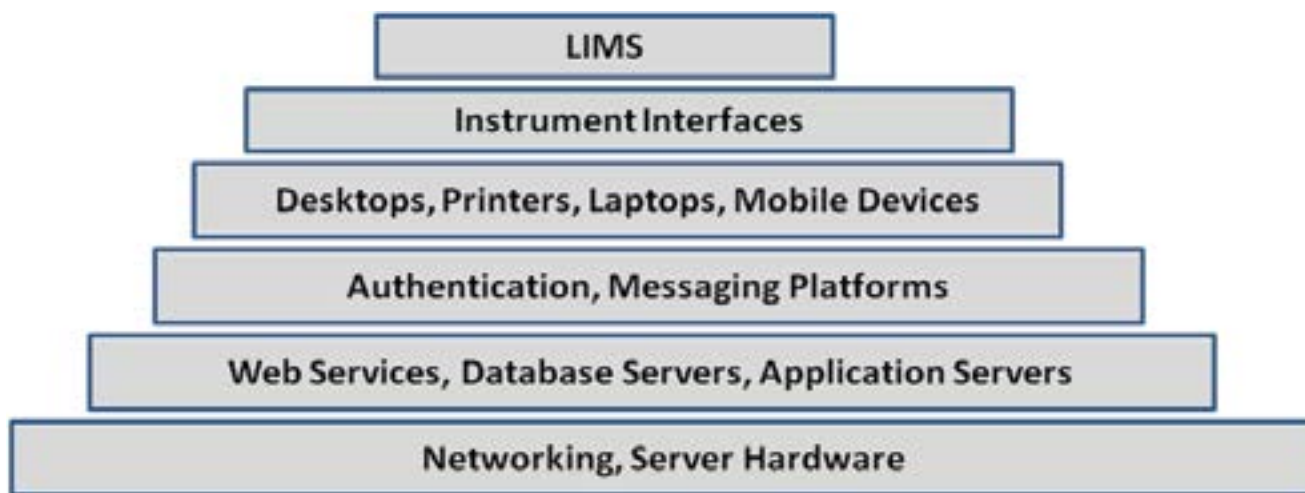
¹⁵http://www.aphl.org/AboutAPHL/publications/Documents/COM_2011_ITConsolidatedandSharedServices.pdf

¹⁶An emerging discipline focused on the formal management of data assets throughout an organization.

Modern governmental laboratories require a variety of IT technologies. Some of these, such as laptop computers and budgeting software, will be familiar to IT leaders outside the laboratory. Others, such as computerized analytical instruments and instrument interfaces, are specific to the laboratory, unfamiliar to most IT professionals. Needs associated with these technologies and services must be explicitly discussed. Figure 2 provides a summary of essential laboratory IT technologies.

Once the MOU and SLA are in place, continued dialogue and negotiation are essential to provide feedback on implementation, to maintain a close working relationship with IT managers, and to offer guidance for the future.

Figure 2: The Laboratory's Multi-tiered, Physical IT Infrastructure



MOU Provisions

Although each laboratory operates within a unique political and business environment, there exist some vital, common needs that every laboratory leader should consider incorporating into an MOU:

1. Prioritizing the LIMS as a critical adjunct to laboratory instruments, and a core component of the laboratory infrastructure.
2. Prioritizing the need for dedicated application-level LIMS support.
3. Assuring 24/7 on-site IT support.
4. Assuring authority for the laboratory to manage instrument vendors.
5. Addressing security clearances and protection of personal identifiers in laboratory data.
6. Defining partnerships with high visibility agencies that have a governance role in IT affairs.
7. Prioritizing IT support for emergency response activities.
8. Assuring oversight and project management at the laboratory level.

Standardized Electronic Data Deliverable

In this age of increased electronic communication, it is common for multiple data users to request laboratory data as an electronic data deliverable (EDD). Reporting EDDs saves laboratorians time by sending data directly from a LIMS, minimizing and possibly eliminating manual data entry. Additionally, EDDs reduce transcription errors and speed up data delivery in a secure manner. For the data user, EDDs save time by standardizing the data collected from multiple laboratories, sometimes using multiple analyses. It also allows the use of automated data review software to approve and share data. Overall, EDDs minimize the need to harmonize and cleanse data.

