

The Electronic Health Record – A Fresh Perspective

*A standards development approach for achieving interoperability
across disparate Electronic Health Record (EHR) systems*

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Executive Summary

Background

Standards organizations have been working for over a decade toward the definition of a universally acceptable “Electronic Health Record” (EHR) standard. The primary benefit expected from an EHR standard, is *system interoperability* for providers and other users of health information. For providers, system interoperability is a mission-critical requirement, driven by the inherently collaborative nature of healthcare. Lack of provider system interoperability significantly increases both the cost and risk of care. It can prevent physician access to critical health information at the point of care, potentially resulting in injury and death. Therefore, “standardization of the EHR” has been identified as an urgent, national priority.

Historically, the paper-based health record, or “chart”, has been regarded as the linchpin of a provider’s clinical record system. When we began “computerizing” provider business operations during the 1980s, the natural inclination was to create a digital replica of the paper-based record system, starting with the patient’s financial and insurance data. As Electronic Medical Record (EMR) systems became available, the centralized record model was retained. The lack of a standard information model, however, resulted in EMR information that still could not be shared easily between providers, unless both had identical systems, configured with the same user-definable EMR template... reinforcing each provider’s concept of being the custodian of a unique, but comprehensive repository of his own patients’ health information.

With the removal of the physical constraints of paper, the inherent flexibility of relational databases, and our expanding capabilities for moving information across computer networks, today’s digital health information could be stored and managed efficiently, using both centralized and distributed record architectures. The “central repository” or “chart” concept is, clearly, no longer a universal requirement for any user category. There will be requirements for repositories of *some* individual health information, but it is virtually certain that no single user will require that *all or most* health information about a single patient be stored in a single repository.

In today’s digital world, it is much more helpful to simply consider the requirement to have the *right information available* at the *right time*, in the *right form*, to the *right user*... in order **to support the required healthcare operation**. The universal need for a “master health record” no longer exists in healthcare.

Pursuit of the Elusive EHR Standard

Our approximately 15-year quest for an EHR standard has produced a useful body of knowledge regarding the functional requirements of healthcare... but still no standard EHR. While health information requirements are well known for

managing each type of health problem, the great variety that exists among provider organizations in the types of problems they choose to manage, results in a variety of practice-specific health record requirements. Unique combinations of trading partner requirements and business settings can also impact local record keeping requirements. Consequently, each user of health information is likely to have a unique opinion regarding what information belongs in a “standard EMR”, even within the same general care domain.

Despite the nearly infinite variety that is possible in user business requirements, however, there remains nearly universal agreement among U.S. healthcare providers regarding the *information requirements to support healthcare processes*. The requirements of care are driven expressly by evidence-based practice guidelines, comprising what we generally refer to as a Standard of Care (SOC).

The Opportunity

The opportunity, therefore, is to leverage the modeling work that we have undertaken in our quest for the standard EHR... into one master process model, essentially representing the universe of evidence-based medical practice for “Western Medicine”. From the SOC-based process model, we can derive a master *information model*, from which a standards-based health record template could be derived to support any organization’s potentially unique spectrum of care services. From the general process model, a developer should be able to create a sub-model or view that is constrained to exactly the same set of health problems that the provider wishes to manage... resulting in a set of practice-specific functional requirements for care.

Functional interoperability... at least, around critical care processes... should be reasonably assured, simply by requiring that all provider systems respect to the standard information model.

Next Steps

1. The most critical step is to identify an accredited Standards Development Organization (SDO), willing to develop and maintain comprehensive, integrated healthcare process and data models, covering all major care domains within “Western Medicine”.
2. A core team of experts should be permanently retained at the SDO level to accomplish the modeling work, manage the continuous vetting processes within user communities, and consider change requests, while maintaining the integrity of the overall model.
3. Develop a business plan to support a professionally managed, full-time development process. This should include a program of active outreach to users, requiring minimal user volunteer effort. Efficient, online, collaborative working environments should be utilized to maximize productivity and to minimize the cost to the [largely voluntary] vetting pool.

