

Lab Interoperability Cooperative (LIC) Final Report

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“Recovery Act” Standard and Reusable Solutions for Hospital
Laboratory Submission of Reportable Laboratory Results to
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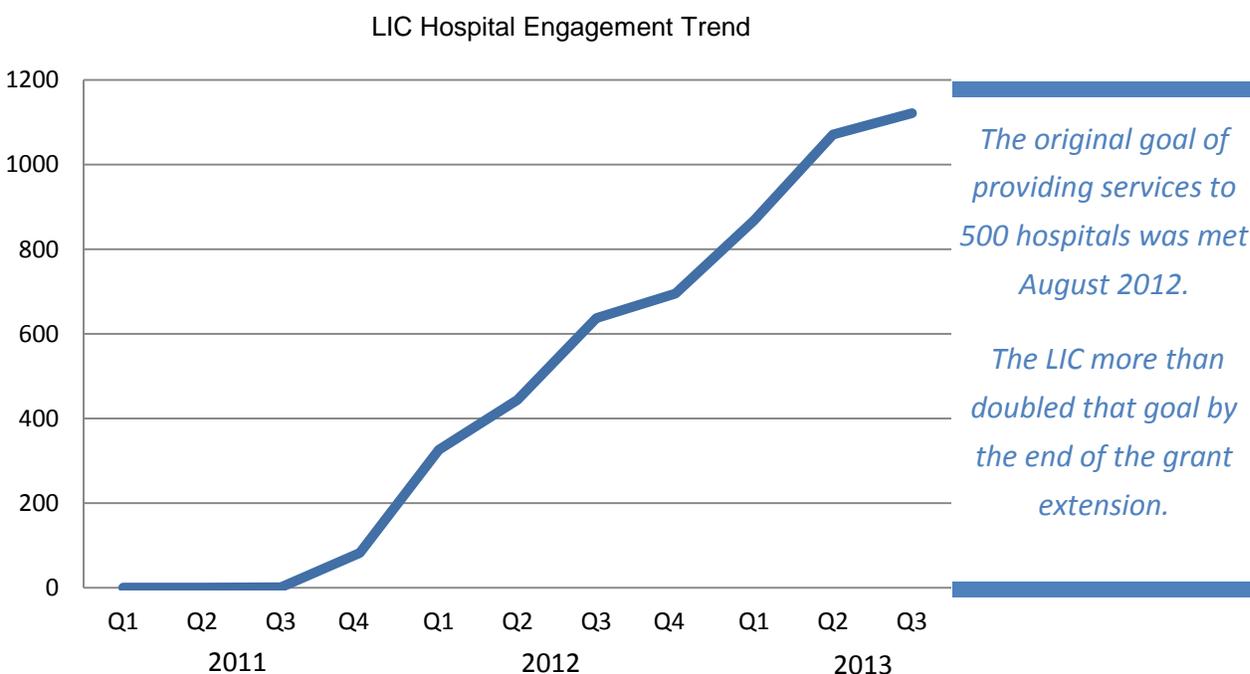
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Executive Summary

On February 1, 2011, the **Lab Interoperability Cooperative (LIC)**, convened representatives from the American Hospital Association (AHA), the College of American Pathologists (CAP), and Surescripts to collaborate on providing an array of services to hospital laboratories to enable submission of reportable laboratory results to Public Health Agencies (PHAs) as defined in the Meaningful Use (MU) final rules. The first deliverable under the two year grant was the recruitment of a minimum of 500 hospital laboratories, of which 100 were Critical Access (CAH) or Rural hospitals, within six months of the beginning of the grant. The LIC recruited 1,200 hospitals within the expected timeframe.

The following graph highlights the delivery of LIC services to hospitals electing to receive the services throughout the program lifecycle and how the LIC reached more than double the expected hospital laboratories target.



The LIC applied for and was granted a no-cost extension allowing the program to continue for an additional eight months through September 2013. This extension allowed the LIC to provide services to an additional 428 hospitals. This was a 62% increase from the 693 hospitals the LIC had engaged at of the original grant end date of January 31, 2013.

This report provides information about the outreach and recruitment approach, education strategy, and technical assistance support provided to hospital laboratories. Significant value was received by the hospital laboratories, through access to subject matter experts in the areas of (1) terminology education and (2) technical assistance for connectivity and transport of ELR transactions from the hospital to the appropriate PHA. The LIC program had a positive impact on promoting and improving interoperability between hospitals and PHAs.

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Purpose

In February 2011, the United States Department of Health and Human Services (HHS) Centers for Disease Control and Prevention (CDC) launched a program entitled “Recovery Act” Standard and Reusable Solutions for Hospital Laboratory Submission of Reportable Laboratory Results to Public Health Cooperative Agreement Program, commonly referred to as the Lab Interoperability Cooperative (LIC). As stated in the grant documents the purpose of the program was to provide assistance to organizations with membership that includes healthcare stakeholders and to focus on leadership for optimal use of Health Information Technology (HIT) (including laboratories) in support of patient care and Public Health Agencies (PHAs). This included providing an array of services to hospital laboratories to satisfy the Stage 1 Meaningful Use (MU) objective to submit electronic data on reportable laboratory results to PHAs.

Hospital Laboratory Information Systems (LIS), hospital interface engines, and information exchange hubs contain information on laboratory results that are reportable (as required by state or local law) to PHAs and could fulfill reporting requirements for the hospital (and associated physicians) if structured lab results could be submitted to PHAs. Support was needed for technical assistance to hospitals and its laboratories to understand and implement. This included changes to the LIS and/or interface engines, integration or other mapping services, and other associated technologies necessary to achieve MU of reportable laboratory results. This funding supported the LIC with the ability to identify and coordinate expertise in outreach and recruitment, education and technical assistance programs.

LIC Management and Organization

As a whole, the LIC included staff experienced in hospital and laboratory outreach, standardized terminology, functional interoperability, health information exchange, laboratory system interface engines, Electronic Health Records (EHR), LIS technology, implementation, and project management.

Member Organizations

The LIC assembled subject matter experts from the AHA, CAP, and Surescripts. Surescripts was the lead awardee and responsible for overall project management and program outcomes. In addition, Surescripts provided technical assistance and education for hospitals related to connectivity and transport options that enabled transmission of reportable Electronic Laboratory Results (ELR) to the appropriate PHA. The LIC provided education and training for hospital laboratory staff that was:

- Coordinated and organized by the AHA, providing outreach and recruitment services to almost 5,000 hospitals in the United States which included more than 9,000 contacts, and
- Developed and presented by the nation’s foremost terminology experts from the CAP. CAP provided terminology education and best practices for Logical Observation Identifiers Names and Codes (LOINC®) and Systematized Nomenclature of Medicine - Clinical Terms (SNOMED CT®) mapping.