Unfortunately, local, state and federal agencies possess different reporting requirements and systems, including unique EDDs with unique data elements and inter-relationships. The existence of multiple EDDs places a large burden on laboratories, and reduces the ability of laboratories to network and integrate information. Even within agencies, there can be multiple technical implementations of a data standard. Ultimately, support of multiple data deliverables, may result in slower reactions to public health threats, possibly increasing morbidity and mortality.

A standardized EDD often provides more than just analytical results, demographic and metadata. The EDD can also provide data useful for the validation of results. For example, the LRN-C EDD includes information about the analytical method for which the PHL has demonstrated training and proficiency, instrument hardware and software, and typically three proficiency level tests. Unfortunately, other federal programs (EPA ERLN) may not accept LRN-C's EDD as sufficient for validation, due to limited quality control data. Likewise, the LRN-C might not accept data from another federal program if the method, instrument, instrument software, and training do not meet stringent CDC requirements. The LIMS¹⁷ EDD may be foreign to local, public health jurisdictions and is not standardized across programs or agencies.

This lack of interagency standardization of analytical results compromises surge capacity during a large event. Agencies can accept and validate data interoperably within their various networks, but not outside of the network. The more comprehensive an EDD collects and presents key data elements, the more ability the EDD has to support multi-agency interoperability. This EDD need not be used in normal communications with all partners, but the ability of a LIMS to produce an EDD with a standardized comprehensive list of data elements may serve important needs during an emergency or surge.

APHL's Environmental Health Committee, Environmental Laboratory Subcommittee, and Informatics Committee proposed a granular-level EDD with a standardized, defined list of data elements and their associated data structures and components.¹⁸ This EDD is agnostic with regard to method, matrix, or governmental program. Two EDD data deliverables and their associated data elements are defined. The "Type 1t" remains transitional, includes a limited set of data elements, and is reported as a spreadsheet. The "Type 2" includes an expanded set of data elements and is reported as an xml file. Appendix 2 provides a short summary of the EDD's Data Exchange Template.

Over time, APHL envisions vendors able to provide such an EDD to laboratories that are replacing or updating their LIMS and to federal, state and local agencies adopting this EDD. Ultimately, as federal, state, and local agencies make changes to reporting requirements, APHL envisions that standardization will improve interoperability and increase efficiency both for data reviewers and generators.

¹⁷During a large-scale emergency, the local public health system requires data not collected by CDC's Results Messenger (RM) system, such as demographic data, metadata (e.g., an individual's location relative to the event) and quality control data. LIMSⁱ, on the other hand, utilizes a fully-functioning LIMS, and supports a pathway of analytical test reporting more consistent with the need to provide data consumers with a full spectrum of data. Given this, the focus of this section is on LIMSⁱ.

