White Paper

LIS Vendor Landscape and Options for Meeting ELR Meaningful Use

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Developed by the Council of State and Territorial Epidemiologists (CSTE) and the Centers for Disease Control and Prevention (CDC) Electronic Laboratory Reporting (ELR) Task Force
Laboratory Information System (LIS) Vendors & Large Labs Workgroup

Executive Summary

The *LIS Vendors & Large Labs Workgroup*, under the direction of the CSTE & CDC Electronic Laboratory Reporting (ELR) Task Force, was charged to assist and advise laboratories and the vendors who supply laboratory information system software (LIS or LIMS) with the implementation of electronic laboratory reporting.   An additional catalyst was the inclusion of the Stage 1 Meaningful Use (MU) population health menu objective for reportable lab results. Continuing the progress made with large laboratories to fully implement ELR, this workgroup seeks to engage LIS vendors on solutions for sending laboratory results to jurisdictional public health departments or agencies. This process began with a survey of LIS vendors.

Discussed in this white paper are system architecture options that a hospital may use to submit electronic data on reportable laboratory results to public health agencies as required by state or local laws and practice with particular focus on the role of LIS systems as a component. Three objectives of the paper include:

- Documenting a set of architectural options and best practices for LIS vendors to support ELR from eligible hospitals to Public Health Agency (PHA)
- Identifying several approaches that LIS vendors and the laboratories implementing LIS systems may adopt to meet MU requirements
- Providing pros & cons for different approaches

This paper describes many of the challenges to successful MU ELR implementation. As a generic Meaningful Use solution that addresses these challenges, the EHR-LIS sender must perform six steps: (1) collect laboratory order-local codes, (2) analyze specimens and collect results, (3) map results to standards, (4) filter results by reportable condition, (5) create the HL 7- 2.5.1 message, and (6) send results to the PHA securely.

To address these steps there are several architectural options that can be chosen, as listed below:

- LIS Native
- Use of LIS Vendor Off-Site
- Use of Lab-Deployed Broker
- Use of PHA Receiver

- Use of Health Information Exchange (HIE) generated message and vocabulary
- Other approaches, that require

In summary, any option or combination of options that automatically and securely provides reportable laboratory results to PHAs with appropriate filtering of reportable conditions, and mapping to standard vocabulary in a message that complies with applicable standards is worthy of consideration. A common component of many of the options is the use of integration brokers to assist in vocabulary mapping, filtering, message generation, and secure transport. LIS vendors provide an important component of ELR and should be recognized as important partners to public health.

Background

This paper focuses on best practices for data providers to send ELR to public health agencies. Recent changes in national laws provide a catalyst for promoting ELR implementation. In July 2010, the Centers for Medicare and Medicaid Services (CMS) published the final rule that implements the provisions of the American Recovery and Reinvestment Act of 2009 (ARRA) and resultant Health Information Technology for Economic & Clinical Health (HITECH) act. This regulation provides incentive payments to Eligible Professionals (EPs), Eligible Hospitals (EHs) and Critical Access Hospitals (CAHs) participating in Medicare and Medicaid programs that adopt and successfully demonstrate meaningful use of certified electronic health record (EHR) technology. Also, the Office of the National Coordinator for Health Information Technology (ONC) has issued a closely related regulation that specifies the adoption of an initial set of standard implementation specifications for electronic health records; these specifications form the basis for certification criteria for Health Information Technology (HIT). Certified EHR technology used in a meaningful way is one piece of a broader HIT infrastructure needed to reform the health care system and improve health care quality, efficiency, and patient safety- this concept has been commonly called "Meaningful Use" (MU).

There are 3 public health objectives in Meaningful Use Stage 1, namely the capability to submit electronic data to public health in the context of- Immunization, Reportable Laboratory Results (Eligible Hospitals [EH] only) and Syndromic Surveillance. In order to meet Stage 1 Meaningful Use criteria, EHs must choose one of these three public health objectives.

