Laboratory Results Interface: EHR Test Methods for CLIA Compliance

Megan E. Sawchuk, MT(ASCP), *Centers for Disease Control and Prevention*, Robert Snelick, MS and Sheryl Taylor, BSN, RN,
National Institute of Standards and Technology, Toni Williams, MPH, *Emory Rollins School of Public Health*

Background

Meaningful use of *certified* electronic health record (EHR) technology is required as part of the Medicare and Medicaid EHR Incentive Programs. Associated with these incentive programs, the Office of the National Coordinator for Health IT (ONC) established the Health IT Certification Program, which publishes certification criteria. The 2014 Edition ONC Final Rule included Laboratory Results Interface (LRI) criteria designed to ensure that minimal regulatory requirements for exchange of clinical laboratory test results were met by certified EHR technologies (CEHRT). The 2014 Edition certification test methods, including an automated LRI HL7 V2 test tool, were developed by the National Institute of Standards and Technology (NIST) based upon those ONC certification criteria. Use cases (patient scenarios) were supplied through the former Standards & Interoperability Framework (most workgroups are now organized under HL7).

Goal

The goal of this project was to work with NIST to develop a more rigorous LRI HL7 V2 test tool to verify that electronic messages conform with enhanced specifications for the Laboratory Results Interface (LRI). These specifications address compliance with all test report requirements in the federal CLIA regulations, not just the minimal LRI requirements included in the 2014 Edition ONC Final Rule. (NIST does not conduct certification testing; the NIST LRI test tool can be used by health IT certification programs to validate if an electronic message conforms with the HL7 standards.)

Objectives

For laboratory test report elements required by the CLIA regulations:

1. **Existing Use Cases:** Enhance existing use cases to ensure the NIST EHR Certification test methods adequately address inclusion of the laboratory test report elements required by:
   - ONC 2014 Edition EHR Certification (CLIA-7)
   - CLIA Regulations (CLIA-4)
   - Deemed Accreditor Standards, when possible (Accreditor-4)
2. **New Use Cases:** Evaluate the need for new use cases to adequately test all CLIA required test report elements (CLIA-7 & CLIA-4).
3. **Corrected Reports:** Evaluate the need for new use cases to assess EHR software performance with corrected test reports and the integrity of CLIA required test report elements. For example, if one CLIA element is corrected, are other contingent CLIA required elements properly updated, e.g., age and reference range.

Data Sources

The data used for this project were derived from existing use cases utilized by the NIST LRI HL7 V2 Validation Tool for ONC 2014 Edition certification testing. Other resources used as references for this project included:

1. CLIA Regulations (42 CFR 493)
2. Meaningful Use Stage 2 / CMS EHR Incentive Program Regulations (42 CFR 495)
3. ONC EHR Certification Criteria (2014 Edition FR) (45 CFR 170)
4. ONC Health IT Certification Criteria (2015 Edition NPRM) (45 CFR 170)
5. HL7 Version 2.5.1 Implementation Guide: Laboratory Results Interface
6. ONC SAFER Guides: Test Results Reporting and Follow Up (January 2014)

Laboratory Test Report Elements*

NIST Test Method Category	Laboratory Test Report Elements
CLIA-7 Laboratory Test Report Elements required by CLIA and incorporated into MU Stage 1 by reference	Patient name and identifiers
	Laboratory name and address
	Test report date
	Test performed (test name)
	Specimen source, when appropriate
	Test results and interpretation
	Specimen condition and disposition
CLIA-4 Laboratory Test Report Elements required by CLIA to be incorporated into MU Stage 3 by reference	Reference intervals
	Critical result flags
	Reference laboratory results cannot be revised
	Corrected report identifier
Accreditor-4 Laboratory Test Report Elements exceeding CLIA requirements	Name of authorized person requesting the test
	Patient's sex
	Patient's age or date of birth
	Specimen collection date and time

*Acknowledgement to the ONC S&I Framework and Laboratory Tiger Team

Methods

A grid was developed to map use cases against the required or desirable elements.

