Advancing Laboratory Interoperability in Health IT

Introduction & CDC LabHIT Update

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Clinical Laboratory Improvement Advisory Committee (CLIAC)
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Background

- The Health Information Technology for Economic and Clinical Health (HITECH) Act
  - Enacted as part of American Recovery and Reinvestment Act of 2009 (ARRA)
  - Promotes widespread adoption and standardization of health information technology (HIT)
  - Unprecedented investment in HIT
  - Lightning speed advancement of regulations
Meaningful Use of Health Information Technology

2 Sets of “Bookend” Regulations for Electronic Health Records

Working together to ensure quality

EHR Certification Requirements

- Regulations overseen by the Office of the National Coordinator (ONC)
- EHR test methods developed and implemented by the National Institute of Standards and Technology (NIST)
- Methods applied by Authorized Testing and Certification Bodies (ATCBs)

EHR Incentive Program

- Regulations overseen by the Centers for Medicare and Medicaid Services (CMS)
- EHR performance measures are used to determine incentive payments for eligible healthcare providers
- Administered by CMS and State Medicaid Agencies
A Conceptual Approach to Meaningful Use

Stage 1 - 2012
Infrastructure

Stage 2 - 2014
Information Exchange

Stage 3 - 2016
Advanced Uses of Data

- Improved outcomes
- Advanced clinical processes
- Data capture and sharing

http://www.cms.gov/EHRIncentivePrograms/
Overview of Laboratory Data Related Meaningful Use Objectives and EHR Certification Criteria

- **Meaningful Use Objectives**
  - Laboratory Results in EHR
  - Laboratory Results to Ambulatory Providers
  - Lab Orders by Computerized Provider Order Entry (CPOE)
  - Reportable Lab Results to Public Health Agencies

- **EHR Certification Criteria Which Include Laboratory Data**
  - Patient Lists
  - Patient Reminders
  - Clinical Decision Support
  - Patient Specific Education
Standards Supporting Electronic Transmission of Data

Standard Interoperability
“Building Blocks”

- **Vocabulary & Code Sets**
  How should well-defined values be coded so that they are universally understood?

- **Content Structure**
  How should the message be formatted so that it is computable?

- **Transport**
  How does the message move from A to B?

- **Security**
  How do we ensure that messages are secure and private?

- **Services**
  How do health information exchange participants find each other?

Semantic Interoperability
Syntactic Interoperability

Standards Supporting Electronic Transmission of Laboratory Data

- **Vocabulary Standards**
  - Logical Observation Identifiers Names and Codes (LOINC)®
    - Version 2.40, June 2012
  - Systematized Nomenclature of Medicine-Clinical Terms (SNOMED CT)®
    - International Release, July 2012 and US Extension to SNOMED CT,® March 2012 Release

- **Content Structure Standards**
  - Technical specifications defined in HL7 Implementation Guides
    - HL7 v2.5.1 Lab Orders Interface (LOI)
    - HL7 v2.5.1 Lab Results Interface (LRI)
    - HL7 v2.5.1 Electronic Laboratory Reporting to Public Health (ELR)
    - HL7 Version 3 (Infobutton)
Meaningful Use Objectives
Which Include Laboratory Data

<table>
<thead>
<tr>
<th>CORE OBJECTIVE</th>
<th>MEANINGFUL USE Stage 2 Objective 42 CFR 495.6(j)-(m)</th>
<th>MEANINGFUL USE Stage 2 Measure 42 CFR 495.6(j)-(m)</th>
<th>EHR CERTIFICATION CRITERIA 2014 Edition 45 CFR 170.314</th>
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| Eligible Providers | Lab Results in EHR | > 55% of all clinical lab tests results whose results are either in a positive/negative affirmation or numerical format are incorporated in CEHRT as structured data. | Ambulatory setting:  
• Electronically receive and incorporate clinical laboratory tests and values/results in accordance with specified standards.  
• Electronically display the tests and values/results received in human readable format.  
Inpatient setting only:  
• Electronically receive clinical laboratory tests and values/results in a structured format.  
• Electronically display such tests and values/results in human readable format.  
• Electronically display all the information for a test report specified in CLIA at 42 CFR 493.1291(c)(1) through (7).  
• Electronically attribute, associate, or link a laboratory test and value/result with a laboratory order or patient record. | HL7 Version 2.5.1  
Lab Results Interface (LRI)  
LOINC® version 2.40, June 2012  
A universal code system for identifying laboratory and clinical observations produced by the Regenstrief Institute, Inc. |
| Eligible Hospitals | | | | |

