

November 6, 2015

Karen DeSalvo, MD, MPH, MSc
National Coordinator
Office of the National Coordinator for Health IT
Department of Health and Human Services
200 Independence Ave, SW
Washington, DC 20201

Dear Dr. DeSalvo,

On behalf of Integrating the Healthcare Enterprise (IHE) International and 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 2016 Interoperability Standards Advisory](#). IHE appreciates the opportunity to leverage our members' expertise in commenting on the DRAFT 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 in the final Standards Advisory release for 2016. We believe that this effort will provide the necessary foundation for more rapidly advancing interoperability in the United States.

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. Since 1998, IHE has achieved global consensus on a common framework for applying health IT standards to the real world.

In general, IHE supports the structural changes to the way in which the content is organized and presented in the DRAFT 2016 Interoperability Standards Advisory (ISA). Our primary observations focus on the following issues:

- 1. IHE appreciates that ONC included standards of all maturity levels in the DRAFT 2016 Interoperability Standards Advisory to advance the achievement of nationwide interoperability.**
 - IHE would like to emphasize, however, that standards maturity is not a two-dimensional concept (in the case of the Interoperability Standards Advisory, either "draft" or "final"). There could be risks in trying to reduce it to such that could overly simplify a complex or nuanced topic. IHE recommends ONC consider the following three questions to better articulate standards maturity in future versions of the Interoperability Standards Advisory:
 1. Is the proposed standard being developed to advance new technologies?

2. Is the proposed standard a competing standard for an existing standard that is currently adopted?
 3. Is the proposed standard an update of an existing standard that has achieved broad adoption?
- We support and encourage the testing of emerging standards and tools such as application programming interfaces (APIs) and Fast Healthcare Interoperability Resources (FHIR) to further clarify this effort.
2. **IHE applauds ONC on the six new informative characteristics that have been included for best available standards, implementation specifications, and the addition of a section for security patterns.**
- ONC should consider articulating success criteria and metrics for measuring the impact of the ISA on interoperability to include outlining a process for measuring interoperability improvement or identifying a percentage rate for measuring the adoption level characteristic.
3. **IHE appreciates that IHE Profiles (IHE-XDS, IHE-PDQ, IHE-PIX, IHE-MHD and parallel imaging versions) were chosen to enable query-based exchange for documents within a specific health information exchange domain.**
- We recommend that ONC leverage the ConCert by HIMSS™ program and test tools for query based exchange using IHE Profiles.
 - We note that IHE International will be launching a Conformity Assessment program in 2016 that will provide for additional test tools relevant for IHE Profiles.

IHE has prepared comments on the items in the attached pages, listed according to the proposed best available standards and questions related to the DRAFT ISA. We welcome the opportunity to meet with you and your team to discuss our comments in more depth. Please feel free to contact [Joyce Sensmeier](#), President, IHE USA at 312-915-9281, or [Celina Roth](#), IHE Liaison, at 312-915-9213, with questions or for more information.

Thank you for your consideration.

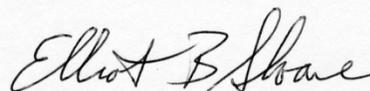
Sincerely,



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



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



Elliot B. Sloane, PhD
Co-chair, IHE International Board

Attachment: IHE's Response to ONC's DRAFT 2016 Interoperability Standards Advisory

Section I: Best Available Vocabulary/Code Set/Terminology Standards and Implementation Specifications

I-A: Allergies

Interoperability Need: Representing patient allergic reactions

| Type | Standard/Implementation Specification | Standards Process Maturity | Implementation Maturity | Adoption Level | Regulated | Cost | Test Tool Availability |
|--|---------------------------------------|----------------------------|-------------------------|--|-----------|------|------------------------|
| Standard | SNOMED-CT | Final | Production | ●●●●○ | No | Free | N/A |
| Limitations, Dependencies, and Preconditions for Consideration: | | | | Applicable Security Patterns for Consideration: | | | |
| <ul style="list-style-type: none"> Feedback requested | | | | <ul style="list-style-type: none"> Feedback requested | | | |

Interoperability Need: Representing patient allergens: medications

| Type | Standard/Implementation Specification | Standards Process Maturity | Implementation Maturity | Adoption Level | Regulated | Cost | Test Tool Availability |
|--|---------------------------------------|----------------------------|-------------------------|--|-----------|------|------------------------|
| Standard | RxNorm | Final | Production | ●●●●○ | Yes | Free | N/A |
| Limitations, Dependencies, and Preconditions for Consideration: | | | | Applicable Security Patterns for Consideration: | | | |
| <ul style="list-style-type: none"> When a medication allergy necessitates capture by medication class, NDF-RT is best available (as recommended by the HIT Standards Committee) | | | | <ul style="list-style-type: none"> Feedback requested | | | |

Interoperability Need: Representing patient allergens: food substances

| Type | Standard/Implementation Specification | Standards Process Maturity | Implementation Maturity | Adoption Level | Regulated | Cost | Test Tool Availability |
|--|---------------------------------------|----------------------------|-------------------------|--|-----------|------|------------------------|
| Standard | SNOMED-CT | Final | Unknown | Unknown | No | Free | N/A |
| Limitations, Dependencies, and Preconditions for Consideration: | | | | Applicable Security Patterns for Consideration: | | | |
| <ul style="list-style-type: none"> Feedback requested | | | | <ul style="list-style-type: none"> Feedback requested | | | |

Interoperability Need: Representing patient allergens: environmental substances

| Type | Standard/Implementation Specification | Standards Process Maturity | Implementation Maturity | Adoption Level | Regulated | Cost | Test Tool Availability |
|----------|---------------------------------------|----------------------------|-------------------------|----------------|-----------|------|------------------------|
| Standard | [See Question 4-5] | | | | | | |

| Limitations, Dependencies, and Preconditions for Consideration: | Applicable Security Patterns for Consideration: |
|---|--|
| <ul style="list-style-type: none"> Currently, there are no vocabulary code sets considered “best available” for environmental allergens. | <ul style="list-style-type: none"> Feedback requested |

I-B: Care Team Member

Interoperability Need: Representing care team member (health care provider)

| Type | Standard/Implementation Specification | Standards Process Maturity | Implementation Maturity | Adoption Level | Regulated | Cost | Test Tool Availability |
|----------|--|----------------------------|-------------------------|----------------|-----------|------|------------------------|
| Standard | National Provider Identifier (NPI) | Final | Production | ●●○○○ | No | Free | N/A |

| Limitations, Dependencies, and Preconditions for Consideration: | Applicable Security Patterns for Consideration: |
|--|--|
| <ul style="list-style-type: none"> For the purpose of recording a care team member, it should be noted that NPI permits, but does not require, non-billable care team members to apply for an NPI number to capture the concept of ‘person’. There is a SNOMED-CT value set for a “subject’s role in the care setting” that could also be used in addition to NPI for care team members. <i>IHE suggests the continued use of NPI. In the event an NPI is not available a nurse’s state license number could be used.</i> | <ul style="list-style-type: none"> |

I-C: Encounter Diagnosis

Interoperability Need: Documenting patient encounter diagnosis

| Type | Standard/Implementation Specification | Standards Process Maturity | Implementation Maturity | Adoption Level | Regulated | Cost | Test Tool Availability |
|----------|---------------------------------------|----------------------------|-------------------------|----------------|-----------|------|------------------------|
| Standard | SNOMED-CT | Final | Production | ●●●●○ | Yes | Free | N/A |

| Type | Standard/Implementation Specification | Standards Process Maturity | Implementation Maturity | Adoption Level | Regulated | Cost | Test Tool Availability |
|--|---------------------------------------|----------------------------|-------------------------|--|-----------|------|------------------------|
| Standard | ICD-10-CM | Final | Production | ● ● ● ● ○ | Yes | Free | N/A |
| Limitations, Dependencies, and Preconditions for Consideration: | | | | Applicable Security Patterns for Consideration: | | | |
| <ul style="list-style-type: none"> Feedback requested | | | | <ul style="list-style-type: none"> Feedback requested | | | |

I-D: Race and Ethnicity

| Interoperability Need: Representing patient race and ethnicity | | | | | | | |
|---|---|----------------------------|-------------------------|--|-----------|------|------------------------|
| Type | Standard/Implementation Specification | Standards Process Maturity | Implementation Maturity | Adoption Level | Regulated | Cost | Test Tool Availability |
| Standard | OMB standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity, Statistical Policy Directive No. 15, Oct 30, 1997 | Final | Production | ● ● ● ● ● | Yes | Free | N/A |
| Limitations, Dependencies, and Preconditions for Consideration: | | | | Applicable Security Patterns for Consideration: | | | |
| <ul style="list-style-type: none"> The CDC Race and Ethnicity Code Set Version 1.0, which expands upon the OMB standards, may help to further define race and ethnicity for this interoperability need as it allows for multiple races and ethnicities to be chosen for the same patient. The HIT Standards Committee noted that the high-level race/ethnicity categories in 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. <i>IHE suggests a cautious approach when collecting multiple ethnicities for one patient to avoid creating barriers for successful data capture.</i> | | | | <ul style="list-style-type: none"> Feedback requested | | | |

I-E: Family Health History

| Interoperability Need: Representing patient family health history | | | | | | | |
|---|---------------------------------------|----------------------------|-------------------------|----------------|-----------|------|------------------------|
| Type | Standard/Implementation Specification | Standards Process Maturity | Implementation Maturity | Adoption Level | Regulated | Cost | Test Tool Availability |
| Standard | SNOMED-CT | Final | Production | ● ● ● ● ○ | Yes | Free | N/A |

| | |
|---|--|
| Limitations, Dependencies, and Preconditions for Consideration: | Applicable Security Patterns for Consideration: |
| <ul style="list-style-type: none"> Some details around family genomic health history may not be captured by SNOMED-CT (recommended by the HIT Standards Committee) | <ul style="list-style-type: none"> Feedback requested |

I-F: Functional Status/Disability

Interoperability Need: Representing patient functional status and/or disability

| Type | Standard/Implementation Specification | Standards Process Maturity | Implementation Maturity | Adoption Level | Regulated | Cost | Test Tool Availability |
|----------|---------------------------------------|----------------------------|-------------------------|----------------|-----------|------|------------------------|
| Standard | [See Question 4-5] | | | | | | |

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|--|--|
| Limitations, Dependencies, and Preconditions for Consideration: | Applicable Security Patterns for Consideration: |
| <ul style="list-style-type: none"> | <ul style="list-style-type: none"> Feedback requested |

