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October 24, 2016

B. Vindell Washington, MD, MHCM, FACEP
National Coordinator for Health IT
U.S. Department of Health and Human Services
200 Independence Ave, SW
Washington, DC 20201

Dear Dr. Washington:

On behalf of Integrating the Healthcare Enterprise USA (IHE USA), we are pleased to provide written comments to the Office of the National Coordinator for Health Information Technology (ONC) in response to the Draft 2017 Interoperability Standards Advisory. IHE USA appreciates the opportunity to leverage our members' expertise in commenting on the Standards Advisory, and we look forward to continuing our dialogue with ONC on identifying, assessing, and determining the best available interoperability standards and implementation specifications. We feel that this effort will provide the necessary foundation for more rapidly advancing interoperability in our country.

IHE USA (www.iheusa.org) is a 501.c.3 not for profit organization founded in 2010. Its vision is to improve the quality, value, and safety of healthcare by enabling rapid, scalable, and secure access to health information at the point of care. IHE USA operates as a national deployment committee of IHE International in order to advance its mission to improve U.S. healthcare by promoting the adoption and use of IHE and other world-class standards, tools, and services for interoperability. IHE USA engages all levels of public and private sector participants to test, implement, and use standards-based solutions for all health information needs.

IHE USA is committed to supporting and educating all stakeholders to achieve interoperability leading to information exchange that improves the quality and cost effectiveness of healthcare delivery. We will continue to leverage our resources and volunteers to ensure they have access to the tools necessary to share health information in a secure and appropriate manner.

Historically, IHE USA has taken a lead role to support the development and deployment of consensus-based interoperability specifications. IHE USA and our parent organization, IHE International (www.ihe.net), began developing IHE Profiles, or technical specifications leveraging our committee-level interoperability expertise in 1997.

IHE USA has further ensured the proper implementation of IHE Profiles and now hosts the health IT industry's largest, most rigorous interoperability testing events to achieve health information exchange and support widespread adoption and implementation of standards-based interoperable health IT systems.

Our primary observations on the Draft 2017 Interoperability Standards Advisory(ISA), focus on the following issues:

1. **IHE USA applauds ONC's focus on standards for "electronic health information created in the context of treatment." However, given that the ISA contains several interoperability needs related to clinical research in Sections I and II, IHE USA recommends that the ISA Scope (within the Introductory part of the ISA document) be expanded to include interoperability standards and specifications related to *secondary use* of clinical data for clinical research purposes.**

2. **IHE USA is concerned that removal of the "Best Available" characteristic from the ISA standards and specifications will minimize the importance of the ISA as guidance to the industry, and does little to encourage implementers to adopt and align on the standards identified.**
    - Therefore, we recommend ONC consider stronger language to direct users to implement the standards identified in the ISA while also encouraging consideration of the emerging standards that will enable innovation.

3. **IHE USA would like to highlight the importance of Data Provenance as an Interoperability Need. We would like to suggest to ONC that more research be conducted on appropriate standards to capture and preserve details of the data source and the systems that the data travelled though.**
    - IHE USA recommends that ONC conduct field analysis to better understand how provenance data is captured in existing information systems. We think that existing and emerging standards should focus on enabling capture and exchange of provenance information at the data element level to ensure traceability of data to a sufficiently granular level.
    - Data provenance is an important topic that is continuing to increase in importance as new trends emerge. Statewide and regional Health Information Exchanges are stimulating increased exchange of health information; the amount of data is exponentially increasing; patient-generated data is playing an increasing role in patient care; the number of devices (FDA regulated and non-FDA regulated) that generate new data is increasing on a daily basis; and health information travels through parallel and/or serially connected information systems (and may be modified by the systems or humans on the way). All of these emerging and growing healthcare trends will depend on understanding source information in order to be adopted and effectively used by the healthcare community.
    - IHE USA also recommends initiating a discussion with stakeholders to explore ways to indicate credibility of data sources (e.g. physician or nurse vs. medical device, health monitoring device, etc.)

4. **As the richness and volume of data continues to grow and become available from sources other than the clinical setting, IHE USA recommends that ONC focus efforts on identifying standards for patient-generated health data such as patient-provided goals, notes, etc.**
    - We also recommend that efforts be made to identify interoperability standards for health tracking devices (devices that currently do not require FDA approval) to facilitate integration of data from such devices with EHR systems.

5. **IHE USA suggests that ONC provide more clarification for implementers when an Interoperability Need lists more than one Standard or Implementation Guide.**
    - IHE USA recommends that, when multiple standards are listed, the ONC provide a list of preferences or additional guidance for conditions to use each. This was at times included in the "Limitations, Dependencies and Preconditions for Consideration" field, but should be done consistently throughout the ISA.
    - Furthermore, IHE USA believes clarification is needed regarding the purpose of standards that are listed in the "Applicable Value Sets/Starter Sets" field that were not included in the main table. For example, some Interoperability Needs listed Value Sets that were drawn from the SNOMED CT code system, while SNOMED CT wasn't mentioned as a standard in "Type" field. Is there a reason that these standards are not listed as main standards for the Interoperability Need?

6. **IHE USA recommends aligning the standards included in the ISA with those listed in the 2015 ONC Certification rule.**
    - Currently, these standards are often listed in the "Limitations, Dependencies, and Preconditions for Consideration" field. IHE USA believes that since such standards are federally required, they should be listed within the tables for the applicable Interoperability Need.

