

Senate Committee on Commerce, Science and Transportation
Subcommittee on Technology, Innovation and Competitiveness
June 21, 2006

John D. Halamka, MD, MS
Chair, Health Information Technology Standards Panel
CIO, Beth Israel Deaconess Medical Center and Harvard Medical School

Mr. Chairman and distinguished members of the Subcommittee, I am Dr. John Halamka, the Chair of the Health Information Technology Standards Panel. I am grateful for the opportunity to testify before you today on the need for harmonized electronic data exchange standards to empower patients and healthcare providers.

The Current Landscape of Healthcare Information Technology

As an Emergency Physician at Beth Israel Deaconess Medical Center in Boston, I treat patients using incomplete medical information. Patients often do not know their medications, their medical history or their latest laboratory results. Patients seek care from a heterogeneous collection of primary care providers, specialists, hospitals, clinics, laboratories, imaging centers and pharmacies—all of which have disconnected pieces of their medical record.

Patients, providers and payers believe that communication among caregivers is key to delivering quality, personalized medicine. Many think that electronic records shared across the entire community of clinicians is key to care coordination.

At this point, only 18% of clinicians in the U.S. have electronic health records in their offices. Massachusetts, one of the most wired states, has 52% adoption of electronic health records. However, data does not flow among all these systems because of the inconsistent use of data standards, lack of a consistent architecture for exchange of data, and lack of community-wide agreement on privacy policies.

The Need for Standards

While traveling anywhere in the world, I can walk up to an ATM, insert my card (issued by a rural New England Bank), and retrieve whatever local currency I need. This is made possible by the worldwide adoption of electronic standards for banking and cash transfers.

However, if I suffer a major medical problem while in my hometown of Boston, my medical records cannot be electronically exchanged among the world's best teaching hospitals that are located across the street from each other.

This is because there has not been consistent adoption of standards for the storage and exchange of medical information among clinicians, hospitals and insurance companies in the U.S. But all of this is changing in 2006.

Health and Human Services (HHS) Secretary Michael Leavitt has established the American Health Information Community (AHIC), a group of 17 government, business, and non-profit organization leaders charged with fostering adoption of interoperable electronic records throughout the country. Further, the HHS-based Office of the National Coordinator for Health Information Technology (ONCHIT) has funded a coordinated effort to accelerate electronic medical record interoperability efforts. This effort is comprised of three parts:

The first is to harmonize all the electronic standards for healthcare in the country. Currently there are more than a dozen organizations creating healthcare standards in the U.S. These standards are at times redundant, competitive and non-interoperable. There are so many versions and variations that the standards are non-standard. To achieve the kind of universal functionality our ATM cards provide today, the country must agree on a common set of healthcare data standards, implemented consistently by hospitals, clinician offices and nursing homes.

The second step is to ensure electronic medical records provide the basic functions needed for a doctor to record and transmit patient medical information. The average patient over 80 years old has ten medications and three clinicians. Rarely is there any coordination of care among caregivers. Objective criteria to certify that an electronic record system meets the basic requirements for data capture and exchange is essential.

The third step is to standardize privacy and security policies across our 50 states. In Massachusetts, doctors cannot retrieve a complete electronic medical list from insurance companies, even with patient consent, if a medication related to mental health, substance abuse or HIV treatment is present. In Ohio, doctors must use a cryptographic electronic signature to prescribe medications electronically. In California, only paper signed consent forms (not electronic forms) are considered a valid patient consent. The laws that created many of these regulations were appropriate 30 years ago when electronic systems lacked the sophistication available today, but now are an impediment to delivering safe, patient focused care.

The Role of HITSP

The Healthcare Information Technology Standards Panel, which I chair, was established in 2005 to convene all the stakeholders necessary to build consensus around the most appropriate standards for clinical care, public health reporting and consumer empowerment. The Panel brings together experts from across the healthcare IT community – from consumers to doctors, nurses, and hospitals; from those who develop healthcare IT products to those who use them; and from the government agencies who monitor the U.S. healthcare system to those organizations who are actually writing the standards.

The HITSP is sponsored by the American National Standards Institute (ANSI), in cooperation with strategic partners such as the Healthcare Information and Management Systems Society (HIMSS), the Advanced Technology Institute (ATI) and Booz Allen Hamilton. Funding for the Panel is provided via the ONCHIT1 contract award from the U.S. Department of Health and Human Services.

