Summary from the ISA Taskforce Calls

August 26, 2015

Guiding Principles

1. The ISA should qualify standards based on maturity, implementation testing, adoption, preconditions/dependencies, and ability to meet its 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 (i.e. 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 on 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.

ISA Purpose

- 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.) not an individual group or certain groups perspective while also preserving patient privacy
- 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.
- To promote interoperability orchestration patterns, functionalities, and use cases need to be layered and balanced to satisfy healthcare goals
- ISA should reflect objectives of the Interoperability Roadmap to move us towards a learning health system

ISA Annual Update Process

- Security standards create a challenge due to the standards dynamic nature to update in case of a compromise, generating a need to raise awareness around emergent updates in such situations.
- Stability & Maturity of a standard needs to be intertwined with promoting innovation to meet healthcare goals as it may vary from deployment to deployment but the goal should be to maintain consistency.

ISA Scope

- The ISA scope should include a Use Case layer near the beginning and a column to the right for each of the use cases the standard is intended to satisfy.
- Cross walking between use cases and functionalities and explore the ability to tie functionality to use cases
- The ISA scope should point to all the preconditions, dependencies needed to facilitate interoperability or it should have a disclaimer that not all the constraints have been defined.

Comments from General Discussion

- Classifying of technical standards and implementation guides are defined in 3 classes which increase exponentially in maturity and adoptability as they mature: emerging, pilot, and national standards.
- It's important to get a fair representation from the market to classify or declare a standard and should look to models like the IETF (Internet Engineering Task Force) which could help truly define classification of a technical standard in healthcare as either emerging, pilot, or national based on a more conservative approach of broad scale use versus independent usage of a standard. The classification of the standard needs to be explicitly stated so that ISA leads and guides for meeting the expectations and its goal of the standard.
- The healthcare architecture should look to standards that contain a core set of constrained building blocks which are constructed on top of core composables and orchestration patterns to promote Interoperability while keeping the spectrum of uses cases, functionalities and building blocks in balance.

Definitions for Classification of Technical Standards.

In May 2012, the Department of Health and Human Services published a Request for Information (RFI) entitled 'Nationwide Health Information Network: Conditions for Trusted Exchange'13 that included a section that asked questions about a proposed process for classifying technical standards and implementation guides into three classes:

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

SECTION 1:
Best Available Vocabulary/Code Set/Terminology Standards & Implementation Specifications

Allergies (3 groupings)

- **Allergies in General**
  - The ISA needs to clearly differentiate between standards for allergic reactions versus the allergen (the substance creating the reaction).
  - The attributes for the type of allergen (medication vs food vs environmental) which caused the allergic reaction needs to be discretely captured and linked for improved clinical decisions and to see the different types of allergens creating the reactions.
  - Consistency and constraints in vocabulary implementations needs to be articulated clearly for allergen concept as there are currently complex cascades of vocabularies for medications and no current regulatory vocabularies for food or environmental allergens
  - Vocabulary standards used for medication allergies should be in a separate section in ISA from food/environmental allergies.

- **Substances that Cause Allergic Reactions**
  - Medications
    - Medications can be represented by four different code sets:
      - Medication Drug Class (2.16.840.1.113883.3.88.12.80.18) (NDFRT drug class codes)
      - Clinical Drug Ingredient (2.16.840.1.113762.1.4.1010.7) (RxNORM ingredient codes)
      - Unique Ingredient Identifier - Complete Set (2.16.840.1.113883.3.88.12.80.20) (UNII ingredient codes)
      - Substance Other Than Clinical Drug (2.16.840.1.113762.1.4.1010.9) (SNOMED CT substance codes).
    - RxNorm is the best available vocabulary standard for medication allergies. If an allergy needs to be capture by medication class NDF-RT could be used.

  - Food & Environmental Substances
      - As a starting point, ISA should make available the big 8 contributors of the most critical food allergens to encourage developers to start semantically defining in structured fields while letting the market adopt others as needed. For example, FDA has stated, "1. (A) eight major foods or food groups--milk, eggs, fish, Crustacean shellfish, tree nuts, peanuts, wheat, and soybeans-- account for 90 percent of food allergies." See Food Allergen Labeling and Consumer Protection Act of 2004 (Public Law 108-282, Title II): http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Allergens/ucm106187.htm

- **Allergic Reactions**
  - The ISA should advise on the standards ability to qualify the allergic reactions in regards to severity and criticality.
  - An allergy is a subset of an adverse drug event and adverse drug reaction (sometimes referred to intolerances). An allergy is mediated by an activation of the immune response. An adverse drug reaction is usually predictable and based on a drug's primary pharmacologic effect (e.g. bleeding from an anticoagulant, nausea/vomiting from chemotherapy) or low therapeutic index (e.g. Nausea from digoxin). Allergies and Adverse drug Reactions/Adverse drug events should not be lumped together as they are two distinct phenomena with different causes, definitions, and reactions.

