Standards Today

A Journal of News, Ideas and Analysis

A publication of CONSORTIUM INFO.ORG
GesmerUpdegrove LLP

December – January 2009 Vol. VIII, No. 1

THE ELECTRONIC HEALTH RECORD STANDARDS CHALLENGE

Standards Today is a free bi-monthly electronic Journal sponsored by the Boston law firm of Gesmer Updegrove LLP. The current issue of ***Standards Today*** and a subscription form may be found at www.consortiuminfo.org/bulletins. Questions or comments about the articles in this issue or about ConsortiumInfo.org may be directed to Andrew Updegrove at updegrove@consortiuminfo.org, or by telephone at 617/350-7800. To learn more about Gesmer Updegrove's standards and open source practice, visit http://www.gesmer.com/practice_areas/consortium.php, or contact Andrew Updegrove.

Sign up for a free subscription to ***Standards Today*** at

http://www.consortiuminfo.org/subscribe/2.php?addentry=1

EDITOR'S NOTE:

First the Standards, then the Solution

In the last issue ***Standards Today***, titled A Standards Agenda for the Obama Administration, I described the standards-based dependencies of the technology agenda earlier announced by president-elect Obama. That agenda provides for the creative use of technology to advance a number of important policy goals, such as achieving transparent government, equal access to the Internet, and reducing costs of healthcare. In this issue, I focus more closely on the significant role that standards will play in achieving one of (now) President Obama's greatest challenges –lowering healthcare costs, while at the same time keeping a campaign promise to provide universal health coverage.

As these words are being written, the US Congress is debating the final terms of a stimulus bill that will result in the expenditure of $825 billion (or more) of public funds on a wide array of initiatives intended to address an equally challenging goal: resurrecting an economy that seems inexorably headed towards its worst performance since the Great Depression.

One of those initiatives included in the stimulus bill would make the final push towards national implementation of something called "Electronic Health Records," or "EHRs." EHRs are digitized patient records that capture a patient's medical history, treatment and other data in real time, making it available to authorized care givers and researchers, insurers, and the patient herself. EHRs are devilishly complex to design, because they must satisfy an almost impossible set of competing requirements.

The benefits promised by EHRs include dramatic reductions in healthcare costs, fewer medical errors, higher quality medical care, and more productive research results in the health sciences. But the up-front costs of deploying such a system on a national basis are dramatic as well. It is estimated that the expenditure of well over one hundred billion of dollars will be required over the next five years.

Due to the great benefits and enormous costs of this effort, it would be really great if it all worked, after it was deployed and paid for, and that's what this issue is all about.

In my ***Editorial***, Getting EHR Standards Right, I expand on the challenge, and the importance of not rushing headlong into implementation before fine tuning the standards that will make or break the success of EHRs. In the ***Feature Article***, A Guide to Electronic Healthcare Record Standards and the Challenges Ahead, I review the history of EHR development to date, describe the many significant challenges to designing effective EHRs, survey the organizations developing EHRS, provide a timeline of significant government action, and finally provide recommendations regarding the remaining steps that need to be taken before actual deployment begins, in order to ensure that the great promise of ubiquitous EHR deployment is achieved.

Next, I'm very pleased to provide a lengthy ***Interview*** with Dr. Charles Jaffe, the CEO of Health Level 7 (HL7), one of the oldest standards development organizations creating EHR standards. HL7 standards are a cornerstone of all EHR frameworks in development and use today, and Chuck's perspective on what still needs to be done is a must read for those interested in what lies ahead. The interview is appropriately titled View from the Trenches: an Interview with HL7's Charles Jaffe, M.D., and it is a sobering read.

This issue's ***Standards Blog*** returns to an topic that I have followed and supported for over five years: the ongoing litigation involving Rambus Incorporated, a company that has by turns been successful and unsuccessful in avoiding liability for allegedly "gaming" the standards development process for its own profit. I have filed numerous pro bono "friend of the court" briefs involving Rambus in the past in defense of the integrity of the standards development process, and in December of last year I did so once again: this time with the Supreme Court. The title of the blog entry indicates the breadth of the support I was able to gather in this endeavor: 19 Standards Organizations Support Rambus Brief.

For my ***Consider This*** essay, I return to the healthcare theme, and point out that there is more to the patient than digitized data alone. The piece is entitled Standards of (Patient) Care.

I close this issue with a piece from my ***Monday Witness*** series, which focuses on the ethical and moral, rather than the technical, standards of the day. It is entitled Inauguration Day – January 20, 2009. In it, I reflect on inaugural addresses past and present, and look forward with guarded optimism to the next four years.

As always, I hope you enjoy this issue. But whether you do or don't, it's always good to hear from you. You can reach me at andrew.updegrove@gesmer.com.

Andrew Updegrove
Editor and Publisher
2005 ANSI President's
Award for Journalism

The complete series of Consortium Standards Bulletins can be accessed on-line at http://www.consortiuminfo.org/bulletins/ It can also be found in libraries around the world as part of the EBSCO Publishing bibliographic and research databases

Sign up for a free subscription to ***Standards Today*** at

http://www.consortiuminfo.org/subscribe/2.php?addentry=1

EDITORIAL:

Getting EHR Standards Right

Andrew Updegrove

On January 20, a new show opened in Washington D.C. After eight years under one administration, the curtain cascaded down on one set of policies, and a moment later rose to unveil a new administration, with new ideas, new priorities, and a new agenda. Included in that agenda is a commitment to embark on a five year quest to dramatically decrease the cost of healthcare – by investing as much as $50 billion dollars of public funds in the design and deployment of something called "electronic health records," or EHRs.

Readers of this eJournal, but not the public at large, will be immediately aware that the foundation for the DHR vision is standards

As of this writing, $20 billion of that amount is included in the current House draft of the Economic Stimulus bill called for by the new administration. The full cost of EHR implementation, including private expenditures, has been estimated to be $156 billion over five years, not including $20 billion in operational costs. With such a price tag,, the promise of EHRs had best be realized, or the new administration will have some significant explaining to do.

At its most basic conceptual level, an EHR is to a medical chart what an electronic spreadsheet is to its paper analog. And indeed, the roots of the EHR can be traced back to the concept of "computerized patient record" technology that would allow a doctor to enter notes with a stylus on a tablet PC. But the value of these early records were only realized by the hospital that hosted the proprietary system to which the tablet was linked. When the patient left the hospital, his data was left behind, unavailable even to the physician that had entered the data when she returned to her own off-site office. Nor could the data be accessed by any other physician elsewhere in the future, or by the emergency room staff of any other hospital to which the patient might be taken in the future. Instead, islands of isolated data were created by each physician and facility in technically idiosyncratic fashion, and maintained in proprietary systems, never the twain to meet.

The result is that we are constantly filling out new questionnaires in doctors' offices and waiting days or weeks for paper copies of records to be printed by one care giver to be mailed, hand delivered or faxed to another. In emergencies, we are apt to be cared for by medical staff that have no access to vital facts relating to our medical history at all, perhaps with unfortunate and avoidable consequences. Meanwhile, our care providers are weighted down with expensive, tedious and duplicative record keeping.

The ultimate goal of health information technology is therefore a medical record in which a patient's medical information will accumulate over a lifetime as a succession of care givers contribute it. That data will be accessible from anywhere,

and at anytime, by those to whom the patient wishes to give access. Because everyone will enter and access the data in the same way, the quality of care should increase, the incidence of avoidable mistakes should decline, data input and storage and other costs will decrease, insurers will be able to verify claims more accurately and make payment more speedily, and patients will have greater control over their own medical information. With appropriate provision for protection of patient privacy, masses of invaluable, comparable data would also become available to researchers to speed the advance of new treatments and medications.

But in order for this eHealth nirvana to be attained, millions of hospitals, doctors' offices, emergency responder units, insurers and others will need to purchase and install the software and other technology needed to create, maintain and exchange EHRs, and their personnel will need to be trained to use them. All of this can only be achieved at great cost of both public and private funds.

Whether wide uptake of EHR technology and real savings are achieved quickly will in great measure result from how well the standards that enable EHRs are selected, assembled and integrated into actual systems.

Readers of this eJournal, but not the public at large, will be immediately aware that the foundation for this entire vision is standards – taxonomies to ensure uniformity of data input, identifiers for authentication, security requirements for authorization and maintenance, protocols to enable communication between systems, data formats to ensure long term accessibility, and much more. Upon this foundation must rest other standards tools – frameworks, profiles, reference implementations, and guidance documents. Indeed, the blueprint for a successfully deployed, national EHR infrastructure must by definition be a complex and carefully constructed hierarchy of standards.

Designing and deploying this standards-based infrastructure will be comparable in scope and scale to designing and deploying the Internet, minus the requirement to build the telecommunications backbone that is now already in place. But unlike the "opt in" Internet, to which users gradually migrated in increasing numbers over two decades as the Web's capabilities grew and its lure became more seductive, EHR technology must be adopted very widely before cost savings begin to outweigh expenditures. Unless that happens quickly, it will be many years before meaningful savings are achieved.

Whether wide uptake of EHR technology and real savings are achieved quickly will in great measure result from how well the standards that enable EHRs are selected, assembled and integrated into actual systems. Unfortunately, the history of ambitious standards projects has not always been a happy one, and for every grand success like the World Wide Web there is a well intended POSIX that fails to achieve its hoped-for destiny. Moreover, the record of EHR deployment success to date, both within individual hospitals as well as in national programs abroad, has been mixed.

The lesson to be learned, then, is that we had better get the standards right, both from a real world as well as a technical perspective. If the standard suites

mandated do not solve real problems in ways that work for care givers, vendors and other stakeholders, then this ambitious and worthwhile endeavor will be doomed from the outset, and an enormous amount of money will have been squandered.

Getting the standards right is possible, but will not always be easy. As with any other government initiative involving vast amounts of money, those with the most to gain will have the greatest incentives to steer decisions to their advantage. Those in government who do not have deep expertise in standards development but may find themselves charged with achieving rapid results will be hard pressed to know which recommendations to follow. Finally, until the standards are finalized, the greater part of the funding available cannot be spent. All of these forces will work against making the best decisions in the time necessary to make them.

The Obama administration should therefore pursue its EHR agenda with as much caution as speed, and with deliberation as well as determination. Because once these important infrastructural decisions have been made, it will be difficult indeed to turn back.

FEATURE ARTICLE:

A Guide to Electronic Health Record Standards and the Challenges Ahead

Andrew Updegrove

Abstract: *Since 2003, the United States has become increasingly committed to the deployment of comprehensive electronic health records (EHRs) for all Americans in order to dramatically decrease healthcare costs, reduce medical errors, and facilitate research. At the technical level, EHRs comprise multiple component specification frameworks intended to address identified "use cases," such as ordering lab tests, securely archiving the test results, and making the stored information available to authorized physicians, researchers and the patient into the future. Each component framework includes dozens of IT standards of many types. Since 2004, significant funding has been invested, and new administrative resources have been created, under the Department of Health and Human Services to facilitate progress towards developing and implementing EHRs nationwide by 2014. Concurrently, a diversity of private sector and private-public sector standards development initiatives have been actively engaged in developing the standards and related tools (e.g., implementation guidelines and certification tools) needed to enable EHRs. The Obama administration is today requesting, and Congress appears ready to provide, significant additional funding to deploy EHRs on a national basis. In this article, I review the history of EHR development and government activity to date, describe the many significant challenges to designing effective EHRs, survey the organizations developing EHRs, and finally recommend certain next steps needed to ensure that the national deployment of Electronic Health Records will be successful.*

Introduction: In November of 2007, Barack Obama announced an "innovation agenda"[1] for the administration he would lead, should he succeed in being elected president of the United States. One of the major features of that agenda was a pledge to enlist information technology (IT) to make universal health care achievable at an affordable price. Now that he has taken office, he is in a position to advance that agenda, and indeed the current House draft of the economic stimulus bill that he has asked Congress to adopt includes $20 billion of public funds to be spent in creating health IT infrastructure.

Central to this effort is the goal of finalizing the design and deploying the use of "electronic health record" (EHR) technology on a national basis. But achieving this goal will require a massive IT expenditure by the very hospitals and physicians

[1] Barack Obama on Innovation and Technology, November 14, 2007, at http://www.barackobama.com/pdf/issues/technology/Fact_Sheet_Innovation_and_Technology.pdf. This, and all other on-line resources cited in the notes to this article were accessed between January 24 and February 2, 2009.

whose costs are to be reduced. Moreover, it will also require of millions of doctors, nurses, laboratory staff, insurance providers, and others to use the new software and tools developed to support EHRs.

As a result, the current House draft of the American Recovery and Reinvestment Act would authorize reimbursing each physician up to $41,000 over five years, beginning in 2011, to assist her in purchasing and deploying EHR tools that are certified to be compliant to the standards that will be announced. Hospitals will be eligible for incentive payments as well. The bill includes a stick as well a carrot: physicians that are not using a certified EHR system by 2016 would see their Medicare payments decrease.

the IT systems that enable cost-effective EHRs cannot be built before consensus is achieved on the standards and related tools upon which such EHRs must be based.

While the plan described above successfully cleared the House (albeit without the support of a single Republican vote), the speed at which EHR funding could be deployed in order to provide economic stimulus was a matter of discussion. One exchange between Committee members was reported at the Web site of Government Health IT as follows:

> In the Energy and Commerce mark-up session, Rep. Michael Burgess (R-Texas) objected to the fact that most of the incentive payments will not go out until 2011.
>
> Rep. Bart Gordon (D-Tenn.) countered that Congress does not want providers to begin buying systems before the technical standards are established. The legislation calls for the Health and Human Services Department to adopt an initial set of standards, implementation specifications and certification criteria before the end of this year.
>
> Gordon noted there is money in the bill to accelerate standard setting, and argued that the bill will provide certainty in the private sector that will spur providers to get ready for the incentives.[2]

The exchange above highlights a key dependency that underlies the Obama administration's hope to at last provide universal health care at a price the country can afford. Balancing the books on that goal will be dependent on lowering the overall per-patient cost of providing medical care, which in turn most experts agree must rely dependent on the wide deployment of EHRs. But the IT systems that enable cost-effective EHRs cannot be built before consensus is achieved on the standards and related tools upon which such EHRs must be based.

