Standards Insight

An Analysis of Health Information Standards Development Initiatives

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Introduction

In the May *Standards Insight*, we discussed the importance of defining interoperability in order to set expectations, scope, required resources and timing. We indicated our preference for a definition that went beyond describing how computer systems interact to one describing how healthcare organizations interact. And therein is the great problem of interoperability. Computer systems require relatively simple, definitive rules whereas healthcare is very complex, delivered within a highly specialized and decentralized "system."

Seeking to impose IT simplicity on the complex real world of healthcare

Lack of interoperability standards is widely cited as a major impediment to achieving the many proposed benefits of health information technology (HIT). But the very need for interoperability standards points to the reality that there are systems that currently operate differently, not the least among these being paper-based manual systems. These systems operate within the context of human organizations that operate differently and are even operated differently by individuals within each organization. We are, thus, trying not only to standardize computer systems but much more significantly standardize provider organizations' workflow, processes and use of information. In fact, as a matter of strategic policy, some groups, such as the Leapfrog Group, have promoted IT, i.e., computerized physician order entry, to impose practice standards on physicians in an attempt to reduce undesirable variation in real world care delivery.

The HIT industry has long promoted clinical systems as being flexible and configurable to adapt to clinician preferences. Much of the cost of implementation is configuring system tables to mimic the current organizational forms, processes and idiosyncrasies and then training users to accept residual inflexibility. It is nice to imagine systems that could transform free text forms into standardized data, much as systems can provide different views of the same data, but we are nowhere near such natural language processing or trusting that machines can add meaning and precision to that which was not originally input by the clinician. While many in executive leadership positions are willing to concede that hospitals and physician offices are much more alike than they are different, this is still not the prevalent sales and implementation paradigm.

As an aside, we note the ongoing debate within the larger IT space, whether IT is a public utility or strategic asset. Nicholas Carr's *Harvard Business Review* article (May 2003) "IT Doesn't Matter" points to a much different IT landscape than promoted by many leading vendors. HIT is still positioned as providing strategic, competitive value and return on investment for large provider organizations. Thus we implement systems to accommodate organizational differentiation and preferences, which is 180 degrees contrary to inter-system interoperability. An important exception is emerging in the critically important small physician practice segment. Here we see the realization that EHR systems must be delivered as a utility with as little complexity in operation, training and support as possible. The system must be simple and "inflexible." Refer to the recent Key Learnings Report from the Center for Health Information Technology of the American Academy of Family Practice (http://www.centerforhit.org/). Any close reading of the National Coordinator of HIT's objectives for the national health information network shows a much closer fit to the public utility model of computing than a model of proprietary systems for competitive advantage.

An Example from IHE

Healthcare is a complex domain, further layered with specializations organized as a cottage industry paid for piecework. Developing IT standards to overlay this reality is an exercise akin to forecasting weather using a model that incorporates the chaotic "butterfly effect." A recent meeting hosted by Integrating the Healthcare Enterprise (IHE) is an illustrative case study. In April, IHE and its newly formed Patient Care Coordination domain convened an outreach meeting for clinicians and IT standards experts to develop an interoperability profile for a primary care referral to a specialist, certainly a routine, common place event in healthcare. Using the best IT development practices, the group began with a storyboard, to be reduced to use cases and then to requirements to be matched against existing interoperability standards, such as the Health Level Seven (HL7) Clinical Document Architecture (CDA) Care Record Summary or the ASTM Continuity of Care Record. It should be noted that the IT community has such existing, though not widely used or in a final form, standards for patient referrals. The point of the meeting was not to develop interoperability standards but to develop interoperability requirements.

To begin, it was necessary to determine if the storyboard was specific to a specialty, e.g., an orthopedic versus cardiac versus referral, or if it was generic. The former prevailed with the hope it could be abstracted at a future point to cover the generic case. Then the group began to identify the storyboard preconditions. What information, in what form, existed before the referral? What assumptions can be made about whether the referrer has an EHR system, whether its data stores are coded, structured and could be mapped to some reference standard? From there it was necessary to decide what the "minimum" required data to be included in the referral itself. What are the minimum data set and format (coded, free text) that a sender must convey? The minimum data needed to be described in terms of expected human and system interoperability. What then are the role and responsibility of the receiver?

Let's look at two examples of the complexity to simplicity problem. Consider if allergies were included in the minimum data set. Can a receiving system assume that if an allergy is listed, it is true and verified by a clinician, that the list is complete and that a blank field indicates no known allergies. In the latter case, it was recently noted by HL7 that in its reference information model there were twelve forms of null from "no" to unknown, to known but not shared. If the receiving application were a drug checker or decision support application, how would it process these variations? Or would the clinicians at the receiving end simply redo the medical history and manually verify all entries before they are entered into their own systems? One of the assumed underlying benefits of interoperability is that applications can reuse information without manual validation. A second example springs from referral business rules unrelated to the interoperability of the referral record. How is the specialist chosen? Does the specialist have to accept the patient? Is insurance eligibility a pre-condition for acceptance? Is scheduling the referral event necessary? How are privacy and security assured through the series of transactions?

Standardizing Complexity

And now we get back to our initial working assumption - that we can develop requirements for an orthopedic referral that can be abstracted to a level that could also be applied to a cardiology referral. In our two examples, the referral record and business transaction sets will vary significantly at the detail level depending on the nature of the referral. A cardiologist might require a much more complete history than an orthopedic surgeon, for example. Thus even as we simplified and standardized one referral, we confronted the differences of other referrals. How can we create simple standards that handle complex reality? One might consider two options: an information model versus a pragmatic instance approach to resolving complex problems. One can, as has HL7, decide that in order to insure interoperable messages and documents there is a need for an abstract reference model that encompasses all use cases. Rules for applying constraints to the abstract model are employed to derive a single message, e.g., a referral. Alternatively one could, as did ASTM, develop a specific referral structure that included all possible data any referral would need. The former approach is much lengthier and more complex in form, but applicable to many message and document types. The latter approach is shorter and results in simpler structure but cannot be easily extended to other

use cases. Of course, neither approach defined the minimum data content to be sent for any given referral or the business rules for sender and receiver.

The foregoing discussion is not offered to discourage or dissuade those so anxiously seeking interoperability standards. But it is intended as a reminder of the complexity of what we are about and a plea not to saddle IT with solving all the problems of our current complex and fragmented healthcare system. In the end, the HIT industry wants clear interoperability requirements for a highly complex domain - hence our need for definition and scope. Surely we will need to implement in simple, discrete steps, such as proposed by IHE, but implementation should be guided by a roadmap and an interoperability framework that allows us to consistently and progressively map the complexity of the real world to simple technical standards.

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