A CSTE & CDC Electronic Laboratory Reporting (ELR) Task Force was formed with the vision for:
"All labs (public and private) conducting clinical testing identify laboratory results that indicate a potential reportable condition for one of the jurisdictions they serve, format the information in a standard manner, and transmit appropriate messages to the responsible jurisdiction; all jurisdictions can and do receive and utilize the data."

The Centers for Disease Control and Prevention (CDC) is collaborating with the Council of State and Territorial Epidemiologists (CSTE) and the Association of Public Health Laboratories (APHL) on the CSTE/CDC ELR Task Force and have formed five ELR Task Force workgroups. One of these workgroups, LIS (Laboratory Information System) Vendors & Large Labs Workgroup is charged to assist and advise laboratories and the vendors who supply laboratory information system software with the implementation of electronic laboratory reporting. Building on the progress made by large laboratories in implementing ELR, this workgroup seeks to engage LIS vendors on solutions for sending laboratory results to jurisdictional public health departments or agencies.

The first step in this process included a March 2011 LIS Vendor Survey intended to provide a better understanding of the current LIS landscape. Thirty LIS vendors, identified by the November 2010 College of American Pathologists (CAP) Today Laboratory Information Systems article or provided by APHL, were surveyed. The survey results revealed a need to outline architectural options for LIS vendors and eligible hospitals to meet MU ELR.   The analyzed survey results are available at http://www.cste.org/webpdfs/elr/LISVendorSurveyResultsSummary.pdf.

Other sources of information that contributed to these architectural options include the **2010 National Electronic Laboratory Reporting (ELR) Snapshot Survey** performed by the National ELR Workgroup[1].

Steps for reporting ELR

The survey identified steps that need to be performed by ELR partners to meet the Meaningful Use approved standards for reporting. The steps, identified below, do not imply a specific order of execution.

- Lab Receives Test Orders & Specimens
- Lab Analyzes Specimens and Generate Results
- Standardize Codes: Map local vocabulary to PH accepted standard vocabulary
- Filter Results to those that meet the jurisdiction reportable conditions
- Generate a message to meet the Meaningful Use specifications
- Transport Message- Send the formatted message to the PHA using an agreed-upon secure transport protocol.

LIS vendors identified a number of challenges in implementing ELR. These challenges are described below.

Challenges

 ELR implementation challenges in the following four distinct areas are described below: transport, message (structure) generation, vocabulary, and reporting requirements:

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[1] See http://www.coast2coastinformatics.com/ for more information on this Workgroup and to access the survey.

Secure Transport:

Due to the sensitive nature of laboratory data secure transmission of the data is essential. PH and its trading partners deal with multiple, incompatible message transport options. The options include, but are not limited to:

- CDC's Public Health Information Network Messaging System (PHIN MS)
- ONC's Nationwide Health Information Network (NwHIN) DIRECT
- Secure File Transfer Protocol (sFTP)
- Virtual Private Networks (VPNs)

The above options require the sender (eligible hospital) or receiver (PHA) to set up and manage separate interfaces for each transport protocol, because the protocols are incompatible with each other.

Message Generation:

- ELR message structure and format varies by exchange partner and includes spreadsheets and tab or comma-delimited files. These formats do not comply with the ELR Meaningful Use standard message format of ORU R01 HL7 2.5.1.
- Of the surveyed LIS vendors, 79.3 % indicated that they were aware of the HL7-approved Implementation Guide. However, not every laboratory system is currently able to generate messages in the approved format; in addition, not all PHA receivers can accept messages in this format. Until all senders and receivers are supporting the same message structure, both senders and receivers may need to support multiple data exchange formats.
- While message structure does not change often, it is almost guaranteed to happen in the future. Both senders and receivers will need to plan for this possible change.