[2] Foxhall, Kathryn, Health IT stimulus bill zips toward House floor, Government Health IT (January 23, 2009), at http://govhealthit.com/articles/2009/01/23/health-it-stimulus-bill.aspx

It has been widely acknowledged for more than a decade that the design and ubiquitous adoption of effective EHRs can provide for a variety of important benefits in addition to lower costs, and indeed the experiences of some healthcare facilities support this belief. These benefits include fewer medical mistakes, easier sharing and storage, and better patient care. But at the same time, the design and deployment of EHRs has proven to be extremely challenging.

In this article, I will seek to provide an overview of the nature of EHRs, the history of their evolution in this country to date, the organizations involved in their development, the principal standards that currently exist, and the challenges that remain to be addressed before the great promise of EHRs can effectively be realized.

I Electronic Health Records – Promise and Problems

EHR Promises: In its simplest instantiation, an EHR can be little more than the electronic version of the medical chart that has traditionally hung at the end of a patient's bed, to be updated by nurse and physician in the course of a patient's hospital stay, and then filed away for possible future reference. If created within a proprietary software system, such an implementation can have significant benefits, including eliminating illegibility, decreasing storage costs, permitting access from multiple points within the same medical facility, and permitting immediate and accurate orders to be placed by a care giver for medications, radiological studies and lab tests, as well as the reporting back of the results of such tests. If the same patient returns for further treatment, the rich trove of data previously collected can be accessed with ease.

Today, there are many vendors of EHR software, as well as integrators happy to assemble and install complete systems of terminals, servers and software able to support an EHR system.[3] But such systems today most often operate largely or completely as isolated islands of data, unable to transmit complete patient records to remote physicians, other hospitals, emergency responders, payment providers, or others that do not share the same networked computer system. The result is that when another hospital, physician or payment provider needs access to a patient's medical data, the EHR that already exists must be called up and printed, and then faxed or mailed to the new location. The data contained in the hard copy must then be harvested by eye, and entered by hand into the computer system of the recipient.

The grand vision for EHRs is very different. In the immediate and near time frames, the ability of every caregiver, anywhere, to view the complete and up to date health information of a patient moving from diagnosis, through a hospital stay, to follow up care by primary and specialist physicians, should provide more beneficial treatment, by allowing the information and skills of all of those involved in the patients care to be most effectively and efficiently shared, while at the same time avoiding mistakes and duplicative tests.

[3] A list of commercial EHR software products, with price comparison, can be found at the Wikipedia entry for Electronic Patient Records. See, Comparison of EHR Software Solutions, Wikipedia, at http://en.wikipedia.org/wiki/Electronic_health_record#Comparison_of_EHR_software_solutions

In the long term, the capabilities of sophisticated EHR technology should allow every individual's medical history to accumulate throughout her life, permitting any authorized person to easily find the type of deep as well as up to date information to provide the best and most cost-effective health care possible. Today, such access is often limited, because patients frequently move both geographically as well as from payment plan to payment plan, and from provider network to provider network. As a result, baseline scans, historical lab test results, disproven diagnoses and much more of great value to effective patient care can be unavailable when and where needed, and difficult to efficiently consult when they are.

The value of nationally available EHRs would be particularly great in the emergency room, because urgent care givers would have immediate access to essential data regarding allergies to medications and underlying medical conditions, allowing more decisive, comprehensive and error free critical care. Moreover, epidemiological, clinical and other researchers could gain access to vast amounts of hitherto inaccessible data that could lead to new and better treatments, and as importantly, to discarding expensive, ineffective or dangerous ones as well.

Non-Standards-based problems: Lying between the recognition and the realization of this vision exists a host of challenges. While this article focuses on standards, it is worth noting in some detail the non-standards related issues at hand, as each demands an ameliorative strategy in order for EHRs to be successful.

Cost concerns: EHRs, by their nature, must be created on, and accessed from, computer systems. To the extent that in-place (legacy) systems must be upgraded or replaced before they can host EHR software, the costs can be great. Similarly, new systems require new training for those that must use them. If existing paper or electronic information is to be included, this data must be entered or converted as well. The combined costs of deployment and implementation costs can therefore be very great, although estimates vary widely, as pointed out by this knowledgeable commentator:

> The upfront capital costs of fully adopting interoperable EHR systems and health information exchanges have been estimated at $60 billion to $110 billion; some estimates are even higher, up to $200 billion. Annual operating costs add $20 billion to $35 billion. If capital investments are amortized over five years, incremental health IT spending would be approximately $35 billion to $65 billion per year, one to two times the current health IT spending levels.[4]

But the same studies project net savings of $50 to $100 billion per year as a result of the deployment of EHR technology – if all goes according to plan. Regardless of ultimate success, EHR implementation expenses must be incurred before anticipated cost cutting benefits can be achieved. If reimbursements from public funds are only partial or are slow in arriving, already hard-pressed hospital CFOs and private practice physicians will be placed under stress, limiting their appetite for taking action at all.

---

[4] Larsen, Ed, The Obama Healthcare Reform Plan, HIMSS Standards Insight Summary—December 2008, at http://www.himss.org/content/files/standardsinsight/summaries/2008-12.pdf

Caregiver resistance: EHRs will only be useful if data actually finds its way into them, and is entered accurately. Not all physicians and other caregivers will welcome a computer into the examining room, especially if they must turn away and face a terminal instead of the patient they are treating. Nor will they appreciate a further degradation of the quality of their professional lives through the requirement to fill out even more forms. The efficient and intuitive design of EHRs is therefore essential in order to ensure that they make a caregiver's life easier and more productive rather than the opposite.

Achieving success in design is more challenging than might be imagined. According to David J. Brailer, national coordinator for health information technology, as of 2005, up to 30% of EHR installations fail, and only 6% of hospitals nationally had installed systems capable of allowing doctors to input orders via computer. And in some cases, medical staff has rejected (sometimes with ample resulting publicity) EHR systems foist upon them by hospital management. Such experiences inevitably increase the reticence of hospitals and private practice physicians to invest scarce resources in adopting EHRs.[5]

Existing Legal requirements: A variety of state and federal laws already apply to the creation, maintenance and preservation of medical records in order to safeguard the privacy and security of patient health information. Converting from paper-based to computerized records will require attention to be paid once again to these requirements, raising renewed concerns over potential liability.

Privacy: While paper records must pass through multiple hands when they are exchanged and can be copied, they can be largely be maintained within controlled environments by staff that have been instructed on the requirements of applicable law, such as the Health Insurance Portability and Accountability Act of 1996 (HIPAA).[6] Once medical records become not only computerized, but also available online and rendered in a form intended to make them readable on any compliant system, privacy concerns become greatly elevated. The increasing number of well-publicized security breaches allowing criminal access to the personal financial data of millions of Americans maintained on supposedly secure systems has only increased the concern of advocates for consumer rights.

While the federal government committed itself (in 2004) to national deployment of EHRs, progress on guaranteeing the privacy and security of EHRs has until recently been incremental at best. In February of 2007, the Government Accountability Office released a report concluding that the administration, as summarized by the New York Times:

---

[5] Connolly, Ceci, Cedars-Sinai Doctors Cling to Pen and Paper, Washington Post, March 21, 2005; p. A01, at: http://www.washingtonpost.com/wp-dyn/articles/A52384-2005Mar20.html Perhaps the most often cited example failure in EHR design resulted in the abandonment by the Cedars-Sinai Medical Center in Los Angeles of its $34 million custom-designed EHR system after what has been described as a "full-blown staff rebellion." Problems cited included the length of time required for care givers to input data, the inflexibility of the system, and its annoying habit of popping up needless warnings and instructions. *Ibid.* On the plus side, these did not include Microsoft's "Mr. Clippy."

[6] The full text of HIPP can be found at: http://www.cms.hhs.gov/HIPAAGenInfo/Downloads/HIPAALaw.pdf

> …had a jumble of studies and vague policy statements but no overall strategy to ensure that privacy protections would be built into computer networks linking insurers, doctors, hospitals and other health care providers….the G.A.O. said the administration had taken only rudimentary steps to safeguard sensitive personal data that would be exchanged over the network….In written comments on the report, Jim Nicholson, the secretary of veterans affairs, who supervises one of the nation's largest health care systems, said, "I concur with the G.A.O. findings."

Most recently, Secretary of Health and Human Services (HHS) Mike Leavitt announced a set of "new principles" to protect the privacy of patient information, as well as tools to assist consumers in making informed decisions as among available electronic heath products and services. Those principles, a number of which must be technically enabled with standards, are as follows:

- ✓ **Individual Access:** Consumers should be provided with a simple and timely means to access and obtain their personal health information in a readable form and format.

- ✓ ***Correction:*** Consumers should be provided with a timely means to dispute the accuracy or integrity of their personal identifiable health information, and to have erroneous information corrected or to have a dispute documented if their requests are denied. Consumers also should be able to add to and amend personal health information in products controlled by them such as personal health records (PHRs).

- ✓ ***Openness and Transparency:*** Consumers should have information about the policies and practices related to the collection, use and disclosure of their personal information. This can be accomplished through an easy-to-read, standard notice about how their personal health information is protected. This notice should indicate with whom their information can or cannot be shared, under what conditions and how they can exercise choice over such collections, uses and disclosures. In addition, consumers should have reasonable opportunities to review who has accessed their personal identifiable health information and to whom it has been disclosed.

- ✓ ***Individual Choice:*** Consumers should be empowered to make decisions about with whom, when, and how their personal health information is shared (or not shared).

- ✓ ***Collection, Use, and Disclosure Limitation:*** It is important to limit the collection, use and disclosure of personal health information to the extent necessary to accomplish a specified purpose. The ability to collect and analyze health care data as part of a public good serves the American people and it should be encouraged. But every precaution must be taken to ensure that this personal health information is secured, identified when appropriate, limited in scope and protected wherever possible.

- ✓ ***Data Integrity:*** Those who hold records must take reasonable steps to ensure that information is accurate and up-to-date and has not been altered

or destroyed in an unauthorized manner. This principle is tightly linked to the correction principle. A process must exist in which, if consumers perceive a part of their record is inaccurate, they can notify their provider. Of course the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule provides consumers that right, but this principle should be applied even where the information is not covered by the Rule.

- ✓ ***Safeguards:*** Personal identifiable health information should be protected with reasonable administrative, technical, and physical safeguards to ensure its confidentiality, integrity, and availability and to prevent unauthorized or inappropriate access, use, or disclosure.

- ✓ ***Accountability:*** Compliance with these principles is strongly encouraged so that Americans can realize the benefit of electronic health information exchange. Those who break rules and put consumers' personal health information at risk must not be tolerated. Consumers need to be confident that violators will be held accountable.[7]

Despite such assurances, consumer advocates remain concerned today over whether privacy concerns have been, and fact are capable of being, adequately addressed. With the prospect of EHR adoption and implementation accelerating under the Obama administration, these concerns will need to be speedily and convincingly addressed.[8]

Multiplicity and diversity of stakeholders: EHRs are not of value to clinicians alone, nor is the implementation of EHRs of concern only to those that will interact with them directly. In fact, there are many classes of stakeholders, each of which will understandably expect to see its own needs accommodated, and its own stated requirements met. Compromises will inevitably need to be made on many design features, many of which will be important. The list of stakeholders includes the following:

- ✓ ***Health care providers:*** Doctors and nurses; public, private and community hospitals; test facilities and labs; public health agencies and others that will make hands-on use of the systems and EHRs.

- ✓ ***Researchers:*** Universities, laboratories, and pharmaceutical companies conducting clinical trials and other research that will wish to mine EHRs for useful data.

- ✓ ***Insurers:*** Health plan providers, insurance companies, self-insuring employers, and others that review and pay claims based upon the information submitted.

---

[7] Secretary Leavitt Announces New Principles, Tools to Protect Privacy, Encourage More Effective Use of Patient Information to Improve Care, Dept. of Health and Human Services News Release, December 15, 2008, at: http://www.hhs.gov/news/press/2008pres/12/20081215a.html

[8] Noyes, Andrew, Lobbying on health IT portion of stimulus is picking up, CongressDaily, reproduced at NextGov.com, at: http://www.nextgov.com/nextgov/ng_20090123_5018.php

- ✓ ***Government agencies:*** Veterans Administration (VA), HHS, Medicare, Medicaid, and State services administrators, and other public entities that may either have special requirements (e.g., the VA) or regulatory constraints.

- ✓ ***Vendors and service providers:*** Hardware and software vendors and system integrators that must absorb the costs of developing compliant products and systems before selling them, and which will be competitively impacted by the reach and scope of EHR standards.

- ✓ ***Intermediaries:*** Third party physician billing services that will need to process and deal with EHRs.

- ✓ ***Medications***: Pharmaceuticals and pharmacies that will need to interface with EHRs.

- ✓ ***Consumers:*** Patients and patients rights groups, that will have concerns over whether they can access their EHRs, whether the security of their EHRs will be maintained, and on the economic impact of EHRs.

One of the challenges will be to ensure that the final design and implementation of EHRs will be as responsive to those groups of stakeholders (e.g., consumers) that are likely to be less well organized, funded and represented as those (e.g., vendors) that are highly motivated and financially able to watch out for their own best interests.

