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November 6, 2015

Karen DeSalvo, MD, MPH, MSc
National Coordinator for Health Information Technology
Acting Assistant Secretary for Health
U.S. Department of Health and Human Services

Dear Dr. DeSalvo,

We are pleased to provide comments on the Office of the National Coordinator for Health IT (ONC) Draft 2016 Interoperability Standards Advisory (ISA) on behalf of more than 30 members of the Electronic Health Record Association (EHRA), who serve the majority of hospitals and ambulatory care providers across the US who are using EHRs to provide more effective, efficient care to their patients.

First of all, we appreciate that the ISA expresses the standards and interoperability specifications in the context of clearly-defined use cases and interoperability needs. However, the EHRA sees the need for further clarification and specificity to better evaluate the appropriateness of some proposed standards or implementation specifications, particularly as some might need to be split into more discrete descriptions of the market and user needs. Similarly for vocabulary, it is important to not only state the interoperability need, but to also specifically define the subset of terminology rather than just the larger code system (e.g., SNOMED).

The EHRA supports the introduction of the characteristics to assess appropriateness and readiness of standards or implementation specifications. However, some definitions and application of characteristics require further work to provide "apples to apples" comparisons (e.g., Standards Process Maturity), understand the source of the estimates (e.g., Adoption Level), and reference availability of test tools that are explicitly open source. Relative to standards maturity, five levels for Adoption Level appear to be too granular. We suggest that there should be only three levels: early, limited, and widely adopted.

Regarding security and privacy, the applicable pattern section is unclear as to objectives and usage. The EHRA suggests removing these sections until more specificity is available.

While the ISA is helpful in describing a current state of the standards and implementation specifications, it remains unclear how the ISA will be promoted for use in actual deployments, and how the ISA is intended to contribute to the national interoperability roadmap by providing a forward looking path that indicates when a standard or implementation specification may be ready for national adoption

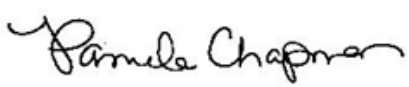
The EHR Association looks forward to working with ONC and other stakeholders to continue to move forward toward achieving our sharing objectives for broader, more standards-based interoperability.

Sincerely,

Leigh Burchell
Chair, EHR Association
Allscripts

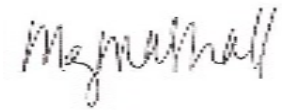
Sarah Corley, MD
Vice Chair, EHR Association
NextGen Healthcare

HIMSS EHR Association Executive Committee



Pamela Chapman
e-MDs

Richard Loomis, MD
Practice Fusion



Meg Marshall, JD
Cerner Corporation

Rick Reeves, RPh
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Ginny Meadows, RN
McKesson Corporation

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Epic

About the EHR Association

Established in 2004, the Electronic Health Record (EHR) Association is comprised of over 30 companies that supply the vast majority of EHRs to physicians' practices and hospitals across the United States. The EHR Association operates on the premise that the rapid, widespread adoption of EHRs will help improve the quality of patient care as well as the productivity and sustainability of the healthcare system as a key enabler of healthcare transformation. The EHR Association and its members are committed to supporting safe healthcare delivery, fostering continued innovation, and operating with high integrity in the market for our users and their patients and families.

The EHR Association is a partner of HIMSS. For more information, visit www.ehrassociation.org.

CC:
Steve Posnack, Director, Office of Standards and Technology, ONC

Detailed EHRA Comments

Interoperability need: [Descriptive Text]

Standard/ Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Standard	Final	Production	●●●●○	Yes	Free	Yes
Emerging Alternative Standard	*Draft*	*Pilot*	●○○○○	*No*	*Free*	*No*

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
● Descriptive text with "(recommended by the HIT Standards Committee)" included in cases where the HIT Standards Committee recommended the text, and on which public feedback is sought.	● Descriptive text

EHRA Comments:

EHRA suggests that while in this version of the Advisory, this description of dependencies is acceptable, there need to be more explicit links when there are required dependencies across sections.

The following describes the six characteristics that were added to the Advisory in detail in order to better inform stakeholders about the maturity and adoptability of a given standard or implementation specification and provides definitions for the terms and symbols used throughout the Advisory.

#1: Standards Process Maturity

This characteristic conveys a standard or implementation specification's maturity in terms of its stage within a particular organization's approval/voting process.

- *"Final"* – when this designation is assigned, the standard or implementation specification is considered "final text" or "normative" by the organization that maintains it.
- *"Draft"* – when this designation is assigned, the standard or implementation specification is considered to be a Draft Standard for Trial Use (DSTU) or in a "trial implementation" status by the organization that maintains it.

EHRA Comments:

While we agree that this is a helpful dimension to consider, the current use of "final" and "draft" does not very well reflect the real maturity of a standard relative to the standards process it is going through. For example, C-CDA 2.1 is marked as "draft" while Direct is marked as "final". One can reasonably argue that both standards are equally mature or immature in their documentation in the standards process. However, one process uses the marker of DSTU (thus "draft" sounds appropriate), while the other does not have that process. EHRA suggests adjusting it so it can reflect better the stability of the publication:

- *Draft: the official publication under the referenced edition/version is still subject to changes based on early implementer's feedback*
- *Final: the official publication under the referenced edition/version has reached a level of stability for a few years and only errors may be addressed by changes*

Draft or Final must have a meaning specific to this ISA and have to be mapped appropriately given the policies of the source of the standard or implementation specification.

#2: Implementation Maturity

This characteristic conveys a standard or implementation specification's maturity based on its implementation state.

- *"Production"* – when this designation is assigned, the standard or implementation specification is being used in production to meet a health care interoperability need.
- *"Pilot"* – when this designation is assigned, the standard or implementation specification is being used at limited scale or only as part of pilots to meet a health care interoperability need.

#3: Adoption Level

This characteristic conveys a standard or implementation specification's approximate level of adoption in health care. The following scale is used:

- "*Unknown*" – indicates no known status for the current level of adoption in health care.
- ●○○○○ indicates 0% to 20% adoption.
- ●●○○○ indicates 21% to 40% adoption.
- ●●●○○ indicates 41% to 60% adoption.
- ●●●●○ indicates 61% to 80% adoption.
- ●●●●● indicates 81% to 100% adoption.

EHRA Comments:

EHRA agrees that this measure has value as we evolve the standards advisory. However, the challenge is to define the denominator that applies to this measure. EHRA suggests the following less granular definitions, which we think can be better supported by available data and provide the needed guidance to the industry:

1. *Still being defined. Not yet being incorporated into HIT products.*
2. *Early adoption. Incorporated in some HIT products, preliminary pilots with healthcare organizations.*
3. *Some adoption. Used by a growing number of providers but not yet the majority.*
4. *Wide adoption. Used by most provider organizations that need to exchange this information*

#4: Regulated

This characteristic (provided as a "*Yes*" or "*No*") conveys whether a standard or implementation specification has been adopted in regulation or required by HHS for a particular interoperability need.

