Laboratory Results Interoperability for Meaningful Use and Beyond
Session #9029

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Product Manager for Laboratory IT
Intelligent Medical Objects (IMO)
Northbrook, IL
October 9, 2014
In the past 12 months, I have had a significant financial interest or other relationship with the manufacturer(s) of the following product(s) or provider(s) of the following service(s) that will be discussed in my presentation.

<table>
<thead>
<tr>
<th>Company</th>
<th>Role</th>
<th>What was received</th>
</tr>
</thead>
<tbody>
<tr>
<td>College of American Pathologists</td>
<td>Employee</td>
<td>Salary and Benefits</td>
</tr>
<tr>
<td>Intelligent Medical Objects</td>
<td>Employee</td>
<td>Salary and Benefits</td>
</tr>
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</table>
Impacts on Laboratory Data Interoperability

- Standards and Regulatory
- Messaging and Exchange
- Terminology and Coding
- Vendor Functionality
Agenda

• Standards and Regulatory Requirements
  – Meaningful Use Introduction and Overview
• (Meaningful Use) Terminology and Coding
  – LOINC, LOINC Axes, LOINC Best Practices
  – SNOMED CT
  – Structured Laboratory Data
• (Meaningful Use) Vendor Functionality
• (Meaningful Use) Messaging and Exchange
• Achieving Interoperability
• Laboratory Interoperability Resources
MEANINGFUL USE INTRODUCTION
Meaningful Use Introduction

- In 2009, the Health Information Technology for Economic and Clinical Health (HITECH) Act was established January 2011-September 2013
- Goal is Interoperability of Healthcare Data
- Incentive payments to Eligible Professionals (EPs) and Eligible Hospitals (EHs)/Critical Access Hospitals (CAHs) for Meaningful Use (MU) of certified electronic health record (EHR) technology (CERHT)
Meaningful Use EH Timeline FY 2014

• Fiscal Year 2014 (FY 2014) concluded September 30, 2014
• 90 day period to collect data for FY 2014 attestation
• 10 EHs met Stage II MU in FY 2014 as of July 4, 2014
• 143 EHs met Stage II MU in FY 2014 as of August 25, 2014
• Over $24.8 billion in incentives paid (through end of July 2014)

Source: http://www.healthit.gov/FACAS/calendar/2014/09/03/hit-policy-committee
Meaningful Use Stage 2 Poll FY 2014
Meaningful Use Stage 2 Beyond FY 2014

• Risks for failing to demonstrate MU in FY 2014
  – Loss of MU incentive payments
  – 1% reduction in Medicare reimbursements (2015)
• Fiscal Year 2015 begins October 1, 2014 for **FULL YEAR**
• How many EH attendees are planning to attest to Stage 2 MU (1\textsuperscript{st} or 2\textsuperscript{nd} year) in FY 2015 (which started October 1, 2015)?
• Stage 3 delayed for EH until October 1, 2016 (FY 2017)
MEANINGFUL USE OVERVIEW
Stage 2 EH Meaningful Use Objectives Directly Impacting Laboratories

- Incorporate clinical laboratory test results into Certified EHR Technology (CEHRT) as structured data (Core)
- Capability to submit electronic reportable laboratory results (ELR) from CEHRT to public health agencies, except where prohibited, and in accordance with applicable law and practice (Core)
- Use CEHRT to provide structured electronic laboratory results to ambulatory providers (Menu)

EH MU: Structured Laboratory Results

Stage I MU
(One of five menu options)

More than 40% of all clinical lab tests results ordered by an authorized provider of the eligible hospital or CAH for patients admitted to its inpatient or ED whose results are either in a positive/negative or numerical format are incorporated in CEHRT as structured data.

Stage II MU
(Required)

More than 55% of all clinical lab tests results ordered by authorized providers of the eligible hospital or CAH for patients admitted to its inpatient or ED whose results are either in a positive/negative or numerical format are incorporated in CEHRT as structured data.

