



Standardization of Laboratory Test Coding Through Collaboration

LabHIT Team in the Division of Laboratory Systems at CDC

Public Health Informatics Conference

Atlanta, GA

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Presenters and Topics

- Introduction
 - Megan E. Sawchuk, BS, MT(ASCP) - *Moderator*
- LOINC[®]: Common Name Project
 - Sonya Strider, PhD, MT (ASCP)
- LOINC[®]: Clinical Laboratory Test Menu Coding Project
 - Graylin Mitchell, MPH, MT
- LOINC[®]: CDC Laboratory Test Menu Coding Project
 - Nancy Cornish, MD FCAP, FASCP
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 - Manjula Gama Ralalage on behalf of Riki Merrick, MPH
- Interoperability & Conclusion
 - MariBeth Gagnon, MS, CT(ASCP)HTL

Introduction

- Megan E. Sawchuk, BS, MT(ASCP)

In this Rapid Fire session, we are pleased to share information on several projects designed to further the semantic interoperability of laboratory test results by standardized coding. Semantic interoperability is imperative to the success of local, regional and national surveillance.

Advancing Interoperability: Patient Safety & Data Integrity (Trust)

Patient Safety: Ensuring Data Integrity in Health Information Exchange



Figure 1: Health Information Exchange in the Healthcare System

Patient safety relies on data integrity or “trust” in every electronic transaction, starting with the laboratory test order and ending with the test result for every potential end user.

The **LabHIT Team** focuses its efforts on interoperability and harmonization of all interfaces transmitting laboratory data within healthcare settings and to public health agencies.

Patient safety relies on data integrity or “trust” in every electronic transaction, starting with the laboratory test order and ending with the test result for every potential end user.

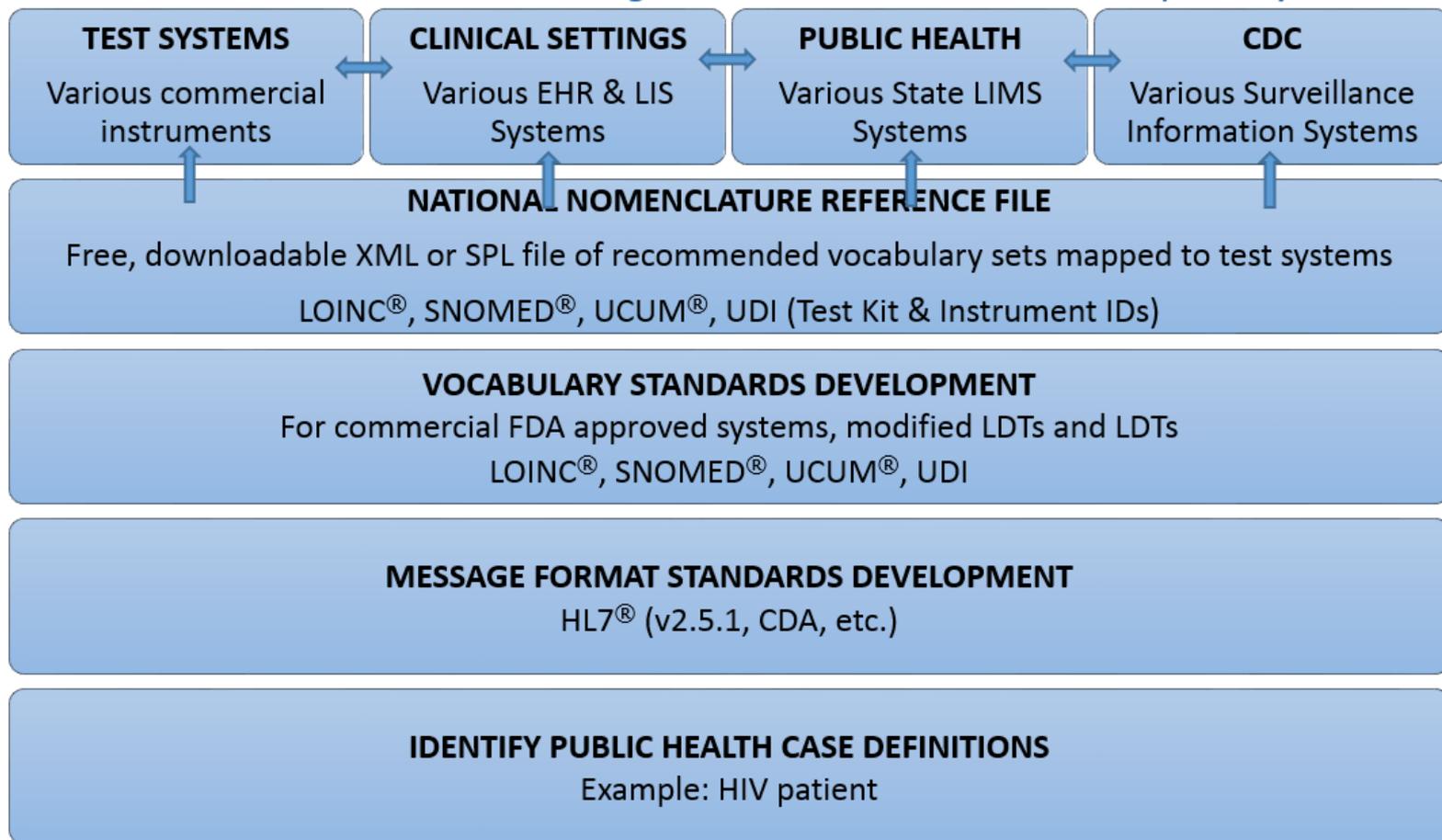
The **LabHIT Team** focuses its efforts on interoperability and harmonization of all interfaces transmitting laboratory data within healthcare settings and to public health agencies.