#5: Cost

This characteristic conveys whether a standard or implementation specification costs money to obtain.

- "*$*" – when this designation is assigned, it signifies that some type of payment needs to be made in order to obtain the standard or implementation specification.
- "*Free*" – when this designation is assigned, it signifies that the standard or implementation specification can be obtained without cost. This designation applies even if a user account or license agreement is required to obtain the standard at no cost.

#6: Test Tool Availability

This characteristic conveys whether a test tool is available to evaluate health IT's conformance to the standard or implementation specification for the particular interoperability need.

- *"Yes"* – when this designation is assigned, it signifies that a test tool is available for a standard or implementation specification and is free to use. Where available, a hyperlink pointing to the test tool will be included.
- *"Yes$"* – when this designation is assigned, it signifies that a test tool is available for a standard or implementation specification and has a cost associated with its use. Where available, a hyperlink pointing to the test tool will be included.
- *"No"* – when this designation is assigned, it signifies that no test tool is available for a standard or implementation specification.
- *"N/A"* – when this designation is assigned, it signifies that a test tool for the standard or implementation would be "not applicable."

EHRA Comments:

The EHRA suggests that a new bullet should be inserted: "Yes, Open (for open source) with rights to modify (e.g., Apache2)". As test tools often need improvements and need to be adapted to various testing environments, having not only "free use", but "access to the source code with rights to modify" is an important characteristics. The EHRA suggests adding a new first bullet and leaving the remaining four bullets unchanged:

- *"Yes, Open" – when this designation is assigned, it signifies that a test tool is available for a standard or implementation specification and is available as open source with rights to modify (e.g. Apache 2 license). Where available, a hyperlink pointing to the test tool will be included.*
- *"Yes" – when this designation is assigned, it signifies that a test tool is available for a standard or implementation specification and is free to use. Where available, a hyperlink pointing to the test tool will be included.*
- *"Yes$" – when this designation is assigned, it signifies that a test tool is available for a standard or implementation specification and has a cost associated with its use. Where available, a hyperlink pointing to the test tool will be included.*
- *"No" – when this designation is assigned, it signifies that no test tool is available for a standard or implementation specification.*

- *"N/A" – when this designation is assigned, it signifies that a test tool for the standard or implementation would be "not applicable."*

The Structure of Sections I through III

For the purposes of the lists that follow, a specific version of the standard or implementation specification is not listed unless it makes a helpful distinction. The standards and associated implementation specifications for clinical health IT interoperability are grouped into these categories:

- *Vocabulary/code sets/terminology* (i.e., "semantics").
- *Content/structure* (i.e., "syntax").
- *Services* (i.e., the infrastructure components deployed and used to fulfill specific interoperability needs)

At the recommendation of the HIT Standards Committee, we have removed the "transport" section which previously referenced low-level transport standards because 1) it was deemed to not provide additional clarity/value to stakeholders; and 2) the standards and implementation specifications in the "services" section included them as applicable. Thus, focusing on that section in addition to vocabulary and content were deemed more impactful and necessary.

EHRA Comments:

EHRA agrees with the HIT Standards Committee decision to remove the "transport" section which previously referenced low-level transport standards because 1) it was deemed to not provide additional clarity/value to stakeholders; and 2) the standards and implementation specifications in the "services" section included them as applicable.

Section IV includes questions on which public input is requested.

Last, as noted in the 2015 Advisory, this Advisory is not intended to imply that a standard listed in one section would always be used or implemented independent of a standard in another section. To the contrary, it will often be necessary to combine the applicable standards from multiple sections to achieve interoperability for a particular clinical health information interoperability purpose.

EHRA Comments:

The following general comments apply across this section:

- *The introduction of the six characteristics (Standards Process Maturity, Implementation Maturity, Adoption Level, Regulated, Cost, and Test Tool Availability) is a good step forward to understand whether a standard is fit for regulatory endorsement and industry-wide adoption. However, we believe that the application of the Standards Process Maturity characteristics need more work, as it gives the impression of the state of a standard that is in some instances unreasonable. This can be improved on over time.*

- *It is important to clarify "the best standard for what?". This issue remains a challenge with this version of the Advisory. While the new organization and section titles are a step in the right direction, it remains a challenge to understand the specific use. This problem is very clear when looking at standards for the care plan, as an example. Depending on the use case, the suggested standard is acceptable or insufficient. We need to re-emphasize that without such perspective, the value of the Advisory remains less than it could be. Endorsing standards without such understanding of specific use cases may result in the unintended consequence of investing in the wrong solutions and even hampering innovation by focusing on the wrong problems. We recommend that*

each "interoperability need" be better described. We make specific proposals in particular in the vocabulary section to refine the definition of the interoperability needs, as well as to make the selected vocabulary subset more specific.

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

I-A: Allergies

Interoperability Need: Representing patient allergic reactions

EHRA Comments:

Which subset of SNOMED-CT is referenced for allergic reactions? That more specific information needs to be specified along with the name of the standard, especially for such a broad standard as SNOMED-CT. It needs to be made clearer that the intention is to represent the type of reaction a patient had to a given medication allergen. As worded, one could expect readers to interpret this as a listing of non-medication allergens.

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:
● Feedback requested	

Interoperability Need: Representing patient allergens: medications

EHRA Comments:

Which subset of Rx-Norm is referenced? That information needs to be specified, along with the name of the standard, especially for such a broad standard as Rx-Norm. Is NDF-RT suitable for classes of medications? Which subset is relevant? Why is medication class not a specific vocabulary defined in its own right?

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:
● When a medication allergy necessitates capture by medication class, NDF-RT is best available (as recommended by the HIT Standards Committee)	

Interoperability Need: Representing patient allergens: food substances

EHRA Comments:
Which subset of SNOMED-CT is referenced for encoding food substances? That information needs to be specified along with the name of the standard, especially for such a broad standard as SNOMED-CT.

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:
● 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:
● Currently, there are no vocabulary code sets considered "best available" for environmental allergens.	● Feedback requested

I-B: Care Team Member

Interoperability Need: Representing care team member (healthcare provider)

EHRA Comments:
We agree with the use of the NPI, which could be relatively easily placed in the C-CDA testing tools since NPI field lengths are standard.
The care provider role should be a distinct entry (interoperability need) under care team member called "care team member role". It is supported today in C-CDA and using an HL7 value set. The continued use of the HL7 V3 value set versus SNOMED should be considered. EHRA recommends that ONC work with HL7 on a single, harmonized value set.

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:
● 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 "subjects role in the care setting" that could also be used in addition to NPI for care team members.	

I-C: Encounter Diagnosis

Interoperability Need: Documenting patient encounter diagnosis

EHRA Comments:

Which subset of SNOMED-CT is referenced here for encounter diagnosis? This information needs to be specified along with the name of the standard, especially for such a broad standard as SNOMED-CT.

