**Summary from the ISA TaskGroup Calls**

**Guiding Principles**

* + The ISA should qualify standards based on maturity, implementation testing, adoption, preconditions/dependencies, and ability to meet its goals.
	+ ISA should define what the standard is best for – innovation, tried and true use cases, functionalities.
	+ To promote innovation, emerging standards should be identified as a potential replacement for current standards.
	+ Standards in regulation should be identified as such.
	+ 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.
	+ 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 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
	+ \*\*\*Update from Lisa on the security standards --to be completed \*\*\*
	+ 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.

Maybe in intro slide:

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**

* 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.
* The ISA should advise on the standards ability to qualify the allergic reactions in regards to severity and criticality.
* 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.
* 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>

**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.
	+ 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 role and 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 directing therapy or clinical decisions
	+ The standard should allow for multiple races and ethnicity's to be chosen.

**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.

To be completed::: slides 17 – 31 for section 1 – will send out tonight.

**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 other 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.

**Unique Device Identification**

* *[R] Unique device identifier as defined by the Food and Drug Administration at 21 CFR 830.3* is best available vocabulary.

**Vital Signs**

* LOINC is the best available vocabulary for Vital Signs and there are ongoing efforts to sharing data in LOINC with IEEE codes 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 Clinical Document Architecture (CDA®), Release 2.0, Normative Edition; HL7 Implementation Guide for CDA® 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.

**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.
* Kim - summary of care r1.1 to 2.1,  is this different imp guide for clinical notes vs summary of care?

**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.

**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.

**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.

**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.
* Take offline -- url based -- rss… looked on line 3 ways -- context aware, url, SOA

**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.
* 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.

**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.

**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.

**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.
* The IHE XDS-I profile shares images, diagnostic reports and related information across a group of care sites and has been implemented by larger vendors and the "DIR" (Diagnostic Imaging Report) which is a standardized document type within Consolidated CDA also allows the exchange of images.
* 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
* 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).
* 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.

**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 .

**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 CDA® 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

**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)

**SECTION III:**

**Best Available Transport Standards & Implementation Specifications**

**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.
* 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..  ???*

**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 Authenticaiton (ATNA);  Consistent Time (CT);  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; Cross-Enterprise User Assertion - Attribute Extensio (XUA++); Enterprise User Authentication (EUA); IHE IT  Infrastructure Technical Framework Supplement - Internet User Authentication (IUA); eHealth Exchange

**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”)](http://www.healthit.gov/policy-researchers-implementers/direct-project); [[R] SOAP-Based Secure Transport Requirements Traceability Matrix (RTM) version 1.0 specification](http://modularspecs.siframework.org/SOAP%2Bbased%2BSecure%2BTransport%2BArtifacts);  [IHE-XDR (Cross-Enterprise Document Reliable Interchange)](http://www.ihe.net/uploadedFiles/Documents/ITI/IHE_ITI_TF_Vol1.pdf);  [NwHIN Specification: Authorization Framework](http://healthewayinc.org/images/Content/Documents/specs/2011/nhin-authorization-framework-production-specification-v3.0.pdf);  [NwHIN Specification: Messaging Platform](http://healthewayinc.org/images/Content/Documents/specs/2011/nhin-messaging-platform-production-specification-v3.0.pdf); [R] XDR and XDM for Direct ; Messaging Specification ; [R] IG for Direct Edge Protocols ; IG for Delivery Notification in Direct  ?? Others

**Query for Documents within a Specific Health Information Exchange Domain**

* Should retitle this segments as 'Query for Patients and associated Documents'  to appropriately convey the steps taken in health information exchange as identifying the patient is a critical first step.
* 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: IHE-XDS (Cross-enterprise document sharing); IHE-PIX (Patient Identity Cross-Reference); IHE-PDQ (Patient Demographic Query) along with 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-XCA (Cross-Community Access); IHE-XCPD (Cross-Community Patient Discovery); NwHIN Specification: Patient Discovery; NwHIN Specification: Query for Documents; NwHIN Specification: Retrieve Documents along with HL7 v3 as a service standard.

**Data Element Based Query for Clinical  Health Information**

* To promote interoperability we need to constrain early and limit optionality's 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.
* The IHE XDS-I profile shares images, diagnostic reports and related information across a group of care sites and has been implemented by larger vendors and the "DIR" (Diagnostic Imaging Report) which is a standardized document type within Consolidated CDA also allows the exchange of images.

**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:
	+ 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

**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, while the *IHE DSUB (Document Metadata Subscription)*  profile allows the subscription to be managed programmatically.

**SECTION V:**

**Questions Posed in the ISA Not Previously Discussed**

Coming soon…..