The IHE USA detailed comments to the Draft 2017 Interoperability Standards Advisory are included in the attached Excel template and are being submitted in collaboration with HIMSS.

We appreciate the opportunity to submit these comments on the Draft 2017 Interoperability Standards Advisory. Our comments are intended to acknowledge the importance of each stakeholder's role in advancing standards-based interoperability and health information exchange, and ensuring that each domain is invested in overcoming the inherent challenges, while further enhancing health IT's pivotal role in enabling healthcare transformation.

We welcome the opportunity to meet with you and your team to discuss our comments in more detail. Please feel free to contact Joyce Sensmeier, President, IHE USA at 312-915-9281, or Celina Roth, Sr. Manager, IHE USA, at 312-915-9213, with questions or for more information.

Thank you for your consideration.

Sincerely,

Joyce Sensmeier, MS, RN-BC, FAAN
President, IHE USA

David S. Mendelson, MD
Co-chair, IHE International

Michael J. McCoy, MD
Co-Chair, IHE International

Attachment: Excel template response to ONC's Draft 2017 Interoperability Standards Advisory

Commenter Name/Title: HIMSS Standards Advisory Work Group

Comment Template Instructions: Please select a topic and section from the dropdown list for each comment provided. Where more than one interoperability need or standard/implementation specification exists, please identify the applicable interoperability