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	ICD-10-CM	Final	Production	●●●●○	Yes	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
	● 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:
● 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.	● Feedback requested

I-E: Family Health History

Interoperability Need: Representing patient family health history

EHRA Comments:

Which subset of SNOMED-CT is referenced here for family health history? Do you mean to only include pre-coordinated codes? That information needs to be specified along with the name of the standard, especially for such a broad standard as SNOMED-CT.

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:
● Some details around family genomic health history may not be captured by SNOMED-CT (recommended by the HIT Standards Committee)	

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]***						

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

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

Interoperability Need: Representing patient gender identity

EHRA Comments:

Which subset of SNOMED-CT is referenced here for gender identity? That information needs to be specified along with the name of the standard, especially for such a broad standard as SNOMED-CT.

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:
• 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.	

Interoperability Need: Representing patient sex (at birth)

EHRA Comments:

For "Unknown, HL7 Version 3 Null Flavor", this should be merged into the row above:

"For Male and Female, HL7 Version 3 Value Set for Administrative Gender. For Unknown, use HL7 Version 3 Null Flavor".

It is not appropriate to identify a standard row for the representation of a single concept (Null Flavor), especially when this is an HL7 V3 convention associated with coded entries. Combine these two rows in a single standard.

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. For Unknown, use HL7 Version 3 Null Flavor	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:
• 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.	

Interoperability Need: Representing patient sexual orientation

EHRA Comments:
Which subset of SNOMED-CT is referenced here for sexual orientation? This information needs to be specified along with the name of the standard, especially for such a broad standard as SNOMED-CT. Referencing an explicit subset was well done above for the HL7 V3 value set to represent patient sex (at birth); a tree of SNOMED concepts should be explicitly referenced.

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:

• 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-H: Immunizations

Interoperability Need: Representing immunizations – historical

EHRA Comments:

As these two standards offer different capabilities, two subsections should be introduced under Interoperability Need: Representing immunizations – historical and administered and the second one being Representing immunizations – Manufacturing Specificity

The EHRA suggests that CVX is designated as the standard with the accompanying notes on pairing of codes from the additional code system as considerations but instead of as a second row, be referenced as a distinct interoperability need: Representing immunizations – Manufacturing Specificity that included the MVX Code Set.

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	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:
• 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.	

Interoperability Need: Representing immunizations – administered

EHRA Comments:

As these two standards offer different capabilities, two subsections should be introduced under Interoperability Need: Representing immunizations – administered:

- *Representing immunizations – historical*
- *Representing immunizations – historical, product specific information*

The EHRA suggests that CVX is designated as the standard with the accompanying notes on pairing of codes from the additional code system as considerations but instead of a second row be referenced as a distinct interoperability need: Representing immunizations – Product Specific information.

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:
● 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.	

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:
● Feedback requested	● Feedback requested

I-J: Lab tests

Interoperability Need: Representing laboratory tests and observations

EHRA Comments:

Which subset of LOINC is referenced here? That information needs to be specified, along with the name of the standard, especially for such a broad standard as LOINC (it also covers radiology procedures).

Adoption level at four dots seems optimistic. LOINC has not been adopted in a uniform way; EHRA would say that it is only in widely use in EHRs, but not by commercial labs. We recommend that it should be ranked at three dots.

EHRA agrees with HITSC that lab test and observation work in conjunction with values or results which can be answered numerically or categorically, but this does not fit the structure. Two subsections (interoperability needs) should be used -- one for numerical laboratory results (LOINC), and one for categorical lab results (SNOMED).

We do not understand why HITSC's recommendation that "organizations not using LOINC should maintain and publish a mapping of their codes to the LOINC equivalent until migration to LOINC has occurred" is only made here for LOINC. This is an implementation strategy question and could apply across the entire set of terminologies referenced in this section. We suggest this statement to be removed.

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:
● 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-K: Medications

Interoperability Need: Representing patient medications

EHRA Comments:

Which subset of Rx-Norm is referenced here? This information needs to be specified, along with the name of the standard, especially for such a broad standard as Rx-Norm.

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:
• 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

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• The case sensitive version is the correct unit string to be used for interoperability purposes per HIT Standards Committee recommendations.	• Feedback requested

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

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

EHRA Comments:

Which subset of SNOMED-CT is referenced here? This information needs to be specified, along with the name of the standard, especially for such a broad standard as SNOMED-CT.

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:
● 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:
● RFC 5646 encompasses ISO 639-1, ISO 639-2, ISO 639-3 and other standards related to identifying preferred language.	● 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:
● CDT is a proprietary terminology standard.	● 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

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

I-P: Radiology (interventions and procedures)

Interoperability Need: Representing radiological interventions and procedures

EHRA Comments:

Unless the intent is to use the older version of LOINC, this designation should be "draft", not "final", as the work to merge with Radlex is not completed. LOINC for radiology procedures is only used by a few health systems (e.g., the VA), if it is the old version. It is the future version that is being merged with Radlex. Its adoption level should be "none" today, as it is being used only in a limited number of pilot sites.

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:
• 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.	

I-Q: Smoking Status

Interoperability Need: Representing patient smoking status

EHRA Comments:

Which subset of SNOMED-CT is referenced here? This information needs to be specified, along with the name of the standard, especially for such a broad standard as SNOMED-CT.

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:
● 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.	

I-R: Unique Device Identification

Interoperability Need: Representing unique implantable device identifiers

EHRA Comments:

*To date the focus has been on conveying the barcode string only (inclusive of the UDI), while the FDA is now pushing for communicating the individual device and product identifier components as well. Consequently, the standard of the UDI definition is final, but the definition on how to communicate it is very much in draft. Specifically, C-CDA does not have any formal structure to communicate anything but a string. There are options on how the UDI components can individually be communicated outside the barcoded string, but there is no agreement yet how to consistently do so. We suggest this situation can be recognized by referencing emerging guidance documentation such as HL7's **Harmonization Pattern for Unique Device Identifiers** as well as further implementation guides necessary to support the exchange of UDI.*

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:

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:
● Feedback requested	● Feedback requested

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

EHRA Comments:

There are many successful implementations of ADT using V2.3.1, V2.4, V2.5, etc., with various pre-adoptions of specific capabilities in more current versions. The Advisory suggests that best available is V2.x rather than being more specific. There is no mention of its use within or across providers. While for intra-provider use, the current variations are manageable; for inter-provider interoperability the EHRA suggests narrowing to a best available as most appropriate.

We suggest promoting V2.5.1 as best available, as most other V2.x-based implementation guides using ADT components are V2.5.1 based (e.g., immunizations, laboratory, etc.) for inter-provider interoperability, with a need to establish implementation guides when communication of ADT events becomes a requirement to ensure consistency.

Accepting multiple versions of HL7 V2.x and any transport will not likely result in interoperability. But being silent on the actual content of the ADT message (e.g., segments) adds risk of incompatibilities. At a minimum, a new sub-category is needed for the interoperability with a classical "MPI". We suggest adding:

- *II-B Patient ID Management within a community*

- *Standard: HL7 2.5.1*
- *Implementation Specification: IHE PIX and PDQ*

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:
● 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.	