## Meaningful Use Objectives

### Which Include Laboratory Data

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<td>Eligible Hospitals (Menu item, not Core)</td>
<td>Lab Results to Ambulatory Providers</td>
<td>Hospital labs send structured electronic clinical lab results to the ordering provider for more than 20% of electronic lab orders received.</td>
<td>EHR technology must be able to electronically create laboratory test reports for electronic transmission.</td>
<td>HL7 Version 2.5.1 Lab Results Interface (LRI) LOINC® version 2.40, June 2012.</td>
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<td>Eligible Providers</td>
<td>Lab Orders by Computerized Provider Order Entry (CPOE)</td>
<td>&gt;30% of laboratory orders</td>
<td>Enable a user to electronically record, change, and access laboratory orders.</td>
<td>HL7 Version 2.5.1 Lab Orders Interface (LOI)</td>
</tr>
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<td>Eligible Hospitals</td>
<td>Reportable Lab Results to Public Health Agencies</td>
<td>Successful ongoing submission of electronic reportable laboratory results from CEHRT to a public health agency for the entire EHR reporting period. *Exclusions apply: see CMS rule for details</td>
<td>EHR technology must be able to electronically create reportable laboratory tests and values/results for electronic transmission.</td>
<td>HL7 2.5.1 Electronic Laboratory Reporting to Public Health (ELR). IHTSDO SNOMED CT® International Release, July 2012 and US Extension to SNOMED CT,® March 2012 Release. LOINC® version 2.40, June 2012.</td>
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# EHR Certification Criteria Which Include Laboratory Data

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<td>Eligible Providers</td>
<td><strong>Patient Lists</strong></td>
<td>Generate at least one report listing patients of the EP, EH, or CAH with a specific condition.</td>
<td>Enable a user to electronically and dynamically select, sort, access, and create patient lists by: date and time; and based on laboratory tests and values/results. In Ambulatory setting only, also create lists by patient communication preferences.</td>
<td>HL7 Version 2.5.1 Lab Results Interface (LRI) LOINC® version 2.40, June 2012</td>
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<td>Eligible Providers</td>
<td><strong>Patient Reminders</strong></td>
<td>More than 10% of all unique patients who have had two or more office visits with the EP within the 24 months before the beginning of the EHR reporting period were sent a reminder, per patient preference when available. *Exclusions apply: see CMS rule for details</td>
<td>Enable a user to electronically and dynamically select, sort, access, and create patient lists by: date and time; and based on laboratory tests and values/results. In Ambulatory setting only, also create lists by patient communication preferences.</td>
<td>HL7 2.5.1 Electronic Laboratory Reporting to Public Health (ELR). IHTSDO SNOMED CT® International Release, July 2012 and US Extension to SNOMED CT,® March 2012 Release. LOINC® version 2.40, June 2012</td>
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<td>Eligible Providers</td>
<td>Clinical Decision Support</td>
<td>Implement five clinical decision support interventions related to four or more clinical quality measures. *Exclusions apply: see CMS rule for details</td>
<td>Enable a limited set of identified users to select one or more clinical decision support interventions based on each one and at least one combination of the following data: (A) Problem list; (B) Medication list; (C) Medication allergy list; (D) Demographics; (E) Laboratory tests and values/results; and (F) Vital signs.</td>
<td>HL7 Version 3 (Infobutton)</td>
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<td>Eligible Hospitals</td>
<td>Patient Specific Education</td>
<td>EP: Patient-specific education resources identified by CEHRT are provided to patients for more than 10% of all unique patients with office visits. *Exclusions apply: see CMS rule for details</td>
<td>EHR technology must be able to electronically identify for a user patient-specific education resources based on laboratory tests and values/results.</td>
<td>HL7 Version 3 (Infobutton)</td>
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CDC’s LabHIT Team Vision: Laboratory information contributes to optimized healthcare decision making.

