

# Collaboration of the Health IT Policy and Standards Committees

Policy and Standards Federal Advisory Committees on Health Information Technology  
to the National Coordinator



July 27, 2016

Karen DeSalvo, MD  
National Coordinator for Health Information Technology  
Department of Health and Human Services  
200 Independence Avenue, SW  
Washington, DC 20201

Dear Dr. DeSalvo,

The 2017 Interoperability Standards Advisory Task Force (ISATF) convened on March 8, 2016, as part of a joint collaboration between the Health IT Policy Committee (HITPC) and Health IT Standards Committee (HITSC). The Task Force was charged to submit recommendations to the Health IT Standards Committee regarding revisions and enhancements ONC should consider as it creates the Draft 2017 Interoperability Standards Advisory (ISA), taking into account feedback from the public comment process. This transmittal offers these recommendations, which are informed by the deliberations among the Task Force members, and consideration of testimony from public and private industry stakeholders.

## Charge:

Over the course of two phases, the 2017 ISA Taskforce is charged to develop recommendations for the HITSC on the following:

### Phase 1 (May ->July)

- Updates to the ISA based on an analysis of public comments;
- Structural and framing improvements to the ISA, including elements that could provide additional clarity and context for stakeholders that would use and consult the ISA;
- Limited set of new “interoperability needs” that should be included in the ISA along with attributed standards and implementation specifications;
- The explicit “best available” designation to a standard or implementation specification, where appropriate (and in consideration of available implementation experience).

### Phase 2 (July ->Nov 1)

- Discussion and recommendations around the TF’s priority list for inclusion in the 2017 ISA’s “Projected Additions” section.

## Background:

The Interoperability Standards Advisory (ISA) was ONC’s first deliverable in support of the Nationwide Interoperability Roadmap towards a Learning Health System. The document provides the industry with a single, public list of the standards and implementation specifications necessary to fulfill specific clinical health information technology interoperability needs. The ISA Documents known limitations, preconditions, and dependencies as well as known security patterns among referenced standards and implementation specifications when they are used to fulfill a specific clinical health IT interoperability

need. It is a non-regulatory “advisory” document, using a straight-forward approach with an interactive and predictable process for updates.

The Interoperability Standards Advisory process represents the model by which ONC will coordinate the identification, assessment, and determination of the “best available” interoperability standards and implementation specifications for industry use to fulfill specific clinical health IT interoperability needs.

## Recommendations

### ISA Scope Recommendations

- The ISA document should focus on data, standards and interoperability needs for Certified Health IT and will, when appropriate, include an appendix which references authoritative sources for other standards in healthcare including security, administrative, research/clinical trial etc.
  - Secondary data used for ISA purposes will be defined as the reuse of the same data that is collected for clinical care.
- ISA TF recommends including standards for interoperability which connect technologies outside the EHR, creating a path where data can be put in once (primary use) but used many times (secondary use).
- ISA TF recommends a section to identify “industry gaps” that exist (per task force/HITSC recommendations) in areas where standards likely would be valuable but are not known to exist. (i.e., data quality in patient matching)
- ISA TF recommends deprecation of listed standards once sufficient experience is gained with newer standards/approaches that offer a clear advantage over previous standards.

### ISA Structure Recommendations

- The ISA should evolve to a more dynamic experience for users:
  - Link to or embed content from websites like the ONC [Interoperability Proving Ground](#) demonstrating interoperability use cases
  - Enable viewing of public comments and ONC responses in the context of which standards/interoperability needs they pertain
  - Link to known profiling entities which coordinate standards listed in ISA to address specific clinical needs and use cases.
  - Link to published assessments of a particular standard’s maturity
  - Link listed value sets to their publication in VSAC
  - In addition to the links mentioned above, allow some content like annotations and available value sets to be updated more frequently than yearly, as industry evolves.
- There is a general pattern of base standards + “profiles” with additional constraints. This pattern appears in many contexts:
  - HL7 v2.5.1 > HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 2 (US Realm), DSTU Release 1.1
  - FHIR DSTU2 (Resource Observation) > US Laboratory Observation Profile
  - LOINC > Value set of LOINC codes for vital signs
- Use of this pattern could be a helpful principle throughout the ISA.
  - Applies to messaging, document, API and vocabulary paradigms.
  - Could help name base standards that are being used everywhere today for some purposes but for which no specific IG has been developed