Care Team Members

- The objective of the curating and maintaining a list of all the care team members needs to be defined.
- The codification system would need to be able to delineate care team members by role and others such as groups, institutions, labs, suppliers etc. Should consider having a separate role identifier similar to the one in the Health Exchange specification about the role attributes.
- The concepts of 'person' and 'role' should be maintained as separate attributes. There is a SNOMED-CT value set for a subjects role in the care setting that is in use.
- The NPI does allow but does not require non-billable care members to apply for an NPI number which appears to capture the concept of 'person'. There is currently no policy which makes care members who do not bill to apply for an NPI.
- One potential option discussed for codifying the care team members is through the National Provider Identifier (NPI) which has been adopted by certain healthcare team members but not all and is required by Medicare as a HIPAA Administrative Simplification Standard. However, it is unclear if the NPI will be able to delineate care team members by 'person' and 'role' to meet the needed objectives.

Ethnicity

- The use case for the need for Race and Ethnicity needs to be defined as the OMB Standard may be suitable for statistical or epidemiologic purposes but may not be adequate in the pursuit of precision medicine and enhancing therapy or clinical decisions
- CDC Race & Ethnicity Code Set is already used in C-CDA as core code system both for Race and Ethnicity and this standard allows for multiple races and ethnicity's to be chosen for the same patient.
- Suggest reviewing all existing code subsets for Race and Ethnicity in use across all MU standards and aligning these. Suggest that duplicative or incomplete value sets be discontinued from use.

Encounter Diagnosis

- Both administrative and clinical functions are both part of the healthcare delivery process and should both be considered for interoperability purposes.

Family Health History

- We need more clarity around the intended purposes of codifying Family Health History as most social and clinical concepts could be capture by SNOMED-CT but other details around family genomic history would not.

Functioning & Disability

- International Classification of Functioning, Disability and Health (ICF) is very complex and been voted on and pushed away in other Standards Development Organizations and would not rush towards this standard.
- The ICF is a conceptual tool which may be better utilized by developers to build templates to capture already coded clinical concept needed for appropriate assessment of function and disability.

Gender Identity

- Should start collecting discrete structured data on Sexual Orientation and Gender identity following The Fenway Institutes approach.

Immunizations - Historical

- [R] *HL7 Standard Code Set CVX—Clinical Vaccines Administered* is the best available code set to identify the immunization and promote interoperability in both historical immunization and in administered immunizations.
- There needs to be consistency in the code set used between Historical immunization and administered immunization and the CVX code should always be listed and the MVX listed when available.

- NDC codes are not maintained and curated by a single entity and can be repurposed over time making NDC less than ideal for interoperability.
- *MVX (Manufacturing Vaccine Formulation*) is the recommended code set to promote interoperability in both historical immunization and in administered immunization when the name of the manufacturer is needed to be exchanged.

Immunizations Administered

- *[R] 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 of immunization history or administration as the NDC codes are not maintained and curated and can be repurposed over time.

Industry & Occupation

- There is not a best available standard for Industry and Occupation and we recommend that the ONC convene a taskforce to discuss and agree on a value set which is maintained by an SDO.
- It is important to have a way to make this information interoperable, but did not feel that it should be a required element of entry at the point of care.

Lab Tests

- *[R] LOINC* is the best available standard for identifying laboratory tests and observations.
- Laboratory test and observation work in conjunction with values or results which can be answered numerically or categorically. If the value/result/answer to a laboratory test and observation is categorical that answer should be represented with the *SNOMED-CT* terminology.
- Organizations not using LOINC codes should be maintained and publish a mapping of their codes to the LOINC equivalent.

Medications

- *[R] RxNorm* is the best available vocabulary standard for medications; however there should be greater specificity on implementation and use of the different term types.
- Re public comment: medical cannabis, RxNorm already contains 3 codes for cannabis as Ingredients: “CANNABIS SATIVA SEED OIL”, “Cannabis sativa seed extract” and “Cannabis sativa subsp. flowering top extract”. Suggest reaching out to NLM to add specific formulations of cannabis to RxNorm.

