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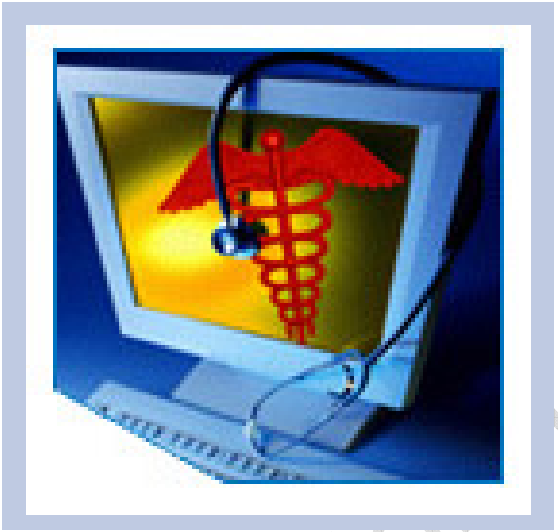
HITSP Interoperability Specification: Lab Terminology Component

HITSP/ISC-35



Submitted to:

Healthcare Information Technology Standards Panel

Submitted by:

Electronic Health Records Technical Committee

DOCUMENT CHANGE HISTORY

Version Number	Description of Change	Name of Author	Date Published
1.0	Final draft	Electronic Health Records TC	08/18/2006

1.0 FOREWORD

Healthcare Information Technology Standards Panel (HITSP) is a multi-stakeholder coordinating body designed to provide the process within which affected parties can identify, select, and harmonize standards for communicating healthcare information throughout the healthcare spectrum. HITSP functions as a partnership of the public and private sectors and operates with a neutral and inclusive governance model administered by the American National Standards Institute. The goal of the Panel is to:

- Facilitate the development of harmonized interoperability specifications and information policies, including SDO work products (e.g. standards, technical reports). These policies, profiles and work products are essential for establishing privacy, security and interoperability among healthcare software applications.
- Coordinate, as appropriate, with other national, regional and international groups addressing healthcare informatics to ensure that the resulting standards are globally relevant.
- Be use-case driven, utilize information from stakeholders and base its decisions on industry needs.

The HITSP shall serve the public good by working to ensure that the combined work of various healthcare information standards organizations supports interoperability, accurate use, access, privacy and security of shared health information.

In order to advance the goal of expanding harmonized interoperability specifications and information policies, HITSP was tasked with developing interoperability specifications for three main use case "breakthroughs areas" in which specific, near term value to the health care consumer could be realized. The harmonized use case areas are:

1.	Biosurveillance	Transmit essential ambulatory care and emergency department visit, utilization, and lab result data from electronically enabled health care delivery and public health systems in standardized and anonymized format to authorized Public Health Agencies with less than one day lag time.
2.	Consumer Empowerment	Allow consumers to establish and manage permissions access rights and informed consent for authorized and secure exchange, viewing, and querying of their linked patient registration summaries and medication histories between designated caregivers and other health professionals.
3.	Electronic Health Record	Allow ordering clinicians to electronically access laboratory results, and allow non-ordering authorized clinicians to electronically access historical and other laboratory results for clinical care.

The interoperability specification provides a detailed mapping of existing standards and specifications such as implementation guides, integration profiles to actions and actors that satisfy the requirements imposed by the relevant use cases. It identifies and constrains standards where necessary, and creates

groupings of specific actions and actors to further describe the relevant contexts. Where gaps and overlaps are identified, the interoperability specification provides recommendations and a roadmap for corrections to be made.

2.0 INTRODUCTION

The purpose of this document is to define the vocabulary for either message-based or document-based laboratory results reporting. The goals supported by this terminology component specification are stated in the EHR Use Case:

- Deploy standardized, widely available, secure solutions for accessing laboratory results and interpretations in a patient-centric manner for clinical care by authorized parties.

- Provide the following functionality for laboratory results reporting and notification, and is applicable to many types of laboratory tests, including but not limited to: clinical chemistry, hematology, serology, and microbiology.

The Use Case notes that there are obstacles to achieving the stated goals. In particular, the following obstacle is delineated:

- Lack of harmonization among data interoperability standards including vocabulary and laboratory and other messaging standards.

This Terminology Component is the result of a considered assessment of the terminologies available and the current practices in electronic laboratory results reporting for the purpose of moving forward in the harmonization of those terminologies. Without standard terminologies, interoperability is severely limited.

2.1 OVERVIEW

This Component Specification describes the vocabularies needed to implement the communication of an electronic standards-based lab result. A guiding principle for these selections was to follow Consolidated Heath Informatics Initiative (CHI) standards selections as appropriate. The following sections describe the selected terminologies, the events that are supported by those standards, and the reason for their selection. Also described are the organizations that maintain the standards and where to obtain more information.