- Hundreds of millions of radiology reports are being shared as plain old HL7 v2 messages
- The ISA structure should be further modified so that it:
  - uses a consistent format to separate vocabulary standards for observations from vocabulary standards for observation values
    - Keep both vocabulary recommendations tied to single interoperability need
    - Apply this both to main vocabulary recommendations, and listing of applicable value sets
      - Sample structure provided in slides.
    - The following sub sections require this format: Section I-A: Allergies, Section I-B: Health Care Provider, Section I-D: Race and Ethnicity, Section I-E: Family Health History, Section I-F: Functional Status/Disability, Section I-G: Gender Identity, Sex and Sexual Orientation, Section I-J: Lab Tests, Section I-Q: Tobacco Use (Smoking Status), Section I-M: Patient Clinical “Problems” (i.e., conditions), Section I-O: Procedures, Section I-M: Patient Clinical “Problems” (i.e., conditions), Projected Additions: Representing nursing assessments & Representing outcomes for nursing
  - makes a visual distinction between core standards and projected additions
    - Sample provided in slides.
  - includes reference annotations (and any available public links) associated with test tool availability
    - Recommend listing only publicly available tools; avoid listing commercial tools in the main ISA. Perhaps an accessory document/web page could catalog commercial tools.

#### “Best Available” Standards Recommendations

- The ISA term “Best Available Standards” be replaced with “Recognized Standards”
  - Recognized Standards will include voluntary consensus standards (see [OMB Circular A-119 Revised](#)) and related implementation specifications
  - To be listed in the ISA, Recognized Standards should be approved by the governing standards development organization (or equivalent governing body) as either
    - a trial standard for pilot use (or equivalent)
    - or approved for production use (or equivalent)
  - Standards that are considered “emerging” may include broader standards that do not meet this criteria.
- The ISA should serve as a filter to identify Recognized Standards which may be considered in a future regulatory process
- Recognized Standards should be dynamically linked in the ISA to the applicable standards specifications and governing body statements regarding the individual standard’s maturity.

#### Recommendations to Improve the Use/Function of Standards

ISA TF recommends that, in the interests of improving the use and function of existing standards already in regulation, that the following additional implementation references be incorporated into the ISA:

- HL7 [Structured Document Examples](#)
- HL7 C-CDA R2.1 and the C-CDA R2.1 Companion Guide ([to be balloted in September](#))
- Direct Trust [Recommendations to Improve Direct Exchange](#)

- Argonaut [Implementation Guide](#)
- NCPDP/HL7 Pharmacy eCare Plan V1.0 (Guidance on the Use of the HL7 Clinical Notes R2.1 Care Plan Template)

### Recommendations on ISA “Characteristics”

- The *Adoption Level* bubbles should be more qualitative in nature than quantitative when possible and should be referenced/sourced to how the adoption level was determined.
  - One consideration could be to have a descriptive field of what is known about *Adoption Level*.
  - Include reference annotations (and any available public links) associated with adoption level classifications, including source used to quantify adoption level.
- The ISA TF recommends linking the maturity assessments to known published criteria about the standards either from the SDO itself to other known evaluation entities (e.g., IHE Standards Matrix Criteria)
- The ISA should add a category under *Standards Process Maturity* to include categories of 'ballot in development' that could reflect emerging standards which may be in rapid development.

### Recommendations on ISA Section I – Vocabulary and Terminology Standards

#### Overarching Section I Recommendations

- Change “Applicable Value Set(s)” to “Applicable Value Set(s) and Starter Set(s)”
  - A brief definition of value sets and starter sets should also be included.
    - Suggested language: Value sets include all allowable values or codes for a data element. Starter sets are smaller subsets that represent the most frequently used values or codes, and are derived empirically from patient data. Starter sets facilitate implementation of value sets and reduce variability in coding.
- Suggest adding reference to VSAC, PHINVADS or other public repositories where appropriate to address public comments requesting “central repository” of value sets.
- Provide direct links (where possible) to value sets.
  - VSAC should consider permalinks for value sets so they can be more easily accessed.

#### Section I-A: Allergies

- The ISA should clearly differentiate between the allergens (substance causing the reaction) and allergic reactions.
- For Allergic Reactions:
  - For use of SNOMED-CT, codes should generally be chosen from the Clinical finding axis
    - A single value set could be created in VSAC called “Clinical Problem Value Set”
- For allergic reactions, there is an ‘Adverse Clinical Reaction’ set in VSAC created by FHIMS which can be considered a candidate as a starter set. FHIMS should consider liaising with SDOs to validate this subset.

#### Section I-B: Care Team Member

- The ISA should reflect work occurring in the HL7 Argonaut FHIR Provider Directory Work Group, which could be an emerging standard for this interoperability need as it becomes more mature.

- The ISA should list vocabularies that expressly differentiate the credentials vs the role of the care team member (e.g., pharmacist vs family member)
  - Consider splitting into separate interoperability needs.
- A gap currently exists for a value set that captures the care team members' role on the care team. ONC should work with appropriate parties to accelerate such a value set's development.
  - The National Uniform Claim Committee (NUCC) should be evaluated to determine its effectiveness at identifying individual care team member roles in future ISA updates.

