



# COLLEGE of AMERICAN PATHOLOGISTS

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The College of American Pathologists (CAP) appreciates the opportunity to comment on the *2016 Interoperability Standards Advisory*. As the leading organization with more than 18,000 board-certified pathologists, the College of American Pathologists (CAP) serves patients, pathologists, and the public by fostering and advocating excellence in the practice of pathology and laboratory medicine worldwide. The CAP's Laboratory Improvement Programs, initiated 65 years ago, currently has customers in more than 100 countries, accrediting 7,600 laboratories and providing proficiency testing to 20,000 laboratories worldwide.

## INTRODUCTION

The CAP supports the high-level goals of the 2016 Interoperability Standards Advisory. The CAP believes that the widespread adoption of interoperable EHR systems will improve health care quality and increase the efficiency of care, benefiting patients, physicians, and payers alike and enabling vitally important new coordinated care models.

It continues to be the case that the vast majority of pathologists' practice settings use laboratory information systems (LISs), not certified EHRs. LISs are highly specialized systems that are required and engineered specifically to support laboratory operations in pursuit of patient testing and interoperability with EHRs. Further, LISs are focused on managing data relative to biospecimens and subsequent diagnostic testing, while in EHRs documentation relative to patient encounters is the focus. Most eligible providers (EPs) and hospitals will need to rely on data that pathologists and their laboratories generate. **Thus, as LISs have special functional and interoperability requirements that differ from EHRs, ONC should ensure that any regulations are applied in a way that takes into consideration unique considerations of LISs and laboratories.**

The CAP appreciates that the 2016 Interoperability Standards Advisory describes a model by which ONC will coordinate the identification, assessment, and determination of the "best available" interoperability standards and implementation specifications for industry use to fulfill specific clinical health IT interoperability needs. We also support ONC's plan for annual updates to the Advisory to promote innovative approaches. At the same time, consideration should be given to minimizing the potential for unnecessary sunk costs.

We agree with the approach to identify section lead-ins by framing an "interoperability need" instead of referencing a general purpose interoperability standard. We also agree with the Advisory's perspective of focusing on electronic health information created in



the context of treatment and subsequently used to accomplish a purpose for which interoperability is needed.

The CAP supports standards and vocabulary development efforts and has been intimately involved in several ONC S&I laboratory initiatives (e.g., Laboratory Reporting TIGER Team; Laboratory Regulatory TIGER Team; ONC EHRs Functional Requirements for Lab Reporting initiative; LOINC Order Code initiative; Structured Data Capture) and actively participated in the 2015 IHE North American Connectathon in the testing of the Structured Data Capture initiative. We also recently presented at the FDA/CDC/NLM Workshop on Promoting Semantic Interoperability of Laboratory Data.

We are encouraged with continued discussions regarding the implementation and use of LOINC and UCUM (Unified Code for Units of Measure). While LOINC has met with mixed success, UCUM has not been widely implemented in laboratory settings. SNOMED CT®, originally developed by CAP, has a longer history with pathology, but even that terminology is not commonly used outside of anatomic pathology. We think it is important to conduct further field testing (e.g., intra- and inter- coder variability) of LOINC, UCUM and SNOMED CT to fully understand the capabilities and limitations of each and to determine the extent and correctness of use across enterprises. This is particularly important as laboratory and pathology data is being used for clinical decision support.

## COMMENTS

We provide our comments to the sections of the Standards Advisory.

In response to **Section I: Best Available Vocabulary/Code Set/Terminology Standards and Implementation Specification, I-E: Family Health History**, we recommend that special use code sets (e.g., trees or code lists) in SNOMED CT be specified rather than simply saying “SNOMED CT”. If possible, code composition (pre and post coordination) could be specifically addressed and standardized if applicable to use cases. This applies to all uses of unrestricted code sets provided in this document. Specifying general use of a large code set is not sufficient to ensure consistency and accuracy and reliability of the coding.

In response to **Section I: Best Available Vocabulary/Code Set/Terminology Standards and Implementation Specification, I-G: Gender Identity, Sex, and Sexual Orientation**, we recommend consistent use of a single standard with post-coordination as needed. SNOMED CT more discretely identifies gender states and can be post-coordinated to signify the presence of a gender finding at birth or at other points in time.

