What Is Going On in U.S. Health IT Standards

W. Ed Hammond, Ph.D.
Immediate Past President, AMIA
Vice-chair, HL7 Technical Steering Committee

Professor Emeritus, School of Medicine
Adjoint Professor, Fuqua School of Business
Duke University

Duke

Health IT Standards

- Work on Health IT standards started in the early 1980s in the U.S.
- Different groups were formed to address a specific perceived need and for a specific purpose.
- Creating Health IT standards was neither a popular activity nor conceived to be a scholarly activity.
- The healthcare community paid little attention to what was happening in developing standards.
- The industry, for the most part, ignored or even opposed the standards development activities.

U.S. SDOs

- ASC X12(N) – transaction standards
- ACR/NEMA (now DICOM) – imaging standards
- ASTM – laboratory instrument standards, laboratory data
- HL7 – data interchange standard focused on inpatient hospital information systems
- IEEE – medical device, object-model based data interchange (abandoned)
- NCPDP – reimbursement for prescribed medications

Changes that occurred

- **Increases in cooperation among U.S. SDOs**
  - **Memoranda of Understanding**
  - **ANSI HISPP later HISB**
  - **JWG – message methodology**
- **Improved international cooperation**
  - **Participation exchanges with Europe's CEN**
  - **Increased discussion and active cooperation with Japan, Australia, Canada, UK, others**
  - **Creation of ISO TC 215 that brought international technical experts together**
  - **Growth of internationalization of US efforts**
    - DICOM became international
    - HL7 International Affiliates
    - X12 and EDIFACT

Today: a new world

- Expanded visibility and interest in Health IT standards
- Increased understanding of need for standards
- Increased vendor participation
- Specific activities influencing current interest
  - Connecting for Health – Phase 1 Standards acceleration, Phase 2 - interoperability
  - IOM – Data standards for patient safety
  - Government (Consolidated Health Informatics) - endorsement and adoption of standards
  - NLM - purchase of SNOMED CT US license
  - RSNA, HIMSS – Integrating the Healthcare Environment effort
  - NAHIT – standards inventory

Growth of HL7

- Version 2.n as messaging standard based on implicit model; little message development framework
- Version 3 based on implicit model and a methodology framework
- Merger of Clinical Context Object Workgroup into HL7
- Merger of SGML into HL7 leading to Clinical Document Architecture and Clinical Templates
- Expanding Vocabulary Effort – integration of terminologies, HL7 tables, tying terms to message components

Growth of HL7 (cont)

- Arden Syntax transfer expanding to massive decision support effort
- Expansion of clinical domain beginning with patient care and including pediatrics, clinical trials, public health, patient safety, EHR, others
- Implementation manuals, tool sets including Common Terminology Services, JAVA APIs
- EHR effort
- Conformance and certification
- Security

Growth of HL7 (cont)

- **International Affiliates**
  - **Growth of International affiliates; now 27 international affiliates and growing**
  - **ISO: Partner SDO (formerly pilot project)**
    - RIM – accepted as work item, submitted for approval of standard
    - V 2.5 – submitted as work item
  - **Acceptance of RIM world-wide; building block for other standards**

Specific influencing events for Health IT standards in U.S.

- DHHS support for EHR and NHII (July 2003)
  - Request IOM and HL7 to create functional standards for EHR
  - VA and Centers for Medicaid and Medicare (CMS) need for EHR standards, other
  - NLM promotion of common terminology based on SNOMED CT, LOINC, RxNorm, others
  - HHS support for EHR transfer among sites
  - HHS support for health data interoperability as a requirement for NHII
- President Bush's numerous support for EHR and a call for ubiquitous EHR within 10 years for all Americans

Impact on HL7

- **Functional Specification for EHR**
  - **Became Draft Standard for Trial Use (DSTU) in 2004**
  - **Largest number of votes cast for any HL7 standard**
    - Expanded number of stakeholders
    - Expanded categories of stakeholders
    - Highest visibility and interest for any HL7 standard
    - Much follow up activity

Agency for Healthcare Research and Quality (AHRQ)

- **Transforming Healthcare Quality through Information Technology (THQIT)**
  - **Planning Grant**
  - **Implementation Grant**
  - **Value of Health Information Technology Grant**
    - Clinical, organizational, financial, or other benefits derived from the adoption, diffusion, and utilization of HIT less the costs of achieving these benefits.
    - 186 submissions
- **State and Regional HIT Demonstration Grants**
  - **$1 M/year for five years to 5 states**