#### Section I-C: Encounter Diagnosis

- For use of SNOMED-CT, codes should generally be chosen from three axes: Clinical finding, Situation with explicit context, and Event. A value set could be created in VSAC to cover these, which can be called the "Extended Problem Value Set"
- A precondition should be added for medical diagnoses that systems should be able to handle older code sets, such as ICD-9, as legacy content still exists and may be used for analysis/decision support/quality measurement needs as retroactive analysis is often required.
- A link to NLM's SNOMED-CT and ICD-10-CM mapping should be provided.
- Add the CORE Problem List Subset as a starter set for SNOMED-CT codes for this interoperability need.
- For dental diagnoses, consider including CDT-2 and provide transcoding from CDT-2 to SNODENT.

#### Section I-D: Race & Ethnicity

- No specific recommendations in this area.

#### Section I-E: Family Health History

- See recommendations on structure and observation/value pairings so context of meaning is not lost. (e.g. WHO the history pertains to, WHAT history condition is recorded).
  - The condition part could be coded with SNOMED CT, referencing the value set "Clinical Problem Value Set" (as in the Allergies slide)

#### Section I-F: Functional Status & Disability

- A number of survey/assessment instruments and tools exist in this area. CMS should work with stakeholders to choose a preferred set of survey instruments for various settings.
  - LOINC and SNOMED-CT should be the preferred vocabularies.

#### Section I-G: Gender Identity, Sex, and Sexual Orientation

- This sub-section should be renamed as "Sexual Orientation and Gender Identity" for consistency with most widely accepted terminology.
- Precision medicine requires an increased focus to document granular, specific information about the patient that aids in targeted delivery of healthcare to the patient. There are other ways to determine gender outside of traditional approaches. ONC should solicit feedback from the community on appropriate genetic identifiers/gender determinants (e.g., gonadal sex, karyotypic sex, etc) for potential inclusion in the ISA.

Section I-H: Immunizations

- No specific recommendations in this area.

Section I-I: Industry & Occupation

- No specific recommendations in this area.

Section I-J: Lab Tests

- The interoperability need should be revised to: “Interoperability Need: Representing laboratory tests”
  - Remove “numerical” from the need name and instead use the general the paradigm of observations and observation values, with LOINC standard for the question/observation, SNOMED-CT as answer/observation value.
- As the TF has been made aware of some misunderstandings about LOINC, we offer the following additional clarifications for the record (and not for the ISA):
  - Observation value codes are not needed when the test reports a numeric quantity
  - Some observation values, particularly in genetics, are best represented with a syntax , or an identifier rather than a code drawn from an enumerated terminology
  - Some observation values are reported as short text strings, which should be permitted
- Label the LOINC Top 2000+ Lab Observations (OID: 1.3.6.1.4.1.12009.10.2.3) as a starter set.

Section I-K: Medications

- The ISA TF acknowledges that RxNorm is used for the exchange of information; however, it should be available also for export and import by end users. This should be listed as a limitation or gap in this area.

Section I-L: Numerical References & Values

- The task force recommends adding a precondition to help stakeholders better understand that UCUM is a syntax rather than an enumerated set of codes.

Section I-M: Patient Clinical “Problems” (i.e. “conditions”)

- For this interoperability need, codes should generally be chosen from three axes: Clinical finding, Situation with explicit context, and Event.
  - A single value set could be created in VSAC to cover these, named the “Extended Problem Value Set” to distinguish it from other value sets
  - The CORE Problem List Subset urn:oid: 2.16.840.1.113762.1.4.1018.240 should be added as a recommended as a starter set.
  - SNOMED CT supports the combination of codes (post-coordination) to generate new meaning. Codes from other axes can be used in post-coordination. The need to pick multiple codes may be seen as a disadvantage. This can be avoided if post-coordination is limited to the backend, exposing a single code for users to pick.

### Section I-N: Preferred Language

- No specific recommendations in this area.

### Section I-Q: Tobacco Use (Smoking Status)

- Use the observation + observation value pattern
- Include the LOINC code ([72166-2](#)) that corresponds with the enumerated SNOMED CT value set
- Develop guidance about using the SNOMED CT codes in the value set.
- Recognize that there are other clinically important smoking variables beyond the SNOMED CT value set. May need to add additional data elements to capture more granular smoking-related facts in a format that allows for accurate interpretations (e.g. tobacco type, frequency, amount, etc)
- ONC should pose a question to ask stakeholders about what surveys, instruments or tools are being used to collect smoking status information.

