Health IT Standards Committee

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

Interoperability Standards Advisory Task Force Recommendations

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Charge to the Task Force

By the August 2015 HITSC meeting, submit final recommendations to the HIT Standards Committee regarding revisions ONC should consider as it creates a 2016 Interoperability Standards Advisory (ISA).

Questions Posed to the Task Force

- What additional information about the standards and implementation specifications would be helpful to represent in the ISA (e.g., maturity, test tool/testing availability, amount of pilot testing completed (if known))
- Are there suggestions for additional characteristics for Best Available, or the process in which they are determined? If so, what are they?
- What are recommendations to better address Immunizations Code Set/Terminology standards within ISA (i.e., Historical and Administered)?
- Should security standards be represented in ISA? If so, how should they be represented?
- How does ONC ensure ISA is relevant for intended stakeholders?
- What are the top priorities for ISA in 2016?
- What are the top priorities for ISA in future (post 2016) releases?

Members of the Task Force

Name	Organization
Robert (Rim) Cothren	**California Association of HIEs**
Kim Nolen	**Pfizer, Inc.**
Calvin Beebe	Mayo Clinic
Janet Campbell	Epic Systems Corporation
Lisa Gallagher	HIMSS
Eric Heflin	The Sequoia Project / HIETexas
LeRoy Jones	GSI Health
Anne LeMaistre	Ascension Health
Arien Malec	RelayHealth Clinical Solutions
Paul Merrywell	Mountain States Health Alliance
Pete Palmer	MedAllies, Inc.
Clem McDonald	National Library of Medicine
Christopher Hills, Federal ex officio	DoD/VA IPO
Brett Andriesen, staff lead	Office of the National Coordinator for Health IT (ONC)
Nona Hall, staff support	ONC & DoD/VA IPO
Mark Roche, SME	Contractor to ONC

Process We Followed

- Met 10 times via teleconference
  - Reviewed public comments, largely organized by ISA section
  - Reviewed work of FACA bodies, other FACA Task Forces, S&I Framework, and other federal agencies (e.g., NIST) as pertinent to issues or discussion
- Supplemented meetings with additional out-of-band email threads to research/discuss specific points
- Conducted additional research, as time permitted
- Drew on expertise of individual Task Force members
- Reviewed and summarized meeting discussion in a set of slides and supplemental word document with more detailed notes from calls and full ISA TF recommendations (available as Task Force products)
- As required by FACA processes, efforts were convened transparently and publicly, with an opportunity for public comment, some of which were incorporated

Process, continued

Input from Public Comments

- Comments received from 59 organizations:
  - 19 (32%) submissions from people/orgs that provide health IT capabilities
  - 17 (29%) submissions from people/orgs that deliver care
  - 8 (13%) submissions from research/quality improvement orgs
  - 7 (12%) submissions from people/orgs that govern, certify, or have oversight
  - 6 (10%) submissions from people/orgs that develop and maintain standards
  - 1 submission for supporter of public good and 1 from payer
  - No comments from consumer groups
- Public comments can be found at http://www.healthit.gov/policy-researchers-implementers/2015-interoperability-standards-advisory-public-comments

Recommendation: The ONC should proactively solicit feed back from Consumer Groups

Process / Recommendations

Recommended Guiding Principles

1. The ISA should qualify standards based on maturity, implementation testing, adoption, preconditions/dependencies, ability to meet goals.
2. Clear purposes and state of the world needs to be defined to identify appropriate standards and specifications, but often the reverse is done (ie. we have this standard/specification to achieve this purpose). The ISA should recommend standards and interoperability specification that are subordinate to achieving a set of real world, value-added outcomes and business functions to better achieve our state of the world in healthcare.
3. ISA should define what the standard is best for – innovation, tried and true use cases, and/or functionalities. For example, some standards support well established use cases, while others are used as building blocks that apply in multiple scenarios. Cross walking between use cases and functionalities and explore the ability to tie functionality to use cases
4. To promote innovation, emerging standards should be identified as a potential replacement for current standards.
5. Standards in regulation should be identified as such.
6. Non-regulatory standards listed in ISA should be evaluated based on the potential for being on Vendors roadmaps, and potential to meet market demands to fill gaps in current capabilities or replace existing standards with alternatives that offer more precision or simpler implementation.

