**Response to ONC Interoperability Standards Advisory**
**by Hammond, Marsolo, Meeker et al**
Comments Submitted on May 1, 2015

## Overview

It is rare that all of the healthcare data on a patient be stored in a single clinical information system of a single healthcare provider. As a result, interoperability, the ability to exchange data between systems, and more importantly, to be able to reason on the information that is received, remains a critical, yet elusive goal of the Health Information Technology (HIT) industry. Although true interoperability has many components, the one area that seems to be getting worse, not better, is semantic interoperability – ensuring that when a piece of clinical data is shared between systems, it retains its meaning. Instead of solving this problem through the standardization of data collection practices and field representations, the healthcare industry embraced variation. Data can be collected locally through multiple workflows and formats, and when it comes time to exchange information, attempts are made to map to a common standard. This mapping often results in a loss of information, and continues to cost time and resources, both for those that must complete the mapping locally, and for those that are responsible for creating mappings between vocabularies. The National Library of Medicine's Unified Medical Language System ®, for instance, contains over 100 source vocabularies, a number that continues to grow.

Using an identified subset of controlled vocabularies as identified in the 2015 Interoperability Standards Advisory is a step in the right direction towards interoperability, but falls short of truly resolving the problem. The controlled vocabularies specified in the document have been defined for multiple purposes, and for the most part, fall short of what is required for true clinical representation of clinical measures and events. Vocabularies originally developed for billing, for example, are frequently inadequate for the required finer granularity required for clinical decision support.

Unfortunately, the request for response to the 2015 Advisory is not organized in a fashion that allows for the best representation or completeness of clinical information. An organization around the clinical workflows and categories of data contained within the Electronic Health Record (EHR) would clarify purpose, permit better recommendations to be made on which existing controlled vocabularies are best suited, and identify those data elements that are missing. In some cases, combinations of existing vocabularies are more appropriate than a single set. For example, a laboratory test might use LOINC ® for the test name and SNOMED-CT® for the result.

Within most clinical information systems, the most commonly used vocabulary is one that is local to the system (or site), and the process to map data to a recommended controlled vocabulary is also local, with little incentive to ensure consistency at the source. Therefore, this mapping process is likely to result in incorrect or incomplete data being shared across sites, and will remain an ongoing expense. Thus, it seems that what is addressed in the 2015 Advisory is at best a temporary measure and falls short of achieving interoperability.

The purpose of standards is to be able to move the required data between heterogeneous sites in which the receiver completely understands both the meaning and context of the data. There are a number of standards available for the transport of data from a number of Standards Developing Organizations. Some of these transport standards are focused on a specific type of data, such as billing (ASC X12) or the National Council for Prescription Drug Programs (NCPDP). Health Level 7 International ® has an evolving set of standards that serve this purpose. Version 2.n is the most widely used standard in the U.S., perhaps due to its simplicity. The version 3.n Standard is complex and has found little implementation in the United States. The HL7 V3 Clinical Document Architecture *(*CDA)®*,* and various implementations such as the Continuity of Care Document *(*CCD®), and the Consolidated Continuity of Care *Document* (C-CCD®) are seeing increased use in patient summaries and test and procedure reports.

In addition to transport standards, interoperability requires knowing what data to send when. The emerging standard Fast Healthcare Interoperability Resources (FHIR)® that includes reusable resources and service profiles has great promise to address these needs. Integrating the Healthcare Enterprise (IHE) has created profiles for certain clinical areas and supports a document registry and a "pull" query for documents. There also remains the problem of unique patient identification, which limits our ability to aggregate patient data across multiple sites. A number of algorithms exist, but all fall short of acceptably matching patients.

A number of other standards need to be included including Clinical Decision Support, Family History, Genetics, Usability, mobile devices, registries, and others. We urge the Office of the National Coordinator for Health IT to move ahead in resolving these issues to address the inconsistencies, information loss, and costly practices of supporting incomplete vocabulary sets.