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Responsibilities of the LIC

The specific responsibilities of the membership organizations included the following services to hospital laboratories and associated hospital EHR and LIS systems:

1. Outreach and Recruitment of Hospital Laboratories

- a. Disseminated knowledge about the MU final rules and the test procedure to hospitals and hospital laboratories to encourage the selection of reportable laboratory results to PHA from the MU “menu set”.
- b. Developed requirements and qualifications for determining which recruited laboratories were to receive technical assistance.
- c. Defined Standard Operating Procedures (SOP) for support and assistance to the recruited laboratories.
- d. Recruited hospital laboratories (and their associated hospital EHRs/LIS) that were interested in PHA reporting.

2. Functional Interoperability and Health Information Exchange

Provided knowledge and expertise for implementation of interoperability solutions, enabling standards-based laboratory messaging between hospital laboratories and their associated PHAs to satisfy MU reportable laboratory results objective in accordance with the published final rules.

3. Implementation and Program Management

Provided end-to end project management support, to include individualized and on-site coaching, consultation, trouble shooting, and other activities required to assure the hospital or hospital laboratory can implement software and/or processes to achieve MU reportable laboratory results, ensure adequate training as necessary for staff and track and adhere to program timelines.

LIC Objectives

The goal of the LIC was to provide an array of services to hospital laboratories to enable submission of reportable laboratory results to PHAs as defined in the final rules. The specific objectives included the following.

1. Recruit a minimum of 500 hospital laboratories, of which 100 are Critical Access or Rural hospitals, must be accomplished in a maximum of six months.
2. Provide services to hospital laboratories beginning in a maximum of six months.
3. Demonstrate MU reportable laboratory results by performing at least one test of certified EHR technology’s capacity to provide laboratory data to PHAs.
4. Implement ongoing reporting to PHAs, where the health agencies have the capacity to receive the information electronically.

LIC Outcomes

The LIC established knowledge of functional interoperability and health information exchange, executed outreach activities to hospital laboratories, engaged Laboratory Information Systems

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(LIS), interface engines, and EHR technology vendors, as well as provided implementation and project management throughout the program. The LIC was expected to reach a minimum of 500 hospital laboratories (of which at least 100 CAH or Rural Hospitals) to implement electronic submission of reportable laboratory results to PHA using certified EHR technology.

The LIC provided assistance to healthcare stakeholders and helped focus hospital leadership for optimal use of HIT in support of electronically transmitting reportable laboratory results to PHA in order to meet Stage 1 MU criteria. The LIC developed solutions to securely transmit electronic data on reportable laboratory results from hospital laboratory systems, interchange engines and EHR systems to designated PHAs that complied with appropriate transaction standards for laboratory reporting resulting in interoperability between hospitals and public health agencies. Technical assistance was provided to hospitals and its laboratories to understand and implement the changes to LIS, EHR systems, and interface engines, including the addition of integration and other associated technologies necessary to achieve MU of reportable laboratory results.

The LIC encouraged hospital laboratories to become meaningful users of certified electronic health record technologies for submission of electronic data on reportable laboratory results to PHAs. The activities outlined in this program supported an information-sharing environment between clinical care and PHAs and supported the foundation for MU. The LIC complied with responsibilities as outlined in the grant by establishing, organizing and managing the LIC, and fulfilling reporting and communication functions as required. The services created by the LIC enabled hospitals to meet their objectives and become eligible for the MU incentive dollars available from the federal government.

Objective #1: Recruit a minimum of 500 hospital laboratories, of which 100 are Critical Access or Rural hospitals, within a maximum of six months.

Result: 1,200 hospital laboratories were recruited by July 15th 2011, resulting in 225% of objective met.

Hospital Outreach and Recruitment Process

The LIC was charged with performing outreach activities and recruiting a minimum of 500 hospital laboratories (100 of which were CAH or Rural Hospitals) by July 31st, 2011. The following processes were executed beginning in March 2011 that resulted in more than 1,200 hospitals being recruited and expressing interest in the program. The recruitment process was completed by July 15, 2011, meeting the expected deadline, and included the following activities:

- Announced the LIC at HIMSS 2011, in Orlando, Florida
- Conducted targeted meetings (focus groups) with:
 - AHA Small, Rural & Critical Access Constituency Section, Regional Executives, CEO Relations, Member Services, State Relations
 - Surescripts' Alliance Team
- Launched industry resource: www.labinteroperabilitycoop.org

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- Maximized AHA and CAP's processes and outreach ability to their respective members by reaching out to:
 - Hospital CEOs: 6,450 contacts
 - Hospital/Hospital System CIOs: 2,500 contacts
 - Hospital System CEOs: 425 contacts
 - Hospital Laboratory Directors: 8,000 contacts
- Leveraged Surescripts existing EHR relationships to communicate with the software vendors deployed in hospital settings. The top 9 EHR vendors were installed in 4,348 hospitals nationwide
- Performed an assessment to determine ELR readiness of each of the hospital and hospital systems responding to the outreach program (staff, systems and infrastructure)
- Coordinated with CDC for outreach to PHAs
- Determined prioritization of qualified participants

A summary of the 1,200 hospital responses received as self-reported information includes the following metrics:

Hospital Metric	Response Percent
Individual Facility	77%
Multi-facility Health System or Network	23%

From the overall responses, additional information was captured:

Hospital Metric	Response Percent
Critical Access Hospital Facility	24%
Rural Acute Care Hospital Facility	38%
MU Certified EHR	51%
LIS within a Hospital Facility Laboratory	94%
Laboratory Results Reported from an LIS to PHA*	29%
Laboratory Results Reported from an EHR to PHA*	12%

* Many hospital facilities reporting this metric were sending electronic data using then existing protocols and formats that did not meet Stage 1 MU requirements.

Hospital Laboratory Selection Criteria

During the early stages of the grant period, it became clear that there was a wide variation in hospital readiness. This was based on several factors including information system capabilities, lack of ELR knowledge, not selecting and/or prioritizing ELR as a Stage 1 MU menu item, lack of LOINC terminology mapping knowledge and capability, and hospital resources and budget. In order to meet grant timeline objectives, the LIC developed the following hospital readiness criteria which identified and prioritized those hospitals most ready to move forward with ELR activities.