This Component specification is part of a series of documents to establish interoperability standards for laboratory results reporting. The following documents are related to this specification:

Related Documents	Document Description
Lab Result Message Component HITSP/ISC36	Interoperability Specification for the HL7 V2.5 Lab Result Message as constrained by HITSP

Related Documents	Document Description
Lab Report Document Structure Component HITSP/ISC37	Interoperability Specification for the HL7 V3 CDA document for Lab Results as constrained by HITSP
Send Lab Result Message (to ordering clinician and providers of care with Optional Patient ID Cross-Referencing) HITSP/ISTP-14	Interoperability Specification for the Send Lab Results Message Transaction Package as constrained by HITSP

Table 2.1-1 Document Relationships

2.2 AUDIENCE

The interoperability specification is designed to be used by analysts who need to understand the interoperability requirements for the described use case, and by implementers working to develop interoperable applications. Understanding and using the relevant interoperability set of specifications is a key requirement for establishing interoperability compliance. In addition, specialized knowledge of healthcare terminologies is desirable.

2.3 TERMS AND DEFINITIONS

The definitions used for the purposes of this document can be found in the glossary. Refer to the appendix for the glossary.

2.4 CONVENTIONS

There are no special conventions used in this specification other than tabular formats to present some of the material. In particular, the binding of values to coded attributes in the messages is shown as a table where the Message Element is the field in the message and the Terminology is the name of a coding system. The format for this table is:

Message Element	Terminology	Comments
PID-5 Patient Name	HL7 V2.5 Table 0200 - Name Type	

2.5 COMMENTS

To submit comments for this interoperability specification, please download the Comment Submission sheet from the HITSP site at www.hitsp.org and provide all relevant information, and then email the completed document to hitspcomments@ansi.org. Comments are consolidated periodically and sent to the Technical Committees for review.

2.6 COPYRIGHT PERMISSIONS

3.0 STANDARDS REFERENCES

The HITSP EHR selected standards June 2006 – version 2 contains a list of all the considered standards and a designation as to which ones were selected and which ones were provisional. This selection was arrived at by a consensus of the members of the HITSP EHR and Biosurveillance Technical Committees. The criteria that were used for selection included the requirements of the use case, compatibility with other HITSP standards, and acceptance by the user community.

3.1 LIST OF BASE STANDARDS

The following base standards are used to form the vocabulary:

Terminology Standards	
Standard	Description/Reason for selection/Reference
Logical Observation Identifiers Names and Codes (LOINC®)	A database of Universal identifiers for laboratory and other clinical observations maintained by Regenstrief Institute. The laboratory portion of the LOINC database contains the usual categories of chemistry, hematology, serology, microbiology (including parasitology and virology), toxicology; etc. Contact the Regenstrief Institute at email: loinc@regenstrief.org or visit www.regenstrief.org/loinc for more information.
Systematized Nomenclature of Medicine – Clinical Terms (SNOMED CT®)	A validated clinical health care terminology and infrastructure that makes health care knowledge more usable and accessible. The SNOMED CT Core terminology provides a common language that enables a consistent way of capturing, sharing and aggregating health data across specialties and sites of care. Among the applications for SNOMED CT are electronic medical records, ICU monitoring, clinical decision support, medical research studies,

Terminology Standards	
Standard	Description/Reason for selection/Reference
	clinical trials, computerized provider order entry, nursing documentation, disease surveillance, image indexing and consumer health information services. Maintained by the College of American Pathologists (CAP), information is available at www.snomed.org/snomedct/index.html.
HL7 V2.5	The HL7 Version 2 Messaging Standard is an application protocol for electronic data exchange in healthcare that is maintained by HL7, an (ANSI) - accredited Standards Developing Organization (SDO) operating in the healthcare arena. In support of the HL7 messaging standard, HL7 also publishes value sets or code tables for use with specified fields in an HL7 message. Visit www.hl7.org for more information
HL7 V3.0	HL7 Version 3 represents a significant departure from "business as usual" for HL7. It uses an object-oriented development methodology and a Reference Information Model (RIM) to create messages. The RIM is an essential part of the HL7 Version 3 development methodology, as it provides an explicit representation of the semantic and lexical connections that exist between the information carried in the fields of HL7 messages. The HL7 Vocabulary TC and the domain TCs maintain a vocabulary for use with Version 3 messages. Visit www.hl7.org for more information.

Table 3.1-1 List of Base Standards

3.2 LIST OF COMPOSITE STANDARDS

The composite standards used in this specification are:

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Composite Standard	Description
Unified Code for Units of Measure (UCUM)	Maintained by The Regenstrief Institute For Health Care, UCUM is a code system intended to include *all* units of measures to facilitate unambiguous electronic communication of quantities together with their units. It is available at http://aurora.regenstrief.org/UCUM

Table 3.2-1 List of Composite Standards

4.0 COMPONENT

4.1 CONTEXT OVERVIEW

160 This component defines the vocabularies and terminologies utilized by laboratories and clinicians to order and report the findings from laboratory tests. The context is defined by a common scenario where a laboratory has received an order to perform routine tests involving a specimen taken from a patient during an inpatient or outpatient encounter. The laboratory performs the tests. Electronic results are coded according to these specifications for electronic transmission. The sender could be the laboratory or an

intermediary such as a clinical repository. The recipient could be an authorized public health agency, an EHR system, or a non-EHR clinical system.