## Introduction

On January 30, 2015 the Office of the National Coordinator (ONC) issued an open draft version of the 2015 Interoperability Standards Advisory: Best Available Standards and Implementation Specifications[1]. This document is in response to the call for public comments[2].

These comments represent the individual views of the authors, each of whom collaborate on the Data Standards, Security, and Network Infrastructure (DSSNI) Task Force of PCORnet, the National Patient-Centered Clinical Research Network. These comments do not necessarily represent the views of the Patient-Centered Outcomes Research Institute

[1] http://www.healthit.gov/sites/default/files/2015interoperabilitystandardsadvisory01232015final_for_public_comment.pdf

[2] http://www.healthit.gov/policy-researchers-implementers/2015-interoperability-standards-advisory-public-comments

(PCORI), the PCORI Board of Governors, or other organizations and governmental entities collaborating in the development of PCORnet.

## Comment on the Scope

*"The advisory does **not** include within its scope administrative/payment oriented interoperability purposes…" [page 4].* The cost of maintaining standardized information is high. Maintenance is not typically part of current operating budgets in health systems. If administrative and payment standards do not reinforce clinical standards, operating budgets will not include costs of maintenance.

## Responses to Section V: Questions Regarding the Interoperability Standards Advisory

*ONC Question 5-1: What other characteristics should be considered for including best available standards and implementation specifications in this list?*

Response:
As currently presented, a "standard" may involve one or more of the categories or purposes. Interoperability depends upon a mutual understanding of this information and the way it is specified. A significant reorganization may facilitate getting at the root cause of our interoperability problem. To implement an operation that might be present in one of these standards, the following are needed:

- Inputs to an operation – what input schema do operations expect?
- Operations – what are the operations this standard purports?
- Outputs of an operation – what is the output schema?

For many of the standards contemplated in this document, the Operations are called "Implementation Guides," and are devoted to generating a structured output from inputs that are underspecified and operational logic that is not computable.

Inputs and outputs should conform to one or more semantic standards with an information model that adheres to specific constraints communicating how they should be parsed.

Knowledge artifacts are often, but not always, bundled with terminology standards – ontologies. Occasionally, these are coupled with generalized relational assertions based on definitional aspects ("is a"; "is an order for"), or knowledge (drug-drug interaction).

The value of terminology standards is directly related to the amount of knowledge that can be accurately linked to them, and the scope under which that knowledge is valid (that is, the "Purpose").

In addition to *Timeliness & Availability* and *Stability & Adoptability:*

- Completeness of the standard
- Extensibility of the standard to meet future needs
- Interoperability with evidence base, knowledge base and other standards.

The **criteria** for demonstrating evidence of "Stability & Adoptability" should be very clear:

- Incentives for adoption and maintenance.
- History of successful implementation in generalizable contexts.
    - If new, reference implementation that allows comparison to alternatives.
- Availability and quality of implementation guide, including the specificity of inputs, operations, and outputs that are assumed in any given implementation.
- Has a reference implementation been demonstrated for a significant number of use-cases?

*ONC question 5-2: Besides the four standards categories included in this advisory, are there other overall standards categories that should be included?*

Response:
We suggest this organization:

- Vocabulary/code sets/terminology (i.e., "semantics").
    - Encoding concepts (and how they should be collected, constructed, or abstracted).
- Knowledge management constructs associated with vocabularies
        - Value Sets and Ontologies
        - Relational assertions (i.e., "is_a"; "treats")
        - Derivation - rules employed to generate concept, if any
        - Scope/**Purpose** wherein assertions are valid
- Structure: Schema/format for information encoding (the constraints that should be honored so that parsing logic is intact.
    - Syntax for specifying constraints
- Operations (i.e., "syntax").
    - Syntax for specifying logical operations and derivation rules
    - Syntax for specifying production rules, if any

These are purposes:

- *Transport* (i.e., the method by which information is moved from point A to point B).
- *Services* (i.e., the infrastructure components deployed and used to accomplish specific information exchange objectives)

If a reorganization is not considered, at a minimum we recommend that **expression syntax for logical rules** related to implementation of clinical algorithms for patient identification, data transformation, and event triggering be considered as a distinct category from semantics and syntax.

