



# Standards Insight

## An Analysis of Health Information

### Standards Development Initiatives

April 2003

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**Background - Reassessing the Outlook for the EHR**

In the last *Standards Insight*, we focused on patient safety initiatives and pointed out how most depended on an integrated clinical information system and its core electronic medical record.<sup>1</sup> We concluded that while technical interoperability issues exist, the primary barriers were economic--demonstrating that an investment in CIS was better than alternative uses of healthcare providers' funds. We concluded that most individual provider organizations would have some difficulty in building business cases, even with full weight given to reducing medical errors. In this issue, we will focus on the state of the electronic health record (EHR). To many in the HCIT industry, it appears that the stars are aligned and real progress toward an EHR can be made. HIMSS has issued a Call to Action and a declaration of its commitment to realizing a universal EHR.<sup>2</sup> However, we suspect the business case again will become the elephant in the corner.

But to begin, we acknowledge the press releases and meeting reports in which the Secretary of HHS and the Director of CMS have endorsed an interoperable EHR and expressed frustration that the healthcare industry has not adopted this technology.<sup>3</sup> As observers of the Washington scene and the standards-industrial complex well know, information technology and interoperability standards long have been presented as a basis for transforming healthcare in the United States. The Institute of Medicine (IOM) has prepared a series of reports, starting with To Err Is Human<sup>4</sup> in 1999, that build the case for using information systems and communication technologies to reduce errors, improve outcomes and reduce costs. However, it is very important to appreciate what else these reports said. Crossing the Quality Chasm<sup>5</sup> in 2001 stressed the importance of changing the "system," not just adding IT. The "system" is cultural, organizational and yes business, not just technical. We in HCIT are often too quick to offer the IT solution without addressing the rest of the "system" problem. That is can be expected, because we are basically technologists, and undoubtedly information technology is an underlying requirement for real transformation in healthcare. Thus, we will use this issue to examine the larger issues surrounding adoption of a universal EHR. While this is two degrees of separation from our business analysis of interoperability standards, we will close the loop by addressing how standards initiatives support, or do not support, the EHR in the next issue of the *Standards Insight*.

**Defining the EHR**

Before we try to understand the dynamics of adopting and deploying an electronic health record, it is useful to try to define the EHR. In wrestling with the definition, we uncover many of the barriers to the EHR.

***The Paper-Based Medical Record***

We might begin with trying to define the paper-based medical record. All healthcare providers, and only healthcare providers, create and maintain a record of their care encounters with individual patients. This record is used primarily in the patient care process to document findings

<sup>1</sup> We begin by using the terms EHR, EMR and CPR interchangeably. The "universal EHR" implies both full population coverage and complete primary and secondary functionality. We will eventually get to the definitional issues.

<sup>2</sup> [www.himss.org](http://www.himss.org). Note that the *Standards Insight* does not reflect the official position of HIMSS but rather of its author whom HIMSS engages to analyze interoperability initiatives. See contact at information at the end of this issue.

<sup>3</sup> <http://www.hhs.gov/news/press/2003pres/20030321a.html>

<sup>4</sup> L. Kohn, J. Corrigan, et. al.; Committee on Quality of Health Care in America. *To Err Is Human: Building a Safer Health System*. Institute of Medicine. National Academy Press. Washington, 2000. [www.nap.edu](http://www.nap.edu)

<sup>5</sup> Committee on Quality of Health Care in America. *Crossing the Quality Chasm: A New Health System for the 21st Century*. Institute of Medicine. National Academy Press. Washington, 2001. [www.nap.edu](http://www.nap.edu)

and communicate plans. Secondly, it is the business record of the provider, used for internal operations and billing. The record is required and regulated by state and, in some cases, federal laws and rules. Providers must keep accurate, confidential and authentic records for prescribed periods of times. Providers may use such records and abstracts of such records in the normal course of their business operations, again subject to legal constraints such as HIPAA. The Privacy rule, unlike Security, applies to paper records as well as any electronic record.

What is noteworthy is that the medical record is the property of individual provider organizations, even though patients have rights to the data and information contained in them. It is prepared, used and maintained, within broad regulatory requirements, at each provider's expense. Depending on business relationships and again subject to appropriate disclosure rules, the record may be copied and shared with others. In many cases, the provider is entitled to charge for duplicating and sending copies of medical records, a detail that looms more important when we speak of interoperable EHRs.

In general concept and in actual specifics, there is no longitudinal lifetime paper-based patient medical record or the infrastructure to support it in the United States. That is, medical records remain with each provider, except as duplicated and sent to another provider. Providers will review past medical care by accessing their own patient record files, a "longitudinal view." It would be an unanticipated result that one's current provider had or even had need for all prior providers' medical records. However, there are key data elements and summaries of previous records that could be very important as part of current care. Thus, many patient records contain an abstract or active problem list for ready reference. Such abstracts might be part of patient referral or discharge reports and communicated to the "next" provider. More likely, each new provider will begin with a medical history, attempting to elicit from patients critical information from their past care history.<sup>6</sup>

The costs of creating and maintaining paper medical records are significant. This is not the place to review the chain of activities from the initial registration and admission, to entering history, notes, orders, test and procedure results, and then assembling, summarizing, coding, abstracting, filing, retrieving and maintaining paper-based medical records. It is sufficient to note that the direct cost of medical records departments as well as the indirect costs of administrative and clinical personnel, would certainly represent 10 percent to 15 percent or more of total healthcare costs, assuming that clinical personnel spend a third of their time documenting medical information.

### ***The Computer-Based Patient Record (CPR)***

With the paper medical record as our baseline, we turn to the electronic health record. In 1991, the IOM published the Computer-Based Patient Record<sup>7</sup>. This was not the first effort to systematically review the field, but it is a convenient historical starting point for us. The IOM study group deliberately chose the term "computer-based patient record" rather than "computer-based medical record" to be more inclusive of administrative and financial data about a patient that might be excluded from a narrowly defined medical record. However, the study makes the important point that only healthcare professionals produce the CPR. The study went on to define a primary and secondary patient record to describe its use in direct patient care and for other purposes such as billing or research.

The IOM study also took care to define not only the CPR but also the CPR system, "i.e., content, format and function," needed to support the CPR. See Table 1 for more definitions. It went on to

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<sup>6</sup> There is a whole separate issue involving the personal medical or health record that is primarily produced and maintained by the individual. Such information can be very useful in providing a history to a new provider. However, a PMR is not a medical record until a provider incorporates the information, based on their evaluation of its validity, into their medical record. This is one of the limitations to a patient maintained record.