Numerical References & Values

- The Unified Code of Units of Measure (UCUM) is the best available vocabulary standard for units of measure and the unit string version to use is the case sensitive version. .

Patient 'Problems' (i.e. Conditions)

- *[R] SNOMED-CT* is the best available vocabulary to represent patient 'problems' (i.e. condition.
- Consider creating subsets or value sets by hierarchy of clinical findings of needed SNOMED-CT codes to represent patient 'problems.

Preferred Language

- Recommend that a smaller value set of language codes be developed in healthcare to handle issues with language that may impact care decisions or analytics.
- ONC should convene a taskforce to define the needed values for a preferred language value set.

Procedures (dental)

- Code set recommended should be open technologies and not proprietary. [R] *Code on Dental Procedures and Nomenclature (CDT)* is a proprietary vocabulary for dental procedures.
- The ISA should point out that CDT is proprietary.
- ONC should convene an industry initiative to create an open vocabulary for dental procedures.

Procedures (medical)

- [R] *SNOMED-CT, the combination of CPT-4/HCPCS, and* [R] *ICD-10-PCS* are best available vocabularies for medical procedures that are not diagnostic tests.
- Code set recommended should be open technologies and not proprietary.

Race

- The use case for the need for Race and Ethnicity needs to be defined as the OMB Standard may be suitable for statistical or epidemiologic purposes but may not be adequate in the pursuit of precision medicine and enhancing therapy or clinical decisions
- The standard should allow for multiple races and ethnicity's to be chosen.
- Race and Ethnicity should be placed next to each other in ISA.

Radiology

- *LOINC* is the best available vocabulary for radiology reports. Radlex and LOINC are in the process of creating a common data model to link both together to promote standardized indexing of radiology terms.

Sex

- *HL7 Version 3 Value Set for Administrative Gender* is a standard for administrative gender but the concepts of sex and gender identity need to be broaden and more widely adopted in healthcare. Recommend using the Fenway Institute report as a foundation.
- Sex and Gender Identity should be grouped together in ISA. The Fenway Institutes approach addresses both sex/gender assigned at birth along with how you identify your gender.
- Administrative gender should be separate and is used more for claims, patient matching, minimizing healthcare fraud.

Sexual Orientation

- The Fenway Institute report evaluated the best way to ask about sexual orientation and this should be considered a foundation for defining structured data in this space.
- The vocabularies for sexual orientation should be updated to reference more modern language (i.e. 'transsexual' is outdated and imprecise)

Smoking Status

- [R] *SNOMED-CT* is the best available standard for Smoking Status; however there is a need to be able to capture other qualifiers of a tobacco user often found in survey instruments which include concepts such as to determine severity of dependency, quit attempts, lifetime exposure etc.
- Chosen vocabulary needs to correlate with emerging methods of nicotine consumption evolve. e-Cigarettes or 'vaping' in not currently captured as a SNOMED-CT term and is a rapidly growing method.
- There needs to be more clarity around processing rules for conflicting information collected at different care settings (i.e. patient is logged as non-smoker in organization A, but as smoker in organization B)

Unique Device Identification

- [R] *Unique device identifier as defined by the Food and Drug Administration at 21 CFR 830.3* is best available vocabulary.
- Suggest capturing UDI information in distinct fields across standards used for MU (and HIE). Currently, UDI is communicated as a string in one field, meaning that every sender and receiver needs to have and maintain algorithm to "de-crypt" string meaning into distinct informational components.

Vital Signs

- LOINC is the best available vocabulary for Vital Signs and there are ongoing efforts to sharing data in LOINC with IEEE codes to obtain vital signs from medical devices and this should be monitored for goal attainment.

SECTION II
Best Available Content/Structure Standards and Implementation Specifications

Admission, Discharge, & Transfer

- HL7 v2.x ADT message standard is the best available.
- HL7 v2 is widely used in the industry and we should promote moving towards advanced versions such v2.5.1.

