



Attention: Office of the National Coordinator for Health Information Technology (ONC)

Re: Open Draft of the 2015 Interoperability Standards Advisory

April 28, 2015

The Regenstrief Institute is a non-profit biomedical informatics and healthcare research organization dedicated to improving quality of care, increasing efficiency of healthcare delivery, preventing medical errors, and enhancing patient safety. Regenstrief is also a global leader in health data standards. It is with these perspectives in mind that these comments are offered.

We want to applaud the ONC for launching this important initiative. We believe that the purposes of the Advisory (to provide a single public list of best available standards and to promote dialogue) are laudable and that the process outlined by the ONC is a reasonable path for accomplishing these goals. We can also understand the rationale for not using the maturity and adoptability criteria proposed by the HITSC in 2012. We also appreciate the opportunity to provide comments to the ONC on their approach with the Advisory.

At a general level, the goal of transparency and straightforward assessment would be aided by not only publishing the list of standards, but by providing links to summary documentation of the ONC assessment (based on the criteria it has established). Although one purpose of the Advisory is to promote industry dialogue and debate, it is curious that no such specific public input went into development of this first draft.

Going forward, we have two recommendations for facilitating open discussion. First, maintaining an open, “threaded” connection between the Purpose + Standard/ Implementation Specification and the forums (whatever format they might be recorded in) where the dialogue is happening will allow interested parties to follow along and participate. Second, a summary statement on the ONCs consideration of the stakeholder discussion about a Purpose + Standards/Implementation Specification should be included in future editions of the Advisory.

We also have several specific comments about the list of best available standards included in the 2015 Advisory.



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

The default model for naming vocabulary standards in this section presumes that only one vocabulary is needed to fulfill the needs of Health IT systems. In reality, for many of these purposes, two standards are needed because the clinical information is recorded, stored, exchanged using a “tried and true” entity-attribute-value (a.k.a. question + answer) information model.

For example, inside many EHRs there is a master table for storing information about a person (i.e. patient) that includes core attributes like their unique ID in the system, name, address, birthdate, etc. Other attributes or results about a particular patient are typically stored in a table of observations that has the EAV model, with one field identifying the observation variable (e.g. body height) and another field containing the observation result value (e.g. 183 cm). In cases where the result value is categorical in nature, the ideal scenario is that a vocabulary standard provides codes or a common syntax for those answers.

The same paradigm holds true in messaging, where the observation (OBX-3 in HL7 V2, Observation.code in V3, or Observation.name in FHIR) is coded and the observation value (OBX-5 in HL7 V2, Observation.value in V3, or Observation.valueCodeableConcept in FHIR).

The long-standing, well-established basic approach is that codes for observables should be drawn from LOINC, and codes for observation values should be drawn from other vocabularies, most often SNOMED CT. (There are a few cases, such as in genetic testing, where the result value is best communicated as an expression in a formal syntax such as HGVS or ISCN). This two-part “question/answer” model is well-established, was recommended across many domains by the HITSC (see September 9, 2011 letter at http://www.healthit.gov/sites/default/files/standards-certification/HITSC_CQMWG_VTF_Transmit_090911.pdf), and is jointly endorsed by Regenstrief and the IHTSDO in their collaborative agreement:

IHTSDO and RII both endorse the statement that, LOINC provides codes that represent the names of information items (e.g. questions) and SNOMED CT provides codes that may represent nominal and ordinal values (e.g. answers) for these named information items.

Therefore, the Advisory should make clear which vocabulary standard is needed for the observation, and which for the observation value. Specifically, we recommend that these



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domains have vocabulary standards identified separately for observations and observation values:

- Family health history (e.g. as recorded using a variables from the U.S. Surgeon General's My Family Health Portrait)
- Functioning and disability
- Gender identity
- Industry and occupation
- Lab tests
- Sexual orientation
- Smoking status

For all of the above categories, LOINC is best available and most appropriate vocabulary standard for observation identifiers. For many kinds of observables, SNOMED CT is the best available vocabulary for result values, as ONC has identified. But, this is only one half (the answer half) of the equation.

Section I. Purpose: Functioning and disability

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?

We agree that this purpose should be included in the Advisory, though it is not quite as straightforward as other more focused domains like vital signs.

Let me explain. The “purpose” of functioning and disability implies the use of vocabulary standards across several different “kinds” of information, such as recording problems, recording clinical observations, and even possibly classifying function according to a common framework. A 2013 paper by Vreeman and Richoz (<http://www.ncbi.nlm.nih.gov/pubmed/23897840>) outlined how the vocabulary standards like LOINC, SNOMED CT, and ICF could fit together in health IT systems for the purpose of achieving semantic interoperability.

We have existing, mature vocabulary standards (i.e. LOINC for observations and SNOMED CT for observation result values) that can communicate the results of clinical measures of function, including standardized assessment instruments. Use of these standards for this kind of functioning and disability content should be encouraged. There has been a longstanding set of recommendations toward this end, including the



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recommendations of the Consolidated Health Informatics Initiative and the HITSC (see September 9, 2011 letter at http://www.healthit.gov/sites/default/files/standards-certification/HITSC_CQMWG_VTF_Transmit_090911.pdf). To date, the implementation of recording this information as structured electronic data has been slower than in other clinical areas, such as laboratory results reporting. But, key professional associations like the American Physical Therapy Association are starting to use LOINC and SNOMED CT in large-scale projects like their national outcomes registry. In addition, the developments of assessments from item-response theory and computer-adaptive testing look promising, and the representation of instruments such as PROMIS and Neuro-QOL, etc in LOINC has helped promote their use in health IT systems.