I-G: Gender Identity, Sex, and Sexual Orientation

Interoperability Need: Representing patient gender identity

| Type | Standard/Implementation Specification | Standards Process Maturity | Implementation Maturity | Adoption Level | Regulated | Cost | Test Tool Availability |
|----------|---------------------------------------|----------------------------|-------------------------|----------------|-----------|------|------------------------|
| Standard | SNOMED-CT | Final | Unknown | Unknown | No | Free | N/A |

| | |
|---|--|
| Limitations, Dependencies, and Preconditions for Consideration: | Applicable Security Patterns for Consideration: |
| <ul style="list-style-type: none"> The HIT Standards Committee recommended collecting discrete structured data on patient gender identity, sex, and sexual orientation following recommendations issued in a report by The Fenway Institute and the Institute of Medicine. IHE would like clarification if the Advisory is suggesting the use of the entire SNOMED-CT code system or a subset of codes? | <ul style="list-style-type: none"> Feedback requested |

Interoperability Need: Representing patient sex (at birth)

| Type | Standard/Implementation Specification | Standards Process Maturity | Implementation Maturity | Adoption Level | Regulated | Cost | Test Tool Availability |
|------|---------------------------------------|----------------------------|-------------------------|----------------|-----------|------|------------------------|
|------|---------------------------------------|----------------------------|-------------------------|----------------|-----------|------|------------------------|

| Type | Standard/Implementation Specification | Standards Process Maturity | Implementation Maturity | Adoption Level | Regulated | Cost | Test Tool Availability |
|----------|--|----------------------------|-------------------------|----------------|-----------|------|------------------------|
| Standard | For Male and Female, HL7 Version 3 Value Set for Administrative Gender | Final | Production | ● ● ● ● ○ | No | Free | N/A |
| Standard | For Unknown, HL7 Version 3 Null Flavor | Final | Production | ● ● ● ● ○ | No | Free | N/A |

| Limitations, Dependencies, and Preconditions for Consideration: | Applicable Security Patterns for Consideration: |
|---|--|
| <ul style="list-style-type: none"> The HIT Standards Committee recommended collecting discrete structured data on patient gender identity, sex, and sexual orientation following recommendations issued in a report by The Fenway Institute and the Institute of Medicine. | <ul style="list-style-type: none"> Feedback requested |

Interoperability Need: Representing patient sexual orientation

| Type | Standard/Implementation Specification | Standards Process Maturity | Implementation Maturity | Adoption Level | Regulated | Cost | Test Tool Availability |
|----------|---------------------------------------|----------------------------|-------------------------|----------------|-----------|------|------------------------|
| Standard | SNOMED-CT | Final | Unknown | Unknown | No | Free | N/A |

| Limitations, Dependencies, and Preconditions for Consideration: | Applicable Security Patterns for Consideration: |
|--|--|
| <ul style="list-style-type: none"> The HIT Standards Committee recommended collecting discrete structured data on patient gender identity, sex, and sexual orientation following recommendations issued in a report by The Fenway Institute and the Institute of Medicine. <i>IHE would like clarification if the Advisory is suggesting the use of the entire SNOMED-CT code system or a subset of codes?</i> | <ul style="list-style-type: none"> Feedback requested |

I-H: Immunizations

Interoperability Need: Representing immunizations – historical

| Type | Standard/Implementation Specification | Standards Process Maturity | Implementation Maturity | Adoption Level | Regulated | Cost | Test Tool Availability |
|----------|--|----------------------------|-------------------------|----------------|-----------|------|------------------------|
| Standard | HL7 Standard Code Set CVX—Clinical Vaccines Administered | Final | Production | ● ● ● ● ● | Yes | Free | N/A |

| Type | Standard/Implementation Specification | Standards Process Maturity | Implementation Maturity | Adoption Level | Regulated | Cost | Test Tool Availability |
|----------|---|----------------------------|-------------------------|----------------|-----------|------|------------------------|
| Standard | HL7 Standard Code Set MVX - Manufacturing Vaccine Formulation | Final | Production | ● ● ● ● ○ | No | Free | N/A |

| Limitations, Dependencies, and Preconditions for Consideration: | Applicable Security Patterns for Consideration: |
|--|--|
| <ul style="list-style-type: none"> HL7 CVX codes are designed to represent administered and historical immunizations and will not contain manufacturer-specific information. When an MVX code is paired with a CVX (vaccine administered) code, the specific trade named vaccine may be indicated providing further specificity as to the vaccines administered. <i>IHE encourages the use of MVX codes so that historical and current immunizations are comparable in databases to manage population health, such as state Public Health registries.</i> | <ul style="list-style-type: none"> Feedback requested |

Interoperability Need: Representing immunizations – administered

| Type | Standard/Implementation Specification | Standards Process Maturity | Implementation Maturity | Adoption Level | Regulated | Cost | Test Tool Availability |
|----------|--|----------------------------|-------------------------|----------------|-----------|------|------------------------|
| Standard | HL7 Standard Code Set CVX—Clinical Vaccines Administered | Final | Production | ● ● ● ● ● | Yes | Free | N/A |
| Standard | National Drug Code | Final | Production | ● ● ● ● ● | No | Free | N/A |

| Limitations, Dependencies, and Preconditions for Consideration: | Applicable Security Patterns for Consideration: |
|--|--|
| <ul style="list-style-type: none"> HL7 CVX codes are designed to represent administered and historical immunizations and will not contain manufacturer-specific information. According to the HIT Standards Committee, National Drug (NDC) codes may provide value to stakeholders for inventory management, packaging, lot numbers, etc., but do not contain sufficient information to be used for documenting an administered immunization across organizational boundaries. | <ul style="list-style-type: none"> Feedback requested |

I-I: Industry and Occupation

Interoperability Need: Representing patient industry and occupation

| Type | Standard/Implementation Specification | Standards Process Maturity | Implementation Maturity | Adoption Level | Regulated | Cost | Test Tool Availability |
|--|---------------------------------------|----------------------------|-------------------------|--|-----------|------|------------------------|
| Standard | [See Question 4-5] | | | | | | |
| Limitations, Dependencies, and Preconditions for Consideration: | | | | Applicable Security Patterns for Consideration: | | | |
| <ul style="list-style-type: none"> Feedback requested | | | | <ul style="list-style-type: none"> Feedback requested | | | |

I-J: Lab tests

| Interoperability Need: Representing laboratory tests and observations | | | | | | | |
|---|---------------------------------------|----------------------------|-------------------------|--|-----------|------|------------------------|
| Type | Standard/Implementation Specification | Standards Process Maturity | Implementation Maturity | Adoption Level | Regulated | Cost | Test Tool Availability |
| Standard | LOINC | Final | Production | ●●●●○ | Yes | Free | N/A |
| Limitations, Dependencies, and Preconditions for Consideration: | | | | Applicable Security Patterns for Consideration: | | | |
| <ul style="list-style-type: none"> The HIT Standards Committee recommended that 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. The HIT Standards Committee recommended that organizations not using LOINC codes should maintain and publish a mapping of their codes to the LOINC equivalent until migration to LOINC has occurred. <i>IHE suggests that LOINC be evolved into one dictionary. National labs, lab vendors and EHR vendors may want to consider leading this process, thereby reducing the cost, complexity and risk for errors in lab ordering and result management.</i> <i>IHE also recommends simplifying the interoperability need to “Representing laboratory test results (observations)”.</i> | | | | <ul style="list-style-type: none"> Feedback requested | | | |

I-K: Medications

| Interoperability Need: Representing patient medications | | | | | | | |
|---|---------------------------------------|----------------------------|-------------------------|----------------|-----------|------|------------------------|
| Type | Standard/Implementation Specification | Standards Process Maturity | Implementation Maturity | Adoption Level | Regulated | Cost | Test Tool Availability |

| Type | Standard/Implementation Specification | Standards Process Maturity | Implementation Maturity | Adoption Level | Regulated | Cost | Test Tool Availability |
|----------|---------------------------------------|----------------------------|-------------------------|----------------|-----------|------|------------------------|
| Standard | RxNorm | Final | Production | ● ● ● ● ● | Yes | Free | N/A |

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|---|--|
| Limitations, Dependencies, and Preconditions for Consideration: | Applicable Security Patterns for Consideration: |
| <ul style="list-style-type: none"> IHE would like clarification if the Advisory is suggesting the use of the entire RxNorm code system? C-CDA is using a subset of RxNorm codes (based on TTY field criteria). | <ul style="list-style-type: none"> Feedback requested |

I-L: Numerical References & Values

Interoperability Need: Representing numerical references and values

| Type | Standard/Implementation Specification | Standards Process Maturity | Implementation Maturity | Adoption Level | Regulated | Cost | Test Tool Availability |
|----------|--|----------------------------|-------------------------|----------------|-----------|------|------------------------|
| Standard | The Unified Code of Units of Measure | Final | Production | ● ● ● ○ ○ | No | Free | N/A |

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| Limitations, Dependencies, and Preconditions for Consideration: | Applicable Security Patterns for Consideration: |
| <ul style="list-style-type: none"> The case sensitive version is the correct unit string to be used for interoperability purposes per HIT Standards Committee recommendations. | <ul style="list-style-type: none"> Feedback requested |

I-M: Patient “problems” (i.e. conditions)

Interoperability Need: Representing patient “problems” (i.e., conditions)

| Type | Standard/Implementation Specification | Standards Process Maturity | Implementation Maturity | Adoption Level | Regulated | Cost | Test Tool Availability |
|----------|---------------------------------------|----------------------------|-------------------------|----------------|-----------|------|------------------------|
| Standard | SNOMED-CT | Final | Production | ● ● ● ● ● | Yes | Free | N/A |

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|--|--|
| Limitations, Dependencies, and Preconditions for Consideration: | Applicable Security Patterns for Consideration: |
| <ul style="list-style-type: none"> IHE would like clarification if the Advisory is suggesting the use of the entire SNOMED-CT code system? C-CDA uses a subset of SNOMED-CT codes called “Problem Value Set.” | <ul style="list-style-type: none"> Feedback requested |

I-N: Preferred Language

| Interoperability Need: Representing patient preferred language | | | | | | | |
|---|---------------------------------------|----------------------------|-------------------------|--|-----------|------|------------------------|
| Type | Standard/Implementation Specification | Standards Process Maturity | Implementation Maturity | Adoption Level | Regulated | Cost | Test Tool Availability |
| Standard | RFC 5646 | Final | Production | Unknown | No | Free | N/A |
| Limitations, Dependencies, and Preconditions for Consideration: | | | | Applicable Security Patterns for Consideration: | | | |
| <ul style="list-style-type: none"> RFC 5646 encompasses ISO 639-1, ISO 639-2, ISO 639-3 and other standards related to identifying preferred language. | | | | <ul style="list-style-type: none"> Feedback requested | | | |