- EHR /LIS was ONC-Authorized Testing and Certification Body (ONC-ATCB) certified based on the Certified HIT Product List (CHPL) <http://oncchpl.force.com/ehrcert?q=chpl>

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- EHR/LIS/Hospital financial and human resources available and dedicated to support implementation effort
- Public Health readiness (PH can accept MU certified reportable laboratory results)
- Public Health financial and human resources are dedicated and available to support implementation efforts

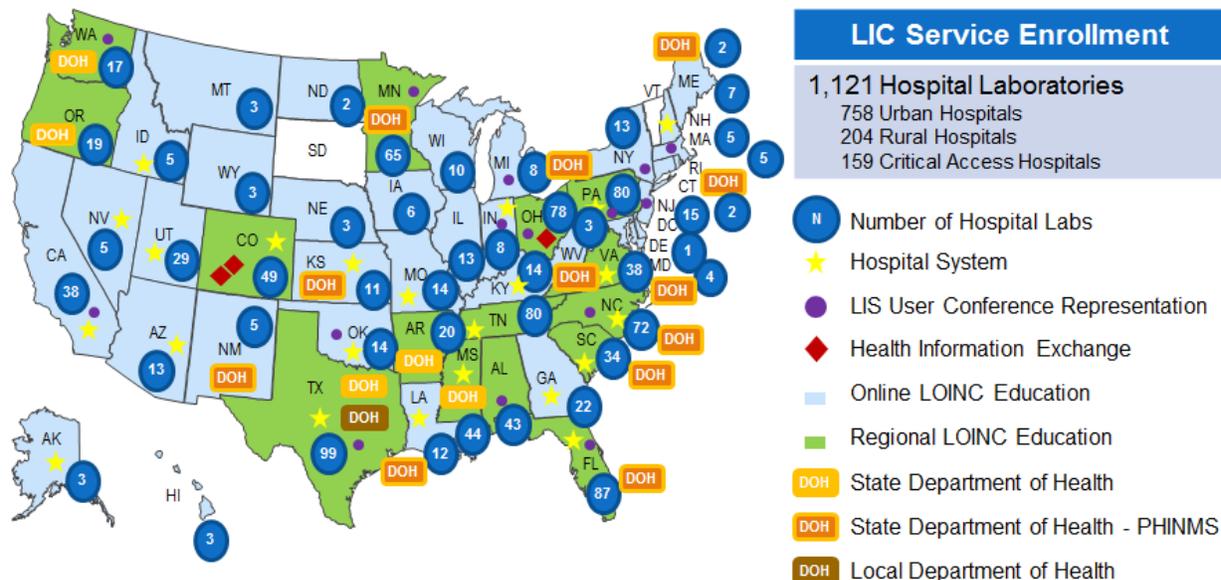
The LIC also developed Hospital Agreement Letters (HAL) which was used to engage and track hospital progress towards meeting ELR criteria. All LIC participants were invited to an education session (live or virtual) via email. Through a link in the invitation they were taken to the RSVP process where they provided their name, title, facility, email, phone number and selected which event they would like to attend. They would then complete the letter, sign it, and submit it either by uploading it to the LIC website or faxing it to the AHA. If the facility name appeared to be that of a health system instead of an individual hospital, LIC staff investigated to determine if in fact it was part of a system and contacted the person submitting the HAL to verify which facilities were included under the signed agreement letter. The event confirmation was sent out to the participant along with an event reminder prior to the event. Accounts were then created on the LIC website and user IDs and login instructions were emailed out to participants. Please refer to *Artifact 3: Hospital Agreement Letters* for an example of the letter used to track hospital engagement with the LIC.

The LIC also developed a system of metrics to successfully measure program performance by the hospital. Metrics reflected goals and objectives, milestones within the program management activities, and favorable/unfavorable progress. The metrics included hospital participants served, types and number of services provided to each participating hospital laboratory, and percent of participating hospital labs that satisfy MU for reportable laboratory results during the grant period. Please refer to *Artifact 6: Hospital ELR Progress Report* for additional information.

The LIC also coordinated with other federally funded HITECH programs including the HHS Health Information Technology (HIT) Extension Program and the Regional Centers Cooperative Agreement Program which is outlined in the Stakeholder Collaboration section of this report.

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As of September 30, 2013, 1,121 hospital laboratories, 363 of which were CAHs or Rural hospitals had engaged with, and received services from, the LIC. This outcome exceeded program expectations by achieving 224% of the overall program goal. A visual representation of the LIC outreach and activities across the country is illustrated below.



Objective #2: Services offered to hospital laboratories beginning in a maximum of six months.

Result: Services offered and available to hospital laboratories by July 15, 2011, meeting the expected deadline of July 31, 2011.

LIC Service Offerings

Guidelines

The LIC defined service offerings that accelerated hospital adoption of EHR/LIS technology for ELR using the following guidelines described in the grant documents:

- **Health Outcomes Policy Priority:** Improve population and public health
- **Stage 1 Objective (Eligible Hospitals and CAHs):** Capability to submit electronic data on reportable (as required by state or local law) laboratory results to PHAs and actual submission in accordance with applicable law and practice.
- **Stage 1 MU Measures:** Performed at least one test of certified EHR technology's capacity to provide electronic submission of reportable laboratory results to PHAs and follow-up submission if the test is successful (unless none of the PHAs to which eligible hospital or CAH submits such information have the capacity to receive the information electronically)

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- **Certification Criterion:** 170.306(g). Electronically record, modify, retrieve, and submit reportable clinical laboratory results in accordance with the standard (and applicable implementation specifications) specified in 170.205(c) and, at a minimum, the version of the standard specified in 170.207(c)
- **Content Exchange Standards:** 170.205(c). HL7 2.5.1 Implementation specifications: HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 (US Realm)
- **Terminology Standards:** 170.207(c). Logical Observation identifiers Name and Codes (LOINC) version 2.27

The LIC initially developed services based on CDC grant language described above. In order to appropriately address the needs of the industry, the LIC added services for:

1. **Public Health Agencies (PHAs):** Even though PHAs were described as out of scope for this program in the grant documents, and could not receive technical assistance from the LIC, it became apparent during the early stages of the outreach and recruitment efforts that close collaboration with PHAs would be necessary to fully meet the expectations of the grant.
2. **SNOMED CT®:** With the announcement of the Stage 2 MU final rules, additional services were developed to meet those requirements including SNOMED CT terminology education.

The following service offerings were developed by the LIC and made available to hospital laboratories beginning in July 2011.

Hospital Laboratory ELR Education

The LIC was charged with disseminating knowledge of Stage 1 MU final rules and encouraging hospitals to select an ELR as their menu option. When Stage 2 MU final rules were announced in August 2012, the LIC expanded education to include both Stage 1 and Stage 2 MU requirements, as well as adding SNOMED CT education related to ELR. The education developed consisted of the following components:

Education Topic	Description
Stage 1 MU, Stage 2 MU Roadmap and Stage 3 MU Overview Education	Overview of MU: PHA Reporting for Stage 1 MU and Beyond
LOINC and SNOMED CT terminology mapping education, mapping best practice guidance, tools and resources developed by the College of American Pathologists subject matter experts	<ul style="list-style-type: none">▪ Introduction and overview of LOINC▪ Guidance regarding the usage of the CDC's Reportable Condition Mapping Table (RCMT) and Regenstrief LOINC Mapping Assistant (RELMA) presentation▪ Guidance on mapping LOINC to data dictionaries presentation

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- LIC ELR Laboratory LOINC Mapping Best Practice Guidelines v 1.0
- LIC ELR Laboratory LOINC Mapping Table Template v1.1 with field descriptors
- SNOMED CT and ELR – LIC Best Practice Guideline

State Reportable Diseases and Conditions

Meetings were arranged in advance of the onsite LIC education sessions, between the CAP laboratory terminology subject matter experts and the applicable PHA staff.