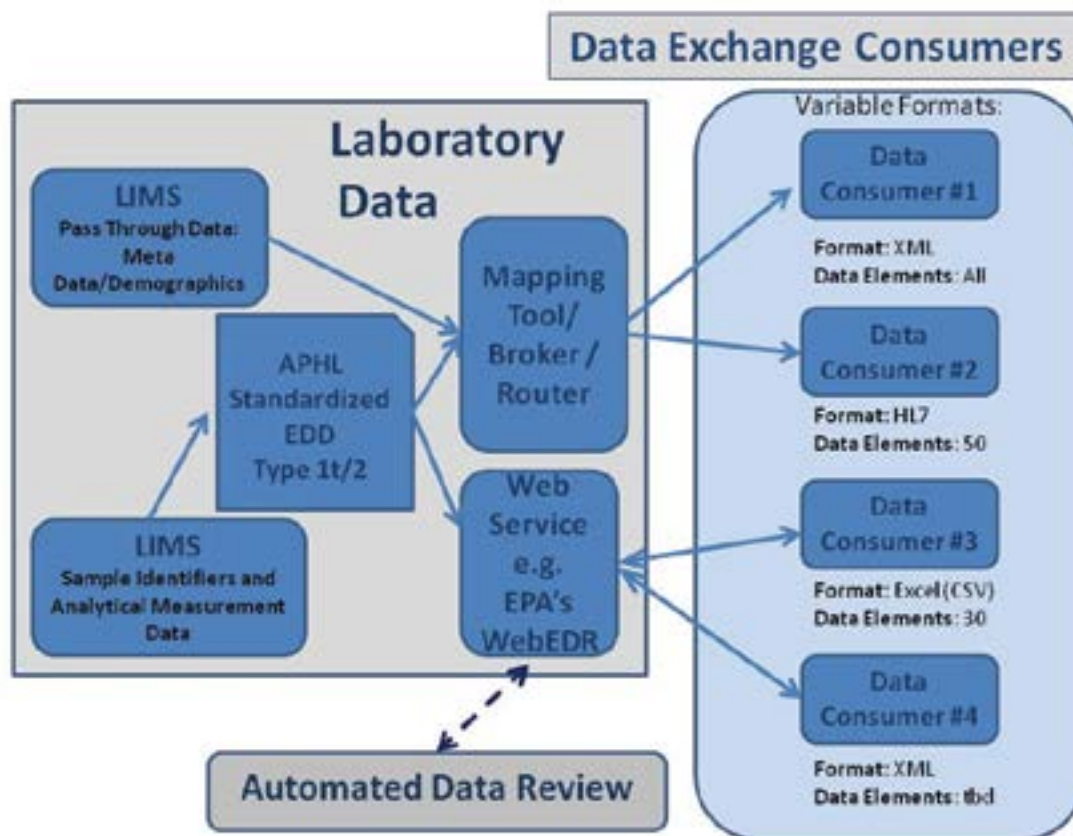
¹⁸Requirements for Environmental EDD Submissions: http://www.aphl.org/AboutAPHL/publications/Documents/EH_2012May_Requirements-for-Environmental-Electronic-Data-Delivery-Submissions-Report.pdf

Figure 3 illustrates the relationship of the APHL EDD to a LIMS and multiple electronic data output options. The LRN-C output can be viewed as one of these data consumer outputs. First, the LIMS should collect the raw and quality control data from the analytical instrument. From there, a standardized EDD allows analytical data (data uniquely created by the laboratory) to be organized using a comprehensive list of data elements and structures. Data not created by the laboratory, called “pass-through” data¹⁹, is stored easily in a LIMS and can be merged with the laboratory data using mapping software. Mapping software facilitates standardized EDD delivery to multiple data consumers, each with unique reporting requirements.

A standardized EDD also facilitates automated data review (ADR) associated with data validation. ADR can replace often-laborious manual review that assures that data are of known quality. Confidence in data quality is essential for the decision-making process, supporting regulatory enforcement, litigation, and policies regarding human health and safety.

A review of the LRN-C RM and the proposed LIMS LRN-C LIMS Configuration Requirements suggests that LRN-C laboratory data requirements are indeed a subset of the APHL EDD. Data that is reported to the LRN-C is Batch ID Centric. In this case, some three PT samples (high, medium, and low) samples and results are included in a specified batch of sample results. If the APHL EDD is utilized, mapping software (inexpensive) is necessary to transform the APHL EDD to the LRN-C deliverable. Examples of mapping functions include valid values (e.g. specific allowed values for matrix, Agent, unit of measure) and data element names (e.g. specific names and formats of analyte result, analyte, run date). If HL7 messages are requested, there are benefits from the use of an integration broker, which many of the SPHLs possess as part of their LRN-B program.

Figure 3: Relationships of LIMS, EDD, and Data Output Options



¹⁹Modern environmental LIMS can typically collect and store significant amounts of data, which exist in two forms. One, analytical measurements and data to support those measurements requires a great deal of programming and development because complex relationships must be made between database tables containing metadata and quality control data. The second is what is referred to as “pass-through data” which is data that the laboratory does not generate, but needs to enter in “side-tables” available to pass through to laboratory reports.