Source: www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/Stage2_MeaningfulUseSpecSheet_TableContents_EligibleHospitals_CAHS.pdf
EH MU: ELR

Stage I MU
(One of three public health options)

Perform one successful transmission of ELR to PH in accordance with applicable law and practice using LOINC in HL7 version 2.5.1.

*Note: ELR is required by law of all laboratories

Stage II MU
(Required)

Successful ongoing submission of ALL ELR to PH, except where prohibited, and in accordance with applicable law and practice using LOINC and SNOMED CT using HL7 version 2.5.1 from CEHRT.

EH MU: Ambulatory Reporting

Stage I MU
(Did Not Exist)

Stage II MU
(Required)

Hospital labs send structured electronic clinical laboratory test results using CEHRT to the ordering (ambulatory) provider for more than 20% of all laboratory orders received, in accordance with the HL7 version 2.5.1 S&I Framework Lab Results Interface (LRI) Implementation Guide.

Stage 2 EP Meaningful Use Objectives Directly Impacting Laboratories

• Incorporate clinical laboratory test results into Certified EHR Technology (CEHRT) as **structured data** (Core)

• Capability to identify and **report cancer cases** to a public health cancer registry, except where prohibited, and in accordance with applicable law and practice

EP MU: Structured Laboratory Results

Stage I MU
(Did Not Exist)

Stage II MU
(Required)

More than 55% of all clinical lab tests results ordered by the EP during the reporting period whose results are either in a positive/negative or numerical format are incorporated in CEHRT as structured data in accordance with the HL7 version 2.5.1 S&I Framework Lab Results Interface (LRI) Implementation Guide.

EP MU: Cancer Reporting

Stage I MU
(Did Not Exist)

Stage II MU
(Required)

Ongoing submission of cancer case information from CEHRT to public health central cancer registry using HL7 Clinical Document Architecture (CDA), except where prohibited, and in accordance with applicable law and practice for entire reporting period.

Stage 2 EH and EP MU: Indirect Impacts

- Computerized Provider Order Entry (CPOE) includes laboratory orders
- Use Clinical Decision Support (CDS)
- Summary of Care Record for Transitions of Care (TOC) must include laboratory results and LOINC codes
- Patients are provided access to their health information online including laboratory results
- Many Clinical Quality Measures (CQMs) integrate laboratory results and LOINC codes

Proposed Stage 3 (Changes Likely)

• Electronic Directory of Service (eDOS) (new)
  – Laboratory compendiums published to EHRs
  – Includes LOINC (orders), SNOMED CT (specimen information)

• Laboratory Orders Interfacing (LOI) (new)
  – Laboratory order specifications from EHRs
  – Includes LOINC (orders), SNOMED CT (specimen information)

• Structured Laboratory Reporting (80%)

• Ambulatory Reporting (55%)
MEANINGFUL USE TERMINOLOGIES
LOINC
Logical Observation Identifiers Names and Codes (LOINC)

LOINC releases and Regenstrief LOINC Mapping Assistant (RELMA) are freely available at www.loinc.org

• Releases in December and June
• Different versions required for each MU Stage
• RELMA Desktop and online versions include latest LOINCs codes
• LOINC and RELMA User Guides
HL7 Implementation Guides: LOINC Details

• LOINC encoding of **laboratory results** in
  • Laboratory Results Interfacing (**LRI**)  
    – Used for Structured Laboratory Reporting (EH and EP), and Ambulatory Reporting (EH)
  • Electronic Laboratory Reporting (**ELR**) for ELR

• LOINC encoding of CDA document sections in Ambulatory Provider Reporting to Central Cancer Registries (EP)

• LOINC encoding of **laboratory orders** (future) in
  • LOI and eDOS
### LOINC Coding Orders (Panels) and Results