Antimicrobial Use & Resistance information to Public Health

- *HL7 Consolidated Clinical Document Architecture (CCDA®), Release 2.0, Normative Edition; HL7 Implementation Guide for CCDA® Release 2 – Level 3: Healthcare Associated Infection Reports, Release 1, U.S. Realm* is the best available to capture Antimicrobial Use and Resistance.
- Direct messaging as a transport standard is not mature enough for this use to be considered best available.
- *The ISA TF feels that CCDA R2.1 is the version to recommend moving forward since it is backwards-compatible with CCDA R1.1 (which was widely implemented by 2014 Edition Certified EHR Technology)*

Care Plan

- *HL7 Clinical Document Architecture (CDA®), Release 2.0, Normative Edition; HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes (US Realm) Draft Standard for Trial Use Release 2* is considered an emerging standard and there is a concern for how the clinician will absorb the added content.
- There should be consideration to any updates in standards and the hardship it could create on both the clinician and the vendors.
- *The ISA TF feels that CCDA R2.1 is the version to recommend moving forward since it is backwards-compatible with CCDA R1.1 (which was widely implemented by 2014 Edition Certified EHR Technology)*

Cancer Registry Reporting

- *HL7 Clinical Document Architecture (CDA®), Release 2.0, Normative Edition; HL7 Implementation Guide for CDA® Release 2: Reporting to Public Health Cancer Registries from Ambulatory Healthcare Providers, Release 1 (US Realm), Draft Standard for Trial Us*e is an emerging standard.
- *The ISA TF feels that CCDA R2.1 is the version to recommend moving forward since it is backwards-compatible with CCDA R1.1 (which was widely implemented by 2014 Edition Certified EHR Technology)*

Case Reporting to Public Health

- *IHE Quality, Research, and Public Health Technical Framework Supplement, Structured Data Capture, Trial Implementation, HL7 Consolidated CDA® Release 2.0* is an emerging standard which is very complex and has not been testing in real settings.
- *The ISA TF feels that CCDA R2.1 is the version to recommend moving forward since it is backwards-compatible with CCDA R1.1 (which was widely implemented by 2014 Edition Certified EHR Technology)*

Clinical Decision Support Knowledge Artifacts

- *HL7 Implementation Guide: Clinical Decision Support Knowledge Artifact Implementation Guide, Release 1.2, Draft Standard for Trial Use* is an emerging standard and evolution is in progress and not matures.
- *More research is needed around standards for CDS that are in development or emerging to could build an interoperable CDS infrastructure. ISA should point to Health eDecision as an emerging initiative that is working on standards for CDS.*

Clinical Decision Support Services

- *HL7 Version 3 Standard: Decision Support Service, Release 2; HL7 Implementation Guide: Decision Support Service, Release 1.1, US Realm, Draft Standard for Trial Use* is an emerging standard.

Clinical Decision Support - Reference Information

- *[R] HL7 Version 3 Standard: Context Aware Knowledge Retrieval Application. ("Infobutton"), Knowledge Request, Release 2.; HL7 Implementation Guide: Service-Oriented Architecture Implementations of the Context-aware Knowledge Retrieval (Infobutton) Domain, Release 1.; HL7 Version 3 Implementation Guide: Context-Aware Knowledge Retrieval (Infobutton), Release 4* is a best available standard for reference information in CDS.

Data Element Based Query for Clinical Health Information

- *Fast Healthcare Interoperability Resources (FHIR)* is an emerging standard which has promise to meet future use cases but has yet to be proven in real practice. HL7 *Argonaut Project is also doing work in this space.*
- Data Element Based Query for Clinical Health Information is an exciting concept which has strong support.
- The Standards Advisory should look to define the profiles needed to meet Data Element Based Query for Clinical Health Information.
- The Data Access Framework (DAF) a joint effort across multiple stakeholders is a catalogue profile which has a harmonized approach with many standards to lay out efficient approaches for clinical querying along with addressing metadata needs.
- The ISA should point to DAF and an emerging profile to address Data Element Based Query for Clinical Health Information which addresses many of the standards needed rather than pointing to a single less mature standard.
- The ISA TF thought this should be in Section III: Best Available Transport Standards & Implementation Specifications.

Drug Formulary Checking

- *[R] NCPDP Formulary and Benefits v3.0* is a standard that exists but does not meet the healthcare needs and goals of getting real-time patient prescription benefit information to the point of care with consistent prescription benefit information that is received in other care settings such as the pharmacies.
- NCPDP is in development of a *Real Time Prescription Benefit Inquiry (RTPBI)* standard and we recommend monitoring the progress and encouraging participation in the development of this standard to better meet the needs of patient level prescription benefit information.

