Electronic Health Record (EHR) Laboratory Results Reporting

Webinar 5  July 24, 2008  |  2:00 – 3:30 pm (Eastern)

Presenters

- Jamie Ferguson, Executive Director, Health IT Strategy and Policy, Kaiser Permanente
- Michael Glickman, President & Founder, Computer Network Architects

Sponsored by the HITSP Education, Communications and Outreach Committee

enabling healthcare interoperability
Learning Objectives

During this 90-minute webinar, participants will explore the basics of the HITSP Interoperability Specification (IS) for EHR Laboratory Results Reporting (IS 01), including:

- the harmonization process and standards utilized by the IS
- potential for use of the IS in direct care and in public health
  - AHIC Use Cases
  - scope of interoperability
- key information on how specification can be used by your own organization
Agenda
a webinar series on U.S. healthcare interoperability

☐ Introduction to HITSP IS 01
  — Review business needs established by AHIC Use Case
  — Use Case Scenarios

☐ Key Concepts

☐ Review of the IS and its Constructs
  — Option #1: Lab Result Messages
    — Option #2: Lab Result Documents

☐ Implementation Considerations

☐ Questions and Answers / Open Dialogue
Patient is a 26-year-old male coping with the long-term effects of a brain tumor that was removed during his childhood

- Patient is required to maintain a strict regimen of visits to his healthcare providers in order to stay up-to-date on his tests and lab results; constant monitoring is essential

Steve is troubled by the recent loss of is grandmother

- Due to a lack of information sharing between multiple doctors, her medications contradicted each other and she lost the ability to absorb a critical thyroid treatment

- Her lab work became grossly abnormal with TSH levels climbing to 75 mIU/L from a normal of 0.5 - 5.0 mIU/L; however, her doctors were unable to “connect the dots” to see the abnormal trends across providers and testing centers

- Death was brought on by complications resulting from the reaction of her medications and other treatments
Introduction: Steve’s story (continued)

The Future: Healthcare in an interoperable world

- The seamless and secure exchange of interoperable lab results data will allow authorized healthcare providers to access laboratory results from multiple repositories
  - Providers will send queries to a locator service, receive pointers to existing documents, and retrieve relevant lab results documents
  - Patients will have the ability to help review their lab results and trend their lab results over time
  - As appropriate, data will be provided to public health agencies in line with requirements for biosurveillance reporting
HITSP is a volunteer-driven, consensus-based organization that is funded through a contract from the Department of Health and Human Services.

The HITSP Panel brings together public and private-sector experts from across the healthcare community to harmonize and recommend the technical standards that are necessary to assure the interoperability of electronic health records.
The HITSP Standards Harmonization Framework

- Identify a pool of standards for an AHIC (American Health Information Community) Use Case
- Identify gaps and overlaps in the standards for this specific Use Case
- Make recommendations for resolution of gaps and overlaps
- Select standards using HITSP-approved Readiness Criteria
- Develop **Interoperability Specifications (IS)** that use the selected standard(s) for the specific context
- Test the IS
IS Status = State in the acceptance process

- **Released**
  Panel approved for submission to HHS

- **Accepted**
  Secretary of HHS has accepted for a period of testing

- **Recognized**
  Secretary of HHS has recognized the IS for immediate implementation

- Revisions and updates may mean that multiple versions of some Interoperability Specifications exist with differing status levels
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This Interoperability Specification defines specific standards to support the interoperability between electronic health records and laboratory systems and secure access to laboratory results and interpretations in a patient-centric manner.

- Version: 2.1 Recognized
- Version: 3.0 Released (Panel Approved)
AHIC EHR-Lab Use Case

Scope

- Deploy standardized, widely available, secure solutions for accessing laboratory results and interpretations in a patient-centric manner for clinical care by authorized parties.
  - Transmission of complete, preliminary, final and updated laboratory results to the EHR system (local or remote) of the **ordering clinician**
  - Transmission of complete, preliminary, final and updated laboratory result (or notification of laboratory result) to the **EHR system** (local or remote) or **other clinical data system** of designated providers of care (with respect to a specific patient)
  - Also enabled: Laboratory result message and/or documents when the test result is within the range and category of interest for **Biosurveillance reporting** as required by federal, state or local legally authorized public health agencies
EHR-Lab Use Case Scenario #1
Sending new lab results