Vocabulary

- Laboratory systems typically use proprietary code sets for lab tests and results. These codes need to be mapped to standard (LOINC® and SNOMED) codes in accordance with the ELR implementation guide which is available for free to HL7 members, or for purchase by non-members at: https://www.hl7.org/store/index.cfm).
    - o The CSTE/CDC ELR Taskforce has developed Reportable Condition Mapping Tables (RCMT), which map LOINC® test codes and SNOMED result codes to reportable conditions.
    - o The RCMT updates and expands upon previous work known as the Dwyer tables and can be used to determine when a test or result may be indicative of a condition that should be reported to public health.
    - o The RCMTs are available via the CDC Vocabulary Access and Distribution System (PHIN VADS). More information on can be found at http://phinvads.cdc.gov.
- Vocabulary management is a complex activity and needs to be supported by and coordinated between senders and receivers.

Reporting Requirements and Criteria

- The list of conditions that are reportable differ among public health jurisdictions. This is evident from the State Reportable Conditions Assessment (SRCA) conducted by CSTE on an annual basis.
- Public health jurisdictions have considerable variations in their reporting criteria and requirements for each condition.

Additional Challenges
- LIS vendor products do not independently meet the Stage 1 Meaningful Use requirements for ELR reporting. LIS vendors seeking certification for their products through an ONC-approved authorized testing and certification body (ATCB)[2] need to be certified as a component or module of a hospital EHR system.
- When LIS vendors and hospitals generate messages that pass the NIST validation requirements for certification, they do not necessarily meet the constrained message requirements (vocabulary & business rules) established by the public health community. Message Quality Framework (MQF), a CDC implemented message validator, can be used to validate messages against public health constrained profile developed collaboratively with the public health community.

The workgroup identified several options that are currently available to address challenges in ELR implementation. Five of these are summarized in the section below, and are followed by tabularized advantages and risks:

POTENTIAL IMPLEMENTATION OPTIONS:

1. **LIS Native:** The LIS software (vendor-supplied or custom-built) at the eligible hospital and/or eligible provider performs all ELR functions, from capturing test order and results to determining the results to send to the PHA system, transforming local vocabulary to standard vocabulary, generating the message structure, and transporting the ELR (HL7 2.5.1 ORU R01) message securely to the jurisdictional PHA system. This is one of the highly utilized options. The survey identified that a majority (93.3%) of the vendors currently have, or plan to implement, public health reporting from their LIS system. Among those that have the capacity today over half of the vendors (56.1%) indicated that their software component is used to report directly to their PHA.
2. **Use of Vendor Off-Site:** In this option the LIS system does not produce the full ELR message. Instead, the LIS vendor provides tools to upload data from the local LIS site to the LIS vendor off-site location and perform the filtering, vocabulary transformation and message generation. The LIS vendor site then sends the ELR message back to the originating LIS for transport to the PHA system. While it is possible for the LIS vendor off-site to send the ELR message directly to the PHA system, to meet Stage 1 MU, the required functionality at the LIS Vendor off-site would have to be certified as part of the eligible hospital's component EHR system.
3. **Use of Lab-Deployed Broker:** A third party message broker/integration engine supports the LIS implementation. In this option the message broker filters and maps the data, converting local codes to standard codes and generates valid message structure and content before securely transmitting it to the PHA system using the agreed-to transport mechanism.   The message broker/integration engine can be a separate stand-alone capability or integrated with the LIS (as a run-time version).
4. **Use of PHA Receiver**: In this option, the PHA Receiver system performs some of the needed functions of the sender system. The LIS is responsible for collecting the laboratory order and results, generating the ELR message, and transporting the message to the PHA system. The PHA receiver may be responsible for: mapping local vocabulary to standard vocabulary; filtering out only the reportable laboratory tests and results; and/or generating an HL7 message in a specific format (e.g., ORU R01 HL7 2.5.1 for Stage 1 MU Reportable Lab Results).

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[2] http://healthit.hhs.gov/portal/server.pt/community/healthit_hhs_gov__standards_and_certification/1153

5. **Use of Health Information Exchange (HIE):** The laboratory sends test results to the HIE and the HIE generates and reports the appropriate ELR messages to the PHA, This may include mapping local codes to standard codes and transporting the message to the local PHA.