I-O: Procedures

| Interoperability Need: Representing dental procedures performed | | | | | | | |
|--|--|----------------------------|-------------------------|--|-----------|------|------------------------|
| Type | Standard/Implementation Specification | Standards Process Maturity | Implementation Maturity | Adoption Level | Regulated | Cost | Test Tool Availability |
| Standard | Code on Dental Procedures and Nomenclature (CDT) | Final | Production | ● ● ● ● ● | Yes | \$ | N/A |
| Limitations, Dependencies, and Preconditions for Consideration: | | | | Applicable Security Patterns for Consideration: | | | |
| <ul style="list-style-type: none"> CDT is a proprietary terminology standard. | | | | <ul style="list-style-type: none"> Feedback requested | | | |

| Interoperability Need: Representing medical procedures performed | | | | | | | |
|--|--|----------------------------|-------------------------|----------------|-----------|------|------------------------|
| Type | Standard/Implementation Specification | Standards Process Maturity | Implementation Maturity | Adoption Level | Regulated | Cost | Test Tool Availability |
| Standard | SNOMED-CT | Final | Production | ● ● ● ● ● | Yes | Free | N/A |
| Standard | the combination of CPT-4/HCPCS | Final | Production | ● ● ● ● ● | Yes | \$ | N/A |
| Standard | ICD-10-PCS | Final | Production | ● ● ● ● ○ | Yes | Free | N/A |

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|---|--|
| Limitations, Dependencies, and Preconditions for Consideration: | Applicable Security Patterns for Consideration: |
| <ul style="list-style-type: none"> IHE recommends listing ICD-10 CM/PCS as PCS is for inpatient procedures only. | <ul style="list-style-type: none"> Feedback requested |

I-P: Radiology (interventions and procedures)

Interoperability Need: Representing radiological interventions and procedures

| Type | Standard/Implementation Specification | Standards Process Maturity | Implementation Maturity | Adoption Level | Regulated | Cost | Test Tool Availability |
|----------|---------------------------------------|----------------------------|-------------------------|----------------|-----------|------|------------------------|
| Standard | LOINC | Final | Production | ●●○○○ | No | Free | N/A |

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| Limitations, Dependencies, and Preconditions for Consideration: | Applicable Security Patterns for Consideration: |
| <ul style="list-style-type: none"> Radlex and LOINC are currently in the process of creating a common data model to link the two standards together to promote standardized indexing of radiology terms as indicated by public comments and HIT Standards Committee recommendations. | <ul style="list-style-type: none"> Feedback requested |

I-Q: Smoking Status

Interoperability Need: Representing patient smoking status

| Type | Standard/Implementation Specification | Standards Process Maturity | Implementation Maturity | Adoption Level | Regulated | Cost | Test Tool Availability |
|----------|---------------------------------------|----------------------------|-------------------------|----------------|-----------|------|------------------------|
| Standard | SNOMED-CT | Final | Production | ●●●●● | Yes | Free | N/A |

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|---|--|
| Limitations, Dependencies, and Preconditions for Consideration: | Applicable Security Patterns for Consideration: |
| <ul style="list-style-type: none"> According to the HIT Standards Committee, there are limitations in SNOMED-CT for this interoperability need, which include not being able to capture severity of dependency, quit attempts, lifetime exposure, and use of e-Cigarettes. IHE recommends changing the interoperability need to “Representing patient tobacco use” so that it triggers greater identification of all tobacco users. IHE also suggests adding a structured data list of dependencies; patient self-identifies to EHR patient assessment and to add a structured data list for the number of attempts to quit tobacco use. | <ul style="list-style-type: none"> Feedback requested |

I-R: Unique Device Identification

| Interoperability Need: Representing unique implantable device identifiers | | | | | | | |
|---|---|----------------------------|-------------------------|--|-----------|------|------------------------|
| Type | Standard/Implementation Specification | Standards Process Maturity | Implementation Maturity | Adoption Level | Regulated | Cost | Test Tool Availability |
| Standard | Unique device identifier as defined by the Food and Drug Administration at 21 CFR 830.3 | Final | Production | ● ○ ○ ○ ○ | Yes | Free | N/A |
| Limitations, Dependencies, and Preconditions for Consideration: | | | | Applicable Security Patterns for Consideration: | | | |
| <ul style="list-style-type: none"> Feedback requested | | | | <ul style="list-style-type: none"> Feedback requested | | | |

I-S: Vital Signs

| Interoperability Need: Recording patient vital signs | | | | | | | |
|---|---------------------------------------|----------------------------|-------------------------|--|-----------|------|------------------------|
| Type | Standard/Implementation Specification | Standards Process Maturity | Implementation Maturity | Adoption Level | Regulated | Cost | Test Tool Availability |
| Standard | LOINC | Final | Production | ● ● ● ● ● | No | Free | N/A |
| Limitations, Dependencies, and Preconditions for Consideration: | | | | Applicable Security Patterns for Consideration: | | | |
| <ul style="list-style-type: none"> IHE recommends the use of IHE-DEC (Device Enterprise Communication) as the appropriate Implementation Specification for Vital Signs recording. LOINC has limited utility for manually entered patient vital signs, but that is only a small fraction of the vital signs available in patient care settings. Further, LOINC is not the copyright owner of the necessary Vital Signs nomenclature. The copyright is owned by IEEE and ISO. LOINC and NIST were provided IEEE's 11073 Vital Signs nomenclature under a limited use MOU which allows A) NIST to continue supporting its well-developed IHE Patient Care Device (PCD) testing tools, B) Allows IHE's Rosetta Terminology Mapping project to have more complete crosswalk mapping between ISO/IEEE 11073 and LOINC, and C) allows all clinical and provider users fee-free use of the nomenclature. IHE DEC and other IHE PCD profiles use HL7 messaging and IEEE 11073 nomenclature to provide a mature, NIST validated, Vital Sign vocabulary that covers all patient physiologic data, including time-stamped raw and computed numeric vital signs, waveforms, events and alarms, annotations, device location and device management information. Also, PCHA/Continua uses IHE DEC for near real-time transmission of personal health and home | | | | <ul style="list-style-type: none"> Feedback requested | | | |

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|--|--|
| <p><i>monitoring data</i></p> <ul style="list-style-type: none"> • NIST has developed a mature set of open source test tools to validate Vital Signs message content, ensuring complete and correct data essential for safe and effective patient care and Health IT integration. • IHE DEC Standards Process Maturity / Implementation Maturity / Adoption Level / Regulated / Cost / Test Tool Availability : Final / Production / Adoption 4 out of 5 / No / Free / NIST testing tool set available | |
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Section II: Best Available Content/Structure Standards and Implementation Specifications

II-A: Admission, Discharge, and Transfer

| Interoperability Need: Sending a notification of a patient's admission, discharge and/or transfer status | | | | | | | |
|---|---------------------------------------|----------------------------|-------------------------|--|-----------|------|------------------------|
| Type | Standard/Implementation Specification | Standards Process Maturity | Implementation Maturity | Adoption Level | Regulated | Cost | Test Tool Availability |
| Standard | HL7 2.x ADT message | Final | Production | ●●●●● | No | Free | No |
| Limitations, Dependencies, and Preconditions for Consideration: | | | | Applicable Security Patterns for Consideration: | | | |
| <ul style="list-style-type: none"> • Any HL7 2.x version messaging standard associated with ADT is acceptable. • A variety of transport protocols are available for use for ADT delivery. Trading partners will need to determine which transport tools best meet their interoperability needs. | | | | <ul style="list-style-type: none"> • Feedback requested | | | |

II-B: Care Plan

| Interoperability Need: Documenting patient care plans | | | | | | | |
|--|--|----------------------------|-------------------------|--|-----------|------|------------------------|
| Type | Standard/Implementation Specification | Standards Process Maturity | Implementation Maturity | Adoption Level | Regulated | Cost | Test Tool Availability |
| Standard | HL7 Clinical Document Architecture (CDA®), Release 2.0, Final Edition | Final | Production | ●●●●● | No | Free | No |
| Implementation Specification | HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes (US Realm), Draft Standard for Trial Use, Release 2.1 | Draft | Pilot | Unknown | No | Free | No |
| Limitations, Dependencies, and Preconditions for Consideration: | | | | Applicable Security Patterns for Consideration: | | | |

| | |
|----------------------|----------------------|
| • Feedback requested | • Feedback requested |
|----------------------|----------------------|

II-C: Clinical Decision Support

Interoperability Need: Shareable clinical decision support

| Type | Standard/Implementation Specification | Standards Process Maturity | Implementation Maturity | Adoption Level | Regulated | Cost | Test Tool Availability |
|----------|---|----------------------------|-------------------------|----------------|-----------|------|------------------------|
| Standard | HL7 Implementation Guide: Clinical Decision Support Knowledge Artifact Implementation Guide, Release 1.3, Draft Standard for Trial Use. | Draft | Pilot | Unknown | No | Free | No |

| | |
|--|--|
| Limitations, Dependencies, and Preconditions for Consideration: | Applicable Security Patterns for Consideration: |
| • Feedback requested | • Feedback requested |

II-D: Drug Formulary & Benefits

Interoperability Need: The ability for pharmacy benefit payers to communicate formulary and benefit information to prescribers systems

| Type | Standard/Implementation Specification | Standards Process Maturity | Implementation Maturity | Adoption Level | Regulated | Cost | Test Tool Availability |
|----------|---|----------------------------|-------------------------|----------------|-----------|------|------------------------|
| Standard | NCPDP Formulary and Benefits v3.0 | Final | Production | ●●●●● | Yes | \$ | No |

| | |
|--|--|
| Limitations, Dependencies, and Preconditions for Consideration: | Applicable Security Patterns for Consideration: |
| • The HIT Standards Committee noted that the NCPDP Real Time Prescription Benefit Inquiry (RTPBI) is an alternative in development that should be monitored as a potential emerging alternative. | • Feedback requested |

II-E: Electronic Prescribing

Interoperability Need: A prescriber's ability to create a new prescription to electronically send to a pharmacy

| Type | Standard/Implementation Specification | Standards Process Maturity | Implementation Maturity | Adoption Level | Regulated | Cost | Test Tool Availability |
|----------|---|----------------------------|-------------------------|----------------|-----------|------|------------------------|
| Standard | NCPDP SCRIPT Standard, Implementation Guide, Version 10.6 | Final | Production | ●●●●● | Yes | \$ | Yes |

| | |
|--|--|
| Limitations, Dependencies, and Preconditions for Consideration: | Applicable Security Patterns for Consideration: |
|--|--|

| | |
|--|--|
| <ul style="list-style-type: none"> The “New Prescription” transaction is best suited for this interoperability need. Both the prescriber and the receiving pharmacy must have their systems configured for the transaction in order to facilitate successful exchange. | <ul style="list-style-type: none"> Feedback requested |
|--|--|