Electronic Prescribing

- *[R] NCPDP SCRIPT Standard, Implementation Guide, Version 10.6* is the best available standard for creating and transmitting a new prescription in the outpatient setting.
- We would advise caution in including all message transaction within the NCPDP SCRIPT Standard as workflows and system capabilities have not been vetted well in real practice.
- There are two message transactions in NCPDP SCRIPT v10.5 that we are in agreement with considering: Cancel Prescription (CANRX, CANRES) and Refill Prescription (REFREQ, REFRES), which could better facilitate prescriber-pharmacist communications.

Electronic Transmission of lab results to Public Health

- *[R] HL7 2.5.1; HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Draft Standard for Trial Use, Release 2 (US Realm), DSTU Release 1.1* is an emerging standard.
- Electronic Transmission of Lab Results to Public Health varies from state to state and the goal should be unified between all states.

- ONC should convene stakeholders (SDOs, states, CDC, vendors, etc.) to identify the variations for reconciliation to come up with a single approach to meet all viable state requirements for both transport and content.

Family Health History (Clinical Genomics)

- *[R] HL7 Version 3 Standard: Clinical Genomics; Pedigree; HL7 Version 3 Implementation Guide: Family History/Pedigree Interoperability, Release 1* is an emerging standard that we feel is best pushed by market demands than by regulations.
- Creating a Clinical Genomic Family Health History is a big undertaking for a very specialized need.
- There is no available vocabulary to capture family genomic health history.
- There is concern about the niche use of this standard, system readiness, and workflow management.
- Issues can arise with transport of this data and the binding of optionalities need to be defined.

Health Care Survey Information to Public Health

- *HL7 Clinical Document Architecture (CDA®), Release 2.0, Normative Edition; HL7 Implementation Guide for CDA® Release 2: National Ambulatory Medical Care Survey (NAMCS), Release 1, US Realm, Volume 1- Introductory Material, Draft Standard for Trial Use* is an emerging standard that was developed for one specific, extremely defined use case used in many healthcare organizations.
- ISA should look at more generalized survey instruments such as the IHE Retrieve Form for Data Capture Profile, Structure Data Capture, and potentially FHIR to enable users to collect a broader variety of data.
- *The ISA TF feels that CCDA R2.1 is the version to recommend moving forward since it is backwards-compatible with CCDA R1.1 (which was widely implemented by 2014 Edition Certified EHR Technology)*

Images

- *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 along with exchange of the textual reports for diagnostic images
- The IHE Cross Enterprise Document Sharing for Images (XDS-I) Integration Profile which enable sharing images, diagnostic reports and related information across a group of care sites and has been implemented by larger vendors.
- The ISA TF felt that exchanging the diagnostic imaging *report* was critical and should be considered more strongly.
- Emerging efforts for structured reporting using RSNA RadReport reporting templates, Radlex terminology, and the IHE MRRT profile, and PS3.20 Digital Imaging and Communications in Medicine (DICOM) Standard – Part 20: Imaging Reports using HL7 Clinical Document Architecture. Supplement 155 was first included in DICOM edition 2015b (April 2015) should be monitored for future consideration.
- HL7 MDM v2 is also widely used for sharing diagnostic reporting for radiology but should be constrained to promote interoperability.
- Clarity is needed around the objectives for images to assess the best available standard.

Immunization Registry Reporting

- There are variations state to state in most public health reporting, including immunization registry reporting, and interoperability would best be achieved by uniformity.
- ONC should convene the vested stakeholders to define as a community what the target goals/use cases that applies to all methods of public health to reduce the variability from state to state

Lab Results

- 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 should be listed as an emerging standard and observed and shepherd by the ONC

Lab Orders/Directory of Services

- Lab Orders and Laboratory Directory of Services ~~should be separated as they~~ have different objectives and functions in the overall architecture and their use should be encouraged to promote interoperability.
- eDOS should be considered an emerging master file framework standard that provides clinicians information on orderable Tests for a laboratory, the components, specimen information and description of what is provided including information needed from the patient that has an impact on the results of the test.

Patient Education Materials

- The standard for Patient Education Materials needs to have the ability to allow organization to include their own patient educational materials in addition to the standard patient education materials available through the EHR library which [R] *HL7 Version 3 Standard: Context Aware Knowledge Retrieval Application. ("Infobutton"), Knowledge Request, Release 2; HL7 Implementation Guide: Service-Oriented Architecture Implementations of the Context-aware Knowledge Retrieval (Infobutton) Domain, Release 1.; HL7 Version 3 Implementation Guide: Context-Aware Knowledge Retrieval (Infobutton), Release 4 seems* to provide.