Standards-related problems: While the goals of EHRs may be clear, the technical road to achieving them is less so, requiring many decisions, and as many concessions, along the way. Achieving consensus on the final design of EHRs is commensurately challenging. In order to appreciate the complexity of the task, it is first necessary to understand exactly what an EHR needs to achieve.

Adoption: While standards can enable interoperability, they can only achieve it for compliant systems. Unless and until EHR standards compliant systems become widely implemented, their benefits will only be realized within the single networks upon which they are deployed. In other words, early adopters will incur additional cost, but will garner little additional benefit over and above what users of existing proprietary EHR products do today.

Design decisions: The reason for the current degree of incompatibility between existing, proprietary EHR systems arises not only from the traditional desire of proprietary vendors to "own" their customers, due to the high data conversion cost necessitated by switching to a new system, but also from the inherent complexity of achieving interoperability between the products of multiple vendors. This complexity results in a number of complications, of which the following is only a sample:

- ✓ ***Viable alternatives:*** There are myriad decisions that can be made at any step along the way in the design of an EHR, from the fundamental architecture of the EHR itself to the type and expression of data to be entered in a single data field. Absent an agreement for all vendors to make

the same decisions (i.e., to comply with a given standard), these decisions will inevitably be made differently from vendor to vendor.

- ✓ ***Multiple use:*** Different specialists, lab personnel, researchers and insurers may traditionally use different qualitative ways of referring to the same information relating to an organ, test, disease condition, behavior or other data, depending upon what that information means to them. Unless a way is found to introduce flexibility into the uses of the EHR without destroying the interoperable exchange of the data in question, all of these different demands regarding the presentation of the same information must be resolved.

- ✓ ***Completeness versus usefulness:*** There may be a hundred individual items of data that could be identified and entered with respect to a single category of observation, but only a subset of that total might be of interest to a given practitioner, and that subset may only overlap slightly with the subset of that is of interest to another specialist. Moreover, depending on the complaint presented by the patient, some of the available data may be irrelevant. If all data that could be accommodated by the EHR must be acquired in every instance, then costs might (and caregiver resistance will certainly) increase rather than the opposite, and additional entry errors might result. Once again, restraint must be exercised in determining the number of data entry fields to be enabled, and some degree of flexibility provided for in the application of the EHR in practice.

- ✓ ***Non-medical characteristics:*** Because of legal constraints, EHRs must also be "legally aware," so that they may include the rules for their usage. For example, prior to a certain age of a child, medical and psychological EHR data may legally be made available to a parent, but not after that age. The rules applying to access may also be state mandated as well as federally imposed, requiring the EHR to be locationally aware in order to be legally aware. Ethical rules may also be applicable, depending upon the type of information or caregiver creating and maintaining the record.

- ✓ ***Enforcement:*** Once the rules of access are included, they must be enabled by legally and technically appropriate standards relating to authentication, such as those relating to digital signatures. Legal rules, or liability concerns, may also lead to standardized features enabling recording and auditing of access.

- ✓ ***Long term accessibility:*** Technology is notoriously evanescent. Operating systems come and go, computer languages go out of fashion, and document formats may be abandoned by their vendors, or the vendors themselves may fail. While paper records may remain readable indefinitely, if properly warehoused, the word processing programs that created them only a decade or two ago may now be difficult or impossible to acquire. As a result, if we are to convert nationally to EHRs, great attention will need to be paid to ensuring that the technology remains available to access these records indefinitely.

- ✓ ***Patient access:*** While a patient may have little need to plumb the complete depths of her EHR, she will have ongoing reasons, as well as legal rights, to obtain a subset of data usually referred to as a Patient Health Record (PHR). In order to ensure full and fair access to all citizens of their PHRs, the standards that display them must allow access on any operating system, using any software, of the citizen's choice, rather than the products of a single vendor. Similarly, the PHR must be accessible to someone with any disability for which there is an existing standards-based solution (e.g., a screen reader for the blind).

Process: A final consideration merits special attention: standards, like laws, are formed through a consensus process. But unlike laws, they are created primarily via the volunteer input and efforts of domain-specific professionals that have full-time jobs in those domains. Creating a single standard therefore typically takes from one to several years. Moreover, the creation of some standards, and of all standards frameworks, is dependent upon the prior existence of other standards, as building blocks. The result is that the process of standards development and approval is slow, and difficult to accelerate. Yet until the standards exist, they cannot be adopted.

Because it is expensive and difficult to switch to other standards after systems have already been deployed, there is therefore a tension between using standards already in existence and available for use, even if they are not ideal, rather than to take the additional time to develop more ideal standards. Where the useful life of the standard is short, the expedient approach makes the best sense. But where compliant systems will be in use for their appointed tasks for many years, investment in added development time will usually prove to be the better choice.

II Anatomy of an EHR

Content and meaning: Translating a medical chart into a computerized form that can be accessed nationally via any compliant computer system would be an ambitious goal. But the vision for EHRs is much more ambitious, and necessarily so if the massive investment that will be required to broadly implement them is to achieve its full promise. The broader range of responsibilities of an EHR is suggested by this typical EHR definition: "digitally stored health care information about an individual's lifetime with the purpose of supporting continuity of care, education and research, and enduring confidentiality at all times."[9]

While suggestive, such a definition is insufficient to establish the parameters of the task involved. The following set of requirements for an EHR architecture, from a clinical perspective, goes a step farther:

- ✓ capture faithfully the original meaning intended by the author of a record entry or set of entries;

[9] Iakovidis, I., Towards Personal Health Records: Current Situation, Obstacles and Trends in Implementation of Electronic Healthcare Records in Europe, International Journal of Medical Informatics (1998) 52(1), 105-115.

- ✓ provide a framework appropriate to the needs of professionals and enterprises to analyze and interpret EHRs on an individual or population basis;
- ✓ incorporate the necessary medico-legal constructs to support the safe and relevant communication of EHR entries between professionals working on different sites, whilst respecting the privacy wishes of individual patients.[10]

Translating these clinical goals into IT standards and ubiquitous public/private networks of actual computer systems sold by a multitude of vendors is a tall order, as suggested by the following assessment of the challenge presented by achieving comprehensiveness while avoiding chaos:

> One of the key premises of our national interoperability initiatives has been if we selected appropriate standards, our healthcare information systems could interoperate. We have learned another step is required: We must unambiguously constrain the selected standards so each is implemented in the "same" way. Thus in addition to the base standard, we need "standard constraints" defining the methods and content to be used in implementing a standard.
>
> But even more is required in order for two different IT systems—whether within the same or between different healthcare organizations—to interoperate. We must define a complete end-to-end information interchange that includes business rules and a sequence of transactions based on constrained base standards. We require a series of transactions that are functionally complementary and technically compatible, that establish secure communications between correctly identified and authorized parties, and that exchange only authorized and semantically understood health information with each other. No one standard even tries to address such end-to-end interoperability. Instead we have turned to implementation guides that aggregate business functions and constrain sets of base technical standards, such as Health Level Seven (HL7) and Systematized Nomenclature of Human and Veterinary Medicine (SNOMED), into transactions often in combination with other standard infrastructure functions, such as record location, directory lookup, security, transmission, networking and wire protocols. A modular package of functions can be mixed, matched and reused in different real system implementations. Implementation guides that bundle functions to meet business requirements are emerging as the most necessary interoperability standards.[11]

The following is a summary of the more significant attributes and capabilities that EHRs will be expected to support, as well as the constraints (besides taming

---

[10] Kalra, D., Electronic Health Record Standards, IMIA Yearbook of Medical Informatics 2006, p. 137, accessible at: http://eprints.ucl.ac.uk/2292/1/schattauer_30_2006_1_136.pdf

[11] Larsen, Ed, Why Interoperability Standards Aren't Enough, Standards Insight Summary – February 2007, Healthcare Information and Management Systems Society, p. 1, at: http://www.himss.org/content/files/standardsinsight/summaries/2007-02.pdf

complexity) that will apply to them. Selecting, assembling, and as necessary, developing gap filler standards to fully address each of these domains presents its own challenges of design, compromise, and consensus building:

- ✓ ***Medical content:*** Patient medical history, immunization history, allergies, test results in data generated by multiple types of data (e.g., from X-rays, CAT Scans, PET Scans, MRIs, ultrasound, and other media for recording observations, such as video and still photography). The richer and more easily searchable the set of such information becomes, and the broader the array of authorized health care providers able to access it, the better and more efficient care can be provided, with fewer mistakes, and less duplication of expensive tests.

- ✓ ***Legal and regulatory compliance:*** Once patient data is made available on a network it becomes more vulnerable, and needs to be protected accordingly. While existing laws already relate to patient privacy, access, record retention and other criteria, more federal and state legal requirements can be expected to be imposed in the future at both federal and state levels. These requirements must be recognized and enabled in the EHR itself to ensure security, limit access only to authorized persons, permit auditing to assure compliance, and more.

- ✓ ***Billing and reimbursement:*** A key goal of EHRs will be to lower processing and reimbursement costs. This requires codes and terminology and other attributes that are universally used and recognized on a national basis.

- ✓ ***Communication and synchronization:*** Any individual EHR will need to be able to be created, accessed and (if the user is authorized) updated on any compliant system by a wide range of potential users, including not only care givers, but also researchers, emergency responders, insurers, and others. As with any other IT record, compliance with a wide range of standards is necessary to enable such communication. Some of these standards will be unique to EHRs.

- ✓ ***Longevity:*** An EHR will need to be accessible not only for the life of the patient, but ideally beyond, as it will contain both useful research data, as well as data relevant to the health of the patient's descendants. The long-term archiving and access of electronic records of any sort represents an as-yet unresolved set of challenges that are only now being confronted, not only in medicine, but in government. Ethical and legal policies will need to be agreed upon first, and then technical standards will need to be developed – and then maintained indefinitely – to ensure the type of access that the policies require.

A complete EHR will thus incorporate hundreds, if not thousands, of standards, grouped into frameworks assembled to support particular tasks and uses.

More than a standard: As can be appreciated from the partial, but intimidating, list of challenges already discussed, it is far easier to create an EHR for a discrete purpose (e.g., cardiology or diabetes management) than to house the lifelong medical history of the complete patient. It is far easier as well for a single vendor

to unilaterally make all of the decisions itself than to reach industry consensus among multiple categories of stakeholders, not to mention competing vendors.

Of course, there have been standard setting organizations (SSOs) in existence for more than 100 years in which vendors and others have come together for the specific purpose of creating consensus-based standards. But these standards were initially intended to achieve discrete and simple purposes – to specify the spacing and depth of the threads on a screw, the wattage of a light bulb, or the thickness of a wire intended to bear a given amperage of current.

Today, standards have become much more complex, and enable sophisticated transactions such as interoperability among wireless advices, and describing complex formats for office suite software. But difficult as achieving consensus on such complex goals may be, it pales in comparison to achieving the reality of EHRs. In point of fact, an effective EHR cannot be described in a single standard.

Rather, the final EHR regime that will be deployed nationally will incorporate hundreds of existing and new standards. Some of these standards will have been created for other, or for generic, IT purposes. Others, such as medical nomenclatures, geographic codes, and weights and measure, will have been created for scientific, medical or other non-IT purposes. Most of the remainder will have already been created specifically for EHR (or precursor medical record) purposes, or will need to be created for this purpose.

These many standards will be assembled within carefully standardized frameworks that enable defined "use cases" to be addressed. These frameworks will, in turn, be supported by guidelines and reference documents intended to guide those responsible for creating and managing the use of EHRs.

The standards themselves will serve a broad array of purposes, and will include specifications and rules for most or all of the following:

Generic IT standards: These standards will generally come from prominent existing SSOs, such as the Internet Engineering Task Force (IETF), the Organization for the Advancement of Structured Information Systems (OASIS) and the World Wide Web Consortium (W3C). These standards will enable basic communication, archival and other functions with appropriate accuracy, security and privacy control as follows:

- ✓ ***User experience:*** These standards will ensure that patients can access their EHRs without having to buy proprietary products of single vendors, and also guarantee equal access to those with disabilities.
  Examples:
  - o Single sign-on and federated identity standards for patient convenience, still to be designated, but from SSOs such as the Liberty Alliance
  - o Open format and open source requirements to ensure independence from expensive proprietary operating systems and application software (see examples below under "Open Formats")

- Web browser application standards to ensure accessibility to those with physical disabilities, still to be designated, but presumably from the W3C

✓ ***Security and authentication:*** To ensure that patient data is securely maintained and accessed only by persons with established credentials. In some cases, inclusion of these standards will be necessary to ensure compliance with law.

Examples:

- European Telecommunication Standards Institute (ETSI) XML Advanced Electronic Signatures
- OASIS WS-Trust Version 1.3
- Audit Trail and Node Authentication (ATNA) Integration Profile

✓ ***XML-based markup languages:*** To allow data to be used more effectively in specific areas (e.g., security and billing applications; additional languages will be needed that are non-generic).

Examples:

- OASIS Security Assertion Markup Language (SAML)
- OASIS eXtensible Access Control Markup Language (XACML)
- OASIS Electronic Business Extensible Markup Language (ebXML), also available as ISO 15000

✓ ***Document formats:*** Document formats (often XML-based) allow multiple vendors to create software able to create documents that can be freely exchanged with users of other compliant software. Maintaining these standards in the long term ensures that new compliant products will be able to access records created many years before by earlier compliant products.

Examples:

- OASIS OpenDocument Format (ODF), also available as ISO/IEC 26300
- ECMA 376 OfficeOpenXML (OOXML), also available as ISO/IEC 26500
- ISO 32000 PDF Series

✓ ***Communication protocols:*** Protocols enable systems to establish communication with each other, and allow data to be transferred between compliant systems.