Stretch Goal for Interoperability

Support full-scale interoperability for laboratory data by providing a single national reference database of recommended vocabulary sets with mapping of test systems to code systems.

Achieving Full-Scale Local, Regional and National Interoperability

The Foundation to Building World-Class Surveillance Capability



Collaborative Partners

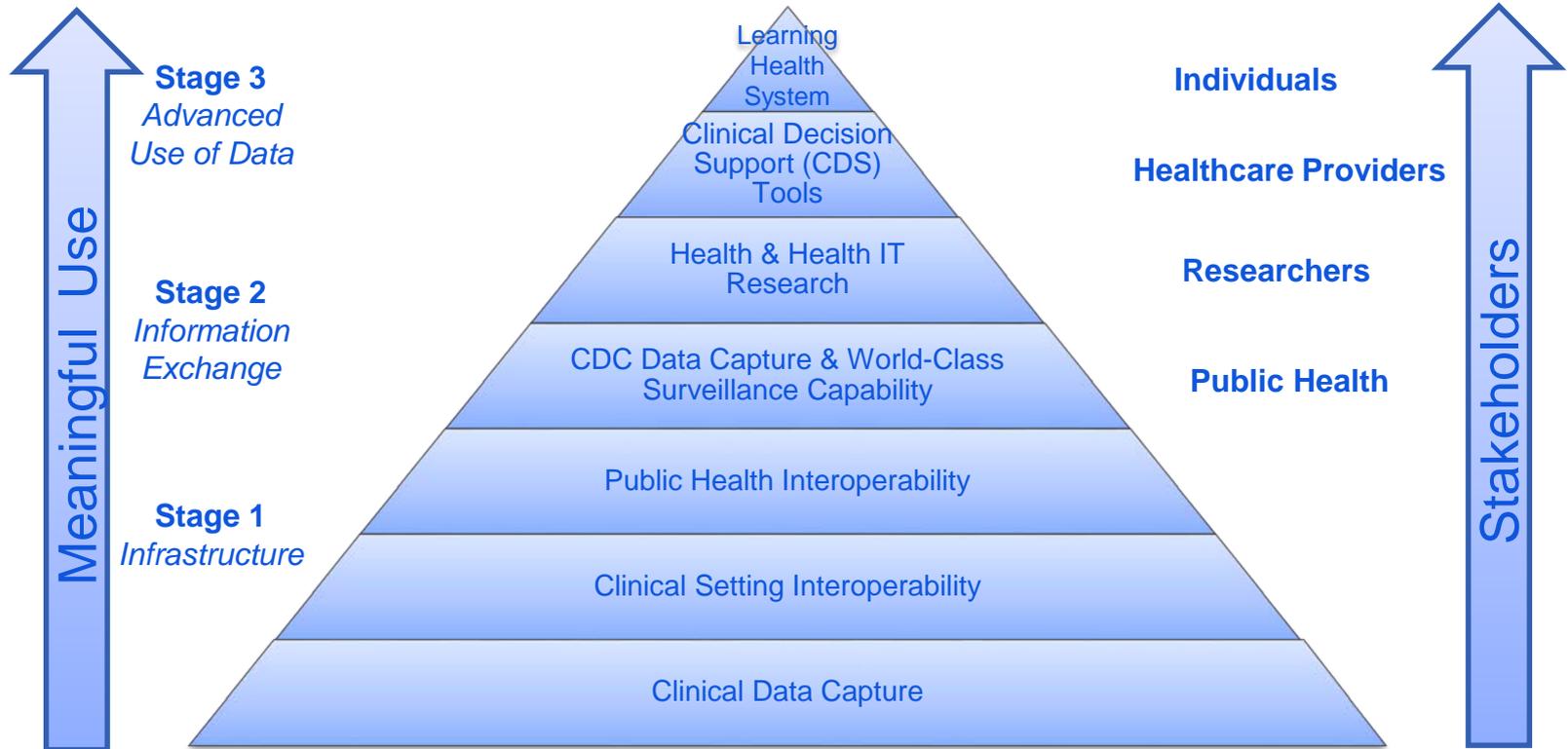
- Association of Public Health Laboratories (APHL)
- Centers for Medicare & Medicaid Services (CMS)
- Centers for Disease Control and Prevention (CDC)
- Food and Drug Administration (FDA)
- International Health Terminology Standards Development Organization (IHTSDO)
- IVD Industry Connectivity Consortium (IICC)
- Medical Device Innovation Consortium (MDIC)
- National Library of Medicine (NLM)
- Office of National Coordinator for Health Information Technology (ONC)
- Regenstrief Institute

