Standards Insight

An Analysis of Health Information Standards Development Initiatives

June 2005

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Overview

In the year since the Department of Health and Human Services (HHS) Secretary's Summit in which David Brailer, MD, PhD, the National Coordinator for Health Information Technology, unveiled ONCHIT's strategic framework, there has been a blossoming of organizations, initiatives and acronyms dedicated to interoperability. This month we will attempt to provide a historical context in which to identify the current players in this exceedingly complex and crowded landscape.

The Primordial Age

Somewhere in the mid 1960's, when IBM first became aware of Medicare billing and realized that there might be a market for computers in hospitals, "informaticists" envisioned an electronic medical record. A very credible system was developed at El Camino Hospital in the 1970's and the vision spread. Technology cooperated, first with the mini-computer, next with the PC and then with local area networking. Many departmental systems and clinical applications were introduced. Many of our current industry leaders and vendors sprang forth in this time frame. ASCII terminals found their way to bedsides. The College of American Pathologists introduced a standard nomenclature called SNOMED to facilitate standard pathology reports and interoperability began its fabled role. As we advanced into the 1980's, Health Level Seven (HL7) was established to develop messaging standards that permitted networked "best of breed" computers to share data. Soon, Diagnostic Related Groups (DRGs) and prospective payment provided motivation to streamline hospital care. The end of this

period was marked with the publication of *The Computer-Based Patient Record* by the Institute of Medicine (IOM) in 1991. The vision of interoperable electronic health records was well defined and prototypes were created. We should note that while there are differences between computerized patient records (CPR), electronic medical records (EMR), and electronic health records (EHR), for the purposes of this brief history we will use EHR as the all-encompassing term.

The HIPAA Zone

The early 1990's marked the beginning of modern times or the dark ages depending on one's bias towards improving care or making it affordable. The payer industry, which coalesced into the Workgroup for Electronic Data Exchange (WEDI), responded to a challenge from then Secretary of Health, Dr. Louis Sullivan, with proposals to save the healthcare system hundreds of millions of dollars a year through "administrative simplification." This became part of the Health Insurance Portability and Accountability Act (HIPAA) enacted in 1996. Along the way, privacy and security provisions were added to the basic standard transactions and codes to assure the public that these computerized records would be well protected. HIPAA clearly spun healthcare information technology in a clear financial direction. HIPAA also mandated interoperability standards and implementation guides, derived from the Insurance Subcommittee of the Accredited Standards Committee (ASC) X12N. It further went on to designate the National Committee on Vital and Health Statistics (NCVHS) as the advisor to the Secretary of HHS on adoption of interoperability standards, including those for personal medical record information (PMRI). This caught the attention of the various standards development organizations (SDOs) as a pathway to success.

We spent the balance of the 1990's in the five stages of HIPAA grief, denial being indulged the longest. At a technology level, the Web "changed everything." Extensible Markup Language (XML) became the lingua franca of the new age. Interestingly we found the dark side of federal mandates that locked HIPAA into old style ASCII messaging, although in light of recent news of the British National Health Service's bold use of emerging standards, such conservatism might be rewarded in the long term. In the case of HL7, which by now was the preeminent clinical messaging standards developer, it saw an opportunity to develop interoperable components derived from a common reference information model (RIM) and so began its Version 3 journey. Healthcare policy, following the collapse of the Clinton initiative, changed little in the 1990's. Managed care was deputized to control costs, economic growth buffered us against hard choices. In the end we rejected the confines of managed care for the easy choices. Although the HIPAA Zone has yet to run its course, the IOM 1999 report *To Err Is Human: Building a Safer Health System* signaled a new era.

The Era of Error

To Err is Human posed that 44,000 to 98,000 Americans were killed every year by medical errors, making this the fourth or fifth leading cause of death, and by simple inference the leading cause of avoidable deaths. Parenthetically, the IOM report noted

that this cost the economy billions of dollars. In subsequent reports, healthcare information technology (HCIT) was identified as a key enabler of patient safety. These reports culminated in a crusade, led by Harvard researchers and other advocates, to focus attention on the inadequacies of our fragmented, autonomous health care system. A key underpinning of this research was medication error rate calculations and the proposition that computerizing physician ordering would not only reduce medication errors but would force adoption of full electronic medical record systems. But no one wanted to deal with the concept that they were delivering or receiving "bad, error-prone" care. And so the Era of Error flamed out early but from its ashes we entered the modern era.

