Health IT Standards Committee
A Public Advisory Body on Health Information Technology
to the National Coordinator for Health IT

2017 Interoperability Standards Advisory Task Force Initial Recommendations to Joint HITSC/HITPC

Kim Nolen, co-chair
Richard Elmore, co-chair

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Membership

Member	Organization	Role
Kim Nolen	**Pfizer, Inc.**	**Co-Chair**
Richard Elmore	**Allscripts**	**Co-Chair**
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Membership, continued

Member	Organization	Role
Kin Wah Fung	*National Library of Medicine*	*Federal Ex Officio*
Christopher Hills	*DoD/VA Interagency Program Office*	*Federal Ex Officio*
Brett Andriesen	*Office of the National Coordinator-Health and Human Services*	*ONC Lead*
Chris Muir *Stacey Perchem* *Nona Hall*	*Office of the National Coordinator-Health and Human Services*	*ONC Project Team / Analysts*

Task Force Charge

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

Phase 1 (Now ->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 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.
- The 2016 Final ISA includes:
  - Vocabulary/Code Set/Terminology Standards (e.g. allergies, race and ethnicity, preferred language, etc);
  - Content/Structure Standards and Implementation Specifications (e.g. ADT, quality reporting, patient education materials, etc);
  - Standards and Implementation Specification for Services (e.g. push and query exchange, image exchange, etc);
  - Projected Additions for Future ISAs
- A sample of one interoperability need from the 2016 ISA is on the next slide for reference.

Section II-H: Laboratory (Sample Interoperability Need Table)

II-H: Laboratory

Interoperability Need: Receive electronic laboratory test results							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
Standard	HL7 2.5.1	Final	Production	●●●●●	No	Free	No
Implementation Specification	HL7 Version 2.5.1 Implementation Guide: S&I Framework Lab Results Interface, Release 1—US Realm [HL7 Version 2.5.1: ORU_R01] Draft Standard for Trial Use, July 2012	Final	Production	●●●●○	Yes	Free	Yes
Emerging Alternative Implementation Specification	*HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Results Interface Implementation Guide, Release 1 DSTU Release 2 - US Realm*	*Balloted Draft*	*Pilot*	●○○○○	*No*	*Free*	*No*

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• HL7 Laboratory US Realm Value Set Companion Guide, Release 1, September 2015, provides cross-implementation guide value set definitions and harmonized requirements.	• **Secure Communication** – create a secure channel for client-to- serve and server-to-server communication. • **Secure Message Router** – securely route and enforce policy on inbound and outbound messages without interruption of delivery. • **Authentication Enforcer** – centralized authentication processes. • **Authorization Enforcer** – specified policies access control. • **Credential Tokenizer** – encapsulate credentials as a security token for reuse (examples – SAML, Kerberos). • **Assertion Builder** – define processing logic for identity, authorization and attribute statements. • **User Role** – identifies the role asserted by the individual initiating the transaction. • **Purpose of Use** - Identifies the purpose for the transaction.

“Best Available” Standards – Initial 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.

Improving Use/Function of Standards – Initial Recommendations

- 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)
  - Additional feedback / resources to be incorporated prior to final recommendations.

ISA Scope – Initial 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 – Initial 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 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 that yearly, as industry evolves

ISA “Characteristics” – Initial Recommendations

- 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*.
  - » Source used to derive adoption level should be provided.
- 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.

API-Based Interoperability Approaches – Initial Recommendations

- 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 Exhaustive)

- 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

Patient Matching – Initial Recommendations

- 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

New Interoperability Needs – Initial Recommendations

- Work on gaps in coded values; value pairs: (i.e., LOINC for questions/SNOMED-CT for observations, etc)
  - A sub-group is currently working to develop recommendations on this.

- The 2016 ISA proposed a number of research-related interoperability needs in the "projected additions" section. This list needs to be further refined to ensure only relevant and necessary "recognized standards" are listed in the body of the ISA.