



Standards Insight

An Analysis of Health Information Standards Development Initiatives

July 2003

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Introduction

In this issue we had planned to complete the analysis of the Electronic Health Record (EHR) and its required interoperability standards. But as we noted in the last issue, the Federal government is taking a much more active interest in the EHR. The Centers for Medicare and Medicaid (CMS) intends to begin a demonstration project in 2004 in which it will pay physician practices for using an EHR system. This initiative, partnering with the Agency for Healthcare Research and Quality (AHRQ) and the Leapfrog Group, is based on the premise that a functional EHR will provide higher quality and lower cost care. It will also yield data needed by CMS for further policy analysis; something the agency cannot obtain with current billing related data. Thus we are beginning, not completing, the analysis of the EHR based on a new approach.

In the April issue, we reviewed past and current efforts to define the EHR. We can summarize these as the most widely shared characteristics.

- It is electronic and replaces existing paper records.
- It supports all patient care processes.
- It is a patient centric clinical record of care encounters.
- It is produced and maintained by the care provider as a business record.
- It is longitudinal across providers, care settings and time.

We note that the definition is inherently contradictory since the EHR is at once produced and maintained by a care provider but must be shared across providers in different care setting over time. This creates the concept of a fractal like structure, in which each encounter is captured in some record and progressively aggregated into the longitudinal, cross provider EHR.¹ In fact in the United States we do not have either a paper-based model of the EHR or the system infrastructure to support it.

However this CMS initiative represents a serious reordering of our approach to the EHR. At a fundamental level one can speak of the EHR record as an entity or as a system. Within standards groups these have been informally referred to as the “small EHR” and the “all EHR”. Thus we have standards for the small EHR, such as ASTM E1384, and for the all EHR as advocated by the HIMSS Electronic Health Record Steering Committee (formerly the Computerized Patient Record Institute). CMS has jumped beyond such distinctions and is seeking a standard EHR functional model. Moreover the functions are not simply those needed to create and maintain an EHR, but are the care process functions that should result in better patient safety and quality outcomes. Example functions given by CMS include ePrescribing (ambulatory CPOE), eLabs and eReminders. Two things are immediately apparent. The functional model is first about process and workflow not interoperability. We are not submerged in the technicalities of traditional interoperability standards, such as messaging, code sets and structured documents. Secondly, CMS proposes financial incentives to help make the business case based on the functional model. Recall that we identified lack of a financial ROI or the business case as the primary impediment to wide spread use of the EHR. This EHR Functional Model creates an interesting “rule-making” dynamic within Health Level 7 (HL7), which has been designated to develop the functional model.

The Electronic Health Record Continued

The CMS EHR Initiative

At the HL7 spring working group meeting at the end of April, CMS and the Veterans Health Administration (VHA) proposed that the HL7 EHR Special Interest Group (SIG) develop an EHR

¹ We assume that there are key characteristics that exist in all medical records including patient and provider identification and patient clinical content. Thus a nursing note is both complete as a record and also a component of patient chart, another record, that is a component of the institutional medical record and so forth.

functional model by September. CMS plans to demonstrate an incentive based quality initiative, focused on physician practices, beginning in January. This initiative is also seen as a way to control process and costs and will probably be at the heart of any Bush administration healthcare reforms. It appears that high administrative sources have bought the Leapfrog proposition, pay for quality, as the next paradigm shift after managed care. CMS intends to provide financial incentives to physician practices for using an electronic health record system. It sees the EHR as an enabling technology to improve patient care and to eventually provide CMS with better clinical data for their database. To make this happen, CMS wants a functional EHR model that it will use to prepare guidelines for what EHR systems qualify for reimbursement. CMS has agreed to make the VA the lead agency in the model project. Both turned to HL7 to develop a standards-based model by September. HL7 was chosen because of its reputation in clinical standards and because it already has a consensus standards process in place with wide industry participation. This process enables appropriate avenues for informative and normative documents, each involving balloting procedures and negative ballot resolution procedures. There is also an obvious concern among vendors that the functional model will become a checklist for EHR products that qualify for reimbursement. In fact a CMS spokesman stated that this initiative was intended to send a signal to the market place. This demonstration will first freeze the market while physician practices, and other providers that note CMS' direction see what is happening, and then it might provide competitive advantage or disadvantage based on who gets what into the standard.