` Examples:

- Internet Engineering Task Force (IETF) HTTP
- IETF Network Time Protocol
- IETF Simple Network Time Protocol (SNTP)
- OASIS Simple Object Access Protocol (SOAP)

Business models: Technology continues to evolve rapidly, with new architectures and business models evolving on a constant basis. New, Internet-based business models will be useful in enabling a national health information network as well as making competition robust. Business models such as Web services, software as a service (SaaS) and cloud computing all rely on standards, some of which will need to be incorporated in to EHRs.

Examples:

- OASIS WS-Trust Version 1.3
- OASIS WS-Federation Web Services Federation Language

Repurposed scientific, medical, etc. standards: These standards have been created over many years by a variety of entities, from government agencies to SSOs.

- ✓ ***Medical Terminology:*** Clinical nomenclatures, observation identifiers, names and codes, taxonomies, and ontologies ensure consistency of data input, so that data can be reliably accessed for reference by care providers, and accurately compared in clinical and epidemiological studies.
  Examples:
  - o NLM Unified Medical Language System
  - o International Classification of Disease Codes

- ✓ ***Other terminology, measures, etc.:*** These standards are of a generic nature. Using them both avoids "reinventing the wheel," as well as follows international standards best practices of referencing and incorporating existing standards that are already in use.
  Examples:
  - o Unified Code for Weights and Measures
  - o Federal Information Processing Standards (FIPS) Codes for the Identification of the States, etc.

- ✓ ***Existing medical record and payment standards:*** The provision of health-related services, communications between care givers, insurance providers, laboratories, pharmaceutical companies and intermediaries has already spawned a multi-billion dollar market for IT products and services, many of which can (and have) been incorporated into EHRs.
  Examples:
  - o American Society for Testing and Materials (ASTM) Standard Guide for Electronic Authentication of Health Care Information
  - o National Library of Medicine (NLM) Unified Medical Language System (UMLS) RxNorm
  - o National Uniform Billing Committee (NUBC) standards
  - o ISO Health Informatics standards

Already developed EHR Standards: The work of developing EHRs has been in process for many years already. These standards, as well as the SSOs that have developed them, are discussed in detail Part IV of this article. These include both individual "gap filler" standards as well as complex frameworks, guidelines, reference materials, and other tools.

The architectural solution: A survey of the approaches taken by the various designers of EHRs to date is well beyond the scope of this article, but suffice it to say that careful forethought in the architectural approach adopted in the design of an EHR is instrumental to its success in the trenches. This challenge has been succinctly described by one commentator as follows:

> The challenge for EHR interoperability is therefore to devise a generalised approach to representing every conceivable kind of health record data structure *in a consistent way*. This needs to cater for records arising from any profession, speciality or service, whilst

> recognizing that the clinical data sets, value sets, templates etc. required by different health care domains will be diverse, complex and will change frequently as clinical practice and medical knowledge advance.[12]

One method of achieving universal consistency while accommodating the needs of specialties is the "Dual Model Approach." In this design methodology, the health record components, and the legal, ethical and geographical requirements and identifiers that can safely be described in a global fashion are segregated into the "reference model" as stable, generic building blocks. Clinical domain data is then accommodated in "archetypes" that can constrain data appropriately to give needed meaning in the context of that domain. This allows templates to be created within the parameters of the archetype without loss of interoperability between compliant systems.

III Investment in EHRs to Date

Individual health care facilities and healthcare networks alike have made substantial investments in EHR and precursor systems, as have national governments. The experiences of these early adopters are of course instructive, and should be carefully reviewed by the Obama administration and Congress as they finalize, and then implement, legislation.

An in depth survey is of existing efforts is also beyond the scope of this article, but the following examples demonstrate the range of results that can be found in the marketplace to date:

Public sector experiences: As is the case with another IT standards-dependent goal of the Obama administration (open government), a number of countries and regions abroad are well ahead of the United States in the design, public commitment, funding and implementation of EHR systems, although not all such efforts have been productive to date.

Abroad: Efforts in support of developing EHRs is longstanding in Europe. In 1988, the EU established the ***Advanced Informatics in Medicine (AIM)*** initiative in order to incentivize, unify and facilitate regional collaboration in this area and to accelerate progress towards the effective integration of health information systems. This initiative resulted in significant investments being made, totaling 265 million ECU in approximately 141 projects between 1988 and 1998, focusing in areas such as research and development leading to electronic health care record architecture, clinical terminology, and clinical care protocols.

One of the resulting projects was eponymously named ***The Good European Health Record (GEHR)***, and pursued the goal of producing its namesake (it operated from 1992- 1994). A successor to that effort, the ***Synapse Project***, was formed to address legacy systems issues. And a lineal descendant of the Synapse

[12] Kalka (2006), p. 138.

Project is the currently active openEHR Foundation, which is described in greater detail in Part IV of this article, below.[13]

In the United Kingdom, the National Health Service has been involved in a protracted effort to include the data of 50 million citizens in a new ***NHS Care Records Service*** to be implemented nationally at a total projected cost of 13.7 billion pounds. However, the plan has been plagued by patient privacy concerns (and occasional actual data incidents, including the much publicized theft of a laptop holding the EHRs of 5,000 patients) as well as implementation difficulties. Originally targeted for launch in 2010, the program is currently slated to be taken live in 2014-2015, assuming that the current financial crisis does not further upset the already delayed plan.[14]

While actual nationwide implementations remain rare, the EU continues to support the development of EHRs through several European SSOs Other nations, such as Australia, have also made substantial investments in EHR planning.

In the United States: Progress abroad in planning for and implementing EHRs has occurred primarily in countries with national health insurance and a more centralized health provider infrastructure. For the same reasons, the most ambitious public sector implementation of EHRs in the United States has been limited to the Veterans Administration, which serves the largest and most distributed patient pool through government owned medical facilities. The VA has invested significant funds and energy in designing and implementing an EHR system, called the Veterans Health Information Systems and Technology Architecture (VistA). Introduced more than a decade ago, the system incorporates an earlier system called the Decentralized Hospital Computer Program (DHCP), which was implemented in individual VHA facilities in the 1980s.

VistA is an integrated system that has been deployed throughout the entire network of Veterans Health Administration (VHA) healthcare facilities. Users interact through a graphical user interface called the Computerized Patient Record System (CPRS). As reported by the VA at its on line Information Resource Center:

> Each VistA application generates at least one data file. Within these files are the clinical, administrative, and computer infrastructure-related data that support day-to-day operations and contain patients' medical and healthcare utilization histories, including data on demographics, episodes of care, medicines, practitioner information, diagnoses, procedures, etc. All patients treated at VA Medical Centers are included in the files, which are updated continuously at the point of care or as part of administrative processes. Data are entered into VistA by way of manual entry, bar codes, and automated instrumentation. Some data are derived from

[13] Ingram, David, The Origins of the openEHR, openEHR Foundation Website, October 2002, at http://www.openehr.org/about/origins.html

[14] Health Service computer scheme faces further delays, Reuters, January 27, 2009 at: http://uk.reuters.com/article/topNews/idUKTRE50Q1M420090127

> central financial, personnel and operational systems and distributed to local facilities' VistA files.[15]

Other VHA IT services are able to utilize the data for purposes such as decision support and pharmacy benefits management. Despite the sophistication of the VistA system, it falls short of the fully integrated EHR system contemplated by the Obama administration's plans.

Private sector experiences: Implementation of EHR systems of varying degrees of comprehensiveness can be found throughout the private sector in the United States. As earlier noted, the vendors supplying such systems are numerous, resulting in systems that cannot be seamlessly interlinked or centrally accessed without the adoption of a common EHR infrastructure. Not surprisingly, these expensive and sophisticated EHR systems are more likely to be implemented in large hospitals rather than in private physician practices groups, and in large practice groups rather than small ones.

As of 2008, use of EHRs was growing significantly. As reported in the preliminary findings of a 2008 survey of 2,000 office-based physicians providing direct patient care in all 50 states:

> 38.4% of the physicians reported using full or partial EMR systems, not including billing records, in their office-based practices. About 20.4% reported using a system described as minimally functional and including the following features: orders for prescriptions, orders for tests, viewing laboratory or imaging results, and clinical notes. Comparable figures for the 2006 NAMCS, the latest available for the full survey, were 29.2% and 12.4%, respectively.

Of those responding, 17% reported use of a "basic system" (defined as supporting patient demographics, problem lists, clinical notes, orders for prescription, and viewing laboratory and imaging results), while only 4% had access to a "fully functional" EHR systems (ones which additionally support medical history and follow-up, orders for tests, prescription orders sent electronically, warnings of drug interactions or contraindications, out-of-range test levels, and reminders for guideline-based interventions).[16]

Current status: After many years of global SSO activity, and (since 2004), significant government funding support by the HHS, the promise of a nationally implemented, compliant EHR network is nearer, but still elusive. To assess progress toward President Bush's goal of attaining national implementation of EHRs by 2014, the Office of the Office of the National Coordinator of Health Information Technology (ONC) (an agency created within HSS by Executive Order of President Bush) requested the Institute of Medicine (Board on Health Care Services) and the

---

[15] Veterans Health Information Systems and Technology Architecture (VistA) – Description, United States Dept. of Veterans Affairs, at http://www.virec.research.va.gov/DataSourcesName/VISTA/VISTA.htm

[16] Hsiao CJ, Burt CW, Rechtsteiner E, Hing E, Woodwell DA, Sisk JE. Preliminary estimates of electronic medical records use by office-based physicians: United States, 2008. Health E-Stat. National Center for Health Statistics. 2008. Available from: http://www.cdc.gov/nchs/products/pubs/pubd/hestats/hestats.htm

National Research Council (Computer Science and Telecommunications Board) to undertake a fast-track review of the standards activities of the ONC.

In response, the Institute of Medicine has formed the Committee on the Review of the Adoption and Implementation of Health IT Standards with "the narrow task of determining whether the Office of the National Coordinator for Health Information Technology is effectively advancing the national Health IT agenda." The Committee held meetings on September 16 – 18, 2007, at which the testimony was not always encouraging. Sam Karp, Vice President of Programs, California Healthcare Foundation testified as follows:

> Our experience with the current national data standards effort is that it is too slow, too cumbersome, too political and too heavily influenced by large IT vendors and other large institutions….In the three years ONC has had the responsibility to "foster the availability and use of health IT standards nationally," not a single data element has been exchanged in real world health care systems using standards this process has either developed or deployed….The current approach to standards development is too complex and too general to effectively support widespread implementation….The current top-down approach, specifying politically desirable use cases, rather than an approach that identifies and attempts to address market need, seems to us to be misguided. We do not believe that, in the long run, standards will enjoy widespread adoption if they do not address the current business needs of those organizations that are asked to implement them. In the absence of widespread adoption, no interoperability standard can achieve its fundamental purpose…[17]

IV EHR Development Organizations and Their Standards

While the computerization of healthcare has been in process for decades, IT spending by hospitals is significantly lower than is typical for other large and sophisticated enterprises, perhaps because of the reticence of the large number of independent (and traditionally technology averse) health professionals that would be required to use EHRs.

Nonetheless, the development of the individual standards and more ambitious standard sets needed to enable fully featured EHRs has been under development for some time. These standards have been developed by a variety of traditional, accredited standards development organizations (SDOs) as well as by representatives of the hundreds of modern standard setting consortia that have been launched in the IT sector over the past 25 years. Some of these organizations have been created specifically for that task, while in other cases EHR-oriented working groups have been set up within SSOs with broader missions. As noted

[17] Karp, Sam, Review of the Adoption and Implementation of Health IT Standards by the Office of the National Coordinator for Health Information Technology, September 17, 2007, at http://www.iom.edu/Object.File/Master/46/380/Day%202%20-%20Karp%20handout.pdf

above, the remainder of the standards needed to enable an effective EHR are more generic, and can be borrowed from unrelated SSOs.

Because creating an effective EHR requires assembling a hierarchy of standards, a number of independent SSOs and ambitious technical committees within existing SSOs have been formed for the purpose of creating frameworks, guidelines and reference documents to address this complex task. The most important of these organizations are described below, listed in descending order of comprehensiveness of their EHR work products.

Core EHR SSOs: The following initiatives are committed to working towards the enablement of complete EHRs

1. Health Information Technology Standards Panel (HITSP): HITSP is the newest of the organizations listed in this section, and was formed as a public-private partnership formed to support the government's EHR initiative. It operates under the auspices of the ONC, but is administered by the American National Standards Institute (ANSI), in cooperation with strategic partners HIMSS, Booz Allen Hamilton, and Advanced Technology Institute. HITSP brings together consumers, healthcare providers, vendors, government agency representatives and SSO personnel to:

- ✓ Serve and establish a cooperative partnership between the public and private sectors to achieve a widely accepted and useful set of standards that will enable and support widespread interoperability among healthcare software applications in a Nationwide Health Information Network for the United States.

- ✓ Harmonize relevant standards in the healthcare industry to enable and advance interoperability of healthcare applications, and the interchange of healthcare data, to assure accurate use, access, privacy and security, both for supporting the delivery of care and public health.