<table>
<thead>
<tr>
<th>Laboratory Order</th>
<th>LOINC Order Code</th>
<th>LOINC Order Long Name</th>
<th>Laboratory Result</th>
<th>LOINC Result Code</th>
<th>LOINC Result Long Name</th>
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<td>PSA panel</td>
<td>53764-7</td>
<td>Prostate specific Ag panel - Serum or Plasma</td>
<td>Total PSA</td>
<td>2857-1</td>
<td>Prostate specific Ag [Mass/volume] in Serum or Plasma</td>
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<td>PSA panel</td>
<td>53764-7</td>
<td>Prostate specific Ag panel - Serum or Plasma</td>
<td>Free PSA</td>
<td>10866-0</td>
<td>Prostate Specific Ag Free [Mass/volume] in Serum or Plasma</td>
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<td>Total PSA</td>
<td>2857-1</td>
<td>Prostate specific Ag [Mass/volume] in Serum or Plasma</td>
<td>Total PSA</td>
<td>2857-1</td>
<td>Prostate specific Ag [Mass/volume] in Serum or Plasma</td>
</tr>
</tbody>
</table>

- **Results:** LOINC OrderObs = Observation or Both
- **Orders (Panels):** LOINC OrderObs = Order or Both
<table>
<thead>
<tr>
<th>LoINC</th>
<th>Property</th>
<th>Timing</th>
<th>System</th>
<th>Scale</th>
<th>Method</th>
<th>Ex</th>
<th>ExUnits</th>
<th>LongName</th>
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<tbody>
<tr>
<td>49483-1</td>
<td>Imp</td>
<td>Pt</td>
<td>Ser</td>
<td>Nar</td>
<td>EIA</td>
<td></td>
<td></td>
<td>HIV 1 [interpretation] in Serum by Immunoassay Narrative</td>
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<tr>
<td>44607-0</td>
<td>Imp</td>
<td>Pt</td>
<td>Ser</td>
<td>Nom</td>
<td>EIA</td>
<td></td>
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<td>HIV 1 [interpretation] in Serum by Immunoassay</td>
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<tr>
<td>21999-6</td>
<td>Imp</td>
<td>Pt</td>
<td>Ser</td>
<td>Nom</td>
<td>IB</td>
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<tr>
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<td>Imp</td>
<td>Pt</td>
<td>Ser</td>
<td>Nar</td>
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<tr>
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<td>Ser/Plas</td>
<td>Nom</td>
<td>EIA.rapid</td>
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<td></td>
<td>HIV 1 and 2 Ab [Identifier] in Serum or Plasma by Rapid immunoassay Both</td>
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<tr>
<td>43185-8</td>
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<td>Pt</td>
<td>Ser</td>
<td>Nom</td>
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<td>Ord</td>
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<td>HIV 1 Ab [Presence] in Serum</td>
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<tr>
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<td>Ser</td>
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<td>HIV 1 Ab [Presence] in Serum by Immunoblot (IB)</td>
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<td>HIV 1 Ab [Units/volume] in Serum</td>
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<td>HIV 1 Ab [Units/volume] in Serum by Immunoassay</td>
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<td>Pt</td>
<td>Ser</td>
<td>Qn</td>
<td>IF</td>
<td></td>
<td></td>
<td>HIV 1 Ab [Units/volume] in Serum by Immunofluorescence</td>
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<tr>
<td>68961-2</td>
<td>Pr</td>
<td>Pt</td>
<td>Ser/Plas</td>
<td>Ord</td>
<td>EIA.rapid</td>
<td></td>
<td></td>
<td>HIV 1 Ab [Presence] in Serum, Plasma or Blood by Rapid immunoassay Both</td>
</tr>
<tr>
<td>21007-0</td>
<td>ACnc</td>
<td>Pt</td>
<td>Ser<em>do</em></td>
<td>Ord</td>
<td></td>
<td></td>
<td></td>
<td>HIV 1 Ab [Presence] in Serum from donor</td>
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<tr>
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<td>Imp</td>
<td>Pt</td>
<td>Ser</td>
<td>Nom</td>
<td>IB</td>
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<td>HIV 1 Ab band pattern [interpretation] in Serum by Immunoblot (IB)</td>
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<td>Pt</td>
<td>Ser</td>
<td>Ord</td>
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<td></td>
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<td>HIV 1 IgG Ab [Presence] in Serum</td>
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<tr>
<td>49965-7</td>
<td>Ratio</td>
<td>Pt</td>
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<td>IB</td>
<td></td>
<td></td>
<td>Deprecated HIV 1 Ab/HIV-2 Ab-Ab [Ratio] in Serum by Immunoblot...</td>
</tr>
</tbody>
</table>
MEANINGFUL USE TERMINOLOGIES
LOINC AXES
LOINC Code Represents Aspects of Six Axes