Origin of the quest for a standard medical record

As long as we have had healthcare, we have had health information stored in some kind of “record”. The earliest such records were probably kept in the provider’s memory, whereas today we use a combination of memory, paper, and computer media for recording health information.

For a variety of reasons, today’s individual health records have become fragmented into multiple information systems and dispersed, quite literally, across the planet. At the same time, the information inside the records has become more complex, and is being required on a regular basis by an increasing number of commercial, educational, and governmental information systems.

Estimates of the costs related to the *inefficiency* of our health information management process, range as high as 40% of the operating costs of the entire industry. In other words, our *inefficient information management paradigm* is needlessly adding upwards of \$ 7 Billion annually to the cost of healthcare.

There is widespread agreement that the dispersed, fragmented, multiform nature of health information... primarily attributable to our “anything-goes”, ad hoc record-keeping system... adds significant cost to the **use** of the information. Therefore, in the interest of reducing these use-related costs, several international standard organizations are presently collaborating toward the common, but elusive goal of a “standard electronic health record” definition. This global effort has come to be known simply as “EHR”.

The attached ISO/TC 215 Technical Report, entitled “Electronic Health Record Definition, Scope, and Context” (V0.1, July, 2003), provides an excellent overview of the most important EHR work to date. This paper assumes that the reader is familiar with the general concepts and references in the ISO report.

Scope and purpose of this document

This paper will outline an approach to the “EHR problem-space” that differs somewhat from the one outlined in the ISO document and the one being used within HL7. The approach recommended in this paper, however, is not new or revolutionary. In fact, most people working in the “EHR” problem space today are keenly aware of this approach, and will “privately” acknowledge that it is likely to be the most appropriate one for achieving our goal of improved interoperability. Unfortunately, few believe that it is implementable, due to perceived political and logistical barriers.

Therefore, the core mission of this paper is to make the case that these perceived barriers can be overcome... and that the approach recommended by most informatics experts is, in fact, the *only* approach that will result in true system interoperability and lower operational costs throughout healthcare.

What is the “real” problem here?

The simplest statement of the core problem being addressed by virtually all EHR work to date is, “*People can’t do everything they need to do with health information.*” The core problem is not that health records are “too fragmented”, “too different”, etc.. The *problem* is that, in the context of our present healthcare system, these and other factors are preventing organizations from properly *executing their missions*.

Record “fragmentation”... arguably, one of the greatest barriers to interoperability in today’s health information landscape... is not invariably a “problem”.

Fragmentation only becomes a business problem when a critical process requires the information fragments be reassembled... and the business system lacks a convenient way to do it. In such a case, however, data fragmentation would be a *secondary* problem. The primary problem would still be that the process requiring the non-fragmented form of the data remains “broken”.

Your computer’s hard drive is a good illustration of an information/record system in which “fragmentation” is only occasionally regarded as a problem. In fact, storing the information in a fragmented manner is actually faster and requires fewer system resources than attempting to keep all files in one piece. Therefore, operating systems have been intentionally designed to make hard drive data fragmentation unimportant for most computer operations, thus avoiding what would be a resource-expensive task of keeping every file contiguous. Fragmentation is simply a state. The problem arises when that state is incompatible with the process.

“I see the problem!”

“Problems” are simply barriers to the smooth execution of processes. Because some processes and problems occur repeatedly throughout our lives, most of us have developed a portfolio of favorite solutions to our most common problems. In fact, we do this so unconsciously that after a while, we may begin to actually *characterize* our most common problems as simply the lack of our favorite solutions. This is a very common trap to fall into and it tends to limit our thinking with respect to the solution space.

Most “EHR” discussions, seem to characterize the core problem as “Health information records are too different”, causing the secondary problem, “Health information that works in one system often will not work in another, without an expensive transformation process”. When the problem is stated this way, the natural solution would seem to be “Make health information records more alike”.

