National Committee on Vital and Health Statistics, June 21, 2017 Meeting, Washington, DC

Health Terminologies and Vocabularies

Clinical Terminology Standards required for US Health Data Exchange: SNOMED CT, LOINC, RxNorm



Outline of Presentation

- NCVHS and NLM's Role Betsy Humphreys, NLM
- SNOMED CT Overview Susan Roy, NLM
- LOINC Overview Daniel Vreeman, Regenstrief Institute
- RxNorm Overview Patrick McLaughlin, NLM
- Discussion



HIPAA (Public Law 104–191—Aug. 21, 1996) required NCVHS to address standards for clinical information

"The Committee

(B) shall study the issues related to the adoption of *uniform data standards for patient medical record information and the electronic exchange of such information*;

(C) shall *report to the Secretary not later than 4 years after the date of the enactment* of the Health Insurance Portability and Accountability Act of 1996 recommendations and legislative proposals for such standards and electronic exchange;"



.

July 2000 NCVHS Report to Secretary Shalala on Uniform Data Standards for Patient Medical Record Information (PMRI)

"3. Provide *immediate funding to accelerate the development and promote early adoption* of PMRI standards. This should take the form of support for:

c. *enhancement, distribution, and maintenance of clinical terminologies* that have the potential to be PMRI standards through:

(1.) government-wide licensure or comparable arrangements so that these terminologies are available for use at little or no cost.

(2.) augmentation of the National Library of Medicine's Unified Medical Language System (UMLS) to embody enhanced mapping capabilities among and between medical vocabularies, and between medical vocabularies and statistical classifications and reimbursement code sets designated in the HIPAA standards for financial and administrative transactions."

• • • • •

....

https://www.ncvhs.hhs.gov/wp-content/uploads/2014/08/hipaa000706.pdf



Key NLM Milestones

- 1990 Unified Medical Language System (UMLS), 1st release
- 1999 LOINC, 1st contract to support ongoing maintenance and free dissemination (based on expected HIPAA requirement)
- 2001 RxNorm, 1st release, to assist UMLS maintenance + fill gap identified by HL7 and drug information providers
- 2003 SNOMED CT License for free US-wide use from College of American Pathologists (IP acquired by International Health Terminology Standards Development Organisation in 2007)



November 2003 NCVHS Letter to Secretary Thompson on Recommendations for PMRI Terminology Standards

Core Set Recommended: SNOMED CT, LOINC, "Federal Drug Terminologies" (including RxNorm, FDA unique ingredient identifiers, VA drug classes)

"The NCVHS recommends that you *designate the National Library of Medicine (NLM) as the central coordinating body* for the PMRI terminology standards."

https://www.ncvhs.hhs.gov/wp-content/uploads/2014/05/031105lt3.pdf

2010: SNOMED CT, LOINC, and RxNorm – designated as US Standards for EHR Certification and Meaningful Use



SNOMED CT Overview

Susan L. Roy NLM SNOMED CT Support Coordinator susan.roy@nih.gov



SNOMED CT - What is it

- Clinical terminology with global scope covering clinical specialties, disciplines and requirements
 - Contains over 330,000 concepts in 19 domains
 - Extensibility mechanisms (reference sets), content extensions and expressions
- Designed to use description logic
 - Enables automation of reasoning and analytical approaches to process EHR data
 - Concept |pneumococcal pneumonia| is a subtype of |bacterial pneumonia|
 - Has a defining relationship that specifies that the |causative agent| is a |Streptococcus pneumoniae|
 - Allows the organism causing the disease to be analyzed



SNOMED CT - Who owns it



- Owned and maintained by SNOMED International (IHTSDO)
 - Provides the standards, guidelines and specifications for SNOMED CT
 - Membership organization (1 member per country) with governance and advisory structure
- Today 30 Members US (NLM) was one of 9 Charter Members





