



Statement of

The American Clinical Laboratory Association

Before

The National Committee on Vital and Health
Statistics

Standards Subcommittee

Alan Mertz, President

February 24, 2009

Enhancing Standards Adoption by Users

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Dr. Warren, Mr. Blair, members of the subcommittee, thank you for the opportunity to testify today on behalf of the American Clinical Laboratory Association (ACLA), which represents national, regional, and local laboratories. My name is Alan Mertz, ACLA President, and I appreciate your interest in enhancing standards adoption by laboratories. ACLA members have an extensive history of providing the nation's hospitals and physicians with leading-edge health information technology (IT) to streamline the laboratory test requisition process and speed the delivery of test results. It is this longstanding experience of providing connectivity to our nation's healthcare system that informs today's testimony.

Today, I would like to focus my testimony on three specific areas concerning enhancing standards adoption by health care providers. These are: (1) past efforts at development and implementation of clinical laboratory test health information exchange; (2) remaining standards development and implementation challenges; and (3) national coordination of health IT efforts and the model for future work.

Past efforts at standards development: Promise and Pitfalls

First, I'd like to discuss past efforts to develop standards for the electronic exchange of laboratory test results. I will focus my comments on the EHR-Lab Interoperability and Connectivity Standards (ELINCS) project and the Health Information Technology Standards Panel (HITSP) electronic health record results reporting interoperability specification.

As some of you may be aware, in the spring of 2005 the California HealthCare Foundation, at the request of former National Coordinator for Health Information Technology, Dr. David Brailer, kicked off a new initiative to develop a national standard for the real-time reporting of lab data to electronic health records (EHRs). Adoption of a national standard would help simplify the use of EHRs; physician practices would reap tangible benefits early in EHR implementation; and reduce costs associated with EHR system installation and configuration. ELINCS worked closely with other national and international efforts to develop the standard to ensure widespread adoption. Participating organizations included the Certification Commission for Health Information Technology (CCHIT); Connecting for Health (Markle Foundation); the eHealth Initiative (eHI); DOQ-IT (Centers for Medicare and Medicaid Services); Integrating the Healthcare Enterprise (IHE); the Public Health Information Network (CDC/PHIN); Health Level Seven (HL7); and ACLA. Fast-forward three years later when, in September of 2008,

the California HealthCare Foundation awarded a second-round of grants to independent physician associations, community clinics, private practices, and other ambulatory care providers across California to provide technical assistance and up to \$15,000 each over 12 months to implement a new version of ELINCS.

This effort was only possible because of broad, equitable stakeholder involvement and the incremental, real-world approach that the ELINCS project took when developing the standard. The result was a standard that health care providers could readily adopt and implement within their existing health IT systems and one that improves access to accurate and timely laboratory results.

In my opinion this success is in stark contrast to what the HITSP experience has been. Sam Karp of the California HealthCare Foundation may have put it best in his testimony to the Institute of Medicine Board on Health Care Services and National Research Council Computer Science and Telecommunications Board when, referring to HITSP, he said, “Not a single data element has been exchanged in real world health care systems using data standards this process has developed or deployed.” He went on to state that, “greater emphasis is placed on ‘ideal’ standards and less on what can be feasibly implemented in the short-term.”¹ One example of this dichotomy of ideal versus real-world standards is the inclusion of the Unified Code for Units of Measure (UCUM) in the HITSP specification for laboratory results reporting. While UCUM is used within the field of radiology, no laboratory, not even the most sophisticated, currently uses UCUM to electronically transmit laboratory result data in the United States.

The reason HITSP has produced futuristic outcomes is that it operates under a governance model in which the team with the most people at the table wins, and IT vendors have consistently had the most people at the table. Unlike IT vendors, most labs do not have the resources to devote full time employees to HIT standards development activities. By contrast, CCHIT should be commended for ensuring more equitable representation among stakeholders, which has resulted in a more practical, incremental approach to certification criteria for EHRs. For example, CCHIT has used a flexible mixture of HITSP and non-HITSP standards and specifications in its certification criteria and acknowledged that UCUM is not yet ready for prime time.

Remaining standards development and implementation challenges

I would now like to briefly talk about the remaining challenges to standards development, implementation, and adoption of electronic laboratory data information exchange. Outside of results reporting, which I’ve already addressed, there are two fundamental issues which remain to be addressed: standard laboratory order codes and, as mentioned in prior comments before NCVHS in our 2006 testimony, updating the Clinical Laboratory Improvement Amendment (CLIA) regulations to accommodate and promote the transmission of laboratory data.

