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

Re: Draft of the 2016 Interoperability Standards Advisory (2016 Advisory)

November 6, 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 an 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 continuing 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 are grateful for ONC's response to comments by us and others that improve the clarity and openness of the recommendations. Specifically, the framing as "interoperability needs", the addition maturity and adoptability characteristics for each recommendation, and the addition of comments known limitations or preconditions are all welcome and important additions. Thank you.

As an SDO, we know that it is often difficult to precisely determine the "Adoption Level" of particular standards. We publish and distribute them, but do not have complete information about how they are being used. We look forward to working with ONC to develop better processes and measures to support the assessment adoption level.

There are several content domains absent from the 2016 Advisory for which vocabulary standards are quite mature and there are clear interoperability needs to support the goal (as described in the Interoperability Roadmap) to send, receive, find and use priority data domains to improve health care quality and outcomes. Here we mention these domains and recommend the appropriate standards. As with the 2015 Advisory, we have several specific comments about the list of best available standards included in the 2016 Advisory.

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Additional content domains and interoperability needs

In order to support the Interoperability Roadmap goals, we recommend the addition of these several new domains.

Clinical measurements and observations
Interoperability need: send, receive, and use clinical measurements and observations
Standard: LOINC

Common examples include: Gestational age [18185-9], Body surface area [8277-6], Color of wound edge [39133-4].

Interoperability need: send, receive, and use clinical measurement and observation result values
Standard: SNOMED CT

Clinical document types
Interoperability need: send, receive, and use clinical documents
Standard: LOINC

LOINC has a robust set of codes and an ontology for constructing codes that identify clinical document types, such as discharge summaries, progress notes, etc. LOINC is the recommended standard for such codes in CDA, and is very widely used for this purpose, both within the U.S. and internationally.

Patient reported outcome measures, survey instruments, and other standardized patient assessments
Interoperability need: send, receive, and use patient reported outcomes measures, survey instruments and patient assessments
Standard: LOINC

LOINC has a mature and well-developed model for representing these kinds of measures (see PMID: 22899966) and much content in this domain. For example, PHQ, PROMIS, Neuro-Qol, Morse Fall Scale, many of the CMS-required instruments in Post Acute Care, all of the PhenX measures, etc. LOINC has been recommended and adopted in this area in nursing, by the Consolidated Health Informatics Initiative, Health IT Standards Committee, etc. We have been using them in clinical care applications, and you can even download depression screening apps with LOINC codes inside.

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

In our comments on the 2015 Advisory, we made a detailed argument for how the prevailing two-part "observation" plus "observation value" information model should be incorporated in naming vocabulary standards for appropriate domains. Specifically, the the Advisory should make clear which vocabulary standard is needed for the observation, and which for categorical (coded) observation values.

We were disappointed that this recommendation was not taken into account in the 2016 Advisory, but encouraged by the opportunity to discuss it with ONC this week. We continue to recommend it's application in future publications of the Advisory.

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, 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.*

In the following sections, we make specific recommendations about how this might be accomplished. In some domains, the observation/observation value pattern is the norm, in others it

Section I-B. Purpose: Care Team Member

The interoperability need should be clarified as "Identifying a care team member". The NPI identifies the person. While the NPI database does contain information about the provider's Healthcare Provider Taxonomy and licensure, I believe the intended interoperability need here is about identity, not professional classification or role with respect to a particular patient (which is handled either in the information model or observation identifier to which the NPI serves as the observation value).

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We recommend adding a statement under Limitations, Dependencies, and Preconditions for Consideration about the use of LOINC to provide codes for related observation identifiers:

> LOINC provides observation codes for use in the observation / observation value pattern for communicating care team member identity. For example, National provider ID [45952-9], Self-dialysis training physician NPI [68357-3].

We are aware of several uses of such an approach, both for providers and facilities. Examples include the CrownWeb system authorized by CMS in their ESRD program that captures facility survey forms, the American Physical Therapy Association's national outcomes registry, and the Nursing Management Minimum Data Set.

Section I-D. Race and Ethnicity

We agree that the OMB's 1997 standard is widely used and that the CDC code set is useful in some contexts. Often, but not always, race and ethnicity have designated slots in the information model of an information system. We recommend adding a statement under Limitations, Dependencies, and Preconditions for Consideration about the use of LOINC to provide codes for related observation identifiers:

> LOINC provides observation codes for use in the observation / observation value pattern for communicating race and ethnicity. For example, Ethnicity OMB.1997 [69490-1], Race OMB.1997 [72826-1], or Race or ethnicity OMB.1997 [59362-4].