SNOMED CT - Releases

Releases

- SNOMED CT International Edition produced by SNOMED International
 - January and July releases
 - Other derivatives releases throughout the year
- SNOMED CT US Edition produced by NLM
 - March and September releases
 - This is the version specified for U.S. EHR certification and Meaningful Use
- Mapping files, subsets, value sets and other derivatives
- All downloads require a free UMLS license (incorporates SNOMED CT license)



SNOMED CT - Maintenance

Maintenance

- Requests for change from users
- Collaborative agreements
 - CMT
 - Orphanet
 - LOINC
- International Advisory Groups
 - Editorial AG, Terminology Release AG, Content Managers AG

Looking Forward

- Frequency of release
- Release specification
 - Other formats



SNOMED CT - Use

- Used in over 50 countries
- SNOMED CT US Edition almost 5,000 downloads in FY16
 - SNOMED CT International Edition over 3,000 downloads in FY16
- Use case Examples
 - US Newborn Screening
 - Member Implementation Use case: India



SNOMED CT - Relationships

• Mappings & Releases

- SNOMED CT to ICD-10-CM map
- SNOMED CT to ICD-10 map
- LOINC Cooperative Project
- GMDNA (SNOMED GMDN equivalency map)

- Key Partnerships
 - AMA
 - GS1
 - HL7
 - IBM Watson Health
 - JIC
 - LOINC
 - Trillium Bridge
 - WHO



LOINC Overview

Daniel J. Vreeman, PT, DPT, MS

Director, LOINC and Health Data Standards at Regenstrief Center for Biomedical Informatics Regenstrief-McDonald Scholar in Data Standards at Indiana University School of Medicine dvreeman@regenstrief.org



LOINC – What is it?



Universal standard for identifying health measurements, observations, and documents.

Owned and maintained by the Regenstrief Institute, Inc who also provide a large set of tools and resources for implementers.

Community-driven development

Currently 84,000+ codes

Free, but invaluable





LOINC – Maintenance and Release

Major releases twice per year (June and December)

Last year 50+ organizations in 14 countries requested new terms

Each release contains about 1,400 new terms (average)

Advisory body: LOINC Committee

Included in NLM's UMLS (since ~1998)



LOINC – Use

47,000+ registered users from 166 countries

Many kinds of LOINC users: federal agencies, reference labs and radiology centers, care organizations, professional societies, insurance companies, health IT vendors, instrument manufacturers, health app developers, etc

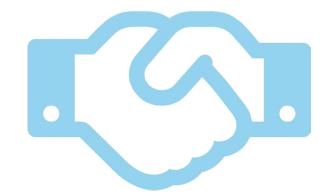
National standard in 30+ countries

Translations into 18 variants of 12 languages

Last year 10,000+ downloads Online browser: 1.2 million pageviews



LOINC – Relationships



Other Standards Organizations

Health Level 7 (HL7), IEEE, SNOMED International, Radiological Society of North America (RSNA), IVD Industry Connectivity Consortium (IICC), Health Standards Collaborative (HSC), College of American Pathologists (CAP), International Collaboration on Cancer Reporting (ICCR), Clinical Data Interchange Standards Consortium (CDISC)

Other Key U.S. Collaborations

NIH Common Fund (*PROMIS*), NCBI (*Genetic Testing Registry*), NHGRI (*PhenX*), NINDS (*NeuroQOL*), NCI (*caBIG*), NICHD (*Hemaglobinopathies*), NIDDK (*Chronic kidney disease care plan*), HRSA + NLM (*Newborn screening*), NEI (*EyeGENE*), CDC (*many national projects*!), CMS (*Meaningful Use, assessment instruments*), FDA (*Lab data in trials, SPL, lab IVD vendors*), SAMHSA (*behavioral data elements*), DOD (*data exchange for lab, radiology, documents*), VA (*data exchange for lab, radiology, documents*))

Funding Support (current)

National Library of Medicine, Regenstrief Foundation, NIDDK, NIBIB, NCCIH, ASPE/CTSI, CMS, bioMérieux, LOINC community



RxNorm Overview

Patrick McLaughlin Head, Terminology QA & User Services

patrick.mclaughlin@nih.gov



RxNorm – What is it?