HITSP creates standards to serve "use cases" defined by the American Health Information Community (AHIC), a comprehensive stakeholder counsel also created under the auspices of the HHS in support of the same goals. Currently, HITSP has 13 Domain Technical Committees addressing a diverse range of use cases, including Laboratory Test Reporting, Biosurveillance, Consumer Empowerment, Medication Management, Personalized Healthcare, Public Health Case Reporting, Patient – Provider Secure Messaging and Remote Monitoring, and more.[18]

2. Health Level 7 (HL7): Health Level Seven is an ANSI-accredited SDO that produces standards in the domain of clinical and administrative data. It is one of the oldest organizations formed to create standards for EHRs, and was formed in 1987, initially to address the need for messaging standards to serve health insurance processing needs. Its mission today is to provide interoperability standards that improve care delivery, optimize workflow, reduce ambiguity and enhance knowledge transfer among healthcare providers, government agencies, the

[18] The complete list of Domain Technical Committees, their work in progress, and their completed standards can be accessed at the home page of HITSP, at: http://hitsp.org/

vendor community, other SDOs and patients. HL7's activities, in addition to standards development, include support of requirements under HIPAA, promotion of its standards, and collaborating with other SSOs to achieve joint goals.

HL7's architecture is based upon a Dual Method approach. At the heart of HL7 standards work is the ***Reference Information Model (RIM)***, which plays the role of the generic standards element. As described by HL7:

> [T]he RIM is a large pictorial representation of the clinical data (domains) and identifies the life cycle of events that a message or groups of related messages will carry. It is a shared model between all the domains and as such is the model from which all domains create their messages. [The RIM] [e]xplicitly represent[s] the connections that exist between the information carried in the fields of HL7 messages.[19]

HL7 templates address the needs of particular clinical and administrative contexts that can be simple (e.g., a blood pressure reading) or complex, incorporating hundreds of pieces of associated information. Related work is carried out by committees such as the Vocabulary Technical Committee, which seeks to standardize vocabularies for use not only by HL7 compliant systems, but between such systems and other EHR regimes.

HL7's current ***Version 3*** standards work takes a different approach from its successful and widely implemented Version 2 standards series. While Version 2 provided great flexibility, it made reliable conformance testing difficult and required more implementation effort when customizing interfaces. The new version seeks to address these limitations.

HL7 also maintains the ***Clinical Document Architecture (CDA),*** now in Version 1.3, and formerly referred to as the Patient Record Architecture (PRA). The CDA provides an XML-based exchange model for clinical documents, such as discharge summaries and progress notes, and results in documents that are machine-readable as well as human-readable.

3. CEN/EHRCom: The European Union has invested substantial energy and resources over the past two decades in evolving the standards and architectures needed to support an EU-wide implementation of EHRs. Much of the standardization work has been accomplished through the European Committee for Standardization (CEN, from the French Comité Européen de Normalisation), acting through EHRCom, a Task Force formed in 2001 by the CEN Health Informatics Technical Committee. EHRCom is building upon work already performed within CEN to develop ***EHR Communications Standard EN 13606 (EN 13606)***, a five-part standard that is also being built using the Dual Model approach. The five parts describe a ***Reference Model, Archetypes***, ***Archetype Interchange Specification***, ***Reference Archetypes and Term Lists***, ***Security***, and ***Exchange Models***.[20] EU-based EHR efforts are supported by the ***European Institute for***

[19] The Reference Implementation Model (RIM), Health Level 7 Website, at http://www.hl7.org/

[20] There are a variety of additional EU-based organizations and initiatives that directly or indirectly support EHR efforts. Examples include IHE in Europe and the European Health Telematics Association,

Health Records (EuroREC), which serves as the authorized European body for the support of EHR certification development, testing and assessment.

4. Integrating Healthcare Enterprise (IHE): IHE is a more specialized, but still ambitious undertaking. It was formed in 1997 by radiologists and information technology experts to create use cases, identify standards and develop guidelines that can be used to create interoperable products. Through local organizations, such as IHE in Europe, it facilitates regional deployment of interoperable products. Work proceeds on a project by project basis, depending on member-identified needs. Unlike the more holistic Dual Model approach followed by HL7 and ERHcom, IHI interoperability goals are achieved through compliance with ***IHE Integration Profiles***, each of which is based upon a clinical information need or workflow scenario. Each profile describes which established standards can be used, and how, to achieve the desired result. Profiles can also be used in procurement orders to establish requirements.

IHE also develops ***IHE Integration Statements,*** which can be used by vendors to self-certify compliance with IHE Integration Profiles, and ***IHE Technical Frameworks***, which relate to Integrated Profiles and associated systems and transactions. IHE is supported by the Healthcare Information and Management Systems Society (HIMSS), the Radiological Society of North America (RSNA), and the American College of Cardiology (ACC). The Eye Care domain is sponsored by the American Academy of Ophthalmology.

"Middleware" SSOs: The following SSOs are examples of organizations that address discrete subsets of the EHR goal, but more than single, stand-alone standards.

1. openEHR Foundation: The openEHR Foundation was formed in 2000 by Ocean Informatics and University College of London, and is distinguished by its focus on creating and sharing EHRs using open source software through the efforts of consumers and clinicians, as compared to vendors. Its mission is also broader, encompassing communications technology (CT) integrated with IT to achieve desired results in the areas of medical research, healthcare and related areas. The openEHR approach contemplates a knowledge-oriented, semantically enabled computing framework based on ontologies and terminology that can economically support the construction of maintainable and adaptable EHRs. Specifically, the initiative develops specifications, open source software and tools to be used in developing and maintaining systems that demonstrate these capabilities, as well as archetypes and formal interfaces to terminology.

Current deliverables of openEHR Foundation include ***ISO 18308 - "Requirements for an Electronic Health Record Reference Architecture***," ***Template Models***, ***Virtual EHR (vEHR) and EHR Service Interfaces***, and ***Template and Schema for the ASTM Continuity of Care Record (CCR) and HL7 CCD***.[21]

2. Digital Imaging and Communications in Medicine (DICOM): DICOM is a standard that permits the interoperable handling, storing, printing, and

[21] OpeEHR Foundation Specifications, Clinical Models, and Standards can be accessed at the Foundations Web site, at: http://www.openehr.org/home.html

transmitting of medical imaging information, combining a file format definition with a network communications protocol. Development of the standard (now in version 3) began in the 1980s, and is the product of the DICOM Standards Committee, a collaboration between the American College of Radiology (ACR) and National Electrical Manufacturers Association (NEMA), which holds the copyright to the DICOM standard. The standard is implemented in scanners, servers, workstations, printers, and network hardware from multiple manufacturers, which can be integrated to create picture archiving and communication systems (PACS).[22]

3. Clinical Data Interchange Standards Consortium (CDISC): CDISC has a research, as compared to a patient care, focus, and supports the acquisition, exchange, submission and archiving of clinical research data and metadata. CDISC standards are incorporated into the work of other SSOs, such as HL7, with which it has a close working relationship. Currently available CDISC standards address study data tabulation, exchange of non-clinical data, operational data, laboratory data, and case report data tabulation.[23]

"Component" EHR SSOs: These organizations provide examples of the many standards organizations that create generic standards that have uses independent of EHRs, but which are essential elements of EHR frameworks and framework components:

1. Logical Observation Identifiers Names and Codes (LOINC®): LOINC universal codes and names are employed to identify laboratory and other clinical observations, and are used to facilitate the exchange and aggregation of clinical results for outcomes management, clinical care, and research. The names and codes, supporting documentation, and the related RELMA mapping program are maintained by the Regenstrief Institute.[24]

2. International Health Terminology Standards Development Organization (IHTSDO): This organization maintains and promotes the usage of the ***Systematized Nomenclature of Medicine - Clinical Terms (SNOMED CT)*** multilingual health information exchange standard. The machine readable terminology included in the SNOMED CT standard embraces most areas of clinical information, including diseases, findings, procedures, microorganisms, and pharmaceuticals, enabling the reliable, consistent and accurate indexing, storage, retrieval and aggregation of clinical data, regardless of medical specialty or location of data. The standard was created in 2002 by combining, restructuring, and over time, expanding the SNOMED RT (Reference Terminology) and the UK National Health Service (NHS) Clinical Terms. Since 2007, it has been maintained by IHTSDO.[25]

EHR frameworks: As earlier noted, because EHRs must be deployed on highly distributed and complex IT systems, a variety of standards that are non-medically specific are also needed to complete a workable EHR, with the result that even a

---

[22] The DICOM standard and relating information can be found at the DICOM Standards Committee Web site, at http://medical.nema.org/

[23] The CDISC Web site can be found at http://www.cdisc.org/

[24] The Loinc Web site can be found at http://loinc.org/

[25] The IHTSDO Web site can be found at: http://www.ihtsdo.org/

component framework of standards intended to perform a single function of a complete EHR will be likely to include dozens of standards (some of which are frameworks themselves), including EHR specific, medically generic, and general IT standards.

The table below illustrates this point by listing the standards and frameworks included in three EHR standards frameworks (some with subparts) just adopted by the United States HHS, as announced on January 21, 2009 in the Federal Register. The sampling also demonstrates the diversity and breadth of goals that an EHR must address: those listed below involve laboratory results reporting, Biosurveillance, "consumer empowerment" and access, and emergency response. Separate columns indicate the SSOs producing standards that are most useful for inclusion in EHRs, including two dedicated EHR SSOs (HL7 and IHE), two generic IT SSOs (OASIS and IETF), and one generic SDO that addresses hundreds of domain areas, only one of which is electronic health standards (ASTM). The final standards column lists a total of 199 other standards developed by both medically specific, IT generic, and general scientific and technical sources.

Standard	***HL7***	***IHE***	***OASIS***	***IETF***	***ASTM***	***Laws, Regs.***	***Other[26]***	***Total***
Electronic Health Records Laboratory Results Reporting V3	7	14	4	3	0	1	0	29
Biosurveillance V3	7	17	5	2	1	1	1 (ETSI)	34
Consumer Empowerment and Access to Clinical Information via Networks V3	6	12	4	2	1	0	3 (ETSI,IHTSDO ,CAQH)	28
Emergency Responder Health Record V1	6	13	4	2	0	0	7 (FIPS,ICD-10-PCS,ICD-9-CM, LOINC,NUBC, UCUM)	32
Consumer Empowerment and Access to Clinical Information via Media V1	10	14	4	0	0	0	4 (DICOM, IHTSDO, ISO, LOINC, UCUM, USB Implementers Forum)	32

[26] The full names of the organizations and standards listed are as follows:
CAQH - Council for Affordable Quality Healthcare
IHTSDO - International Health Terminology Standards Development Organisation
FIPS - Federal Information Processing Standards
ICD-10-PCS - International Classification of Diseases, 10th Revision, Procedure Coding System
NUBC - National Uniform Billing Committee
UCUM - Unified Code for Units of Measure
DICOM - Digital Imaging and Communications in Medicine
LOINC - Logical Observation Identifiers Names and Codes
CMS - Centers for Medicare and Medicaid Services
UMLS - Unified Medical Language System

Quality V1	5	17	5	2	1	0	14 (AMA, CMS, DICOM, ETSI, FIPS, ICD-10-PCS, ICD-9-CM, IHITSDO, ISO (2), LOINC, UMLS, NUBC, UCUM)	44
TOTAL	**41**	**87**	**26**	**11**	**3**	**2**	**29**	**199**

V United States Government Actions and Resources

While the EU has been involved in supporting the development of EHR standards for many years, the U.S. government has become heavily engaged in their support and promotion only since 2003. Historically, however, the level of engagement of the government in standards development matters has been light, and its actions in support of standard setting modest. The result is that while Congress is being thrust into sudden action, it has little institutional knowledge or staff experience to rely upon in addressing either standards development generically, or EHR standards in particular.[27]

The U.S. road to EHRs: Some of the more important milestones in the nation's recent path towards universal EHR deployment are as follows:

- ✓ ***December 8, 2003:*** As part of the ***Medicare Modernization Act***, the creation of a strategic plan for the nation's health IT infrastructure is mandated.

- ✓ ***March 21, 2003:*** HHS announces adoption across federal government of first set of EHR related standards.

- ✓ ***January 20, 2004:*** In his ***State of the Union Address***, President George H.W. Bush states, "by computerizing health records, we can avoid dangerous medical mistakes, reduce costs, and improve care." He also calls for the computerization of the nation's medical health records.

- ✓ ***April 27, 2004:*** President Bush issues an ***Executive Order on Health IT*** intended to improve the quality, increase the efficiency, and make the provision of healthcare more consumer centric, including by ensuring that clinicians will have access to a patient's complete medical history, computerized ordering systems, and electronic reminders. Under the order, HHS is ordered to help achieve the goal of providing most Americans with access to secure electronic health records by 2014. The order also establishes an ***Office of the National Coordinator (ONC)***, and the position of the ***National Coordinator for Health Information Technology*** within

[27] For a review of the consequences of the United States' "bottom up" process of standards development, see Updegrove, Andrew, Behind the Curve: Addressing the Policy Dependencies of a "Bottom Up" Standards Infrastructure, ConsortiumInfo.org, Standards Today, Vol. VII, No. 4, at http://www.consortiuminfo.org/bulletins/#feature

the Office of the Secretary of HHS for the purpose of supporting HHS in achieving that goal.[28]

- ✓ ***May 6, 2004:*** HHS announces second set of EHR-related standards across the federal government.

- ✓ ***August 22, 2004:*** President Bush signs an ***Executive Order on Health IT, Quality and Transparency*** directing HHS, the Departments of Defense and Veterans Affairs and the Office of Personnel Management to adopt interoperable health information-technology standards and quality-improvement measures. Each agency must begin to implement its program by January 1, 2007.