Interoperability Need: Prescription refill request

| Type | Standard/Implementation Specification | Standards Process Maturity | Implementation Maturity | Adoption Level | Regulated | Cost | Test Tool Availability |
|----------|---|----------------------------|-------------------------|----------------|-----------|------|------------------------|
| Standard | NCPDP SCRIPT Standard, Implementation Guide, Version 10.6 | Final | Production | ●●●●○ | No | \$ | No |

| | |
|---|---|
| Limitations, Dependencies, and Preconditions for Consideration: <ul style="list-style-type: none"> The “Refill Request” transaction is best suited for this interoperability need. Both the prescriber and the receiving pharmacy must have their systems configured for the transaction in order to facilitate successful exchange. | Applicable Security Patterns for Consideration: <ul style="list-style-type: none"> Feedback requested |
|---|---|

Interoperability Need: Cancellation of a prescription

| Type | Standard/Implementation Specification | Standards Process Maturity | Implementation Maturity | Adoption Level | Regulated | Cost | Test Tool Availability |
|----------|---|----------------------------|-------------------------|----------------|-----------|------|------------------------|
| Standard | NCPDP SCRIPT Standard, Implementation Guide, Version 10.6 | Final | Production | Unknown | No | \$ | No |

| | |
|---|---|
| Limitations, Dependencies, and Preconditions for Consideration: <ul style="list-style-type: none"> The “Cancel” transaction is best suited for this interoperability need. Both the prescriber and the receiving pharmacy must have their systems configured for the transaction in order to facilitate successful exchange. | Applicable Security Patterns for Consideration: <ul style="list-style-type: none"> Feedback requested |
|---|---|

Interoperability Need: Pharmacy notifies prescriber of prescription fill status

| Type | Standard/Implementation Specification | Standards Process Maturity | Implementation Maturity | Adoption Level | Regulated | Cost | Test Tool Availability |
|----------|---|----------------------------|-------------------------|----------------|-----------|------|------------------------|
| Standard | NCPDP SCRIPT Standard, Implementation Guide, Version 10.6 | Final | Production | Unknown | No | \$ | No |

| | |
|--|---|
| Limitations, Dependencies, and Preconditions for Consideration: <ul style="list-style-type: none"> The “Fill Status” transaction is best suited for this interoperability need. Both the prescriber and the receiving pharmacy must have their systems configured for the transaction in order to facilitate successful exchange. | Applicable Security Patterns for Consideration: <ul style="list-style-type: none"> Feedback requested |
|--|---|

Interoperability Need: A prescriber's ability to obtain a patient's medication history

| Type | Standard/Implementation Specification | Standards Process Maturity | Implementation Maturity | Adoption Level | Regulated | Cost | Test Tool Availability |
|----------|---|----------------------------|-------------------------|----------------|-----------|------|------------------------|
| Standard | NCPDP SCRIPT Standard. Implementation Guide, Version 10.6 | Final | Production | ●●●○○ | No | \$ | No |

| Limitations, Dependencies, and Preconditions for Consideration: | Applicable Security Patterns for Consideration: |
|--|--|
| <ul style="list-style-type: none"> The “Medication History” transaction is best suited for this interoperability need. Both the prescriber and the receiving pharmacy must have their systems configured for the transaction in order to facilitate successful exchange. | <ul style="list-style-type: none"> Feedback requested |

II-F: Family health history (clinical genomics)

Interoperability Need: Representing family health history for clinical genomics

| Type | Standard/Implementation Specification | Standards Process Maturity | Implementation Maturity | Adoption Level | Regulated | Cost | Test Tool Availability |
|------------------------------|---|----------------------------|-------------------------|----------------|-----------|------|------------------------|
| Standard | HL7 Version 3 Standard: Clinical Genomics; Pedigree | Final | Production | ●○○○○ | Yes | Free | No |
| Implementation Specification | HL7 Version 3 Implementation Guide: Family History/Pedigree Interoperability, Release 1 | Final | Production | ●○○○○ | No | Free | No |

| Limitations, Dependencies, and Preconditions for Consideration: | Applicable Security Patterns for Consideration: |
|---|--|
| <ul style="list-style-type: none"> According to the HIT Standards Committee, there is no available vocabulary to capture family genomic health history. According to the HIT Standards Committee, further constraint of this standard and implementation specification may be required to support this interoperability need. | <ul style="list-style-type: none"> Feedback requested |

II-G: Images

[See Question 4-7]

Interoperability Need: Medical image formats for data exchange and distribution

| Type | Standard/Implementation Specification | Standards Process Maturity | Implementation Maturity | Adoption Level | Regulated | Cost | Test Tool Availability |
|--|--|----------------------------|-------------------------|--|-----------|------|------------------------|
| Standard | Digital Imaging and Communications in Medicine (DICOM) | Final | Production | ● ● ● ● ● | No | Free | No |
| Implementation Specification | Image Acquisition Technology Specific Service/Object Pairs (SOP) Classes [See Question 4-8] | Final | Production | ● ○ ○ ○ ○ | No | Free | No |
| Limitations, Dependencies, and Preconditions for Consideration: | | | | Applicable Security Patterns for Consideration: | | | |
| ● Feedback requested | | | | ● Feedback requested | | | |

Interoperability Need: Exchange of imaging reports

| Type | Standard/Implementation Specification | Standards Process Maturity | Implementation Maturity | Adoption Level | Regulated | Cost | Test Tool Availability |
|--|---|----------------------------|-------------------------|--|-----------|------|------------------------|
| Standard | Digital Imaging and Communications in Medicine (DICOM) | Final | Production | ● ● ● ● ● | No | Free | No |
| Implementation Specification | PS3.20 Digital Imaging and Communications in Medicine (DICOM) Standard – Part 20: Imaging Reports using HL7 Clinical Document Architecture. | Final | Production | ● ○ ○ ○ ○ | No | Free | No |
| Limitations, Dependencies, and Preconditions for Consideration: | | | | Applicable Security Patterns for Consideration: | | | |
| ● Feedback requested | | | | ● Feedback requested | | | |

II-H: Laboratory

Interoperability Need: Receive electronic laboratory test results

| Type | Standard/Implementation Specification | Standards Process Maturity | Implementation Maturity | Adoption Level | Regulated | Cost | Test Tool Availability |
|------------------------------|--|----------------------------|-------------------------|----------------|-----------|------|------------------------|
| Standard | HL7 2.5.1 | Final | Production | ● ● ● ● ● | No | Free | No |
| Implementation Specification | HL7 Version 2.5.1 Implementation Guide: S&I Framework Lab Results Interface, Release 1—US Realm [HL7 Version 2.5.1: ORU_R01] Draft Standard for Trial Use, July 2012 | Final | Production | ● ● ● ● ○ | Yes | Free | Yes |

| Type | Standard/Implementation Specification | Standards Process Maturity | Implementation Maturity | Adoption Level | Regulated | Cost | Test Tool Availability |
|--|--|----------------------------|-------------------------|----------------|-----------|------|------------------------|
| Emerging Alternative Implementation Specification | <i>HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Results Interface Implementation Guide, Release 1 DSTU Release 2 - US Realm</i> <i>[no hyperlink available yet]</i> | Draft | Pilot | ● ○ ○ ○ ○ ○ | No | Free | No |

| Limitations, Dependencies, and Preconditions for Consideration: | Applicable Security Patterns for Consideration: |
|--|--|
| <ul style="list-style-type: none"> HL7 Laboratory US Realm Value Set Companion Guide, Release 1, September 2015, provides cross-implementation guide value set definitions and harmonized requirements. IHE encourages the full adoption of HL7 v 2.5.1. However, there are still some data elements that have no assigned fields which cause variability and lead to interface problems and potential errors. | <ul style="list-style-type: none"> Feedback requested |

Interoperability Need: Ordering labs for a patient

| Type | Standard/Implementation Specification | Standards Process Maturity | Implementation Maturity | Adoption Level | Regulated | Cost | Test Tool Availability |
|-------------------------------------|--|----------------------------|-------------------------|----------------|-----------|------|------------------------|
| Standard | HL7 2.5.1 | Final | Production | ● ● ● ● ● ● | No | Free | No |
| Implementation specification | HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Orders from EHR, Release 1 DSTU Release 2 - US Realm <i>[no hyperlink available yet]</i> | Draft | Pilot | ● ○ ○ ○ ○ ○ | No | Free | No |

| Limitations, Dependencies, and Preconditions for Consideration: | Applicable Security Patterns for Consideration: |
|--|--|
| <ul style="list-style-type: none"> HL7 Laboratory US Realm Value Set Companion Guide, Release 1, September 2015, provides cross-implementation guide value set definitions and harmonized requirements. | <ul style="list-style-type: none"> Feedback requested |

Interoperability Need: Support the transmission of a laboratory's directory of services to health IT.

| Type | Standard/Implementation Specification | Standards Process Maturity | Implementation Maturity | Adoption Level | Regulated | Cost | Test Tool Availability |
|-----------------|---------------------------------------|----------------------------|-------------------------|----------------|-----------|------|------------------------|
| Standard | HL7 2.5.1 | Final | Production | ● ● ● ● ● ● | No | Free | No |

| Type | Standard/Implementation Specification | Standards Process Maturity | Implementation Maturity | Adoption Level | Regulated | Cost | Test Tool Availability |
|--|--|----------------------------|-------------------------|--|-----------|------|------------------------|
| Standard | HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Test Compendium Framework, Release 2, DSTU Release 2 <i>[no hyperlink available yet]</i> | Draft | Pilot | ● ○ ○ ○ ○ | No | Free | No |
| Limitations, Dependencies, and Preconditions for Consideration: | | | | Applicable Security Patterns for Consideration: | | | |
| <ul style="list-style-type: none"> HL7 Laboratory US Realm Value Set Companion Guide, Release 1, September 2015, provides cross-implementation guide value set definitions and harmonized requirements. | | | | <ul style="list-style-type: none"> Feedback requested | | | |

II-I: Patient Education Materials

Interoperability Need: A standard mechanism for clinical information systems to request context-specific clinical knowledge from online resources

| Type | Standard/Implementation Specification | Standards Process Maturity | Implementation Maturity | Adoption Level | Regulated | Cost | Test Tool Availability |
|--|--|----------------------------|-------------------------|--|-----------|------|------------------------|
| Standard | HL7 Version 3 Standard: Context Aware Knowledge Retrieval Application. (“Infobutton”), Knowledge Request, Release 2. | Final | Production | ● ● ● ● ○ | Yes | Free | No |
| Implementation Specification | HL7 Implementation Guide: Service-Oriented Architecture Implementations of the Context-aware Knowledge Retrieval (Infobutton) Domain, Release 1. | Final | Production | ● ● ● ○ ○ | No | Free | No |
| Implementation Specification | HL7 Version 3 Implementation Guide: Context-Aware Knowledge Retrieval (Infobutton), Release 4. | Final | Production | ● ● ● ○ ○ | No | Free | No |
| Limitations, Dependencies, and Preconditions for Consideration: | | | | Applicable Security Patterns for Consideration: | | | |
| ● Feedback requested | | | | ● Feedback requested | | | |