PHA staff were offered time during the session to introduce themselves and to make a state-specific presentation to the workshop.

Information was obtained by CAP regarding current functions and preferences of the PHA (Please refer to *Artifact 4: Public Health Agency (PHA) Questionnaire.*)

Individual state and/or local PHA Reportable Disease and Conditions fact sheets were distributed with the LIC education materials.

Connectivity and Transport Interoperability Options

Connectivity and transport options available to hospitals were identified and described to participating hospitals. Options reviewed included:

- LIS vendor solution
- Health Information Exchange (HIE)
- Direct connect to PHA, and
- LIC network

The LIC did not promote, or require any particular option, but encouraged the hospital staff to engage their IT team with LIC experts as soon possible to evaluate how data would be delivered from the LIS to the PHA

Please refer to *Artifact 2: LIC Best Practices, Education and Toolsets* for additional information.

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The hospital participants were provided education through website education resources, conference calls, webinars and live workshop sessions. Details of each are included below.

- **LIC Website** (www.labinteroperabilitycoop.org). The LIC website was built with dual purposes – the public access pages were used to educate site visitors and potential participants about LIC services; and the LIC participant access pages were used to provide primary or reinforcement education to all participants. The tools and resources contained in the LIC Education Portal were developed to mimic the live education sessions so those participants without the opportunity to attend could still have the advantage of hearing from the subject matter experts ‘first-hand’. All participants were encouraged to share these LIC training resources with other colleagues throughout the laboratory and IT areas of their facility to help spread the knowledge deeper into the organization.

LIC Website (Public)	Participant Tools & Resources (User Code and Password Required)
<ul style="list-style-type: none">▪ LIC Mission▪ How to Participate in LIC Services▪ Upcoming LIC Schedule▪ Current Status of ELR▪ LIC News & Headlines▪ General FAQ	<ul style="list-style-type: none">▪ Terminology Education Library▪ Connectivity Resources▪ PHA Resources▪ Progress Tracking▪ Forums▪ FAQs▪ Help

Specifically, the LIC developed resources included a terminology education library covering MU, LOINC, SNOMED CT; and connectivity resources that outlined the steps and requirements for interoperability with PHAs. Additionally, participants had access to discussion forums, frequently asked questions (FAQs), PHA resources, and the ability to track their facility progress towards ELR. The resource library included the following collection:

- 57 instructional videos;
- 75 terminology mapping templates and presentation slides;
- 84 PHA documents and links collected from state and local public health departments; and
- 8 interoperability and connectivity templates and presentation slides.

At the time of this report, 1,752 users representing 1,121 hospital laboratories were utilizing the online MU, LOINC, SNOMED CT, connectivity and transport interoperability education, tool sets, and best practice guidelines. Please refer to *Artifact 1: LIC Website*: www.labinteroperabilitycoop.org for a detailed description of the LIC website.

- **LIC Live Workshop Educational Sessions.** Twenty six live educational workshop sessions were conducted in 14 states reaching more than 538 unique hospital facilities.

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Attendees from those facilities included over 881 hospital staff, 18 hospital association staff, 99 PHA staff and 49 Health Information Exchange (HIE) and Regional Extension Center (REC) staff. These sessions offered participants six hours of hands-on training and one-on-one consultation for hospital laboratory managers and directors, as well as hospital-based health information technology professionals to address questions they had specific to their hospital.

Topics covered included:

- Electronic Laboratory Reporting (ELR) Requirements
- Stage 1 and Stage 2 MU Requirements related to ELR
- PHA ELR Updates*
- LOINC Education
 - Background
 - Demonstration Using RELMA and RCMT
 - Hands-on Training
- SNOMED CT Education (abbreviated demonstration as relates to ELR requirements)
- Messaging and Reporting
- Post-Workshop Online Resources

* PHA representative(s) from local (state or city) jurisdictions were always invited and encouraged to attend workshop sessions. They were available at most sessions.

Feedback from these sessions was extremely positive. As of June 2013, 1,047 participants attended these sessions:

- 97% rated the sessions excellent or good and,
- 96% rated the materials very helpful

In addition to the education, participants found the live workshops were valuable as they interacted with peers from other facilities facing the same obstacles, and were also able to meet PHA representatives for the first time. Please refer to *Artifact 8: LIC Live Workshop Educational Session Summary* and *Artifact 9: LIC Live Workshop Educational Session Feedback Summary* for additional information.

- **LIC National Webinar Educational Sessions.** Fourteen webinar educational sessions were hosted over the duration of the grant period reaching more than 317 hospital facilities. This represents 488 hospital staff, 4 hospital association staff, 93 PHA staff and 14 HIE/REC staff. These sessions offered a condensed version of the live workshop sessions and were divided into two topics: terminology and interoperability. Of those who attended the webinar educational series, 57 were repeat participants from the live or virtual educational sessions.
- **LIC Connectivity Resources Webinar.** This was a virtual 30-minute session intended for hospital laboratory managers and directors, as well as hospital-based health

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information technology professionals. This session focused on the connectivity and transport aspects of ELR including a recap of the filtering and extraction of formatted results. This webinar discussed several ways a hospital laboratory can connect to PHAs such as:

1. A direct connection from the hospital to the agency
 2. An EHR/LIS proprietary solution
 3. An HIE
 4. The LIC Network
- **LIC Terminology Resources Webinar.** This fast-paced virtual workshop was a 2-hour online primer covering LOINC and a short introduction to SNOMED CT. This session was intended for hospital laboratory managers and directors, as well as hospital-based HIT professionals.

This webinar reviewed the following content:

1. LOINC demonstration using RELMA and RCMT
2. SNOMED CT (abbreviated demonstration as relates to ELR requirements)
3. Messaging and reporting
4. Post-Workshop On-line Resources

All of the 1,121 hospital facilities have access to online tools and resources for terminology mapping and interoperability. The LIC also processed 2,008 emails and 990 telephone calls from participants who had additional questions.

Objective #3: Demonstration of MU reportable lab results by performing at least one test of certified EHR technology's capacity to provide lab data to public health agencies.

Result: 242 hospitals sent a test transaction to their PHA using either their EHR/LIS, HIE or the LIC network. In addition the LIC also delivered ELR test transactions to 16 public health agencies using the LIC network.

Hospital ELR Technical Assistance

The LIC provided ELR interoperability expertise, consultation, training, and support to participating hospitals. Activities included readiness assessments, implementation, and production support. The LIC developed technical assistance service offerings that included the following processes:

- Developed Standard Operating Procedures (SOPs) and Implementation procedures for supporting and assisting all hospital laboratories.
- Enabled standards-based laboratory messaging between hospital laboratories and PHA through use of LIC network which was available to participants on 7/1/11.