Patient Consent

- The IHE has two profiles which are currently being used for patient consent, Basic Patient Privacy Consent (BPPC) and Cross Enterprise User Authorization (XUA) which are in broad use internationally and are in final text status.
- There is a national gap for computable patient consent; however there is a mature standard XACML, a rules based approach standard, that could be used but implementation guidance for this standard is low and a vocabulary for this standard is not defined leaving it lacking for full interoperability.
- ONC should convene a stakeholders group to define a vocabulary for a computable patient consent.

Quality Reporting (aggregate)

- The ISA should look how standards could cover multiple uses (QM vs MDS) across multiple settings (ambulatory settings vs LTC) and leverage data for one purpose for other purposes.
- *HL7 Clinical Document Architecture (CDA®), Release 2.0, Normative Edition; [R] HL7 Implementation Guide for CDA® Release 2: Quality Reporting Document Architecture - Category III (QRDA III), DSTU Release 1* should be documented as an emerging standard and only covers quality measure reporting but not for other healthcare purposes like MDS in LTC.
- *The ISA TF feels that CCDA R2.1 is the version to recommend moving forward since it is backwards-compatible with CCDA R1.1 (which was widely implemented by 2014 Edition Certified EHR Technology)*

Quality Reporting (patient level)

- *HL7 Clinical Document Architecture (CDA®), Release 2.0, Normative Edition; [R] HL7 Implementation Guide for CDA® R2: Quality Reporting Document Architecture - Category I (QRDA) DSTU Release 2 (US Realm)* should be documented as an emerging standard .
- *The ISA TF feels that CCDA R2.1 is the version to recommend moving forward since it is backwards-compatible with CCDA R1.1 (which was widely implemented by 2014 Edition Certified EHR Technology)*

Segmentation of Sensitive Information

- There is concern about the use of the full DS4P for segmentation of sensitive information due to a lack of consistent understanding of definitions in what is allowable or not and what is intended in the regulatory policies by federal agencies.
- IHE IT Infrastructure Technical Framework Volume 4 – National Extensions – Section 3.1 Data Segmentation for Privacy (DS4P) allows for markings and obligations at the document level.
- ONC should convene federal agencies such as SAMHSA and include clinicians to define a consistent understanding of what is allowable or not and what is intended in electronic data exchange of sensitive information

Summary Care Record

- *HL7 Clinical Document Architecture (CDA®), Release 2.0, Normative Edition; [R] Consolidated CCDA® Release 1.1 (HL7 Implementation Guide for CDA® Release 2: IHE Health Story Consolidation, Release 1.1 - US Realm); Consolidated CDA® Release 2.1* is to be released in a few weeks and is backwards compatible with other versions of C-CDA but limitations should be listed such as an emerging standard which combines data element and value sets along with their optionality and specificity with R1.1 and R2.0
- *The ISA TF feels that CCDA R2.1 is the version to recommend moving forward since it is backwards-compatible with CCDA R1.1 (which was widely implemented by 2014 Edition Certified EHR Technology)*

Syndromic Surveillance

- The standards used in Syndromic Surveillance are imperfect and the ONC should convene to develop the current standards: [R] HL7 2.5.1; PHIN Messaging Guide for Syndromic Surveillance: Emergency Department, Urgent, Ambulatory Care, and Inpatient Settings, Release 2.0 (need IHE profile from Eric)
- Due to some capability issues like many public health entities not being able to receive data via PHIN, it is hard to determine if it is best available or not. This is not a standards issue, but a capabilities issue; however it limits the ability to know if the standard can fulfill its mission.
- HL7 2.5.1 standard and PHIN guide is capable of meeting the needs of the ambulatory context as well. Encourage ONC set the direction for the industry by unifying the inpatient/emergency/urgent and ambulatory domains until the PHIN guide is a single syndromic standard.

SECTION III:
Best Available Transport Standards & Implementation Specifications

- Recommend that this section be eliminated, as it provides little additional value not already addressed by Section IV: Services

Simple way for participants to 'push' health information directly to known, trusted recipients

- Consider organizing this portion of standards from most constrained to least constrained, so that implementers are aware of relationships to other standards.
- There are many current implementation patterns for 'pushing' data and standardizing to one pattern would promote faster interoperability. Patterns should transcend across multiple transports and whenever possible these security patterns should be interoperable.
- Although many of the transport standards are mature, they do not meet the all the use cases set forth in healthcare limiting the ability to label as best available.
- Need to identify the transport standards that can handle metadata to handle needed business and clinical requirements that need certain technical requirements.
- Recommend standard: *Simple Mail Transfer Protocol (SMTP) RFC 5321 and For security, Secure/Multipurpose Internet Mail Extensions (S/MIME) Version 3.2 Message Specification, RFC 5751.*
- Emerging Standard: FHIR

