COLLEGE of AMERICAN PATHOLOGISTS

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The College of American Pathologists (CAP) appreciates the opportunity to comment on the *2015 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 2015 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 physicians, patients 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 if any regulations are applied in a way that takes into consideration unique considerations of LISs and laboratories.**

CAP appreciates that the 2015 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 to advance clinical health information interoperability. 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.

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) as well as ONC's Structured Data Capture (SDC), and actively participated in the 2015 IHE North American Connectathon where SDC was tested.

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In addition, we are encouraged with discussions regarding the implementation and use of LOINC and UCUM (Unified Code for Units of Measure). While LOINC has met with mixes 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 of LOINC and UCUM to understand fully the capabilities and limitations of each and to determine the extent and correctness of use across enterprises.

COMMENTS
We have general comments to sections of the Standards Advisory as well as comments to specific questions asked by ONC.

General Comments to The 2015 Interoperability Standards Advisory section
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.

We recommend that ONC consider another "Best Available" important characteristics besides those listed on pages 4-5. Omitted from this list, and very important considerations are Completeness and Track Record. These are particularly important in the Terminology/Vocabulary standards. For example, a primary reason why SNOMED CT is used and recommended by many is that this standard has been developed and refined over decades. In addition, organizations that support these types of standards have shown the capability to be responsive in adding to the lexicon as new clinical scenarios present themselves.

Simply testing the exchange of XML blobs may not be a suitable test of true interoperability. We recommend testing of such things as: round-trip EHR integration, with recreation of identical CDAs, coding standards and consistency, user-interface support for data entry and reporting, support for CDEs, and the some basic concept of data integrity with preservation of contextual semantics (e.g., - what tree of questions and answers led the author to provide a value to each data element.) We provide the following reference as a resource to this paragraph:

D'Amore, J. D., Mandel, J. C., Kreda, D. a, Swain, A., Koromia, G. a, Sundareswaran, S., … Ramoni, R. B. (2014). Are Meaningful Use Stage 2 certified EHRs ready for interoperability? Findings from the SMART C-CDA Collaborative. Journal of the American Medical Informatics Association: JAMIA. doi:101136/amiajnl-2014-002883

General Comments to Section I: Best Available Vocabulary/Code Set/Terminology Standards and Implementation Specifications
Overall, literature and experience suggest that differences among coding experts exist when asked to code the same information in a patient record.

A better approach may be to use SDC whenever the structure of the data can be standardized prior to data entry. This may decrease coding issues. SDC can be applicable to most of the clinical content domains in Section 1. SDC templates for these

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domains can be created along with CDEs. We recommend ONC consider this alternative.

Code systems are useful when open-ended value sets are required, such as in general lists for drugs, problems, procedures. Even in these cases however, structured data entry should provide context and constraints around the data sets to ensure that data can be shared across systems.

General Comments to Section II: Best Available Content/Structure Standards and Implementation Specifications
Overall, for each of these standards listed, we recommend that ONC provide documentation and/or publications that record such things as the error rate from data entry to analysis when transmitting and incorporating the data across disparate systems; the existence of simple and less error-prone standards to test against; peer-reviewed publications that analyze error rates; etc. This will help inform participants and possibly avoid errors.

We recommend that each of the listed standards have a short abbreviation created so that users can discuss them unambiguously. The lack of such monikers causes confusion among standards professionals and implementers.

In response to “Case Reporting to Public Health Agencies”: SDC approaches have been in use for many years, particularly in the domain of oncology. The new formats ("original" SDC, and FHIR SDC Questionnaire) standardize the SDC language and syntax by creating standard XML schemas. We are aware that using these similar formats, SDC interoperability has been tested and validated in software systems, particularly by Cancer Care Ontario, where there is a provincial standard for pathology reporting, and a foundational part of quality assessments for cancer care. A similar program is now being initiated by the California Cancer Registry. We recommend ONC monitor these programs for their effectiveness.

CMS, in a recent "Tips" publication for Clinical Decision Support (CDS), noted that the CMS definition of CDS includes the use of standardized templates for data submission to PH registries. ONC may want to consider including this publication in future Standards Advisory releases.