42914-2 Code Axis

1. HER2
2. MCnC
3. Pt
4. Ser
5. QN
6. EIA

LOINC Code Axis

1. Component Analyte
2. Property
3. Time Aspect (Spot, 24)
4. Specimen Type (System)
5. Scale
6. Method (IB, FISH, EIA)

42914-2 HER2 [Mass/volume] in Serum by Immunoassay
Axis II: Property

**MCnc**
- Mass Concentration
- Units are helpful

**Property Aspect**
- ACnc = Arbitrary Concentration
- MCnc = Mass Concentration (mass)
- SCnc = Substance Concentration (moles)
- PRID = Presence/Identity (Organism ID)
- Threshold
- Ratio
Axis III: Time Aspect

Pt

- Pt=point in time
- Common for venous draws

Property Aspect

- 24H, 2H=24 hour, 2 hour (timed urines)
- Pt=spot or random urines
- Although not represented on the time axis, challenge tests (GTT) and trough, peak TDMs have different LOINC codes
- XXX=any time
Axis IV: Specimen Type (System)

Ser

- Ser=serum only
- Ser/Plas= serum or plasma
- Whole Blood- think POCT

Property Aspect

- Bld/Tiss=blood or tissue
- Ser/Plas= serum or plasma
- Body Fluid (BF)
- Urine versus Urine sediment
- XXX=Specimenless. Often used where many specimens/sites may be collected (pCR, micro) or is an unspecified specimen
Axis V: Scale

**Qn**
- Qn=quantitative (numeric, semi-quant)

**Property Aspect**
- Ql=qualitative (pos, neg, indeterminate)
- Ord=ordinal (reactive, nonreactive, 1+, 2+)
- Nom=Nominal (discrete responses, short answer)
- Narr=Narrative (microbiology, pathology reports, interpretations)
**Axis V: Scale**

**EIA**
- EIA = Enzyme Immunoassay
- Groups most IA tests, including chemiluminescence and RIA

**Property Aspect**
- Manual versus automated counts
- Microscopy (light, LPF, HPF)
- Test strip and tests strip automated
- FISH, cytogenetics, molecular
- Culture versus organism specific culture
- IF, IB, RPR, Probe, LA, immune stain
MEANINGFUL USE TERMINOLOGIES
LOINC BEST PRACTICES
Generic Versus Specific LOINC Codes

32293-3 Albumin [Mass/volume] in Unspecified specimen

<table>
<thead>
<tr>
<th>Fully-Specified Name:</th>
<th>Component</th>
<th>Property</th>
<th>Time Aspect</th>
<th>System</th>
<th>Scale</th>
<th>Method</th>
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</thead>
<tbody>
<tr>
<td>Albumin</td>
<td>MCnc</td>
<td>Pt</td>
<td></td>
<td>XXX</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

43605-5 Microalbumin [Mass/volume] in 4 hour Urine

<table>
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<tr>
<th>Fully-Specified Name:</th>
<th>Component</th>
<th>Property</th>
<th>Time Aspect</th>
<th>System</th>
<th>Scale</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Albumin</td>
<td>MCnc</td>
<td>4H</td>
<td></td>
<td>Urine</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- Most specific LOINC should be used to meet many jurisdictional requirements for ELR and Best Practices
- Performing laboratory should be providing LOINC and SNOMED CT codes
Mapping Best Practices and Tips