AHRQ Grants: Health Information Technology Resource Center

- **Funding: $18.6 M US**
- **Provide technical assistance to grantees**
- **Serve as a repository for best practice assimilation and diffusion**
- **Help develop, maintain and export executable knowledge for clinicians and patients**
- **Offer expert HIT support for providers and communities**
- **Perform and sponsor educational activities**
- **Develop and disseminate tools to help providers and organizations utilize HIT to improve patient safety and quality of care.**

Related Activities

- **American Academy of Family Practionners**
  - **Open EHR**
  - **Center for Health Information Technology**
- **Continuity of Care Record**
  - **Massachusetts Medical Society**
  - **Medical Record Institute**
  - **HIMSS**
  - **ASTM Standard**
    - Core set of data elements
    - XML syntax

HL7 – NLM Contract: Vocabulary

- Map bindings between HL7 message fields and attributes and their respective CHI vocabulary value sets
- Develop implementation guides for specific HL7 messages.
- Refine use of the UMLS Rich Release Format as a standard submission format for source providers.
- HL7 v.2 code sets and v.3 code sets in the UMLS Rich Release Format.
- Comparison of HL7 code sets for overlaps with CHI standard vocabularies
- Identification of subsets of CHI vocabularies that will replace HL7 lists of coded values.

HL7 – NLM Contract

- **EHR transfer between independent sites**
  - **Define process of EHR and EHR components exchange**
  - **Implementation manuals**
  - **Master Data Elements Set**
  - **Proof of concept demonstrations**
  - **Actual demonstrations of EHR exchange among sites having an EHR**

National Healthcare Information Technology Coordinator

- Sub-cabinet level position reporting to head of DHHS
- David Brailer, MD, PHD
  - Informatician
  - Major player in Santa Barbara, CA LHII project

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Brailer Goals for HIT in U.S.

- **Informing clinical practice**
  - **Incentivize EHR adoption**
  - **Reduce risk of EHR investment through certification**
  - **Promote EHR diffusion in rural and underserved areas**
- **Interconnecting clinicians**
  - **Foster regional collaborations**
  - **Develop a national health information network**
  - **Coordinate federal health information systems**

Brailer Goals for HIT in U.S.

- **Personalizing patient care**
  - **Encourage use of personal health records**
  - **Enhance informed consumer choice**
  - **Promote use of telehealth systems**
- **Improving population health**
  - **Unify public health surveillance architectures**
  - **Streamline quality and health status monitoring**
  - **Accelerate research and dissemination of evidence**

Product Certification Initiative

- AHIMA, NAHIT and HIMSS have initiated a certification of ambulatory EHR project
- Industry-wide board to certify EHR products

Medicare Modernization Act of 2003

PROCESS of DEVELOPMENT

- Will be supported by an ANSI-accredited standards development organization, or other private or public organization that will assure continuity, efficient updates, and low-cost distributions of the standard over time.
- Have timely developmental, testing, implementation, updating and conformance procedures to realize benefits faster.
- Incorporate flexibility to more easily adapt to changes in the healthcare infrastructure (such as new services, organizations, and provider types) and changes in information technologies (such as new forms of data capture, knowledge representation, and information presentation).

Medicare Modernization Act of 2003

Characteristics of eRX Standards

- Vendor-neutral and technologically independent of the computer platforms and transmission protocols used in the electronic exchange of eRx information.
- Precise and unambiguous but as simple as possible.
- Consistent with the applicable characteristics and attributes for clinically specific PMRI by NCVHS
  - Examples of these characteristics include having the ability to map the standard's terms to broader statistical and payment classifications, formal and systematic term definitions, internal consistency and non-redundancy, and the capacity to evolve and change to remain usable over time.

Future of U.S. Standards

- We need to provide leadership in the overall conceptual framework for interoperability.
- What are the relevant standards required and what are the priorities?
- How do we manage volunteer efforts (and implied freedom) versus priorities and content specification
- How do we consolidate efforts internationally without a single organization appearing to “want to do it all”?
- How do we educate
  - Governments
  - Industry
  - Consumers

Issues for U.S. SDOs

- What is balance between what SDOs initiate versus those activities coming from other groups?
  - Government
  - IOM
  - HIMSS, eHI, AHIMA, NAHIT, AMIA, others
- How do we sell directives coming from these groups in the international arena?
- How do we work internationally to avoid too much U.S.?
- What is the boundary between technical content and domain content? Do we work together or separately?

Critical success factors

- Modify governance structure/processes
- Engage users better
- Promote more efficient execution
- Need new, sustainable business model
- Better timeliness (shorten time from concept to full standards approval)
- Drive decision-making
- Modify organizations to match role

Success Indicators

- Performance indicators
- Standards developed
- Support for and from stakeholders

- We need to become proactive rather than reactive. We need to predict where health care is going and build the appropriate standards to support that model.

- Health IT may be the silver bullet to fix the healthcare system.