



## Standards Insight

### An Analysis of Health Information Standards Development Initiatives

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### Launching the decade of health information technology

We are coming to the end of the first year in the “*Decade of Health Information Technology: Delivering Consumer-Centric and Information-Rich Health Care*”. We can be encouraged at the progress. We have a 10-year goal for electronic health records (EHRs) and a framework for strategic action. We have achieved a level of consensus on the functions to be expected in an EHR system, and we have taken the first steps towards broad implementation of e-prescribing based on open standards. Investment in health information technology, primarily to improve clinical processes, is increasing 10 percent annually. Serious studies have produced proposals for addressing reimbursement, the business case and return on investment (ROI) issues. While this column is being written prior to knowing the outcome of the Presidential and Congressional Elections, we are assured that there is broad bi-partisan support for HCIT. We may be able to look back and say that 2004 was the tipping point.

Nevertheless, interoperability standards continue to be a critical factor in moving forward with this 21<sup>st</sup> Century health system and progress here is less clear. We have argued from time to time that the most significant problem faced by standards developers is lack of clear business requirements not technical or domain complexity. As examples, standards developers are wrestling with two key strategic issues: the role of functional standards

and the goal of semantic interoperability. This month we examine each in terms of technical problems and business solutions.

### **The role of functional standards**

In the spring of 2003, the Department of Health and Human Services (HHS) asked Health Level Seven (HL7) to develop an EHR system functional standard--based on some preliminary work by the Institute of Medicine-- by the end of that year. HHS intended to use such a standard as a basis for differentiated reimbursement, first as pay for use and then pay for performance. While requiring two ballots, HL7 produced its draft standard for trial use (DSTU) in just 15 months. The DSTU process had widespread and open participation and is now the basis for developing minimum function sets (MFS) for the U.S. realm. The MFS are constraints laid upon the full function set, appropriate to a care setting such as a small hospital or physician practice. For example, of the 140 EHR functions enumerated in the model, 40 are proposed to be “essential now” for small-to mid-size physician practice systems. About half of these are clinical, and the rest are supportive or infrastructure. In addition to the constraints, the HL7 EHR Technical Committee is expected to produce a conformance statement for each of the functions in a MFS. The intent of the HL7 EHR TC is to ballot these MFS over the next six months. Although we can expect disagreements, the open consensus process will eventually produce a balloted standard.

However, it is no longer clear how or if HHS will use these MFS in any reimbursement change. In fact, the strategic framework calls for a private sector body to certify “functionality, security and interoperability.” The Certification Commission for Health Information Technology (CCHIT) proposes to provide this function. Certification cannot exist absent standards, and it is not clear that CCHIT sees its role as merely certifying conformance to existing standards. We may see “standards” used by HHS that are being constructed in a non-open and non-consensus process. While we have long called for industry leadership to guide standards developers, we have viewed this as an upfront requirements activity-- not a backend certification step. Thus we have unclear business requirements from HHS and different methods to produce functional standards. This is further confounded if CCHIT certified standards are not authorized and accepted by the ultimate stakeholders, payers and providers.

### **The goal of semantic interoperability**

When HL7 began the journey from Version 2 messages to the current reference information model based Version 3, it envisioned non-ambiguous messaging between systems. This meant developing well-defined terms, structures and transaction rules not from the bottom up message but from a top down information model. Semantic interoperability, while technically the unquestioned goal, was never fully vetted by industry stakeholders in terms of timeframe, transitions, tradeoffs and costs. Meanwhile creating an information model for as complex and detailed a domain as health care has given rise to many delays and challenges. As technologies and systems evolved to

encompass XML, documents and workflow, a single reference information model became fractured between:

- Terminology model - sets of well defined terms
- Static information model –content defined by structures and terms
- Dynamic model – defined roles and transaction rules.

It should be readily apparent that these models overlap and represent different perspectives and in some cases interests. For example, semantics (meaning) can be derived from a highly detailed coded vocabulary, a highly structured container, or some combination. In developing standards it is important to establish these patterns. When HHS designated SNOMED CT as the core reference terminology, it did not solve the semantic interoperability problem, but it did constrain the technical solutions for both the static and dynamic models. Developers are left with how to use the terminology versus structure within clinical statements, messages and documents. For example, the timing of coding, whether pre-coordinated or post-coordinated, becomes exceptionally important in designing systems such as clinical decision support applications and interfaces. If the implemented message requires a SNOMED code, then clinical decision support using that message can only be applied after coded entry or mapping is accomplished. The dynamic model, the rules for using the semantics, defines applications' roles and responsibilities. In a sense the dynamic model is the most granular form of the functional model. Are applications defined by meeting high-level functions or by adhering to the roles and responsibility of the dynamic model? This is no small issue for conformance or system design. Again using the clinical decision support example of drug-allergy checking, an EHR system functionally could be required to support a real time query interface for allergies by a "foreign" e-prescribing system. How is this interface mandated in the functional model, implemented in a dynamic model and generated with content produced from the static model? What is the level of conformance certification? How does the goal semantic interoperability fit into the national business requirements, frameworks and roadmaps?

### **The business requirement – technical solution interface**

The problems faced by the standards developers are not unlike those of any IT project team. Without clear business requirements, priorities, resources and timelines at the front end, development becomes an endless task. It is clear that HL7, the pre-eminent standards development organization, is being driven more by international affiliates that are being charged with solving real problems and meeting real requirements within a constrained timeframe. Hence the UK and Canada, in particular, and other early adopters have pushed HL7 to move forward past model and method building to implementation guides. We have yet to produce an equivalent focused urgency in the U.S. and it is unlikely to come without specific project requirements backed by a critical mass of stakeholders.

Let us be clear, technical standard development organizations are not equipped or empowered to define up front business requirements and make the tradeoffs necessary to meet business objectives. This may be why MFS development should not be the

responsibility of HL7, but in fact should be left to stakeholders. On the other hand, commissions, advisory boards and executive leadership are unsuited to design or develop technical solutions.

Once again, we have policy makers making technical decisions about code sets but not setting out clear business requirements. In particular economic stakeholders must set requirements for which they will pay. We have encouraged CMS as the largest single purchaser of healthcare to propose specific pay for use/performance terms. We need to know these EHR system requirements (how the EHR is to be used, how it is to be paid for and how we make the transition) and the infrastructure plan. Yet such policy makers and industry leaders continue to want to specify and develop interoperability standards whether directly or through conformance certification and not to define what they will require and consequently pay for.

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