LOINC[®]: Common Name Project

- Sonya Strider, PhD, MT (ASCP)

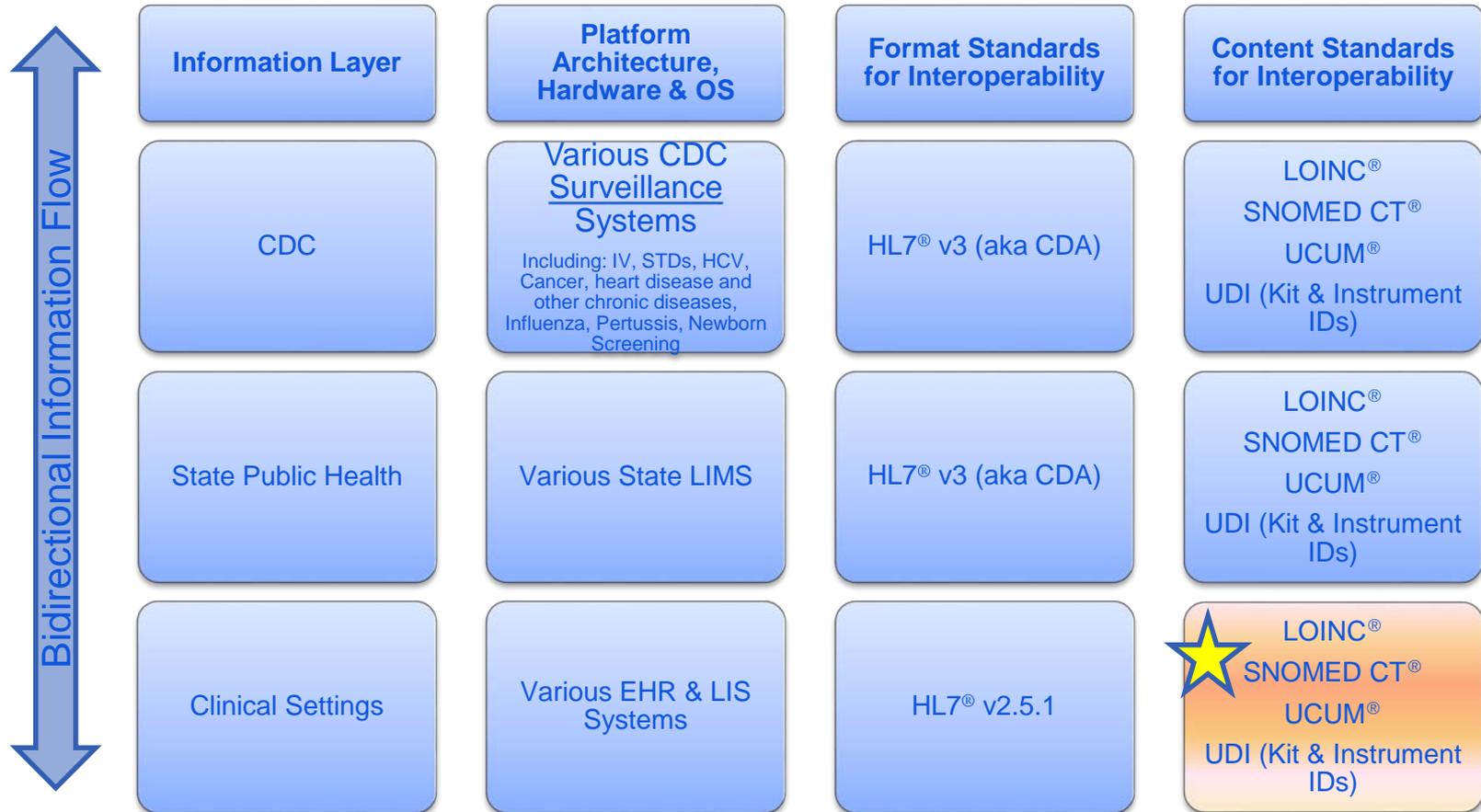
Abstract: Business rules developed under the ONC Laboratory Tiger Team creates a standard approach to establish a common name for laboratory test ordering. The common name can then be linked to other codes and metadata transmitted by the electronic health record (EHR); thus, enhancing the understandability and usability of reports and information by patients and health care providers. This presentation describes how the rules were created and how to apply these rules to LOINC[®] laboratory test order long and short names.