Recommendations Regarding ISA Purpose and Scope

- ISA guidance needs to cover a much broader healthcare solution (provider vs public health vs patient vs HC Organization) that crosses the full spectrum of healthcare needs (research, emergency medicine, DOJ, etc.)
- It is much easier to enable interoperability when you start with less optionality's that increase over time and tight constraints and then loosen over time as more flexibility is needed.
- ISA should reflect objectives of the Interoperability Roadmap to move us towards a learning health system
- ISA should include a description of functions and outcomes near the beginning and identify how each standard maps to a required function or outcome
- ISA scope should point to all the preconditions, dependencies needed to facilitate interoperability
- ISA should include (but identify) emerging standards as well as Best Available
- Interoperability orchestration patterns, functionalities, and use cases need to be layered and balanced to satisfy healthcare goals

Recommendations, continued

Recommendations that Apply to the Entire Document

Tables that describe each standard and implementation guide should be adjusted such that:

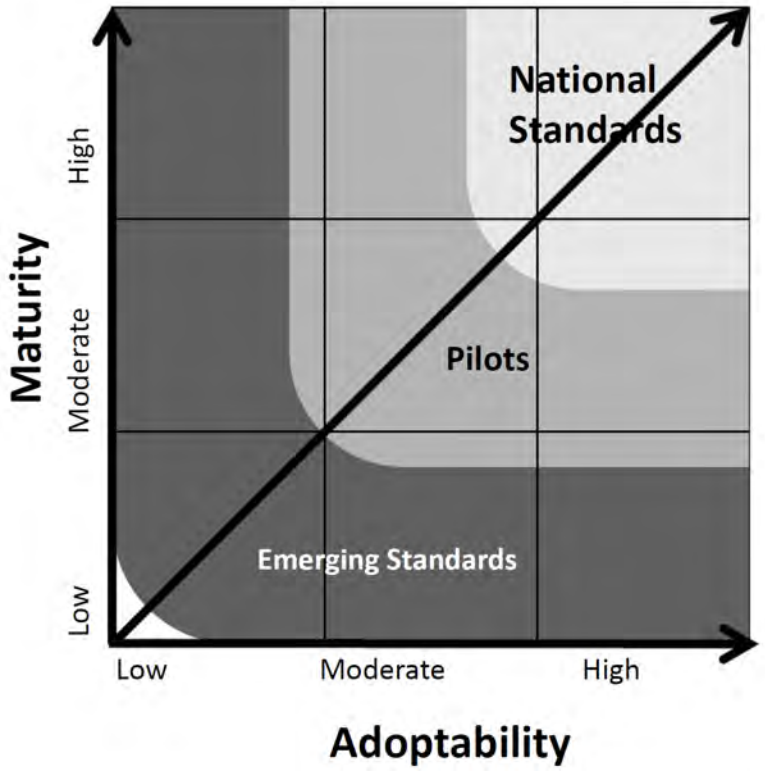
- Standards and implementation guides are classified in term of maturity and adoptability, including emerging, pilot, and national standards classifications, along with pre-conditions, and ability to meet the goals
  - See the NwHIN Power Team Preliminary Recommendations for Standards Evaluation Criteria
- Standards and implementation guides are mapped to outcomes or business functions they address
  - See S&I Task Force recommendations to the Health Information Technology Standards Committee (HITSC)
- Innovation should be promoted
  - Emerging standards should be identified as a potential replacement for current standards
  - Stability/Maturity of a standard needs to be intertwined with promoting innovation to meet healthcare goals

Recommendations, continued

Maturity Model

- Maturity Criteria:
  - Maturity of Specification
  - Maturity of Underlying Technology Components
  - Market Adoption
- Adoptability Criteria:
  - Ease of Implementation and Deployment
  - Ease of Operations
  - Intellectual Property