TABLE 1
ELR REPORTING OPTIONS

	Reporting Option	Step 1 Collect Orders	Step 2 Analyze Specimens and Collect Results	Step 3 Map Local to Standard Codes	Step 4 Filter Results	Step 5 Generate Message	Step 6 Transport Message	Comments
1.	LIS Native	LIS Performs	LIS Performs	LIS Performs	LIS Performs	LIS Performs	LIS Performs	Meets MU
2.	LIS Use of Vendor Off-Site	LIS Performs	LIS Performs	Performed Off Site by Vendor	Performed Off Site by Vendor	Performed Off Site by Vendor	LIS or Transport Tool at Lab	Meets MU, challenged by transport back and forth between LIS and LIS Vendor
3.	LIS use of Lab-Deployed Broker	LIS Performs	LIS Performs	Performed by 3rd Party Broker at LIS Site	Performed by 3rd Party Broker at LIS Site	Performed by 3rd Party Broker at LIS Site	Broker or Transport Tool at Lab	Meets MU
4.	LIS Use of PHA Receiver	LIS Performs	LIS Performs	LIS, Off site (Performed by PHA) or Broker	PHA System	LIS, Off-site PHA, or Broker	Broker or Transport Tool at Lab	Meets MU, PHA challenged by need to be responsible for mapping of results from multiple providers
5.	LIS use of HIE	LIS Performs	LIS Performs	LIS, broker or passed to HIE to map	LIS, Broker, or HIE	LIS, Broker, or HIE	Transport Tool at HIE	Depends if the HIE is certified as a component of the EHR

Each of these options is described in the following sections of this paper.

Advantages & Challenges of Each Option

Option	Advantages	Challenges and Risks
LIS Native	- If certified as an integrated component of a modular EHR, may qualify for Stage 1 MU. - Implementation at provider/hospital locations makes management of coding and mapping activities easier. - Simplifies the reporting flow as dependency on multiple systems is removed.	- LIS software may need to be updated to comply with periodic changes in message structure or reporting requirements. - LIS software may have to implement numerous versions of reports to meet requirements that vary from jurisdiction to jurisdiction. Variations may exist in transport, coding and structural requirements. - PHAs often request that vocabulary is reported at a less granular level than what is used within the LIS. - PHA data requirements (e.g., demographic data) are often not available in the LIS and necessitate an additional step to populate. - Implementing ELR data exchange with PHA may not be the highest priority for LIS vendors.
Use of Vendor Off-Site	By moving the message generation and vocabulary mapping activities to an offsite location, the cost of maintaining and managing the reporting system could be reduced	- The LIS vendor must ensure secure transport of messages between the LIS client site and the LIS vendor site. - The LIS vendor has the additional overhead of handling communications/messaging between the LIS client site and the LIS vendor site. - Since data for many labs is stored centrally, the LIS vendor has additional overhead for ensuring the security of lab-specific data. - Individual labs may need to comply with jurisdiction-specific reporting requirements (e.g., lab tests or results that qualify for reporting, data exchange formats that differ across jurisdictions) that translate to customizations in the LIS vendor software. These site-specific requirements increase complexity and may not be high priorities for the vendor to implement.
Use of Lab-Deployed Broker	- Integration engines have built-in functionality to filter, route and standardize messages which can be leveraged when using this option. - The integration engine can be used to map local	- It can be expensive for a hospital to implement, maintain and cover licensing costs for an integration broker. - Implementing and managing a message broker requires IT resources. IT professionals are needed on an on-going