Conclusion

Many laboratories face the challenge of survival as never before, while governments grapple with greater community expectations with fewer resources. These challenges provide an opportunity to excel, adapt, and change as necessary. APHL recognizes the importance of informatics as a critical component of public health laboratory operations, the delivery of services, and as a contributing factor to future success, especially to the LRN-C. Several themes emerged from this research.

- LRN-C laboratories prioritized limited financial resources to assure analytical capability. This includes high quality instrumentation, availability of standards and reagents, and a trained workforce. Financial resources can barely support this analytical capability.
- Standardization for LRN-C is primarily limited to analytical capability—this standardization of method, instrument versions and software, and training is the backbone for LRN-C interoperability. Due to the fact that such strong standardization exists, there is no need to collect other quality control samples that would support more universal data validation. As such, this interoperability is limited to the LRN-C and may not lend itself to inter-agency interoperability, during a surge event.
- The LRN-C RM approach is perhaps the least expensive model for data collection and transfer and has achieved wide-spread success for the transfer of limited data with or without a LIMS.
- LIMS_i for LRN-C represents an important step forward in standardization and interoperability of LRN-C data. Further progress will benefit from beta testing and also a more uniform approach to informatics planning within states. Examples of such planning include:
 - o LIMS vendor groups established for all major LIMS vendors,
 - o Communication between the laboratory director & IT director regarding the availability of core functional informatics support,
 - o Recommended templates for MOU and SLA between laboratories and state information managers,
 - o Increased knowledge transfer between LRN-B and LRN-C (e.g., use of integration brokers, learn from experiences with LRN-B messaging, vocabulary, and transport),
 - o Continued partnerships with LIMS vendors with a goal to standardize delivery of key data elements that support LIMS_i,
 - o Inclusion of modern-day informatics competencies within laboratories, and
 - o Provision of a blog, website, or conference calls to discuss approaches to networking and workarounds (e.g., the mouse jiggler in the call-out box above) to assist laboratorians with state-wide area network requirements.
- LIMS vendors can support a standardized approach to electronic data delivery that is agnostic to matrix, method and program, but they need customers requesting such a universal approach. LIMS vendors make money supporting multiple reports, while funding agencies tend to be parochial in defining program-specific unique standards.
- Very few similarities exist between individual laboratory informatics models.
- With rare exception, few MOUs or SLAs exist between state laboratories and state information managers.

Overall, findings reinforce that LIMS implementations and interoperable data exchange depend upon appropriate resources (both funding and staff), as well as competencies. However other issues also remain relevant, such as: provision of information technology (IT) services in the age of consolidation, networking, security, and laboratory participation in IT management. The gaps identified included barriers to (a) LIMS implementations, (b) integration of laboratory instruments and collection devices, and (c) automated delivery of LRN-C data to the Centers for Disease Control (CDC). Recommendations for ways to bridge these gaps included:

1. Use of an independent laboratory-wide “sub” network within the larger state or local IT-networked domain.
 2. Automate data flow within the laboratory.
 3. Develop and maintain the necessary informatics competencies within the laboratory.
 4. Implement policies and practices to promote improved communication and service-level support between the laboratory and IT authority.
 5. Configure your LIMS to adopt standardized electronic data outputs.
-

Appendix 1: LRN-C Informatics February 2012 Survey Results

Question 2: Would you like to be contacted for a more in depth discussion of LRN-C IT issues?		
Answer Options	Response Percent	Response Count
Yes	54.20%	26
No	45.80%	22
Comments:		10
answered question		48
skipped question		0
Question 3: Many laboratory instruments require a dedicated computer to manage the instrument, collect data and perform calculations. Please provide answers below to instruments that support the LRN-C: Please select all that apply.		
Answer Options	Response Percent	Response Count
Your instrument computers are networked and must comply with IT network standards	30.00%	12
Laboratorians have the necessary independence and support to assure instrument computers can operate according to the instrument manufacturers needs	80.00%	32
If your instrument computer is networked, are operating system and software patches automatically uploaded without your permission?	12.50%	5
If your instrument computer is networked, does your computer time out even when samples are being analyzed?	5.00%	2
These instrument computers can utilize the operating systems supported by the instrument manufacturer	80.00%	32
IT networking requirements do not compromise your instrument computer functions	35.00%	14
Laboratorians have authority to work directly with instrument vendors to maintain instrument computers	90.00%	36
Comments:		21
answered question		40
skipped question		8