<sup>7</sup> R. Dick, E. Steen, et. al. *The Computer-Based Patient Record: An Essential Technology for Health Care*, Institute of Medicine. National Academy Press. Washington. 1991. Revised Edition published in 1997. [www.nap.edu](http://www.nap.edu)

describe attributes that the IOM team thought were essential.<sup>8</sup> These attributes vary in significance and apply to a single vendor solution rather than interoperable EHRs. These have not been adopted as formal ANSI national standards. The study did correctly identify many of the barriers to adoption of a CPR. In particular, the study identified the need for confidentiality and privacy of the CPR, which certainly played a role in the crafting of HIPAA five years later. It also called for uniform standards for data and data exchange. While all of its seven recommendations are historically interesting and some still right on target, the sixth recommendation requires special attention.

“RECOMMENDATION 6. The costs of CPR systems should be shared by those who benefit from them. Specifically, the full costs of implementing and operating CPRs and CPR systems should be factored into reimbursement levels or payment schedules of both public and private sector third-party payers. In addition, users of secondary databases should support the costs of creating such databases.”

### **ASTM EHR Standard Guide**

Contemporaneously, ASTM E31 Committee on Healthcare Informatics<sup>9</sup> was working on its “Standard Guide for Content and Structure of the Electronic Health Record (EHR)”. This also was first published in 1991. E1384-01 is the current version, and it is instructive to see how E31 defines the EHR (see Table 1). E31 focuses on the EHR as a “document,” noting that it is part of a patient record system but not providing system standards. The guide provides the standard content that would be included in an EHR. It does not address larger issues, such as the costs and benefits of an EHR. E1384:

- validates the premise that an EHR is produced and normally maintained by a healthcare provider
- equates the patient record with the health and medical record
- adds the concept of a longitudinal patient record, perhaps based on synopsis, as distinct from the patient health record.

### **HL7**

As discussed in the October 2001 issue of *Standards Insight*, Health Level Seven<sup>10</sup> formally expanded its mission to include support for sharing electronic health records. It created an EHR Special Interest Group at that time. As we have chronicled, the EHR SIG has been attempting to define the EHR, a task complicated by different underlying healthcare delivery models in different national domains. There also has been a running debate over the “all” and “small” EHR. The latter focuses on the EHR structure and content, while the former also encompasses the system applications and infrastructure necessary to deploy an EHR. The “all” EHR raises the difficult issues of security, authentication, long-term non-repudiation and inter-enterprise trust agreements as well as its use in decision support and other clinical care applications.

It is unclear whether the HL7 EHR SIG will contribute to the overall definition of the EHR in the U.S. The SIG is likely to continue to reflect international interests, such as open EHR, CEN and primary care EHR systems, which are more fully established and supported within national realms. Rather HL7’s reference information model, Clinical Document Architecture, Templates

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<sup>8</sup> Refer to the current (April 2003) issue of *Advance for Health Information Executives* for more information on the attributes and how well current vendor systems meet them. [www.advanceforhie.com](http://www.advanceforhie.com).

<sup>9</sup> [www.ASTM.org](http://www.ASTM.org)

<sup>10</sup> [www.HL7.org](http://www.HL7.org)

and Vocabulary groups will produce the tools to construct an interoperable EHR, after the United States determines the requirements for our national realm.

## **ISO**

Finally, we should note that the definition of and standard for an EHR is being addressed within ISO Technical Committee 215 Working Group 1.<sup>11</sup> WG1's recent meeting during the HIMSS conference illustrates the definitional problems. Like the debate in HL7, WG1 also distinguishes between the EHR and the EHR platform and associated system. The EHR is both a "medical record" and a longitudinal record, having a historic, current and prospective view of an individual's healthcare. As in our previous definitions, there appears to be consensus that the EHR is produced and stewarded by a healthcare provider. The EHR has "sameness" across care settings, e.g., hospital, clinic, or lifetime, although each has setting specific characteristics. Schloeffel, in a discussion paper draft, proposes a useful set of EHR definitions also shown in Table 1.<sup>12</sup> While not formally adopted definitions, the compilation reinforces the understanding that the EHR is more encompassing than the record of a specific encounter or episode as captured in an EPR. We also see a formalization of the concept of a personal health record, which is maintained by an individual. Finally, he acknowledges that the EHR might be virtual, i.e., existing only at distinct nodes that can be assembled on the fly.

## **NCVHS**

In addition to the formal standards bodies, there are many working definitions of the EHR and related terms used informally by other initiatives and interests. The National Committee on Vital and Health Statistics (NCVHS) is attempting to discern and recommend to HHS patient medical record information (PMRI) standards. It made recommendations to the Secretary of HHS, under its HIPAA mandate, that specific data messaging standards from HL7, DICOM, NCPDP and IEEE be adopted.<sup>13</sup> Last month, Secretary Tommy Thompson did announce the adoption of these standards for the exchange of clinical information within the federal government.

In addition to the PMRI messaging standards, NCVHS hopes to make recommendations on nomenclature and code sets used in a patient medical record. Thus, without defining the EHR itself, NCVHS is proposing a set of interoperability standards. This implies a system of and business case for many instantiations of patient records, which interact at the data or message level, not necessarily as a whole "document." To the extent that each EHR must have interchangeable data, then some elements of the EHR are "standard," indirectly creating an EHR standard.

We also should note that the EHR is a centerpiece of the National Healthcare Information Infrastructure (NHII) as proposed by the NCVHS. Here, we get into a more expansive functional vision of the EHR, in which NCVHS describes the NHII as an EHR in three dimensions: the healthcare provider dimension (the traditional view), the personal health dimension and the population health dimension. Figure 1. At the most basic level, the source electronic medical record produced by the care provider must be able to support through standard messages (content, structure and triggers) all of the other uses.