• Mapping takes time. Plan accordingly!
• Ensure staff are trained for each terminology
• Laboratory professionals are best suited to map laboratory orders, laboratory results and test result values
• Plan resources for primary mapper and validator
• Start with easier items to map and advance to more complicated ones like microbiology
Mapping Best Practices and Tips Continued

- Single test may fulfill multiple MU requirements
- High volume tests may help you achieve MU without mapping your entire data dictionary
- Focus on items reported outside of laboratory, not internal items such as quality control
- Don’t forget to update terminology(ies) with test menu changes
- Review each terminology release for changes (added or deprecated codes)
Mapping Best Practices: Validation

• Automapping and Terminology Services
  – May only map 60% of content, if 40% is not mapped, it requires manually mapping
  – Of the 60%, 20% may be inaccurate, which requires manual mapping

• External Sources of codes
  – Diagnostic vendors
  – Reference and commercial laboratories

• Validate ALL External Maps!!

SG by refractometry ≠ SG by test strip
LOINC Poll
MEANINGFUL USE TERMINOLOGIES
SNOMED CT
MU Terminologies: Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT)

- Releases in June and July.
- US releases from National Library of Medicine (NLM)
- Licensing may be required for other countries
- Version requirements differ with each MU Stage
Free SNOMED CT Browsers

- Virginia-Maryland Regional College of Veterinary Medicine:  http://vtsl.vetmed.vt.edu
- CliniClue Xplore: http://www.cliniclue.com/cliniclue_xplore
- Apelon Mycroft: http://support.apelon.com/mycroft/users/default.asp
HL7 Implementation Guides Requiring SNOMED CT

- Electronic Laboratory Reporting (ELR) for ELR (EH)
- Laboratory Results Interfacing (LRI)
- Used for Structured Laboratory Reporting (EH and EP), and Ambulatory Reporting (EH)
- Ambulatory Provider Reporting to Central Cancer Registries (EP)
- eDOS and LOI (future)
SNOMED CT Laboratory Impacts

• Mapped to Laboratory Test Result Values
  – Organisms from Organism Hierarchy
  – Pos/Neg, Reactive/Nonreactive, Resistant, Susceptible, etc. result values from Qualifier Hierarchy

• Mapped to Specimen Information
  – Specimens from Specimen Hierarchy
  – Source from Anatomical Concepts (Body Structure) Hierarchy
Cancer Reporting (EP) SNOMED CT Needs

- Histologic type
- Smoking Status
- Procedure Type
- Approach Site
- Primary Tumor Site, Body Site of Procedure (Body Site Hierarchy)
- Diagnosis
- Problem List
- Unknown Information
- Lack of Medication Information
- TNM Staging (Before Treatment)

Anatomic Pathology Reporting
### SNOMED CT Organism Search

**VTSL Terminology Browser**

Terminology Loaded: SNOMED CT® (January 2014) with VTSL Veterinary Extension.

<table>
<thead>
<tr>
<th>Search SNOMED CT®:</th>
<th>Narrow By Hierarchy</th>
</tr>
</thead>
<tbody>
<tr>
<td>salmonella typhi</td>
<td>+ Substance (9)</td>
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</tbody>
</table>