<p>Question 4: Do you have a modern LIMS capable of managing and tracking your clinical chemical laboratory activities? We are also interested to hear your comments regarding limitations with your LIMS or LIMS support of the LRN-C. [As an example a modern LIMS can be roughly defined as one that supports the follow general 16 business practices. You are NOT being asked to respond to each of these business practices-they are only examples.]</p> <ol style="list-style-type: none"> 1. Laboratory Test Processing (Clinical and Environmental), i.e. Receive/Process Test Orders 2. Test Scheduling 3. Proactive Specimen/Sample Collection (Pre-Scheduled Tests) 4. Specimen and Sample Tracking/Chain of Custody 5. Media, Reagent, Stains, Control, etc. Manufacturing 6. Inventory Control Including Kits & Forms Management 7. General Laboratory Reporting, i.e., Report Test Results 8. Statistical Analysis and Surveillance 9. Billing for Laboratory Services 10. Contract and Grant Management 11. Training, Education and Resources Management 12. Laboratory Certification/Licensing 13. Customer Concerns/Suggestions 14. Quality Control and Quality Assurance Management 15. Laboratory Safety and Accident Investigation 16. Laboratory Mutual Assistance/Disaster Recovery 		
Answer Options	Response Percent	Response Count
Yes	60.50%	26
No	39.50%	17
Comments:		28
answered question		43
skipped question		5
<p>Question 5: Does your LIMS vendor or developer provide workgroups to assure LIMS support for your clinical chemistry laboratory consistent with other LRN-C laboratories?</p>		
Answer Options	Response Percent	Response Count
Yes	22.50%	9
No	77.50%	31
Comments:		22
answered question		40
skipped question		8
<p>Question 6: Does your LIMS provide and/or support data capture utilities (or interfaces) to automate the delivery of your clinical chemistry instrument data to your LIMS?</p>		

Answer Options	Response Percent	Response Count
Yes	52.50%	21
No	47.50%	19
Comments		23
answered question		40
skipped question		8
Question 7: Does your LRN-C LIMS provide the capability to automatically review your clinical analytical data, associated quality control data, and tracking information prior to reporting out of your laboratory?		
Answer Options	Response Percent	Response Count
Yes	36.80%	14
No	63.20%	24
Comments:		18
answered question		38
skipped question		10
Question 8: Is your laboratory LIMS capable of the following? Please select all that apply.		
Answer Options	Response Percent	Response Count
Capable of storing instrument results	60.00%	21
Capable of storing metadata and demographic data associated with LRN-C specimens	77.10%	27
Capable of storing quality control data	62.90%	22
Capable to report data as an electronic data deliverable to CDC and other public health partners.	65.70%	23
Comments		24
answered question		35
skipped question		13
Question 9: Is your LRN-C LIMS able to automate electronic data exchange with the LRN-C and send required data elements/results directly to Result Messenger (RM)?		
Answer Options	Response Percent	Response Count
Yes	23.70%	9
No	76.30%	29
Comments:		22