Electronic health record data is used to inform decision making for individuals, healthcare providers, researchers and public health.



The Cornerstone to Building World-Class Surveillance Capability

Developing Content Standards for Local, Regional and National Interoperability



LOINC[®] Common Name



LOINC[®] Common Name

- Problem
 - Thousands of laboratory tests
 - Variation in reporting across laboratories
 - Laboratory results reviewed by different physicians
- Goal
 - Develop business rules for universal naming and abbreviation schematic.
- Benefit
 - More commonly understood by providers and patients.
 - Easier for providers to select the correct test
 - Allow test result data from multiple laboratories to be grouped and grafted for trending overtime.
 - Increase providers and patients understanding of laboratory data

Putting It All Together

- Standardized naming convention allows:
 - Laboratory test data to be universally exchanged by electronic health systems
 - Faster and more efficient interpretation of laboratory results by medical personnel
 - Improved continuity of care
 - Reductions in repeat testing
 - Reductions in errors



LOINC[®]: Clinical Laboratory Test Menu Coding Project

- Graylin Mitchell, MPH, MT

Abstract: Standardizing the codes for test ordering will facilitate computerized provider order entry between the EHR and the Laboratory Information System (LIS). This product produced a common order code value set which has been incorporated as a tool in Regenstrief's LOINC[®] Mapping Assistant (RELMA)[®]. How to use this tool to facilitate coding of laboratory test orders and lessons learned from this project will be presented.

LOINC[®] Order Code Value Set Project - Background

- Standards & Interoperability (S&I) Framework Initiatives identified the need to incorporate LOINC[®] order codes in the EHR to improve interoperability of test ordering between the EHR and the laboratory information system (LIS)
- Planning group was formed with CDC, National Library of Medicine (NLM), Office of the National Coordinator for Health IT (ONC), Regenstrief Institute, laboratory industry
- aLOINC[®] Order Code S&I Initiative began January 8, 2014
 - aLOINC[®] - “a” stands for “agreed upon”, reflecting the consensus approach with stakeholders
- S&I Framework created a wiki site and held webinars for all and monthly for public health subgroup for 14 months (January 2014 - March 2015)



LOINC® Order Code Value Set Project – Purpose

- Identify and provide standardized LOINC® order codes for two sets of most commonly performed laboratory tests
 - Baseline Test List - clinical laboratory tests performed in ambulatory care settings
 - Public Health Test List - laboratory test requiring exchange of information between public health agencies and clinical laboratories
- Provide a way to group “like” tests that may be reported by a different name or measurement to decrease duplicative ordering
- Help public health agencies conduct surveillance activities
 - Example - food borne outbreak (LIS could automatically report an increased ordering of stool cultures)

LOINC[®] Order Code Value Set Project - Approach

- aLOINC[®] Common Order Code Value Set was developed by wiki members based on a comparison to LOINC[®]'s Top 2000 Result Codes and Top 300 Order Codes
- Data reviewed from the following sources:
 - Indiana Network for Patient Care (INPC) laboratory order data analyzed by Regenstrief
 - MarketScan commercial carrier and Medicare data base of LOINC[®] result codes analysis
 - Test directory of services for four reference laboratories



LOINC® Order Code Value Set Project - Deliverables

- aLOINC® Common Orders Value Set
 - Contains 1377 codes for single analytes
 - Contains 157 codes for panels
- Input to Regenstrief on guidance for comparing user panels to LOINC® panels
 - Provides some flexibility to laboratories that change tests ordered in a panel
 - Decreases the number of new tests codes requested
- Recommendations to ONC for using LOINC® for laboratory orders
- Recommended content updates for Regenstrief based on review of laboratory order LOINC® codes
- aLOINC® Common Orders Value Set: Published in Regenstrief LOINC® Mapping Assistant (RELMA)® tool in June 2016 - free and online!

Get LOINCing >

<http://loinc.org/relma>

LOINC[®]: CDC Laboratory Test Menu Coding Project

- Nancy Cornish, MD FCAP, FASCP

Abstract: CDC has a number of laboratory developed tests that need to be coded so they may be standardized for reporting across sites. A number of steps have been taken to develop models to group tests and ease the burden of requesting LOINC[®] codes for these tests.

Vision

The right code at the right time!