A. Identify/create lab result terminology
B. Send results message to ordering clinician
C. Cross-reference patient’s identity
D. Send results message to other authorized providers of care
E. Structure lab result as lab report document
F. Send document to repository, store, and register in data locator service (Note: data repository may be part of EHR or an independent actor)
G. Notification of availability of lab report
H. Send report to authorized providers of care
EHR-Lab Use Case Scenario 2
Query repository for retrieval of historical lab results

F. Send document to repository, store, and register in data locator service
G. Notification of availability of lab report
I. Query data locator service for lab results location and retrieve from repository
J. Query repository and retrieve lab report directly from repository
K. Merge lab results into EHR
L. View lab results from a web application
Key Concepts of HITSP IS 01

- Defines both an HL7 2.5.1 message and HL7 CDA R2 XML document for conveying the content of the report.

- Defines alternate actions for retrieval of lab result documents from a repository for web viewing of historical records.

- Either a v2 message or an XML document may fulfill the initial lab result and interpretation reporting from the lab; only XML documents are used for historical results.
Key Concepts (continued)

- Pre- and Post-Conditions
  - Lab orders are a pre-condition, common meta-data is assumed

- Constraints
  - Use of ISO Object IDentifier standard (OIDs) for identifiers
    - Globally unique ID for each object
  - Notification and distribution of results

- Security and Privacy
  - Deferred in v2.1, and integrated in the current version, v3.0

- Gaps
  - Terminology standards for reporting laboratory results
## Constructs

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Overview

HITSP IS 01: EHR – Laboratory Results Reporting

Transaction Packages

- Transaction Package (TP 14): Send Lab Result Message to Ordering Clinician and POC
- Transaction Package (TP 13): Manage Sharing of Documents
- Transaction Package (TP 22): Consumer/Patient Id X-ref
- Transaction Package (TP 23): Patient Demographics Query
- Transaction Package (TP 29): Notification of Document Availability

Transactions

- Transaction (T 18): View Lab From Web
- Transaction (T 23): Patient Demographics Query
- Transaction (T 29): Notification of Document Availability

Components

- Component (C 44): Secure Web Connection
- Component (C 36): Lab Report Message
- Component (C 35): Lab Terminology
- Component (C 37): Lab Report Document

Base Standards

- Base Std HL7 V2.5.1
- Base Std LOINC
- Base Std SNOMED CT coding
- Base Std UCUM
- Base Std Others
- Base Std HL7 V3 Lab
- Base Std HL7 CDA r2
- Base Std ISO 15000 ebRS 2.1/3.0
- Base Std HL7 V2.5
Selected Acronyms
This will be useful for the next slide

- **LOINC** Logical Observation Identifiers Names and Codes
  *Identifies laboratory and other clinical observations*
  - [www.loinc.org](http://www.loinc.org)

- **HEDIS** Healthcare Effectiveness Data and Information Set
  *Tool to measure care are service performance*
  - [www.ncqa.org](http://www.ncqa.org)

- **SNOMED-CT** Systematized Nomenclature of Medicine-Clinical Terms
  *Comprehensive clinical terminology*
  - [www.ihtsdo.org](http://www.ihtsdo.org)

- **HL7** Health Level Seven
  *Develops healthcare informatics standards, mostly for interoperability*
  - [www.hl7.org](http://www.hl7.org)
Terminologies used by IS 01 C 35 EHR Lab Terminology

Key Concept

- Augments minimum terminologies and vocabularies required by the base standard
- Specifies vocabulary for Laboratory Results data
  - LOINC for top 95% of routine tests reported in HEDIS, plus microbiology and cytology
  - SNOMED-CT for Problem List, Lab Test Findings and Organisms
  - HL7 V2.5 Code Sets and HL7 V3.0 Code Sets
EHR-Lab Use Case
Two options for interoperability

- **Option 1: Lab result messaging**
  - **New** result to ordering provider EHR
  - **Via Lab Result** **Messages**
    - Uses Base Standard HL7 V2.5.1 for transmission of lab result messages