- All descriptions | Fully Specified Name Only | Concept Identifier

- Search | Reset

**Description Term Search Results:**

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<tr>
<th>Fully Specified Concept [Active; Inactive]</th>
<th>Other Description(s)</th>
<th>Hierarchy</th>
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<tbody>
<tr>
<td>Typhoid fever (disorder) (4834000)</td>
<td>Typhoid fever; Infection by Salmonella typhi</td>
<td>Disorder, Clinical findings</td>
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<tr>
<td>Murine typhus (disorder) (25668000)</td>
<td>Urban typhus; Shop typhus; Murine endemic flea typhus; Typhus due to Rickettsia typhi; Flea-borne typhus; Endemic typhus; Murine typhus</td>
<td>Disorder, Clinical findings</td>
</tr>
<tr>
<td>Rickettsia typhi (organism) (79284001)</td>
<td>Rickettsia mooseri; Rickettsia typhi</td>
<td>Organism</td>
</tr>
<tr>
<td>Salmonella Typhuisuis (organism) (52730003)</td>
<td>Salmonella enterica subsp. enterica ser. Typhuisuis; Salmonella Typhuisuis; Salmonella typhi-suis</td>
<td>Organism</td>
</tr>
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<td>Serologic test for Rickettsia typhi (procedure) (33241003)</td>
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<td>Salmonella typhi group D, O antibody assay (procedure) (122089002)</td>
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<td>Salmonella typhi group D, H antibody assay (procedure) (122087000)</td>
<td>Salmonella typhi group D, H antibody assay</td>
<td>Procedure</td>
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<td>Salmonella Typhi (organism) (5595000)</td>
<td>Salmonella enterica subsp. enterica ser. Typhi; Salmonella 9,12,V1:d:-; Salmonella 9,12, [V1]:d:-; Salmonella Typhi; Typhoid bacillus; Eberthella typhi; Salmonella typhosa</td>
<td>Organism</td>
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Search SNOMED CT®:

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- All descriptions | Fully Specified Name Only | Concept Identifier

Click here for Advanced search help

Description Term Search Results:

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<th>Other Description(s)</th>
<th>Hierarchy</th>
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</thead>
<tbody>
<tr>
<td>Cerebrospinal fluid sample (specimen) (258450006)</td>
<td>CSF - Cerebrospinal fluid sample; Cerebrospinal fluid specimen</td>
<td>Specimen</td>
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</tbody>
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1-1 of 2 Records Next 30
SNOMED CT Qualifier Search

VTSL Terminology Browser

Terminology Loaded: SNOMED CT® (July 2014) with VTSL Veterinary Extension.

Search SNOMED CT®:

reactive

- All descriptions | Fully Specified Name Only | Concept Identifier

Click here for Advanced search help

Description Term Search Results:

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<tr>
<th>Fully Specified Concept [Active; Inactive]</th>
<th>Other Description(s)</th>
<th>Hierarchy</th>
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<td>Weakly-reactive</td>
<td>Qualifier value</td>
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<td>Non-Reactive (qualifier value) (131194007)</td>
<td>NR - Non-reactive; Non-Reactive</td>
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<td>Reactive (qualifier value) (11214006)</td>
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1-3 of 4 Records Next 30
### VTSL Terminology Browser

Terminology Loaded: SNOMED CT® (July 2014) with VTSL Veterinary Extension.

#### Search SNOMED CT®:

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<th>polycythemia vera</th>
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- **All descriptions** | **Fully Specified Name Only** | **Concept Identifier**

Click here for Advanced search help

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</thead>
<tbody>
<tr>
<td>Polycythemia vera (disorder) (109992005)</td>
<td>Erythrocythaemia; PRV - Polycythemia rubra vera; Primary proliferative polycythemia; PPP - Primary proliferative polycythemia; Polycythemia vera; Polycythemia rubra vera; PRV - Polycythemia rubra vera; Polycythemia vera; Polycythemia rubra vera; PPP - Primary proliferative polycythemia; Primary proliferative polycythemia; Primary poly</td>
<td>Disorder, Clinical findings</td>
</tr>
<tr>
<td>Erythrocytosis (disorder) (127062003)</td>
<td>Polycythemia; Erythrocytosis; Polycythemia; Peripheral blood red cell count above the normal range</td>
<td>Disorder, Clinical findings</td>
</tr>
</tbody>
</table>
SNOMED CT Poll
STRUCTURED LABORATORY DATA
Structured Laboratory Results

- February 2014 ONC Data Brief focused on Health Information Exchange among Clinical Laboratories
- 2012 survey indicated 67% of clinical laboratories had the capability to send structured laboratory results to EPs
- Structured format (defined by ONC): Documentation of discrete data using controlled vocabulary, creating fixed fields within a record or file, or another method that provides clear structure to information (is not completely free text).