- For Regenstrief (LOINC[®] owner), in partnership with CDC, State PHLs, and clinical laboratory SMEs to produce standard code sets for each test to advance interoperability between institutions
- Support selection of the correct standardized laboratory order codes to advance interoperability for local, regional and national surveillance of outbreaks and laboratory data quality

Need: State PHLs are requesting CDC's codes for their test systems

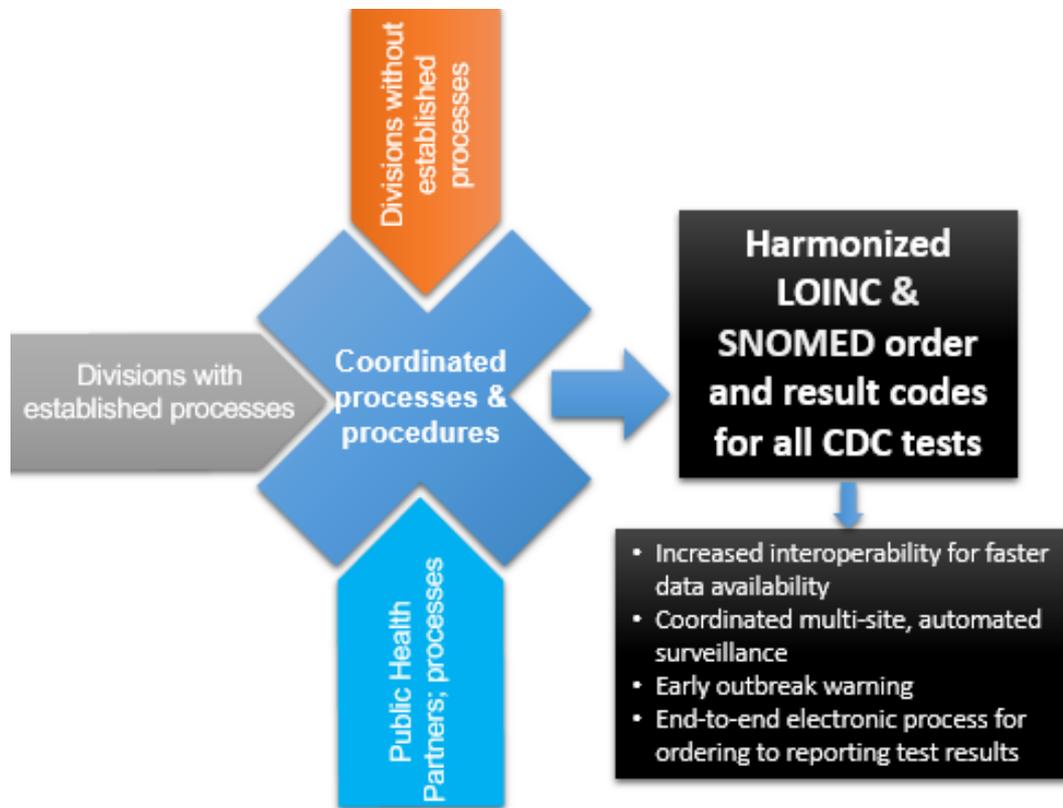
- Supports ordering and resulting for bidirectional electronic message exchange between state PHLs and CDC
- CDC Workgroup reviewed code assignment challenges for tests, including laboratory developed tests (LDTs)
- Identified Issues & Opportunities
 - Variability amongst state code coordination within CDC surveillance programs, e.g. Influenza
 - Variability in dissemination to the states of clinical laboratory codes and state PHL codes
 - Variability in APHL support for coding services across state public health laboratories

CDC Workgroup Proposal

- A national standardized process is needed for LOINC[®] & SNOMED CT[®] code development and implementation.
 - The process is currently de-centralized with multiple laboratories developing order and results codes for their tests of interest (or not)
 - Lack of coordination can lead to a single test or result having multiple codes which limits interoperability.

CDC Workgroup

Proposal: Create a “one-stop shop” for laboratory LOINC® and SNOMED CT® coding, nationally centralized and coordinated.



Conceptual Framework for LOINC® & SNOMED CT® Implementation

- Benefits:
 - A well-organized, agency-wide implementation plan with management and administrative support is critical.
 - Coordination across CIOs is fundamentally necessary
 - Educating staff on benefits of coding and interoperability is key
 - It is important to promote harmonization, standardization and collaboration for consistent use of coding between CDC, state and local PHLs and will benefit clinical laboratories as well
 - The knowledge of a few can be shared with the whole

SNOMED CT[®]: Laboratory Specimen Coding Project

- Manjula Gama Ralalage on behalf of Riki Merrick, MPH
- Abstract: The Laboratory Messaging Community of Practice (LMCoP), comprised of laboratory and standards experts from state and federal public health laboratories, national clinical laboratories, the National Library of Medicine and professional organizations, harmonized terms describing specimens to be tested. The resulting Specimen Cross Mapping Table (CMT) supports accurate portrayal of the specimen, which is crucial for appropriate processing and correct clinical interpretation by providers, using a single term pick list mapped to SNOMED CT[®] for the specific information in respective HL7[®] message fields.