Data Sharing through Service Oriented Architecture (SOA) - that enables two system to interoperate together

- Since ISA is done on a annual bases and the TSL could have compromises, it is best to list the floor for the standard while pointing to the federal body which updates the standard regularly for the most current version.
- Certain transport standards are good for certain things. Recommend putting an entire frame around use cases to organize this section of ISA to show which transport to use when sending this data from point to point along with implementation guide. For example: if you need to batch share large documents, then FTP may be the best option but not really useful in other healthcare exchanges.
- Recommend Standard and implementation guides: *Hypertext Transfer Protocol (HTTP) 1.1, RFC 723X* (to support RESTful transport approaches); S*imple Object Access Protocol (SOAP) 1.2 ; For security, Transport Layer Security (TLS) Protocol Version 1.2, RFC 5246* along with additional IHE standards: Audit Trail and Node Authentication (ATNA); Consistent Time (CT);
- *Trial or Pilot:* Cross-Community Access (XCA); Cross-Community Patient Discovery (XCPD); Cross-Enterprise Document Sharing (XDS.b); Cross-Enterprise Sharing of Scanned Documents (SDS-SD); Cross-Enterprise User Assertion (XUA); Although there are many transactions that occur within an exchange (intra-organizational), there is still much coordination in an inter-organizational implementation.
- Trial or Pilot: IHE IT Infrastructure Technical Framework Supplement - Internet User Authentication (IUA); eHealth Exchange. Need to make trust work compatible, but standards are not well tested in certain domains.
- *Emerging: DAF is pointing to IUA and Argonaut Project is looking at an OAuth2 profile. Although a lot of great work is going on these should still be considered emerging.* Enterprise User Authentication (EUA)

SECTION IV:
Best Available Standards and Implementation Specifications for Services

An Unsolicited 'push' of clinical health information to a known destination

- Some standards can serve as both a standard and an implementation guide and there needs to be clarity on when to use both.
- Recommended standards and implementation guides: [R] Applicability Statement for Secure Health Transport ("Direct"); [R] SOAP-Based Secure Transport Requirements Traceability Matrix (RTM) version 1.0 specification; IHE-XDR (Cross-Enterprise Document Reliable Interchange); NwHIN Specification: Authorization Framework; NwHIN Specification: Messaging Platform; [R] XDR and XDM for Direct ; Messaging Specification ; [R] IG for Direct Edge Protocols ; IG for Delivery Notification in Direct
- Should look to the ONC Direct Coordinator for advice.

Query for Documents within a Specific Health Information Exchange Domain

- The ISA TF recommends separating this into two sections: Patient Matching & Query for Documents. ~~Should retitle this segments as 'Query for Patients and associated Documents' to~~ This would appropriately convey the steps taken in health information exchange to identifying the patient is a critical first step and also allow for patient matching beyond when querying for documents.
- Standards should be listed as to whether they are used for patient matching or for document exchange
- Standard needs to be able to carry attributes in the message to do resolution logging and access control decisions around patient privacy. Recommend adding the IHE XUA (Cross Enterprise User Authorization) to accomplish this.
- Standard needs to be able to convey security attributes for an authorization profile when at rest. Recommend adding IHE IUA (Internet User Access) to achieve this function.
- Recommended Standards for Patient Matching: IHE-PDQ (Patient Demographic Query)); IHE-PIX (Patient Identity Cross-Reference)
- Recommended Standards for Query for Documents: IHE-XDS (Cross-enterprise document sharing; IHE MHD (Mobile Assess to Health Document) as an emerging standard to watch.

Query for documents outside a specific health Information Exchange Domain

- Recommended Standards: IHE-XCPD (Cross-Community Patient Discovery) along with IHE-PIX (Patient Identity Cross-Reference) ; NwHIN Specification: Patient Discovery; NwHIN Specification: The ONC should recognize the IHE XCPD, and XCA, and PIX standards, as further constrained by the eHealth Exchange Patient Discovery, Query for Documents, and Retrieve Documents specifications as best available standards.
- Emerging: FHIR DSTU2 with some record locator and discovery patterns in CommonWell and IHE. IHE MHD as emerging.

