Progress → Rising Expectations:
Standards, Interoperability, Health, Research

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September 19, 2016

UMLS Project Context – late 1980s

◆ **Overall Goal:** Seamless integration of automated clinical data and knowledge-based information to support informed decisions

◆ **Prerequisites:**
  - Technical connections – *Simplified by Web, 1993--*
  - Organizational connections
  - Added later: Conducive Federal public policy
NLM and Health Data Standards

- **Expertise/Perspective gained from UMLS project**

- **Vocabulary/coding standards a prerequisite for:**
  - Efficient access to clinical decision support (including NLM resources) from within electronic health records (EHRs)
  - EHRs able to generate useful public health and research data as a by-product of health care
Strategy for standardizing electronic health data, 1990--*

“*A journey not a destination...*”

- Establish a mechanism for picking US national standards
- Pick best available as starting points
- Broaden participation in standards development
- Support development (last resort!! – for critical gaps), ongoing maintenance, expansion, enhancement, and no/low cost distribution
  - fees and restrictive licensing discourage use
- Promote use and improvement through:
  - early Federal adoption, conformance & production testing, demonstration projects, cost/benefit research, incentives, eventual mandates
- Coordinate development to achieve interlocking set of standards
  - responsive to feedback from real use

* Outlined in numerous reports and (from 1996--) reflected in multiple Congressional and Executive Branch actions
* Advanced across Administrations of 4 U.S. Presidents
Clinical vocabulary/coding standards:
NLM’s Principal Focus

* Develop, support, or license and disseminate for US use
* Coordinate to achieve interlocking set

Implementation Resources
NLM provides clinical vocabulary standards and tools that support implementation of Meaningful Use, C-CDA, and other programs.
VSAC – provides:

- Source of truth for value set definitions
- Downloadable expansions (actual lists of codes)
- An API (based on an IHE standard – moving towards FHIR)
- Authoring and collaboration environment
- Duplicate content checking (based on Jaccard overlap)
- Warnings for inactive/obsolete codes
- Checking for invalid codes
Many C-CDA value sets are in VSAC or going into VSAC now to support implementation. Some of these value sets are very large and potentially burdensome for individual sites to generate/maintain on their own. VSAC can provide an always-up-to-date expansion of these value set definitions.

Examples:
- SNOMED CT ‘Findings’ value set > 105k concepts
- SNOMED CT ‘Body site’ value set > 30k concepts
- RxNorm ‘Medication Clinical Drug/Brand Name’ > 30k concepts each

These large value sets really act as ‘filters’ (am I using a code from the right part of the vocabulary?), but nonetheless the community needs validation and expansion support.
MedlinePlus Connect
Uses HL7 compliant Request (Infobutton) and Response (Web service version)

1. Problem, medication, or lab code-based request
Consumer health information targeted response

MedlinePlus Connect

EHR

Patient portal

Clinical system
Progress – since ARRA/HITECH (2009)

◆ Big increases in:
  ● use of electronic health records (EHRs)
  ● use of related standards
  ● health information exchange
  ● patient access to health data

-- substantive collaborations to improve clinical terminology standards
Rising Expectations for:

- User-friendly EHRs with greater value for clinicians; standards “under the hood”
- Easy-to-implement standards
- More interoperability/health information exchange – more data liquidity
- “The Learning Health System”
- Seamless access to pre-clinical, clinical research, and EHR data for scientific discovery and medical product development, evaluation, and approval
- Participants as partners in research
- Ubiquitous “Precision Medicine”
Many reasons for optimism

- SMART on
- Argonaut project
- Bluebutton on
- Sync 4 Science
- Structured Data Capture
RxNorm = significant success story

- Constrained universe, i.e., FDA-approved drugs
- Collaborative, win-win solution for NLM, FDA, VA, & commercial drug information providers
- Active user feedback/enhancement loop
- Enables analysis and aggregation of electronic medication data for US patients at multiple useful levels
RxNorm Usage

- RxNorm downloads
  - ~900 downloads monthly
- API usage
  - > 1 billion queries in 2015
  - 30,000 unique users monthly
- Users
  - NLM applications (e.g., MedlinePlus Connect)
  - EHR product developers
  - Pharmacy benefit managers
  - Healthcare insurance companies
  - Clinical institutions
  - Academic researchers
Features enabled by NLM drug APIs

- Integrating information from RxNorm (and other sources) into applications
  - Mapping drug names and codes to RxNorm
  - Support medication lists
  - Link drugs to drug classes / Find all RxNorm drugs for a given class
  - Map obsolete codes (NDC) to active drugs

Available functionalities:
* Track unlimited health chronicles that include symptom description, pain intensity, capture pain images, medications taking and doctors seen.