Topic	Section	Interoperability Need	Standard/Implementation Specification	Comment (No Action)	Comment (Request for Action)
Introduction			Removal of "Best Available" for Standard characteristics		IHE USA is concerned that removal of the "Best Available" characteristic from the ISA standards and specifications will minimize the importance of the ISA as guidance to the industry, and does little to encourage implementers to adopt and align on the standards identified. Therefore, we recommend ONC consider stronger language to direct users to implement the standards identified in the ISA while also encouraging consideration of the emerging standards that will enable innovation.
Scope					IHE USA suggests that the Scope of the ISA includes the use of health information for secondary purposes (e.g. public health, research) in addition to already stated "electronic health information created in the context of treatment", given that several interoperability standards such as IHE SDC Profile, CDISC and others were mentioned that are intended for secondary use of health data.
Scope			Two Standards for One Interoperability Need	IHE USA suggests that when ONC lists two standards for the same need, an explanation for why two are listed should be provided. It would also be helpful to provide more guidance on whether one standard is preferred or both are acceptable. Some Interoperability Needs provide this context, but not all include such information.	
Scope				IHE USA would like to see more guidance provided on standards. It would be helpful for some standards to have clarity on the level of governance required to implement the standard successfully. HL7 FHIR, for example, requires coordination of many resources in the information ecosystem to be successful.	
Purpose		Security Patterns definition			IHE USA suggests providing a definition for "security patterns" included in the 3rd bullet.
Structure		Section III			IHE USA recommends that "Services" be more clearly defined and that infrastructure and services be separated into two distinct "Sections" of the ISA document. IHE USA further recommends that examples for both be provided: provider directories and trust framework are examples of Infrastructure, while APIs is an example of services.
Structure					IHE USA recommends providing a more detailed explanation and example for the Applicable Value Set/Starter Sets (Section I) and Applicable Security Patterns (Sections II and III) to better define what will be included in this section throughout the rest of the document.
Structure		Adoption Level			IHE USA suggests that the inclusion of "federally required" should not be considered as a criterion of Adoption Level since this is listed in its own characteristic. Adoption Level should focus only on adoption in the field by the industry.
Structure		Interoperability Proving Ground		IHE USA appreciates the additional information provided in the Interoperability Proving Ground, but sees challenges in navigating the projects due to the fact that the link leads to the complete list of projects, instead of the specific project referenced. IHE USA recommends linking to the specific project(s) that relate to the Interoperability Need with the link.	
Section I: Vocabulary/Code Set/Terminology Standards and Implementation Specifications	I-A: Allergies			IHE USA applauds ONC for their inclusion of all three types of allergic reaction substances. All three types of allergens are common, and should be clearly documented in the patient's electronic record.	
Section I: Vocabulary/Code Set/Terminology Standards and Implementation Specifications	I-A: Allergies	Representing Patient Allergic Reactions	LOINC®		IHE USA believes that ONC should reconsider selecting LOINC® for the Standard for Observation. There are many cases in EHR databases or CDA documents that already have Allergic Reactions defined as a standard data element within the template without a LOINC code. It would be counterproductive to require such templates to retro-fit their already existing fields with this Standard. In addition, LOINC nomenclature does not have LOINC codes for every question (data field) used to capture clinical data in EHR systems and requiring LOINC code as a default standard for encoding questions would require both Regenstrief Institute to develop additional LOINC codes and EHR vendors to modify their EHR systems to support these LOINC codes (for every clinical data field).
Section I: Vocabulary/Code Set/Terminology Standards and Implementation Specifications	I-A: Allergies	Representing Patient Allergic Reactions	LOINC®		IHE USA suggests that, if the LOINC® Standard remains, the specific LOINC code(s) for Allergic Reactions be provided. LOINC includes thousands of possible terms. ONC should be specific as they are for I-R and I-S, where they list the value sets for Gender Identify, Birth Sex, etc.
Section I: Vocabulary/Code Set/Terminology Standards and Implementation Specifications	I-A: Allergies	Representing Patient Allergens: Medications	NDF-RT, RxNorm	IHE USA commends ONC for their explanationof the use of the NDF-RT standard included for this interoperability need. However, IHE USA recommends clarification of the relevance and use of both NDF-RT and RxNorm standards. For example, when should RxNorm be chosen over NDF-RT? If the source (health data originating system) uses only one standard, does the recipient (health data receiving system) need to support both standards (RxNorm and NDF-RT? We are also concerned that by providing a cascading selection in the Applicable Value Sets, it may result in a lack of consistency in implementations in the standard utilized for this Interoperability Need.	
Section I: Vocabulary/Code Set/Terminology Standards and Implementation Specifications	I-A: Allergies	Representing Patient Allergens: Food Substances	UNII, SNOMED CT®		IHE USA recommends labelling the Implementation Maturity for both standards as "Production" and the Adoption Levels for both standards as Level 4.