II-B: Care Plan

Interoperability Need: Documenting patient care plans

EHRA Comments:

The EHRA suggest changing the title of this section to "Documenting Care Plans for Simple Hand-offs ".

As noted under the characteristic "Standards Process Maturity", the reference to "draft" is inconsistent throughout the Advisory. If it is meant to reflect DSTU, then this one is right, but some others are not.

The Advisory includes the C-CDA for exchange of care plan data. While that capability exists, in the rapidly evolving shift from fee-for-service to value-based payment models that require tight coordination across providers, static exchange of care plans may work for simple use cases, but not for those patients where tight coordination is most critical. The Advisory does not provide the context that much more work is required to develop an approach to coordinate care across providers and the standards needed for that process. This work will drive the need to have more advanced standards than what we have today. Consequently the current line item gives a false sense of comfort in a very challenging area which should be reflected in the limitations.

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	Draft	Pilot	Unknown	No	Free	No

	Standard for Trial Use, Release 2.1						

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

II-C: Clinical Decision Support

Interoperability Need: Shareable clinical decision support

EHRA Comments:

This is not a standard (that would be HL7's Clinical Decision Support Knowledge Artifact Specification, Release 1.3), but an implementation guide.

There is considerable work in progress to harmonize standards for clinical decision support and quality measures, with a focus on moving towards FHIR. It is not clear from the advisory that this is work in progress and that some of the standards referenced as a result would change soon. To clarify this evolution, the emerging standards should be referenced to provide context and direction.

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

EHRA Comments:

Additionally, the EHRA suggests that considering the anticipated requirements to support Appropriate Use Criteria (AUC), efforts are underway to establish the appropriate standards to support the interaction with an AUC service provider, communicating the resulting AUC along with the order for an image service, provide it to a patient accounting application, and to move it along on a claim. We suggest recognition of these current efforts, based primarily on HL7 V2 and FHIR, as emerging implementation specifications to provide an early indication how these requirements can be consistently supported. The following are two proposed additional entries:

Interoperability Need: Provide access to appropriate use criteria

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Emerging Implementation Specficiation	IHE: Guideline Appropriate Ordering (GAO)	Draft	Pre-Pilot	None	No	Free	No

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
	•

Interoperability Need: Communicate AUCs with the order and charge to the filling provider and billing system for inclusion on claims.

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Emerging Implementation Specification	IHE: Clinical Decision Support Order Appropriateness Tracking (CDS-OAT)	Draft	Pre-Pilot	None	No	Free	No

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
	•

II-D: Drug Formulary & Benefits

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

EHRA Comments:

This is an implementation guide, not a standard.

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.	

II-E: Electronic Prescribing

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

EHRA Comments:

This is an implementation guide, not a standard. This section should reference the subset of the SCRIPT implementation guide where it describes the creation of new prescriptions.

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:
• 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.	

Interoperability Need: Prescription refill request

EHRA Comments:

This is an implementation guide, not a standard. This section should reference the SCRIPT implementation guide where it describes the creation of 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:	Applicable Security Patterns for Consideration:
• 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 accomplish successful exchange.	

Interoperability Need: Cancellation of a prescription

EHRA Comments:

This section should reference the SCRIPT implementation guide where it describes the cancellation of prescriptions.

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:	Applicable Security Patterns for Consideration:
• 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 accomplish successful exchange.	

Interoperability Need: Pharmacy notifies prescriber of prescription fill status

EHRA Comments:

This section should reference the SCRIPT implementation Guide where it describes the notification of the 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:	Applicable Security Patterns for Consideration:
• 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 accomplish successful exchange.	

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

EHRA Comments:

This section should reference the SCRIPT implementation guide where it describes obtaining patient 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:
● 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 accomplish successful exchange.	

II-F: Family health history (clinical genomics)

EHRA Comments:

The implementation guide is an informative, not a normative document. Marking it as final is, therefore, somewhat confusing. HL7 should have this in normative state before it should be considered final.

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:
● 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.	

II-G: Images

[See Question 4-7]

Interoperability Need: Medical image formats for data exchange and distribution

EHRA Comments:

Those DICOM SOP Classes are widely implemented and used today in thousands of sites worldwide across all vendor products. Adoption level should be five dots.

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	

Interoperability Need: Exchange of imaging reports

EHRA Comments:

What is described above as an Implementation Specification is actually a specific component of the DICOM standard, not an implementation guide. The EHRA suggests merging it with the line above and to read: "Digital Imaging and Communications in Medicine (DICOM) Standard – Part 20: Imaging Reports using HL7 Clinical Document Architecture."

The Adoption Level should be two dots.

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	

II-H: Laboratory

Interoperability Need: Receive electronic laboratory test results

EHRA Comments:

The implementation guide is "draft" if a DSTU is considered a draft. Otherwise C-CDA should also be marked "final".

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
Emerging Alternative Implementation Specification	*HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Results Interface Implementation Guide, Release 1 DSTU Release 2 - US Realm [no hyperlink available yet]*	*Draft*	*Pilot*	●○○○○	*No*	*Free*	*No*

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• HL7 Laboratory US Realm Value Set Companion Guide, Release 1, September 2015, provides cross-implementation guide value set definitions and harmonized requirements.	

Interoperability Need: Ordering labs for a patient

EHRA Comments:

This implementation guide needs to be described as "emerging", given the state of maturity (i.e., not yet published).

There is a LOI IG R1 DSTU 1 which is published and is, therefore, the best available, although not recommended to be endorsed given implementation gaps. LOI IG R1 DSTU 2 is almost published. As soon as that is published, LOI IG R1 DSTU 1 should be removed from the list. Perhaps a note should be made if the final version is published and LOI IG R1 DSTU 2 is not out yet.

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 *[no hyperlink available yet]*	Draft	Pilot	●○○○○	No	Free	No

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• HL7 Laboratory US Realm Value Set Companion Guide, Release 1, September 2015, provides cross-implementation guide value set definitions and harmonized requirements.	

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

EHRA Comments:
The second line below is an implementation guide, not a standard.

The prior three guides are listed as "pilot". We urge ONC and CMS to create an environment where providers and vendors can collaborate to pilot these guides without being penalized in any incentive program for not using the versions referenced in the rules for LRI IG. Such pilots can result in essential enhancements that can be published before wider roll-out through regulations.

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
Standard	HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Test Compendium Framework, Release 2, DSTU Release 2	Draft	Pilot	●○○○○	No	Free	No

	[no hyperlink available yet]						

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• HL7 Laboratory US Realm Value Set Companion Guide, Release 1, September 2015, provides cross-implementation guide value set definitions and harmonized requirements.	

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

EHRA Comments:

We suggest clarification that these profiles operate in conjunction with the IHE XDS, XCA, and XDR profiles.