To meet the CMS deadlines HL7 decided to offer the model as a Draft Standard for Trial Use for the September ballot cycle. This means that the ballot must go out to members and interested parties by August 1st with the intention of achieving the necessary reconciliation and two-thirds consensus at the HL7 September plenary meeting. Depending on the ballot feedback, a ballot on a normative standard (90 percent approval) for the functional model and at least the ambulatory (physician practice) care setting will be set for approval at the January meeting. This is a very aggressive timeline and open to many technical and political hurdles.

The EHR Functional Model

To launch the effort, the EHR SIG co-chairs developed a functional model and presented it to the SIG and other interested parties in a meeting June 17 and 18. The co-chairs created a general functional model that could be extended through profiles to different care settings and national realms. As shown in the accompanying graphic, the model is constructed on two axes: one defining functions and the other care settings. Thus there is a set of essential (core) infrastructure functions, e.g., security, that are common to all EHRs in any care setting. Similarly there are essential care delivery functions, e.g., order management. Care setting profiles intersect the functions. Different care settings, e.g., inpatient or ambulatory, might have different specific functional requirements for a generic requirement. Moreover, different care settings might have a specific functional requirement "unique" to the care setting.

A function will be hierarchical, with greater granularity and increasing specificity as one traverses downward. For the initial model in September, the essential functions will probably be defined to no more than three levels. Each function will be described as a triplet: function, rationale and metric. Depending on where one starts, one may or may not drill down to the detail necessary to create a metric or conformance statement, which will be necessary for CMS' use.

The functional model development is further complicated by the decision to align the care settings with an Institute of Medicine (IOM) patient safety study now in process. The IOM study, scheduled to be published in August, is expected to describe at least four care settings: inpatient, ambulatory, nursing home and personal health. These settings caused considerable debate within the EHR SIG. The first issue is the timeline. If the IOM care settings are used, they may not be available when the HL7 ballot is opened August 1st. As now understood, the four settings are inadequate, particularly in terms of categorizing non-inpatient care. A physician practice EHR is unlikely to have the same detailed functions as an outpatient department or emergency department EHR. Home-based care will require different functions than a skilled nursing home EHR. The personal health record is incompatible with the formal definition of an EHR, which is a provider-generated record of care. Nonetheless, a personal health record may be an important

New England Journal of Medicine shows the relative softness of the data.³ There is only one reference to actual improvement in patient outcomes, i.e., reduced mortality with remote ICU monitoring. All of the other references are to reducing errors or other process improvements. While we all accept the fact that improving processes and reducing errors should improve patient outcomes and reduce costs, we have little hard evidence. Reducing medication errors is certainly an important goal, but at what costs and compared to what other uses of funds?

HL7 is being thrust into a new and potentially uncomfortable role at a time when it is attempting to move Version 3.0 forward. As a Standards Development Organization (SDO) it has never published EHR standards or functional models of care processes. It has deliberately tried to avoid setting standards for “applications” and has yet to gain much market acceptance for its conformance profiles. It has been an organization of studiously observed vendor neutrality. Some of the overall EHR standard process and potential application by CMS will smack of picking winners and losers. Moreover, this new “model” is potentially incongruent with its Version 3.0 reference information model and HL7 Development Framework. In fact an EHR functional model could well represent the superstructure that rationalizes and organizes the messaging and document standards. But as noted, HL7 recognizes the importance of this activity – if it leads to incentives to use EHRs – and the need for an organization with the necessary governance and size to produce a document that will be viewed as an open consensus. One final note, while CMS sees the EHR as the basis for improving care and, potentially, controlling costs, it may not be willing or able to provide the necessary financial incentives, particularly to physician practices. At best this demonstration will start out as a zero sum game. Peering intently over the shoulder of this experiment, the rest of healthcare, particularly the hospital industry, will be watching to see how this plays out. Just as we noted in the March issue of *Standards Insight* in regards to Leapfrog’s realization that it had to share a value proposition with providers, CMS will also have to make the business case.⁴ Is it willing to pay for quality clinical care rather than quality clinical billing to paraphrase Bates and Gawande?⁵ At a minimum it must show providers how they will earn some operating return on their investment. Requiring use of an EHR through regulation as a “cost of doing business” is an unfunded mandate, which will be strongly resisted by the industry still trying to afford HIPAA. Again we note that each function to be included in the model is to be supported by a “rationale”, which will be critical to the EHR’s real world acceptance.