This interregnum featured Y2K "upgrades" and the bursting dot com bubble. HIPAA consumed the funds left over from Y2K displacing spending on clinical systems. Fulfilling its HIPAA mandate, NCVHS made recommendations to HHS on the PMRI messaging standards including HL7 (Version 2 now and Version 3 when ready), the National Council of Prescription Drug Plans (NCPDP) for prescriptions, DICOM for imaging and others in early 2002. The federal eGov initiative enshrined these within its Consolidated Health Informatics (CHI) initiative for implementation at all government agencies. HL7 struggled with its massive reference information model (RIM) undertaking and produced little to induce a large scale shift away from its venerable Version 2.x messaging standards. Its Clinical Document Architecture (CDA) was an exception. The XML-based CDA took HL7 beyond messages to documents or persistent containers of patient data, map able to the RIM, but capable of including all data types, an essential feature for transitioning from unstructured paper records to an interoperable EHR.

ASTM E31, which had slipped from prominence in healthcare informatics, proposed the Continuity of Care Record (CCR) as an alternative lightweight means to transfer patient data between providers. Integrating the Healthcare Enterprise succeeded where prior efforts to constrain standards failed, with rigorous profiles and produced "plug and play" radiology department implementation guides. IHE began as a collaboration of organizations between the Radiological Society of North America (RSNA) and the Healthcare Information and Management Systems Society (HIMSS). This effort enabled the rapid growth in picture archiving and communications systems (PACS) seen in recent years. But there was no overarching business or technology integration force, and the leading HCIT vendors moved into the void with monolithic enterprise clinical information systems that provided proprietary implementations of EHRs and computerized physician order entry (CPOE).

Saving Lives-Saving Dollars

While reducing errors to improve patient safety did not ignite healthcare reform and transformation, reducing errors to control costs did. The Leapfrog Group advanced a proposition to the Fortune 50, starting with the hard pressed auto manufacturers; you can reduce your healthcare benefit spending by 25 percent or more if you insist on "quality" from healthcare providers. This was intuitively accepted by corporate America that had already embraced quality improvement programs, such as Six Sigma, Baldridge, and TQI ET.AL. Leapfrog collapsed its initial quality measures into three, led by CPOE.

This theme of improving quality and reducing costs found fertile ground in the new MBA led administration, as preached by Newt Gingrich and the Center for Health Transformation. The administration got it: "saving lives means saving dollars." Other policy advocates, particularly the eHealth Initiative, the Center for Information Technology Leadership, and Connecting for Health, were important through their sponsorship of meetings, white papers and analyses for getting Washington to re-vision a health care system that was paid for performance and enabled by interoperable information systems. We were no longer talking about hundreds of millions in savings but rather a hundred billion. Pay for performance and consumer choice became the new paradigm replacing managed care.

In structuring Medicare drug benefit legislation, Congress and the administration included requirements for e-prescribing and interoperability. All Medicare prescription drug plans were required to offer an e-prescribing option based on HHS promulgated standards. As with HIPAA, the Medicare Modernization Act (MMA in 2003) designated NCVHS to recommend these standards to the Secretary. This began a frenetic series of hearings in 2004 that recommended use of SCRIPT standards from NCPDP as mandatory foundation standards for use starting in 2006.

Like twins separated at birth, the EHR was traveling a parallel but different path than e-prescribing. We noted earlier that the proponents of CPOE and e-prescribing saw these as part of an EHR System. When the Centers for Medicare and Medicaid Services (CMS) first approached HL7 in 2003 about developing a standard for EHR system functions, it asked for three key components: e-prescribing, e-lab results and e-reminders. MMA not only mandates e-prescribing but also the use of electronic medical history to inform the prescriber when practical. HL7 produced a draft standard in record time, but the haste left many of the hard details, such as designating the minimum functions for different care settings for future work.

The seminal event of our current timeframe was President Bush's call for a universal EHR for all Americans within 10 years during his state of the union address in 2004. This kicked off a series of events culminating in the creation of the Office of the National Coordinator for Health Information Technology (ONCHIT) and the appointment of Dr. Brailer as National Coordinator.