Section I-E. Family Health History

In this domain there is a range of needs from simple annotations to a full pedigree with genomic details. Simple assertions can be coded with SNOMED CT, but other structures (and codes) are needed for other methods for recording history. Many such models, like the U.S. Surgeon General's My Family Health Portrait use an observation/observation value model. LOINC has created a full set of codes to represent this tool (see US Surgeon General family health portrait [USSG-FHT] [54127-6]).

Similarly, HL7's Family History/Pedigree Interoperability Implementation Guide (which is also named in the 2016 Advisory) makes heavy use of that pattern, and names specific LOINC codes for specific kinds of observations. For example, Age range at onset of

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disease (family member) [54115-1] or Estimated Age [21611-9]. Here's an illustration of the XML indicating that the patient's maternal grandfather is 98 years old.

```
<!--maternal grandparents-->
<relative classCode="PRS">
        <!-- MATERNAL GRANDFATHER -->
        <code code="GRFTH"/>
        <relationshipHolder classCode="PSN" determinerCode="INSTANCE">
                <id root="2.16.840.1.113883.6.117" extension="555.004"/>
        </relationshipHolder>
        <subjectOf1 typeCode="SBJ">
                <livingEstimatedAge classCode="OBS" moodCode="EVN">
                        <code code="21611-9" codeSystemName="LOINC" displayName="estimated age"/>
                        <value value="98"/>
                </livingEstimatedAge>
        </subjectOf1>
</relative>
```

Because the observation/observation value pattern is common in this domain, we recommend that the Interoperability Need be defined as two pieces:

Interoperability Need: Representing patient family health history observations
Standard: LOINC

Interoperability Need: Representing patient family health history observation values or assertions
Standard: SNOMED CT

Section I-F. Functional Status / Disability

> *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).*

As we noted previously, 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 measures and observations of functioning and disability should be encouraged.

There has been a longstanding set of recommendations toward this end, including the 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. 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.

Section I-G. Gender Identity, Sex, and Sexual Orientation

Both gender identity and sexual orientation are concepts that are typically recorded in the observation/observation value pattern. Thus, two vocabulary standards are recommended: LOINC for the observation, and SNOMED CT for the observation value. We recommend modifying this section as:

Interoperability Need: Representing patient gender identity observations
Standard: LOINC
Preconditions: Recommended LOINC code Gender identity [76691-5]

Interoperability need: Representing patient gender identity observation result values or assertions
Standard: SNOMED CT

Interoperability Need: Representing patient sexual orientation observations
Standard: LOINC
Preconditions: Recommended LOINC code Sexual orientation [76690-7]

Interoperability need: Representing patient sexual orientation observation result values or assertions
Standard: SNOMED CT

Section I-J: Lab tests

Lab tests always follow the observation/observation value pattern of reporting. When the result is categorical in nature, the LOINC is the question, SNOMED is the answer paradigm works well in most cases. You have acknowledged this in the comments. But, there are some cases (such as in genetics) where the observation value is better communicated as a syntax, e.g. HGVS, ISCN, or the star allele nomenclature. Like the other domains, we recommend separating this into two interoperability needs: one for observations (LOINC) and one for observation result values (SNOMED CT with the caveats as mentioned above).

Section I-L: Numerical References & Values

As noted last time, the name for this is a bit wonky. Numerical values don't need a standard, but units do. Given the choice of UCUM, I think a more appropriate name might be simply "Units of measure" (for use with numerical references and values).

Also, the full name is of UCUM is The Unified Code for Units of Measure. (For, not "of" as listed in the Advisory).

Section I-P. Radiology (interventions and procedures)

We fully support the recommendation of LOINC in this domain.

Section I-Q. Smoking status

Smoking status is a concept routinely recorded and transmitted using the observation/observation value paradigm. ONC noted and acknowledged the comments from HITSC to this end, which note how there are various patterns of recording this information, including severity of dependency, lifetime exposure, etc.

Thus, while we fully support the use of SNOMED CT for the observation value, the interoperability need should be represented as two parts.

Interoperability Need: Representing patient smoking status observations
Standard: LOINC
Preconditions: LOINC includes codes that support recording smoking status in the CDC's preferred (and sometimes required) responses (e.g. Tobacco smoking status NHIS

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[76691-5]) and other kinds of observations (e.g. Have you smoked at least 100 cigarettes in your entire life [PhenX] [63581-3] or How old were you when you first started smoking cigarettes every day [PhenX] [63609-2].

Interoperability need: Representing patient smoking status observation result values or assertions
Standard: SNOMED CT

Section I-S. Vital Signs

We fully support the recommendation of LOINC in this domain.

Thank you for the opportunity to provide comments on the 2016 Advisory. If you have any questions or would like to discuss these matters further, please contact do not hesitate to contact me.

Sincerely,

Daniel J. Vreeman, PT, DPT, MSc

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