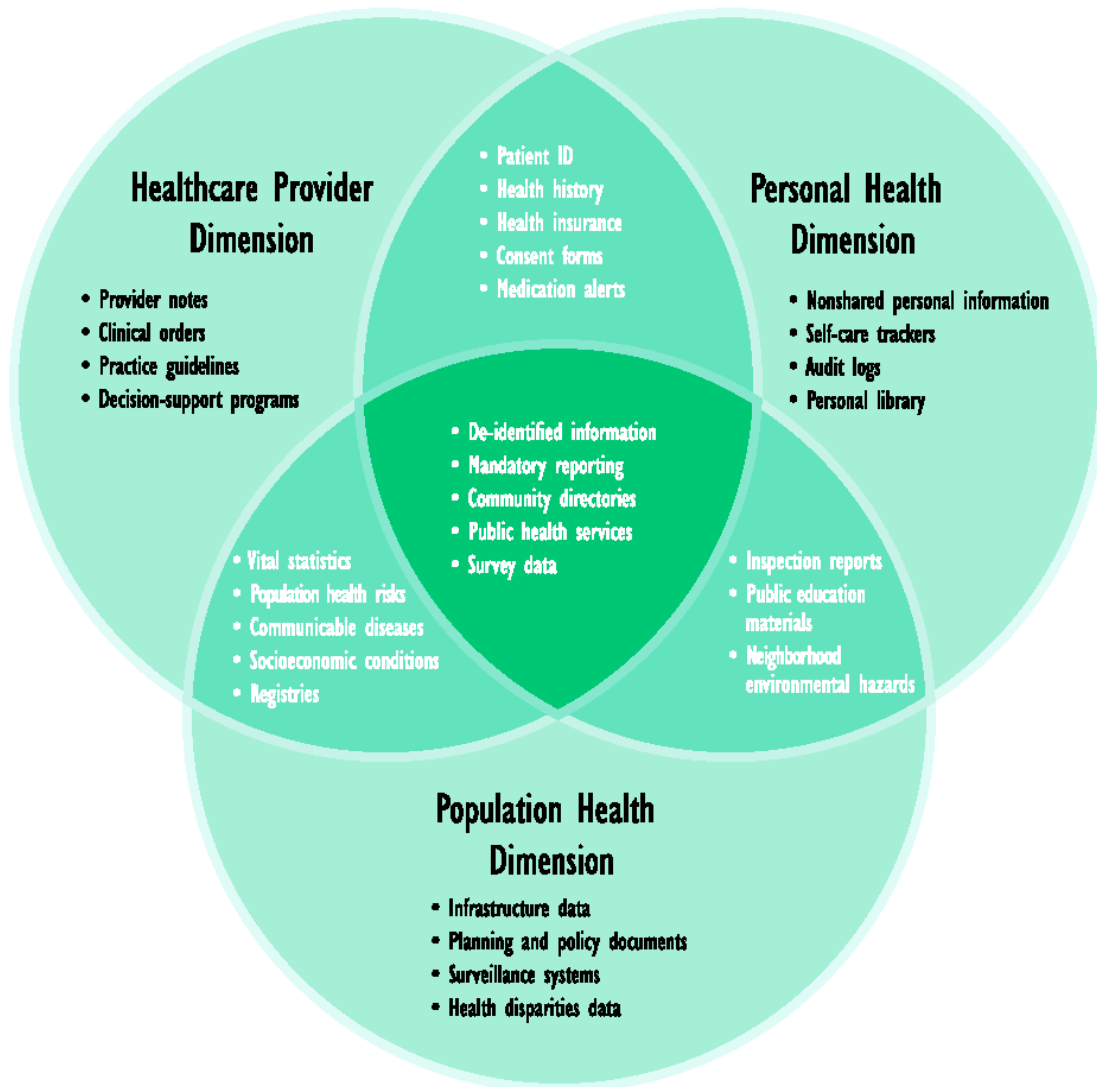
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<sup>11</sup> [www.iso.org](http://www.iso.org)

<sup>12</sup> P. Schloeffel. Electronic Health Record Definition, Scope, and Context. ISO/TC 214 Discussion Paper. Draft. October 2002.

<sup>13</sup> <http://www.ncvhs.hhs.gov/>

**Figure 1. NHII and the Three Dimensions of the EHR.**



From INFORMATION FOR HEALTH A STRATEGY FOR BUILDING THE NATIONAL HEALTH INFORMATION INFRASTRUCTURE. Report and Recommendations from the National Committee on Vital and Health Statistics. 1999.

**A Value Proposition View of the EHR**

As noted above in regards to the NHII, the EHR often is used as a catchall for a set of functions and uses to produce specific results. What do we want from an EHR? What problem are we trying to solve? What is the value proposition(s) of the EHR?

- Improve individual patient care and outcomes through better availability, presentation and analysis of clinical information
- Control costs through standardized processes
- Reduce medical errors and improve patient safety

- Integrate the care of chronic disease (e.g., the Medicare population) across independent providers (disease management)
- Provide a lifetime EHR for each individual for coordinated care available anywhere nationally (or internationally) at any time
- Support medical research and clinical trials
- Conduct outcomes studies and quality benchmarking
- Enable real-time bioterrorism surveillance and public health reporting.

If we do not know the problem(s) we are attempting to solve or the value we want to create, the broad rubric of a national healthcare infrastructure will not mobilize the necessary efforts as embodied in the HIMSS Call to Action nor result in a universal EHR of value to the stakeholders.

### ***The Market Definition of the EHR***

Fundamentally, the HCIT industry and the standards initiatives have paralleled the evolution of healthcare enterprises, which are, after all, the customers. We just witnessed the overwhelming interest in CPOE and the underlying enterprise CIS at the 2003 HIMSS conference. Healthcare providers are adopting an electronic medical record (frequently called the CPR for inpatients and EPR for ambulatory patients<sup>14</sup>) not because the technology is available but because it is deemed a necessary component of a system to improve patient safety and outcomes, standardize processes, and control costs.

If we define the EHR as a CPR or EPR created and maintained by each care provider, then we are well on our way to adoption in the U.S (Figure 2). The previously cited article in *Advance for Health Information Executives* rated 48 vendors that supply CPR systems. The major HCIT vendors all provide some form of an integrated EHR and enterprise CIS. These products not only provide a CPR/EHR but also add many valuable functions to automate processes and workflows. Integration, such as it is within the enterprise, is generally at the data messaging level. Feeder systems send and receive data to and from the core EHR through interface engines and HL7 messages. In the most recent HIMSS Leadership Survey<sup>15</sup>, 46 percent of responding healthcare organizations have or are implementing the CPR. Another 23 percent are currently developing plans.<sup>16</sup> Motivations vary, from leveraging services to their networked physicians and patients, to underpinning advanced patient safety initiatives, such as CPOE, automated medications management and clinical decision support. We can assume that the individual provider organization has found a positive value proposition for this investment.

If, on the other hand, we define the EHR as an electronic health record readily sharable and transportable among different provider networks and other third parties, we have a long way to go. Finally, if one sees the EHR as an integrated lifetime health record of an individual, we have no underlying business or technical model or economic driver. Interoperability between enterprises, which we reviewed in the *Standards Insight* of June 2002<sup>17</sup>, is not primarily a clinical messaging problem. Rather, interoperability depends on administrative, business associate,

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<sup>14</sup> The early commercial implementations of EHR systems were hospital products often based on a central clinical data repository. These systems inherited the CPR terminology. As ambulatory EHR systems were introduced into the market, they needed a different term and often the term electronic patient record or ambulatory patient record was adopted.

<sup>15</sup> 14th Annual HIMSS Leadership Survey sponsored by Superior Consultant Company. It and previous Leadership Surveys are available at [www.himss.org](http://www.himss.org).