- **Option 2: Lab result document exchange**
  - New result to ordering provider and to copy-to list on lab test order
  - All queries for historical results used in clinical care
  - **Via Lab Result** **Documents**
    - Uses Composite Standard IHE XDS which references Base Standard HL7 CDA and Base Standard XML
Option #1
C 36 Lab Report Message

- Defines constraints on an HL7 2.5.1 message specification to address the AHIC use case requirements
- Does not include support for anatomic pathology
- Refers to C 35 for vocabulary and terminology support where HL7 is optional
- Constrains data types and cardinality to meet AHIC requirements
HL7 v.2.5.1
Interoperable Lab Result Message

- Unique Order Numbers: ISO Object IDs (OIDs)
- Patient ID, Patient Visit Information
- Observation Request and Result Segments
- Specimen Segment
- Culture and Susceptibilities
- Inpatient and Ambulatory Consistency
**TP 14**
**Send Lab Result**

- Defines the requirements for sending the HL7 2.5.1 Lab Message
  - Specific transport technology not constrained to allow NHIN flexibility
  - Defaults to HL7 specified methods
  - Transport specification update was made to construct this year in Panel Approved v2.2 of T 14 and is used by IS 01 v3.0

- Uses HL7 Acknowledgements
  - Specifies system acknowledgement behavior during message transmission
HL7 v.2.5.1
Secondary Use of Lab Message for Public Health Use

- Key Features
  - Standardized vocabularies
  - Specimen information
  - Ordering provider
  - Patient class, admission type, location
  - Patient birth, death

- Pseudonymization and Anonymization for Public Health Reporting is out of scope for this presentation
Option #2:  
C37 Laboratory Report Document Structure

- **Key Concepts**
  - Information is fully computable (not free text)
    - In HL7 CDA terms, this is referred to as “Level 3” data encoding
  - Constrains the use of the IHE XD*-Lab Profile which itself is a constrained implementation of HL7 CDA R2
  - Refers to C 35 for terminology and vocabulary support
HL7 CDA R2
Standardized XML Lab Result Document

Key Features

- Clinical statement pattern templates
- Content follows HL7 v.2.5.1 Specification
- Human and machine readable
- Stylesheet required for rendering without EHR
- Inpatient and ambulatory consistency
- Simple Hashing Algorithm validates electronic document integrity
TP 13
Manage Sharing of Documents

- Defines the requirements for the registration, storage and retrieval of documents across repositories
  - Specifies a subset of transactions defined in the IHE Cross Document Sharing (XDS) Specification, Dec 2006
    - ITI 14 Register Document Set
    - ITI 15 Provide & Register Document Set
    - ITI 18 Registry Stored Query
    - ITI 17 Retrieve Document

- Key Concepts
  - Sharing of source attested documents, document content neutral, document registry, document repositories distributed or centralized.
Querying for, retrieving, and submitting documents

XDS = “FedEx”

A transport envelope, document format- and content-agnostic, with generic search and retrieve. Supports both push and pull models. Actors are not bound to any RHIO/NHIN architecture.
Gaps

— An identified gap in v2.1 of the IS was the ability to share documents across communities

— The gap was addressed by an IHE extension to Cross Document Sharing Profile (XDS) called Cross Community Access Profile (XCA)
  
  ▪ XCA was demonstrated in the HIMSS ‘08 Interoperability Showcase

— IS 01 v3.0, which is Panel approved, includes support for cross-community sharing of documents
T 23
Patient Demographics Query

- Defines the methodology for obtaining a patient identity (or list of patient identities) that match a provided set of patient demographics
- IHE IT Infrastructure (ITI) Technical Framework (TF), Volume 2 (ITI TF-2)
- ITI-21: Patient Demographics Query [§3.21.1]

**Key Concepts**
- Patient Identity Demographics, HL7 Query/Response
- Used to send initial results to non-ordering recipients, and for historical results

pkg T23

«transaction»
Patient Demographics Query
+ docId = T23

consains

«composite standard»
IHE PDQ

consains

«base standard»
HL7 V2.5 Message
TP 22
Patient Identity Cross-Referencing

- Defines the methodology for identifying and cross-referencing different patient attributes for the same patient.