Creating Structured/Discrete Clinical Laboratory Results

• Synoptic reporting in anatomic pathology
• Nominal, not narrative reports
• Analyte and result value for numeric results
• Think LOINC as the Question and SNOMED CT as the answer
Synoptic/Discrete Reporting
Hematology EP Example

- Specimen: Peripheral blood smear
- Procedure: Venipuncture
- Histologic Type: Polycythemia vera
Structured/Discrete Reporting Clinical Laboratory EH Example

• Albumin 4.2 ng/ml
• Lyme IgG Ab Positive
• Urine Culture E. coli
MEANINGFUL USE VENDOR FUNCTIONALITY
MU EHR Vendor Certification

- Certified for Ambulatory (EP) versus Inpatient (EP and EH) practice
  - EH EHRs typically have functionality to SEND structured laboratory data
  - EH and EP EHRs typically have functionality to RECEIVE structured laboratory data
- 2014 certified products required for FY 2015 attestation (EH)
- Certified as complete EHR or modular EHR (i.e. LIS)
MU EHR Vendor Certification and Functionality

• Certified products listed at http://oncchpl.force.com/ehrcert

• Certified vendor products should be able to provide functionality listed in 2014 certification including:
  – LOINC encoding of results
  – SNOMED CT encoding of specimens, source, organisms, results, etc.
  – HL7 2.5.1 messaging
MU LIS Certification and Functionality

- LIS can be certified (modular) if LIS provides (EHR) MU functionality
  - Most LIS vendors have 2014 MU Certified product(s), but not many Anatomic Pathology (AP) LISs
  - May be challenge if lower volume tests in AP LIS used for MU attestation
  - Consider setting up test reporting from LIS if AP LIS unable to provide needed functionality or is not certified (i.e. does AP LIS have LOINC functionality?)
LIS Vendor MU Functionality

- Functionality varies by vendor!
- ELR is in EHR for some, so LIS not certified
- Many LISs not initially certified for MU, but many now 2014 certified (but not all)
- Other vendors have ELR functionality in LIS, while others require purchase of module certified for ELR
- Vendors can provide full details of product functionality
- Reference laboratory LIS and/or EHR may not be certified
LIS Terminology Functionality

• LOINC code mapping often in test set up screen with for orders and results with mnemonics (local codes)
• Although LOINC encoding of orders not required now, some vendors have capabilities to map orders
• SNOMED CT lacking in LIS in December 2012, but now available with 2014 certification
• SNOMED CT functionality may be in microbiology module and/or in tables
LIS MU Functionality and Non Hospital Laboratories

• Non hospital (EH) laboratories ineligible for MU, so may not provide MU compliant laboratory results
  – EPs & EHs may need to add MU terminologies to results in EHR
  – EHs may need to convert incoming laboratory result messages to HL7 2.5.1
  – Many reference laboratories provide LOINC codes
  – SNOMED CT coding in progress by many laboratories
MEANINGFUL USE MESSAGING AND EXCHANGE
LIS Messaging and Interfacing

• Many LISs separate from EHR and can be interfaced to
  – EHR for results reporting for patient care (EHs & EPs)
  – Public Health Information Systems for ELR
  – Reference Laboratories for send out tests
  – Research Repositories
  – Health Information Exchanges (HIEs)

• HL7 2.5.1 messaging required for MU
HL7 Messaging of Laboratory Data

• HL7 Implementation Guides
  – Laboratory Results Interface (LRI)
  – Electronic Laboratory Results (ELR)
  – Laboratory Order Interface (LOI)
  – Electronic Directory of Service (eDOS)
• Many laboratories moving from HL7 version 2.3.1 messaging to HL7 version 2.5.1
• Messages from non hospital laboratories may be HL7 version 2.3.1 since they are excluded from MU
Implementing HL7 Laboratory Messaging

• How laboratory results messages provided for?
  – Providers (outreach)
  – Exchange with other laboratories or hospitals
  – ELR to Public Health

• Via
  – Interfacing directly to each EHR
  – Direct Protocol
  – Health Information Exchanges (HIE)

• Don’t forget interface validation requirements
Implementing Public Health (PH) Messaging