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- Collaborated with a third-party middleware vendor to develop an automated solution for hospitals that provided multifaceted functionality offering extraction and transport capabilities for ELR transaction submission to PHAs.
- Provided implementation and project management services to hospital laboratories throughout the grant timeline.
- Provided support to 1,121 engaged hospitals to remind participants of online services and introduce them to the new SNOMED CT tools, determine LOINC progress and identify assistance needs, and determine connectivity and transport method, progress, and identify assistance needs.
- Expanded services to reach PHAs to test ELR transactions. Throughout the program period, the LIC was able to test with 16 PHAs. The LIC also used the Message Quality Framework (MQF) tool as standard practice to verify valid transactions prior to transmitting to PHAs.

Please refer to *Artifact 6: Hospital ELR Progress Report* for a list of all participating hospital laboratories and other entities including entity description type, services provided and status of current LIS and laboratory data exchange capabilities.

Stakeholder Collaboration

In order to drive successful outcomes, the LIC determined early in the grant period, that the program would not only need to engage hospital laboratories in this effort as outlined in the grant, but also provide outreach to and engage all ELR stakeholders associated with reportable events. The following stakeholders were approached and collaborated with the LIC at various levels throughout the grant period.

Hospital Laboratories, Integrated Networks (IDNs) and Hospital Systems

Hospital laboratories were the focus of the program and the primary audience for education and technical assistance. The LIC conducted outreach to hospitals using AHA and CAP membership rosters and engaged more than 20% of the U.S. hospital market. The hospital laboratories that participated in the program ranged from somewhat knowledgeable about terminology mapping requirements and activities, to having no knowledge whatsoever. The LIC identified that smaller, rural or CAHs do not have internal IT resources and typically rely heavily on the functionality and support of their LIS vendors for transactional assistance, specifically with the extract and transport of the ELR transaction to their PHA. In most instances, the vendor did not have the knowledge or bandwidth to provide additional support to the hospital. This issue will continue to grow as more of the hospitals need to meet MU requirements in order to remain competitive. The hands-on consultation offered to participating hospitals was well received and considered to be extremely valuable to hospital staff.

Once the LIC began working directly with the hospitals, it became apparent that a common denominator among many was their shared IDNs or hospital systems. The LIC began identifying targeted IDNs and hospital systems to approach and participate in the program with a significant success rate of moving them towards ELR adoption and testing.

The LIC selected an IDN to conduct a study to demonstrate LOINC readiness, state PHA readiness, and LIS system functionality and laboratory informatics organizational activities.

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The benefit of the IDN study was that an IDN would have vast complexities in supporting data governance, from both a clinical terminology and connectivity perspective that would not exist in the single facility environment. In addition, lessons learned from the LIC pilot program would aid other hospital laboratories nationwide to become successful in mapping and transport of a single laboratory result to PHA, based on Stage 1 MU and beyond.

In March 2012, a letter of interest was signed, between the LIC and an IDN, with 18 hospital laboratories. The focus of the study was to specifically address the support for the LOINC mapping task regardless of the method for transport of the reportables to PHA. The LIC provided options to these hospital laboratories to support and provide guidance on various connectivity methods to be offered. All hospital laboratories of this IDN received the LIC education, access to the LIC website, best practice guidelines, references and tools offered by the LIC. Two hospital laboratories were selected to participate with the requirement that the hospital laboratories were willing to work together in order to demonstrate an end-to-end successful transmission of a reportable condition to PHA. The sites selected had the following characteristics:

1. Different LIS vendors;
2. One hospital had experience with LOINC and SNOMED CT mapping in addition to already supporting electronic laboratory reporting to a PHA; and
3. One hospital had the willingness to work closely with their internal Laboratory Standards Council and the LIC team. The Laboratory Standards Council consisted of representatives across all hospital laboratory facilities within the IDN.

Please refer to *Artifact 15: White Paper: "The Implications of Meaningful Use (MU) – A Multi-facility Health System Integration Approach" A Lab Interoperability Cooperative (LIC) and Catholic Health East (CHE) Division of CHE Trinity Health White Paper* for more information.

To learn more about the specific needs of CAH laboratories, a CAH study site was selected to receive LIC services. Once a signed HAL was submitted to the LIC, two representatives from each of the LIC member organizations visited the CAH laboratory to discuss services available from the LIC. The LIC team received information concerning reportable laboratory tests performed by the CAH to begin mapping LOINC to the laboratory test results.

The LIC visited the CAH laboratory to train personnel involved with ELR on LOINC mapping their reportable tests using the LIC ELR LOINC Mapping template and also into their LIS data dictionary. Personnel were taught how to utilize LIC materials such as the Best Practices Guidelines and LIC ELR LOINC Mapping Template to aid their LOINC mapping process. During the visit, several tests were successfully mapped in the LIS to enable connectivity testing. This process allowed the LIC to enhance the best practices document provided to participating hospital laboratories.

Laboratory Information System (LIS) Vendors

Based on the feedback received on an assessment checklist that was distributed to all hospitals that were recruited at the start of the grant, the most common EHR and LIS vendors were identified and contacted by the LIC team. Varied levels of vendor responses were

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received that ranged from very supportive of the LIC initiative to completely uninterested. Some vendors realized the LIC services were a value-add service for their hospital customers, while others deemed the LIC as a competitor. One LIS vendor invited the LIC to provide a one-day terminology mapping workshop at their annual user group conferences for two consecutive years. Please refer to *Artifact 5: Stakeholder LIS Vendor Questionnaire* for more information.

Third-party Vendors

The LIC uncovered a need to collaborate with third-party middleware vendors to address a gap in existing EHR/LIS functionality. Some hospital laboratories did not have the functionality needed to filter, sort, extract and format a transaction that met the MU criteria. This was either because the vendor didn't provide it, or because an upgraded version of the LIS had not yet been purchased or installed. In either case, the middleware vendor solution provided hospitals with a cost-effective option. Using automation of ELR workflow within the hospital setting as a guideline, the LIC was able to work with one third-party middleware vendor to provide functionality that addressed the following needs:

- Enable extract of the ELR required data elements to meet Stage 1 MU reporting criteria;
- Filter the reportable ELRs;
- Format the ELR to meet Stage 1 MU reporting criteria (including HL7 2.5.1 format with LOINC and SNOMED CT);
- Transport to PHAs; and
- ATCB modular certification.

Health Information Exchanges (HIEs) and Regional Exchange Centers (RECs)

The HIE and REC framework represent an excellent opportunity to serve as a conduit for delivery of reportable laboratory events from participating hospitals and health systems to related PHAs. HIE staff were engaged prior to all education sessions and invited to attend and present as appropriate. Most HIEs took advantage of the opportunity for collaboration. The LIC understood that for HIEs to achieve their objectives, they would need to:

- Qualify their transaction delivery for onboarding with related PHAs;
- Support the changing requirements of vendors, hospitals, regulations especially for MU be able to adapt to the varying local PHA requirements;
- Maintain participation levels that benefit the PH laboratories;
- Work collaboratively in states where multiple HIEs exist and/or HIE geographic boundaries overlap; and
- Sustain themselves after subsidy funding ceases.