### Recommendations on Research

- Limit focus only to data, standards and interoperability needs for Certified Health IT in the ISA .
  - Different standards for clinical care data and research will create barriers for research efforts.
- The following ‘projected’ interoperability needs should not be included in ISA itself (due to scope limitations). An appendix for additional research standards may be more appropriate:
  - Representing analytic data for research purposes (p. 57)
  - Research- submission of analytic data to FDA for research purpose (p. 61)
    - Including SEND, which is primarily used for animal-based studies
  - Pre-population of research case reports from electronic health records (p. 62)
  - Integrate health care and clinical research by leveraging HER and other IT systems while preserving FDAs requirements (p. 63)
  - Registering a clinical trial (CDSC clinical trial registry) (p. 65)
- A cautious approach should be used in including vocabularies which differ/conflict with vocabulary standards listed in Section I (or adopted in regulation) as this may obstruct much research dependent on data present in EHRs.
  - FDA itself has as moved toward adopting LOINC as "part of a larger FDA effort to align the use of data standards for clinical research with ongoing nationwide health information technology initiatives"
- Be aware of (and evaluate for future inclusion) efforts underway using FHIR-based approaches to better support research based interoperability needs (e.g. CDASH, Data Capture, etc)

### Recommendations on Patient Matching

- Patient matching is a critical factor in achieving interoperability. The ISA should highlight what standards are available and in what manner they should be used. Suggested recognized standards applicable to patient matching should include (at minimum):
  - IHE XCPD (Cross-Community Patient Discovery)
  - IHE PDQ and PDQ v3 (Patient Demographics Query)
  - IHE PIX and PIX v3 (Patient Identifier Cross Reference)
  - IHE MPQ (Multi-Patient Queries)
  - IHE PDQm (Patient Demographics Query for Mobile)

- HL7 FHIR Patient resource based searches
- HL7 v2 query messages such as VXQ for immunizations
- Standards criteria to consider for patient matching should include:
  - Data formats needed for submission for patient matching
  - Standards for algorithms needed for patient matching
  - Standards to assess data quality for patient matching
- When developing criteria for patient matching we should think beyond tradition attributes used today and look for other attributes and to other industries which 'link' people through other attributes and activities.
  - Commonwell - <http://www.commonwellalliance.org/specifications/>
  - Sequoia - <http://sequoiaproject.org/wp-content/uploads/2015/11/The-Sequoia-Project-Framework-for-Patient-Identity-Management.pdf>

### Recommendations on API-Based Interoperability Approaches

- ONC should add a section to the ISA which highlights key differences between API-based interoperability standards and previous approaches.
- ISA should continue to focus on a use-case driven approach to interoperability guidance, but in so doing will need to maintain clear distinction between the lower-level standards that make up the "building blocks" (e.g., FHIR, OAuth 2) and the higher-level use-cases that leverage the lower-level building blocks.
- Higher-level use-cases should produce *Implementation Guides* that document their use of the core API standards, but which also include additional specifications and constraints, potentially including:
  - Use-case specific profiles of the required FHIR resources (including resource extensions, value sets, query parameters, etc.)
  - Use-case specific profiles for security standards such as OAuth 2 and OIDC (including authentication and authorization strategy, transport security, etc.)
  - Orchestration patterns that define the sequence of interactions between the key actors and the access patterns to the core APIs (including sequence diagrams, network topology, etc.)
  - Enumeration of external infrastructure that may be required for deployment (e.g., directories, certificate authorities, etc.)
- Emerging API Examples (Not an exhaustive list)
  - Core standards – the building blocks:
    - FHIR for access to healthcare data contained in typical Health IT systems
    - OAuth 2 and Open ID Connect for authentication and authorization handshakes
    - HTML5 for interoperability that requires user interaction (UX)
    - Other building blocks TBD
  - High-level API-based use-cases that leverage the building blocks:
    - Argonaut Project – implementation guides for vendor agreement on use of FHIR and OAuth2 APIs to meet the 2015 Edition Certification tests.
    - SMART on FHIR – specifications for apps that can be deployed directly into Health IT workflows
    - CDS Hooks – specifications for deployment of "clinical decision support as a service" into Health IT workflows
    - Synch for Science (S4S) – consumer-directed donation of health data to research
    - Others TBD



## Phase II of ISA Task Force

Due to time constraints, the ISA task force was unable to formalize recommendations for several portions of the 2016 ISA. As such, a second phase of the ISA Task Force will commence and run through November, providing recommendations in the following areas:

- Section I-P: Imaging
- Section I-R: Unique Device Identification
- Section I-S: Vital Signs
- Section II
- Section III

While work will commence in these areas, one priority recommendation for Section III-A: Push Exchange was provided for inclusion in future ISA updates:

- The preconditions for Section III-A: Push Exchange should explicitly reference the leading trust communities that help ISA users better understand where to turn to ensure Direct implementations can communicate effectively with other users.
- Link to DirectTrust (for provider messaging) and NATE (for consumer-mediated exchange)

We appreciate the opportunity to provide these recommendations and look forward to discussing next steps.

Sincerely yours,

/s/

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