From NwHIN Power Team Preliminary Recommendations for Standards Evaluation Criteria



Guiding Principle #4: Promote Innovation

Recommendations, continued

Maturity Model, continued

Potential definitions from DHHS RFI 'Nationwide Health Information Network: Conditions for Trusted Exchange':

1. 'Emerging'—technical standards and implementation specifications that still require additional specification and vetting by the standards development community, have not been broadly tested, have no or low adoption, and have only been implemented with a local or controlled setting
2. 'Pilot'—technical standards and implementation specifications that have reached a level of specification maturity and adoption by different entities such that some entities are using them to exchange health information either in a test mode or in a limited production mode
3. 'National'—technical standards and implementation specifications that have reached a high level of specification maturity and adoption by different entities

Recommendations, continued

Maturity Model, continued

- Should push for international, not just national, standards.
- Should be considered a classification system to articulate maturity and help in the decision making process, but should not preclude Innovation
  - Should recognize the value of emerging standards.
- The absence of a mature standard should not be a reason not to include a standard in an advisory or guidance document as long as it meets a value added healthcare need.
  - Intended to describe expectations, limitations, issues, etc.
- Adoption can be tiered by market and domain and that should be taken into account versus broadly stating national adoptions

Recommendations, continued

Outcomes and Functions

- The ISA should include a description of outcomes and clinical functions that standards and interoperability specifications must support in order to identify Best Available.
- Should focus on functionality and outcomes rather than use cases.
  - Use cases can be too specific to meet more general functional requirements to meet additional clinical needs.

From S&I Task Force recommendations to the Health Information Technology Standards Committee (HITSC)

- Define critical needs, desired outcomes, and evaluation criteria for projects and ensure they have traceability to National Priorities.
- Develop, identify, or refine use cases.
- Include front-end clinical and other requirements into the use case development.

Guiding Principle #2: Standards which support achieving a set of real world, value-added outcomes and business functions

Recommendations, continued

Recommendations on Document Structure

- Remove section on transport standards
  - Produced confusion regarding transport versus services
  - Provides little additional value to the ISA, as they do not map well to outcomes or required functions on their own
  - Let the section on services call out the transport standards that are incorporated into them
- Do not include an explicit section on security standards
  - Other federal agencies already make recommendations that need not be repeated and should not be confused
- Instead, include a section on security patterns (e.g., disclosing party has adequate information before making an access control decision)
  - Describe reproducible patterns built upon national standards and recommended for use within healthcare by the ISA
  - Patterns should transcend multiple transports, and whenever possible these security patterns should be interoperable

Recommendations, continued

Recommendations on Section I: Vocabulary/Code Set

- See the more detailed document for specific recommendations on standards and interoperability specifications; this is a summary of high-level topics
- Anytime there is an identified gap in a vocabulary, the ONC should convene a process to remediate the gap.
- Consistency, sufficient constraints need to be articulated in all vocabularies
- Should clearly differentiate between standards for allergic reactions and allergens, and include both medications and food allergies
- Medication allergies should be in a separate section from vocabulary standards used for food/environmental allergies
- Specify codes for common food and environmental allergens; let market adopt others as needed
- May need to promote adoption of NPI by broader complement of care team
- Should consider having a separate role identifier similar to the one in the Health Exchange specification about the role attributes. There is a SNOMED-CT value set for a subjects role in the care setting that is in use.
- Start collecting discrete structured data on Sexual Orientation and Gender identity following The Fenway Institutes approach
- Concepts of sex and gender identity need to be broadened, more widely adopted in healthcare; recommend Fenway Institute report as a foundation
- The vocabularies for sexual orientation should be updated to reference more modern language (ie 'transsexual' is outdated and imprecise) ; use Fenway Institute report as a foundation for defining appropriate capture of structured data

Recommendations, continued

Recommendations on Section I: Vocabulary/Code Set (cont.)