State Hospital Associations

The AHA leveraged their relationships with the state hospital associations which played an important part in the hospital engagement process by assisting the LIC in outreach efforts to promote LIC services and activities for hospitals in their states. Many of these associations also were represented at the live workgroup sessions.

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Public Health Agencies (PHAs)

Even though PHAs were out of scope for this grant, the LIC understood the need to engage with them and worked closely with CDC to coordinate outreach efforts between hospital laboratories and PHAs throughout the grant period. Meetings were arranged in advance of the onsite education sessions between the CAP laboratory terminology subject matter experts and the applicable PHA officials, where information was exchanged and the PHA staff and were offered time to introduce themselves and to make state-specific presentation to the workshop participants. Please refer to *Artifact 4: Public Health Agency (PHA) Questionnaire* for information gathered from PHAs. Some of the collaborative activity included:

- PHA MU Website <http://www.cdc.gov/ehrmeaningfuluse/>
- Nationwide PHA MU Use Conference Calls
- MU for PHA Professionals: Basic Training
- MU Mailbox (MeaningfulUse@cdc.gov) for PHAs and partners to submit requests and questions about MU

Often times, the LIC education workshop were a “first meeting” between PHA staff and laboratory professionals and the evaluations from these LIC sessions recorded very high scores. The LIC connectivity and transport team has worked with the following PHAs to successfully send a properly formatted ELR test transaction. Testing with the following agencies was prioritized based on the number of hospitals engaged with the LIC, the PHAs readiness to receive ELR transactions, and whether they had staff available to engage in the testing process.

- Arkansas
- Colorado
- Connecticut
- Florida
- Kansas
- Louisiana
- Maine
- Minnesota
- New Mexico
- North Carolina
- Oregon
- Pennsylvania
- South Carolina
- Texas
- Houston (local)
- Washington

In addition, opportunity remains for providing PHA connectivity and transport services for the following engaged PHAs. Because of technical and resource limitations, transaction testing was not completed by the end of the grant period:

- California
- Idaho
- Hawaii
- New Hampshire
- Vermont
- Virginia

The LIC had numerous discussions with PHAs and found they used a variety of transport protocols which was confusing to hospital staff. Often times, the LIC team had to clearly articulate the differences between transport protocols (Public Health Information Network

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Messaging System (PHINMS), Secure File Transfer Protocol (SFTP), web services, etc.) and transaction standards (Health Level 7 (HL7)). Another significant barrier to ELR adoption was PHA readiness. According to CDC, as of July 2013, despite the 12 month delay of Stage 2 MU reporting period, only 73% (42 of 57) of PHAs were able to accept the MU ELR transaction in the HL7 2.5.1 format, and only 33% (19 of 57) are capable of receiving ongoing production volume.

Other HITECH Act-funded Health IT Programs

The LIC collaborated and participated with several HITECH Act-funded Health IT Programs throughout the program period. Please refer to *Artifact 10: HITECH Act-Funded Health IT Program Collaboration* for additional information.

The LIC participated in industry conferences to provide education on service offerings and progress. Please refer to *Artifact 7: Industry Conference Participation* for additional information. In addition, the LIC produced press releases, articles and publications, used to further inform stakeholders about LIC services and industry wide progress towards ELR. Please refer to *Appendix B: List of LIC Artifacts* for additional information.

Objective #4: Implementation of ongoing reporting to PHAs, where the health agencies have the capacity to receive the information electronically.

Result: Ongoing reporting to PHAs did not occur during the grant period. This was due to the 12 month delay in Stage 2 MU rules, hospital priorities, PHA readiness and LIS functionality.

LIC Engaged Hospital ELR Progress

The LIC conducted follow-up emails and phone calls with every engaged hospital (for many hospitals there were multiple calls and emails) to provide assistance, gain an understanding of progress made towards completing the necessary steps for successful implementation, and production of reportable ELR with PHAs. The summary of hospital ELR progress overall, by hospital type and by connection type is below.

ELR Progress by Hospital Type

Stage of ELR Completion by Hospital Type	Urban	Rural	CAH	Total
Reviewed LOINC Best Practice Guidelines	616	183	135	934
Researched LOINC Codes	486	126	96	708
Mapped All Reportable LOINC Codes	400	100	73	573
Updated LOINC Mapping Tables in LIS	283	67	71	421
Verified PHA Received Test Message	191	26	37	254

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ELR Progress by Connection Type

Stage of ELR Completion by Connection Type	EHR/ LIS	HIE	LIC	SFTP/ PHINMS	Unknown
Reviewed LOINC Best Practice Guidelines	485	254	9	2	184
Researched LOINC Codes	392	250	6	2	58
Mapped All Reportable LOINC Codes	296	203	5	2	67
Updated LOINC Mapping Tables in System	247	90	4	2	78
Verified PHA Received Test Message	197	43	2	0	12

Please refer to *Artifact 6: Hospital ELR Progress Report* for a complete listing of all participating hospitals, the LIC services provided and their self-reported ELR progress status.

LIC Findings

The LIC found that ELR stakeholders were, as a whole, underserved in the adoption and promotion of terminology standards, knowledge of MU objectives, and hospital interoperability to PHAs for purposes of ELR. There was a tremendous demand from hospitals for education and training related to terminology services throughout the grant period. However, the demand for connectivity and transport services is only just beginning to materialize. Hospital staff consistently underestimated the effort required for terminology mapping, and were, therefore, very engaged during the LIC training sessions. In addition to providing specific information on ELR requirements, the trainees found the information and processes to be applicable to the entire test menu of the laboratory, providing even more value than they originally anticipated.

There were several factors that support these findings:

1. ELR was viewed the most difficult PH menu item to implement and very few hospitals selected this for their Stage 1 MU attestation.
2. LIS vendors did not have the functionality to extract the ELR HL7 2.5.1 transaction in the format accepted by PHAs.
3. Hospital laboratory staff was the primary contact for ELR activity, yet are not familiar with, nor are they responsible for connectivity and interoperability solutions. For those hospitals without a technical resource available, a basic education was needed to describe differences between transaction standards (e.g. HL7) and transport protocols (e.g. Direct, SFTP, PHINMS).
4. PHAs were not ready to accept the Stage 1 MU ELR transaction.
5. Stage 2 MU timeline was delayed which impacted the driving force for hospitals to prioritize human and financial resources to implement ELR.

Even though the LIC provided services to over 1,100 hospitals, there remains a large and growing need for hospital laboratory personnel to have more and ongoing opportunities for LOINC and SNOMED CT training. While training hospital laboratory personnel we found that the Information Technology (IT), HIEs and PHA personnel in any given state also benefited from the discussions when hospitals came together during training events.