1. Evaluated existing use cases for inclusion of CLIA elements (example below)
2. Evaluated contingent test report elements (meaning if one CLIA element is changed, are changes appropriately corrected in other elements, e.g. change in DOB causing a change in reference range and result interpretation)
3. Reviewed SAFER Guides for high priority risk concerns, e.g. presence of critical flags
4. Considered "Best Practices" recommended the ONC's Laboratory Tiger Team (EHR functions and behaviors, such as clear on screen pagination or end of report cue)
5. Submitted use cases/patient scenarios to S&I Framework and NIST for consideration

Scenario	Changed elements	Contingent elements
1. CBC on pediatric male Reported as adult female (correct specimen/incorrect patient)	Gender DOB	Reference range Interpretation Critical result flag Corrected report identifier
2. Critical creatinine Normal after repeat testing (correct patient/incorrect specimen)	Results	Critical result flag Corrected report identifier Comment
3. Critical potassium Recognized as unacceptable specimen (hemolyzed)	Specimen condition/disposition	Interpretation Corrected report Identifier
4. Lipid panel corrected after lipemia removed	Specimen condition	Results Comments Corrected report identifier
5. hCG on male Reported as female	Patient name Gender	Reference range Interpretation
6. AM Cortisol Reported as PM Cortisol	Collection date/time	Interpretation Reference range Critical result flag Corrected report identifier
7. Aseptic spinal tap is determined to be from a spinal fluid leak	Specimen source	Interpretation Reference range Critical result flag Corrected report identifier

Results

- Previously existing use cases (sed rate, stool culture, hepatitis with reflexive testing) included all CLIA and accreditor laboratory test report elements
- The CLIA-7 elements are mandatory for certification; the CLIA-4 and Accreditor-4 elements are considered voluntary.
- The existing use cases were enhanced to include as many elements as possible, such as critical result flags and corrected report identifier.
- The existing use cases did not support testing of all combinations of corrected reports, thus additional use cases were proposed.
- Proposed use cases were merged into existing use cases to simplify test methods with the same use cases for orders and results interfaces.
- Proposed use case #1 has been adopted into the NIST test methods. This use case is a complex corrected report for a wrong patient scenario.
- The project objectives were exceeded in regards to including more stringent test report requirements (Accreditor-4) of the laboratory accrediting agencies that inspect on behalf of CLIA.
- The NIST HL7 V2 LRI Validation Tool, Release 2, was developed to support testing for the more stringent test report requirements
  http://hl7v2-lab-r2-testing.nist.gov/lri-r2/#/home

Discussion and Next Steps

- In conclusion, additional use cases were developed for testing LRI electronic messages based on the analysis of CLIA and existing standards for laboratory results. The use cases were successfully designed to capture realistic patient scenarios. As a result, health IT vendors that use all the NIST LRI test methods will be able to determine whether their systems are compliant with CLIA.
- Mechanisms need to be identified to promote voluntary compliance with the CLIA-4 and Accreditor-4 elements and all laboratory use cases, including the more complex wrong patient/corrected report scenario.
- For more robust HL7 standards conformance testing of health IT, additional use cases are needed to assess other laboratory report types, such as microbiology susceptibilities, blood bank, pathology and calculated results.
- Use cases should be as realistic as possible. However, in order to minimize the number of cases (reduce testing burden), elements can be included in a use case for testing purposes that may not otherwise make sense clinically. Example: For a wrong patient/correct specimen scenario, laboratories may opt to reorder a new test under a correct patient registration rather than update the patient demographics (use case #1).
- Several desirable elements could not be addressed through this project since the required test methods are more complex than the current capability of the NIST conformance test method, possibly requiring a visual review by an assessor. These items are being deferred to the HL7 workgroup that will develop an unprecedented functional behaviors implementation guide for laboratory data. Examples included:
  - CLIA requirement to not revise reference laboratory reports
  - SAFER Guide suggestions, e.g. the ability to track order status
  - ONC Laboratory Tiger Team suggestions, e.g., an end of report cue

Center for Surveillance, Epidemiology, and Laboratory Services
Division of Laboratory Systems

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