Engagement
- Forum to Engage and Coordinate Laboratory Efforts
- Laboratorians Participate Early In EHR/HIT Planning
- Regulations and Guidelines Incorporate Lab Input

Interoperability
- Support Harmonization (SNOMED & LOINC)
- Harmonized Interfaces
- Meaningful Comparisons of Lab Information

Usability & Contextuality
- Explore Innovative Information Display
- Results Interpreted Correctly
- Adverse outcomes reduced
LabHIT Activities

- ONC Laboratory Report Workgroup Tiger Team
  - Producing recommendations intended to reduce the cost and burden associated with implementing an ambulatory EHR to LIS interface (Laboratory Orders and Laboratory Results Interfaces).
  - Includes the Tiger Team and three subgroups:
    - Policy
    - Standards
    - Certification
LabHIT Activities

- **Content Standards Development and Related Activities**
  - S&I Laboratory Order Interface (LOI) – HL7 Implementation Guide for EHR vendors
  - S&I Laboratory Results Interface (LRI) - HL7 Implementation Guide for EHR vendors
  - S&I electronic Directory of Service (eDOS) - HL7 Implementation Guide for EHR vendors
  - S&I LOI/LRI CLIA Compliance Workgroup (active) – Crosswalk of CLIA requirements to HL7 field sets to support the Implementation Guides
  - NIST CLIA Certification Profile (pending) – Enhance online LRI certification tool for EHR vendors to test for CLIA requirements
  - NIST Big Data workgroup (new) – Engaged Dr. Michael Becich (pathology informatics geneticist) from UPenn to participate
  - Electronic Laboratory Reporting (not active, ad hoc) – Provided input to improve clinical relevance of certification use cases
LabHIT Activities

- **Content Standards Development and Related Activities**
  - S&I Health eDecisions (ad hoc)
  - S&I Query Health (ad hoc)
  - S&I Structured Data Capture (active workgroup – considering resources for LabHIT participation)
  - S&I Data Access Framework (active)
  - HL7 Variant Call File Transmission (active) – HL7 Implementation Guide for the technical specifications of transmitting molecular genetics files from research laboratory to EHR. (Note this is not an S&I related activity. HL7 is operating this implementation guide workgroup in parallel to CDC’s Next Generation Sequencing workgroup activities.)
LabHIT Activities

- **Vocabulary Standards Development**
  - APHL’s Laboratory Community of Practice (ongoing) – Harmonizing and updating SNOMED specimen type coding, map to LOINC
  - CDC’s Reportable Conditions Cross Mapping Table – Mapping reportable conditions to SNOMED coding
  - LOINC Enhancement Project (proposed) – Identifying top 80-90% order code set for ambulatory providers
  - Advancing Laboratory Interoperability (draft proposal) – short, mid and long range planning for full-scale semantic interoperability for laboratory data. Vision is to create a single national reference database of recommended vocabulary sets with mapping of FDA approved test systems to vocabulary code systems (e.g. LOINC, SNOMED, UCUM)
  - NIH LOINC for Variant Call Files (proposed, pending funding) - Mapping LOINC to molecular genetics terms
EMAIL THE CDC’S LABHIT TEAM IF YOU OR YOUR ORGANIZATION CAN PARTICIPATE ON A STANDARDS DEVELOPMENT WORKGROUP.

LABHIT@CDC.GOV
Introduction of Speakers

- **Dr. Doug Fridsma**
  - ONC Chief Science Officer & Director, Office of Science & Technology

- **Mr. Robert Dieterle**
  - ONC Contractor for S&I Framework and Laboratory Tiger Team and CEO EnableCare Group, LLC

- **Dr. Alexis Carter**
  - Director of Pathology Informatics, Emory University School of Medicine

- **Dr. Sundak Ganesan**
  - CDC Health Scientist, Division of Informatics Solutions and Operations

- **Dr. Nancy Cornish**
  - CDC Medical Officer, Division of Laboratory Programs, Standards, and Services (proposed)
References

- ONC EHR Incentives and Certification: [http://www.healthit.gov/providers-professionals/ehr-incentives-certification](http://www.healthit.gov/providers-professionals/ehr-incentives-certification)
Thank you!
For more information please contact Centers for Disease Control and Prevention

1600 Clifton Road NE, Mailstop F-11, Atlanta, GA 30333
E-mail: LabHIT@cdc.gov Web: http://wwwn.cdc.gov/clia/

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.