	vocabulary to standard LOINC and SNOMED codes. The standard codes can be used to identify and send only the qualifying result reports, resulting in more targeted reporting to the PHA. • The ability to use the integration broker to develop profiles and algorithms for automating public health reporting can result in more complete and timely reporting to public health agencies. New profiles can be added to support changes to public health reporting with less impact on the LIS or EHR. • If the integration engine mapping and message construction capabilities are part of a component certified EHR then they can be used to help meet Stage I Meaningful Use requirements for ELR. • The integration engine can be used to collect data from multiple systems for an eligible hospital, and integrate those data into a single message to support ELR.	basis to configure the business rules to be supported, manage the installed broker, monitor message traffic during production operations, and maintain and update profiles and routing.
Use of PHA Receiver	• A PHA receiver used to map local vocabulary to standard vocabulary may result in a cost-savings for the eligible hospital. However, it will still require participation by each hospital lab to map their local codes to the standard codes. • If a PHA receiver activity is limited to mapping of vocabulary, it may help meet the requirements of MU.	• The brokering tool has been configured for a single jurisdiction will not be easily translatable to other jurisdictions • Since vocabulary mapping is done at the PHA it makes it less available for supporting other data exchange needs at the eligible hospital.
Use of Health Information Exchange (HIE)	• Reduces the burden on providers by allowing them to submit data to the HIE, which will then generate and disseminate ELR to the appropriate PHAs. • HIEs can often support multiple message transport protocols. • Can reduce the complexity of hospital / provider systems if vocabulary mapping, filtering, message construction and/or transport of ELR are moved to the HIE.	• Operating HIEs are often not sufficiently funded. • HIEs may not be able to respond to changes in reporting requirements for various jurisdictions on a timely basis. • There may be potential challenges in establishing communication channels between HIEs and jurisdictional trading partners.

Summary

Any option that automatically and securely provide reportable laboratory results to PHAs with appropriate filtering of reportable conditions, mapping to standard vocabulary, and generation of the standard ELR message is worthy of consideration. Each option in this whitepaper has advantages and challenges. The LIS vendor survey is a companion document to this report. Several findings from that survey may be helpful in streamlining ELR from hospital labs. Summarized below, are some of the findings from the survey and additional information learned as a result of investigating ELR options.

- Many LIS systems experience difficulties mapping local laboratory codes/results for reportable conditions to standard codes (e.g., LOINC® and SNOMED).
- Hospitals are invested in a secure transport process and it is unlikely that they will change to meet specific PH requirements.
- LIS vendors welcome the opportunity to partners with PH to pilot/test automated electronic laboratory reporting software functionality.
- LIS vendors indicate that some PHA currently lack resources (e.g., people & systems) to receive and consume the MU ELR standardized message. Additional investments are needed to fully implement the ELR capacity.
- Public Health data requirements vary by PH program. This increases the complexity of reporting for the labs. To streamline ELR it is critical to both reduce variation of reporting across jurisdictions and to implement a knowledgebase of jurisdiction-specific reporting requirements and reporting criteria.
- Integration brokers can help streamline ELR. They can be used to assist in data mapping, filtering, message generation and/or transport. There may be strong advantages to using an integration broker where multiple message formats, transport protocols, and data integration and mapping needs exist.
- There are a number of components that would be useful in streamlining ELR. The Reportable Conditions Mapping Table (RCMT) available through PHIN VADS, and the Message Quality Framework test message validator are examples of existing components.
- LIS vendors should be viewed as important partners in implementing ELR with PHAs. Successful LIS vendor solutions can inform public health and hospitals of working options for consideration as they implement ELR. As an example, a real case best practice review would demonstrate the efficacy of the certification process for LIS components.

It should be mentioned that an additional survey of ELR reporting from the four major large reference laboratories: Mayo, LabCorp, ARUP, and Quest Diagnostics, is the subject of a separate whitepaper. These laboratories provide a significant portion of the national ELR data, but are not covered in this LIS Vendor whitepaper. This workgroup recommends a future activity which follows-up on the survey of LIS vendor capabilities. In addition, it recommends collaboration between hospitals, providers, HIEs, labs, PHAs, and supporting vendors (e.g., EHR and integration broker vendors) in recognition of their varied, yet important, roles in ELR