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	*Yes*[Open] http://wiki.ihe.net/index.php?title=IHE_Test_Tool_Information#IT_Infrastructure
Implementation Specification	IHE Cross Enterprise User Authorization (XUA)	Final	Production	●●●●○	No	Free	*Yes*[Open] http://wiki.ihe.net/index.php?title=IHE_Test_Tool_Information#IT_Infrastructure

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

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:
• 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.	• 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:
• 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.	• Feedback requested

Interoperability Need: Case reporting to public health agencies

EHRA Comments:

We note that the title is incorrect: the words "HL7 Consolidated CDA Release 2.0" at the end should be removed. It should read: IHE Quality, Research, and Public Health Technical Framework Supplement, Structured Data Capture, Trial Implementation. The URL is correct.

Structured data capture is largely based on IHE RFD, which is final and in production. RFD should be added as a supporting standard.
IHE IT Infrastructure Technical Framework, Volume 1 (ITI TF-1): Integration Profiles, Section 17: Retrieve Form for Data Capture (RFD).
(http://www.ihe.net/uploadedFiles/Documents/ITI/IHE_ITI_TF_Vol1.pdf)

We believe that the Adoption Level of SDC should be 2 or 3 dots.

It also seems that case reporting is just one of the needs supported (i.e., research data capture is also supported).
We suggest also referencing the versions of FHIR (DSTU 2), and the SDC IG (Release 1 DSTU), as well as the IHE test tools.

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
(1) Standard	*IHE IT Infrastructure Technical Framework, Volume 1 (ITI TF-1): Integration Profiles, Section 17: Retrieve Form for Data Capture (RFD).*	Final	Production	●●●○○	No	Free	*Yes*[Open] http://wiki.ihe.net/index.php?title=IHE_Test_Tool_Information#IT_Infrastructure
(1) Implementation Specification	IHE Quality, Research, and Public Health Technical Framework Supplement, Structured Data Capture, Trial Implementation,~~HL7 Consolidation CDA® Release 2.0~~	Draft	Pilot	●○○○○	No	Free	No
(2) Standard	Fast Healthcare Interoperability Resources (FHIR)	Draft	Pilot	●○○○○	No	Free	No
(2) Implementation Specification	Structured Data Capture Implementation Guide	Draft	Pilot	●○○○○	No	Free	No

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• Electronic case reporting is not widespread and is determined at the state or local jurisdiction.	

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:
● 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.	● 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
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:

• 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.	• 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:
• 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.	• 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

Emerging Alternative Implementation Specification	*PHIN Messaging Guide for Syndromic Surveillance: Emergency Department, Urgent Care, Inpatient and Ambulatory Care Settings, Release 2.0*	*Final*	*Pilot*	●○○○○	*No*	*Free*	*No*

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
● 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.	● 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:
● Feedback requested	● 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
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"

EHRA Comments:

We are concerned with this use case as it does not represent a user need, but rather a technology approach. A use case should focus on the users' needs that in turn may indicate whether it is most appropriate to use a document, message, or service approach, or whether a query for data should be able to return data element level responses. The latter is properly reflected further below by data element-based query for clinical health information, thus obviating the need for this section.

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	

II-N: Segmentation of sensitive information

Interoperability Need: Document-level segmentation of sensitive information

EHRA Comments:

As we commented on the first version of the Interoperability Standards Advisory in May 2015, we are concerned with the maturity of this standard. At best this should be referred to as an emerging implementation specification.

We believe that there still remains too much variance within this subset to be recognized for use now, i.e., the vocabulary is not universally understood and although some concepts are well-defined, others are completely un-usable. There is a mix of codes that are just flags with other codes that are demands (obligations). This approach makes it unclear as to what should be done with them either on the publication side or the use side. Ultimately, even this subset of DS4P requires further implementation guidance or profiling. We recommend that the Advisory includes no more than the DS4P subset refined by the IHE IT

Infrastructure Technical Framework Volume 4 – National Extensions – Section 3.1 Data Segmentation for Privacy (DS4P) (http://www.ihe.net/uploadedFiles/Documents/ITI/IHE_ITI_TF_Vol4.pdf), noting that piloting is insufficient.

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	

II-O: Summary care record

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:
● 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.	● 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

EHRA Comments:

When there are multiple implementation specifications, the relationship and dependencies between these implementation specifications and standards should be explicit. We suggest adding a note that explains the various "elements" and their dependencies. We also suggest adding a (1) for the SMTP/Direct (2) for the XDR/SOAP and (3) for the MHD/FHIR.

The reference to FHIR is very confusing in this context; is it intended as a transport or a representation of a payload? We suggest that, in this context, FHIR should be replaced with a reference to IHE's MHD (Provide Document Bundle Transaction) (which in turn references the FHIR Document Resource with any payload).
http://www.ihe.net/uploadedFiles/Documents/ITI/IHE_ITI_Suppl_MHD.pdf

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Regulated	Cost	Test Tool Availability
Standard (1)	Applicability Statement for Secure Health Transport v1.1 ("Direct")	Final	Production	●●●●●	Yes	Free	Yes
Emerging Alternative Standard (1)	*Applicability Statement for Secure Health Transport v1.2*	*Final*	*Pilot*	●○○○○	*No*	*Free*	*No*
Standard (2)	SOAP	Final	Production	●●●●●	Yes	Free	Yes
Implementation Specification (1) & (2)	XDR and XDM for Direct Messaging Specification	Final	Production	●●●●○	Yes	Free	Yes
Implementation Specification (1)	IG for Direct Edge Protocols	Final	Production	●●○○○	Yes	Free	Yes

Implementation Specification (1)	IG for Delivery Notification in Direct	Final	Production	●●●○○	No	Free	No
Emerging Alternative Standard (3)	*Fast Healthcare Interoperability Resources (FHIR)*	*Draft*	*Pilot*	●○○○○	*No*	*Free*	*No*
Emerging Alternative* Implementation Specification *(3)	*IHE IT Infrastructure Technical Framework Supplement - Mobile access to Health Documents (MHD): Provide Document Bundle Transaction*	*Draft*	*Pilot*	●○○○○	*No*	*Free*	*No*

Limitations, Dependencies, and Preconditions for Consideration:	**Applicable Security Patterns for Consideration:**
● "Direct" standard is based upon the underlying standard: Simple Mail Transfer Protocol (SMTP) RFC 5321and 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.	● **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

EHRA Comments:

When there are multiple implementation specifications, the relationship and dependencies between these implementation specifications and standards should be explicit. We suggest adding a note that explains the various "elements" and their dependencies.

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:
• 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.	• **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:
• Feedback requested	• 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

EHRA Comments:

We want to recognize this use case as one where the interoperability need is very well documented with enough specificity. This level of clarity should be applied throughout this document.

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

III-C: Image Exchange

EHRA Comments:

The corresponding profiles outside of health information exchange domains with XCA-I need to be added to this section, thus creating two instead of one interoperability needs. See below.