Specimen Coding

- The Laboratory and Messaging Community of Practice
- SNOMED CT®
- Overview of the Specimen Cross-Mapping Table (Specimen CMT)
 - Background
 - Expected uses
 - Planned next steps

The Laboratory Messaging Community of Practice

- Started at Public Health Information Network (PHIN) conference in 2009
- Lab Messaging Community of Practice is a forum for laboratory professionals to discuss issues related to:
 - Vocabulary to use in messaging
 - Improvement for vocabulary standards to support electronic data exchange
 - LIMS set up
- State PHLs, CDC PHLs, national labs, terminology services, NLM, LIMS and EHR-S vendors
- Professional Organizations as reviewers and SME input

See:

https://www.aphlweb.org/aphl_departments/Strategic_Initiatives_and_Research/IP/MG/ConfigMgt/LabMCoP/SitePages/Home.aspx

SNOMED CT[®]

Provides codes the computer can understand re description for that concept is

Has many hierarchies, depending on the context clinical area (Specimen, Body structure, substan

See: <http://www.ihtsdo.org/snomed-ct/>

Current Concept:
Fully Specified Name: Stool specimen (specimen)
ConceptId: 119339001
Source:

Defining Relationships:
Is a Body substance sample (specimen)
Specimen substance (attribute) [Feces \(substance\)](#)
This concept is sufficiently defined.

Descriptions (Synonyms):
Fully Specified Name: Stool specimen (specimen)
Synonym: Feces specimen [2161478014]
Synonym: Faeces specimen [2161344016]
Synonym: Stool specimen [180864010]
Synonym: Stool sample [1220453017]
Synonym: Feces sample [1217410015]
Synonym: Faeces sample [1215907019]

US English:
Preferred: Stool specimen [180864010]
Acceptable: Feces specimen [2161478014]
Acceptable: Stool sample [1220453017]
Acceptable: Feces sample [1217410015]

GB English:
Preferred: Stool specimen [180864010]
Acceptable: Faeces specimen [2161344016]
Acceptable: Stool sample [1220453017]
Acceptable: Faeces sample [1215907019]

Related Concepts
[- All "Is a" antecedents -](#)
[- All descendants -](#)
[- Related concepts demo -](#)

The Specimen Cross-Mapping Table (Specimen CMT)

- Background:
- State and CDC PHLs collected specimen terms in use and attempted to harmonize usage and map to HL7[®] terms (Table 70 or 487)
- Mapping process revealed gaps:
 - Missing common terms
 - Ambiguous terms
 - Decision to move to use of SNOMED CT[®]
- Applied National Animal Health Lab Network (NAHLN) principles in mapping to Specimen (SPM) segment

Specimen Fields in HL7[®]

Field	HL7 Name	Consider for coding	Value sets suggested in ELR to PH v2.5.1
SPM-4	Specimen Type	HL70487 SNOMED CT specimen hierarchy	HL70487 SNOMED CT specimen hierarchy
SPM-5	Specimen Type Modifier	SNOMED CT qualifier, morphologic abnormality hierarchy	SNOMED CT qualifier hierarchy
SPM-6	Specimen Additives	HL70371 SNOMED CT substance, product hierarchy	HL70371
SPM-7	Specimen Collection Method	HL70488 SNOMED CT procedure hierarchy	HL70488 SNOMED CT specimen collection subtree (procedure hierarchy)
SPM-8	Specimen Source Site	SNOMED CT body site, substance, physical object hierarchy	SNOMED CT body site hierarchy (per HITSP)
SPM-9	Specimen Source Site Modifier	SNOMED CT qualifier hierarchy	SNOMED CT qualifier hierarchy

Note: SPM-10 – Specimen Collection Site also available
– will review when looking at catheter infections

7 HL7[®] fields vs 1 for data capture...

Most labs have 1 field, possibly 2 for specimen source – some labs support all SPM fields

Idea of Specimen CMT was born to allow use of single term to map across multiple fields

Specimen CMT – Expected Uses

- Mapping from local terms to single specimen term (historical data)
- Mapping from single specimen term to ALL specimen source term fields in the SPM segment
- Education (definition for each term, with link to collection instructions, use etc.)
- Guidance on specimen term based on type of lab test ordered by lab specialty; Microbiology test urine – must know that collection method was sterile, not in chemistry
- Harmonize/standardize use of terms
- National resource of curated vocabulary - a starting specimen table for EHR and LIS vendors

Specimen CMT – Historic Data

1	Local Description	PHLIPPrefName
3	Stool	Stool
4	FECES	Stool
5	STL Stool = Fecal HL70070	Stool
6	SNV Synovial fluid (Joint fluid) HL70070	Synovial fluid
7	Joint fluid	Synovial fluid
10	NP aspirate	NasopharyngealAspirate
11	Nasopharyngeal aspirate	NasopharyngealAspirate
12	NP swab	NasopharyngealSwab
13	Nasopharyngeal swab	NasopharyngealSwab
15	PERIA Abscess, Perianal HL70070	Abscess_Perianal
16	Perianal Abscess	Abscess_Perianal

Specimen CMT – 1 : 7 in HL7[®]