Section I: Vocabulary/Code Set/Terminology Standards and Implementation Specifications	I-A: Allergies	Representing Patient Allergens: Enviornmental Substances	UNII		IHE USA recommends labelling the Implementation Maturity for UNII as Production. IHE USA also suggests clarifying in the"Limitations, Dependencies, and Preconditions for Consideration" section which clinical scenarios for deciding when to chose UNII over SNOMED-CT and vice versa.
Section I: Vocabulary/Code Set/Terminology Standards and Implementation Specifications	I-B: Encounter Diagnosis	Representing Patient Medical Encounter Diagnosis	SNOMED CT®, ICD-10		IHE USA recommends including GEM maps (ICD-9 to ICD-10 maps) in the "Limitations, Dependencies, and Preconditions for Consideration" section. However, we caution that both GEM and SNOMED CT-to-ICD-10-CM maps are approximate maps and recommend that terminology experts provide more guidance on how to consistently apply those maps in a clinical setting.
Section I: Vocabulary/Code Set/Terminology Standards and Implementation Specifications	I-C: Family Health History	Representing Patient Family Health History			IHE USA would like to suggest a higher level of granularity in documenting genetic mutations for family members. It would be beneficial to include both mutation details and risks related to such a mutation.
Section I: Vocabulary/Code Set/Terminology Standards and Implementation Specifications	I-C: Family Health History	Representing Patient Family Health History	SNOMED CT ®	IHE USA would like clarification as to why SNOMED-CT is listed as the standard for genomic data when better standards are available, and are included in the Applicable Value Sets. What is the relationship between the LOINC/SNOMED-CT standards and the Value Sets listed?	
Section I: Vocabulary/Code Set/Terminology Standards and Implementation Specifications	I-C: Family Health History	Representing Patient Family Health History Observation			IHE USA suggests removing this Interoperability Need as it is duplicative based on the information provided in the preceding Interoperability Need (I-C Family Health History: Representing Patient Family History). By listing standards for observation and observation value, it now seems unnecessary to split into two Interoperability Needs.
Section I: Vocabulary/Code Set/Terminology Standards and Implementation Specifications	I-D: Functional Status/Disability	Representing Patient Functional Status and/or Disability			IHE USA suggests including links to the Social Security Association's Disability Determination Process (https://www.ssa.gov/disability/determination.htm) and the American College of Occupational and Environmental Medicine (www.acoem.org) in the additional notes for this Interoperability Need, as both are strong resources on Functional Status/Disability.
Section I: Vocabulary/Code Set/Terminology Standards and Implementation Specifications	I-D: Functional Status/Disability	Representing Patient Functional Status and/or Disability	SNOMED CT® , ICF	IHE USA recommends that if SNOMED-CT or ICF are selected as a standard, ONC provide mapping between the two standards to ensure consistency across competing vocabulary systems	
Section I: Vocabulary/Code Set/Terminology Standards and Implementation Specifications	I-E: Health Care Provider	Representing Care Team Member	NPI		IHE USA urges ONC to consider methods to represent non-billable care team members, as these individuals are becoming increasingly critical to care coordination efforts. The NPPES works well in the physician space but consideration is needed on how to represent the broader care team.
Section I: Vocabulary/Code Set/Terminology Standards and Implementation Specifications	I-E: Health Care Provider	Representing Provider Role in Care Setting	SNOMED CT®	IHE USA would like some clarity on the three different value sets provided in the Applicable Value Sets. Why are the additional value sets included when SNOMED-CT is the only standard listed for this Interoperability Need? Is there a more narrow SNOMED-CT subset that can be included in this section? Is it redundant to include all three value sets?	
Section I: Vocabulary/Code Set/Terminology Standards and Implementation Specifications	I-F: Imaging (Diagnostics, interventions and procedures)	Representing Imaging Diagnostics, Interventions and Procedures	DICOM	IHE USA is curious as to why DICOM is listed as a Vocabulary standard. Did ONC mean to specify RADLEX and LOINC, which is DICOM supported, for this Interoperability Need?	
Section I: Vocabulary/Code Set/Terminology Standards and Implementation Specifications	I-F: Imaging (Diagnostics, interventions and procedures)	Representing Imaging Diagnostics, Interventions and Procedures		IHE USA is curious as to why SNOMED-CT and ICD-10 are not included, as they are used for diagnostic reports for imaging. Several data analytics organizations use SNOMED-CT to encode unstructured reports from imaging.	
Section I: Vocabulary/Code Set/Terminology Standards and Implementation Specifications	I-G: Immunizations		CVX		IHE USA suggests including CVX as a standard within Section I-A Allergies to allow for fluidity between codes for immunizations and allergies to those immunizations. RxNorm provides that type of fluidity in codes between immunization, medication and allergic reactions, but is less adopted. We further recommend clarifying when to use CVX codes versus NDC codes.
Section I: Vocabulary/Code Set/Terminology Standards and Implementation Specifications	I-G: Immunizations	Representing Immunizations - Administered	RxNorm		IHE USA suggests moving the RxNorm value sets from the Applicable Value Set to the Limitations Box since it is not recommended as a standard for this Interoperability Need.