Interoperability Need: Exchanging imaging 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 Specification	IHE Cross Community Access for Imaging (XCA-I)	Final	Pilot	●○○○○	No	Free	Yes Open

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

Interoperability Need: Exchanging imaging documents within a specific health information exchange domain

EHRA Comments:
EHRA believes that for consistency with the other interoperability needs in this ISA, instead of using the terms "set of affiliated entities", one should use the expression "within a specific health information exchange domain." We suggest replacing "set of affiliated entities" with "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 Cross Enterprise Document Sharing for Images (XDS-I)	Final	Pilot	●○○○○	No	Free	Yes Open

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

III-D: Provider Directory

Interoperability Need: Listing of providers for access by potential exchange partners

EHRA Comments:
HPD is now used is several settings. We suggest that the Adoption Level can be two dots, with more than 20 Directory Servers being deployed in production.

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:
• Feedback requested	• Feedback requested

III-E: Publish and Subscribe

Interoperability Need: Publish and subscribe message exchange

EHRA Comments:

The NwHIN Specification: Health Information Event Messaging Production Specification has had minimal deployment and is being phased out in favor of IHE-DUSB. This implementation specification should be removed, given that DSUB has a good production deployment. It is not an emerging alternative, but a much more robust solution. Remove emerging alternative and put three dots for Adoption Level.

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***~~ ***Implementation Specification***	*IHE Document Metadata Subscription (DSUB), Trial Implementation*	Draft	Pilot	●○○○○	No	Free	Yes Open http://wiki.ihe.net/index.php?title=IHE_Test_Tool_Information#IT_Infrastructure

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

III-F: Query

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

EHRA Comments:

MHD is based on the FHIR document resource. The EHRA suggests creating a separate category for the FHIR based requirements – i.e., Interoperability Need: Query for documents from Mobile devices within a specific health information exchange domain. This approach should then include the corresponding implementation specifications for PDQm and PIXm as well.

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	Yes Open http://wiki.ihe.net/index.php?title=IHE_Test_Tool_Information#IT_Infrastructure
Implementation Specification	IHE-PDQ (Patient Demographic Query)	Final	Production	●●●●○	No	Free	Yes Open http://wiki.ihe.net/index.php?title=IHE_Test_Tool_Information#IT_Infrastructure
Implementation Specification	IHE-PIX (Patient Identifier Cross-Reference)	Final	Production	●●●●○	No	Free	Yes Openhttp://wiki.ihe.net/index.php?title=IHE_Test_Tool_Information#IT_Infrastructure
Emerging Alternative Implementation Specification	*IHE – MHD (Mobile Access to Health Documents)*	*Draft*	*Pilot*	●○○○○	*No*	*Free*	*No*

Limitations, Dependencies, and Preconditions for Consideration:	**Applicable Security Patterns for Consideration:**
• IHE-PIX and IHE-PDQ are used for the purposes of patient matching and to support this interoperability need.	• Feedback requested

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

EHRA Comments:

We suggest reorganizing the order of the specification in the table below as follows:

- *Start with XC.A*
- *Next, NwHIN Query for Doc+ eHealth Exchange specifications.*
- *Next, NwHIN Retrieve documents + eHealth EXchange Specification.*
- *Then, XCPD or PIX.*
- *And, finally, NwHIN Patient Discovery.*

These dependencies need to be explained in this context:

- *XCA is used by other deployments than eHealth EXchange and NwHIN. It needs to be on its own row.*
- *NwHIN Query and Retrieve for Docs are further constrained by the eHealth Exchange specifications and can be grouped in two rows.*
- *Finally, XCP or PIX from the fourth row and the NwHIN Patient Discovery the fifth row.*

Query Request ID is a low level protocol tool that need not be mentioned here.

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	Yes Open http://wiki.ihe.net/index.php?title=IHE_Test_Tool_Information#IT_Infrastructure
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	Yes Open http://wiki.ihe.net/index.php?titl

							e=IHE_Test_Tool_Information#IT_Infrastructure
Implementation Specification	NwHIN Specification: Query for Documents further constrained by eHealth Exchange Query for Documents v 3.0	Final	Production	●●●○○	No	Free	No
Implementation Specification	NwHIN Specification: Retrieve Documents further constrained by eHealth Exchange Query for Documents v 3.0	Final	Production	●●●○○	No	Free	No

Limitations, Dependencies, and Preconditions for Consideration:	**Applicable Security Patterns for Consideration:**
• IHE-PIX and IHE-XCPD are used for the purposes of patient matching and to support this interoperability need.	• **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

EHRA Comments:

This should be specific with reference to DSTU 2. Considering the development stage of FHIR, we suggest that it would be helpful to note that some FHIR resources are further along than others. We suggest that, in the limitations section, the reader is referred to the FHIR web site, which identifies for each resource its current maturity.

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	• **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	Yes Open http://wiki.ihe.net/index.php?title=IHE_Test_Tool_Information#IT_Infrastructure

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

EHRA Comments:

EHRA agrees that this version of the Standards Advisory does provide better context. The Advisory needs to be further refined in cases where there are several "sub-needs" covered that result in multiple standards and/or implementation specifications that are not alternatives. The Advisory should be further clarified to distinguish between these more complex needs.

EHRA believes that the Advisory is heading in the right direction, but is not yet sufficient in providing clear, consistent use cases. For example, the care plan use case requires more work; the patient education use case is well stated.

Additionally, without a clear understanding of the path (e.g., timing, maturity level) for a standard to determine when it is ready for national endorsement and adoption, the value of the advisory remains limited beyond an annual informational summary that may not be actionable. Any further guidance can enable industry stakeholders to begin their appropriate planning steps.

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.

EHRA Comments:

EHRA has provided this information above. In general, we find that the Standards Process Maturity definition is not adequate. See our comments above.

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.

EHRA Comments:
As it is, the usefulness of this approach is not clear. A security/privacy risk analysis cannot be avoided and these elements really do not help. We suggest that they should be removed.

We suggest that further analysis of the issues and needs is needed in order to define a robust solution for the next version of the Standards Advisory which should account for the transport specificity and the policy environment.

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.

EHRA Comments:
This structure is good, but EHRA does not recommend including other standards and/or implementation specifications (e.g., for lab results, the Advisory states that for categorical results do not use LOINC but SNOMED). This is an example of where more granular interoperability requirements must be addressed.

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).

EHRA Comments:
We did not find a situation where a solution existed and was not listed for vocabulary/code sets. See detailed comments above.

Section II: Content / Structure

4-6. Should more generalized survey instruments such as the IHE Profile Retrieve Form for Data Capture be considered?

EHRA Comments:
Yes, this was recommended to be explicitly introduced before SDC, because of its maturity and the fact that SDC requirements were met at over 90% by RFD. This reinforces the need to be more explicit in terms of dependencies between standards and between standards and implementation specifications.

The Advisory should clearly state that the CDC based on FHIR is distinct from the SDC based on RFD

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?

EHRA Comment:
Yes we proposed adding XCA-I to support access across domains (the imaging content to be used alongside XCA).