* Auto retrieves Rx (RxCUI/RxNorm)
Analytics – one example

◆ “Multi-stakeholder, interdisciplinary collaborative to bring out the value of health data through large-scale analytics”

◆ OHDSI/OMOP Common Data Model
  ● Standard vocabularies (RxNorm for drugs)

◆ Investigation of treatment pathways
  ● For 3 chronic diseases (3 year-follow up)
    ■ > 1M patients with hypertension
  ● Across multiple clinical institutions
  ● In several countries

http://www.ohdsi.org/
Characterizing treatment pathways at scale using the OHDSI network

George Hripcsak, Patrick B. Ryan, [...], and David Madigan

ABSTRACT

Observational research promises to complement experimental research by providing large, diverse populations that would be infeasible for an experiment. Observational research can test its own clinical hypotheses, and observational studies also can contribute to the design of experiments and inform the

Fig. S1.

Treatment pathways for type 2 diabetes mellitus. The inner circle for each source shows the first relevant medication that the patient took, the second circle shows the second medication, and so forth. The data source abbreviations are defined in Table ...
ABOUT AccessGUDID

The Global Unique Device Identification Database (GUDID) contains key device identification information submitted to the FDA about medical devices that have Unique Device Identifiers (UDI).

The FDA is establishing the unique device identification system to adequately identify devices sold in the U.S.-from manufacturing through distribution to patient use. You can use AccessGUDID to search for specific medical devices or download all the GUDID data at once. AccessGUDID also offers RSS feeds and APIs to connect you directly to the data.

MORE INFO
ABOUT UDI
ABOUT GUID

DOWNLOAD

Download Data
Download the latest full releases and update files provided to the NLM by the FDA.

API

API Documentation
Resources for application developers to get the most out of AccessGUDID.

RSS

RSS Documentation
Subscribe to RSS feeds to receive the latest files.

HELP

Help using AccessGUDID
Searching AccessGUDID
Downloading Release Files
NLM Web Guidelines
NIH CDE Resource Portal

Home
NIH encourages the use of common data elements (CDEs) in clinical research, patient registries, and other human subject research in order to improve data quality and opportunities for comparison and combination of data from multiple studies and with electronic health records. This portal provides access to information about NIH-supported CDEs, as well as tools and resources to assist investigators developing protocols for data collection. NIH CDEs can also be searched directly through the NIH Common Data Elements Program.

What is a CDE?


NIH CDE Collections
Sets of CDEs that have been identified for use in particular types of research or research domains after a formal evaluation and selection process.

NIH CDE Tools and Resources
Databases and repositories of data elements and case report forms that may assist investigators in identifying and selecting data elements for use in their projects.

Summary Table
Subject Areas
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Some NIH programs have issued specific guidance for using CDEs in funded research.
The CDE Resource Portal also includes Other CDE Resources and Relevant Standards. Descriptions of all four groups can be found in the Glossary.
The CDE Working Group of the Trans-NIH BioMedical Informatics Coordinating Committee (BMIC) developed this Portal to improve the coordination of CDEs. BMIC encourages researchers to use CDEs from the Resources in this Portal where applicable, and to consider existing CDE initiatives before starting additional initiatives.

Are we missing a CDE Resource? Contact us.

https://www.nlm.nih.gov/cd
The NIH Common Data Elements (CDE) Repository has been designed to provide access to structured human and machine-readable definitions of data elements that have been recommended or required by NIH Institutes and Centers and other organizations for use in research and for other purposes. Visit the NIH CDE Resource Portal for contextual information about the repository.

The Repository is a platform for identifying related data elements in use across diverse areas, for harmonizing data elements, and for linking CDEs to other existing standards and terminologies, including the value sets in the Value Set Authority Center (VSAC).

Search
Search for individual data elements, by definition, users or sources. Search for sets of data elements ("boards") identified by a particular group for a particular use (e.g. particular research solicitation).

Compare / Harmonize
Analyze and resolve differences between data elements. Assure that your forms are using variables that will be usable by certified EHRs.

Create
Draw upon the experience of colleagues and others to design unique data elements and measures.

https://cde.nlm.nih.gov/home
More freely available data e.g.,
Patricia Flatley Brennan, RN, PhD sworn in as NLM Director, by Francis Collins, MD, PhD, Director, NIH, on September 12, 2016

Dr. Brennan’s talk begins 9 min. 50 sec. into video
NLM Health Data Standards Players - partial list

- Swapna Abhyankar
- Liz Amos
- Vivian Auld
- Olivier Bodenreider
- Jim Case
- Pishing Chiang
- Philip Chuang
- Ivor D’Souza
- Steve Emrick
- Kin Wah Fung
- Rebecca Goodwin

- Vojtech Huser
- Jen Jentsch
- John Kilbourne
- Lisa Lang
- Christophe Ludet
- Maureen Madden
- Clem McDonald
- Patrick McGlaughlin
- Duc Nguyen
- Tammy Powell
- Suzy Roy
NLM’s Federal Partners

AHRQ, CDC, CMS, FDA, NRSA, IHS, NIH, Office of the National Coordinator, SAMHSA, VA