Section I: Vocabulary/Code Set/Terminology Standards and Implementation Specifications	I-H: Industry and Occupation	Representing Patient Industry and Occupation			IHE USA suggests the inclusion of the value sets already created as part of the Cancer Report CDA, which is currently mandated for Meaningful Use Stage 3. The value sets suggested for this Interoperability Need are: 1. PHVS_Industry_CDC_Census2010 urn:oid:2.16.840.1.114222.4.11.7187 2. PHVS_Occupation_CDC_Census2010 urn:oid:2.16.840.1.114222.4.11.7186
Section I: Vocabulary/Code Set/Terminology Standards and Implementation Specifications	I-I: Lab tests	Representing Laboratory Tests			IHE USA recommends condensing the second and third bullets in the "Limitations, Dependencies..." section. They are redundant as they currently read.
Section I: Vocabulary/Code Set/Terminology Standards and Implementation Specifications	I-I: Lab tests	Representing Laboratory Tests	LOINC®		IHE USA applauds the inclusion of the LOINC Top 2000 Lab Observations Starter Set, and suggests the inclusion of the LOINC Universal Lab Orders Value Set represented by OID: 1.3.6.1.4.1.12009.10.2.2 . IHE USA also suggests adding a row of Standards for Orders, specifying LOINC for that standard.
Section I: Vocabulary/Code Set/Terminology Standards and Implementation Specifications	I-J: Medications	Representing Patient Medication	RxNorm	IHE USA would like to better understand the justification behind the Adoption Level of 5 for the RxNorm standard.	
Section I: Vocabulary/Code Set/Terminology Standards and Implementation Specifications	I-J: Medications	Representing Patient Medication		IHE USA would like to know if there is an order of preference for the implementation of the three standards included for this Interoperability Need. Should adopters utilize all three standards for this Interoperability Need?	
Section I: Vocabulary/Code Set/Terminology Standards and Implementation Specifications	I-K: Numerical References & Values	Representing Units of Measure	UCUM		IHE USA agrees that inclusion of these standards are critical to the robustness of the ISA, but believes the IO Need name "Numerical References and Values" is confusing and does not reflect what the standards represent. IHE USA suggests remaining the IO Need to "Units of Measure" as this is used in the UCUM name. IHE USA also suggests moving the last bullet in Limitations ("UCUM is a syntax...") to the top of the list, as it captures the most critical difference between UCUM and other code systems
Section I: Vocabulary/Code Set/Terminology Standards and Implementation Specifications	I-L: Nursing	Representing Nursing Assessment		IHE USA suggests referencing the ANA's guidance on Nursing Documentation for this Interoperability Need and the maturity level for standards to capture nursing assessments.	
Section I: Vocabulary/Code Set/Terminology Standards and Implementation Specifications	I-M: Patient Clinical "Problems" (i.e., conditions)	Representing Patient Clinical "Problems" (i.e. Conditions)			IHE USA recommends removing the language "i.e. conditions" from the title of this Sub-Section. Many conditions are not considered patient problems and vice versa, and equating the two in this Section is not representative of how the standard categorizes "problems".
Section I: Vocabulary/Code Set/Terminology Standards and Implementation Specifications	I-O: Procedures	Representing Medical Procedures Performed	SNOMED CT®, ICD-10, CPT-4		IHE USA understands the importance of including all three of these standards for this Interoperability Need, but thinks it will be helpful for implementers if the use of each standard is more explicitly stated. SNOMED-CT should be highlighted as the standard used for treatment purposes while CPT-4 and ICD-10 are necessary for reimbursement and clinical purposes. It should also be stated that CPT-4 is the standard for use in outpatient procedures and ICD-10 is used for inpatient procedures.
Section I: Vocabulary/Code Set/Terminology Standards and Implementation Specifications	I-O: Procedures	Representing Medical Procedures Performed	SNOMED CT®		IHE USA recommends including a refined value set for SNOMED CT as it related to procedures, and offer guidance on a mapping approach between SNOMED CT and ICD-10.
Section I: Vocabulary/Code Set/Terminology Standards and Implementation Specifications	I-P: Race and Ethnicity	Representing Patient Race and Ethnicity	CDC Race and Ethnicity Code Set Version 1.0		IHE USA suggests that "CDC Race and Ethnicity Code Set Version 1.0" be listed as a Standard in the Interoperability Need table because it is required by the 2015 E-Certification Rule.
Section I: Vocabulary/Code Set/Terminology Standards and Implementation Specifications	I-Q: Research	Representing Analytic Data for Research			IHE USA believes that this Interoperability Need does not fit within the ISA Scope as defined by ONC. We suggest either broadening the ISA Scope to include interoperability for research purposes or removing it from the ISA.
Section I: Vocabulary/Code Set/Terminology Standards and Implementation Specifications	I-R: Sexual Orientation, and Gender Identity	Representing Patient Gender Identity	LOINC®, SNOMED CT®		IHE USA suggests Adoption Levels of 3 out of 5 for both of the listed standards.
Section I: Vocabulary/Code Set/Terminology Standards and Implementation Specifications	I-R: Sexual Orientation, and Gender Identity	Representing Patient Sex (at Birth)		In light of precision medicine and the increase in gender-specific, specialized surgeries such as sex reassignment procedures, it is clinically relevant that additional gender characteristics be captured beyond person's externally identifiable (phenotypical) characteristics such as: karyotypical sex (XX, XO, XY, XYY, XXY,etc), gonadal sex (presence or absence of gonadal tissue), and ductal sex (presence or absence of Wolffian/Muellerian ducts). IHE USA recommends field analysis with EHR vendors and healthcare providers and organizations to understand how these gender characteristics are currently being captured and stored in information systems. We recommend identification and/or development of standards that support capture and exchange of these additional gender characteristics.	