The role of the ICF in this domain is more complex, less well-accepted, less urgent, and therefore less compelling.

We would like to point out, however, that there are really three distinct components/levels of the ICF that various organizations (and individuals) have embraced. For the sake of illustration, we'll call them:

Level 1: ICF conceptual framework

Level 2: Level 1 + taxonomic list of elements in various domains of functioning

Level 3: Level 2 + classification using ordinal qualifiers on several dimensions (performance, capacity, etc).

These are not WHO delineated or endorsed "levels", but are useful for discussion because they reflect how ICF is currently being viewed and used.

As a conceptual framework (Level 1), everyone loves the ICF. Describing functioning as an interaction between the health condition and contextual factors (environmental and person) is intuitive and clear. ICF's concept of how the body, person, and society interact in terms of Body Functions, Body Structures, Activities, and Participation are also well accepted. Most rehabilitation professional training programs have replaced the Nagi model language with the ICF language.

The use of ICF's domain codes (Level 2 - e.g. walking, lifting and carrying objects, etc) has been a more tepid. From a research perspective, some authors have been designing standardized assessments based on the ICF domains. A few have tried to map the concepts measured by existing instruments to ICF domains. I know of one electronic health record system that uses the ICF domains as an organizing principle for the data in



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the EHR viewed by rehabilitation providers. Anecdotally, the interest in ICF domain codes have been mostly in the areas of Activity and Participation. There are other vocabulary standards (e.g. SNOMED CT, Foundational Model of Anatomy, etc) that are more advanced/adopted in information systems for anatomy than the ICF domain codes, so if people are using codes for such things (in the vast majority of practice they aren't) it would be something other than ICF.

Almost no one is using ICF with its (multiple levels of) qualifiers (Level 3). There are likely several reasons why. Clinicians assess these dimensions using existing standardized instruments, physical examination, and observation. The ICF isn't an assessment instrument, so clinician's can't interpret or use it in decision-making the same way they would a standardized scale with known psychometric properties. There is no clear way to get from the outcomes measures they are currently using to assigning ICF qualifiers. The scientific community is just starting to investigate these associations. Further, no one is paying clinicians to spend the time making these code assignments.

On this last point, we should mention that many of these same issues arose in the discussion around CMS's new requirements of "G-codes" for functional status. Functional outcomes measures and ICF qualified domain codes aren't the same thing. Further, we lament the fact that they opted to create their own non-ICF approach, which defeats the goals of standardization. If the case for Level 3 use of ICF is murky, even more so for the CMS-invented G-codes.

Therefore, in summary, we do believe that using the ICF domains as the common language to identify different functional capabilities (i.e. specific kinds of activities and participation) would help advance the field. However, asking clinicians to "magically" convert existing assessment scores/scales to ICF qualifiers would be ill-advised.

A key priority should be to get the existing ways that clinicians are recording the more basic "raw" observations to start flowing electronically using LOINC for observations and SNOMED CT observation result values. Studying the properties of reproducible methods to convert the "raw data" (tests, measurements, and observations) into fully-qualified ICF classifications is interesting and needed work, but not a first order of business.



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Section I. Purpose: Numerical references and values

The name for this purpose is a bit murky. Given the choice of UCUM, I think a more appropriate name might be simply “Units of measure” (for use with numerical references and values).

Section I. Purpose: Radiology (interventions and procedures)

The designation of Radlex as the best available standard does not meet the “best available” criteria here. LOINC is quite well established in this domain, is used in DICOM as the document code, used in CCDA to identify diagnostic study reports, HITSC recommended LOINC for radiology more than once (first as part of non-lab diagnostic studies, and again under the image sharing recommendation), etc. Further, Regenstrief and the RSNA have a unification project that is underway to unify the radiology models used in LOINC and the RadLex Playbook (<http://loinc.org/collaboration/rsna>), and under that agreement, the LOINC code will be the primary identifier for radiology procedures. The proposed approach is that overall content will be jointly managed by Regenstrief and the RSNA. It seems vividly clear that LOINC should replace Radlex in this designation (and will actually be content jointly curated by Regenstrief-RSNA, which is in our view an ideal situation).

Section II. Question 5-14

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?

We agree that these standards should be considered the best available once they have been finalized. These three standards have had a long gestation period, and the majority of the changes are incremental improvements and modifications for consistency across the triumvirate.

Section II. Question 5-17

5-17. [Section II] 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?

In contrast to the three lab standards mentioned above, Consolidated CDA Release 2.0, while recently published as a DSTU, did *not* have a long gestation period. Large sections



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were rushed into development, and the terminology bindings are a blooming mess. The document that went to ballot completely ignored HITSC and ONC recommendations, and only some were corrected for the final publication. There are still terminology bindings that are completely wrong (i.e. the code selected is inappropriate for intent of the template). Worse, many areas added specificity in the form of entry templates with data representations that seemed to have been invented out of thin air, rather than being based on clinical realities or even theoretical frameworks. There is also wide variation in the level of specificity across domains, with some having extraordinary detailed entry level templates and some with little to no structure at all. Some of these issues have already been cataloged on the DSTU page, and we expect more to emerge with time.

In short, we do not believe that C-CDA Release 2.0 is ready for prime time. Thus, yes, C-CDA R1.1 should be listed.

Sincerely,

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