COLLEGE of AMERICAN PATHOLOGISTS

Comments on the
FDA/CDC/NLM Workshop
on
Promoting Semantic Interoperability
of Laboratory Data
(Docket No. FDA-2015-N-2372)

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The College of American Pathologists (CAP) appreciates the opportunity to respond to the Federal Conference Discussion Paper and working group session on Promoting Semantic Interoperability of Laboratory Data. The CAP is the largest medical association of board-certified pathologists serving 18,000 physician members and the global laboratory community. The CAP has significant Health Information Technology and Clinical Informatics expertise and was the creator of what is now SNOMED CT®. The CAP actively participates in standards development including the governing body of SNOMED (the International Health Terminology Standards Development Organisation or IHTSDO), Health Level Seven International (HL7); and several Office of the National Coordinator (ONC) initiatives. The CAP is also the primary Secretariat for Integrating the Healthcare Enterprise (IHE) Laboratory and Anatomic Pathology domains.

The purpose of this response is to provide some insights into the issues pathologists face regarding the use of Logical Observations Identifiers Names and Codes (LOINC) and the Unified Code for Units of Measure (UCUM).

LOINC

We acknowledge the complexity of LOINC and the on-going efforts to improve it for daily use. We agree that LOINC has the potential to enhance interoperability; however, we are concerned that reliance solely on LOINC in its present form does not achieve expectations for interoperability within and across health care institutions. In addition, many laboratories do not have sufficient expertise or resources to assign and maintain LOINC codes.

LOINC was originally designed as a non-hierarchical "flat list" of codes, some of which are generic and correspond to multiple more specific LOINC codes; consequently, each receiving system in need of grouping similar specific LOINC codes into a more general group are left to reinvent the groupings independently each time new LOINC codes are released unless they are pre-specified in an up-to-date multiaxial list. Otherwise, this creates inconsistent groupings across different organizations and therefore has the potential to adversely impact patient care.

We present two “real-world” categories of challenges in using of LOINC:

1. **Commonly ordered but hard to code tests**: For example, there are 240 laboratory terms in LOINC for HIV testing. Filtering to common specimen types such as serum or plasma results in 145 LOINC matches. If we filter on method, there are: 25 possible enzyme immunoassays, 63 possible immunoblots, 25 possible probe and/or target amplifications, and 30 possible methodless codes. Which does a coder choose?
2. **High-throughput sequence analysis:** This has many challenges.
    - For many genes, there is a code for the presence of a mutation in a gene and a different code for the test being performed on that same gene. Which does a coder choose?
    - If coding of an actual test result is intended, then this presents challenges to information systems when the result is embedded in a free-text interpretation, as they commonly are.

- It is not clear whether the word “mutation” is intended to represent a pathogenic variant, as it does in the molecular community, or whether it is intended to represent any variant, for which the word is commonly used.
- For some genes such as *BRAF*, specific variants such as the presence of the V600E are specifically coded. However, specific codes for many other clinically significant variants are missing in the existing release.
- The specific molecular genetics method is not described for many molecular LOINC codes, and this has the potential to cause tests performed by non-comparable methods to be mapped to the same code.
- Specimen types for many genetic LOINC codes are limited or ambiguously categorized.
- Finally, the scalability of LOINC for molecular test results in its current format is of serious concern. Even if only “variant present” is recorded for each entire human gene with an unspecified specimen type, then at least 19,000 LOINC codes would be required. If testing for specific clinically significant variants are included, the LOINC terminology and LOINC staff will not be able to keep up with demand.

Therefore, we recommend that Regenstrief Institute clarifies whether it intends to encode the test performed or the result of the test and to what level of granularity it should occur. Better yet, the best answer to the question of which coding system should be used for the test’s “answer” is the first one to develop a sound, scalable mechanism for coding each possible genomic variant for primary and secondary uses.

Laboratories are regularly deploying new tests as they come to market, and test results must be transmitted to receiving systems in a timely fashion. There will be periods when results will file without a LOINC code if none is available or with a newly generated LOINC code that is not yet recognized receiving system.

With regard to the use of LOINC for laboratory orders, we recommend that ONC’s *a*LOINC Order Code S&I Framework Final Report be widely distributed. This initiative, which was developed with the assistance of CAP members, put together a proposed list of 1532 orderable tests including single analyte tests and test panels. This could be utilized to help standardize HL7 interfaces between an EHR and the multiple Laboratory Information Systems to which it is connected.

We also recommend further field testing be conducted before asserting that LOINC encoding will allow comparable analysis.

UCUM

The CAP supports the use of standardized units of measure to help promote interoperability and to reduce errors related to translation of units of measure from one system to another. While we generally support the use of the

Unified Code for Units of Measure (UCUM), there are important problems which need to be solved within the UCUM standard before CAP can recommend it for general use.

1. The abbreviations used for a few of the units of measure listed in the UCUM standard are currently on lists of *prohibited* abbreviations from the Institute for Safe Medication Practices (ISMP; https://www.ismp.org/tools/errorproneabbreviations.pdf) and by The Joint Commission (TJC; http://www.jointcommission.org/facts_about_do_not_use_list/).
2. Some abbreviations for units of measure include symbols which are in conflict with the HL7 standard.
3. Some abbreviations for units are nonstandard for human understanding. For example, if a result for a White Blood Cell count is 9.6 x 10^3/µL, the UCUM recommendation for rendering this value in a legacy character cell application is 9.6 10*3/uL. Because the "*" is a symbol for multiplication in some systems, we are concerned that this recommendation may result in errors either by the information system or the human reading the result.
4. Some other abbreviations used in UCUM are not industry standard for the tests that use these units of measure.

We recommend that the FDA, CDC and NLM work with UCUM, laboratory professionals and other organizations such as ISMP and TJC to resolve the above issues so that UCUM may be implemented as the official standard for units of measure in the United States.

With any coding system that is used, the CAP is concerned about the possibility of loss of important meta-information surrounding the result. For example, a positive result must be interpreted in the context of the prevalence of the condition being tested for in the population. A positive HIV test in a population where the prevalence of HIV is low is more likely to be a false positive than a true positive.

We strongly recommend that the FDA, CDC and NLM involve pathologists and other laboratory professionals in the resolution to the issues that we have described.

Again, the CAP appreciates the opportunity to comment on these important issues regarding semantic interoperability and look forward to working with the government agencies to move these efforts forward. Thank you for your serious consideration of the CAP comments as we all strive to provide the best care for our patients. Please feel free to contact Mary Kennedy (mkenned@cap.org) if you have any questions on these comments.