We also suggest the inclusion of algorithms – e.g., patient-matching, computed phenotypes.

*ONC question 5-3: 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.*

Response:

- Section I
    - Phenotypic characteristics – Human Phenotype Ontology
    - Signs and symptoms
    - Geocoding
    - Bar coding
    - Supplies
    - Demographic content should be expanded.
        - How should addresses be identified? What address should be included? Should dates of address be retained?
    - What items should be dated and a historical trail be retained? Examples include addresses and occupation.
    - Condition-specific data elements captured during the course of sub-specialty care
    - Patient-reported outcomes
- Section II
    - Disposition
    - Advance Directive should be standardized
    - HL7 has defined a number of tables that have been created as part of v2 over many years. These tables should be included. Examples include a code for the type and place of encounter.
    - Personal preferences should be coded.

*ONC question 5-4: 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?*

Response:

- MedDRA codes are in frequent use for recording adverse events
- Any controlled vocabularies implied by standards specifying operations in the Transport and Services purposes (I am not familiar with these).
- Controlled vocabulary for expressing operations on clinical data (Quality Data Model Syntax/HQMF, Clinical Quality Framework syntax, HL7 processing rules)

*ONC question 5-5: 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?*

Response:

- NDC codes should not be included as codes to be used in the future.
- While FHIR appears to be emerging as the only potential standard that supports querying at the data element level, it only allows queries on a partial subset of the

data that might be in a patient's record (http://www.hl7.org/FHIR/clinical.html). In addition, it is unclear, once implemented in a system, whether it will allow queries on "all" of the data that are available for a given clinical concept, or only after a specific point in time or for those data captured using a specific workflow.

*ONC question 5-6: Should more detailed value sets for race and ethnicity be identified as a standard or implementation specification?*

Response:

- The answer depends on how the data are to be used. If the purpose is to satisfy grant requirement to ensure minorities are included, then OMB categories are adequate. If other purposes, including race-related clinical implications, then the sets need to be richer. Ideally, the value set for race needs to be hierarchically defined so data can be collected at the level needed but can be queried at the appropriate level.

*ONC question 5-7: 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?*

Response:

- Definitely not. Administrative variables are important for both research and clinical purposes.
- Knowledge artifacts, such as relational mappings and value sets, should be standardized to ensure that the scope of mapping between clinical concepts and administrative concepts are valid across purposes. It is also worth considering whether to include additional "legacy" standards such as ICD-9. In many cases, data that have been collected previously may not be "upcoded" to a more recent standard. If administrative concepts/standards are valid across purposes, but will *not* be included, then guidance should be provided on what to do with previously collected information. At a minimum, there should be a way for external systems to know that information may exist about a patient for a certain purpose/domain, but not in a standard that is compatible with the interoperability roadmap. Otherwise, users may be led to the false assumption that they are working with a complete dataset. Consider including additional administrative standards (e.g., ICD-9-Proc, NDC, Multum), but marking them as deprecated.

*ONC question 5-8: 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?*

Response:

- Food allergies should be included. For one reason, nutritional data and prescribed diets should be part of the EHR. In the same way we worry about drug allergies, we need to worry about food allergies. Environmental allergies should be considered as well.

*ONC question 5-9: Should this purpose category be in this document? Should the International Classification of Functioning, Disability and Health (ICF) be included as a standard? Are there similar standards that should be considered for inclusion?*

Response:

- Purpose is a critical component of the granularity of the data we collect and record. The purpose and use of a code or code class strongly influences and determines what are the use cases and value sets. An example is sex and another is race. How does a problem code or diagnosis code documented as part of the encounter relate to a problem list. If the purpose of an encounter code is billing and the purpose of a problem list is clinical, that fact will influence the choice of codes.
- In fact, the objective of this advisory would be better served if a standard ontology for *Purpose* were contemplated. This would allow respondents to unbundle the terminology for clinical concepts that cross multiple purposes from the terminology specific to a purpose. Assertions that are implied in value sets and knowledge artifacts have a scope of validity, and that is the "Purpose".