- ✓ ***January 10, 2005:*** ONC Coordinator Dr. David Brailer states, "Those who adopt electronic health records now do so at a disadvantage. It's unclear whether (early adopters) are financing everyone else, or whether it's better to wait….You could spend time and money and end up with nothing….What we have now is a deadlock."[29]

- ✓ ***June 6, 2005:*** Health and Human Services Secretary Leavitt announces formation of the ***American Health Information Community (AHIC)*** as "the cornerstone" of the President's EHR effort. The private-public collaboration is intended to enable the "nationwide transition to electronic health records -- including common standards and interoperability -- in a smooth, market-led way."[30]

- ✓ ***October 8, 2005:*** HHS awards contract to the Certification Commission for Healthcare Information Technology to support EHR initiative by develop a certification program for compliant EHRs, a program intended to become self-sustaining through certification revenues.

- ✓ ***October 10, 2005:*** Health Information Standards Technology Panel (HITSP) founded.

- ✓ ***November 10, 2005:*** The ONC concludes that the lack of interoperability standards represents a serious impediment to establishing the President's goals, and issues contracts totaling $18.6 million to develop a prototype ***National Health Information Network (NHIN)***.[31] The NHIN is charged with:

    - o Developing capabilities for standards-based, secure data exchange nationwide

---

[28] Link unavailable; all Bush administration Executive Order links are temporarily broken due to the recent cutover of the new Obama WhiteHouse.gov Web site.

[29] Gross, Grant, Lack of standards hinders electronic health records, ITWorld, January 10, 2006, at http://www.itworld.com/050110healthstandards

[30] Secretary Leavitt Takes New Steps to Advance Health IT, Dept. of Health and Human Services News Release, June 6, 2005, available at: http://www.hhs.gov/news/press/2005pres/20050606.html

[31] HHS Awards Contracts to Develop Nationwide Health Information Network, HHS News Release, at http://www.hhs.gov/news/press/2005pres/20051110.html

- Improving the coordination of care information among hospitals, laboratories, physicians offices, pharmacies, and other providers
- Ensuring appropriate information is available at the time and place of care
- Ensuring that consumers' health information is secure and confidential
- Giving consumers new capabilities for managing and controlling their personal health records as well as providing access to their health information from EHRs and other sources
- Reducing risks from medical errors and supporting the delivery of appropriate, evidence-based medical care
- Lowering healthcare costs resulting from inefficiencies, medical errors, and incomplete patient information[32]

✓ ***May 17, 2006:*** AHIC provides first formal input, making 28 recommendations "on how to make health records digital and interoperable while protecting patient privacy and the security of those records."[33]

✓ ***February 10, 2007:*** Candidate Barack Obama releases a technology agenda that calls for spending $10 billion a year for five years, "to move the U.S. health care system to broad adoption of standards-based electronic health information systems, including electronic health records."[34]

✓ ***September 16 – 18, 2007:*** Committee formed at request of the ONC to determine "whether the Office of the National Coordinator for Health Information Technology is effectively advancing the national Health IT agenda" meets.

✓ ***October 5, 2007:*** Contracts awarded for first trial NHIN implementations.[35]

✓ ***June 25, 2008:*** U.S. consumer groups, insurers, privacy advocates, and vendors (e.g. Google Inc. and Microsoft Corp.) announce agreement on standards intended to speed adoption of personal electronic health records.[36]

✓ ***January 20, 2009:*** President Barack Obama takes office.

VI Conclusions and Recommendations

The promises of EHRs are great, and their eventual deployment is doubtless a practical necessity if healthcare costs are to be contained, medical errors are to be

---

[32] Nationwide Health Information Network (NHIN): Background, HHS Web site, at http://www.hhs.gov/healthit/healthnetwork/background/

[33] American Health Information Community Approves First Set of Recommendations, HHS News Release at http://www.hhs.gov/news/press/2006pres/20060517a.html,

[34] Barack Obama on Innovation and Technology, November 14, 2007, at http://www.barackobama.com/pdf/issues/technology/Fact_Sheet_Innovation_and_Technology.pdf.

[35] HHS Awards Contracts for Trial Implementations of the Nationwide Health Information Network, HHS News Release, at http://www.hhs.gov/news/press/2007pres/10/pr20071005a.html

[36] U.S. electronic health record standards agreed, Reuters, June 25, 2008, at http://www.businessinsurance.com/cgi-bin/news.pl?newsId=13298

reduced, and proper medical care to be given. But there are risks associated with pursuing the implementation of EHRs blindly. The process of developing standards that are not only technically able to achieve desired goals but also likely to be broadly implemented and used is a delicate one based upon consensus, and must be sensitive to the needs of all of those whose collaboration in implementation is necessary. To that extent, the development of EHRs is like pushing a string: it is difficult to impossible to accelerate beyond a certain, limited point.

While it is true that this conundrum of implementation could be addressed simply through regulations that would give caregivers, insurers and other stakeholders no choice but to adopt and use whatever framework of EHRs might be assembled without further delay, utilizing this approach to force feed the marketplace with an inefficient, inexact EHR system would incur great costs without achieving all of the benefits that the entire process was intended to enable. The real challenge, then, is ensuring that we get the standards *right* as well adopted.

As with any other project of similar ambition and scale, whether it be creating a national highway system or reaching the moon, compromises – and indeed many compromises – are required, where there are so many variables, so many constituencies, and so many dependencies. In each of these endeavors, it was necessary to enlist the support of all those whose contributions were required in order to achieve the goal, by providing opportunities for input, participation, and ultimately financial incentives to get on the bus.

So it will be in the case of nationally implementing EHRs in the United States. The reality is that much work has already been done, and careful and sometimes difficult decisions will need to be made regarding what can be used that has already been created, and what must be retooled, or even discarded and replaced. These decisions may be the most crucial of all, because a nationally deployed system of EHRs will cost as much as two hundred of billion dollars. Once implemented, it would take many billions more to change.

The lesson, then, is clear. If Congress grants the Obama administration $5 billion to accelerate the implementation of EHRs, the first dollars spent should be used to ensure that the architecture and components currently on the roadmap are the right ones, and to determine whether the prototype systems already funded and deployed meet real-world usability, as well as technical, tests before they are mandated for national adoption.

The next dollars should be dedicated to facilitating the standards development process to the limited extent that this string can be effectively pushed: by underwriting meeting expenses, facilitating collaboration between the many SSOs involved in the development of components and frameworks, and by funding rapid gap filling where necessary and productive.

Tellingly, it is a different step that has received the most attention in the current debate in Congress: designing and funding the incentives for EHR adoption. This is a necessary aspect of planning, because while the per-physician estimates of enabling EHRs in individual and group medical practices are great, the IT staffing resources of such practices are typically not. Just as hundreds of millions of dollars in government support was needed to pay for the stringing of hundreds of the

thousands of miles of power lines that extended the blessings of electric power to millions of rural Americans in the last century, underwriting the upgrading of millions of distributed, privately-owned computer systems will be needed in our era before the benefits of EHRs can reach the patients served by the physician-owners of those systems.

But in order for these necessary and very expensive incentives to bear fruit, the upgrades they pay for must be easy to use – so that they will be used – and carefully designed so that they will deliver.

That goal is within sight, and the tools are almost ready. It only remains to take the next steps carefully and skillfully so that our reach for a national network of EHRs does not exceed the grasp of the systems that taxpayer dollars pay for and deploy.

Sign up for a free subscription to ***Standards Today*** at

http://www.consortiuminfo.org/subscribe/2.php?addentry=1

Appendix: An EHR Glossary

- ***Archetype:*** A term used to describe a re-usable, formal model of a domain concept in an openEHR framework, e.g., weight measurement, blood pressure, prescription, or diagnosis.

- ***Clinical Decision Support Systems (CDSS):*** Software that provides situation specific best practices guidance and/or recommendations, based upon information pertaining to the individual patient. It may be a stand-alone product, or a module within an EHR, CPOE or similar product.

- ***Computerized Physician Order Entry (CPOE):*** A networked capability allowing a physician or other caregiver to enter orders (e.g., for medication or tests) that are communicated to those responsible for carrying them out; one of the first electronic health record-related capabilities to be implemented in patient care.

- ***Continuity of Care Record:*** A computerized record of a patient's health care, complying with the standard developed by ASTM.

- ***Electronic Health Record (EHR):*** An interoperable computerized record of a patient's lifetime health and healthcare, including not only medical information, such as medical history, prescriptions, allergies, immunization, laboratory tests, radiology images, and billing records, but also location based legal information and other data supporting the patient's healthcare and enabling data collection for research.

- ***Electronic Medical Record (EMR):*** A near synonym for EHR. An EMR should enable computerized orders for prescriptions, computerized orders for tests, reporting of test results, and physician notes.

- ***Electronic Prescribing (eRx):*** A tool of varying degrees of sophistication that allows the placement of prescription orders by physicians, and may also provide treatment advice and other services. It can be a standalone product, or be a module within an EHR system or other product.

- ***Electronic Records Management (ERM):*** The practice of effectively and responsibly specifying and preserving EHRs. ERM best practices cover topics such as proper specification of file formats and digital media, file naming, electronic records management strategies, establishment and maintenance of storage facilities and procedures, e-mail and web content management, and electronic and digital signatures.

- *Health informatics (also medical informatics):* The resources, devices, and methods required to properly and effectively acquire, store, retrieve and use health and biomedical information.

- ***Health Information Technology:*** Broadly speaking, information technology that supports healthcare delivery.

- ***Health Information Exchange (HIE):*** The provision of digitized healthcare information between organizations within a region or community.

- ***Health Insurance Portability and Accountability Act (HIPAA):*** The principle legislation in the United States protecting the security and privacy of patient data. Enacted in 1996. HIPAA also protects workers and their families when they change or lose their jobs, and mandates national standards for electronic health care transactions and national identifiers for providers, health insurance plans, and employers.

- *The Integrated Care EHR (ICEHR):* A repository of digitized health information able to be stored and transmitted securely, and accessible by multiple authorized users.

- ***National Health Information Network (NHIN):*** The secure, nationwide, interoperable health information infrastructure mandated by an Executive Order signed by President George W. Bush, intended to connect providers, consumers, and others involved in supporting health and healthcare.

- ***Office of the National Coordinator for Health Information Technology (ONC):*** An office within the U.S. HHS mandated by an Executive Order signed by President George W. Bush. The ONC is charged with facilitating the design and deployment of the NHIN and the national usage of EHRs.

- ***Practice Management Software (PMS):*** Computer system software intended to support aspects of medical practice, such as billing, office administration, scheduling and workflow management.

- ***Regional Health Information Organizations (RHIOs):*** A group of health care providers (e.g., hospitals, clinics, pharmacies, and laboratories), frequently in the same geographical area, that (a) share a network allowing them to exchange multiple types of healthcare data, and using standardized information formats and transmission conventions, and (b) follow common rules relating to aspects of their operations, such as billing.

- ***Personal Health Record (PHR):*** A record of all aspects of a patient's health and healthcare treatment, compiled and maintained by the patient.

- ***Veterans Health Information Systems and Technology Architecture (VistA):*** The EHR system developed for, and deployed by, the Veterans Services Administration throughout its facilities nationally.

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

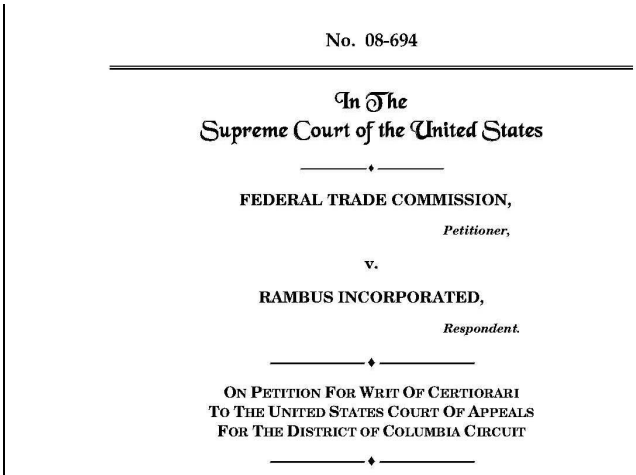
membership fees to dictate the limits of the reach. Lastly, we must rededicate ourselves to responding to the needs of the government agencies that rely so much on the productivity of our organization, whether or not these requirements are consistently and clearly articulated.

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.

19 Standards Organizations Support Rambus Brief

Andrew Updegrove

Date: December 24, 2008
Views: 2,506



No. 08-694

In The
Supreme Court of the United States

FEDERAL TRADE COMMISSION,
Petitioner,
v.
RAMBUS INCORPORATED,
Respondent.

ON PETITION FOR WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

Yesterday I filed a pro bono amicus curiae ("friend of the court") brief with the United States Supreme Court in support of the Federal Trade Commission's petition for writ of certiorari in its suit against Rambus Technologies. I'm pleased to report that 19 standard setting organizations (SSOs), representing *over 13,300 members*, joined as amici curiae supporting this brief; the list of participants appears later in this blog entry. As noted in the brief itself, these SSOs:

> *...represent a broad range of SSOs that participate in the standard setting process, and each is greatly concerned by the adverse effects that it anticipates will result from the [lower court reversal of the FTC's sanctions of Rambus]. Those effects will reach virtually all aspects of modern society, commerce, education and government, because all of these interests rely heavily upon the efficient development and broad adoption of standards by the private sector.*
>
> *The pervasiveness of standards, and of the potential reach of the decision on petition, is indicated by the range of focus of the amici curiae that have joined in this brief. They include SSOs that develop standards or support standards development in sectors as diverse as defense, consumer electronics, photography, on-line learning, geospatial information, credit "smart" cards and a broad array of computer system products and services.*

In agreeing to be parties to the brief, these organizations demonstrated their concern over maintaining the integrity of the standards development process, as well as their belief that SSOs, their members, and non-members alike must be able to rely upon the support of the courts when they believe that SSO intellectual property rights (IPR) policies have been violated. (I outlined the facts and disputes underlying the Rambus case in this blog entry ten days ago.)

