Interoperability Standards Advisory Overview and Roadmap

ASSESS CT EU-US Workshop
Amsterdam, Netherlands
3 May 2016

Robert Hausam MD
Contractor to the Office of the National Coordinator for Health Information Technology (ONC)
US Department of Health and Human Services

Purpose

- To provide the industry with a single, public list of the standards and implementation specifications that can best be used to achieve a specific clinical health information interoperability purpose
- To prompt dialogue, debate, and consensus among industry stakeholders when more than one standard or implementation specification could be listed as the best available

Scope

- Focus explicitly on clinical health IT systems' interoperability
- Includes electronic health information created in the context of treatment and subsequently used to accomplish a purpose for which interoperability is needed
- **Does not** include administrative/payment oriented interoperability purposes or administrative transaction requirements

Background

- 2001-2007 – Consolidated Health Informatics (CHI) initiative
- 2006-2009 – ONC process to “accept” and “recognize” health IT standards and implementation specifications
- 2009 – Health Information Technology for Economic and Clinical Health (HITECH) Act
- 2012 - ONC RFI seeking comments on health information exchange governance
  - RFI approach was not implemented

2015 Interoperability Standards Advisory

- With past approaches in mind, the ISA reflects ONC's decision to pursue a straightforward approach to advising the industry on interoperability standards and implementation specifications
- This approach is designed to more clearly link standards and implementation specifications to a specific purpose and interoperable use
- **Best available standard(s) and implementation specification(s)**

2016 Interoperability Standards Advisory

- Questions
  - What is it again?
  - Where are we in the process?
  - What's changed?
  - What's up next?

What is it: Interoperability Standards Advisory

- **Scope = clinical health IT interoperability**
- **Non-regulatory, straight-forward approach with an interactive, predictable process for updates**
- **Reflects "best available" standards and implementation specifications as of end of the calendar year**
  - Updated annually

What is it: Interoperability Standards Advisory

- **Designed to create common ground**
  - To get specific
  - To provide a single, public list of the standards and implementation specifications to fulfill specific clinical health information technology interoperability needs
  - To reflect the results of on going dialogue, debate, and consensus
  - **(New) To document known limitations, preconditions, and dependencies among referenced standards and implementation specifications**

What is it: Interoperability Standards Advisory

- **Overall Goal**
  - A widely vetted resource – in one place, done right (before/without regulation)
  - Enable a "look first" philosophy for government programs, procurements, testing or certification programs, standards development, etc.

Interoperability Standards Advisory (Ideal) Process

December of Preceding Year

- The new Interoperability Standards Advisory for the next calendar year is published (e.g., December 2015 for the 2016 Advisory) and public comment period is opened.

April/May

- ONC staff present a summary of received comments to the HIT Standards Committee (or designated Task Force) in order to prepare them to make recommendations on updates for the following year's Interoperability Standards Advisory.

August

- The HIT Standards Committee submits recommendations to the National Coordinator concerning updates to the following year's Interoperability Standards Advisory and a second round 60-day public comment is opened on the HIT Standards Committee's recommendations.

October-December

- ONC reviews the HIT Standards Committee recommendations as well as public comments on those recommendations and prepares the next year's Interoperability Standards Advisory for publication.

What's changed?
2016 Interoperability Standards Advisory

- **Major Restructuring**
  - Changed "Purpose" to "Interoperability Need"
  - Added "Emerging" row for standards and implementation specs
  - Removed "Transport" Section
    - Categories now include:
      - Vocabulary/code sets/terminology (i.e., "semantics")
      - Content/structure (i.e., "syntax")
      - Services (i.e., the infrastructure components deployed and used to fulfill specific interoperability needs)
  - Inserted Appendix that contains "Sources for Security Standards"

What's changed?
2016 Interoperability Standards Advisory

- **Added six "informative characteristics" for each standard and implementation specification**
  - Standards Process Maturity (Final, Balloted Draft)
  - Implementation Maturity (Production, Pilot)
  - Adoption Level (Scale between 1-5, Unknown)
  - Federally Required (Yes, No)
  - Cost ($, Free)
  - Test Tools Availability (Yes, Yes$, Yes – Open, No, N/A)
- **Added additional context structure**
  - Limitations, Dependencies, Preconditions and Other Qualifying Information (free text)
  - Applicable Value Sets
  - Security Patterns (free text)
- **Revision history**

Other Task Force Recommendations - Disposition

- Principles are being built into new processes – adopted incrementally into operations
- Recommendations to convene groups to address specific sections/standards are being considered but not yet fully addressed
- Several additions and changes to standards and implementation guides
- Other recommendations are being considered incrementally