Further EHR Interoperability Considerations

A careful reader will have noted that the EHR Functional Model does not directly address interoperability requirements either within a care setting profile, or more significantly between care setting profiles. What is true in the model will also be true in the instance of an individual provider organization’s implementation of an EHR system. One could use the EHR functions as embodied in a care setting profile as a good requirements document. However, one could implement the EHR as a series of best of breed modules or as a single vendor’s monolithic solution, the same choice one has today. The former requires more extensive messaging interfacing of course. When HL7 delivers interoperable Version 3.0 messaging standards that facilitate conformance to application roles, one would have additional opportunity to combine applications from various sources. In the meantime, Integrating the Healthcare Enterprise (IHE) may target development of its next set of integration profiles, using existing standards such as HL7 Version 2.X, on EHR functions. But in either case the primary focus is interoperability within an enterprise.

It is highly likely that some interoperability across care settings will naturally come out of defining EHR functions. Longitudinal records and clinician access to whatever data is needed will lead to access across care settings. Certainly, ePrescribing cannot be well implemented without data exchange between the physician practice and a pharmacy. We have previously discussed the

³ D. Bates and A. Gawande. “Improving Safety with Information Technology”. *N Engl J Med* 2003; 348: 2526-34.

⁴ The March 2003 issue of *Standards Insight* and other past issues are available to all HIMSS members on their personal Start Page at www.himss.org.

⁵ D. Bates and A. Gawande. Op. cit.

significant challenge of interoperability outside a single enterprise.⁶ Technical and business issues concerning security, privacy and business agreements are the key barriers in addition to the technical issues of data exchange.

The Continuity of Care Record

The Massachusetts Medical Society along with ASTM E31 and HIMSS are addressing the issue of patient data summaries used for transfers, referrals and discharges more directly. They propose a standard for a Continuity of Care Record (CCR) that is modeled on a paper form required in Massachusetts. The CCR will include basic minimum data, such as diagnoses, procedures, medications and care plans, that is needed by a new care provider. The CCR is seen as an intermediate, short-term solution to an interoperable EHR system. It is not clear whether the CCR is simply a new XML based form to be created by each provider or if it can be derived from other computer sources. Structure, codes and message standards are yet to be addressed. The use of a standard summary or abstract may in fact be the most viable means of sharing patient information between other providers and with secondary users. Whether this initiative has the support of other standards bodies and potential primary and secondary users or if it can be aligned with other efforts, such as the EHR Functional Model, open EHR, the HL7 CDA and so forth remains to be seen. Specifically the CCR may precede EHR interoperability but should be compatible with those initiatives to avoid being a non-conforming standard that cannot be derived from an EHR.

State of EHR interoperability standards

Interoperability standards depend on the definition of the EHR and the expected level of interoperability. Specifically we need to understand if the standard is to define the content of the EHR, the functions of the EHR, the interoperability within or between EHRs, or the interoperability of the EHR systems.

Today as in the past, most clinical interoperability standards are at the level of data messaging. As we all well know, the challenge of fully specifying the semantics and syntax of individual messages and assembling them into integrated profiles to support workflow is the current challenge of HL7, IHE and others. Most of the work is based on the presumption of messages and workflow within an enterprise. This reflects the relative value of using data effectively within the enterprise to provide care as well as the complexity of security and business partner relationships outside the enterprise. The core rationale for the EHR is to improve patient care and efficiency within a provider organization. But this internal value does not address the EHR's inherent value in providing continuity and coordination of care among providers or in supporting the needs of secondary users, such as public health, clinical researchers and others. This requires a supra organizational or cross enterprise record.

The National Healthcare Information Infrastructure

There are at least three sets of interrelated parameters one must address in looking at cross enterprise EHR interoperability.

- Centralized or decentralized records
- Complete EHR or abstracted summary and/or pointer system
- Shared system or silo applications.

These parameters are currently being considered within the context of the National Healthcare Information Infrastructure (NHII). As outlined by the NCVHS in its 1999 report, the NHII is much more than an interoperable EHR but nonetheless builds upon the EHR. As we discussed in April, the NHII is envisioned as supporting three health domains including those of the provider, personal health and the community or public. William Yasnoff, M.D., the senior HHS advisor on the NHII adds a distinct fourth domain for research and policy.

⁶ *Standards Insight*, June 2002.