Data Element Based Query for Clinical Health Information

- To promote interoperability we need to constrain early and limit optionalities to avoid implementation conflicts.
- Recommended Standard: Fast Healthcare Interoperability Resources (FHIR) as an emerging standard.

Image Exchange

- To promote safe exchange of images you have to consider all the requirements in the layers and standards needed to have secure transport and discovery.
- Recommend that the ONC convene a taskforce to discuss the requirements needed in a secure transport of an image especially across organizational boundaries.
- Recommended standards: 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.

- The IHE Cross Enterprise Document Sharing for Images (XDS-I) Integration Profile which enable sharing images, diagnostic reports and related information across a group of care sites and has been implemented by larger vendors.
- The ISA TF felt that exchanging the diagnostic imaging *report* was critical and should be considered more strongly.
- Emerging efforts for structured reporting using RSNA RadReport reporting templates, Radlex terminology, and the IHE MRRT profile, and PS3.20 Digital Imaging and Communications in Medicine (DICOM) Standard
    - Part 20: Imaging Reports using HL7 Clinical Document Architecture. Supplement 155 was first included in DICOM edition 2015b (April 2015) should be monitored for future consideration.
- HL7 MDM v2 is also widely used for sharing diagnostic reporting for radiology but should be constrained to promote interoperability.

Resource Location

- Need to define resource utilization/location in the US as it would be defined differently in third world countries.
- Care Services Directory (CSD) when developed was meant to be somewhat broad to include thing like the availability of power at certain times in third world countries.
- We recommend the following profiles for three types of defined resources' however we consider this whole category as emerging:
    - Finding people within an organization -- IHE PWP (Personal White Pages)
    - Finding people across organizations -- IHE HPD (Health Provider Directory)
    - Finding non-human resources across organizational boundaries -- IHE CSD
- ONC should help to see that work in this area is done if Argonaut Project does not take it on.

Provider Directory

- Would request the ONC to convene a taskforce to develop directory services or a data model of people, organizations, and relationships, using either SOAP or FHIR while maintain compatibility with existing IHE profiles to have one underlying standard.
- Recommended standard: IHE IT Infrastructure Technical Framework Supplement, Healthcare Provider Directory (HPD), Trial Implementation is an emerging standard with current low level adoption.

Publish & Subscribe

- There is a real need for some type of publish and subscribe message and exchange pattern to be implemented; however, to maintain interoperability optionality needs to be constrained.
- Recommend pointing to the Data Access Framework which has defined published and subscribed capabilities.
- Would recommend both the *NwHIN Specification: Health Information Event Messaging Production Specification* which assumes a private business arrangement for subscription.
- Emerging: *IHE DSUB (Document Metadata Subscription)* profile allows the subscription to be managed programmatically. FHIR in a RESTful transport.
- Recommend the ONC facilitate work in this domain to encourage pilot testing for standards maturity in Publish & Subscribe.

SECTION V:
Questions Posed in the ISA Not Previously Discussed

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?

- The ISA TF felt that it was more important to point to specific constrained, implementations that reduce optionality's than to list certain versions. It is not that certain versions do not work, but that broad implementation with broad optionality's lead to less interoperability. (refer to ISA Purpose #2)
- Codes/Vocabularies are a key component to all message typed to enable interoperability.

Security Standards

- For security we feel that you cannot use the maturity model in silo as many security standards are mature but may not meet the healthcare purposes needed.
- Security standards are very important but there needs to be sound policy considerations that are locked down before technology solutions can work, because no one will trust a machine without sound policy.
- There has been a lot of work and recommendations made through the years in various workgroups under the HITSC on security. All of these recommendations need to be collated, reviewed, and taken into consideration.
- Vocabularies for security standards need to be constrained down to purpose of use.
- Security focus should go beyond regional or national interoperability, but should also take in international security interoperability as well.
- The ISA TF did not believe it would be wise to have a separate security section as there are other federal entities in which security is their core strength. The ISA should instead point to these entities (e.g. applicable NIST security standards) as the list is maintained and curated in a timely manner. There should be an explanation as to why there is not a separate security section in ISA.
- The highest level goal for all security standards is that they maintain interoperability as a key capability.
- There are current examples such as ePCS (electronic prescribing of controlled substances) which have very specific guidance on identity assurance frameworks that make nice examples of national implementation.

Maturity & Adoptability

- The maturity of a standards should also be based on the Standards Development Organizations own objective metrics that define the maturity of a technology within its life cycle such as draft, trial implementation, or final text status.