On the other hand, if we state the problem as “People can’t do everything they need to do with health information”, then the natural follow-up question is, “What is it that people are trying to do?”... leading to an analysis of the process and data requirements of the organizations using health information.

You can't avoid looking at the functional process requirements.

As you can see by reading the ISO report, it has proven nearly impossible for the standards community to agree on even the most basic definition of "Electronic Health Record" ... mainly because the participants have been attempting to imbed various process requirements into the definition of "health record". But if you accept the final, requirements-free ISO recommendation, you are left with a relatively unhelpful statement of the obvious: that the health *record* is simply the *container* for health *information*. To get from that definition to a useful understanding of why people are having problems making different systems work with information that providers would consider "the same", you must examine the functional requirements of the user processes... in each setting and circumstance, in which that health information is created or used.

Even if we agree that "difference in form" is the universal or greatest problem with health information and that "sameness in form" is our goal, it is still not obvious which data attributes would have to be kept the same across the industry. That can only be determined by analyzing the requirements of the processes that use the information. There are significant costs associated with keeping information forms *exactly* the same across potentially millions of disparate computer systems. Before we burden all of these systems with a highly specific "sameness" requirement for an element of health data, we should be certain that the proposed degree of "sameness" is truly necessary. Sometimes it is. But only a rigorous analysis of all potential users' functional requirements will provide justification for the **cost** of implementing such a "sameness" requirement as a national standard.

The origin of provider requirements

In Healthcare, as in most industries, the enterprise mission directly or indirectly drives all business process requirements. The typical healthcare provider describes his enterprise mission simply by listing the types of health problems he intends to manage, typically determined by his training and board certification. A provider may, however, further constrain his practice and may even choose to combine health problems from several certification areas into a single, "hybrid" practice. Thus, while an almost infinite number of possibilities exist for the *set of* care-requirements for a particular provider business, the individual component requirements should be relatively uniform across the industry.

Hospitals use essentially the same approach as "out-patient" providers, in defining scope of service. A hospital's service-mission is also constrained by its physical configuration and the certified capabilities of its doctors and staff. Its mission-critical requirements will be more numerous and possibly more complex than those of a professional practice, but they are still driven by the care-related aspects of the enterprise mission.

Regardless of the type of provider organization, the actual processes of rendering care are guided by both convention and a broad concept known as

“Standard of Care” (SOC). Other mission-critical business requirements are imposed by government regulation and trading partner contract.

Within broad healthcare paradigms like “Western Medicine”, there are generally recognized and well-understood minimum standards for the most appropriate ways to respond to presenting health problem information... the best tests to order, questions to ask, etc.... essentially, a set of “best practice” guidelines for how to manage virtually any collection of health problem information.

Formal treatment guides, produced by specialty societies and educational institutions are the principal components of SOC. Medical literature, case law, findings of peer review and quality assurance boards, and even the requirements of large insurance plans also impact our common understanding of SOC. SOC will never be stated as rigorously as the formal, “balloted standard” that we are familiar with in the informatics world, because the ultimate disposition of a patient’s health problem is always left to the judgment of the attending provider. Nevertheless, SOC remains a concrete and relatively uncontroversial guide to the “best” healthcare processes to invoke in response to the most common problem scenarios presented by patients.

In a very real sense, SOC represents a rational basis for a map or “cross-walk” between patient health problems and the typical provider’s care-process requirements. General business needs like scheduling, inventory control, and supply chain management, may also have special requirements related to each care specialty. Therefore, the mission-critical process requirements for any U.S. based provider organization can be expressed as the union of:

1. Known (SOC-suggested) care requirements for the provider’s specialty
2. Known general business requirements, modified as necessary for the care specialty
3. Known requirements imposed by trading partner contract and government regulation.