II-J: Patient Preference/Consent

[See Question 4-9]

Interoperability Need: Recording patient preferences for electronic consent to access and/or share their health information with other care providers

| Type | Standard/Implementation Specification | Standards Process Maturity | Implementation Maturity | Adoption Level | Regulated | Cost | Test Tool Availability |
|--|---|----------------------------|-------------------------|--|-----------|------|------------------------|
| Implementation Specification | IHE Basic Patient Privacy Consents (BPPC) | Final | Production | ● ● ● ● ○ | No | Free | No |
| Implementation Specification | IHE Cross Enterprise User Authorization (XUA) | Final | Production | ● ● ● ● ○ | No | Free | No |
| Limitations, Dependencies, and Preconditions for Consideration: | | | | Applicable Security Patterns for Consideration: | | | |
| ● Feedback requested | | | | <i>IHE would like to note the following:</i> | | | |

| | |
|--|---|
| | <ul style="list-style-type: none"> • Secure Communication – the use of a secure data transport layer for client-to-serve and server-to-server communication. • Secure Association – make secure interaction between two entities such as protecting the session between browser and web server using SSL or TLS and secure emails using encryption and proxies. • Secure Message Router – facilitate secure XML communication with multiple partner endpoints. • Check Point or Security Provider– centralizes authentication and authorization process logic to a “checkpoint” entity or identity service provider. • Credential Synchronizer – securely synchronize credentials and principles across multiple applications using identity provisioning. • Assertion Builder – define how an identity assertion can be built. • User Role - identifies the role asserted by the individual initiating the transaction. • Purpose of Use - Identifies the purpose for the transaction. • Patient Consent Information - Identifies the patient consent information that may be required before data can be accessed. <p>Sources: http://wiki.ihe.net/index.php?title=Basic_Patient_Privacy_Consents http://wiki.ihe.net/index.php?title=Cross-Enterprise_User_Assertion_(XUA) https://en.wikipedia.org/wiki/Security_Patterns Core Security Patterns by Steel, Nagappan and Lai, Prentice Hall PTR</p> |
|--|---|

II-K: Public Health Reporting

| Interoperability Need: Reporting antimicrobial use and resistance information to public health agencies | | | | | | | |
|---|--|----------------------------|-------------------------|--|-----------|------|------------------------|
| Type | Standard/Implementation Specification | Standards Process Maturity | Implementation Maturity | Adoption Level | Regulated | Cost | Test Tool Availability |
| Standard | HL7 Clinical Document Architecture (CDA®), Release 2.0, Final Edition | Final | Production | ●●●●● | No | Free | No |
| Implementation Specification | HL7 Implementation Guide for CDA® Release 2 – Level 3: Healthcare Associated Infection Reports, Release 1, U.S. Realm. | Final | Production | ●●○○○ | No | Free | No |
| Limitations, Dependencies, and Preconditions for Consideration: | | | | Applicable Security Patterns for Consideration: | | | |
| <ul style="list-style-type: none"> • This is a national reporting system to CDC. Stakeholders should refer to implementation guide for additional details and contract information for enrolling in the program. | | | | <ul style="list-style-type: none"> • Feedback requested | | | |

Interoperability Need: Reporting cancer cases to public health agencies

| Type | Standard/Implementation Specification | Standards Process Maturity | Implementation Maturity | Adoption Level | Regulated | Cost | Test Tool Availability |
|---|---|----------------------------|-------------------------|----------------|-----------|------|------------------------|
| Standard | HL7 Clinical Document Architecture (CDA®), Release 2.0, Final Edition | Final | Production | ● ● ● ● ● | No | Free | No |
| Implementation Specification | HL7 Implementation Guide for CDA® Release 2: Reporting to Public Health Cancer Registries from Ambulatory Healthcare Providers, Release 1 - US Realm | Draft | Production | ● ● ● ○ ○ | Yes | Free | Yes |
| Emerging Alternative Implementation Specification | HL7 CDA ® Release 2 Implementation Guide: Reporting to Public Health Cancer Registries from Ambulatory Healthcare Providers, Release 1, DSTU Release 1.1 – US Realm | Draft | Pilot | ● ○ ○ ○ ○ | No | Free | No |

| Limitations, Dependencies, and Preconditions for Consideration: | Applicable Security Patterns for Consideration: |
|---|--|
| <ul style="list-style-type: none"> Stakeholders should refer to the health department in their state or local jurisdiction to determine onboarding procedures, obtain a jurisdictional implementation guide if applicable, and determine which transport methods are acceptable for submitting cancer reporting data as there may be jurisdictional variation or requirements. | <ul style="list-style-type: none"> Feedback requested |

Interoperability Need: Case reporting to public health agencies

| Type | Standard/Implementation Specification | Standards Process Maturity | Implementation Maturity | Adoption Level | Regulated | Cost | Test Tool Availability |
|----------------------------------|---|----------------------------|-------------------------|----------------|-----------|------|------------------------|
| (1) Implementation Specification | IHE Quality, Research, and Public Health Technical Framework Supplement, Structured Data Capture, Trial Implementation, HL7 Consolidated CDA® Release 2.0 | Draft | Pilot | ● ○ ○ ○ ○ | No | Free | No |
| (2) Standard | Fast Healthcare Interoperability Resources (FHIR) | Draft | Pilot | ● ○ ○ ○ ○ | No | Free | No |

| Type | Standard/Implementation Specification | Standards Process Maturity | Implementation Maturity | Adoption Level | Regulated | Cost | Test Tool Availability |
|----------------------------------|--|----------------------------|-------------------------|----------------|-----------|------|------------------------|
| (2) Implementation Specification | Structured Data Capture Implementation Guide | Draft | Pilot | ● ○ ○ ○ ○ | No | Free | No |

| Limitations, Dependencies, and Preconditions for Consideration: | Applicable Security Patterns for Consideration: |
|--|---|
| <ul style="list-style-type: none"> Electronic case reporting is not wide spread and is determined at the state or local jurisdiction. | <ul style="list-style-type: none"> Feedback requested` |

Interoperability Need: Electronic transmission of reportable lab results to public health agencies

| Type | Standard/Implementation Specification | Standards Process Maturity | Implementation Maturity | Adoption Level | Regulated | Cost | Test Tool Availability |
|---|--|----------------------------|-------------------------|----------------|-----------|------|------------------------|
| Standard | HL7 2.5.1 | Final | Production | ● ● ● ● ● | Yes | Free | No |
| Implementation specification | HL7 Version 2.5.1: Implementation Guide: Electronic Laboratory Reporting to Public Health (US Realm), Release 1 with Errata and Clarifications and ELR 2.5.1 Clarification Document for EHR Technology Certification | Final | Production | ● ● ● ● ● | Yes | Free | Yes |
| Emerging Alternative Implementation Specification | HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 2 (US Realm), Draft Standard for Trial Use, Release 1.1 | Draft | Pilot | Unknown | No | Free | No |

| Limitations, Dependencies, and Preconditions for Consideration: | Applicable Security Patterns for Consideration: |
|---|--|
| <ul style="list-style-type: none"> Stakeholders should refer to the health department in their state or local jurisdiction to determine onboarding procedures, obtain a jurisdictional implementation guide if applicable, and determine which transport methods are acceptable for submitting ELR as there may be jurisdictional variation or requirements. | <ul style="list-style-type: none"> Feedback requested |

Interoperability Need: Sending health care survey information to public health agencies

| Type | Standard/Implementation Specification | Standards Process Maturity | Implementation Maturity | Adoption Level | Regulated | Cost | Test Tool Availability |
|------|---------------------------------------|----------------------------|-------------------------|----------------|-----------|------|------------------------|
|------|---------------------------------------|----------------------------|-------------------------|----------------|-----------|------|------------------------|

| Type | Standard/Implementation Specification | Standards Process Maturity | Implementation Maturity | Adoption Level | Regulated | Cost | Test Tool Availability |
|------------------------------|--|----------------------------|-------------------------|----------------|-----------|------|------------------------|
| Standard | HL7 Clinical Document Architecture (CDA®), Release 2.0, Final Edition | Final | Production | ● ● ● ● ● | No | Free | No |
| Implementation Specification | HL7 Implementation Guide for CDA® R2: National Health Care Surveys (NHCS), Release 1 - US Realm [See Question 4-6] | Draft | Pilot | ● ○ ○ ○ ○ | No | Free | No |

| Limitations, Dependencies, and Preconditions for Consideration: | Applicable Security Patterns for Consideration: |
|--|--|
| <ul style="list-style-type: none"> This is a national reporting system to CDC. Stakeholders should refer to the National Health Care Survey Program at: http://www.cdc.gov/nchs/nhcs/how_to_participate.htm for information on participation. | <ul style="list-style-type: none"> Feedback requested |

Interoperability Need: Reporting administered immunizations to immunization registry

| Type | Standard/Implementation Specification | Standards Process Maturity | Implementation Maturity | Adoption Level | Regulated | Cost | Test Tool Availability |
|---|--|----------------------------|-------------------------|----------------|-----------|------|------------------------|
| Standard | HL7 2.5.1 | Final | Production | ● ● ● ● ● | Yes | Free | No |
| Implementation Specification | HL7 2.5.1 Implementation Guide for Immunization Messaging, Release 1.4 | Final | Production | ● ● ● ● ● | Yes | Free | Yes |
| Emerging Alternative Implementation Specification | HL7 2.5.1 Implementation Guide for Immunization Messaging, Release 1.5 | Final | Pilot | ● ○ ○ ○ ○ | No | Free | No |

| Limitations, Dependencies, and Preconditions for Consideration: | Applicable Security Patterns for Consideration: |
|--|--|
| <ul style="list-style-type: none"> Stakeholders should refer to the health department in their state or local jurisdiction to determine onboarding procedures, obtain a jurisdictional implementation guide if applicable, and determine which transport methods are acceptable for submitting immunization registry data as there may be jurisdictional variation or requirements. | <ul style="list-style-type: none"> Feedback requested |