4-8. Should a more specific/precise aspect of DICOM be referenced for the implementation specification for this interoperability need?

EHRA Comments:
The imaging SOP classes are very specific and all that is needed for interoperability. Such SOP classes include CT Image, MRI Image, DR Image, US Multiframe Image, etc.

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?

EHRA Comments:
At a generic national level, XUA and BPPC are fine. Project-specific extensions are often added, but they are not always used or can vary greatly. A national policy harmonization would be required before becoming more specific and prescriptive. The proposal to explicitly reference the XUA options (see above) will help.

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?

EHRA Comments:
EHRA believes that this is an excellent approach. Services most often have built in a specific transport or a choice that has to be dealt with.

There is only one remaining issue related to content/structure – that is, where there are services that are bundled (e.g., the HL7 V2 and V3 messages include their own service (and choice of transport)). This is not stated and may give the impression that one could push such a message using Direct or XDR. Although technically possible, and useful in specific cases, a proliferation of such combinations would become counterproductive in achieving interoperability.

Appendix II: Sources of Security Standards

4-11. Are there other authoritative sources for Security Standards that should be included in Appendix II?

EHRA Comments:
See EHRA comments in Appendix II.

Appendix I - Annual Process to Update the Interoperability Standards Advisory

ONC intends to implement the following timeline and process to update the Interoperability Standards Advisory for subsequent years. Note that timelines are approximate and may vary slightly for a variety of reasons.

- **December Preceding the Upcoming Calendar Year**
  - The new Interoperability Standards Advisory for the next calendar year is published (e.g., December 2016 for the 2017 Advisory).
  - A first round of an approximately 90- to 120-days of public comment period will be opened on that year's Interoperability Standards Advisory.
- **April/May**
  - Sometime during late April/early May the comment period will expire.
  - ONC staff will compile all comments received during the first round comment period.
  - ONC staff will present a summary of received comments to the HIT Standards Committee (or designated Task Force) in order to prepare them to make recommendations on updates for the following year's Interoperability Standards Advisory.
- **August**
  - The HIT Standards Committee submits recommendations to the National Coordinator concerning updates to the following year's Interoperability Standards Advisory.
  - A second round of approximately 60-days of public comment will be opened on the HIT Standards Committee's recommendations concerning the Interoperability Standards Advisory.
- **October – December**
  - Sometime during October the comment period will expire.
  - ONC will review the HIT Standards Committee recommendations as well as public comments on those recommendations.
  - ONC will prepare the next year's Interoperability Standards Advisory for publication.

If a standard or implementation is under development and expected to be completed during this process, it could be considered for inclusion in the next year's Interoperability Standards Advisory. For example, if an implementation guide is expected to be completed in October 2016 for a particular standard, this process should be able to anticipate and accommodate the potential addition of that implementation guide in the 2017 Interoperability Standards Advisory.

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
- Information Organization for Standardization (ISO) Information Security Standards: http://www.27000.org/
- 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

EHRA Comments:

ONC may consider adding reference to IHE ITI with profiles such as ATNA.

Appendix III - Revision History

Summary Level Description of Changes

ISA Area	Summary Level Description of Revision History	Revision History, Expanded
Abbreviated Introduction	With the 2015 Advisory, a great deal more 'explanatory' detail was offered to lend context and history and to spark necessary feedback. That level of information for the ISA 2016 within the Introduction was determined unnecessary. Any interest to access history and/or to gain context however, would be supported via link to 2015 Advisory.	• The ISA 2016 bypassed the need of an Executive Summary. The introduction sustained content deemed most relevant • Scope precedes Purpose • The two Purposes were mildly enhanced and one was added. The third addresses the biggest ISA 2016 change; namely, the added meta data to the table standards/implementation specification structure
Document Restructuring	The Public Comments and ISA Task Force received appreciable comments and direction from the Health IT Standards Committee (HITSC). In order to best serve the range of interests with this and subsequent ISA releases, the primary focus for the 2016 ISA was to address table restructuring -- particularly focused on finding the best way to add relevant characteristics of a standard/implementation specification thus offering added context. The breadth of changes to document structure has introduced	• Instead of using the term "purpose," a section's lead-in is framed to convey an "interoperability need" stakeholders may express to convey an outcome they would want to achieve with interoperability. • Meta Data describing six informative characteristics has been added to each referenced standard and implementation specification to give readers an overall sense of maturity and level of adoption: Standards Process Maturity; Implementation Maturity; Adoption Level; Regulated; Cost & Testing Tool Availability • Interoperability Need has two subsections. ▪ The first would identify any known limitations, dependencies, or preconditions associated with best available standards and implementation specifications. ▪ The second would identify, where applicable, known "security patterns" associated with best available standards and implementation specifications. This subsection's goal would be to identify the generally

	noteworthy content which did extend the volume of the ISA, e.g., greater than 40 pages as compared to the 13 with the original ISA 2015.	reusable security techniques applicable to interoperability need(s) without prescribing or locking-in particular security standards. • Transport Section (previously ISA 2015 Section III)), has been removed: 1) it was deemed to not provide additional clarity/value to stakeholders; and 2) the standards and implementation specifications in the "services" section included them as applicable. • A security standards sources appendix is included to point stakeholders to the entities that maintain and curate relevant security standards information
Revised Questions	The questions offered, were structured to solicit feedback on changes made to the ISA 2016 and to assist in addressing recommendations where disposition is pending. These are found within Section IV	
Revision History	In order to capture the changes the first ISA received, a Revision History has been introduced and is found in Appendix III.	• The Revision History, Appendix III, records summary & detailed levels changes and will record for the applicable ISA version, the additions, deletions and/or enhancements made as part of the annual review process. • Given changes will continue during the Public Comment period and beyond, the Revision History will likewise be updated as changes occur and be cumulative in nature offering traceability.

Additions/Enhancements

Section / Interoperability Need	Standard Added	Description
Overarching		The Interoperability Needs reflected have received edits to expand the context and support the consolidation of like interoperability needs
I-A: Allergies	SNOMED-CT (Food Allergy) NDF-RT (Medication Allergen)	• Per HITSC recommendation, allergies were organized to add distinction between the reaction, the allergen

		causing the reaction and types of allergen • HITSC recommendation were added via Limitations, Dependencies & Preconditions supporting medications and environmental substances allergens
I-B: Care Team Member		HITSC views/recommendations added via Limitations, Dependencies & Preconditions
I-D: Race and Ethnicity	CDC Race and Ethnicity Code Set Version 1.0	HITSC views/recommendation added via Limitations, Dependencies & Preconditions
I-E: Family Health History		HITSC views (around family genomic health history) added via Limitations, Dependencies & Preconditions
I-G: Gender Identity, Sex and Sexual Orientation	Reference/link to Fenway Institute of Medicine report offered For Male and Female patient sex (at birth), HL7 Version 3 Value Set for Administrative Gender For Unknown patient sex (at birth), HL7 Version 3 Null Flavor	• Area renamed & reorganized to address interoperability needs connected to Gender Identity, Sex & Sexual Orientation • HITSC recommendation added via Limitations, Dependencies & Preconditions
I-H: Immunizations	For administered: HL7 Standard Code Set CVX—Clinical Vaccines Administered	Historical & Administered: HITSC views / recommendations (surrounding use of CVX and MVX codes) added via Limitations, Dependencies & Preconditions
I-P: Radiology (interventions and procedures	LOINC	Replaced RadLex; per HITSC recommendation added via Limitations, Dependencies & Preconditions
I-Q: Smoking Status		HITSC recommendation describing the limitations in what SNOMED-CT captures added via Limitations, Dependencies & Preconditions
II-A: Admission, Discharge, and Transfer		• HITSC recommendation added via Limitations, Dependencies & Preconditions citing acceptability of any HL7 2.x version messaging standard • HITSC recommendation added via Limitations, Dependencies &