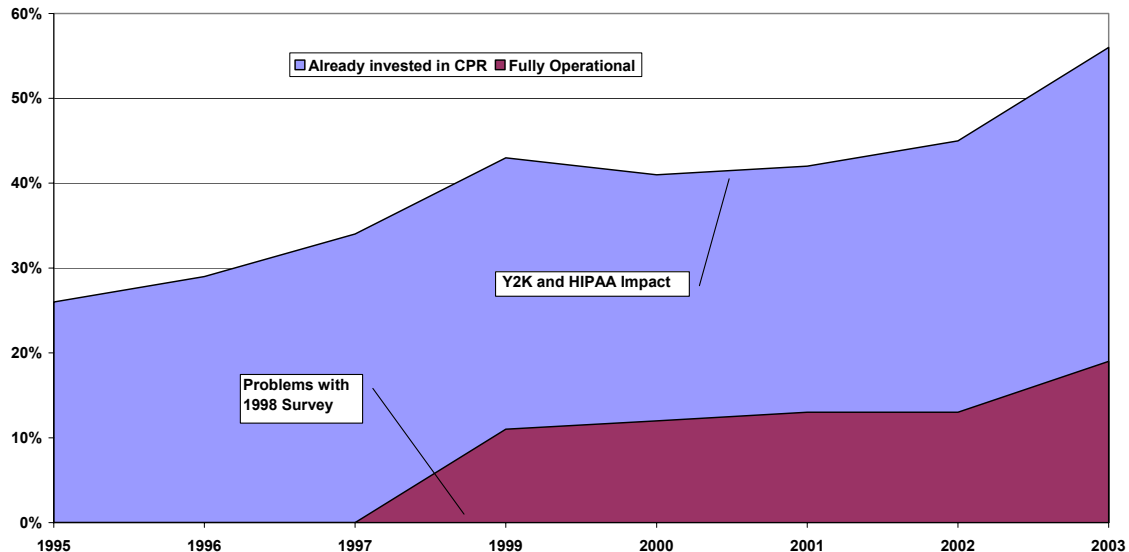
<sup>16</sup> We readily acknowledge that the HIMSS Leadership Survey is not a representative sample of all care providers. Recent studies show that an EHR is used in 5 percent or less of physician practices for example. As part of any serious attempt to develop a "universal" EHR, there must be clear segmentation and specific needs assessments. See Roadmap.

<sup>17</sup> This and other past issues of the *Standards Insight* are available on the individual member's start page at [www.himss.org](http://www.himss.org).

security and trust agreements and standards. Such interoperability frameworks, e.g., ebXML for healthcare, only now are being conceived.

**Figure 2. Adoption of Computerized Patient Record**

Source: HIMSS Leadership Surveys 1993 - 2003



We should be clear on whether the universal EHR and enabling interoperability standards initiatives are focused on the internal adoption of electronic medical records, a component of an enterprise CIS, or on the interoperability of these records across business enterprises. We might assume that the EHR produced by a single enterprise is a necessary condition of a shared EHR. We would suggest that the former is not necessarily the proper goal of public policy. Telling hospitals or physician practices how to implement their electronic medical record system for their own use and benefit seems overreaching and unproductive, as well as unnecessary if the HIMSS surveys are correct. Public policy could more properly be aimed at requirements to support a super-organizational or cross-enterprise EHR of societal and public benefit. Making interoperability of current systems within the enterprise easier might be better handled by voluntary efforts of the users, e.g., the IHE initiative and improved reimbursement.

### ***The EHR as an Individual's Lifetime Record***

We have noted a definition of the EHR as a patient-centric longitudinal view of care that spans different providers. We now move beyond a single enterprise's EHR implementation to meet its own patient care and business needs. Immediately one faces the issue of ownership, stewardship and economic support as well as rights of privacy. In the case of the patient-centric EHR, a lifetime of the encounter records of an individual, one must confront the issue of who will own, maintain and pay for this super-organizational record. Here, we obliquely encounter the impact of the national health system on the EHR. There is no provider, payer or governmental agency in the U.S. to exercise control over all individual health records as there is in other countries. This is one reason why the efforts to define a standard EHR at the international level are not particularly useful in providing a national standard. One might assume that the individual owns and pays for this record (through taxes or levies on providers or payers), because each individual is the direct beneficiary and only constant in the lifetime EHR equation. However, we do not entrust the EHR to each individual as steward; rather, we enlist healthcare professionals to

do so.<sup>18</sup> Thus, there are two major policy issues to solve if one wants a lifetime EHR for each individual, well before we get to the technical issues: how is the lifetime (cross-provider) EHR paid for and who is the steward?

### **Secondary Uses of EHR**

We also must look at the value of an EHR in other endeavors, including public health, population studies, pharmacy benefits plans, clinical trials and research, quality benchmarking and outcomes analysis. One must start with the business case-driven requirements: what do the third party users want or need and how do they fund it, recalling the CPR study’s recommendation on fair-share funding. For example, real-time bioterrorism detection necessitates a far different system requirement than periodic benchmarking of quality indicators, or retrospective clinical research (data mining). None of these necessarily need the entire EHR. In some cases, the need is only for specific data but in real-time. In other cases, only de-identified data is needed, and it is not time-sensitive. In some cases, one does not know beforehand what data is important.

This may be getting close to the key issue in the universal EHR. Most clinical trials conducted by commercial interests know that they must pay to collect their data. Through third party services, more trials are being conducted using specialized computer software provided to caregivers to record clinical data--very tightly abstracted EHRs, if you will. Academic research, whether a prospective trial or retrospective review of records, also requires incremental funding to support data collection and abstraction. Payers require EHR abstracts or summaries to justify payment. They buy and sell their population data. State and federal government do have certain reporting requirements that are not reimbursed but a condition of providing licensed care. In other words, there is a large, diverse industry involved in making paper-based EHRs interoperate for secondary purposes. There are both vested interests and a “free-rider” tendency among the secondary users. Who pays and who gains?

### **EHR Conclusions**

How we define the EHR greatly impacts its adoption. Table 1 summarizes our previous list of definitions.

**Table 1. EHR Definitions**

	<i>IOM Computer-Based Patient Record 1991</i>	<i>ASTM E1381-01 1991 - 2001</i>	Schloeffel – ISO TC215 WG1 Discussion Paper 2002	Comment
Electronic health record (EHR)	Same as CPR (see below)	<i>Previously known as Computer-based Patient Record (CPR), an electronic patient record that resides in a system specifically designed to support users by providing accessibility to complete and accurate data, alerts, reminders, clinical decision support systems, links to scientific knowledge, and other aids.</i>	A longitudinal collection of personal health information concerning a single individual, entered or accepted by health care providers, and stored electronically. The information is organized primarily to support continuing, efficient, and quality health care and is stored and transmitted securely. The EHR contains	This is the most encompassing term. It combines the concepts of the patient record, the longitudinal record and support for computer based support.  This is most like the universal EHR.