Interoperability Need: Reporting syndromic surveillance to public health (emergency department, inpatient, and urgent care settings)

| Type | Standard/Implementation Specification | Standards Process Maturity | Implementation Maturity | Adoption Level | Regulated | Cost | Test Tool Availability |
|--|---|----------------------------|-------------------------|----------------|-----------|-------------|------------------------|
| Standard | HL7 2.5.1 | Final | Production | ● ● ● ● ● | Yes | Free | No |
| Implementation Specification | PHIN Messaging Guide for Syndromic Surveillance: Emergency Department and Urgent Care Data Release 1.1 | Final | Production | ● ● ● ● ○ | Yes | Free | Yes |
| <i>Emerging Alternative Implementation Specification</i> | PHIN Messaging Guide for Syndromic Surveillance: Emergency Department, Urgent Care, Inpatient and Ambulatory Care Settings, Release 2.0 | <i>Final</i> | <i>Pilot</i> | ● ○ ○ ○ ○ | <i>No</i> | <i>Free</i> | <i>No</i> |

| Limitations, Dependencies, and Preconditions for Consideration: | Applicable Security Patterns for Consideration: |
|---|--|
| <ul style="list-style-type: none"> Stakeholders should refer to the health department in their state or local jurisdiction to determine onboarding procedures, obtain a jurisdictional implementation guide if applicable, and determine which transport methods are acceptable for submitting syndromic surveillance data as there may be jurisdictional variation or requirements. | <ul style="list-style-type: none"> Feedback requested |

II-L: Quality Reporting

Interoperability Need: Reporting aggregate quality data to quality reporting initiatives

| Type | Standard/Implementation Specification | Standards Process Maturity | Implementation Maturity | Adoption Level | Regulated | Cost | Test Tool Availability |
|------------------------------|---|----------------------------|-------------------------|----------------|-----------|------|------------------------|
| Standard | HL7 Clinical Document Architecture (CDA®), Release 2.0, Final Edition | Final | Production | ● ● ● ● ● | No | Free | No |
| Implementation Specification | HL7 Implementation Guide for CDA® Release 2: Quality Reporting Document Architecture - Category III (QRDA III), DRAFT Release 1 | Draft | Production | ● ● ● ● ○ | Yes | Free | Yes |

| Limitations, Dependencies, and Preconditions for Consideration: | Applicable Security Patterns for Consideration: |
|--|--|
| <ul style="list-style-type: none"> Feedback requested | <ul style="list-style-type: none"> Feedback requested |

Interoperability Need: Reporting patient-level quality data to quality reporting initiatives

| Type | Standard/Implementation Specification | Standards Process Maturity | Implementation Maturity | Adoption Level | Regulated | Cost | Test Tool Availability |
|----------|---|----------------------------|-------------------------|----------------|-----------|------|------------------------|
| Standard | HL7 Clinical Document Architecture (CDA®), Release 2.0, Final Edition | Final | Production | ● ● ● ● ● | No | Free | No |

| Type | Standard/Implementation Specification | Standards Process Maturity | Implementation Maturity | Adoption Level | Regulated | Cost | Test Tool Availability |
|--|--|--|-------------------------|----------------|-----------|------|------------------------|
| Implementation Specification | HL7 Implementation Guide for CDA® Release 2: Quality Reporting Document Architecture – Category I, DSTU Release 2 (US Realm) | Draft | Production | ●●●●○ | Yes | Free | Yes |
| Emerging Alternative Implementation Specification | HL7 CDA® R2 Implementation Guide: Quality Reporting Document Architecture - Category I (QRDA I) DSTU Release 3 (US Realm) | Draft | Pilot | ●○○○○○ | Yes | Free | Yes |
| Limitations, Dependencies, and Preconditions for Consideration: | | Applicable Security Patterns for Consideration: | | | | | |
| ● Feedback requested | | ● Feedback requested | | | | | |

II-M: Representing clinical health information as a “resource”

| Interoperability Need: Representing clinical health information as “resource” | | | | | | | |
|---|---|--|-------------------------|----------------|-----------|------|------------------------|
| Type | Standard/Implementation Specification | Standards Process Maturity | Implementation Maturity | Adoption Level | Regulated | Cost | Test Tool Availability |
| Standard | Fast Healthcare Interoperability Resources (FHIR) | Draft | Pilot | ●○○○○○ | No | Free | No |
| Limitations, Dependencies, and Preconditions for Consideration: | | Applicable Security Patterns for Consideration: | | | | | |
| ● Feedback requested | | ● Feedback requested | | | | | |

II-N: Segmentation of sensitive information

| Interoperability Need: Document-level segmentation of sensitive information | | | | | | | |
|---|--|--|-------------------------|----------------|-----------|------|------------------------|
| Type | Standard/Implementation Specification | Standards Process Maturity | Implementation Maturity | Adoption Level | Regulated | Cost | Test Tool Availability |
| Standard | HL7 Clinical Document Architecture (CDA®), Release 2.0, Final Edition | Final | Production | ●●●●● | No | Free | No |
| Implementation Specification | Consolidated HL7 Implementation Guide: Data Segmentation for Privacy (DS4P), Release 1 | Final | Pilot | ●○○○○○ | No | Free | No |
| Limitations, Dependencies, and Preconditions for Consideration: | | Applicable Security Patterns for Consideration: | | | | | |
| ● Feedback requested | | ● Feedback requested | | | | | |

| Interoperability Need: Support a transition of care or referral to another provider | | | | | | | |
|---|--|----------------------------|-------------------------|--|-----------|------|------------------------|
| Type | Standard/Implementation Specification | Standards Process Maturity | Implementation Maturity | Adoption Level | Regulated | Cost | Test Tool Availability |
| Standard | HL7 Clinical Document Architecture (CDA®), Release 2.0, Final Edition | Final | Production | ●●●●● | No | Free | No |
| Implementation Specification | Consolidated CDA® Release 1.1 (HL7 Implementation Guide for CDA® Release 2: IHE Health Story Consolidation, DSTU Release 1.1 - US Realm) | Draft | Production | ●●●●● | Yes | Free | Yes |
| Emerging Alternative Implementation Specification | HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes (US Realm), Draft Standard for Trial Use, Release 2.1 | Draft | Pilot | Unknown | No | Free | No |
| Limitations, Dependencies, and Preconditions for Consideration: | | | | Applicable Security Patterns for Consideration: | | | |
| <ul style="list-style-type: none"> There are several specific document templates within the C-CDA implementation specification. Trading partners will need to ensure that their systems are capable of supporting specific document templates. | | | | <ul style="list-style-type: none"> Feedback requested | | | |

Section III: Best Available Standards and Implementation Specifications for Services

[See Question 4-10]

III-A: An unsolicited “push” of clinical health information to a known destination

[See Question 4-3]

| Interoperability Need: An unsolicited “push” of clinical health information to a known destination between individuals | | | | | | | |
|--|---|----------------------------|-------------------------|----------------|-----------|------|------------------------|
| Type | Standard/Implementation Specification | Standards Process Maturity | Implementation Maturity | Adoption Level | Regulated | Cost | Test Tool Availability |
| Standard | Applicability Statement for Secure Health Transport v1.1 (“Direct”) | Final | Production | ●●●●● | Yes | Free | Yes |
| Emerging Alternative Standard | Applicability Statement for Secure Health Transport v1.2 | Final | Pilot | ●○○○○ | No | Free | No |

| Type | Standard/Implementation Specification | Standards Process Maturity | Implementation Maturity | Adoption Level | Regulated | Cost | Test Tool Availability |
|--------------------------------------|---|----------------------------|-------------------------|----------------|-----------|-------------|------------------------|
| Implementation Specification | XDR and XDM for Direct Messaging Specification | Final | Production | ●●●●○ | Yes | Free | Yes |
| Implementation Specification | IG for Direct Edge Protocols | Final | Production | ●●○○○ | Yes | Free | Yes |
| Implementation Specification | IG for Delivery Notification in Direct | Final | Production | ●●●○○ | No | Free | No |
| <i>Emerging Alternative Standard</i> | Fast Healthcare Interoperability Resources (FHIR) | <i>Draft</i> | <i>Pilot</i> | ●○○○○ | <i>No</i> | <i>Free</i> | <i>No</i> |

| Limitations, Dependencies, and Preconditions for Consideration: | Applicable Security Patterns for Consideration: |
|--|---|
| <ul style="list-style-type: none"> “Direct” standard is based upon the underlying standard: Simple Mail Transfer Protocol (SMTP) RFC 5321 and for security uses Secure/Multipurpose Internet Mail Extensions (S/MIME) Version 3.2 Message Specification, RFC 5751. For Direct, interoperability may be dependent on the establishment of “trust” between two parties and may vary based on the trust community(ies) to which parties belong. <i>IHE suggests that ONC encourage or foster efforts to map existing standards in broad use to new emerging standards.</i> | <ul style="list-style-type: none"> System Authentication - The information and process necessary to authenticate the systems involved Recipient Encryption - the message and health information are encrypted for the intended user Sender Signature – details that are necessary to identity of the individual sending the message |

Interoperability Need: An unsolicited “push” of clinical health information to a known destination between systems

| Type | Standard/Implementation Specification | Standards Process Maturity | Implementation Maturity | Adoption Level | Regulated | Cost | Test Tool Availability |
|------------------------------|--|----------------------------|-------------------------|----------------|-----------|------|------------------------|
| Standard | SOAP-Based Secure Transport Requirements Traceability Matrix (RTM) version 1.0 specification | Final | Production | ●●●○○ | Yes | Free | Yes |
| Implementation Specification | IHE-XDR (Cross-Enterprise Document Reliable Interchange) | Final | Production | ●●●●○ | No | Free | No |

| | | | | | | | |
|-------------------------------------|--|-------|------------|-----------|----|------|----|
| Implementation Specification | NwHIN Specification: Authorization Framework | Final | Production | ● ● ● ○ ○ | No | Free | No |
| Implementation Specification | NwHIN Specification: Messaging Platform | Final | Production | ● ● ● ○ ○ | No | Free | No |

| | | | | | | | |
|---|--|--|--|--|--|--|--|
| Limitations, Dependencies, and Preconditions for Consideration: | | | | Applicable Security Patterns for Consideration: | | | |
| <ul style="list-style-type: none"> The IHE-XDR implementation specification is based upon the underlying standards: SOAP v2, and OASIS ebXML Registry Services 3.0 The NwHIN Specification: Authorization Framework implementation specification is based upon the underlying standards: SAML v1.2, XSPAv1.0, and WS-1.1. <i>IHE recommends using the ConCert by HIMSS™ certification program for testing the IHE-XDR implementation specification. Test tool availability should be changed to 'Yes'.</i> | | | | <ul style="list-style-type: none"> System Authentication - The information and process necessary to authenticate the systems involved Purpose of Use - Identifies the purpose for the transaction Patient Consent Information - Identifies the patient consent information that may be required before data can be accessed. | | | |

