A Guide to Electronic Health Record Standards and the Challenges Ahead

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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

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[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.

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 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.

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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.
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> 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]

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[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

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.

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.

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[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

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.

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]

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[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

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.

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.

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[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

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:

> …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.

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[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

✓ **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.

✓ **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]

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[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.

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;
- ✓ 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

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[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

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 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 –

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[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

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")
  - o 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:
  - o European Telecommunication Standards Institute (ETSI) XML Advanced Electronic Signatures
  - o OASIS WS-Trust Version 1.3
  - o 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:
  - o OASIS Security Assertion Markup Language (SAML)
  - o OASIS eXtensible Access Control Markup Language (XACML)
  - o 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:
  - o OASIS OpenDocument Format (ODF), also available as ISO/IEC 26300
  - o ECMA 376 OfficeOpenXML (OOXML), also available as ISO/IEC 26500
  - o 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:
  - o Internet Engineering Task Force (IETF) HTTP
  - o IETF Network Time Protocol
  - o IETF Simple Network Time Protocol (SNTP)
  - o 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:
- o OASIS WS-Trust Version 1.3
- o 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

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

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 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

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[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

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 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),

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[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

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 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,

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[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

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 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

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[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/

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 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

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

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 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**,

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[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,

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 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

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

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 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,	32

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

							LOINC,NUBC, UCUM)	
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
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

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[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

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 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

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[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

National Health Information Network (NHIN).[31] The NHIN is charged with:

- o Developing capabilities for standards-based, secure data exchange nationwide
- o Improving the coordination of care information among hospitals, laboratories, physicians offices, pharmacies, and other providers
- o Ensuring appropriate information is available at the time and place of care
- o Ensuring that consumers' health information is secure and confidential
- o 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
- o Reducing risks from medical errors and supporting the delivery of appropriate, evidence-based medical care
- o 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.

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

[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

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 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.

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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.

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