4.1.1 CONTEXTUAL CONSTRAINTS

The constraints on this terminology component are imposed for the sake of defining a path to the future for healthcare interoperability. The lack of consistent terminologies across laboratories and institutions is well known. These inconsistent terminologies pose an obstacle to interoperability and must be addressed before universal roll-out of the HITSP recommended interoperability specifications, but early adopters can use this specification by aligning with the recommended vocabularies and implement the supported scenarios sooner. A standard terminology must be defined for Service Identifiers (a code for the type of test). For this interoperability specification, the terminology for the Observation Identifier must be LOINC, and the terminology for the observation value must be SNOMED-CT where applicable.

Typically, laboratories use local codes for Observation IDs and Values. To communicate results according to this Interoperability Specification, the results need to be transmitted in the specified vocabularies. This may be done using mapping tools available today. This mapping process is a constraint for this terminology component.

Some implementers of electronic laboratory results reporting today utilize some form of translation between terminologies. It is recognized that National Library of Medicine (NLM) maintains cross-maps of terms for some of the major coding systems. A subset of these cross-maps can be utilized by a Common Terminology Service (CTS) to provide an equivalent term for a concept in a different terminology.

4.1.2 TECHNICAL ACTORS — Not Applicable

4.2 TERMINOLOGY COMPONENTS: RULES FOR IMPLEMENTING

This Component Specification supports the reporting of laboratory results. The value sets or Code Systems selected for each selected coded attribute in the lab results message are shown in the HL7 V2.5 Standard. Tables are included here that constrain or vary from HL7 published standards.

HL7 V2.5 OBR - Observation Request Segment

Message Element	Terminology	Comments
OBR-4 Universal Service Identifier	(Noted terminology gap)	

Table 4.2-1 HL7 V2.5 OBR – Observation Request segment

HL7 V2.5 OBX – Observation segment

Message Element	Terminology	Comments
OBX-3 Observation Identifier	LAB LOINC	
OBX-15	CLIA ID	May include allowed exceptions.

Table 4.2-2 HL7 V2.5 OBX – Observation segment

4.2.1 TERMINOLOGY CONSTRAINTS

Terminologies have subsets for each specific type of lab result. In particular, the Laboratory subsets of LOINC and SNOMED, which are used to identify the type of result, have subsets defined by numerous private and public organizations in addition to the subsets defined within the terminology.

Lab LOINC:

Code sets, vocabularies, terminologies and nomenclatures that need to be constrained:	• All LOINC lab result codes
Minimum attributes of the component:	• Minimum data set = - HEDIS (Health plan Employer Data and Information Set) reported tests accounting for 95% of routine Lab orders (Note: ELINCS selections refer to 90% of HEDIS) - Category A, B, & C bioterrorism agents/diseases - Public Health jurisdiction and Federal reportable disease conditions. • (NEED INCORPORATION BY REFERENCE, ALL OTHER REQUIREMENTS FOR PUBLIC HEALTH JURISDICTIONS) • Minimum requirements to satisfy CLIA
Other Comments:	• We are spelling out what we need to have for today, but need to capture what future considerations are also desirable. • Consider requirements for identifying subsets

Table 4.2.1-1 Lab LOINC

SNOMED-CT

Code sets, vocabularies, terminologies and nomenclatures that need to be constrained:	• SNOMED-CT
Minimum attributes of the component:	• SNOMED-CT VA Problem List Subset • SNOMED-CT Lab Test Findings Table • SNOMED-CT Organisms

Other Comments:	• VA Problem List Subset same as FDA/DoD/KP subset list

Table 4.2.1-2 SNOMED-CT

Note: PAP Smears / Bethesda Terminology

4.2.2 ADDITIONAL SPECIFICATIONS

Not Applicable

5.0 CONSTRAINTS FOR REUSE

This Terminology Component can be reused for a variety of scenarios in addition to Lab Results reporting. The only constraints for reuse are the applicability of the described vocabulary for fields not currently selected for transmission.

6.0 APPENDIX

6.1 GLOSSARY

Included is the common interoperability glossary that is used for all the Use Cases. This is the HITSP glossary that spans all the interoperability specifications, which can be found at:
http://publicaa.ansi.org/sites/apdl/Documents/Forms/AllItems.aspx?RootFolder=http%3a%2f%2fpublicaa%2eansi%2eorg%2fsites%2fapdl%2fDocuments%2fStandards%20Activities%2fHealthcare%20Informatics%20Technology%20Standards%20Panel

6.2 NOTED GAPS

- May be a need for additional specialized terminologies for particular uses that require further analysis. Candidates previously selected as provisional requiring further analysis include:
  - CPT
  - ICD-9 CM
  - NDF-RT
  - COAS
  - RxNorm
  - HCPCS
- There is no universally agreed to vocabulary for the Universal Service Identifier, which is required on the order and result. LOINC has some coverage, but not enough.