- There is not a best available standard for Industry and Occupation. International Classification of Functioning, Disability and Health (ICF) is very complex, pushed away in other SDOs; do not rush towards this standard
- ONC should convene stakeholders to discuss and agree on a value set for Industry and Occupation and be maintained by an SDO
- ONC should convene a taskforce for a smaller value set of language codes for issues with preferred language that may impact care decisions, analytics
- Code on Dental Procedures and Nomenclature (CDT) is a proprietary; ONC should convene an industry initiative to create an open vocabulary
- The purpose declaring Race and Ethnicity needs to be explicit, as the OMB Standard may be suitable for some purposes but inadequate for precision medicine and directing therapy or clinical decisions
- Need to capture other qualifiers of a tobacco user often found in other survey instruments: severity of dependency, quit attempts, lifetime exposure etc.; include e-Cigarettes not currently captured in SNOMED-CT
- Note a specific question regarding immunizations from HITSC later in presentation

Recommendations, continued

Recommendations on Section II: Content/Structure

- HL7 Clinical Document Architecture (CDA®), Release 2.0 is considered an emerging standard, and there should be consideration to updates in standards and the hardship on both the clinicians and the vendors
- Should consider C-CDA Release 2.1 and its attempt to remain compatible with Release 1.1
- ONC should convene stakeholders (SDOs, states, CDC, vendors, etc.) to identify to reconcile variability in public health reporting
- Several standards in this section are emerging standards, evolution is in progress, not mature enough for Best Available
- While FHIR includes both content and services, it is probably best described in Section IV

Recommendations, continued

Recommendations on Section II: Content/Structure (cont.)

- NCPDP Formulary and Benefits v3.0 does not meet goals of getting real-time patient benefit information to the point of care; recommend monitoring Real Time Prescription Benefit Inquiry (RTPBI) standard
- Advise caution in including all message transactions within the NCPDP SCRIPT Standard as workflows, system capabilities not well vetted
- Genomics are emerging standards best pushed by market demands rather than by regulations; concerned about large undertaking, niche use
- ONC should investigate more generalized survey instruments such as the IHE Retrieve Form for Data Capture Profile, Structure Data Capture
- Need clarity round the objectives for exchanging images versus radiology reports to assess best-available standard
- The ISA TF felt that exchanging the diagnostic imaging *report* was critical and should be considered more strongly.
- ONC should convene a stakeholder group to address computable patient consent; there exist standards but without clear implementation guidance
- There remains concern about the use of DS4P; ONC should convene federal agencies and clinicians to define a consistent understanding of allowed exchange

Recommendations, continued

Recommendations on Section III: Transport

- Transport is vital
- However, recommend that this section be eliminated, as it provides little additional value not already addressed by Section IV: Services

Recommendations, continued

Recommendations on Section IV: Services

- Include Data Access Framework (DAF) as an emerging, harmonized approach for clinical querying, along with addressing metadata needs
- Consider separating patient matching from queries for health information; patient matching has broader use than query exchange
- Consider grouping intra- and inter-domain patient matching and intra- and inter-domain query exchange
- Include more complete authorization standards (e.g., IHE XUA, IUA, etc.); ensure authorization standards are compatible across disparate networks
- Include Fast Healthcare Interoperability Resources (FHIR) as emerging
- ONC should convene stakeholders to discuss the requirements for image transport before proceeding with a best-available standard
- Digital Imaging and Communications in Medicine (DICOM) is one standard to consider for images at rest; however there should be consideration for exchange of images across organizations along with exchange of the textual reports for diagnostic images
- Exchanging the diagnostic imaging report is critical and should be considered more strongly; note use of MDM today
  - TF has insufficient experience on whether more recent DICOM standards PS3.20 DICOM Supplement 155, XDS-I might be more appropriate; further engagement with radiology industry recommended
- All listed standards for resource location are emerging
- ONC should convene a stakeholder group to explore use of FHIR for resource location if Argonaut Project does not add it to near-term sprints
- ONC should convene a workgroup to address need for publish/subscribe