<sup>18</sup> This is the key difference between a longitudinal health record and a personal health record as created and maintained by individuals.

	<i>IOM Computer-Based Patient Record 1991</i>	<i>ASTM E1381-01 1991 - 2001</i>	Schloeffel – ISO TC215 WG1 Discussion Paper 2002	Comment
			information which is: <ol style="list-style-type: none"> <li>1. retrospective: an historical view of health status and interventions;</li> <li>2. concurrent: a "now" view of health status and active interventions; and</li> <li>3. prospective: a future view of planned health activities and interventions.</li> </ol>	
Patient health record	<p><i>A patient record</i> is the repository of information about a single patient. This information is generated by healthcare professionals as a direct result of interaction with a patient or with individuals who have personal knowledge of the patient (or with both). Traditionally, patient records have been paper and have been used to store patient care data.</p>	<p>The primary legal record documenting the healthcare services provided to a person, in any aspect of healthcare delivery. This term is synonymous with: medical record, health record, patient care record (primary patient record), client record, resident record. The term includes routine clinical or office records, records of care in any health-related setting, preventive care, life style evaluation, research protocols, special study records and various clinical databases.</p> <p>As the repository of information about a single patient, this information is generated by healthcare professionals as a direct result of interaction with a patient or with individuals who have personal knowledge of the patient (or with both). The record contains information about the patient and</p>	<p><i>Electronic Patient Record (EPR)</i> - An electronic record of episodic or periodic health care of a single individual, provided mainly by one institution.</p>	<p>This is the basic unit of an EHR produced by a healthcare provider as the record of a discrete patient encounter.</p> <p>The analog to the paper medical record.</p>

	<i>IOM Computer-Based Patient Record 1991</i>	<i>ASTM E1381-01 1991 - 2001</i>	Schloeffel – ISO TC215 WG1 Discussion Paper 2002	Comment
		other individuals as they relate to the health of the patient, for example, family history, caregiver support.		
Patient record system	The set of components that form the mechanism by which patient records are created, used, stored, and retrieved. A patient record system is usually located within a health care provider setting. It includes people, data, rules and procedures, processing and storage devices (e.g., paper and pen, hardware and software), and communication and support facilities.	The set of components that form the mechanism by which patient records are created, used, stored, and retrieved. A patient record system is usually located within a healthcare provider/practitioner setting. It includes people, data, rules and procedures, processing and storage devices (for example, paper and pen, hardware and software), and communications and support functions.	The set of components that form the mechanism by which electronic health records are created, used, stored, and retrieved. It includes people, data, rules and procedures, processing and storage devices, and communication and support facilities. From IOM CPR	All adopted the CPR definition. This is the "all" EHR.  It only begins to look beyond technology to the business issues.
Longitudinal patient record		A permanent, coordinated patient record of significant information, in chronological sequence. It may include all historical data collected or be retrieved as a user designated synopsis of significant demographic, genetic, clinical and environmental facts and events maintained within an automated system.		A formal definition of the serialization of patient records or their abstracts.
Electronic Medical Record (EMR)			The EMR could be considered as a special case of either the EHR or EPR but restricted in scope to the medical domain or at least very much medically focused.	
Computerized Patient Record (CPR)	<i>A computer-based patient record (CPR) is an electronic patient record that resides in a system specifically designed to support users by</i>		This term is mainly used in the USA and seems to have a wide range of meanings, which may encompass the EMR,	We informally use this to primarily mean the inpatient patient record.

	<i>IOM Computer-Based Patient Record 1991</i>	<i>ASTM E1381-01 1991 - 2001</i>	Schloeffel – ISO TC215 WG1 Discussion Paper 2002	Comment
	providing accessibility to complete and accurate data, alerts, reminders, clinical decision support systems, links to medical knowledge, and other aids.		EHR, or EPR.	
Personal Health Record (PHR)			The key features of the PHR are that the information it contains is totally or largely entered by the subject of care (consumer, patient) and is under the control of the subject of care. The report of the ISO/TC 215 Taskforce on Consumer Policies discusses five different types of PHR.	
Virtual EHR			Consists of some form of logical view or physical assembly of two or more EHR extracts "on the fly" from two or more distributed EHR sources. These EHR extracts may "belong" to a single clinician or healthcare organization but reside in different locations (e.g. different offices of a healthcare clinic or different departments of a hospital). Alternatively, the components may be from different healthcare organizations, different types of clinicians, or different healthcare sectors. Some extracts may consist of detailed information whilst others may be summaries.	This begins to address the technologic design issues for the universal EHR.  We explore this in the next issue of <i>Standards Insight</i> .

From our summary table, we can draw several conclusions about what the EHR is:

- The EHR is the most encompassing term and can be defined as a fractal-like aggregation of provider record(s) of a patient care encounter(s). Variant terms, such as the electronic

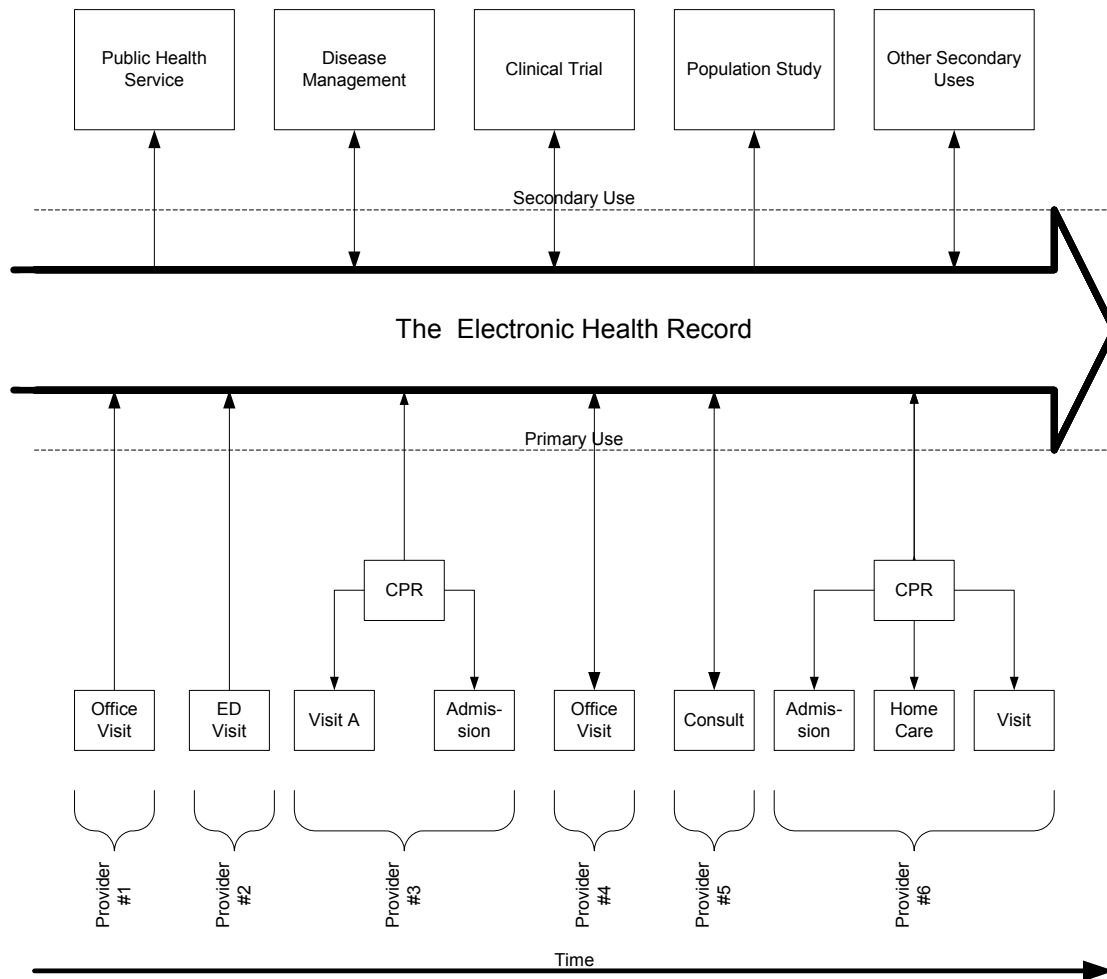
medical record (EMR) may connote specifically medical information about a particular care episode. Computerized patient record (CPR) appears to be more associated in the U.S. with a hospital patient record, and an electronic patient record (EPR) may connote ambulatory or outpatient care.