There are a set of technical issues that derive from the definition of the EHR and its uses within the context of the NHII. We must assume that all providers have a computerized patient record and record system – the source system. We know that these systems are generally of proprietary design but supportive of some level of transaction based exchange of data. Such exchange is based on existing standards, primarily HL7 Version 2.x.whose site-specific implementations do not support plug and play. If such EHR systems existed at each provider organization, we move to a basic design concept of whether the EHR is a centralized aggregation of all a person's encounter records, e.g., a copy of the electronic medical record from each provider, or a abstracted version (key clinical information of ongoing value such as the CCR) of all of an individual's encounter, or a directory system that points to all of the patient's encounter records in each of the providers' systems. This design decision will dictate how each provider must interact with the supra organizational record and what type of interoperability standards one requires. For example, if key data is extracted, then one could imagine requiring each provider to simply have software to abstract and code according to some standard template, regardless of how the provider organization actually uses and stores the data for internal use. On the other hand, if one were uploading an entire medical record to be serialized with records from other providers then one might want a standard medical record used by all providers. We would presume that an EHR system would not want all the data in a medical record. For example much of the data in a hospital inpatient record would not be of value for future patient care although it must be maintained for medical legal reasons. Obviously we are coming full circle back to the policy issues surrounding the purpose, creation and maintenance of the EHR.

The EHR within the NHII

| | Real Time Access | Periodic Access | Type of Standards Required | Stewardship and Business Structure |
|-------------------------|--|--|--|--|
| Functional EHR | Care provider | | Functions by care settings Plus EHR standards | Provider organization |
| EHR | Care provider | Medical-legal Operations and billing | Standard EHR context (structured documents) and content (pre-coordinated coding) | Provider organization |
| EHR Copy | New care provider Lifetime EHR | Clinical data mining | EHR standard as above or transforms with template repository (post coordinated coding) | National/regional repositories NHII |
| Extracts* and summaries | Lifetime EHR Public Health Discharge, transfer or referral Disease Management | QA/Outcomes Billing Population Studies Trials | Extraction Templates /Parser Standard messaging and codes | Potentially silo applications and national infrastructure (NHII) |
| Pointers | Emergency care, transfer or referral | Drill downs from extracts | EHR standard or templates | National infrastructure |

| | | | | |
|--|--|--|-------------------------|--|
| | | | Mark-ups Directories | |
|--|--|--|-------------------------|--|

*One might want extracts with pointers to the actual record.

As shown in the matrix, depending on the EHR model and use case, different standards would be needed, different stewards would be tasked and a different infrastructure would be developed. The NHII is at this point more concept than reality, lacking real program funding. As envisioned by Dr. Yasnoff and others the NHII will be a distributed system, which allows different users to exchange information with others as needed. The NHII is probably an Internet based series of directories and repositories and a set of defined abstract based reporting and querying standards. The NHII would have to be supported by new regulation, business processes and arrangements. The problem is funding the infrastructure since no one participant would have the interest or resources to build it even if the technical model and standards existed.

A National Standard Medical Terminology?

The Core Terminology Group

We noted last issue that the National Committee on Vital and Health Statistics (NCVHS) is analyzing codes and vocabularies in order to make recommendations to the Secretary of HHS, addressing the creation/promotion of national terminology standards for Patient Medical Record Information (PMRI). This is part of a larger undertaking by the NCVHS to study the issues related to the adoption of uniform data standards for PMRI and the electronic exchange of such information, as mandated by the HIPAA legislation of 1996. One recalls that NCVHS made similar recommendations in regards to PMR messaging standards in February 2002. Interestingly NCVHS' charter does not define the EHR/PMR or its purpose.

As described in the Draft Report from Walter Sujansky,

“The Core Terminology Group is intended to comprise a “core” set of medical terminologies that, together, are sufficiently comprehensive, technically sound, mutually consistent, and readily available so as to deliver most of the envisioned functionality of a national standard medical terminology. These related terminologies include standard administrative, financial, and regulatory terminologies, as well as important legacy terminologies. No terminologies in these related groups would be selected as part of the PMRI terminology standards recommendations. The recommendations may, however, highlight the need to map the core terminologies to certain of these related terminologies in order to facilitate adoption and use of the proposed standard.”⁷

NCVHS Hearings

Last month NCVHS held hearings on the candidate code sets. The author, on behalf of HIMSS, provided testimony questioning not the overall need for standard codes but the timing, the lack of clear definition of the EHR and inadequate consideration of market acceptance.⁸ In particular, we noted that without a definition of the EHR, as discussed in the matrix, and its system, choosing code sets was premature and potentially counter productive. It is one thing to have a reference terminology for post-coordination coding for secondary users. It is another to have a pre-coordinated code set for real time clinician entry, decision support and public health reporting. However, the political reality is that the Federal government, nominally through the eGov initiatives and Consolidated Health Informatics (CHI), will set its own terminology and code standards by the end of the year, with or without recommendations of the NCVHS.

