National Coordinator for Health Information Technology
Office of the National Coordinator for Health Information Technology
Department of Health and Human Services
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Washington, D.C. 20201

Submitted electronically at: http://www.healthit.gov/policy-researchers-implementers/2015-interoperability-standards-advisory-public-comments

Re: 2015 Interoperability Standards Advisory

Dear Dr. DeSalvo,

Thanks you for this opportunity to comment on 2015 Interoperability Standards Advisory.

Epic is an electronic health records (EHR) developer based in Verona, Wisconsin. Epic participates in industry standards development in order to further interoperability efforts, including Health Level 7 (HL7), Integrating the Healthcare Enterprise (IHE), National Council for Prescription Drug Programs (NCPDP), Standards & Interoperability Framework, and others. Epic staff have also chaired several HL7 and IHE committees. In addition to developing and implementing standards, we've taken a leadership role in the industry in interoperability governance. In February 2014, we co-founded Healtheway's Carequality (www.carequality.org) initiative, which aims to go a step beyond the eHealth Exchange to allow members of different exchange networks, such as Epic's Care Everywhere network, the eHealth Exchange, CommonWell, and state HIEs, to interoperate freely with one another. We also are a supporting member of Healtheway, which provides standards, rules, and a directory to power nationwide record sharing on the eHealth Exchange network.

Our interoperability and industry standards experiences, as well as our broad general experience developing a sophisticated EHR and supporting the healthcare organizations that use it, inform the suggestions we make attached to this letter.

Sincerely,

Peter DeVault
Epic

General comments

We agree that most of the standards proposed are the best available, and we've commented only in places where we disagree or have additional input. Standards identified as the best available are at various stages of implementation and adoption. Users of the Standards Advisory will need to account for appropriate implementation timelines for their particular purpose.

Comments on proposed standards

Gender identity

SNOMED-CT is the appropriate terminology to code Gender Identity, though specific terms suggested in other regulations are not the best available, specifically the SNOMED CT codes 407377005-Female-to-male transsexual and 407376001-Male-to-female transsexual. "Transsexual" is considered offensive in some contexts, and as the purpose of this field is to determine the individual's gender identity, "transsexual" is not appropriate. In addition, SNOMED CT code 446131000124102-Identifies as non-conforming gender would be more appropriate as "Identifies as gender-variant."

Industry and occupation

A unified value set for Occupation and Industry would be helpful. The existing value sets for Occupation and Industry are not consistent across different use cases and implementations. For example, the IHE PRPH-Ca Cancer registry specification includes occupation and industry using the value sets "PHVS_Occupation_Census" and "PHVS_Industry_Census." The HL7 implementation guide for Cancer registries uses "PHVS_Occupation_CDC_Census_2010" and "PHVS_Industry_CDC_Census_2010".

Numerical references and values

UCUM represents the most comprehensive and authoritative value set available for this domain. However, any standard using UCUM should explicitly specify that the case-sensitive notations of UCUM be used, to avoid ambiguity. For example, C-CDA 1.1 explicitly specifies "UCUM Units of Measure (case sensitive)."

Antimicrobial use and resistance information to public health agencies

We recommend including a short list of recommended standard transport methods, such as Direct. Standardization here will reduce cost and speed adoption. Today, there is great diversity in the capabilities of and standards used by public health agencies.

Case reporting to public health agencies

With SDC, the industry needs more direction for using an encoded form or non-encoded form, in addition to pre-populated and auto-populated options, and will need more direction on what is acceptable to exchange for security. Given the current level of development of SDC, we

recommend implementing SDC only with the URI option as the others are not precise enough yet. As the XML or FHIR options mature, we hope to support including them for future advisories.

Structured Data Capture provides many approaches for implementation of encoded methods, which could vary greatly from agency to agency. These varying approaches may compound the difficulties of reporting to multiple agencies with differing requirements. For example, the specification allows the EHR to request encoded data but does not allow the EHR to request how the data is encoded. If a case reporting form is returned from Public Health to the EHR in XML, it does not specify what stylesheet to use to render the document or what version of XSLT be used to perform the rendering.

In addition, different vendors for forms may include different levels of scripting that may not be acceptable to render or store within an EHR that houses intentional security limitations on HTML content.

Data element based query for clinical health information

Epic recommends defining FHIR profiles for clinical information. A failure by standards bodies and the industry to quickly define FHIR profiles that are widely adopted will result in multiple, contradictory implementations of FHIR. Similarly, only defined resources should be required, to avoid the same problem.