- Within an inpatient stay, there will be many EHR/CPR components created, including physician and nursing notes, test results and procedure summaries, which will be assembled into an electronic medical record. Similar documents, paper-based or electronic, are created for office visits, home care visits and other alternative care encounters. Each is a complete record of the encounter. Whether or how they are assembled together over time does not change their EHR-ness. But it is the aggregating, sharing and maintenance of the EHR fractals that is at the heart of the EHR definitional problem.
- The EHR currently exists as a business record of individual provider organizations. The provider uses and maintains the EHR to provide care, to support its operations and billing, and for medical-legal purposes. The provider is the steward of the information ensuring its accuracy, authenticity and security. Patients have certain rights over their data contained within the records.
- There is no organization or entity for formatting, abstracting, assembling and managing a longitudinal EHR for individual patients. To the extent an individual receives a “lifetime” of care from a single provider organization or takes individual care to see that one’s individual medical records are serially transferred to new care providers, there may be an ad hoc longitudinal EHR. The longitudinal EHR has the most value to the individual.
- There are many secondary users and uses of the data in the EHR. Besides improving the internal processes and outcomes of the provider organizations, access to all or excerpts of the EHR are essential to public health, clinical research and public policy organizations.

### ***The Universal EHR***

We note that the HIMSS Call to Action speaks of the universal EHR. Let us define the term “universal EHR” to encompass the EHR and EHR system that meets all of the requirements of first, all providers’ care and business records; second, each individual’s lifetime patient-centric record; and third, all of the secondary users’ needs. One can make a simple framework as shown in Figure 3 to illustrate the scope of the universal EHR. First, every individual would have a lifetime EHR, as shown in the center. That would be the focal point for both care providers and secondary users. That is, providers’ EHR systems would interoperate with the universal EHR to enable future providers to have appropriate access to the patient’s record as well as to meet the needs of secondary users. In some cases, the interaction might be in real time, as when a primary care physician or ED encounters a new or reportable disease. In other cases, the secondary use might be later, after a full encounter record is completed. The point to be made is that the diagram is not the technical design but rather the “business concept.” The alternative model is point-to-point interfaces and silo applications in which different users, whether future providers or secondary users, define their own path from the provider, creating the patient record to their own usage. Thus the universal EHR might be an actual repository of records (centralized or distributed) or virtual based on abstracts and pointers. What are the technical and business barriers to the all-encompassing universal EHR? What is the roadmap to implementing a universal EHR? In this issue of the *Standards Insight*, we focus on the business barriers to an interoperable universal EHR. Next issue we will address the technical issues.

**Figure 3. A Model of the Universal EHR**



**What are the barriers to the Universal EHR?**

We often hear that a primary impediment to the EHR is technologic, both in terms of the application software and interoperability standards. We need more funding and projects to demonstrate the technology. But if we are to make real progress with EHRs, we should examine this premise to ensure that we have identified the real barriers to EHR adoption.

**Why hasn't the EHR been adopted?**

In some form, a computerized patient record has been described and demonstrated since the 1970s. Certainly the IOM report in 1991 defined the CPR and CPR systems, their functions and benefits as well as any current study or report. For our answer, it is instructive to look at the reasons provided by the HIMSS Leadership Survey from 1993. Respondents were asked to identify the two primary hurdles to the CPR. Table 2 shows the combined results. Note that funding, availability of technology and regulatory concerns were major perceived barriers. If we jump ahead to the most recent HIMSS Leadership Survey results from 2003, we now ask a slightly different question. The new question is, what are the most significant barriers to IT? We find that financial issues--having funds and proving a return on investment--are at the top of the list. This result is confirmed by the Medical Records Institute's recent EHR survey, which found

that lack of adequate funding and resources was the major barrier, according to 59 percent of respondents.<sup>19</sup> That's not exactly a decade of progress.

**Table 2. Barriers to CPR/EHR 1993 and 2003**

1993 HIMSS Leadership Survey Primary Hurdles to Achieving the CPR		2003 HIMSS Leadership Survey Most Significant Barriers to Implementing IT					
All		All	CEO	CMO	CIO	Vendor	
Don't have funds	43%	Lack of Financial Support	21%	25%	21%	23%	15%
		Provable ROI	17%	17%	15%	13%	23%
			38%	42%	36%	36%	38%
Technology is lacking	35%	Vendors Ability to Deliver	14%	10%	17%	19%	9%
Need federal standards and uniform state regulations	61%	Lack of Strategic Plan	12%	10%	13%	5%	18%
Caregivers Acceptance	24%	Lack of Standards	6%	8%		5%	5%
		End-use Acceptance	9%	4%	7%	10%	14%

We note two other important shifts in the last decade. First, the earlier concern over federal reporting standards and state regulations has greatly diminished. At a global level, this is certainly a result of HIPAA although we only now are beginning to address paper-based, not computerized, trust relationships and business associate agreements. At a narrower level, given the industry's experience with CPRs, lack of strategic planning may have supplanted federal rules in deciding how to set CPR directions. There also has been a marked drop in concern about available technology. Computing technology has advanced and is "cheap." Computer use permeates everything. Many CPR products exist.