*ONC question 5-10: Should the MVX code set be included and listed in tandem with CVX codes?*

Response:

- Yes, both CVX and MVX should be included and listed in tandem. MXV should be directly linked to individual items in CVX.

*ONC question 5-11: 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?*

Response:

- Vaccines should be entered as a type of medication, distinctive from a drug. Similarly, blood products, and other things that are prescribed should be separately identified. Vaccine administration should be driven by algorithms relating to what vaccine and when. But certain vaccines can create adverse events and be part of a drug-drug interaction so should be included in the same section as drugs.
- NDC codes should be retained for historical data. Many clinical databases have

medications identified by NDC codes. However, NDC codes should not be used for the present and future coding of medications. RX Norm should be used for that purpose.

*ONC question 5-12. Is there a best available standard to represent industry and occupation that should be considered for inclusion in the 2016 Advisory?*

Response:

- Yes. Recommend adopting Census Standards (Current Population Survey).

*ONC question 5-13. 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?*

Response:

- Value sets should be listed as a separate column. When the value sets may be different for a data element as a function of use, the relevant data elements should be separately identified along with the specific value set. An example may be administrative gender versus clinical gender.
- Value sets should be listed at the maximum set. A given site should not have to use all items listed in the value set (i.e., may locally use a subset), but no value not included in the full data set should be used.

*ONC question 5-14: 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?*

Response:

- Yes. HL7 should expedite the process to insure that the updated standards are ready for use in 2016. These standards are being defined by the experts in the field and will represent the best available. Problems and issues should be fed back into HL7 to be accommodated in future versions. Further, interested parties should immediately participate in the updating of these standards.

*ONC question 5-15: 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?*

*ONC question 5-16: For the specific purpose of exchanging behavioral health information protected by 42 CFR Part 2, does an alternative standard exist to the DS4P standard?*

*ONC question 5-17: For the 2015 list, should both Consolidated CDA® Release 1.1 and 2.0 be included for the "summary care record" purpose or just Release 2.0?*

Response:

- Would recommend just Release 2.0. The evolution from Release 1.1 to 2.0 is a reflection of identifying and correcting problems and issues, and we should move to the best expected. However, as with data coded to legacy terminologies/value sets, CDA 1.1 should be considered as a deprecated standard that can be used to exchange legacy records.

*ONC question 5-18: Should specific HL7 message types be listed? Or would they be applicable to other purposes as well? If so, which ones and why?*

**Comments**

While specifying preferred terminologies for data domains is important, in many cases, there may be multiple valid options for a given term both within and across controlled semantic systems (there are 17 different versions of Serum Potassium within LOINC, for instance). When trying to reason on this information, users will either need to be aware of all possible codes, or terminologies should provide information on the relationship between codes (including whether there are preferential codes for a given term).

While it is important for the Value Set Authority Center and Interoperability Standards Advisory to promote the UMLS alignment with this objective and define best available standards and implementation specifications, more guidance must be provided on how to handle legacy data that do not conform to these new standards. It is unlikely that most health care institutions will have the time or resources to map all possible data of a Purpose (context) to a listed standard. This can lead to situations where institutions are only exchanging those elements that have been made interoperable.. The result will be a partial view of the patient (or the exchange of lengthy text documents).

**Summary**

We are delighted and congratulate the Office of the National Coordinator in taking the lead to address a major barrier to achieving interoperability. We do suggest this initiative is just a start, but a key first step. There are areas not addressed, and incomplete vocabularies exist in all areas. We suggest that a better organization aligned with EHR architecture would be a better way of recognizing how terminologies will be used and identifying missing areas. We propose to stay engaged with ONC to complete the journey to true interoperability.

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