ONCHIT produced its strategic framework in three months. It set forth four overriding objectives for the nation to fulfill the President's EHR goal. Paraphrased these are:

- Care providers should be informed by having a complete electronic health record when making decisions
- To insure a complete record, patient data must be shared among providers (systems)
- The record must be patient centric and extend over time
- The data needs of secondary users should be met as a derivative of the above system.

Dr. Brailer, partly because he had neither Congressional mandate nor buying clout and partly because of his market-based orientation, masterfully finessed the limitations of his resources by enlisting many interest groups to compete to be at the table. First from the blocks were HIMSS, the American Health Information Management Association, and the National Alliance for Health Information Technology. These organizations identified the "market" need for assurance that systems and standards met minimum requirements. They established the Certification Commission for Health Information Technology to certify that EHR applications met such standards including the ability to interoperate with other systems. This prompted the vendor industry, already nervous about the HL7 EHR System draft standard, to call on HIMSS to sanction the EHR Vendor Association to represent industry in this product standardization exercise. ONCHIT, CMS and other payers have made no commitment to use such certification but the "threat" hangs heavy.

Another of ONCHIT's market agents are regional health information exchanges (RHIO) that are to organize and manage the business rules for exchanging data among independent and, often competitive, providers. So far millions of federal, state and private funds have come forth to conduct pilots but we have seen no sustainable business model. IHE has expanded its role well beyond radiology and has developed through its IT infrastructure committee inter-enterprise profiles for looking up and exchanging documents. It is committed to demonstrating basic RHIO interoperability using existing standards by 2006.

What group or acronym have we missed? Certainly the industry aggregators, such as the ubiquitous HIMSS, gracious sponsor of the *Standards Insight*, the American Academy of Family Physicians (AAFP) the American College of Physicians (ACP) at and NAHIT have been leaders in representing the interests of their constituents within the larger national agenda. The President's Information Technology Advisory Committee (PITAC) at) proffered recommendations that will be most remembered for an initial one that ICD-10 not be adopted but be replaced by a mismatched SNOMED CT. And, like HIPAA, MMA spawned an interoperable advisory board, the Commission on Systemic Interoperability (CSI). CSI will report back to the President and Congress on barriers and a roadmap for achieving interoperable HCIT by this fall. Our hope would be that CSI focuses on the business case necessary to drive adoption and use of interoperable EHR systems. This means tackling in a detailed manner the issue of aligning incentives and more generally how to mold a seamless, patient-centric system out of our fractured healthcare system. This would usher in the next and last age considered.

The Coming Age of Alignment

The future is more difficult to predict than the past and based on the condensed and simplified history above the reader may be justly skeptical. For reasons beyond our scope, national policy hangs on the adoption of EHR systems by physicians in small (1 to 4) practices and their participation with larger groups, hospitals and other care providers in a collaborative, team approach, constrained by best practices and performance evaluations. That is a bigger challenge than technology and requires changed roles and realigned incentives as well as consumer pressure on payers and providers to deliver

more efficient and effective care. Together they will induce industry restructuring and reward those early-to-get-it provider organizations that change their business model and transform care. Use of interoperable EHR systems by themselves may save clerical efforts associated with data exchange, but without fundamental transformation, we will automate our fractured system and not realize the big payoff of saving lives and saving money. But we now are treading on new ground and the subject for futurists not historians.

The current administration may not fully usher in this new age given their aggressive agenda on Social Security, tax reform and necessary foreign issues. We expect that Medicare will become a bigger economic problem than Social Security left unchanged. The next administration, if not as enthusiastic in embracing market based healthcare transformation, could provide a new paradigm that will ripple down to HCIT requirements and priorities. If in fact Dr. Brailer and ONCHIT can produce a national health information network (NHIN) that lays out the technical and organizational steps required for universal, interoperable EHRs, then perhaps we can follow such a roadmap in the fits and starts of our policy and economic initiatives.

Please direct any questions, suggestions or comments regarding *Standards Insight* to Joyce Sensmeier, HIMSS director of professional services, at jsensmeier@himss.org or to its author Ed Larsen at erlarsen@erlinc.com.

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