Matching provider requirements and system capabilities

In an ideal world, any provider seeking a business management system would simply compare his known process requirements to the stated capabilities of the “off the shelf” applications under consideration... and determine the optimal price-performance-value point for his company. Alternatively, he could present his list of requirements to a group of vendors, with a request for proposals to build custom software.

As we know, however, the world of provider system development is far from ideal. In our real world, smaller vendors typically piece together a unique understanding of provider business requirements for the area(s) of medical specialty they have chosen to support. Typically, this understanding is gained through an iterative process of speaking with users about what they believe is

“wrong” with the present version... implementing user recommendations... and listening to comments about the new version. Even when the PMS developer is a board certified provider in his chosen specialty area, his understanding of process requirements may be incomplete.

Among larger vendors, producing management systems for hospitals, large clinics, etc. the client is a little more likely to have the resources with which to present the vendor with a complete specification of system requirements. But the tendency to underestimate the cost and difficulty of “requirements analysis” is legendary in the world of software development... and is why this critical step rarely receives the attention it deserves. Incomplete understanding of system requirements is routinely claimed to be the “number one” cause for project failure.

Smaller providers frequently choose to “live with” non-fatal mismatches between their requirements and the capabilities of “off the shelf” PMS applications... in the hope that the practice will still see a net improvement in efficiency with the new system. To justify the enormous cost of a yet another evaluate-select-implement-train cycle, the “impedance mismatch” would have to be unusually painful or costly for the provider, or an obvious detriment to care.

Competition and Intentional Product/Service Differentiation

It is common and considered ethical for Company A to advertise that its products and services are superior to those of Company B... in almost every area of our marketplace *except healthcare*.

Healthcare professionals face almost unachievable business missions, in the sense that we all wish to provide the “best care possible” to each patient we see. Our rigorous certification system ensures that providers have the capabilities implied by their credentials. If the presenting problems are beyond the attending provider’s capabilities, however, a consulting provider is brought into the case or the patient is referred to another facility. In fact, doctors and hospitals strive valiantly and cooperatively toward our recognized SOC requirements... even when the payment model does not support that level of quality or cooperation.

This orientation toward the common good of our patients has produced a strong aversion to advertising that one provider’s healthcare services are “superior” to those of another within the same specialty. We tolerate such claims around products... even prescribed drugs and medical devices... but regard them as unconscionable when applied directly to healthcare services.

Quality differences among software applications

Providers and vendors not only expect to discuss qualitative differences among software products, but the provider’s purchase decision will ultimately turn on that

discussion and price. The areas of software quality most important to the provider are:

1. Ability to meet mission critical (care related) requirements
2. Ability to meet less essential, but desirable requirements
3. General system performance and reliability
4. Subjective quality of the user interface
5. Customer service

The most important area of software quality... how well the system meets mission-critical requirements... should always be tested against a rigorous requirements specification. Regardless of size, there will be a definable area of the provider's need that is essentially mandated by SOC. If all providers strive to deliver the core processes of healthcare in conformance with the generally accepted Standard of Care, then the functional system requirements for that area of business should be published as a national standard.

For smaller providers, there is no practical way to arrive at a list of measurable system requirements in the absence of a national standard. Quality considerations 2 through 5 above can be evaluated on a relatively informal basis in many cases, but any requirement that is essential to care... in the opinion of the provider community... should be expressed rigorously, as a national standard.

The dilemma of the standards committee

This leaves standards organizations with something of a dilemma. SDO membership tends to be dominated by large organizations, including government agencies, large hospital systems, clearinghouses, payers, larger software vendors, and large consulting firms. The all-volunteer labor model and high meeting costs favor larger organizations, who are able to send senior IT staff to the meetings and to absorb the cost of the labor intensive standards work that must be done between meetings. Smaller providers, comprising over 80% of the provider community, are virtually unrepresented at the SDO level.

