

## INTERVIEW:

### View from the Trenches: an Interview with HL7's Charles Jaffe, M.D.

#### Andrew Updegrove



The number of standard setting organizations (SSOs) from which specifications have been drawn to create Electronic Health Records (EHRs) are legion, due to the complex nature of these goal. Some of the standards utilized are generic, and common to any sophisticated Internet-enabled commercial system. Others are specific to science, but usable generally in paper as well as information technology (IT) based health care systems. Only a few SSOs, however, have taken up the challenge of developing the major components essential and unique to EHRs. One of the oldest and most important is Health Level 7, more commonly referred to as HL7.

HL7 has been at the center of global EHR development since 1987, as well as a key player in the more recent U.S. efforts to design and implement a national EHR system by 2014, a commitment made by President George W. Bush in his State of the Union Address in January of 2004.

With the Obama Administration's pledge to meet that commitment, and to direct massive amounts of funding towards ensuring its success, it is critical that the standards needed to support this ambitious goal are not only available, but the right tools for the job as well.

In this interview, HL7 CEO Charles Jaffe, M.D. shares his perspective on what's been accomplished, what remains to be done, and where the critical decisions that will lead to success or failure in creating a national EHR system must be made.

#### I. Overview Questions

**AU:** *Please tell me what the historical role of HL7 has been in the standards area.*

**CJ:** HL7 was founded at the University of Pennsylvania 22 years ago in order to facilitate the exchange of administrative data. It rapidly evolved into the standards

by which clinical data is shared in hospital and ambulatory settings. In order to support a broader range of stakeholders, HL7 adopted the development requirements of the American National Standards Institute (ANSI). The adoption of HL7 specifications and the associated standards development process soon became the foundation of healthcare IT infrastructure around the world, and today is embraced by affiliates in 35 countries. By virtue of charter agreements and far-reaching cooperative initiatives, HL7 has formed major development initiatives with other global standards development organizations, including ISO and CEN (European National Standards body), clinical research bodies, such as CDISC (Clinical Data Interchange Standards Consortium) and the US FDA, government agencies including the National Library of Medicine, Canada Health Infoway, National Health Service Connecting for Health (UK), terminology developers such as International Health Terminology Standards Development Organization (IHTSDO / SNOMED CT) and LOINC (Laboratory), pharmacy standards developers (NCPDP), as well as international profiling organizations (IHE / Integrating the Healthcare Enterprise).

**AU:** *What are the current standards maintained by HL7, and what purposes are they intended to serve?*

**CJ:** Briefly stated, they are specifications to support interoperability. Messaging is the more traditional area for which HL7 is recognized and is embodied in the Version 2 family of standards. These specifications support interoperability for greater than 95% of the hospitals and healthcare systems in the United States. Version 3, which began more than a decade ago, provides a model-based development system and insures a higher level of interoperability. Within Version 3 lies the Clinical Document Architecture (CDA), which provides both the higher level of interoperability and the persistence of common documents or clinical templates. HL7 has also developed functional and interoperability models for EHRs and for Personal Health Records (PHR). Concurrently, HL7 is creating a Services Oriented Architectural (SOA) framework as well as the definition of a SOA-based Enterprise Architecture that supports all HL7 products.

**AU:** *What categories of stakeholders are active in HL7 today?*

**CJ:** In addition to those stakeholders identified in question 1, above, HL7 is also supported by academic institutions, system and electronic health record vendors, system integrators, hardware and software technology developers (such as IBM, Intel, and Microsoft), clinical research institutions (including the NIH / National Cancer Institute) and pharmaceutical companies, quality institutes and privacy advocate organizations, national healthcare standards organizations, as well as national and international professional medical, nursing, informatics and other healthcare (dental, pharmacy, veterinarian) societies. HL7 also has important relationships with granting bodies (Robert Wood Johnson Foundation and the Rockefeller Foundation) as well as with the World Health Organization.

## **II. The Task Ahead**

**AU:** *Where do things stand at this moment in Congress relating to EHR legislation?*

**CJ:** At this moment, there is a high level of flux in the plans for both the Recovery Act (stimulus package) and long-range investment. The proposals brought forth by the Senate and the House differ in their language and intent. At the same time, the approach to creating stimulus packages reflects the divergent economic philosophies of the Democrats and Republican platforms. Nonetheless, there is bi-partisan support for healthcare reform and healthcare IT as a vehicle for improving quality, diminishing medical errors, and suppressing the upward spiral of healthcare costs.

In the current legislation, both houses of Congress support a strong central body to oversee national initiatives for healthcare IT (Office of the National Coordinator) and healthcare IT standards (Healthcare IT Standards and Policy Committees). The funding, both near-term and long range, is significant. Dollars will be devoted to infrastructure, standards, and the goal of the Administration is to provide some form of interoperable healthcare records for all Americans within five years.