¹ Carol Diamond and Clay Shirky, “Health Information Technology: A Few Years of Magical Thinking?” *Health Affairs* 27, no.5 (2008): w383-w390 (published online 19 August 2008).

Developing standard order codes will prove to be an effort exponentially more difficult than ELINCS ever was. We know this because a number of ACLA member laboratories have already attempted to do so to no avail. Without delving into what efforts have taken place and why they failed, I only caution that any successful effort will need to be incremental. The other requisite for a successful outcome is that it offer even, fair representation on the standards development organization charged with coming up with the standard. We know efforts are ongoing within the Library of Medicine as well as HHS' Office of the National Coordinator to develop standard laboratory order codes and hope that they will follow these guidelines for a successful outcome that laboratories and other providers can get behind, adopt, and implement within their current IT systems. We are concerned, however, that the HITSP General Lab Orders Working Group is already proceeding with an ambitious agenda to harmonize lab order standards for an extremely broad use case, including ambulatory care, acute care, public health, order status queries, and electronic order updates, under the same governance structure that allowed IT vendors to dominate the outcome of the lab result use case. Standardizing lab order messages will bring tremendous value to labs and the healthcare system generally by resolving many issues that negatively impact the delivery of lab results. However, the process for achieving this important advancement should not repeat past errors, but instead acknowledge that adoption will only be maximized if those most directly affected - labs - have an equal voice in its creation and have confirmed its operational feasibility.

The other remaining challenge I wish to raise has to do with CLIA. Pursuant to CLIA, when test result report information is disclosed by the physician to another provider, such as a regional health information organization (RHIO), the clinical laboratory is still responsible for the content and format of that report. In addition, when an EHR vendor changes the test result report that is provided to the physician, the clinical laboratory is still responsible for the content and format of that report, in accordance with CLIA requirements. Taking this one step further, laboratories would then be responsible for test result report information in the RHIO, despite the potential for reports to be modified several times over for each and every manipulation made to them when an EHR vendor modifies the content, and for each and every time the content was used (e.g., primary care visit, office visit to a specialist, hospital admission, nursing home stay, etc.). This regulatory burden needs to be addressed in order to facilitate the exchange of electronic health data for treatment purposes.

ACLA has a proposal to address this situation. In order to address the issue of EHR vendors modifying laboratory result report content, we propose the following solution: amend the CLIA Interpretive Guidelines or the CLIA regulations to clarify that the laboratory's responsibility ends once a CLIA-compliant report is received by either the client or the vendor (or other contractually obligated intermediary). Second, to address the issue of information shared with other health care providers aside from the ordering physician, the clinical laboratory's responsibility for the test result should end once the result is provided to the ordering physician or vendor. The Interpretive Guidelines should make clear that the laboratory is not responsible for subsequent disclosure of test result information made by the physician.

National coordination of health IT efforts and the model for future work

The last topic I would like to address is the need for greater coordination of health IT efforts by the federal government and the model for future work. While I have spent much of my time today discussing clinical standards adoption, it's important to note that a number of administrative standards will be adopted over the next few years – claims attachment, ICD-10, etc. In addition, with the recently enacted stimulus bill, providers must implement significant changes to their privacy policies. Between the administrative & clinical standards mandated by the federal government and the newly enacted privacy provisions, providers will be continuously updating their practice management and health IT systems over the next several years. The potential for these efforts to overwhelm providers, including laboratories, is very real and greater coordination by the Office of the National Coordinator is badly needed.

Finally, regarding the model for the development, adoption, and implementation of HIT standards for the nation as a whole, I will reiterate a number of points I have already raised. Future work needs to be incremental and based on real-world health care systems. ELINCS is a great example of how the process should work. The initial version of ELINCS established standards for result reporting of approximately 80% of performed tests. A little over a year after that effort started, clinical care providers and laboratories in California were exchanging lab results using ELINCS through the use of EHRs. The success of this effort was due largely to the fact that it was incremental, and operated under an equitable governance model. Standards adoption will only be maximized when ambitious goals are tempered by operational realities and equal shareholder representation.

Thank you for the opportunity to testify today. At this time I'm happy to answer any questions.