Section I: Best Available Vocabulary/Code Set/Terminology Standards and Implementation Specifications

- I-A: Allergies
  - Representing patient allergic reactions
    - **SNOMED CT**
  - Representing patient allergens: medications
    - RxNorm
    - NDF-RT
  - Representing patient allergens: food substances
    - **SNOMED CT**
  - Representing patient allergens: environmental substances
    - **SNOMED CT**

Section I: Best Available Vocabulary/Code Set/Terminology Standards and Implementation Specifications

- I-B: Health Care Provider
  - Representing care team member (health care provider)
    - National Provider Identifier (NPI)
- I-C: Encounter Diagnosis
  - Representing patient medical encounter diagnosis
    - **SNOMED CT**
    - ICD-10-CM
  - Representing patient dental encounter diagnosis
    - **SNOMED CT**

Section I: Best Available Vocabulary/Code Set/Terminology Standards and Implementation Specifications

- I-D: Race and Ethnicity
  - Representing patient race and ethnicity
    - OMB standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity, Statistical Policy Directive No. 15, Oct 30, 1997
      - CDC Race and Ethnicity Code Set Version 1.0 (may help further refine)
      - LOINC (provides observation codes)
- I-E: Family Health History
  - Representing patient family health history
    - **SNOMED CT**

Section I: Best Available Vocabulary/Code Set/Terminology Standards and Implementation Specifications

- I-F: Functional Status/Disability
  - Representing patient functional status and/or disability
    - Not yet determined – feedback requested
      - SNOMED CT?
      - ICF?
- I-G: Gender Identity, Sex, and Sexual Orientation
  - Representing patient gender identity
    - **SNOMED CT**

- Representing patient sex (at birth)
  - HL7 Version 3 Value Set for Administrative Gender
  - HL7 Version 3 Null Flavor (for unknown)
- Representing patient-identified sexual orientation
  - **SNOMED CT**

- I-H: Immunizations
  - Representing immunizations – historical
    - HL7 Standard Code Set CVX—Clinical Vaccines Administered
    - HL7 Standard Code Set MVX -Manufacturing Vaccine Formulation

- Representing immunizations – administered
  - HL7 Standard Code Set CVX—Clinical Vaccines Administered
  - National Drug Code (NDC)
- I-I: Industry and Occupation
  - Representing patient industry and occupation
    - Not yet determined – feedback requested
      - National Institute for Occupational Safety and Health (NIOSH) list (strongest support)

Section I: Best Available Vocabulary/Code Set/Terminology Standards and Implementation Specifications

- I-J: Lab tests
  - Representing numerical laboratory test results (observations)(questions)
    - LOINC
- I-K: Medications
  - Representing patient medications
    - RxNorm
    - National Drug Code (NDC)
    - National Drug File – Reference Terminology (NDF-RT)

Section I: Best Available Vocabulary/Code Set/Terminology Standards and Implementation Specifications

- I-L: Numerical References & Values
  - Representing units of measure (for use with numerical references and values)
    - The Unified Code for Units of Measure (UCUM)
- I-M: Patient Clinical "Problems" (i.e., conditions)
  - Representing patient clinical "problems" (i.e., conditions)
    - **SNOMED CT**

Section I: Best Available Vocabulary/Code Set/Terminology Standards and Implementation Specifications

- I-N: Preferred Language
  - Representing patient preferred language
    - RFC 5646
- I-O: Procedures
  - Representing dental procedures performed
    - Code on Dental Procedures and Nomenclature (CDT)
    - **SNOMED CT**
  - Representing medical procedures performed
    - **SNOMED CT**

- The combination of CPT-4/HCPCS
- ICD-10-PCS

- I-P: Imaging (Diagnostics, interventions and procedures)
  - Representing imaging diagnostics, interventions and procedures
    - LOINC
- I-Q: Tobacco Use (Smoking Status)
  - Representing patient tobacco use (smoking status) observation result values or assertions (answers)
    - **SNOMED CT**

Section I: Best Available Vocabulary/Code Set/Terminology Standards and Implementation Specifications

- I-R: Unique Device Identification
  - Representing unique implantable device identifiers
    - Unique device identifier as defined by the Food and Drug Administration at 21 CFR 830.3
    - HL7 Harmonization Pattern for Unique Device Identifiers
- I-S: Vital Signs
  - Representing patient vital signs
    - LOINC

Public Comment

- 2016 Interoperability Standards Advisory
  - posted on healthit.gov
  - https://www.healthit.gov/standards-advisory/2016