- Required by law of ALL laboratories for ELR and Cancer Reporting
  - Jurisdictional requirements vary (timing, criteria, what’s reported, etc.).
  - Often based on patient residence
- How are messages created which meet PH reporting criteria? With LIS rules?
- How are these messages routed or filtered from LIS or EHR to PH?
Implementing Public Health Connectivity

• Are messages sent to PH centrally or to each area?
• What’s the PH onboarding process? Each jurisdiction has their own requirements.
• For EH patients with reference laboratory testing, who reports, performing laboratory or both EH and reference laboratory?
• Messages not meeting PH requirements may be rejected, impacting MU attestation
• Start early to avoid queues for resources (vendor, PH)!
ACHIEVING INTEROPERABILITY
Achieving Interoperability

• Once foundational work completed with
  – Terminology aspects
  – Messaging and connectivity aspects

• Exchange of structured data can begin among:
  – Providers
  – Hospitals
  – Laboratories
  – Health Information Exchanges (HIEs)
  – Public Health
Downstream Laboratory Data Uses

- Patient care (EP outpatient, EH inpatient)
- Public Health
  - Hospital Cancer Registries
  - Central Cancer Registries
  - ELR to each section (TB, HIV, lead, STDs, etc.)
- Research
- Laboratory internal analytics, statistics, queries, etc.
- Insurance, supplementing claims data with clinical data
Downstream Laboratory Data Uses for Meaningful Use and Beyond

- Clinical Quality Measures
- Transfers of Care
- Healthcare Acquired Infections (HAIs)
- Surveillance Reporting
- Clinical Decision Support
- Population Health
- Analytics, including Big Data
- Other use cases
HIE Example

- Hospital A correctly assigns LOINC code 718-7 to CBC Hgb.
- Hospital B correctly assigns 718-7 to CBC HgB and incorrectly assigns LOINC 718-7 to ABG Hgb and VBG Hgb.
- ER MD in performs an HIE query for a patient’s results for 718-7 Hemoglobin [Mass/volume] in Blood.
- What are the implications on clinical decision making and patient safety when different results are comingle?
LABORATORY INTEROPERABILITY RESOURCES
EHR Resources

• Safety Assurance Factors for EHR Resilience (SAFER) Guides:  http://www.healthit.gov/safer/

• Guides and self assessment checklists for safe EHR practices

• Laboratory aspects include:
  – Test Results Reporting and Follow-Up
  – System Interfaces
  – Computerized Provider Order Entry with Decision Support
LIS Resources

• Association for Pathology Informatics LIS Functionality Assessment Toolkit:
  http://pathologyinformatics.org/toolkit
  – White paper about toolkit components
  – Functionality Statements for LIS assessment
  – LIS Scenarios for live vendor demonstrations
  – Total Cost of Ownership Worksheet
LIS Resources

- Association for Pathology Informatics LIS Functionality Assessment Toolkit:
  http://pathologyinformatics.org/toolkit
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  - LIS Scenarios for live vendor demonstrations
  - Total Cost of Ownership Worksheet
CDC Laboratory Resources

• Essential Role of Laboratory Professionals: Ensuring the Safety and Effectiveness of Laboratory Data in Electronic Health Record Systems: 
  
  www.cdc.gov/labhit/paper/Laboratory_Data_in_EHRs_2014.pdf

  – Engagement: laboratory expertise valuable in design and implementation
  – Data Integrity and Usability: accurate lab data available for many downstream end users
  – Innovation: solutions for laboratory data related EHR errors
Conclusion

• MU is driving laboratory data interoperability via foundational building blocks in:
  – Standards and regulatory requirements
  – Terminology requirements (LOINC and SNOMED CT)
  – Vendor functionality and certification
  – Connectivity and Exchange
Conclusion Continued

• Quality terminology coding and messaging is essential for laboratory data interoperability!

• Differences matter for:
  – **clinically care** and **patient safety**,  
  – analytics and statistics, and  
  – **interoperability** versus **inoperability**.
Questions?

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