Family health history (clinical genomics)

The Pedigree standard does not include recommended communication options. We recommend including recommended binding options for transport/communication layers, such as Direct.

Health care survey information to public health agencies

Direction on communication/submission protocols would help speed adoption because currently there is variation from submitter to submitter.

Lab - results (receipt)

The implementation guide should be listed in the Implementation Specification(s) column instead of the Standards column. HL7 2.5.1 should be listed as the Standard.

Syndromic surveillance to public health (emergency department, inpatient, and urgent care settings)

ONC's 2015 Proposed Rule for Certified HIT discusses the lack of an industry standard for reporting syndromic surveillance data in an ambulatory context. The current HL7 2.5.1 standard and PHIN guide for existing surveillance reporting is capable of meeting the needs of the ambulatory context as well. We encourage ONC to set the direction for the industry by unifying

the inpatient/emergency/urgent and ambulatory domains until the PHIN guide is a single syndromic standard.

Image exchange – Section IV

DICOM is used to move images between systems within a single healthcare organization. We instead recommend using IHE-XCA-I (Cross-Community Access for Imaging), which can be used to move images between healthcare organizations.

Questions

5.2 [General] Besides the four standards categories included in this advisory, are there other overall standards categories that should be included?

> We recommend that you do include the intentionally omitted category for standards regarding information security. Although there are many technologies and techniques that are indeed applicable to all industries, there are also some standards and design principles that are more relevant to health care and are worth calling attention to. This category should address de-identification of patient information, minimum necessary amount of data to achieve a purpose, access/audit logging, and potentially consider encryption options for data in transit since certain standards already include them and others don't. Specific standards to consider including are the IHE ATNA profile for access logging and the ITI de-identification white paper. Additionally, areas that need formalization include requirements for mutual authentication, root certificate authorities, and minimum levels of encryption.

5.3 [General] For sections I through IV, what "purposes" are missing? Please identify the standards or implementations specifications you believe should be identified as the best available for each additional purpose(s) suggested and why.

> Immunization registry reporting should be broken up into two separate purposes: Vaccination Administration and Vaccination Patient History/Forecast. Both use the same implementation specification, but the purposes are distinct and can be implemented independent of each other. For example, Vaccination Administration has been part of Meaningful Use Stage 1 and 2, but Patient History/Forecast has not. Similarly, it would make sense to separate them with the new proposal for the code set for administrations to move to using NDC while querying continues to use CVX.
>
> We have also found that many interoperability domains, particularly EHR submission to registries, would benefit from stronger patient identity and identifier tools. Therefore, we propose inclusion of Patient Identity Management as a dedicated purpose that would be well-served by IHE's PIX, PDQ, and XCPD profiles for an implementation guide and may reliably use both HL7 v2 and v3 (possibly FHIR in the future) messaging as content standards.

5.4 [General] For sections I through IV, is a standard or implementation specification missing that should either be included alongside another standard or implementation specification already associated with a purpose?

We recommend also including these standards:

- **Immunizations**: Include CDC WSDL (http://www.cdc.gov/vaccines/programs/iis/technical-guidance/SOAP/wsdl.html) for Vaccination Administration Reporting. We suggest adding this reference to the Standard(s) or Implementation Specification(s) column of Section II for immunizations. There is currently a wide variety of communication methods that immunization registries use. It would be beneficial to identify and use a national standard, and CDC WSDL is the preferred communication method identified by the CDC.
- **Query for documents within a specific health information exchange domain:** Allow IHE-XCPD (Cross-Community Patient Discovery) and IHE-XCA (Cross-Community Access) in addition to the listed standards.
  We also recommend using version 3 of IHE-PDQ.
- **Simple way for participants to "push" health information directly to known, trusted recipients**: Include XDR as a transport standard in addition to SMTP. Many EHR systems have already implemented the XDR standard instead of or in addition to SMTP.
- **Research:** Include all of the following:
  Content standard – HL7 v3 Study Design
  Content implementation guide – IHE QRPH CRPC (Clinical Research Process Content)
  Service standard – BPMN (Business Process Model and Notation) and HL7 v3 Study Participation
  Service implementation guide – IHE QRPH RPE (Retrieve Process for Execution)

5.5 [General] For sections I through IV, should any of the standards or implementation specifications listed thus far be removed from this list as the best available? If so, why?