Recommendations, continued

Recommendations on Security

- There must be sound policy considerations before any technology solution can be implemented
- Recommend against a section that calls out low-level security standards
  - Likely will fall into the same issue as transport standards; little additional value for well-accepted low-level building blocks
  - Redundant with, and therefore potentially confusing of, other well-done national and federal agency recommendations concerning security standards
  - The ISA should instead point to these entities (e.g. applicable NIST security standards) as the list in maintained and curated in a timely manner
  - There should be an explanation as to why there is not a separate security section in ISA
- Instead, recommend a section on best available security patterns used in healthcare and recommended for implementation
  - Similar to services: profiles for how security standards and implementation guidance is used to accomplish specific outcomes and functions in healthcare
- The highest level goal for all security standards is that they maintain interoperability as a key capability

Questions Posed in ISA

Recommendation

Question 5-18: *Should specific HL7 message types be listed? Or would they be applicable to other purposes as well? If so, which ones and why?*

- ISA should call out a specific message and HL7 version number.
- Also need to reference specific implementation guides whenever available

Summary

Importance and Use of the ISA

- The ISA provides industry guidance on a spectrum of recommended standards and implementation guides
- To become more effective, the ISA must:
  - Identify a maturity model and the maturity of standards listed
  - Discuss national outcomes and common functional requirements
  - Relate best-available standards to clear, real-world outcome goals and functional requirements
  - Recognize implementation guidance that enables interoperability (tighter vs looser constraints)
  - Recognize common vocabularies whenever possible
  - Curate emerging standards as they become ready for implementation
  - Include broader stakeholder functional representation
  - Work with industry to remediate all identified gaps with standards
  - Promote Innovation

Summary, continued

Answers to Questions Posed to the Task Force

- What additional information about the standards and implementation specifications would be helpful to represent in the ISA?
  - Include not only Best Available, but emerging standards that warrant attention and need stakeholder input (refer to Guiding Principle #1)
  - Ensure good separation between standards and implementation guidance, and include implementation guidance whenever possible
- Are there suggestions for additional characteristics for Best Available, or the process in which they are determined? If so, what are they?
  - Refer to maturity model and outcomes and functionality discussion earlier

Summary, continued

Answers to Questions Posed to the Task Force, continued

- What are recommendations to better address Immunizations Code Set/Terminology standards within ISA?
  - HL7 Standard Code Set CVX—Clinical Vaccines Administered is the recommended code set to identify the immunization and promote interoperability in both historical immunization and in administered immunizations
  - NDC codes could be used on local systems at the time of administration for inventory management, packaging, lot numbers, etc., but should not be the code system used for interoperability as the NDC codes are not maintained and curated and can be repurposed over time making NDC less than ideal for interoperability.
- Should security standards be represented in ISA? If so, how should they be represented?

  Yes, but in a limited way:
  - The ISA should reference other organizations that make recommendations on security standards when possible rather than reproduce that work and create ambiguity
  - The ISA should include a section on security patterns prevalent in or specific to healthcare

Summary, continued

Answers to Questions Posed to the Task Force, continued

- How does ONC ensure ISA is relevant for intended stakeholders?
  - Relate standards to real-world, value-added outcomes, clinical processes, and business functions to ensure they address real world requirements
- What are the top priorities for ISA in 2016?
  - Adjust organization as recommended, include implementation guidance
  - Characterize Best Available standards in terms of maturity, testing, adoption, preconditions and dependencies, and ability to meet goals
  - Identify a set of real-world, value-added outcomes and business functions to which standards are subordinate
  - Do not rush to identify standards if a Best Available is not evident, but do not stifle innovation by requiring full maturity in all cases
- What are the top priorities for ISA in future (post 2016) releases?
  - Continuously update maturity and adjust outcomes and functions as necessary
  - Expand to include information on adoption/commitment to emerging standards, vendor roadmaps
  - Broaden to include the full spectrum of healthcare needs
  - Refer to Guiding Principles, ISA Scope and Purpose , and Document Structure (slides 6-8)

Questions and Discussion