**AU:** *Does it appear that the legislation in process is addressing the same challenge that, for example, HITSP was created to address, or has the goal changed to require something new or additional, and if so, in what ways? (Are these the right ways?)*

**CJ:** It appears that the goal of accelerated development of healthcare IT standards and technology remains. It is unclear to me at this time if the process will undergo some fundamental rethinking. Various legislative packages provide for different infrastructure, although it appears that the burden of administrative responsibility will rest with the Office of the National Coordinator for Healthcare IT (ONCHIT) and the National Institute of Standards and Technology (NIST). The pathway to standards development is not clearly defined within the legislation, although provisions for oversight are important in all of the packages.

**AU:** *At a high level, what are the categories of standards and related tools that will be needed to make EHR's possible?*

**CJ:** Electronic Health Records that share institutional or in some cases system-wide health information have been broadly deployed in hospitals and large ambulatory clinics and group practices. There is still a significant need for certified EHR systems in small group and independent physician practices where most clinical information is still maintained on paper. Examples of successful implementation exist within the Veterans Health Administration and within Kaiser Health System. These are not complete, not portable, and not easily scalable in other environments. The national goal of sharing data and achieving true interoperability has many obstacles, however. The standards needed for the process are only one of them. Certainly one of them is a strong business case (or value case) for data exchange. Public health demands, clinical research requirements and cost mitigation are issues that make a compelling case. Other hurdles include increasing privacy demands, infrastructure deficiencies, the lack of a national patient identifier, as well as vocabulary and terminology ambiguity. Even the most successful of these in Canada and England have been marked by missteps and complex priority decisions. Perhaps one of the most significant impediments to implementation in the US is the disparity between the beneficiaries of EHRs and the stakeholders (physicians and providers) who are required to bear the costs.

**AU:** *How many of these categories of tools are available today?*

**CJ:** If, by tools, you mean the technology that now may be considered electronic health records, there are many. They have varied objectives, cost structures and breadth of implementation. If you mean fully-implemented electronic health records, with full integration with lab and x-ray, for example, and providing robust decision support, the penetration is very limited. If you mean stand-alone electronic medical record solutions, or electronic personal health record implementations, or even electronic prescribing systems, the adoption is higher, albeit modestly so. Even if the technology and funding hurdles were overcome, there would be significant remaining barriers related to policy considerations, including provisions for opt-in/opt-out of respective systems. For example, in some metropolitan regions in the Northeast, some patients live in one state, work in another, and receive significant healthcare in a third.

**AU:** *Which other standard setting organizations (SDOs) do you see as being most important (i.e., technically competent, well enough established, and robust enough to do what needs to be done)?*

**CJ:** Like the question above, the answer implies significant political ramifications. In addition, some SDOs are global, while others are very US-centric. Globally, ISO remains a critical arbiter of standards. CDISC is the pre-eminent standard for clinical research. Among the vocabulary standards, there are several important players. SNOMED CT (from IHTSDO) may be the most important in the English speaking world, but the International Classification of Diseases (from WHO; ICD 9 in the US, ICD in the rest of the world) and LOINC (Logical Observations: Identifiers, Names, Codes for labs) are widely used for some data exchange in the US. NCPDP (National Council for Prescription Drug Programs) for pharmaceuticals in the US.

**AU:** *Where work still needs to be done, do you see voids where no qualified standards organization exists to meet the need? What are those areas?*

**CJ:** There is not a lack of standards, there are, in fact, too many standards and too many organizations writing them. There are some standards that are easy to implement or easy to understand, but which lack coherence, scalability, or broad adoption, while others are difficult to understand or cumbersome to write code for implementation. Some organizations write specifications or artifacts that are useful but painfully limited. Some are built on strict models and development frameworks to improve interoperability. Others meet the needs of the specific domain but are incapable of being used to share data with our healthcare environments. Some are meant to be international while others are simply realm-specific. Perhaps the most difficult challenge is to bind the standards to structured vocabularies to ensure that there is the unambiguous transfer of meaning. And as always, most lack the tools to adequately facilitate implementation.

**AU:** *The US has always been more of a vendor-driven, "bottom up" rather than a government directed, "top down" standards development system. What role do you think government needs to play in order to accomplish this broad, complex and accelerated process?*

**CJ:** From the perspective of HL7, the US government must provide the funding to support the development of standards and conformance testing. Among the other English-speaking countries, we trail far behind in providing the federal leadership and resources for healthcare standards creation and management. For more than a decade in the UK and nearly as long in Canada, we have seen far-reaching federal management of healthcare resources that greatly overshadow the efforts of US agencies and organizations. While Canada and the UK have approached this process very differently, both have achieved significant progress to enable healthcare IT to improve the delivery of care and reduce its cost. The philosophy articulated in the very early hours of the new Administration is focused on reversing that position and committing the needed resources to this complex process.