The final list of amici is as follows:

ADVANCED MEDIA WORKFLOW ASSOCIATION (AMWA)
CONSUMER ELECTRONICS ASSOCIATION (CEA),
GLOBALPLATFORM INC.
IMS GLOBAL LEARNING CONSORTIUM, INC. (IMS)
INTERNATIONAL IMAGING INDUSTRY ASSOCIATION, INC. (I3A)
IPC, ASSOCIATION CONNECTING ELECTRONICS INDUSTRIES
LINUX FOUNDATION
MIDI MANUFACTURERS ASSOCIATION
MOBILE PRINTING AND IMAGING CONSORTIUM, INC.
OPEN GEOSPATIAL CONSORTIUM, INC. (OGC)
OPENSAF FOUNDATION
ORGANIZATION FOR THE ADVANCEMENT OF STRUCTURED INFORMATION STANDARDS (OASIS)
PICMG-PCI INDUSTRIAL COMPUTER MANUFACTURERS GROUP, INC. (PICMG)
SOCIETY OF MOTION PICTURE AND TELEVISION ENGINEERS (SMPTE)
THE SOFTWARE DEFINED RADIO FORUM, INC. (SDR FORUM)
THE OPEN GROUP (TOG)
VIDEO ELECTRONICS STANDARDS ASSOCIATION (VESA)
VMEBUS INTERNATIONAL TRADE ASSOCIATION (VITA)
XBRL INTERNATIONAL, INC.

The brief itself can be viewed on line here, and the Summary of Argument is as follows:

> *The purpose of this amicus brief is not to make legal arguments, but to acquaint the Court with information supporting a decision by the Court to allocate its limited time to consideration of the legal questions at issue. In brief, amici curiae wish the Court to understand the increasing dependency of all aspects of society, commerce and government on standards, and the fragility of the process by which such standards are developed. Amici curiae believe that the type of conduct that the FTC found Rambus Incorporated (Rambus) to have engaged in, if allowed to go unredressed, would severely undermine and jeopardize the continued existence of that fragile process.*
>
> *Standards are vital to government procurement, national competitiveness, and the efficiency and safety of society. Standards are created by voluntary, self-governing organizations that have no effective enforcement power to police the conduct of their members. In the information and communications (ICT) sector, the implementation of standards often results in the infringement of the patents of members and/or non-members. If the owners of these patent claims are only willing to license their claims selectively, or on unreasonable or discriminatory terms, then severe consequences will follow, including unreasonable costs to end-users, unfair discrimination against individual industry participants, and often the complete failure of the standard in question. While such a result*

cannot easily be avoided in the case of a patent claim owned by a non-participant in the standard setting process, it would be highly inequitable for a patent owner to deceptively exploit its participation in an SSO to ensure such a result for its own benefit.

The value and importance of standards in the modern world is profound. As an example, the Department of Commerce concluded in 2004 that standards affect an estimated 80 percent of world commodity trade. U.S. Department of Commerce, Standards and Competitiveness – Coordinating for Results 1 (May 2004). In the ICT sector, the role of standards is particularly crucial, as vital infrastructural elements such as telecommunications, the Internet and the Web literally cannot exist without common agreement on, and universal implementation of, enabling protocols and other standards.

Moreover, private sector standards are often incorporated by reference into laws. But unlike public laws and regulations, standards are developed within a process that is not only self-regulating, but also largely unsupervised, except by those that directly participate. As a result, the success or failure of private sector standards development is highly dependent upon trust. If those that participate conclude that abusing the system is too easy to accomplish, and that such abuse is too lightly punished if discovered, then the entire system can find itself in danger of collapse, because the risks of participation and adoption of standards become greater than the benefits to be gained. Were such a collapse to occur, virtually no aspect of society would be immune from the consequences.

More specifically, amici curiae wish to acquaint the Court with the following facts, as developed in greater detail in the arguments that follow:

1. Interoperability standards and other technical specifications play a vital and essential role in all aspects of modern society, commerce, government, and indeed, virtually every other aspect of our modern, networked world. With the increasing utilization of the Internet to support and enable finance, emergency response, homeland security, defense, healthcare, government services, education, communications, entertainment and much more, the efficient development and ongoing maintenance of hundreds of new ICT standards each year is becoming especially critical.

2. In enacting the National Technology Transfer and Advancement Act of 1995 (NTTAA), Pub. L. No. 104-113, 110 Stat. 775 (1996), Congress instructed each Federal agency to utilize standards created by SSOs in preference to "government unique" standards to the extent "practicable." In so doing, Congress deferred to the private sector to supply the tens of thousands of standards upon which the operations of government, and the

implementation of its policies, must rely. In contrast to the government-supported process that is followed in many other nations, the United States depends upon representatives of industry, academia, consumers and government to participate, at their own cost, in hundreds of non-profit SSOs to develop standards for the good of all.

3. Since the enactment of the NTTAA, government has become far more dependent upon standards to achieve its goals. Examples of current top-level policy areas that will be heavily dependent upon the rapid development of essential ICT and other standards include homeland security, electronic records for healthcare, E-Government and global warming.

4. SSOs adopt IPR policies that are intended to identify patent claims that would be "necessarily infringed" by an implementation of a standard under development, and to ensure that such "necessary claims" will be made available to all would-be implementers under at least RAND terms. Absent such knowledge and commitments, a patent owner may gain a degree of monopoly power over the implementation of a standard that can be greatly abused, to the detriment of consumers.

5. The standards development process relies heavily on a presumption of trust, and specifically on the assumption that members will honor their obligations under IPR policies. If that trust can be violated with impunity, then there is more for participants to lose than to gain by participating, and the very existence of the standards development infrastructure can become in danger of collapse.

6. Due to budget constraints and other concerns, SSOs are not capable of enforcing their rules in court. Because of the great cost of patent infringement litigation, it is extremely expensive for SSO members, and others that adopt standards, to defend themselves when IPR policy rules are violated.

7. SSOs, their members, those that adopt standards, and those that rely upon the standards they produce, therefore need to be able to rely on the courts to defend, regulators to robustly enforce, their interests when standards development participants betray their duties of trust and violate IPR policy rules.

8. If the decision of the Circuit Court stands, then the integrity and viability of the standards development process will be endangered, at great cost to society, to the national interest, and to those that have made the substantial investment in time and money, and undertaken the business risk, to participate in good faith in the development of standards.

> *The antitrust laws are particularly important to preserving the integrity of the standards development process. Unlike contract and fraud remedies available under state laws, the antitrust laws are national in scope, and therefore provide greater predictability of result. They also permit both public (via the regulators) and private (by aggrieved parties) action, and are specifically constructed to protect competition. If the courts decline to enforce the integrity of standard setting when such laws are violated, then the option of "gaming" the system will become more attractive to SSO members. As a result, additional litigation will reach federal and civil courts, discouraging companies from adopting the standards in question, and over-burdening those courts.*
>
> *Given the rapid pace of innovation in standards-dependent areas such as the technology and telecommunications sectors and the increasing dependence of the world on the products of such innovation, amici curiae strongly support granting certiorari in this case.*

There are several other amicus briefs being filed, one by JEDEC, the SSO that hosted the process underlying the dispute itself. Another has been filed on behalf of four high tech companies that rely heavily on standards (HP, Cisco, Sun and Oracle), another by CCIA, a trade association that focuses on policy issues, and still another is expected to be filed by two law professors. Each of these will argue the points of law that they hope the Court would consider. My partner, Lee Gesmer, is collecting all of the amicus briefs as they are filed, as well as those of the parties themselves, at this ScribD page. But first, the Court has to agree to take the case, and that's where the SSO amicus brief comes in.

Whether the Supreme Court chooses to take the case is, of course, always a long shot. Lee points out in his own blog entry (which provides a good overview of the legal significance of the Rambus case), that:

> Persuading the Supreme Court to review a case is harder than getting into Harvard. In its most recent term the Court decided about 70 cases, out of over 7,000 appealed.

Hopefully, the arguments made in the SSO brief, and the impressive list of organizations on the cover, will incrementally raise those odds. I appreciate their support, and their willingness to associate their names with this brief.

Bookmark the Standards Blog at http://www.consortiuminfo.org/newsblog/ or set up an RSS feed at: http://www.consortiuminfo.org/rss/

No. 08-694

In The Supreme Court of the United States

FEDERAL TRADE COMMISSION,

Petitioner,

v.

RAMBUS INCORPORATED,

Respondent.

ON PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

BRIEF OF *AMICI CURIAE* IN SUPPORT OF PETITION FOR WRIT OF CERTIORARI OF ADVANCED MEDIA WORKFLOW ASSOCIATION (AMWA); CONSUMER ELECTRONICS ASSOCIATION (CEA); GLOBALPLATFORM INC.; IMS GLOBAL LEARNING CONSORTIUM, INC. (IMS); INTERNATIONAL IMAGING INDUSTRY ASSOCIATION, INC. (I3A); IPC, ASSOCIATION CONNECTING ELECTRONICS INDUSTRIES; LINUX FOUNDATION; MIDI MANUFACTURES ASSOCIATION; MOBILE PRINTING AND IMAGING CONSORTIUM, INC.; OPEN GEOSPATIAL CONSORTIUM, INC. (OGC); OPENSAF FOUNDATION; ORGANIZATION FOR THE ADVANCEMENT OF STRUCTURED INFORMATION STANDARDS (OASIS); PICMG-PCI INDUSTRIAL COMPUTER MANUFACTURERS GROUP, INC. (PICMG); SOCIETY OF MOTION PICTURE AND TELEVISION ENGINEERS (SMPTE); THE OPEN GROUP (TOG); THE SOFTWARE DEFINED RADIO FORUM, INC.; VIDEO ELECTRONICS STANDARDS ASSOCIATION (VESA); VMEBUS INTERNATIONAL TRADE ASSOCIATION (VITA); XBRL INTERNATIONAL, INC.

Andrew Updegrove
Counsel of Record
GESMER UPDEGROVE LLP
40 Broad Street
Boston, Massachusetts 02109
(617) 350-6800

Counsel for Amici Curiae

***December 23,* 2008**

THE LEX GROUP^{DC} ♦ 1750 K Street N.W. ♦ Suite 475 ♦ Washington, DC 20006
(202) 955-0001 ♦ (800) 815-3791 ♦ Fax: (202) 955-0022 ♦www.thelexgroupdc.com

CONSIDER THIS:

#56 Standards of Patient Care

Andrew Updegrove

There are not a few commentators that would tell us that the latter half of the 20th century will best be remembered as the Computer Age, a time when advances in information technology truly transformed the way we live our lives. If medical science continues to advance at current rates, I believe that the first half of this century will as likely be recalled as the Age of Life Science – the time when our lives were transformed at the metabolic level. Indeed, on every front, whether it be genomics or oncology, neurology or stem cell research, reports of dramatic discoveries arrive almost daily, many suggesting the promise of cures that only a short time ago would have seemed little short of miraculous.

With these advances has come a mighty proliferation of medical specialties, technology and tools. The hospital of today veritably swarms with health care providers, and hitherto unitary disciplines continue to speciate with an energy that would astound Charles Darwin.

There is art as well as science to healing. And so it is that there are, human standards for health care that cannot be quantified, and should not be forgotten.

At their beck and call are a host of room-sized diagnostic tools developed by their engineering peers, and no modern hospital can now compete for business unless it is chockablock full of CAT Scan, MRI, PET Scan and other wildly expensive machinery that peers into the body to extract information hitherto unavailable, often illuminated by exotic dyes and radioactive imaging agents.

Happy the modern citizen must be, then, to live in this age of science and specialists; how fortunate to be at the center of so much science, technology and expert attention.

Happy and fortunate indeed. That is, unless that citizen actually has to be in a hospital, beset upon by those swarms of specialists, and constantly wheeled through forbidding corridors to the nether regions of the facility to be splayed under, inserted inside, or (worse yet, as I am informed by patients of the feminine persuasion) have sensitive parts of her body mashed between the frigid plates of an infernal medical device delivering images that too often hold prospect of only worse to come.

But at least with so much exquisitely trained attention, the quality of the care must be of the highest, and unfortunate outcomes lower than ever before. Right? *Right?*

Well. (How to say delicately?) Ah yes – here we are.

Let us consider this:

Back in the Dark Ages of Medicine (i.e., just before that Computer Age we were discussing a little while ago), only about a dozen medicines – most of ancient, herbalist origin – were of known efficacy in the ages-old battle against disease. Aspirin to treat fever, inflammation and pain (Native Americans chewed willow bark to extract the same active agent); quinine to suppress malarial attacks (the Quechua Indians of Peru used cinchona bark to quell fevers and tame chills – and invented tonic water in the process); opium from poppies to alleviate physical pain (some employed the substance to address other types of pain); digitalis from foxglove for heart arrhythmia; mercury in its elemental form as a brutal treatment for syphilis ("spend a night with Venus, and a lifetime with Mercury"). A handful of other medicines completed the pharmacopoeia of efficacious remedies throughout most of our national existence, from Colonial time until World War II. Those compounds, and a few early vaccines – most notably for hydrophobia (rabies) and smallpox.

Eventually, and thank heaven, the blessings of ether were discovered for surgery. No longer, at last, was the measure of a surgeon's skills his ability (there were no "hers" in the surgical theatres of the time) to cut a patient for the stone in less than seven minutes. Around the same time, the importance of antiseptic care was appreciated, and patients at last became more likely to survive a hospital stay than not.