	F	J	K	L	M	N	O	P	Q	R	S	T	U
1	PHLIPrefName	Specimen type (SPM-4)		Specimen type modifier (SPM-5)		specimen source site (SPM-8)		specimen source site modifier (SPM-9)		specimen collection method (SPM-7)		specimen additives (SPM-6)	
3	Stool	119339001	Stool specimen (specimen)										
6	Synovial fluid	119332005	Synovial fluid specimen (specimen)										
11	NasopharyngealAspirate	258411007	Nasopharyngeal aspirate (specimen)			18962004	Structure of nasopharyngeal cavity (body structure)			225711009	Collection of nasal pharyngeal aspirate (procedure)		
12	NasopharyngealSwab	258500001	Nasopharyngeal swab (specimen)			71836000	Nasopharyngeal structure (body structure)			285570007	Taking of swab (procedure)		
16	Abscess_Perianal	119371008	Specimen from abscess (specimen)			397158004	Perianal region structure (body structure)						

Specimen CMT - Education

	PHLIPPrefName	Definition	Comment
1			
2	Bowel_Contents	Something contained in the intestine or gut; also : one of the divisions of the intestines. Combined search for contents: http://www.merriam-webster.com/dictionary/content?show=0&t=1349473611 and bowel: http://www.merriam-webster.com/dictionary/bowel	Don't use this term for human samples - use Stool instead animal would use small intestinal contents, large intestinal contents
3	Stool	Evacuated fecal matter. The American Heritage® Medical Dictionary Copyright © 2007, 2004 by Houghton Mifflin Company. Published by Houghton Mifflin Company. All rights reserved. (http://medical-dictionary.thefreedictionary.com/stool) For collection and processing see: http://www.cdc.gov/getsmarth/healthcare/learn-from-others/resources/clinician-guide.html#Stool	
6	Synovial fluid	synovia: a clear, viscous fluid resembling the white of an egg, secreted by synovial membranes and acting as a lubricant for many joints, bursae, and tendons. It contains mucin, albumin, fat, and mineral salts. Also called synovial fluid. Mosby's Medical Dictionary, 8th edition. © 2009, Elsevier. (http://medical-dictionary.thefreedictionary.com/synovia)	
11	NasopharyngealAspirate	Nasopharyngeal swab/aspirate: Fine flexible wire swab or aspirate with direct smear where appropriate. Application: Viral Culture Suspected pertussis (whooping cough); severe bronchiolitis in infants; investigation of severe respiratory infection (including pneumonia), particularly if viral infection is suspected. (http://www.rcpamanual.edu.au/index.php?option=com_pttests&task=show_test&id=150&Itemid=34)	
12	NasopharyngealSwab	NASOPHARYNGEAL SWAB COLLECTION PROCEDURE: Procedure: 1. Insert dry swab through one nostril straight back (not upwards), along the floor of the nasal passage until reaching the posterior wall of the nasopharynx. The distance from the nose to the ear gives an estimate of the distance the swab should be inserted. 2. Rotate swab gently and leave in place for up to 1 etc. http://health.utah.gov/epi/fact_sheets/nasopharyngealswab_collect.pdf	
16	Abscess_Perianal	A perianal abscess is an infection characterized by a collection of pus that has formed under the skin within the soft tissue just outside the anus. http://emedicine.medscape.com/article/935226-overview#a0101	add collection method

Specimen CMT– Domain preference

A	B	F	G	H	I
Domain	Usage	PHLIPPrefName	Definition	Comment	additional field required
Micro	discouraged - domain	Swab_anorectal	The anorectal swab was taken by inserting a sterile cotton wool swab about 1 1/2 inches into the anal canal http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1045429/pdf/brjvendis00047-0039.pdf illustraion for self collection: http://journals.lww.com/stdjournal/Fulltext/2006/06000/lllustrated_instructions_for_Self_Collection_of.10.aspx	not recommended for cultures - use rectal or vagina/rectal swabs instead - can be used for <i>Neisseria gonorrhoeae</i> testing, when proctoscopy is not possible. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1045429/pdf/brjvendis00047-0039.pdf and	
Molecular testing	preferred	Swab_anorectal		Works well for HPV molecular testing	
Micro	discouraged - domain	Urine	the fluid secreted by the kidneys, transported by the ureters, stored in the bladder, and voided through the urethra. Normal urine is clear, straw-colored, and slightly acid; has the odor of urea; and has a specific gravity between 1.003 and 1.035. Its normal constituents include water, urea, sodium chloride, potassium chloride, phosphates, uric acid, organic salts, and the pigment urobilin. Abnormal constituents indicative of disease include ketone bodies, protein, bacteria, blood, glucose, pus, and certain crystals. See also bacteriuria, glycosuria, hematuria, ketoaciduria, proteinuria. urinary, adj. Mosby's Medical Dictionary, 8th edition. © 2009, Elsevier. (http://medical-dictionary.thefreedictionary.com/urine)	need to use more specific terms that include the collection method for microbiological studies	need to have source site (SPM-8) and spatial orientation (at minimum laterality) (SPM-9) need to know collection method (SPM-7)
Molecular testing	Prototype	Urine		Outstanding question: How important are collection methods for molecular testing?	need to have source site (SPM-8) ? need to know collection method (SPM-7)
Chemistry	Prototype	Urine		Outstanding question: How important are collection methods for chemistry?	? need to know collection method (SPM-7)