**AU:** *Are there other governments abroad that are moving to implement EHRs? Who are they, and what can we learn from them?*

**CJ:** As noted earlier, both the UK and Canada have taken bold steps to develop healthcare IT infrastructure and implementation. With any ground-breaking initiative, mistakes have been made. Certainly, the business model of each cannot be easily reconfigured to the US environment because of the central payer system in those countries. As the US Federal agencies (principally CMS) gradually exceed the 50% level of healthcare funding in our country, that concern becomes less problematic. In addition, the UK and Canada have recognized many of the shortcomings of their respective approaches and have made even more significant efforts to mitigate them. The US can learn a great deal from the experiences of these countries.

### **III. The Major Challenges**

**AU:** *Do we have a chicken and egg problem here? Can we productively spend \$10 billion the first year, or do we have to get farther down the road with the standards before we can spend money at this scale without wasting it?*

**CJ:** I don't think we can wisely spend one hundred cents of every investment dollar. Mistakes will be made, but we need bold initiatives to prevent continued erosion of our healthcare delivery and further escalation in the rate of our healthcare expenditures. It has been over a decade since the Institute of Medicine issued its landmark report, *To Err is Human*, which detailed the deficiencies in our healthcare system. This startling condemnation was followed two years later by *Crossing the Chasm*, which provided recommendations to remedy some of the most significant problems. Not much progress has been made since then to rectify the problems in our delivery process which lead to the erosion of the quality of care. Of course, the expenditure of such large sums cannot be accomplished without significant oversight. Success needs to be clearly defined and metrics for success must be established. Nonetheless, the amount of the proposed funding is not out of proportion with the per capita resources dedicated to healthcare delivery in the UK and Canada.

**AU:** *Do we have consensus on the standards approach to take, or will even that take time to achieve? How about the architectures upon which the standards must be based?*

**CJ:** There is a growing consensus to the approach we must take, but it is far from unanimous. Without exception, every effort and initiative is hampered with self-interest and complex fiscal philosophies. In the past, the US has relied almost exclusively on the marketplace to drive decision making. As the percentage of our GDP devoted to healthcare skyrockets beyond 16%, we no longer need to ask questions about the efficiency of the marketplace. We can no longer commit over 20% of our healthcare dollar to administration nor can we accept the fact that the most affluent nation in the world trails twenty other countries in the delivery of healthcare quality. The commitment of the Federal government to healthcare IT for improving our delivery system is the first step for which no price tag can be assigned.

**AU:** *Does Congress have the expertise to finalize the legislation that will launch the program, or could they use more help in understanding the standards based issues?*

**CJ:** I don't believe that Congress will ultimately codify specific standards or programs within its broad legislative agenda. I expect them to provide broad objectives and identify the agencies to translate that agenda into an action plan. Early drafts of the legislation have carefully articulated certain stakeholder groups and important guidelines (such as privacy). Ironically, the draft of the legislation from the House Ways and Means Committee fails to mention two important stakeholders: physicians (care providers in general) and standards development organizations.

**AU:** *Is five years a reasonable period of time for this project – to not only develop the standards, but also design the products, widely deploy them in the marketplace, and train medical personnel to use them? If not, what would be reasonable?*

**CJ:** Five years is very ambitious on any budget. I don't believe we have the manpower to install and maintain the necessary technology and systems even if the funding were available to pay for all of it. One of the HL7 goals is the acceleration of training of individuals to provide these skill sets. Perhaps the biggest obstacle is the human factor. What incentive (carrot or stick) will we provide to caregivers to promote adoption of these technologies that will surely alter workflow, re-prioritize incentives, and perhaps restructure the way we represent knowledge.

**AU:** *What are the most critical standards-related first steps to be taken, in your judgment, to make sure that the EHR initiative proves to be successful?*

**CJ:** For HL7, the most vital task is the addition of professional staff with high levels of technical expertise to the cadre of dedicated volunteers who make standards development possible. Secondly, we must change the funding model of our organization so that we no longer rely upon voluntary contributions and membership fees to dictate the limits of the reach. Lastly, we must rededicate ourselves to responding to the needs of the government agencies that rely so much on the productivity of our organization, whether or not these requirements are consistently and clearly articulated.

In a more global environment, the US government can learn from the experiences, both positive and less so, from other countries that have paved the way for healthcare information interoperability. In many instances, other government agencies have cooperated with and benefited from the expertise of the HL7 rank and file. While the technology may not be immediately transferable, the experience on many fronts certainly is.

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