General Comments to Section IV: Best Available Standards and Implementation Specifications for Services
Overall, we recommend that ONC consider other important services not covered here including exchange of information regarding patient identification (VUHID) and exchange of biometric patient identification between different health providers.

Comments to Specific ONC questions
We include comments on specific questions in the 2015 Interoperability Standards Advisory below:

In regards to question 5-1[General]: What other characteristics should be considered for including best available standards and implementation specifications in this list? We think that standards must be able to support round trip interoperability, from Point-A Data Entry Form (DEF) through message creation, transmission, parsing, display, storage, data-set integration, aggregated data analysis at Point-B. Point B must then be able to recreate the same data from its parsed data set, and send the same data to

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Point C. Point C must process the same data in the same way as Point-B, and return it to Point-A with 100% integrity. This must be achievable with any sender/receivers, and any arbitrary number of hops. This has been discussed in the ONC S&I Laboratory Reporting TIGER Team.

We are not referring to a static C-CDA document or raw text or pdfs. We think it is important to ensure that data can be decomposed and integrated into each node's host database system, and be able to regenerate the identical record for sending to another node, with no inconsistencies or errors. We think this can be achieved using SDC.

In regards to question *5-7. [Section I]: Should more traditionally considered "administrative" standards (e.g., ICD-10) be removed from this list because of its focus on clinical health information interoperability purposes?* In general, the healthcare community would be best served by minimizing the number of coding standards in use. For example, if SNOMED CT is suitable for procedure and disease coding, then there may be no reason to add ICD-10, which is an administrative code system adding little value over SNOMED CT.

In regards to question *5-13. [Section I]: If a preferred or specific value set exists for a specific purpose and the standard adopted for that purpose, should it be listed in the "implementation specification" column or should a new column be added for value sets?* We suggest adding a new column for the value sets.

In regards to question *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?* While LOINC is used in many labs, we are unclear of its comparability across institutions. We recommend further field testing be conducted before asserting that LOINC encoding will allow comparable analysis. We give two examples of the complexity of LOINC:

1. HIV testing – There are 240 lab terms in LOINC for HIV testing. If you narrow down the search to testing performed on serum and/or plasma (most common specimen used), there are 145 LOINC matches. If that search is further narrowed down by method, there are: 25 possible EIA (enzyme immunoassay), 63 possible IB (Immunoblot), 25 possible probe (or probe and target) amplification, and 30 possible methodless LOINCs. This poses quite a daunting challenge to the beginner LOINC coder.
2. Albumin testing – There are 194 LOINC values for Albumin. This can be further limited by specimen type (serum/plasma in this example) to 88 possible matches. However, without knowing the exact methodology and reagents used in the test analysis (albumin method? Bromocresol purple? Bromocresol green? Electrophoresis?), it is impossible to choose the most specific and accurate LOINC value for this test result.

The use of LOINC for laboratory orders is certainly not simple. Many laboratories do not have sufficient expertise or time to identify and maintain the proper LOINC codes in the laboratory information systems that are expected to be transmitted to the EHR. It is also unclear to what level of detail LOINC codes should be assigned in order to be useful for data analysis. Further field testing using LOINC across a wide range of clinical labs needs to be conducted to better understand the nuances of sharing what is considered comparable LOINC codes. Plus, order-side LOINC codes may be different from result-

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side LOINC codes. We also recommend that LOINC codes should be provided by the manufacturers of the tests or the instruments which run those tests.

Regarding UCUM, we agree with the statement that "UCUM (Unified Code for Units of Measure) appears to be a viable option for reporting units of measure but must be pilot tested in order to understand the impact of key issues identified by various stakeholders. This guide does not preclude the use of UCUM coding where senders and receivers have localized this guide by mutual agreement." UCUM is not a widely used system in the laboratory. Further field testing to compare the use of UCUM across laboratories is needed. Educational opportunities are also needed so that healthcare givers understand UCUM.

CONCLUSION

The CAP appreciates the opportunity to comment on this draft version of the Standards Advisory and as a leading laboratory organization looks 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.

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