Section I: Vocabulary/Code Set/Terminology Standards and Implementation Specifications	I-S: Social Determinants [See Questions 10 and 11, Section IV]	All	LOINC®		IHE USA recommends that the Adoption Level for LOINC be lowered for each of the Interoperability Needs in this section since collection and mapping of data to LOINC is not widely used.
Section I: Vocabulary/Code Set/Terminology Standards and Implementation Specifications	I-T: Tobacco Use (Smoking Status) [See Question 12, Section IV]	Representing Patient Tobacco Use (Smoking Status) Observation Result Values or Assertions	LOINC®		IHE USA fears the use of interpretive values for smoking status can lead to different interpretations of tobacco use in the population. For example, there is no single definition for "Light tobacco smoker" or what distinguishes "Light tobacco smoker" from "Current some day smoker". The lack of specificity in terms of type of tobacco consumed, quantity consumed, form of consumption etc leads to limited data usability from clinical and population health perspective. We suggest adopting distinct data elements that can capture detailed quantitative and qualitative characteristics of tobacco use, such as form of consumption, type of tobacco or substance, quantity consumed, length/duration of exposure, etc. In addition, we recommend documenting "Alcohol Use" along with "Tobacco Use" since concomitant consumption of both substances/agents significantly raises incidence and prevalence of certain malignancies such as ENT malignancies. IHE USA also believes that LOINC adoption is not as widespread as SNOMED CT and that Adoption Level should be reduced.
Section I: Vocabulary/Code Set/Terminology Standards and Implementation Specifications	I-U: Unique Device Identification	Representing Unique Implantable Device Identifiers	IEEE 11073 PHD Harmonization Pattern for Unique Device Identifiers		IHE USA recommends updating ""IEEE 11073 PHD Harmonization Pattern for Unique Device Identifiers" to "HL7 Harmonization Pattern for Unique Device Identifiers".
Section I: Vocabulary/Code Set/Terminology Standards and Implementation Specifications	I-V: Vital Signs	Representing Patient Vital Signs	IEEE 11073-10101, ISO/IEE 11073-XXXXX		IHE USA recommends adding IEEE 11073 PHD Harmonization Pattern to the list of Standards because there are already many devices and systems implementations in the market that utilize the IHE PCD framework, and many are, or will soon be, certified by PCHA/Continua. We further recommend that LOINC be removed as a standard since it is not specifically designed with the necessary rigor, precision, range and clarity that is required for personal health de vices. It is also important to note that IHE PCD has adopted the HL7 Harmonization Pattern for UDI which will support the communication of UDI directly from medical devices.
Section II: Content/Structure Standards and Implementation Specifications	II-B: Care Plan	Documenting Patient Care Plans			IHE USA recommends providing knowledge resources, tools and library with clinical examples that improve consistent adoption and use of C-CDA. While HL7's Example Task Force provides a library of snippets of codes for specific uses cases (http://wiki.hl7.org/index.php?title=CDA_Example_Task_Force), we encourage provision of complete clinical cases with matching complete C-CDA documents. We recommend more guidance on how to develop usable graphical user interfaces that display C-CDA information in a way that is most conducting to and supporting of clinical care.
Section II: Content/Structure Standards and Implementation Specifications	II-C: Clinical Decision Support	Shareable Clinical Decision Support	HL7 FHIR		IHE USA suggests Adoption Level 1 of 5 (20%) for "HL7 Implementation Guide: Clinical Decision Support Knowledge Artifact Implementation Guide, Release 1.3, Draft Standard for Trial Use." We suggest updating the name of IS from "HL7 FHIR Implementation Guide: Clinical Quality Framework (CQF on FHIR), Release" to "Clinical Reasoning Module of FHIR" (https://www.hl7.org/fhir/20165ep/clinicalreasoning-module.html). Please note that this module is expected to supercede many of the existing specifications once sufficiently mature.
Section II: Content/Structure Standards and Implementation Specifications	II-D: Clinical Quality Measurement	Sharing Quality Measure Artifacts for Quality Reporting Initiatives	All		IHE USA recommends clarifying whether listed standards are alternatives, overlapping or complementing standards. We also suggest prioritizing standards to help adopters determine which standards require immediate focus.IHE USA also recommends updating names of HL7 FHIR profiles to reflect those on the HL7 FHIR website.
Section II: Content/Structure Standards and Implementation Specifications	II-E: Clinical Quality Reporting	Reporting Aggregate Quality Data to Federal Quality Reporting Initiatives	HL7 Implementation Guide for CDA® Release 2; HL7 CDA® R2 Implementation Guide	IHE USA believes that Adoption levels (4 out of 5) for the following Implementation Specifications seem high: - HL7 Implementation Guide for CDA® Release 2: Quality Reporting Document Architecture - Category III (QRDA III), DRAFT Release 1. - HL7 CDA® R2 Implementation Guide: Quality Reporting Document Architecture - Category I (QRDA I) DSTU Release 3 (US Realm) IHE USA recommends revising aforementioned Adoption Levels or providing sources that substantiate current level (4 out of 5).	
Section II: Content/Structure Standards and Implementation Specifications	II-E: Clinical Quality Reporting	Reporting Aggregate Quality Data to Federal Quality Reporting Initiatives	HL7 CDA® R2 Implementation Guide		IHE USA recommends correcting the title of the standard "HL7 CDA® R2 Implementation Guide: Quality Reporting Document Architecture - Category I (QRDA I) DSTU Release43 (US Realm)". We assume that in lieu of version "43", ONC meant version "3.1". IHE PCD specifies the use of the ISO/IEEE 11073-10101 Nomenclature for vital signs as well as for other medical devices such as ventilators, pumps, anesthesia systems, etc. LOINC does not have the breadth of vocabulary to support these classes of devices.
Section II: Content/Structure Standards and Implementation Specifications	II-E: Clinical Quality Reporting	Reporting Aggregate Quality Data to Federal Quality Reporting Initiatives	HL7 Implementation Guide for CDA® Release 2: Quality Reporting Document Architecture - Category III (QRDA III)	IHE USA would like to stress the importance of QRDA Category III in the role of population health. We advise adding the following Implementation Guide to The "Type" section of this IO need: "CMS Implementation Guide for Quality Reporting Document Architecture Category I Hospital Quality Reporting", Implementation Guide for 2017 (July 8, 2016). Link here: https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/eCQM_2017QRDA_HQR_CMS_IG.PDF	
Section II: Content/Structure Standards and Implementation Specifications	II-F: Data Provenance	Establishing the Authenticity, Reliability and Trustworthiness of Content between Trading Partners		IHE USA recommends that ONC conduct field analysis to better understand how provenance data is captured in existing systems. We think that existing and upcoming standards should focus on enabling capture and exchange of provenance information at the data element level to ensure traceability of data to a sufficiently granular level.	We recommend adding HL7 FHIR provenance resource as an emerging core standard.