		Preconditions surrounding available transport protocols
II-B: Care Plan		HITSC recommendation added via Limitations, Dependencies & Preconditions citing availability of transport protocols
II-C: Clinical Decision Support		The standards and specifications supporting what were 3 areas have been combined under interoperability need of "Shareable clinical decision support
II-D Drug Formulary & Benefits		HITSC recommendation added via Limitations, Dependencies & Preconditions related to monitoring NCPDP Real Time Prescription Benefit inquiry (RTPBI)
II-E: Electronic Prescribing • A prescriber's ability to create a new prescription to electronically send to a pharmacy • Prescription refill request • Cancellation of a prescription • Pharmacy notifies prescriber of prescription fill status • A prescriber's ability to obtain a patient's medication history		Area reorganized to address five connected interoperability needs each with recommendations via Limitations, Dependencies and Preconditions to leverage their area's particular transaction and of necessity to have prescriber and receiving pharmacy systems configured to facilitate the exchange
II-F: Family Health History		HITSC recommendation added via Limitations, Dependencies & Preconditions related to lack of vocabulary for family genomic health history and a reference to transport of this data
II-G: Images	Image Acquisition Technology Specific Service/Object Pairs (SOP) Classes	HITSC recommendation added via Limitations, Dependencies & Preconditions related to need for feedback on new SOP
II-H: Laboratory		

• Receive Lab test results	- HL7 2.5.1 as Standard - 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 from Standard to Implementation Specification - HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Results Interface Implementation Guide, Release 1 DSTU Release 2 - US Realm as Emerging Alternative Implementation Specification	Area reorganized to address the three connected interoperability needs and also notes the HL7 Laboratory US Realm Value Set Companion Guide, Release 1, Sep 2015 as a resource for each
• Ordering labs for a patient	- HL7 2.5.1 as Standard - HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Orders from EHR, Release 1 DSTU Release 2 - US Realm as Implementation Specification	
• Support the transmission of a laboratory's directory of services to health IT	- HL7 2.5.1 as Standard - HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Test Compendium Framework, Release 2, DSTU Release 2 as Standard	
II-J: Patient Preference/Consent	IHE Basic Patient Privacy Consents (BPPC) IHE Cross Enterprise User Authorization (XUA)	Per HITSC recommendations, two implementation specifications added

II-K: Public Health Reporting		
• Reporting antimicrobial use and resistance information to PH agencies		• Area reorganized to consolidate seven applicable PH Reporting interoperability needs • HITSC recommendation added via Limitations, Dependencies & Preconditions for stakeholders to refer to health departments in their jurisdiction for added information when transmitting information
• Reporting cancer cases to PH agencies	HL7 CDA ® Release 2 Implementation Guide: Reporting to Public Health Cancer Registries from Ambulatory Healthcare Providers, Release 1, DSTU Release 1.1 – US Realm as Emerging Alternative Implementation Specification	
• Case reporting to PH agencies	• Fast Healthcare Interoperability Resources (FHIR)& Structured Data Capture Implementation Guide as Standard • Structured Data Capture Implementation Guide as Implementation Specification	
• Electronic transmission of reportable lab results to PH agencies	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 as Implementation Specification	
• Sending health care survey information to PH agencies	HL7 Implementation Guide for CDA® R2: National Health Care Surveys (NHCS), Release 1 - US Realm inserted as replacement	
• Reporting administered immunizations to immunization registry	HL7 2.5.1 Implementation Guide for Immunization Messaging, Release 1.4 added as an implementation	

	specification HL7 2.5.1 Implementation Guide for Immunization Messaging, Release 1.5 reflected an emerging alternative as Emerging Alternative IS	
• Reporting syndromic surveillance to PH (ED, inpatient, and urgent settings)	PHIN Messaging Guide for Syndromic Surveillance: Emergency Department, Urgent CareData Release 1.1 as Implementation Specification	
II-L: Quality Reporting	HL7 Implementation Guide for CDA® Release 2: Quality Reporting Document Architecture – Category I, DSTU Release 3 (US Realm)	
II-O: Summary care record • Support a transition of care or referral to another provider	HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes (US Realm), Draft Standard for Trial Use, Release 2.1 as emerging alternative Implementation Specification	HITSC recommendation added via Limitations, Dependencies & Preconditions regarding specific document templates within the C-CDA Implementation Specification and need for trading partners to have systems supporting the document templates
III-A: An unsolicited 'push' of clinical health information to a known destination • between providers • between systems	Fast Healthcare Interoperability Resources (FHIR) as an emerging alternative standard	• HITSC recommendation added via Limitations, Dependencies & Preconditions regarding Direct standard and its basis standard (SMTP) and for security uses; Direct dependencies also relayed. • Approximate nine Applicable Security Patterns were also listed for both interoperability needs • The alignment of standards / implementations specifications received minor updates

III-E: Resource Location	IHE IT Infrastructure Technical Framework Supplement, Care Services Discovery (CSD), Trial Implementation reflected from standard to an Implementation Specification	
III-F: Provider Directory	IHE IT Infrastructure Technical Framework Supplement, Healthcare Provider Directory (HPD), Trial Implementation reflected from standard to an Implementation Specification	
III-G: Publish and Subscribe	NwHIN Specification: Health Information Event Messaging Production Specification reflected from standard to an Implementation Specification IHE Document Metadata Subscription (DSUB), Trial Implementation as an Emerging Alternative Implementation Specification	

Deletions / Refinements

Section / Interoperability Need	Standard Removed	Description
I-N: Preferred Language	Refined from 4 to 1: RFC 5646	HITSC recommendation added via Limitations, Dependencies & Preconditions citing the fact RFC 5646 contains the others originally listed
I-P: Radiology (interventions and procedures	RadLex	Replaced by LOINC
II-K Public Health Reporting Sending health care survey information to PH agencies	HL7 Implementation Guide for CDA® Release 2: National Ambulatory Medical Care Survey (NAMCS), Release 1, US Realm, Volume 1- Introductory Material, Draft Standard for	

	Trial Use replaced	