For Publish and subscribe in section IV, we recommend using IHE DSUB (Document Metadata Subscription) instead of NwHIN Specification: Health Information Event Messaging Production Specification because it is more concretely defined and implementable. For example, the NwHIN specification requires that you subscribe to a topic using a topic expression. However, it doesn't define what a topic is. IHE DSUB requires a topic expression and does define what a topic is.

5.7 [Section I] Should more traditionally considered "administrative" standards (e.g., ICD-10) be removed from this list because of its focus on clinical health information interoperability purposes?

ICD-10 has widespread support and is the best option currently available for encounter diagnoses. Exchanging many commonly used concepts like encounter diagnoses is valuable to clinicians because encounter diagnoses fit a widely understood role in the medical chart that represents part of the historical record of how the patient was treated in that context. However, we caution that any implementation specifications including concepts such as encounter diagnoses clearly define the use of the data for clinical purposes to ensure that it is used appropriately. If there are specific needs that a concept fails to meet, then the specific implementation guide should specify alternatives (such as LOI and LRI specifying ask-at-order-entry questions for patient sex if needed for reference ranges, rather than relying on the administrative sex from HL7 demographic data).

5.8 [Section I] Should "Food allergies" be included as a purpose in this document or is there another approach for allergies that should be represented instead? Are there standards that can be called "best available" for this purpose?

Documentation and tracking within EHR systems must look at a broader view of allergies and intolerances. We strongly recommend identifying a unified vocabulary for allergies and intolerances and a comprehensive exchange standard which encompasses medication, environmental, food and other related conditions to avoid harm and ensure a complete and accurate representation of the patient's needs.

For example, as a particular use case, the records exchanged for a patient presenting with severe shortness of breath in an ED must include the ability to communicate a serious birch tree pollen allergy to inform the diagnosis and must also include a latex allergy to guide patient treatment protocols. Furthermore, although the industry lacks a conclusive outcome in cross-sensitivities, there are a number of studies that recommend at least caution, if not contraindication, for giving propfol based on egg allergies. Oral allergy syndrome involves a level of cross-reactivity between environmental pollen allergies and foods, which may in some cases reach life-threatening anaphylaxis outcomes.

5.10 [Section I] Should the MVX code set be included and listed in tandem with CVX codes?

It is appropriate to include MVX along with CVX codes for immunizations, as Immunization Registries use this to infer additional information on the brand of vaccine administered. When a CVX (vaccine administered) code is paired with a MVX (manufacturer) code, the specific trade named vaccine may be indicated. This provides a higher level of granularity then sending the CVX codes alone, which is preferred by many registries.

5.11 [Section I] Public health stakeholders have noted the utility of NDC codes for inventory management as well as public health reporting when such information is known/recorded during the administration of a vaccine. Should vaccines administered be listed as a separate purpose with NDC as the code set?

We strongly recommend keeping CVX as the primary identifier of immunizations and not separating historical from current administrations as separate purposes. However, we agree that NDC is useful for secondary uses and propose that it be included as an additional data element when possible.

5.13 [Section I] If a preferred or specific value set exists for a specific purpose and the standard adopted for that purpose, should it be listed in the "implementation specification" column or should a new column be added for value sets?

Specific value sets should be defined by the implementation specification and should not need to be explicitly called out in these tables. The value sets could be repetitive or conflicting.

5.14 [Section II] Several laboratory related standards for results, ordering, and electronic directory of services (eDOS) are presently being updated within HL7 processes. Should they be considered the best available for next year's 2016 Advisory once finalized?

These standards are the best available for new implementations but they don't bring a large benefit for organizations that have already implemented successful lab integrations. Organizations that have already been successful should not need to redo their integrations.

5.15 [Section II] Are there best available standards for the purpose of "Patient preference/consent?" Should the NHIN Access Consent Specification v1.0 and/or IHE BPPC be considered?

Given the increasing volume of reporting to external agencies outside of a health care network and the lack of a consistent mechanism in existing required messaging standards, we strongly encourage development of a comprehensive standard to track, communicate, and respect patient preference and consent statuses. We don't know of a best available standard for this purpose.

5.16 [Section II] For the specific purpose of exchanging behavioral health information protected by 42 CFR Part 2, does an alternative standard exist to the DS4P standard?

Epic is unaware of any fully developed standards for segmentation as alternatives to DS4P. Given that DS4P has not been evaluated for impact on patient safety or clinical workflows, we strongly encourage delaying the endorsement and adoption of a standard in this space until more research is done.