It is likely that even if every hospital in the United States had the highest level of expertise possible for the mapping efforts of the laboratory transaction data in terms of LOINC and SNOMED CT codes, and were ready to deliver data to PHAs, those agencies would not be able to manage the hospital demand for onboarding and receipt of ELR transactions. The process for a hospital to engage with Public Health for full testing and onboarding can take between two to twelve months to complete. As Stage 2 MU demands much more engagement between hospitals and PHA, the resource limitation issue will become more obvious throughout country.

LIC Study – Critical Access Hospital (CAH) Findings

In the fourth quarter 2011, the LIC selected one CAH, based on specific criteria, to insure the LIC education, documentation, and processes would appropriately address the needs of the CAH market. The LIC team found that many laboratory professionals, especially those in smaller hospitals, were overwhelmed with implementing MU requirements in addition to trying to provide patient care with limited resources. LIC resources given to CAH laboratory

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professionals to aid their ELR LOINC mapping were well received. Following education on LOINC mapping, it was determined that LIC resources would meet both the needs of CAHs and larger hospital based laboratories, both targets of grant services.

During initial discussions and training, the LIC team learned most of the reportable laboratory tests at the CAH were sent to a reference laboratory. The LIC team worked with the commercial reference laboratory to obtain the LOINC codes for the reportables sent to the reference laboratory and also requested that the reference laboratory begin providing LOINC codes mapped to the results in the messages sent back to the CAH providers. Although the CAH had an LIS and EHR which were both Stage I MU certified, it was learned that the LIS functionality did not support mapping a LOINC or a SNOMED CT code to any of its microbiology laboratory orders or results. Therefore, the CAH needed to continue reporting any of their microbiology test results which met the PHA's reportable criteria using their existing fax based methodology.

Discussions occurred with the LIS vendor about the functionality limitations and their understanding of Stage 1 MU requirements. The LIS vendor provided support services to the CAH laboratory, as the hospital did not have the technical expertise to implement LIS functionality needed for ELR on their own.

Connectivity options to the CAH's PHA were discussed with the LIC team and it was determined that, despite ATCB certification, the vendor was unable to provide a transaction delivery option to deliver the ELR to PHA. The LIC provided a web based, secure transport solution that was Direct compliant. While this was a manual solution (similar to a web based email solution with a file attachment), it met the transport needs for a Stage 1 test transaction, and the ease of use for both the hospital and the PHA made it ideal for use in testing transactions.

Several LOINC maps were completed, but mapping of the entire test menu was not completed due to the limitations described above. Due to resource limitations at the hospital and LIS vendor, the LIC team decided to suspend work on the CAH study site to focus on hospital laboratories that would be better enabled to transmit an ELR test message to their PHA.

LIC Study – Integrated Delivery Network (IDN) Findings

In the first quarter 2012, the LIC selected one IDN for another study. The goal of this study was to provide key lessons learned on the implications of ELR on an IDN, from end-to-end: mapping the appropriate terminology to a data dictionary test menu, adding the mapped test result codes into the LIS, and transmitting the result(s) to PHA. The LIC IDN Study was successful. The end result was a completed pilot test transaction to PHA for Stage 1 MU. This successful transaction was achieved due to a collaborative effort by the IDN team members, the LIC, the PHA, and the LIS vendor.

To achieve success in implementing ELR, it is essential to achieve an in-depth understanding of the many different areas of the laboratory, the hospital, and outside sources (i.e. Infection Control, IT, PHA, reference laboratory, etc.). These areas include items such as familiarization with the laboratory workflow and laboratory orders with their corresponding result components, as well as understanding the laboratory interfaces and their functionality and capability to

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support Stage 1 and Stage 2 MU requirements. Detailed knowledge and understanding best practices of mapping LOINC and SNOMED CT terminology, is key to the success of meeting MU requirements.

There were key lessons learned from the LIC Study, which included:

- ELR Use Case Scenario: Determining Common Roles and Responsibilities
- Laboratory/Hospital Workflow: Internal vs. External
- Tests Performed Within the Laboratory: Orders and/or Results
- Using the Appropriate Terminology: LOINC Codes and SNOMED CT Codes
- EHR / LIS Integration Within the Laboratory
- Public Health Agency (PHA) Requirements for ELR

A detailed description of the study and its findings are included in *Artifact 15: White Paper: “The Implications of Meaningful Use (MU) – A Multi-facility Health System Integration Approach” A Lab Interoperability Cooperative (LIC) and Catholic Health East (CHE) Division of CHE Trinity Health White Paper.*

Other Factors Impacting ELR Adoption

PHAs participation was an important component to the commitment level of these hospitals the LIC was trying to engage, motivate and educate. For instance, the readiness checklist of hospitals indicated that numerous facilities felt that their own PHA was unable to receive ELR transactions even if they were properly coded after attending an LIC training event. The LIC contacted the PHAs to verify and confirmed that it was in fact true. Therefore, the hospitals were not using their new terminology mapping skill set and they de-prioritized ELR activities, resulting in slow ELR adoption all together.

Observations from PHA collaboration included:

1. While most PHAs can technically accept properly formatted messages (HL7 2.5.1), not all have the ability to consume that version of the standard message and some even reformat to a lower version for message consumption. Additionally, the team found that not all PHAs have the resources required to manage the onboarding and production processes for all hospitals within the reporting jurisdiction – this considers both staffing and technical systems.
2. The onboarding process and submission requirements for hospitals varies significantly across PHAs, creating information systems standardization problems for facilities that report to more than one state and for health systems with facilities geographically located in multiple states. Additionally, for some PHAs, ELR submission requirements go well beyond those required by MU guidelines, placing an additional burden on hospital laboratories and their LIS vendors to provide that additional information.
3. PHA staffing and knowledge may be limited and some PHAs have prioritized ELR behind the other two MU public health reporting criteria (immunizations and surveillance), making it difficult for hospitals to engage in testing.
4. Some PHAs have prioritized the onboarding of hospital facilities based solely on the volume of reportables, as on boarding a low volume hospital requires the same effort as

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onboarding a high volume hospital. This creates significant MU access issues for small and rural hospital facilities that are held to the same requirements as their larger counterparts. One PHA estimates that it will cost between \$7,000 and \$10,000 per hospital to enable the receipt of ELR transactions, and the PHA simply doesn't have the resources available to accommodate all hospitals that may be ready to deliver ELR transactions.

5. Direct involvement, communication and commitment from PHAs are important for hospitals to follow through with completing ELR testing. In some cases, hospital efforts slowed or stopped altogether when facilities lacked the confidence that PHA's had the ability to accept and process ELR according to the MU guidelines.

Personnel turnover and regulatory changes in healthcare drive an ongoing need for education, training, terminology mapping, and connectivity and transport activities. These factors demand that a diligent effort across the healthcare industry to standardize the processes for PHAs and LIS vendors is needed in order to achieve a measurable volume of public health reporting transactions that meet MU criteria.