But while anatomy and principles of public health became better understood, the causality of non-infectious diseases like cancer and the nature of debilitating heredity diseases remained locked in black boxes of mystery, until Watson and Crick cracked the lid. Worse, a host of implacable maladies now virtually unknown to modern society harvested their victims year by year: scarlet fever, diphtheria, pertussis (whooping cough), measles, mumps, tetanus, rheumatic fever, the dreaded summer visit of the polio virus, and more. Together, these grim and common diseases culled the children of families everywhere. Indeed, any American above the age of 80 who came from a large family would as likely as not be able to tell you of the loss of one or more or siblings to these scourges.

In these still-recent days before the advent of penicillin and sulfa drugs, decoded DNA and modern cytology, there was only so much that a doctor (like my grandfather) could do. Indeed, the principle role that a physician could play in the case of infectious or hereditary disease was to visit the sick at their homes, try to make them comfortable, and predict for their families with some degree of accuracy what would happen next. Almost as the shaman of primitive societies was brought by the family to mediate between the real and the spirit world on behalf of the afflicted, doctors before the age of modern medicine too often could only share what they knew from observation, and like their patients, patiently wait.

The result was a special bond between patient, family and physician – with the patient and doctor at the center, both engaged in a conjoint, often powerless struggle with forces largely beyond their control. A good doctor was therefore humble, knowing the limits of his ability to influence the outcome. With so little to

offer by way of efficacious care, the ability to give comfort and courage was as important as the limited ability to take curative action. And with so few investigative tools available – all of which could be carried in the legendary doctor's black bag (my father still had one for house calls when I was young) - the physician's powers of visual and tactile observation in days gone by were acute; much more so than those of today's lab-dependent doctors. As Lewis Thomas reminisced in his wonderful book, The Youngest Science: Notes of a Medicine-Watcher, a physical exam performed by a skilled physician could be a beautiful, as well as an informative, thing to behold.

Today, almost all of that world is gone from the modern American medical scene. Instead of the single physician visiting the patient at home, or visiting the hospitalized patient twice a day, there is now a post-operative care team that commonly includes the surgeon, anesthesiologist, pain-control physician, plastic surgeon, oncologist, medical attending physician, multiple interns, and more. Each treats a piece of the patient for a few minutes out of the day, and each may contribute to the chart. Mistakes – thousands of them every year and many of them fatal – are made.

Somehow, we have become possessors of (or perhaps possessed by) a vastly expensive and too-often fallible medico/pharma/insurer/industrial complex.

Almost as regrettably, from the standpoint of effective treatment, none of the attending physicians really "knows" the complete patient, because each is a specialist, and so much has been delegated to so many other professionals to whose professional judgment each must, to some degree, defer. Such a system could conceivably work if the entire school of physicians swam together through the hospital on twice-daily rounds, but of course they do not. Instead, each must follow the breadcrumbs of the others via common review of the paper and/or electronic medical record of the patient, supplemented by occasional one-on-one consultations.

And, perhaps, a few words with the patient. But the number of doctors that sit on the end of the bed, or put a reassuring hand on the shoulder, is fewer year by year. With the proliferation of specialties, it is easy for a medical student to find one where patient skills might seem to no longer matter so much (but of course they always do, to the patient). As one physician recently said to me, "There are only two types of oncologists: saints and jerks."

The patient, it seems, is no longer truly at the center of the health care concept. Instead, it seems that role has been taken by the reimbursable "disease condition" around which vital signs, laboratory tests, scans and specialists orbit.

Somehow, we have become possessors of (or perhaps possessed by) a vastly expensive and too-often fallible medico/pharma/insurer/industrial complex. When in its custody, the patient (no matter how sick) is awakened every four hours, night and day, to have vital signs taken, and at least once a day (usually at 5:00 AM), to be pointed at and discussed upon by a resident with multiple interns in tow as part of the hospital's medical training program. When the appointed hour finally comes,

the patient is delivered (by wheelchair) back to the street, often too soon for ideal care and comfort, due to the outrageous costs of so much Balkanized attention.

How did we arrive at such a pass, where the humanity and well being of the patient has receded so far beyond the horizon, to be replaced by some cold and clinical abstraction of the word "care?" And what of the future, when the doctor need not even visit the hospital room to review a chart? In the imminent future of electronic health records, will the patient find herself speaking not to a doctor at her bedside, but to an image on the television hanging high on the wall, as each specialist makes his "rounds" via video link as expeditiously as possible, sitting at his remote computer terminal, patient records displayed on a second screen?

A ridiculous suggestion? Perhaps. But things tend to happen once they can – and especially so when they become more cost-effective than the ways of the past.

If we are to pull back in time from such an Orwellian future of patient "care," we need to remember that there is still an art as well as a science to healing. The time is now, if indeed it is not already too late, to recognize that there are human standards for health care that cannot be quantified, and should not be forgotten.

Read more ***Consider This...*** entries at: http://www.consortiuminfo.org/blog/

Sign up for a free subscription to ***Standards Today*** at

http://www.consortiuminfo.org/subscribe/2.php?addentry=1

MONDAY WITNESS:

Inauguration Day – January 20, 2009

Andrew Updegrove

I ask you to share with me today the majesty of this moment. In the orderly transfer of power, we celebrate the unity that keeps us free. Each moment in history is a fleeting time, precious and unique. But some stand out as moments of beginning, in which courses are set that shape decades or centuries. This can be such a moment.

When I was much younger, still in school, I was fortunate enough to receive a ticket to a Presidential inauguration. It was a good ticket, allowing me to stand not a hundred yards from the podium where the new president would stand as first he was sworn in, and then as he delivered his inaugural address.

Then, as now, it was a time of uncertainty, with wars both cold and hot raising tensions internationally and inflaming passions at home. The campaign just ended had been divisive, as had the primaries preceding it. There was much to weigh down the shoulders of a new president as he waited to take his oath of office, and many reasons to doubt his ability to deliver on the vision for the future that he would share.

The address that I heard that day was eloquent and high-minded. In it the new President asked:

> *What kind of nation we will be, what kind of world we will live in, whether we shape the future in the image of our hopes, is ours to determine by our actions and our choices....If we succeed, generations to come will say of us now living that we mastered our moment, that we helped make the world safe for mankind. This is our summons to greatness. I believe the American people are ready to answer this call.*

As I recall it, the day was gray, with lowering clouds and a threat of rain, matching the national mood that it would be the new President's task to lift. Underscoring the uncertainties of the day, platoons of armed National Guards stood at parade rest every fifty yards along the iron fence that surrounded us, as we faced the East Portico of the Capitol, where inaugurations were then held. At the same interval atop every building with a sight line of the podium stood a sharpshooter, scanning the crowd. Above, helicopters criss-crossed the sky.

It was, after all, a time not only a time of war abroad, but of unrest and assassinations at home. The President who spoke that day had promised to "bring us together," and the need to achieve that goal was great, both politically as well as socially. His predecessor had left office with abysmal approval ratings, dragged down by a war that had overshadowed all of the great hopes he had nurtured, and his successes as well. A substantial percentage of the electorate could not wait to witness his departure.

The electorate was, in a word, exhausted, and the need to restore unity great. Addressing this somber truth, this is what he said:

> *The simple things are the ones most needed today if we are to surmount what divides us, and cement what unites us. To lower our voices would be a simple thing. In these difficult years, America has suffered from a fever of words; from inflated rhetoric that promises more than it can deliver; from angry rhetoric that fans discontents into hatreds; from bombastic rhetoric that postures instead of persuading. We cannot learn from one another until we stop shouting at one another—until we speak quietly enough so that our words can be heard as well as our voices.*

Then, as now, the contrasts that day were stark - between the opportunity for the new President to achieve grand results, and the certainty that, almost immediately, events and forces as yet unknown would inevitably work to thwart him. Would he be able to rise to the challenge? Would he have within him the force of character, the reserves of strength and dispassionate judgment to hold true to his purpose, and deliver upon the hopes of those that had elected him? Would he even remember those promises, and remain true to those hopes? Or would he allow himself to be distracted and seduced by the trappings of power? This is what he said:

> *For its part, government will listen. We will strive to listen in new ways—to the voices of quiet anguish, the voices that speak without words, the voices of the heart—to the injured voices, the anxious voices, the voices that have despaired of being heard. Those who have been left out, we will try to bring in. Those left behind, we will help to catch up. For all of our people, we will set as our goal the decent order that makes progress possible and our lives secure.*

There was, of course, no way to tell that day whether these promises would be kept. Only the slow, day by day unwinding of a new administration would reveal whether this leader would rise to the challenge, and not succumb to the centripetal forces of politics that would constantly stand in the way of achieving these high ideal. Of course, he promised that he would stand fast:

> *As we reach toward our hopes, our task is to build on what has gone before—not turning away from the old, but turning toward the new. In this past third of a century, government has passed more laws, spent more money, initiated more programs, than in all our previous history. In pursuing our goals of full employment, better housing, excellence in education; in rebuilding our cities and*

> *improving our rural areas; in protecting our environment and enhancing the quality of life—in all these and more, we will and must press urgently forward.*

As importantly, I wondered, would he be able to inspire the nation, to gather not only the political support of the electorate but also to recruit its active assistance in doing what needed to be done? Too many Americans had become jaded or cynical, too demoralized to even make their voices heard. To them, he said:

> *Our greatest need now is to reach beyond government, and to enlist the legions of the concerned and the committed. What has to be done, has to be done by government and people together or it will not be done at all. The lesson of past agony is that without the people we can do nothing; with the people we can do everything.*

Of course, in those days, issues of domestic racial and social injustice were even more urgent. Most of the post World War II laws enacted and social programs deployed to address those concerns had either just been created or lay still in the future. The urgency to move forward in these areas was felt palpably by millions of Americans on a daily basis. Of this crisis, he said:

> *This means black and white together, as one nation, not two. The laws have caught up with our conscience. What remains is to give life to what is in the law: to ensure at last that as all are born equal in dignity before God, all are born equal in dignity before man.*

Internationally, it was the age of the "Ugly American." In many quarters, the United States was regarded as arrogant and indifferent, too often concerned only with its own well being and self-interest. In the eyes of many in the first world and third world alike, we were insensitive to the cultures and callous to the concerns of others, unable to recognize or appreciate the realities of those different from ourselves. And locked in the embrace of an enduring Cold War, we viewed every nation not as a potential ally, but as yet another battleground upon which a proxy war for hearts and minds must be won in a global war of ideologies. That day, the new President pledged himself to bring change. He said:

> *As we learn to go forward together at home, let us also seek to go forward together with all mankind. Let us take as our goal: where peace is unknown, make it welcome; where peace is fragile, make it strong; where peace is temporary, make it permanent. After a period of confrontation, we are entering an era of negotiation. Let all nations know that during this administration our lines of communication will be open. We seek an open world—open to ideas, open to the exchange of goods and people—a world in which no people, great or small, will live in angry isolation. We cannot expect to make everyone our friend, but we can try to make no one our enemy....*

All of these concerns, and more, were in the air that inauguration day of so long ago. And all of the hopes of those both present and at home, both in this country and of many abroad, were, for that moment and on that day, invested in the man

that stood at the podium, hand on bible, assuming the awesome duties of the U.S. presidency. He closed his inaugural address with these words:

> *We have endured a long night of the American spirit. But as our eyes catch the dimness of the first rays of dawn, let us not curse the remaining dark. Let us gather the light. Our destiny offers, not the cup of despair, but the chalice of opportunity. So let us seize it, not in fear, but in gladness—and, "riders on the earth together," let us go forward, firm in our faith, steadfast in our purpose, cautious of the dangers; but sustained by our confidence in the will of God and the promise of man.*

To me, the inspiring words quoted above sound as if they could have been spoken by Barack Obama. I expect - and indeed hope - that what we hear today will be much the same. Sadly, though, the day that I attended the inauguration was January 20, 1969, exactly 40 years ago today. And the man that gave the speech was Richard M. Nixon, about to begin his first term in the White House.

On that gray and threatening day lay the prospect of both endless promise and depths of danger too awful to contemplate. Had Nixon been true to the vision he shared that day, had he been able to find within himself the strength of character and the clear and selfless vision that the tasks at hand demanded, all could have been so very different.

Like all Americans, as well as many people around the world, I will be listening to the inaugural speech of Barack Obama today with the greatest of anticipation and hope. Four decades ago, everyone hoped that Richard Nixon would succeed, but few that had followed his career were inspired to believe that day that he would succeed.

As then, our times today are dark, and the way ahead is unclear. But unlike those dark days of the 1960s, this is a time of true celebration and genuine inspiration. Not because the times are less troubling, but because the President elect is less troubled. Unlike the paranoid and conflicted Nixon, Barack Obama seems at ease with himself, and projects an ability to selflessly lead. Never before in my lifetime has there been such a wave of hope converging upon a single leader, nor such a confluence of goodwill from all sides.

When the crowds disperse from the Capitol today, the hopes and dreams of millions will be left on the slender shoulders of this largely untested President. He will carry those burdens every day of his presidency, and their weight will be great.

Whether Barack Obama will be able to maintain the clarity of vision and calmness of spirit that elevated him above the other candidates remains to be seen. Many of his most talented predecessors have allowed themselves to be dragged down by events, enmired in crises, or embroiled in scandals. The odds against his success will be great as well.

But there is much about the man that promises well. During the difficult days that are sure to lie ahead, perhaps it will help Mr. Obama if he reads his own inaugural

address from time to time. There he may find what it takes to keep his compass true, and his convictions strong.

Like so many others, my hopes and dreams and prayers for his success - and ours - will be with him.

You can read the full text, and hear Nixon deliver his first inaugural address here. A video of Obama's inaugural speech can be viewed and heard here.

Read more ***Monday Witness*** entries at:

http://www.consortiuminfo.org/standardsblog/index.php?topic=3584

Sign up for a free subscription to ***Standards Today*** at

http://www.consortiuminfo.org/subscribe/2.php?addentry=1