- Drug terminology developed and maintained by NLM
 - Drugs and codes (RXCUIs)
- Represents drugs from prescribers' point of view
 - Ingredient + Strength + Dose Form (e.g., Warfarin Sodium 1 MG Oral Tablet)
- Derived from other commonly-used public and private drug terminologies, including FDA structured product labeling (SPL)
- Does not contain
 - Drug classes, indications, adverse events, drug-drug interactions



RxNorm – What is it?

- June 2017 release
 - 19,000 generic and 11,000 branded products
 - 113,000 total concepts
- NDCs and other attributes
 - 230,000 NDCs for drugs currently marketed in the US
 - Access to 400,000 NDCs for previously marketed drugs available through API
 - FDA application number, UNII, DEA schedule, UMLS CUI, etc.
- Rich graph of associative relationships between concepts



Reverse And Andrews		3 String	• Warfarin Sodium	Warfarin Sodium 1 MG Oral Tablet		Q
RxNorm Graph	RxNorm Properties NDC	Warfarin RxTerms NDF-RT	Sodium 1 MG Ora Pill Images Class View	al Tablet [RxCUI =		ttps://rxnav.nlm.nih.gov/
Views Classic Simple Table Filters H K G Group Form Links K V	H Rx S Warfarin	rug Component (1) MG	HRX S Warfarin Sodiu	recise Ingredient (1) um		
Legend MIN Pack Multi Download	SCD/GPCK H RX S Warfarin Sodium 1 M SCDG Clinical Do H RX S Warfarin Oral Produ H RX S Warfarin Pill	MG Oral Tablet	DFG D HVRX S Oral Product HVRX S Pill	ose Form Group (2)	HRXS Jant SBDG HRXS Cou HRXS Cou	toven Oral Product

RxNorm – Maintenance and Release Process

Maintenance

- Acquire most data sources monthly, except daily FDA SPL
- Editing utilizes source codes and descriptions, NDCs, SPL text, etc.
- Major editorial policy changes informed by user feedback, NCPDP and other stakeholders

Releases

- Monthly: full release
- Weekly: new drug updates from SPL
- Available through downloads*, APIs, DailyMed, RxNav browser, RxMix data processing tool, etc.

*Downloads require free UMLS license



RxNorm – Use

- Monthly releases downloaded over 5,200 times in FY16
- API queried over 800 million times by more than 20,000 unique users in FY16
- Use cases:
 - E-prescribing
 - NCPDP SCRIPT standard for e-prescribing requires RxNorm
 - Information exchange
 - DoD and VA rely on RxNorm to mediate drug information across their electronic medical record systems
 - Formulary development
 - CMS uses RxNorm in their Formulary Reference File, as part of the guideline for Medicare drug benefits
 - Reference value sets
 - The drug value sets used in clinical quality measures for Meaningful Use are defined in reference to RxNorm
 - Analytics
 - OHDSI, the Observational Health Data Sciences and Informatics research group, uses RxNorm to analyze prescription data



RxNorm – Relationships

- Relationships to other terminologies inherent in RxNorm data:
 - Government Sources
 - CDC: CVX Vaccines Administered
 - FDA: SPL (DailyMed)
 - VA: National Drug File/Reference Terminology
 - NIH/NLM: MeSH
 - Commercial Sources
 - FDB, Gold Standard, Medi-Span, Micromedex, Multum
 - International Sources
 - DrugBank
 - SNOMED CT
 - WHO: Anatomical Therapeutic Chemical Classification System (ATC)
 - Code Sets
 - UMLS CUI, UNII, NDC



Questions?