III-B: Clinical Decision Support Services

Interoperability Need: Providing patient-specific assessments and recommendations based on patient data for clinical decision support

| Type | Standard/Implementation Specification | Standards Process Maturity | Implementation Maturity | Adoption Level | Regulated | Cost | Test Tool Availability |
|------------------------------|---|----------------------------|-------------------------|----------------|-----------|------|------------------------|
| Standard | HL7 Version 3 Standard: Decision Support Service, Release 2. | Draft | Pilot | ● ○ ○ ○ ○ | No | Free | No |
| Implementation Specification | HL7 Implementation Guide: Decision Support Service, Release 1.1, US Realm, Draft Standard for Trial Use | Draft | Pilot | ● ○ ○ ○ ○ | No | Free | No |

| | | | | | | | |
|--|--|--|--|--|--|--|--|
| Limitations, Dependencies, and Preconditions for Consideration: | | | | Applicable Security Patterns for Consideration: | | | |
| <ul style="list-style-type: none"> Feedback requested | | | | <ul style="list-style-type: none"> Feedback requested | | | |

Interoperability Need: 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

| Type | Standard/Implementation Specification | Standards Process Maturity | Implementation Maturity | Adoption Level | Regulated | Cost | Test Tool Availability |
|------|---------------------------------------|----------------------------|-------------------------|----------------|-----------|------|------------------------|
|------|---------------------------------------|----------------------------|-------------------------|----------------|-----------|------|------------------------|

| Type | Standard/Implementation Specification | Standards Process Maturity | Implementation Maturity | Adoption Level | Regulated | Cost | Test Tool Availability |
|--|--|----------------------------|-------------------------|--|-----------|------|------------------------|
| Standard | HL7 Version 3 Standard: Context Aware Knowledge Retrieval Application. (“Infobutton”), Knowledge Request, Release 2. | Final | Production | ●●●○○ | Yes | Free | No |
| Implementation Specification | HL7 Implementation Guide: Service-Oriented Architecture Implementations of the Context-aware Knowledge Retrieval (Infobutton) Domain, Release 1. | Final | Production | ●●●●○ | No | Free | No |
| Implementation Specification | HL7 Version 3 Implementation Guide: Context-Aware Knowledge Retrieval (Infobutton), Release 4. | Final | Production | ●●●●○ | No | Free | No |
| Limitations, Dependencies, and Preconditions for Consideration: | | | | Applicable Security Patterns for Consideration: | | | |
| <ul style="list-style-type: none"> Feedback requested | | | | <ul style="list-style-type: none"> Feedback requested | | | |

III-C: Image Exchange

| Interoperability Need: Exchanging imaging documents among a group of affiliated entities | | | | | | | |
|---|--|----------------------------|-------------------------|--|-----------|------|------------------------|
| Type | Standard/Implementation Specification | Standards Process Maturity | Implementation Maturity | Adoption Level | Regulated | Cost | Test Tool Availability |
| Implementation Specification | IHE Cross Enterprise Document Sharing for Images (XDS-I) | Draft | Pilot | ●○○○○ | No | Free | No |
| Limitations, Dependencies, and Preconditions for Consideration: | | | | Applicable Security Patterns for Consideration: | | | |
| <ul style="list-style-type: none"> IHE recommends using XDS-I.b, XCA-I, XDS-I, XCPD, XDM and XDR. ONC may also want to consider adding MHD-I. IHE suggests that this implementation specification inherit the same IHE PIX and/or PDQ dependencies as XDS in Section III-F. <ul style="list-style-type: none"> IHE-PIX and IHE-PDQ are used for the purposes of patient matching and to support this interoperability need. IHE also notes that XDS-I is a final text profile with a higher adoption level (3 out of 5) and NIST tooling is currently available. | | | | <p>IHE would like to note the following:</p> <ul style="list-style-type: none"> Secure Message Router – facilitate secure XML communication with multiple partner endpoints. Check Point or Security Provider– centralizes authentication and authorization process logic to a “checkpoint” entity or identity service provider. Credential Synchronizer – securely synchronize credentials and principles across multiple applications using identity provisioning. <p>Source: http://wiki.ihe.net/index.php?title=Cross-Enterprise_Document_Sharing</p> | | | |

III-D: Provider Directory

| Interoperability Need: Listing of providers for access by potential exchange partners | | | | | | | |
|---|---|----------------------------|-------------------------|---|-----------|------|------------------------|
| Type | Standard/Implementation Specification | Standards Process Maturity | Implementation Maturity | Adoption Level | Regulated | Cost | Test Tool Availability |
| Implementation Specification | IHE IT Infrastructure Technical Framework Supplement, Healthcare Provider Directory (HPD), Trial Implementation | Draft | Pilot | ● ○ ○ ○ ○ | No | Free | Yes |
| Limitations, Dependencies, and Preconditions for Consideration: | | | | Applicable Security Patterns for Consideration: | | | |
| <ul style="list-style-type: none"> Feedback requested | | | | <p><i>IHE would like to note the following security patterns:</i></p> <ul style="list-style-type: none"> Secure Message Router – facilitate secure XML communication with multiple partner endpoints. Check Point or Security Provider– centralizes authentication and authorization process logic to a “checkpoint” entity or identity service provider. Credential Synchronizer – securely synchronize credentials and principles across multiple applications using identity provisioning. User Details - identifies the end user who is accessing the data. User Role - identifies the role asserted by the individual initiating the transaction. <p>Source: http://wiki.ihe.net/index.php?title=Healthcare_Provider_Directory</p> | | | |

III-E: Publish and Subscribe

| Interoperability Need: Publish and subscribe message exchange | | | | | | | |
|--|--|----------------------------|-------------------------|--|-----------|------|------------------------|
| Type | Standard/Implementation Specification | Standards Process Maturity | Implementation Maturity | Adoption Level | Regulated | Cost | Test Tool Availability |
| Implementation Specification | NwHIN Specification: Health Information Event Messaging Production Specification | Final | Production | ● ● ● ○ ○ | No | Free | No |
| Emerging Alternative Implementation Specification | IHE Document Metadata Subscription (DSUB), Trial Implementation | Draft | Pilot | ● ○ ○ ○ ○ | No | Free | No |
| Limitations, Dependencies, and Preconditions for Consideration: | | | | Applicable Security Patterns for Consideration: | | | |
| <ul style="list-style-type: none"> Feedback requested | | | | <ul style="list-style-type: none"> Feedback requested | | | |

III-F: Query

| Interoperability Need: Query for documents within a specific health information exchange domain | | | | | | | |
|---|--|----------------------------|-------------------------|---|-----------|-------------|------------------------|
| Type | Standard/Implementation Specification | Standards Process Maturity | Implementation Maturity | Adoption Level | Regulated | Cost | Test Tool Availability |
| Implementation Specification | IHE-XDS (Cross-enterprise document sharing) | Final | Production | ●●●●○ | No | Free | No |
| Implementation Specification | IHE-PDQ (Patient Demographic Query) | Final | Production | ●●●●○ | No | Free | No |
| Implementation Specification | IHE-PIX (Patient Identifier Cross-Reference) | Final | Production | ●●●●○ | No | Free | No |
| <i>Emerging Alternative Implementation Specification</i> | <i>IHE – MHD (Mobile Access to Health Documents)</i> | <i>Draft</i> | <i>Pilot</i> | ●○○○○ | <i>No</i> | <i>Free</i> | <i>No</i> |
| Limitations, Dependencies, and Preconditions for Consideration: | | | | Applicable Security Patterns for Consideration: | | | |
| <ul style="list-style-type: none"> IHE-PIX and IHE-PDQ are used for the purposes of patient matching and to support this interoperability need. IHE recommends using the ConCert by HIMSS™ certification program for testing the IHE-XDS, IHE-PDQ and IHE-PIX implementation specifications. Test tool availability should be changed to Yes. | | | | <p><i>IHE would like to note the following:</i></p> <ul style="list-style-type: none"> Secure Communication – the use of a secure data transport layer for client-to-server and server-to-server communication. Secure Association – make secure interaction between two entities such as protecting the session between browser and web server using SSL or TLS and secure emails using encryption and proxies. Secure Message Router – facilitate secure XML communication with multiple partner endpoints. Check Point or Security Provider– centralizes authentication and authorization process logic to a “checkpoint” entity or identity service provider. Credential Synchronizer – securely synchronize credentials and principles across multiple applications using identity provisioning. Message Interceptor Gateway – provide a single entry point solution for centralization of security enforcement for incoming and outgoing XML Web Service messages. <p>Sources: http://wiki.ihe.net/index.php?title=Cross-Enterprise_Document_Sharing http://wiki.ihe.net/index.php?title=Patient_Demographics_Query http://wiki.ihe.net/index.php?title=Patient_Identifier_Cross-Referencing</p> | | | |

Interoperability Need: Query for documents outside a specific health information exchange domain

| Type | Standard/Implementation Specification | Standards Process Maturity | Implementation Maturity | Adoption Level | Regulated | Cost | Test Tool Availability |
|-------------------------------|--|----------------------------|-------------------------|----------------|-----------|------|------------------------|
| Implementation Specifications | the combination of IHE-XCPD (Cross-Community Patient Discovery) and IHE-PIX (Patient Identifier Cross-Reference) | Final | Production | ● ● ● ● ○ | No | Free | No |
| Implementation Specification | NwHIN Specification: Patient Discovery | Final | Production | ● ● ● ○ ○ | No | Free | No |
| Implementation Specifications | IHE-XCA (Cross-Community Access) further constrained by eHealth Exchange Query for Documents v 3.0 | Final | Production | ● ● ● ● ○ | No | Free | No |
| Implementation Specification | NwHIN Specification: Query for Documents | Final | Production | ● ● ● ○ ○ | No | Free | No |
| Implementation Specification | NwHIN Specification: Retrieve Documents | Final | Production | ● ● ● ○ ○ | No | Free | No |

| Limitations, Dependencies, and Preconditions for Consideration: | Applicable Security Patterns for Consideration: |
|---|--|
| <ul style="list-style-type: none"> IHE-PIX and IHE-XCPD are used for the purposes of patient matching and to support this interoperability need. <i>IHE suggests that support for the standards and/or implementation specification identified in Section III-G, would facilitate a discovery of the anticipated dynamic configuration environment.</i> | <ul style="list-style-type: none"> System Authentication - The information and process necessary to authenticate the systems involved User Details - identifies the end user who is accessing the data User Role - identifies the role asserted by the individual initiating the transaction Purpose of Use - Identifies the purpose for the transaction Patient Consent Information - Identifies the patient consent information that may be required before data can be accessed. Query Request ID - Query requesting application assigns a unique identifier for each query request in order to match the response to the original query. |