System vendors who *have*, through their own diligence, developed proprietary application models that are well aligned with the mission-critical requirements of their customers, are reluctant to share that hard-won information with their competitors... who are also at the standards table. Therefore, when the requirements conversation becomes "a little too granular", the larger software vendors tend to object¹. Yet, all vendors realize that a clear standard will vastly

¹ Conversely, if the larger software vendors attempt to "drive" the national standard to be more aligned with their proprietary models... often suitable only for very large enterprises... then the smaller PMS vendors may consider this an "unfair bias" toward the wishes of the large vendors. The fact is, that every vendor secretly wants something very close to *his* model to be adopted as the national standard, because that will allow him to get a "standard" product to market in the shortest time, with the least effort.

lower future development costs and reduce the numbers of software iterations that are required to discover and meet critical provider requirements the “hard way”.

Doctors will not suddenly begin attending SDO meetings... even if the importance of such representation is widely understood and acknowledged throughout the provider community. Generally speaking, doctors do not have the time or capability to undertake the highly technical work of the SDO. Instead, a consortium of clinical subject matter experts will have to undertake the analysis and produce a “straw man” standard/model, on which “regular” providers may register comments. Eventually, with the collaboration of the standards committee, a final process model and requirements list can be sent to formal ballot.

Obtaining useful feedback from providers “in the field” will be challenging, but not impossible. Essentially the same requirements exist in other large enterprises outside of healthcare. Every day, project managers must find ways to explain process models and technical software specifications to the executives and business managers who will ultimately pay for and use the system. There are commercially available tools, able to create “doctor understandable” views of the type of standards products that I am proposing... and they can be used by standards committees to offer such views to doctors, office managers, hospital administrators, and PMS vendors for review and comment.

Larger hospital providers and system vendors often retain their own clinical subject matter experts and are directly represented within relevant standards committees. The needs of smaller hospitals, most “out patient” service providers, and smaller PMS vendors, however, are not being carried to the standards committee... because, quite simply, there is no one presently charged with that responsibility.

We simply must find a way to represent small provider business needs in our national standard... or we risk the demise of the small provider business model.

How do we resolve this dilemma... fairly?

Providers tend to want what is best for their patients. With respect to information management, that would be frictionless movement of structured, electronic health information throughout the industry. Functionally, this would be as though individual provider organizations were “departments” within a single, well-organized, global enterprise.

If providers were seated at the EHR standards table, there would be no reticence whatsoever to discuss their most granular care requirements in the presence of “competing” providers. There should be no such reticence among their system

developers. If their clients wish to collaborate around their most critical business requirements, and gather them into a single healthcare model, then vendors should help bring that to fruition.

When deciding how to differentiate their products for the sake of competition, system vendors should take their cues from their provider customers. If providers do not wish to compete with each other on the basis of critical care processes, then software vendors should steer clear of product differentiation in those critical areas, as well. The truth is that, despite their anti-advertising rhetoric, providers do actually compete with each other around the “softer” aspects of customer service or patient relationship management. System vendors could certainly exploit those areas for product differentiation... as well as improved business analysis tools, a more attractive or intuitive user interface, speedier performance, better technical support, more attractive licensing models, etc., etc.

It will be in the best long term interests of system vendors and users to agree on which functional processes the providers would like to keep uniform and consistent, across the industry... and which functional areas they would like to leave free for differentiation and competition. There is nothing wrong with honest competition. But we must not forget that this is the healthcare industry and that lives literally depend on system interoperability and efficiency. We should endeavor to respect the wishes of doctors in this important area. We must also work together to enable providers with an effective voice in the standards arena.

A healthcare provider should not accept a business system that is unable to meet essential, care-related requirements of his specialty area. It remains the burden of providers, however, to collectively express those requirements to the software industry in the form of a national standard.

Remaining sections:

- Describe internal SDO process for creating and managing process models and other components of provider business standards
- Propose a regulatory role for the federal government