In fact, recent HIMSS Leadership Surveys have shown that most hospitals, at least, have or are planning to implement a CPR (as discussed earlier). Finally, we note that interoperability standards are relatively unimportant. In fact, they were ranked last in the HIMSS survey.

### **The Business Case for the EHR**

Perhaps we should take the Leadership Surveys at face value: the business case is the major barrier to IT spending and the EHR. So let's examine the components of business decision-making. First, we need to understand the investment decision surrounding an EHR.

One knows that business decisions are based on analysis of costs, benefits and tradeoffs given one's own business purpose and economic resources. But there is really a standard hierarchy of business decision rules, beginning with maintaining daily operations, then complying with laws and regulations, next making strategic investments and finally nice-to-have things. In healthcare investment, we rarely get to nice-to-have things. IT spending obviously crosses all these levels. In particular, the EHR is generally at the strategic or nice-to-have level. Spending for Y2K and HIPAA is an obvious example of the first two levels and illustrates the disruptive impact of regulation on strategic decisions.

Certainly the EHR could be a strategic decision, and healthcare organizations, in growing numbers, appear to be considering it an operational necessity. In fact, one might conclude that the EHR is becoming a necessary element of the An EHR is essential to support other initiatives, such as computerized physician order entry, clinical decision support and process improvements

<sup>19</sup> Fourth Annual Medical Record Institute's Survey of Electronic Health Record Trends and Usage Sponsored by SNOMED®. [www.medrecinst.com](http://www.medrecinst.com).

that are the highest IT priorities. The recent decision by Kaiser Foundation to invest \$1.8 billion in a universal EHR represents the result of a business analysis of its strategic and operational value.

### **Costs**

The costs of the EHR depend on its definition. For a large hospital or multi-provider system, EHR system acquisition costs will easily exceed \$10 million. Physician practice EHR systems are estimated to cost \$10,000 to \$20,000 per physician. Operating costs will probably represent another 25 percent of the total per year. It is well understood that the costs are not just technologic but also operational. Barriers are not just economic but also cultural and organizational. In particular, we note the issue of acceptance by end users, often presumed to be physicians.

At the single enterprise level, there is no requirement for or assurance of interoperability with other EHR systems. One EHR system supports its own provider network. Interoperability standards, such as HL7 messaging, support simple workflow and data transfer with feeder (departmental or functional) systems within the enterprise. While requiring site-specific configuration and use of interface engines, basic enterprise connectivity is well-established in hospitals and health systems.

The costs of an interoperable universal EHR are not well understood. The infrastructure, whether constructed as a series of real repositories or virtual directories, must be designed, created and operated. All cooperating EHR systems must conform to the master template. Support of secondary users must be defined and implemented. All of these interconnections must be automated, secure and longstanding.

### ***Unclear and Misaligned Benefits***

There are many potential and some documented direct benefits to an EHR. These include reduction in cycle times, duplicated tests, medical records administrative costs, as well as improved communications, better reporting and more complete documentation. The previously cited Medical Records Institute's survey showed that sharing patient data within a multi-entity delivery system and improving clinical documentation are the two most important administrative factors driving the EHR in their organizations. Similarly, the survey showed that the primary clinical driver was sharing patient data among care providers in the enterprise. Whether or not these and the other factors reflect a consensus view, each individual healthcare enterprise can identify its own expected benefits and can compare them against costs. While the ROI of an EHR system to a single enterprise is calculable, the costs and benefits of interoperability between organizations are less clear. We need to clearly differentiate between benefits to the enterprise itself and those to healthcare and society in general. Most large healthcare organizations already have decided that the EHR is necessary or strategically valuable to their own enterprise. They have not waited for nor are they necessarily investing in EHR systems that interoperate with other providers or with a "universal" EHR. Conversely, secondary users of EHR data, with some exceptions, have not stepped forward to embrace or fund their share of the universal EHR.

### ***Return on Investment***

The real financial problem with the interoperable EHR is the lack of connection between costs and benefits. While the full costs of the EHR are borne by the provider organization, much of the benefit flows directly to patients, to public and private payers and to other secondary users, such as public health. For example, if the EHR shortens length of stay, we should expect cost savings to providers. However, whether that represents any financial return would depend on whether the reimbursement mix favored fixed rate payments vs. charge or per diem based methods. Such a disconnect does not reduce the net benefit of the EHR, but it does create disincentives.

In the current issue of *Health Affairs*, Leatherman, et. al. “make the business case for quality”.<sup>20</sup> The authors argue that without a “business case” it is doubtful “that nonfinancial motivations are sufficient, without a financial return, to drive and sustain widespread adoption of improved quality practices.”

Providers will incur most of the direct costs of an EHR because they produce it, use it and maintain it. If the EHR is to be shared, abstracted or aggregated, there must be an infrastructure based on interoperability standards of proper granularity, with acceptable stewardship and trust relationship, which are supported by all participants’ business cases. While the study mentioned above is focused on quality initiatives, the findings are generally applicable to any initiative in which the business case does not align benefits and costs. The authors suggest that when the social case (benefits to the patient or society) and the economic case (benefits to stakeholders in total) are positive but the business case for the investing organization is “elusive or negative,” then there must be reforms in payments and policies to align the business case.

More simply, as the Leapfrog Group has come to realize, it is necessary to pay for quality, not for defects. If we want a universal EHR, the stakeholders must pay in order that all see an ROI, not only for their own internal system but for participating in the universal EHR.

### **The Roadmap for a Universal EHR**

There are many proposals and initiatives for the universal EHR. Many however, begin promoting technology as the solution without defining the value proposition of an EHR and identifying the problems blocking its adoption. Thus we humbly add our own simple list that puts technology last and starts by asking what are we trying to do.

#### ***Agree on a definition of the universal EHR, its scope and purpose in the United States***

This is the most important and most difficult step. It is not primarily a technology question. It is a public policy, social, economic and business question. There is no universal EHR in the US today. It must be defined before it can be created. Without the framework for a universal EHR, we cannot produce the business case or marshal the technical solutions. The first order is even to define a forum for developing the definition. Undoubtedly, there are many stakeholders and, first among them, is the federal government. All EHR initiatives, one way or another, have called for federal leadership. As we discuss below, such leadership is not because the federal government is the biggest payer or most powerful regulator, but rather because it is the steward of the public’s interest. It is in a position to establish a forum and framework for defining the EHR, its scope and purpose. From this flows identification of stakeholders and their economic interests in the universal EHR.