More than 170 stakeholder members and 15 standards developing organizations are working together in HITSP to identify the most appropriate standards for specific use cases involving patients, providers, and government agencies. Panel members and experts have committed themselves to setting and implementing standards that will ensure the integrity and interoperability of health data.

A standard specifies a well-defined approach that supports a business process and has been agreed upon by a group of experts, has been publicly vetted, provides rules/guidelines/characteristics, helps to ensure that materials, products, processes and services are fit for their intended purpose, is available in an accessible format and is subject to an ongoing review and revision process. Harmonization is required when a proliferation of standards prevents progress rather than enables it.

In some cases, redundant or duplicative standards will be eliminated. In other cases, new standards may be established to span information gaps. In all cases, the resulting standards serve the consumer and other healthcare stakeholders by addressing issues such as data accessibility, privacy and security.

The Standards Harmonization Process

HITSP's most important work is the development of a well-defined, repeatable process to identify the most appropriate standards for each AHIC use case. Our process to date is:

- a. AHIC and its working groups develop Breakthroughs.
- b. AHIC Working Groups or other customers prepare a HITSP Harmonization Request.
- c. HITSP Technical Committees identify candidate standards, which are harmonized into a final list of standards. They also identify overlaps and highlight gaps. Gaps are forwarded to standards developing organizations for their guidance as to emerging candidate standards or new standards requirements.
- d. HITSP Coordinating Committees provide technical committees with important background information to support their work, such as objective criteria to evaluate the appropriateness of standards for a given purpose.
- e. The final chosen standards produced by the Technical committees are discussed and ratified by the full Panel.
- f. These standards are made available for public comment and feedback.
- g. Technical committees work with standards developing organizations and other groups to produce detailed specifications, an unambiguous "cookbook" for the implementation of chosen standards. HITSP provides a convening and facilitation function for this activity.
- h. HITSP work products are delivered to AHIC for their endorsement.
- i. After AHIC endorses HITSP work, the Certification Commission on Healthcare Information Technology will include HITSP specifications in its certification work. Hospitals and clinicians will be more likely to buy products, which are certified as interoperable. This will lead to increased success of vendors, which embrace standards and interoperability.

Coordination with other HHS activities

The standards harmonization activities of HITSP are well coordinated with the efforts of the three other Health and Human Services Healthcare IT projects:

National Health Information Network architecture (NHIN)

Four lead contractors – Computer Sciences Corporation, Northrop Grumman, IBM, and Accenture have been given contracts to develop a nationwide architecture for the secure exchange of medical records using HITSP harmonized standards. These contractors generate requests for harmonization to HITSP and the Panel shares its work products with NHIN contractors through ongoing group forums that ensure ongoing coordination and communication.

Health Information Security and Privacy Collaboration (HISPC)

HITSP work products will be shared with the HISPC program management and harmonized privacy use cases will undoubtedly be shared with HITSP in the future to inform the selection of technical standards which enforce security.

Certification Commission on Health Information Technology (CCHIT)

CCHIT staff attend HITSP meetings and CCHIT has committed to include HITSP work products in its future certification criteria as described above.

Progress to date and next steps

HITSP has established an initial process for resolving gaps and overlaps in the HIT standards landscape. In May of 2006, HITSP reduced 570 candidate standards to 180 appropriate standards for secure exchange of medication, lab, allergy and demographic data. By June of 2006, these 180 standards will be further reduced to a few dozen.

By October 30, 2006, HITSP will deliver unambiguous interoperability specifications, which will enable vendors, hospitals and government to create software components for clinical data exchange.

Beyond 2006, HITSP will develop harmonized standards and unambiguous implementation guides, which provide precise instructions for data sharing for all future requests for harmonization. Also, it will standardize the interoperability specifications for technology products, while permitting differentiation and competitive advantage in the marketplace. HITSP hopes to empower patients and care providers with Electronic Health Records (EHR) that facilitate easy access to critical health data that is accurate, private and secure.

HITSP is a key component of the Health and Human Services vision to create an interoperable healthcare system, and we look forward to our work products empowering patients, providers and government stakeholders in 2006 and beyond.