Section II: Content/Structure Standards and Implementation Specifications	II-G: Drug Formulary & Benefits	Ability of Pharmacy Benefit Payers to Communicate Formulary and Benefit Information to Prescribers Systems	NCPDP Formulary and Benefits v3.0	IHE USA agrees with the Adoption Level (5 out of 5) for this standard.	
Section II: Content/Structure Standards and Implementation Specifications	II-H: Electronic Prescribing	Allows the Pharmacy to Respond to Prescriber with a Change on a New Prescription	NCPDP SCRIPT Standard, Implementation Guide, Version 10.6		IHE USA recommends Adoption Level of 4 out of 5.
Section II: Content/Structure Standards and Implementation Specifications	II-H: Electronic Prescribing	Cancellation of a Prescription	NCPDP SCRIPT Standard, Implementation Guide, Version 10.6		IHE USA recommends Adoption Level of 4 out of 5.
Section II: Content/Structure Standards and Implementation Specifications	II-H: Electronic Prescribing	Pharmacy Notifies Prescriber of Prescription Fill Status	NCPDP SCRIPT Standard, Implementation Guide, Version 10.6		IHE USA recommends Adoption Level of 1 out of 5.
Section II: Content/Structure Standards and Implementation Specifications	II-H: Electronic Prescribing	A Prescriber's Ability to Obtain a Patient's Medication History	NCPDP SCRIPT Standard, Implementation Guide, Version 10.6		IHE USA recommendsAdoption Level of 4 out of 5.
Section II: Content/Structure Standards and Implementation Specifications	II-I: Family health history (clinical genomics)	Representing Family Health History for Clinical Genomics	HL7 Version 3 Standard: Clinical Genomics; Pedigree		IHE USA recommends that Federally Required indicator for "HL7 Version 3 Standard: Clinical Genomics; Pedigree" be updated to "No", since this Interoperability Need is not federally required.
Section II: Content/Structure Standards and Implementation Specifications	II-I: Family health history (clinical genomics)	Representing Patient Family Health History Observations	LOINC®		IHE USA recommends that this standard (LOINC) be mentioned in Section I (Family History) because LOINC is a vocabulary/code standard.
Section II: Content/Structure Standards and Implementation Specifications	II-J: Images	Medical Image Formats for Data Exchange and Distribution	Digital Imaging and Communications in Medicine (DICOM)	IHE USA agrees with Adoption Level 5 out of 5 for standard "Digital Imaging and Communications in Medicine (DICOM)". We also recommend the RSNA Image Share Validation program as a means of achieving interoperability.	
Section II: Content/Structure Standards and Implementation Specifications	II-J: Images	Format of Medical Imaging Reports for Exchange and Distribution			IHE USA recommends an Adoption Level of 4 out of 5. IHE USA further recommends adding HL7 v2.6 and IEEE 11073-10101 as underlying core standards since IHE PCD technical framework uses information model and nomenclature from IEEE 11073-10101, while transactions are based on HL7 v2.6 standard. Lastly, we recommend updating the Test Tool Availability to "Yes" since test tools are available from NIST.
Section II: Content/Structure Standards and Implementation Specifications	II-J: Images	Format of Radiology Reports for Exchange and Distribution			IHE USA suggests removing this Interoperability Need since Radiology is a subset of medical imaging. We suggest moving the Interoperability Specification "IHE Management of Radiology Report Templates (MRRT)" to the Interoperability Need "Format of Medical Imaging Reports for Exchange and Distribution".
Section II: Content/Structure Standards and Implementation Specifications	II-L: Medical Device Communication to Other Information Systems/Technologies	Transmitting Patient Vital Signs from Medical Devices to Other Information Systems/Technologies			IHE USA recommends listing a specific version of the IHE PCD profile: Revision 5.0, October 2015; this is the latest publication. We also recommend adding IEEE 11073 as a core standard, which is used to develop IHE PCD profile. IHE USA recommends that the Test Tool Availability for IHE-PCD be updated to "Yes", as these test tools are available through NIST. Lastly, we recommend adding technical specification available at http://hitsp.org/ConstructSet_Details.aspx?&PrefixAlpha=5&PrefixNumeric=905 to "Limitations, Dependencies, and Preconditions for Consideration" field.
Section II: Content/Structure Standards and Implementation Specifications	II-M: Patient Education Materials	A Standard Mechanism for Clinical Information Systems to Request Context-Specific Clinical Knowledge From Online Resources			IHE USA suggegests all the Interoperability Needs in this sub-section be moved to Section III and combined with Section III-B because Infobutton defines a service mechanism (vs. content/structure). IHE USA also recommends proofreading the sub-section title and correcting "form" to "from".
Section II: Content/Structure Standards and Implementation Specifications	II-O: Public Health Reporting	Case Reporting to Public Health Agencies			IHE USA recommends adding hyperlink for the Pilot project currently run by College of American Pathologists (CAP) https://www.healthit.gov/techlab/ipg/node/4/submission/48.
Section II: Content/Structure Standards and Implementation Specifications	II-O: Public Health Reporting	Reporting Administered Immunizations to Immunization Registry	HL7 2.5.1 Implementation Guide for Immunization Messaging, Release 1.4; HL7 2.5.1 Implementation Guide for Immunization Messaging, Release 1.5		IHE USA recommends clarifying in "Limitations, Dependencies, and Preconditions for Consideration:" field the circumstances when v1.5 is preferred over 1.4 for Implementation Specification "HL7 2.5.1 Implementation Guide for Immunization Messaging".
Section II: Content/Structure Standards and Implementation Specifications	II-P: Representing clinical health information as a "resource"	Representing Clinical Health Information as "Resource"	FHIR		IHE USA recommends that HL7 FHIR, FHIR resources and any FHIR profiles be listed under the category that describes the function it provides; "resources" per-se only describe the way data is grouped together.
Section II: Content/Structure Standards and Implementation Specifications	II-Q: Research	All			IHE USA would like to point out that the ISA Scope currently doesn't include "research" or any other "secondary use of clinical data". Therefore, this sub-section should either be removed from ISA or the Scope should be broadened to include data for "secondary use".
Section II: Content/Structure Standards and Implementation Specifications	II-R: Segmentation of sensitive information	Document-Level Segmentation of Sensitive Information			IHE USA recommends including 42 CFR Part 2 Data related to treatment from http://www.samhsa.gov/. 42 CFR Part 2 data restrictions depend on how the data is managed at the source (data from the patient vs. data from a Part 2 provider).