#### ***Develop the business cases for the EHR***

As shown in our EHR model in Figure 3 and as delineated by NCVHS in their National Healthcare Information Infrastructure report, there are many stakeholders and users of the universal EHR, beginning with us as individuals. As a first order deliverable, we must weigh the costs and benefits of a universal EHR – in other words, develop the value proposition. We presume that a fully implemented interoperable EHR system would improve patient care and, potentially, lower overall costs. We need to show how. Moreover, we need to show how the universal EHR, if made interoperable among providers and secondary users, provides incremental value over an enterprise-centric CPR. From this macro analysis of the economic and social benefits of an EHR, we need to drill down to the key stakeholder segments. We have described some, identifying the central source role of healthcare providers. We must define each of the segments of stakeholders to the level of a common business case. Then, all need to develop their business

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<sup>20</sup> S. Leatherman, D. Berwick, et. al. The Business Case for Quality: Case Studies and an Analysis. *Health Affairs*. March/April 2003: 17-30.

cases for using the interoperable and universal EHR.<sup>21</sup> That is, what do they need from a universal EHR, what are the benefits to them, what does it cost and what can they contribute? Without this accurate assessment of the business case for each segment, we will not be able to enlist necessary economic and technical support and resources.

### ***Align funding to support the business cases***

We have been clear to this point that lack of funding and demonstrable ROI are the primary barriers to HCIT investment, including the EHR. Despite this, many healthcare enterprises are investing in EHR systems. Costs alone do not determine whether to invest. While it is true that many smaller healthcare organizations, such as physician practices, are not investing in EHR systems and might not claim to have the funds, the real reason is that there is no ROI. Funding can be found when there is a positive business case. We thus have the problem of uneven adoption of an EHR system across all segments. Secondly, we have the problem of inducing incremental investment to insure interoperability among EHR systems and to develop and maintain the infrastructure for a universal EHR.

To induce internal investment by providers in EHR, or its extensions such as CPOE, Leapfrog and other larger payer consortia are exploring how to align financial returns with investments. Simply, Leapfrog and the others want to pay for quality, not mistakes. However, in the current reimbursement environment, providers who invest in technologies and changes that improve care may not receive the economic benefits. As we discussed, these benefits flow to us, the patients, and to the payers and society generally. Several state governments, including Michigan, New York and Wisconsin, are developing Medicaid-based plans to pay incentives to providers that implement EHR systems. These are all steps in the right direction. However, we really need to build an EHR infrastructure, not based on short-term incentives, but long-term operating returns.

Ultimately each stakeholder will have to pay its fair share of the costs of the EHR based on its own value proposition and business model. Just as in our simple world of paper-based medical records, those who want copies of records may have to pay those who produced them. Ensuring that this alignment is a leadership role of the federal government but this will lead it to a political challenge.

### ***Develop and implement the EHR system***

If we can define the EHR, identify the stakeholders, and make the business case after realigning funding, then we can turn to the technical issues. While, as in all systems development, these activities occur concurrently and interactively, we need the business case to justify the technology investment. We will defer the EHR design issues and interoperability standards until our next issue. We have great confidence that a universal EHR and its infrastructure could be implemented quickly by the HCIT industry if the policy and business case issues were resolved.

### **The Federal Role**

We need federal policy-level leadership followed by operational funding of its share of the costs of the EHR. We do not need regulation, more pilot projects (at least until we understand the purpose of the pilot on the roadmap to a universal EHR), more standards initiatives or more seed money for ad hoc acceleration efforts. As discussed earlier, the primary federal role should be leadership on behalf of the public good. It can, of course, assume many other roles as the largest purchaser, the largest provider and, ultimately, the most powerful regulator. We will briefly review each, in reverse order, as a means of focusing our recommendation to the federal government.

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<sup>21</sup> As we have in the past, we use the term “business” to represent the organizational entity that pursues some purposeful set of managed activities. In our context, such purpose is healthcare. Nonetheless all activities require and use economic resources.

## ***Regulation and the EHR***

We are still in the process of implementing interoperable managed-care transactions based on HIPAA. In the simpler domain of payers, with a significant EDI penetration and relatively standard documents and transactions, HIPAA administrative simplification is, at best, a questionable model for driving adoption of a universal EHR. In particular, despite a four-year run-up to final rules and three years to get ready, the likelihood of a successful switchover in October is in doubt and savings, if any, are years away. HIPAA did not match economic costs and benefits and did not provide any new funding. More than that, HIPAA showed that mandates do not repeal complexity or assure success.

We find great comfort in the decision of NCVHS to only recommend, not mandate, patient medical records interoperability standards and HHS' acceptance of that position in its recent announcement to accept NCVHS' recommended messaging standards for use within the federal government. On the other hand we have seen the rapid capitalization that the standards-industrial complex made of HIPAA. The just finalized Security Rule is generating interest in CERT-like certification of healthcare systems. The federal government must take care not to freeze or distort market-driven solutions by intimating an impending solution mandated by regulation.

## ***The Largest Provider of Healthcare***

The federal government, through the Department of Defense, the Veterans Health Administration and the Indian Health Services, is the largest provider of healthcare in the U.S. Such market clout could be used to shape HCIT directions. We have noted the adoption of existing messaging standards by these agencies, which shows their intent to lead by example and potentially by economic suasion. The eGov initiative Consolidated Health Informatics is an important signal to the private sector.<sup>22</sup> This, in fact, was part of the recommendations of another IOM study Leadership by Example: Coordinating Government Roles in Improving Health Care Quality.<sup>23</sup> The study, released in 2002, recommended that the federal government, both as the largest purchaser of healthcare services and the largest provider, lead by example.

## ***The Largest Buyer of Healthcare***

While HHS is the largest buyer of healthcare, it is only our agent to provide the healthcare we want. If it acts as the largest buyer, for example, by requiring all Medicare providers to submit standard electronic patient records in order to be reimbursed, it may well force adoption of some form of EHR. We have an example how Medicare cost-based billing requirements of the 1960s shaped hospital financial and administrative systems for decades.

## ***Paying for Quality***

If the federal government assumes the role of leader in defining the universal EHR, identifying stakeholders, analyzing the business cases and establishing the technology framework and requirements, it will have to do one thing more. As the biggest payer and as a major secondary user of the EHR, the federal government will have to develop new operational funding. As Leapfrog and other private initiatives have learned, financial investments must be aligned with financial benefits. More simply, the healthcare system must pay for quality not mistakes. Ultimately, quality care should be the most cost-effective care. However, there is a chicken-and-egg problem, not amenable to the budget-neutral approach of the federal government. Here in funding more than anywhere else, the federal government should lead by example.

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<sup>22</sup> [www.egov.gov](http://www.egov.gov)

<sup>23</sup> Institute of Medicine. *Leadership by Example: Coordinating Government Roles in Improving Health Care Quality*. National Academies Press. October 2002.

**Next Issue**

In our June issue, we will examine the technical framework options and interoperability issues involved in developing a universal EHR. This will include an update from HL7, which remains the most important source of EHR-related standards.

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