Interoperability Need: Data element based query for clinical health information

| Type | Standard/Implementation Specification | Standards Process Maturity | Implementation Maturity | Adoption Level | Regulated | Cost | Test Tool Availability |
|------|---------------------------------------|----------------------------|-------------------------|----------------|-----------|------|------------------------|
|------|---------------------------------------|----------------------------|-------------------------|----------------|-----------|------|------------------------|

| Type | Standard/Implementation Specification | Standards Process Maturity | Implementation Maturity | Adoption Level | Regulated | Cost | Test Tool Availability |
|--|---|----------------------------|-------------------------|--|-----------|------|------------------------|
| Standard | Fast Healthcare Interoperability Resources (FHIR) | Draft | Pilot | ● ○ ○ ○ ○ | No | Free | No |
| Limitations, Dependencies, and Preconditions for Consideration: | | | | Applicable Security Patterns for Consideration: | | | |
| <ul style="list-style-type: none"> Feedback requested | | | | <ul style="list-style-type: none"> System Authentication - The information and process necessary to authenticate the systems involved User Details - identifies the end user who is accessing the data User Role - identifies the role asserted by the individual initiating the transaction Purpose of Use - Identifies the purpose for the transaction Patient Consent Information - Identifies the patient consent information that may be required before data can be accessed. Query Request ID - Query requesting application assigns a unique identifier for each query request in order to match the response to the original query. | | | |

III-G: Resource Location

| Interoperability Need: Resource location within the US | | | | | | | |
|--|---|----------------------------|-------------------------|--|-----------|------|------------------------|
| Type | Standard/Implementation Specification | Standards Process Maturity | Implementation Maturity | Adoption Level | Regulated | Cost | Test Tool Availability |
| Implementation Specification | IHE IT Infrastructure Technical Framework Supplement, Care Services Discovery (CSD), Trial Implementation | Draft | Pilot | ● ○ ○ ○ ○ | No | Free | No |
| Limitations, Dependencies, and Preconditions for Consideration: | | | | Applicable Security Patterns for Consideration: | | | |
| <ul style="list-style-type: none"> Feedback requested | | | | <ul style="list-style-type: none"> Feedback requested | | | |

Section IV: Questions and Requests for Stakeholder Feedback

Similar to the 2015 Advisory, this draft gives stakeholders a body of work from which to react in order to prompt continued dialogue to improve the Advisory. As stated in the Introduction, this draft 2016 Advisory will continue to be refined during the public comment period. Additionally, because this draft includes both new structural and content sections please note that content for many of the new structural subsections is intentionally incomplete. Those sections that are more fully populated were done so to give the public an early opportunity to weigh in on and react to perceived value that these subsections could provide. Your feedback is critical to improve and refine these new subsections. Please visit <http://www.healthit.gov/standards-advisory> to provide your comments and suggestions.

General

- 4-1. In the 2015 Advisory, each standard and implementation specification was listed under a “purpose.” Prior public comments and HIT Standards Committee [recommendations](#) suggested that the Advisory should convey a clearer link to the ways in which standards need to support business and functional requirements. This draft attempts to do so and lists standards and implementation specifications under more descriptive “interoperability needs.” Please provide feedback on whether revision from “purpose” to “interoperability need” provides the additional requested context and suggestions for how to continue to improve this portion.
- *IHE is supportive of this change as it provides the reader with a clearer understanding and linkage between the need and the standards and implementation specifications that can fulfill the interoperability need.*
 - *IHE notes that in terms of guidance provided in a Standards Advisory document, the shift to this new labeling helps to identify the specific problem that the solution is targeting to address. The term “purpose” may set the high level business need, but leaves the opportunity for interpretation and variability by the reader when associating this need with the specific specification entry.*
- 4-2. For each standard and implementation specification there are six assessment characteristics. Please review the information provided in each of these tables and check for accuracy. Also, please help complete any missing or “unknown” information.
- *IHE notes that there are a number of rows in Section II and III where IHE Profiles are applicable and should be minimally identified as an “emerging alternative implementation specification.” Also, there are inconsistencies with the use of the “IHE” prefix with one of its profiles.*
 - *In addition, IHE has included comments to the specific rows in Section III where the Concert by HIMSS™ program is applicable as providing a test tool in 2016. In this regard, there are other test tools targeted for use by the IHE International Conformity Assessment program planned for launch in 2016 which could change a “no” to “yes” in the Test Tool column.*
- 4-3. For each standard and implementation specifications, there is a table that lists security patterns. This draft only includes select examples for how this section would be populated in the future. Please review examples found in Sections III-A and III-F and provide feedback as to the usefulness of this approach and any information you know for a specific interoperability need.
- *IHE notes that the title of “Applicable Security Patterns for Consideration” implies that the reader may or may not have to support one or more of these security requirements to accomplish the implementation solution. The various entries in the sample rows also reflect requirements that span different levels of the security stack as well as aspects of access controls metadata. IHE suggests that this section could be improved if it would reflect mandatory transactional*

requirements for completing a “typical” secure exchange and clearly differentiate between security requirements and privacy/access control considerations.

- 4-4. For each interoperability need, there is a table beneath the standards and implementation specifications that includes limitations, dependencies, and preconditions. This draft only includes select examples for how this section would be populated in the future. Please review populated sections and provide feedback as to the usefulness of this approach and any specific information you know for a specific interoperability need.
- *IHE is supportive of this new layout as it provides much needed direction about how to address the interoperability needs that currently impact the health IT industry.*
 - *IHE notes that entries in this table are critical to the usability of the Advisory for actual deployment initiatives intending to leverage the listed standards.*

Section I: Vocabulary/Code Set

- 4-5. Based on public feedback and HIT Standards Committee review, there does not appear to be a best available standard for several “interoperability needs” expressed in this section of the draft Advisory. Please provide feedback on whether this is correct or recommend a standard (and your accompanying rationale).

Section II: Content / Structure

- 4-6. Should more generalized survey instruments such as the IHE Profile Retrieve Form for Data Capture be considered?
- *IHE suggests that more generalized survey instruments be considered.*
 - *IHE Retrieve Form for Data Capture Profile (RFD) provides a generic polling mechanism to allow an external agency to indicate issues with data that have been captured to enable the healthcare provider to correct the data. When IHE RFD is used as an infrastructure profile that integrates with domain-specific standards, it can realize a much greater level of interoperability. Also, IHE RFD is included in the 2015 Edition Health IT Certification Criteria.*
 - *Sources:*
 - o http://wiki.ihe.net/index.php?title=Retrieve_Form_for_Data_Capture
 - o <http://www.iheusa.org/learnmore.aspx>
- 4-7. In addition to the two interoperability needs already listed, are there others that should be included related to imaging? If so, what would the best available standard and/or implementation specifications be?
- *IHE encourages the use of the IHE Radiology domain’s suite of profiles pertinent to the full Scheduled Work Flow (SWF) for image and report exchange within a healthcare enterprise. In addition, a new IHE profile entitled Guideline Appropriate Ordering (GAO) developed by the Patient Care Coordination domain should be listed as an emerging alternative implementation specification.*
- 4-8. Should a more specific/precise aspect of DICOM be referenced for the implementation specification for this interoperability need?
- *IHE recommends that a more specific aspect of DICOM be referenced.*

- *DICOM enables the integration of scanners, servers, workstations, printers, and network hardware from multiple manufacturers into a picture archiving and communication system (PACS). DICOM has been widely adopted by hospitals and is making inroads in smaller practices such as dentist and physician offices.*
- *The health IT community can compare two vendors' DICOM conformance statements to determine if two devices can interoperate – vendors can achieve interoperability by following the implementation specification that ONC recommends.*
- *NOTE: IHE Cross-enterprise Document Sharing for Imaging (XDS-I.b) extends XDS to share images, diagnostic reports and related information across a group of care sites.*
- *Sources:*
 - o <https://en.wikipedia.org/wiki/DICOM>
 - o [http://wiki.ihe.net/index.php?title=Cross-enterprise Document Sharing for Imaging](http://wiki.ihe.net/index.php?title=Cross-enterprise_Document_Sharing_for_Imaging)

4-9. The HIT Standards Committee recommended to ONC that clearer implementation guidance is required. Are there additional implementation specifications that should be considered for this interoperability need?

- *IHE agrees with the HIT Standards Committee.*
- *Additionally, it is prudent to ensure recommendation consistency across all implementation guidance and to ensure that relevant implementation guides include the appropriate clinical data elements and code sets. IHE also suggests commissioning companion guides to clarify implementation guidance as needed.*

Section III: Services

4-10. The 2015 Advisory's Section III, Transport has since been removed with content representation migrated as applicable within Section IV Services. What is your view of this approach?

- *IHE agrees with this approach, as Transport is a more general term applying to a wide variety of different interoperability environments. This term is appropriate when making a binary segmentation between "transport" and "content" but for a Standards Advisory document, the more granular specification categorization is better.*

Appendix II: Sources of Security Standards

4-11. Are there other authoritative sources for Security Standards that should be included in Appendix II? Please see IHE's additions and suggestions below.

Appendix II – Sources of Security Standards

[See Question 4-11]

In this draft Advisory, a structure to capture necessary security patterns associated with interoperability needs is represented (see Section III-A and III-F for examples, and related Question 4-3). To address public comments that requested a distinct security standards section the list below provides a number of sources to which stakeholders can look in order to find the latest applicable security standards. Note that this list is not meant to be exhaustive.

- ASTM: <http://www.astm.org/Standards/computerized-system-standards.html>
- International Organization for Standardization (ISO) Information Security Standards: <http://www.27000.org/>
 - *More specifically change this to be International Organization for Standardization (ISO) Information Security Standards, ISO/IEC 27000-series.*
- National Institute for Standards and Technology (NIST) Special Publications 800 Series: <http://csrc.nist.gov/publications/PubsSPs.html>
- NIST's Federal Information Processing Standard (FIPS): <http://www.nist.gov/itl/fipscurrent.cfm>

IHE encourages ONC to consider adding the following resources:

- ISO IT Security techniques – evaluation criteria for IT security, ISO/EC 15408 series: <http://standards.iso.org/ittf/PubliclyAvailableStandards/index.html>
- **NIST Special Publication: 800-63-2.** Electronic Authentication Guideline. August 2013. <http://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.800-63-2.pdf>
- **FIPS PUB 202.** SHA-3 Standard: Permutation-Based Hash and Extendable-Output Functions. August 2015. <http://dx.doi.org/10.6028/NIST.FIPS.202>
- **NIST SP 1800-a-e.** Securing Electronic Health Records on Mobile Devices. July 2015. https://nccoe.nist.gov/sites/default/files/nccoe/NIST_SP1800-1a_Draft_HIT_Mobile-ExecSummary.pdf **and** <https://nccoe.nist.gov/library/nist-sp-1800-1a-e-securing-ehrs-mobile-devices-all-volumes-plus-template-and-manifest-files>.
- **Fair Information Practice Principles (FIPPs).** <http://www.nist.gov/nstic/NSTIC-FIPPs.pdf>