Section II: Content/Structure Standards and Implementation Specifications	II-S: Summary care record	Support a Transition of Care or Referral to Another Health Care Provider			IHE USA recommends listing available knowledge resources with C-CDA examples (e.g. specific projects within the ONC Interoperability Lab).
Section III: Standards and Implementation Specifications for Services	III-A: "Push" Exchange	An Unsolicited "Push" of Clinical Health Information to a Known Destination Between Individuals and Systems			IHE USA recommends rephrasing the title of the Interoperability Need from "An Unsolicited "Push" of Clinical Health Information to a Known Destination Between Individuals and Systems" to "An Unsolicited "Push" of Clinical Health Information to a Known Destination Between Information Systems Users".
Section III: Standards and Implementation Specifications for Services	III-A: "Push" Exchange	An Unsolicited "Push" of Clinical Health Information to a Known Destination Between Individuals and Systems	IHE-MHD (Mobile Access to Health Documents)		IHE USA recommends that "IHE-MHD (Mobile Access to Health Documents)" be deleted since this Implementation Specification (IS) is not a "push" standard like "Direct".
Section III: Standards and Implementation Specifications for Services	III-A: "Push" Exchange	An Unsolicited "Push" of Clinical Health Information to a Known Destination Between Systems			IHE USA recommends that the Standards and Implementation Specifications from this Interoperability Need be equivalent to all Standards and Implementation Specifications from Interoperability Need (An Unsolicited "Push" of Clinical Health Information to a Known Destination Between Individuals and Systems).
Section III: Standards and Implementation Specifications for Services	III-A: "Push" Exchange	Push Communication of Vital Signs from Medical Devices			IHE USA recommends expanding this Interoperability Need to include medical devices that capture health-related information beyond Vital Signs. IHE USA recommends including section for non-FDA approved wearable devices, due to the emergence of wearable technology that monitors vitals. For example, some non-FDA devices such as smart watches and fitness trackers include functionality for heart rate; information from such devices may be integrated into EHR in the future.
Section III: Standards and Implementation Specifications for Services	III-A: "Push" Exchange	Push Communication of Vital Signs from Medical Devices			IHE USA recommends that the "ISO/IEEE 11073 Health informatics - Medical / health device communication" standard's Test Tool Availability be updated to "Yes" and that Adoption Level be updated to 3 out of 5. We also recommend that "IEEE 11073 Nomenclature" and "IHE Patient Care Devices Technical Framework" (http://www.ihe.net/Technical_Frameworks/#pcd) be added as Implementation Specifications (IS). If IHE is added, then we also recommend adding HL7 v2.6 as a core Standard with Standards Process Maturity indicated as "Final" and Implementation Maturity indicated as "Production". We also recommend indicating in "Limitations, Dependencies, and Preconditions for Consideration" field that IEEE 11073 data elements are mapped to those in HL7 v2.6. Lastly, we recommend adding a new Interoperability Need to support chronic condition management, care coordination and care management, and listing ITU standards with H.810, H.811, H.812, and H.813 Implementation Specifications for remote patient monitoring interoperability.
Section III: Standards and Implementation Specifications for Services	III-B: Clinical Decision Support Services	Providing Patient-Specific Assessments and Recommendations Based on Patient Data for Clinical Decision Support			IHE USA recommends that the names of the Standards listed in this section be proofread for missing spaces and lower-to-upper case corrections. Specifically, we noticed typos in the QICore Standard which should read "QICore/QUICK, Draft Standard for Trial Use". We further recommend that the name "CDS on FHIR, Draft Standard for Trial Use" be updated to "HL7 FHIR Clinical Reasoning Module".
Section III: Standards and Implementation Specifications for Services	III-B: Clinical Decision Support Services	Retrieval of Contextually Relevant, Patient-Specific Knowledge Resources from Within Clinical Information Systems to Answer Clinical Questions Raised by Patients in the Course of Care	HL7 Version 3 Standard: Context Aware Knowledge Retrieval Application		IHE USA recommends updating the Adoption Level to 4 out of 5.
Section III: Standards and Implementation Specifications for Services	III-C: Image Exchange	All	DICOM		IHE USA recommends that the DICOM standard be added for both Interoperability Needs because the listed IHE profiles are based on the DICOM standard.
Section III: Standards and Implementation Specifications for Services	III-D: Healthcare Directory, Provider Directory	Listing of providers for access by potential exchange partners	IHE IT Infrastructure Technical Framework Supplement, Healthcare Provider Directory (HPD), Trial Implementation		IHE USA recommends that ELPD and ILPD be added as core Standards. We also recommend that, for "IHE IT Infrastructure Technical Framework Supplement, Healthcare Provider Directory (HPD), Trial Implementation", Adoption Level be updated from to 2 out of 5.
Section III: Standards and Implementation Specifications for Services	III-E: Public Health Exchange	Query/Response for Immunization Reporting and Exchange			IHE USA recommends adding two Interoperability Specifications: HL7 v2.5.1 standards for Immunization Registry versions 1.4 and 1.5). Both of the aforementioned Interoperability Specifications contain both push and query functions.
Section III: Standards and Implementation Specifications for Services	III-G: Query	Query for Documents Within a Specific Health Information Exchange Domain	IHE-XDS, IHE-PDQ and IHE-MHD		IHE USA suggests that Adoptions Levels for the three Implementation Specifications (IHE-XDS, IHE-PDQ and IHE-MHD) be updated to 5 out of 5.
Section III: Standards and Implementation Specifications for Services	III-G: Query	Query for Documents Outside a Specific Health Information Exchange Domain Data Element Based Query for Clinical Health Information			IHE USA recommends that HL7 FHIR DAF (Data Access Framework) profile be added to as Implementation Specification.

Appendix I – Sources of Security Standards and Security Patterns					IHE USA applauds ONC for compiling the list of valuable resources! We recommend that the listed resources be broken down into categories for easier navigation, such as authentication, authorization, secure communication, etc. We also recommend that hyperlinks to specific standards be provided (whenever perma links are available); for example, hyperlink for ASTM standard should be specific to only those parts of ASTM standards that pertain to security standards. We also recommend the addition of references to two recently updated standards for cybersecurity: STIX v1.2.1 and TAXII v1.1.1 (more information on how DHS uses these standards can be found at https://www.dhs.gov/blog/2015/07/23/dhs-leads-effort-transition-automated-cybersecurity-information-sharing). We also recommend adding the following two hyperlinks: http://oauth.net/2/ and https://forgerock.org/openuma/.