answered question		38
skipped question		10
Question 10: Does your IT Department provide the following support to your laboratory? Please select all that apply.		
Answer Options	Response Percent	Response Count
24 x7 IT staff available for emergency support of your laboratory	40.00%	16
Dedicated application level LIMS support	50.00%	20
Partnering with Laboratory Staff to manage vendors	50.00%	20
Security clearances and protection of personal identifiers in laboratory data	57.50%	23
Defined partnerships with high visibility agencies within your state and/or local government to assure that the laboratory has a role in IT governance	22.50%	9
Oversight and project management at the laboratory level	60.00%	24
Administrative rights to the laboratory to manage key LIMS operations	70.00%	28
Comments		14
answered question		40
skipped question		8
Question 11: Does your laboratory leadership have a signed memorandum of agreement (MOU) or a service level agreement (SLA) with your jurisdiction's IT leadership that specifically defines support for IT functions?		
Answer Options	Response Percent	Response Count
Yes	26.50%	9
No	73.50%	25
Comments:		18
answered question		34
skipped question		14
Question 12: Many LRN-B laboratory data exchanges have utilized modern broker tools (e.g. Orion Rhapsody, MIRTH etc) and staff trained to use these tools to map your LIMS data elements, provide vocabulary harmonization, and transport messages. Will your LRN-C laboratory have access to such tools and staff?		
Answer Options	Response Percent	Response Count
Yes	55.00%	22
No	45.00%	18
answered question		40
skipped question		8

Question 13: Please provide any informatics solutions that you wish to share. [As an example of a workaround to reduce the burden of networking compliance requirements (such as automatic updates and timing out) some states keep their instruments off of the jurisdiction network and have a smaller network (sometimes sneaker net!) for inputting instrument data to a fully networked LIMS.]		
Answer Options	Response Count	
	15	
answered question	15	
skipped question	33	
Question 14: Please provide any additional comments you wish to share.		
Answer Options	Response Count	
	10	
answered question	10	
skipped question	38	

Appendix 2: APHL Environmental Electronic Data Deliverable

APHL developed an Electronic Data Deliverable and published a data exchange template entitled “Requirements for Environmental Electronic Data Delivery.” The document defined a universal EDD: one that supports the varied data requirements of multiple agencies such as EPA (including its multiple program offices), CDC, FDA, and others. After reviewing multiple EDDs used to represent environmental data, APHL believes this particular model is the most modern and comprehensive. The proposed EDD is: based on accepted standards, flexible and capable of meeting emerging standards. Components of this goal include:

- The EDD focuses on a set of discrete data elements and their relationship to each other, i.e. how they relate to the collection of analytical measurements (e.g., the analytical sequence). As an example, by collecting the time of a preparation step for each analyte and sample type, the reviewer can compare this time to sample login time and assure that preparation took place in a timely fashion.
- The EDD does not negate the ability of multiple agencies to receive data in their individual, unique reporting formats. Figure 3 in the document illustrates that various reporting formats of electronic data messages can be tailored from the data elements. Standardization allows EDDs with fewer data elements to be easily mapped.
- The use of XML allows the creation of relationships between data elements.
- The EDD focuses on those data elements generated by the laboratory. While associated demographic and metadata remains important, it also remains very program-specific and does not lend itself to standardization. However, this data can be linked to the laboratory data via reference numbers. For example, many environmental agencies manage metadata through a separate data delivery. This data is often referred to as “pass-through data.” The referenced Figure shows this “pass-through data” separately, as this data is typically much simpler to store and retrieve from a LIMS, compared with the interwoven measurements data.
- The EDD comprehensively manages quality control data/measurement quality objectives (MQOs). Collection of quality control data allows results to be validated against measurement quality objectives and promotes accountability.
- A standardized EDD facilitates the use of automated data review (ADR) and validation. Many data consumers may not wish to see quality control data or MQOs, but appreciate knowing that the data was validated. For example, EPA’s WebEDR provides a web service to upload and perform ADR review both within the laboratory and by a reviewer.
- Lastly, the APHL EDD schema allows new measurements to be added on the fly without the need to edit the data type definition (DTD).

²⁰Many relatively inexpensive third-party tools and data brokers can convert one message type to another, so long as the data elements exist in both messages.

²¹MQOs are defined as specified performance criteria used in a sampling and analysis plan and may include evaluation of quality control data for completeness, sequence, frequency, correctness, and limits. The process for collecting this inclusive set of data is referred to as the “analytical sequence”. By linking MQOs to target results for field samples, the data reviewer adds accountability to the data set. While certification and accreditation provide evidence of capability at some point in time, MQOs provide direct accountability to the actual data set. This accountability is particularly useful during surge or when standardized testing may not be available or there are new variables.

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