A summary of the evolution of activities impacting ELR adoption and usage during this program is found in the following table:

Expectation (CDC RFP Nov. 2010)	Present Circumstance
LIS are ONC-ATCB certified for Stage 1 MU	ONC-ATCB certification for Stage 1 MU did not include connectivity and extract criteria
Hospitals had MU certified LIS solutions	Competing hospital resources and budget to upgrade systems to meet Stage 1 MU criteria
Stage 2 MU drove ELR adoption	Stage 2 MU delayed from 2013 to 2014
Hospitals selected ELR for PHA reporting to meet Stage 1 MU	Hospitals shifted and changed priorities for ELR due to difficulty implementing
Hospitals dedicated technical resources for ELR	Competing hospital resources; ICD-10, and other higher priority projects
PHAs were ready to receive ELR	Initially PHAs were not ready; ELR requirements differ by PHA, priority was given to larger volume senders, human and financial resource constraints, and lengthy onboarding processes
HIEs had infrastructures that support connectivity and are connected to hospitals	HIEs moved slower than industry demand and sustainability is an ongoing concern for many

Conclusion and Recommendations

The LIC has built a strong foundation of ELR resources and expertise, and is recognized across the country as a neutral, credible industry resource that provides valuable, cost-effective ELR education and connectivity solutions to hospital laboratories, PHAs and LIS vendors.

Throughout duration of this program, significant milestones were achieved including:

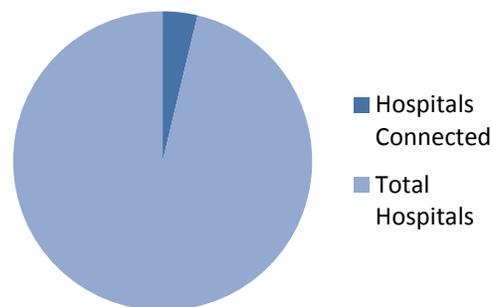
- Recruitment of over 1,200 hospitals meeting 240% of program objectives;
- Terminology education and technical assistance provided to 1,121 hospitals meeting 224% of program objectives. 363 of these hospitals were rural and Critical Access hospitals, meeting 363% of program objectives;
- Development of tools, resources and communication processes described as very helpful by 96% of the participating hospitals; and
- Collaboration with public health agencies to provide added value to hospital participants during terminology and technical assistance education sessions.

Stage 2 MU requirements mandate an unprecedented level of standards, adoption, and use of technology for public health reporting going forward. The implementation of new standards is difficult, especially for ELR. This requires hospitals to upgrade their information technology systems, adjust workflow within the care setting, and conduct extensive and ongoing training of laboratory staff. Based on the experience of the LIC during the grant period, it is apparent that the challenges ahead were much greater than they are today. An effective transition to standards adoption and utilization needs to be supported by consistent, comprehensive educational, and technical resources that are easy to find and understand, yet this will not be sufficient by itself. All ELR stakeholders must collaborate in a neutral environment to drive ELR adoption. Support for ELR adoption and implementation through development of educational sessions, ongoing national webinars and conference calls, showcasing of best practices, and monitoring of progress are all crucial to the overall adoption of ELR standards and successful transmission of electronic transactions to PHAs.

As we stand on the eve of the Stage 2 MU reporting period, the demand for LIC services from all stakeholders continues to increase.

According to the CDC ELC ELR All Hands Meeting in September 2013, there were only 193 hospitals in 17 states that were sending ELR transactions to public health agencies that met Stage 1 MU criteria.

Over 4,800 hospital labs will need to connect to public health agencies by July 1, 2014 in order to meet the Stage 2 MU reporting period objectives and be eligible to receive the federal incentive dollars.



Momentum is building towards improving public and population health through the use of technology, and achieving true interoperability through the PHA reporting criteria established

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under the MU objectives. However, at the same time, valuable resources available to hospitals and PHAs will disappear as many HITECH grantees will be ceasing operations due to the termination of grant funding and/or lack of sustainable business models. PHAs are under extreme pressure to connect hospital laboratories to their systems to receive ELR transactions, yet have limited resources available to effectively execute their plans.

At the time when the knowledge and tools of the LIC are needed most, hospitals, their systems vendors, and public health agencies will lose access to this valuable resource. If LIC funding were in place to mirror the three stages of meaningful use, measureable transaction volume to public health agencies could be achieved during the Stage 2 MU reporting period. Based on feedback received from PHAs, the LIC estimates that a minimum of \$50 to \$75 million dollars will be spent in total by PHAs across the country in an understandable, but inefficient attempt to meet the deadlines imposed on hospitals for PHA reporting. These same services could be provided through a centralized, standardized program like the LIC at a fraction of the cost.

The LIC strongly recommends that additional funding be allocated to leverage and build upon the collaborative relationships already in place with hospitals and PHAs, as well as the efficient, standardized, and centralized services now established by the LIC. The additional funding should support Stage 2 MU activities related to ELR for hospitals, PHAs and other ELR stakeholders by:

1. Increasing communication to hospitals and other stakeholders of best practices and meaningful use requirements for ELR;
2. Providing terminology education sessions for hospital laboratory staff, LIS vendors, reference labs and others;
3. Providing technical assistance related to onboarding, connectivity, transaction validation and transaction verification for both hospitals and public health agencies; and
4. Establishing additional collaborative opportunities for hospitals, public health agencies and LIS vendors to reach consensus on the implementation and use of standardized transactions related to ELR and public health reporting.

Now is the time. The LIC services are in great demand and highly needed by all stakeholders. Industry leadership is required for successful engagement and collaboration with hospitals, public health agencies and software vendors. Continued support of these activities is critical to achieving the aggressive timelines required to meet Stage 2 MU requirements, which will ultimately result in improved population and public health outcomes.

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Appendix A: Terms and Abbreviations

AHA	American Hospital Association
ATCB	Authorized Testing and Certification Body
CAH	Critical Access Hospital
CAP	College of American Pathologists
CDC	Centers for Disease Control and Prevention
CMS	Centers for Medicare and Medicaid Services
EHR	Electronic Health Record
ELR	Electronic Laboratory Reporting
FAQ	Frequently Asked Questions
HAL	Hospital Agreement Letter
HIE	Health Information Exchange
HIMSS	Health Information Management Systems Society
HIT	Health Information Technology
HL7	Health Level Seven
IDN	Integrated Delivery Network
LIC	Lab Interoperability Cooperative
LIMS	Laboratory Information Management System
LIS	Laboratory Information System
LOINC	Logical Observation Identifiers Names and Codes
MU	Meaningful Use
ONC	Office of the National Coordinator for Health Information Technology
PHA	Public Health Agency
PHIN	Public Health Information Network
PHINMS	PHIN Messaging System
RCMT	Reportable Conditions Mapping Table
REC	Regional Extension Center
RELMA	Regenstrief LOINC Mapping Assistant
SFTP	Secure File Transfer Protocol
SNOMED CT	Systematized Nomenclature of Medicine - Clinical Terms
SOP	Standard Operating Procedure