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Letter

# Managing beyond the laboratory information system

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Sir,

Prior to the advent of electronic health records (EHRs) the issue of segregating or integrating laboratory observations reported from two or more independent laboratories was of little or no concern to pathologists. However, the intersection of two realities has and will significantly increase the complexity of laboratory results management: first is the utilization of multiple laboratories for the testing performed on a given patient. This trend is being driven in part by requirements of third party payers as well as preferences and contracts of different clinical practice groups. The second pressing reality is the government mandate for the implementation of EHRs and their meaningful use.

During the early phases of EHR adoption and before full interoperability of EHRs is required, the pathology community has the opportunity to thoughtfully assess how to facilitate integrated access to observations reported by various laboratories not otherwise formally associated with a given health care institution.

The simplest solution in the face of multiple laboratory data streams is segregation, e.g., Lab A Sodium, Lab B Sodium, Lab C Sodium. This solution has at least two undesirable consequences: (1) multiple rows in any spreadsheet-like view for each unique test with results being dispersed over a large sparse matrix requiring considerably more scrolling on the part of the user to assess laboratory observations over time, and (2) the loss of the facility to graph numerical results over time when observations for the same test are reported by two or more laboratories. The alternative is to integrate results from the various source laboratories allowing display each test on a single row assuming the methodology is the same or similar and units of measure (UOM) are the same. Not surprisingly physicians favor an integrated approach that would allow trend review and minimize the number of rows required to display laboratory observations in a spreadsheet-like presentation. Unfortunately, integration of observations from multiple laboratories requires deliberate manual mapping of tests that must rely on expert human review of test metadata supplied by each reporting laboratory.

Use of the Logical Observations Identifiers Names and Codes (LOINC) would seem an appropriate system to utilize for automated mapping of test observations reported by multiple laboratories.[1] Unfortunately, complete semantic inoperability, the intended goal of LOINC, is currently limited. The LOINC coding system, while intended to facilitate sharing of laboratory and clinical observations across systems, is currently insufficient in terms of specification to support a computational solution for mapping observations made by different laboratories in an integrated EHR. Even if observations from different laboratories match in all six (6) dimensions representing a fully specified LOINC code the observations may still differ in methodology and/or UOM.[1] While in some cases methodological differences may not result in a significantly different interpretation of laboratory observations it is also true that certain drugs or other substances can interfere with different methods

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to varying degrees and hence could significantly influence interpretation of integrated laboratory observations. Likewise, incorrect interpretation of results can arise when disparate UOM are used for reporting observations even if the same methodology is employed. Thus at this time the LOINC coding system, while providing a controlled vocabulary, does not sufficiently specify laboratory observations to the extent needed to allow for automated integration of laboratory observations in an EHR. Suffice it say that manual efforts to map and maintain appropriate mapping between multiple laboratories for use in an EHR is a tedious and time consuming task. Errors are likely to be made particularly in regard to integration of observations using different methods and/or UOM.

The issue raised here takes on greater significance when it is generalized to encompass management of laboratory observations arising from numerous unaffiliated laboratory sources, a reality that will ultimately result from the level of data interchange between health care institutions mandated by the Health Information Technology Economic and Clinical Health Act (HITECH) and the goal of "meaningful use" of EHRs. Expectations defined in Centers for Medicare and Medicaid Services (CMS) and the Office of the National Coordinator for Health Care Technology (ONC) rules assume that laboratory data exchanged between institutional systems can be fully integrated into the EHR with the use of HL-7 messaging and LOINC codes, and that integrated laboratory observations will be used in clinical decision support engines as well as assessment and reporting of clinical quality measures within and across systems to name only a few of the specified certification criteria for EHRs.

Ming-Ching Lin and others have confirmed the limitations of LOINC for achieving full semantic interoperability envisioned in the HITECH legislation and CMS and ONC rules.[2] In a relatively recent report they demonstrated that the use of LOINC does not and likely cannot compensate for the highly variable UOM, codes and modifiers, acronyms, and synonyms used in reporting laboratory observations, to say nothing of the heterogeneous formats employed for reporting more complex observations related to phenotypic and genotypic analysis. In my opinion the real issue is not simply the failure of LOINC to fully specify laboratory observations but the complete lack of standardization of laboratory observation report formats; an issue that cannot be readily compensated for by a controlled vocabulary system like LOINC.

One might argue that just-in-time mapping could be managed by comparing local LOINC codes and locally registered UOM with incoming LOINC and UOM to determine if results should be judged sufficiently similar to allow full integration of the incoming information in the EHR. However, considering the list of issues identified by Lin *et al*. this solution is likely an inadequate alternative and certainly does not address the variability inherent in more complex observations.

Considering the lack of standardization of laboratory observation formats today it is important to address at least several basic issues. First, what possible value is there in continuing to support independent selection of UOM for medically relevant laboratory observations? It should be abundantly clear that the time has come to adopt a national standard, like SI units, for the reporting of common laboratory observations at the least, such as C-reactive protein and bilirubin for example, as a first step. Likewise additional standards should be adopted to deal with reporting of nominal and ordinal observations. Are variations like "Positive", "Pos" and "+" really necessary to describe the same laboratory observation? Assuming progress can be made in standardizing reporting formats, it would then makes sense to reconsider the definition of a fully specified LOINC code, e.g., make UOM a part of the minimum specification. LOINC has become the de facto standard (45 CFR 170.207) and presumably will be the foundation for achieving full interoperability of laboratory observations. It would seem that the best path forward is standardization of reporting formats coupled with an enhanced definition the LOINC specification. The time has come to think differently about standardization of certain aspects of laboratory testing and reporting, like UOM, to allow for realistic solutions for real world problems that will be encountered as we move toward the goal of a universal EHR.

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