In response to **Section I: Best Available Vocabulary/Code Set/Terminology Standards and Implementation Specification, I-J: Lab tests**, 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 genomic 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 additional LOINC codes would be required. LOINC will require far greater (ongoing) expansion if testing for specific clinically significant variants are to be represented.

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. A sound, scalable mechanism for coding each possible genomic variant for primary and secondary uses is a critical need that requires further study and likely will require a paradigm outside the scope of an existing standard. Formation of a working group to address this issue may be the best next step. The CAP welcomes the opportunity to collaborate on this matter.

With regard to the use of LOINC for laboratory orders, we recommend that ONC’s aLOINC 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 subset could be utilized to help standardize HL7 interfaces between an EHR and the multiple Laboratory Information Systems to which it is connected. As previously stated, we recommend that ONC conduct further field testing (e.g., intra- and inter- coder variability) of LOINC to fully understand its capabilities and limitations and to determine the extent and correctness of use across enterprises.

In response to **Section I: Best Available Vocabulary/Code Set/Terminology Standards and Implementation Specification, I-L: Numerical References and**



**Values**, we support 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 the 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>).
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  $9.6 \times 10^3/\mu\text{L}$ , the UCUM recommendation for rendering this value in a legacy character application is  $9.6 \times 10^3/\text{uL}$ . 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 to resolve the above issues so that UCUM may be implemented as the official standard for units of measure in the United States.

In response to **II-G: Images, Interoperability Need: Medical image formats for data exchange and distribution**, we seek clarification whether pathology imaging as supported in the DICOM standard are included in this recommendation and if so, the specific uses cases deemed most critical for interoperability (whole slide microscopic images, gross examination images, scanned documents, etc).

In response to **II-H: Laboratory, Interoperability Need: Receive electronic laboratory test results**, the CAP encourages the use of the HL7 Version 2.5.1 Implementation Guide: S&I Framework Lab Results Interface, Release 1 – US Real [HL7 Version 2.5.1: ORU\_Ro1] Draft Standard for Trial Use, July 2012. In addition, we encourage the continued development of the S&I Structured Data Capture initiative as a possible adjunct for more complex interoperability needs.

In response to **II-H: Laboratory, Interoperability Need: Ordering Labs for a Patient**, the CAP encourages the continued development of the HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Orders from EHR, Release 1 DSTU Release 2 - US Realm. In addition, we encourage inclusion of the emerging draft IHE LCC (Laboratory Clinical Communication) profile to provide for a robust mechanism of communication between the ordering provider and the laboratory and to serve as an interoperability framework for laboratory driven clinical decision support.

In response to **II-K: Public Health Reporting, Interoperability Need: Reporting cancer cases to public health agencies**, we recommend consideration of the ONC S&I Structured Data Capture initiative as an alternative. Several pilot projects in California (California Cancer Registry (CCR)/CDC sponsored) have resulted in about 20 sites transmitting this SDC variant data on a daily basis. The SDC team is now in the process of ramping up to implement the Phase II SDC XML Schemas with ONC, CDC and CCR support. This latest Phase II SDC version is currently entering its pilot phase.



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In addition, we participated in the successful testing of the CAP's electronic Cancer Checklist (eCC) using SDC at the 2015 IHE Connectathon.

In response to **Section IV: Questions and Requests for Stakeholder Feedback, General 4-9**, we recommend that the HIT Standards Committee also offers guidance on additional implementation specifications such as the expected degree of difficulty of implementation; the length of time required for implementation and the amount of maintenance that will be required post go-live.

**General Comments to the 2016 Interoperability Standards Advisory:**

Overall, we commend ONC on its attempt to begin to represent many available standards and implementation specifications. We agree that this list does not yet represent the full breadth and depth necessary to recognize all of the purposes that stakeholders will find necessary for interoperability. We recommend that ONC continue to investigate and test alternative approaches to C-CDA including HL7 FHIR and ONC's Structured Data Capture (SDC) initiative.

**CONCLUSION**

The CAP appreciates the opportunity to comment on this draft version of the 2016 Standards Advisory. As a leading laboratory organization, we look forward to continued updates from ONC on the Standards Advisory to not only address pathologists' concerns but also to advance interoperable EHRs to improve care for our patients. Should you have any questions on our comments, please contact Mary Kennedy, Director, Clinical Informatics Initiatives at (847) 832-7261 or via email at [mkenned@cap.org](mailto:mkenned@cap.org).