Value Sets for Ordinal Lab Results

Temporarily Out of Scope
1. We are not standardizing interpretations that accompany quantitative measurements yet, but we should do this soon. (Note: This seems easier than I initially thought, should be include this?)
2. We will develop the design for value sets in languages other than English at a later date.
3. We are not doing anatomic pathology findings yet.
4. Standardization of nominal lab test value sets will be done sometime in the future.

Principles
1. We will not make design decisions or policies that will not work internationally.
2. We assume that the value sets will initially be expressed in English.
3. We need to allow adequate time for people to adopt the ordinal value sets, but we assume that people will eventually need to change current practices in order to achieve the value of standardization.
4. Tests that have the same clinical meaning and use should be assigned the same LOINC code.
5. When a numeric result value is available and is legally reportable, then the number is reported as the result (OBX-5) and the associated interpretation in (OBX-8).
6. Semi-quantitative results:
   a. Deprecate sending both a numeric range and an ordinal value
   b. Scores are sent/stored as ordinals
   c. Numeric ranges with units (including units of “unity”) are sent/stored as the numeric range datatype in OBX-5 and using the LOINC quantitative LOINC code
   d. True ordinals – 1+, 2+, 3+ - are stored as ordinal values (OBX-5) with the ordinal LOINC code, not the quantitative LOINC code
7. The results of non-specific orderable tests (“order only” tests) (serum protein electrophoresis, Prader-Willi and Angelman, cell differentials, cell morphology, urine microscopic exam, drug plus metabolite screens) will be stored as specific results (Prader-Willi Pos/Neg, Angelman Pos/Neg, Waxy casts 3+, etc.).
8. Value sets will not contain “reasons that data is not present” such as: test not done, sample hemolyzed, quantity not sufficient, patient refused, etc.
9. Value sets for ordinals can be heterogeneous, i.e. the same value set could contain: 1+, 2+, 3+, and none, small, medium, and large. (Controversial, needs more discussion)
10. There are use cases when the value set identifier and its version number will need to be sent in the data stream to provide proper context for interpreting the value sent. In these situations, originators of the data will send the value set identifier and its version number in the data instance as OBX-5, fields 15 and 16.

Process for Making Ordinal Value Sets
1. We will make a list of ordinal labs for which we will create value sets. Criteria for prioritizing items to include in the list are:
   a. Lab tests that have a scale of Ord
b. High volume tests
c. Urine and blood test strips
d. Antibody detection
e. Opioid screening tests
f. Testing for immune status e.g. measles
g. Susceptibility testing when reported as an ordinal

2. A subgroup with broad representation will be convened to make final decisions on:
   a. Which values will be considered synonyms: Negative, Not Detected, Positive, Detected, Immune, Not immune, Indeterminate, Borderline, Gray Area, etc.
   b. The policy of how to manage “Not Detected” versus “X Not Detected”.

3. IVD test developers will be asked to assign LOINC answer list text and a SNOMED concept code for each allowed value for ordinal tests. This information will be in a new table that will be part of the LIVD catalogue/publication by the manufacturer.

4. Regenstrief LOINC staff will aggregate value set information across different vendors where the assigned LOINC code is the same. The aggregated value set elements will be added as elements as “normative” value sets of the ordinal LOINC codes in the LOINC database.

5. New SNOMED CT concept codes for ordinal values will be added as needed.

6. A SNOMED CT refset will be created that contains all of concepts that are used as values for ordinal tests. SNOMED International will make the refset available worldwide at no cost and will be free for all uses.

7. IICC will work with HL7 to make tools and capabilities that make it easy for implementers to use the value set information in production systems. We anticipate that efforts in HL7 and IHE to take advantage of these new capabilities. IICC will work with FHIR to unify the new parts added to LIVID.

**Try it out, Proof of concept**

1. Who, what, when?

**Actions**

1. Do 10 examples to show how it works.
2. IICC members do assemble values some values in next 3-4 months. – Ed
3. Choose 10 tests that are each done by at least 2 manufacturers.
4. Regenstrief will make the value sets and put them in the LOINC file.
   a. Will need to make LOINC answers and answer codes
   b. Will need to make SNOMED CT codes
      i. Review US extension for existing concepts
5. Proof of concept
   a. Potential participants
      i. Intermountain
      ii. Geisinger?
      iii. Children’s Hospital
      iv. Find some labs that have not done any LOINC mapping yet
   b. What proof of concept means
      i. Review test and values to mappings in lab and receiving systems (EHR)
ii. Actually sending of LOINC codes and values on the wire (both LOINC values and SNOMED CT codes)
iii. Comparison of same test from different labs

6. Need to review why people are not using LOINC codes natively in their systems.
7. Convene a group to talk about semantic mappings of answer strings in ordinal tests.
   a. MDIC/NEST will do (Carolyn Hiller) – get into framework then to CLSI (Clinical and Laboratory Standards Institute)
   b. Check with CDISC about their experience with this kind of discussion