- IHE IT Infrastructure (ITI) Technical Framework (TF), Volume 2 (ITI TF-2):
  - ITI-8: Patient Identity Feed [§3.8.1]
  - ITI-9: PIX Query [§3.9.1]

- Key Concepts
  - HL7 Query/Response
  - Used to send initial results to non-ordering recipients, and for historical results
T 29

Notification of Document Availability

- Notifies a recipient that a document is available and provides the information needed to retrieve the document

- IHE IT Infrastructure (ITI) Technical Framework (TF), Volume 2 (ITI TF-2) Supplement for Notification of Document Availability (NAV)

- Key Concepts
  - Recommended a ‘publish and subscribe’ mechanism to IHE to make NAV a feasible tool
T 18
View Lab Results via Web Application

- Defines the ability to view a lab result using a web browser
- Transform from CDA to any appropriate display format (HTML, XHTML, PDF, etc.)
- No predefined style sheets required, follows HL7 CDA R2 for recipients responsibilities ([§1.3.1])
- Calls for a secure web connection for patient privacy
C 44
Secure Web Connection

- Defines specifications for the use of IETF HTTPS to establish a secure web connection
  - IETF HTTPS = Internet Engineering Task Force Hypertext Transfer Protocol over Secure Socket Layer
- The current Panel approved version of IS01 v3.0 has been updated to include additional security updates
HITSP IS 01 – EHR Lab Results Reporting Implementation

- Recognition of standards triggers legal requirements under EO 13410
  - Federal health contractual requirements for interoperability standards and certified systems, e.g. 2008 FEHB includes a pilot testing requirement

- Phased implementation options
  - NHIN-2 trial implementations
  - CCHIT 2008 criteria and 2009 roadmap
Steve’s story

The Future: Healthcare in an interoperable world

- The seamless and secure exchange of interoperable lab results data will allow authorized healthcare providers to access laboratory results from multiple repositories
  - Providers will send queries to a locator service, receive pointers to existing documents, and retrieve relevant lab results documents
  - Patients will have the ability to help review their lab results and trend their lab results over time
  - As appropriate, data will be provided to public health agencies in line with requirements for biosurveillance reporting
Use or specify HITSP Interoperability Specifications in your HIT efforts and in your Requests for Proposals (RFPs)

Ask for CCHIT certification

Leverage Health Information Exchanges to promote HITSP specifications and make connections easier in the future

Ask . . . Is there a HITSP standard we could be using?

Get involved in HITSP . . . Help shape the standards
A Successful Collaboration

- Interweaving many different standards to address business needs

- A successful collaboration between HITSP and several HITSP member organizations developing base standards and implementation guides/profiles
Learn more about specific HITSP activities during these upcoming webinars:

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Electronic Health Record (EHR) Laboratory Results Reporting

Questions and Answers
Electronic Health Record (EHR) Laboratory Results Reporting

ANNEX 1 – Glossary

Sponsored by the HITSP Education, Communications and Outreach Committee
## Annex 1

### Glossary

- **AHIC** - American Health Information Community
- **ANSI** - American National Standards Institute
- **CCHIT** - Certification Commission for Health IT
- **CDA** - Clinical Document Architecture
- **EHR** - Electronic Health Record
- **FEHB** - Federal Employee Health Benefit Plan
- **HHS** - US Department of Health and Human Services
- **HITSP** - Healthcare Information Technology Standards Panel
- **HL7** - Health Level Seven
- **IHE** - Integrating the Healthcare Enterprise
- **ISO** - International Organization for Standardization
- **LIS** - Laboratory Information System

(continued next slide)
Annex 1
Glossary (continued)

- **LOINC** Logical Observation Identifiers, Names, and Codes (Regenstrief Institute)
- **ONC** Office of the National Coordinator for Health Information Technology, U.S. Department of Health and Human Services
- **PDQ** IHE Patient Demographics Query
- **PIX** IHE Patient Identification Cross-Referencing
- **SNOMED-CT** International Healthcare Terminology Standards Development Organization Systematized Nomenclature of Medicine – Clinical Terms
- **SOAP** previously stood for “Simple Object Access Protocol”
- **UCUM** Unified Code for Units of Measure (Regenstrief Institute)
- **XCA** IHE Cross-Community Access
- **XDS** IHE Cross-Enterprise Document Sharing
- **XML** Extensible Markup Language