Specimen CMT – A Nationally Curated Vocabulary

- Create governance
- Engage all stakeholders
- Engage the subject matter expert (SME) community
- Define change control and review processes
- Define and provide distribution

Specimen CMT – along the way

Improve SNOMED CT®

- Submit for new terms (all SNOMED CT® hierarchies: specimen, procedure, substance, morphologic abnormality)
- Clarify issues with existing terms (better names, missing synonyms, updating relationships, updated modeling)

Specimen CMT – Next Steps

Continue review of terms by professional societies:

- American Society for Microbiology (ASM) - completed
- Association of Molecular Pathology (AMP) - completed
- College of American Pathologist (CAP) - engaged
- American Clinical Laboratory Association (ACLA)
- American Association for Clinical Chemistry (AACC)

Input on feasibility for use in EHR and LIS/LIMS systems

Publish specimen collection manual

Find distribution home for the Specimen CMT

Interoperability & Conclusion

- MariBeth Gagnon, MS, CT(ASCP)HTL

The FDA/CDC/NLM Workshop started the process to include manufacturers in the selection of laboratory test codes. Activities surrounding this meeting present a unique opportunity to participate in the selection of SNOMED-CT[®] result value sets for tests that have qualitative results. Discussion will include how best to accomplish this task and how public health influence can impact all of the activities reported during this rapid fire session.

FDA/CDC/NLM Semantic Interoperability Public Workshop

September 28, 2015

FDA White Oak Facility in Silver Springs, MD

Presentations and panel discussions

- Adopting LOINC[®]: Industry, laboratory, and others
- Reporting results: SNOMED CT[®]/UCUM[®] and laboratory results
- Moving forward

<http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm453897.htm>

FDA/CDC/NLM Semantic Interoperability Public Comments

Industry concerns posted by AdvaMed[®]:

- Should not be an FDA mandated regulated activity
- Need a specified disclaimer (address product promotion concerns)
- Industry-defined publishing format, not in product insert
- Focus should be on LOINC[®] first; 2 years to implement
- Should not expand the FDA's Global Unique Device Identification Databases (GUDID) deadlines
- Regenstrief review to promote consistency
- Generic codes could be used to allow for different uses

FDA/CDC/NLM Semantic Interoperability Public Comments

Laboratory concerns:

- Suggest formation of a standard coding review committee
- Define format/structure for vendors to describe coding
- Support all federal agencies use of same standards
- Continue evaluation of UCUM[®]
- Sustainability and maintenance issues
- Issues around coding of molecular test
- Need to make it easier to select correct code from many

Follow-up

Medical Device Innovation Consortium (MDIC) convened a meeting of industry and government – July 22, 2016

- MDIC's mission is to advance regulatory science with public, private and patient advocacy partners; est. 2012.
- Meeting topics
 - Clarify regulatory issues
 - Provide white paper for the technical guidance
 - Pilot

CDC/FDA/NLM/ONC/CMS planning a second meeting

Thank you!

For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov

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.

Reference: Strategic Authorities To Advance Laboratory Interoperability

- **Federal Health IT Strategic Plan**
 - Identify, advance, and streamline technical standards to support secure and interoperable health information
 - Increase use of common standards among federal agencies, private industry, and the biomedical research community
- **CDC Office of Public Health Scientific Services Surveillance Strategy**
 - Accelerate the utilization of emerging tools and approaches to improve the availability, quality, and timeliness of surveillance data
 - Through cross-cutting agency initiatives, improve surveillance by addressing data availability, system usability, redundancies, and incorporation of new information technologies in major systems or activities
- **CDC Center for Surveillance, Epidemiology and Laboratory Services Laboratory Integration Strategic Initiative**
 - Improve Public Health laboratories' information exchange via interoperable systems
 - Advance the safety, interoperability, and usability of laboratory information in EHRs

Reference: Acronyms

- LOINC® = Logical Observation Identifiers Names and Codes®
 - Name of test or electronic field name (numeric code and test description)
 - Regenstrief Institute
- SNOMED CT® = Systematized Nomenclature of Medicine - Clinical Terms®
 - Results or descriptive clinical terms (numeric code and results description)
 - International Health Terminology Standards Development Organisation (IHTSDO)
- UCUM® = Unified Code for Units of Measure®
 - Units for interpreting laboratory data
 - Regenstrief Institute
- UDI = Unique Device Identifier
 - Numeric or alphanumeric code identifying the device (test) and product (lot, expiration, etc.)
 - FDA Issued identifier – guidance published
- HL7® IGs = Health Level Seven® Implementation Guides
 - Electronic message format standards (sequence of codes in transmitted message, syntax)
 - Health Level Seven® Standards Developing Organization