⁷ Summary and Analysis of Terminology Questionnaires Submitted by Developers of Candidate Terminologies for PMRI Standards. A Draft Report to the National Committee on Vital and Health Statistics. Subcommittee on Standards and Security. March 25, 2003.

⁸ Testimony is available at the NCVHS web site under the May 20-22 Meetings of the Subcommittee on Standards and Security. www.ncvhs.hhs.gov

SNOMED CT is widely perceived as the strongest and most comprehensive clinical terminology. However, it is not widely implemented, and is less comprehensive for drugs, lab values, devices and nursing terminology. According to testimony, it is perceived by vendors as too expensive to embed in their systems and has not been widely deployed commercially. But many vendors appear to be using subsets as reference terminology with some expectation that the Federal government will arrange better licensing terms. Finally SNOMED is a good reference terminology but not a good user interface language, i.e., it is unwieldy for end users to use in directly entering data. This was the concern raised earlier in this issue regarding the purpose and scope of the EHR. It has serious implications in regards authenticity of records if the medical record is “post coordinated”, i.e., semantic meaning given to the record after the fact through a coding process.

In addition to the problem of post-coordination, not using the codes at the time of entry defeats clinical decision support use. Most vendors expect to use proprietary coding and forms for user entry mapped to the reference code set. The mapping process was identified as a difficult and expensive maintenance activity.

The Markle Foundation and its Connecting for Health initiative offered 16 preliminary terminology consensus statements. The most important may have been pointing to the need for Federal authority, governance and maintenance oversight. While the National Library of Medicine (NLM) appears to be one governmental candidate, this is an opportunity for an organization or organizations looking for a role as a quasi-public agency. This certainly was the pattern in the growth of the HIPAA industry

The Security and Standards subcommittee and the full NCVHS committee are going to make their recommendations by September. They may send a letter to the Secretary by July to simply confirm progress and reinforce the directions that CHI is taking. They appear headed towards designating SNOMED, one of the drug code sets, and LOINC (for labs only) as the recommended clinical core terminology group for the national medical standards. They may make it conditional on agreement of these standards groups to coordinate activity, to make their standards available at “no” cost and to allow some derivative works. Note that other code set developers, such as LOINC may also be concerned about the direction this is going. LOINC clinical codes would not be approved since they overlap with the Reed codes in SNOMED CT. Currently, nursing terminology is not being considered as part of the core group. One of the drug code bodies, including First Data Bank, NDS, NDF RT and RX Norm, will be chosen at the expense of the others. Governance and ongoing maintenance and coordination will cause political problems. And finally the business case will dictate whether any of this matters. Even the subcommittee acknowledged that clinical terminologies would not be adopted if they add costs or require process changes without clear benefit to the user.

Post Script

As this issue was being finalized, the Department of Health and Human Services (HHS) announced that it had signed the long anticipated agreement with the College of American Pathologists to license SNOMED.⁹ The license allows the National Library of Medicine to distribute SNOMED CT and previous versions as part of its Unified Medical Language System (UMLS). The license extends to all United States based healthcare users at no charge and subject to certain use restrictions. It is a perpetual license for SNOMED releases during the five years of the agreement. Access to new SNOMED releases after 5 years is conditional upon a new agreement.

The HHS press release also noted that it had commissioned the IOM to develop an EHR model, and that HL7 would evaluate the model. Although this was initially understood to be a misstatement, it appears as if HHS leadership does expect the IOM model to be adopted. IOM will produce a functional model in August. IOM is aware of the HL7 Functional Model and it is anticipated that the IOM model can be mapped into the HL7 EHR Functional Model for evaluation

⁹ www.hhs.gov/new/press/2003pres/20030701.html

and potential inclusion in the ballot process. While this has created some concerns and confusion about the relative roles of IOM and HL7, it is likely that the IOM “model” will be a sufficiently high-level to be broadly acceptable. The press release also stated that HHS would distribute the model free of charge. This issue has not been resolved with HL7, which retains copyright to all its standards. Moreover, some reports, such as those in the Wall Street Journal, went further to say that HHS would distribute EHR software freely. While it is possible that public domain software, such as the VHA’s VistA, may meet the new EHR standard, the expectation is that the HCIT industry will develop, sell and support most EHR implementations.

Thus we end our EHR analysis encouraged by the zeal with which HHS is looking to healthcare IT to help improve quality and reduce costs. Now the hard part for all of us that have promoted the use of clinical information systems - delivering on the promises.

Please direct any questions, suggestions or comments regarding *Standards Insight* to Joyce Sensmeier (jsensmeier@himss.org) or its author, Ed Larsen (erlarsen@erlinc.com).