Standards Insight

An Analysis of Health Information Standards Development Initiatives

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Defining Interoperability on the Road to Clinical Transformation

Introduction

Last month, I mentioned the ongoing controversy over defining interoperability. During its town hall meeting at HIMSS 2005 Annual Conference and Exhibition, the Certification Commission for Healthcare Information Technology (CCHIT) had announced its intent not to define "interoperability." Rather they planned to define interoperability through specific use case requirements. The Health Level Seven (HL7) EHR Technical Committee has had a lengthy exchange about a definition of interoperability on its list serve. The Technical Committee is now formally taking on the issue as a project to define the interoperability requirements necessary to support their EHR system functional model. The National Alliance for Health Information Technology (NAHIT) has also weighed by developing a definition and convening a teleconference to generate dialog. NAHIT's view is made more important since its president is Chair of the Commission for Systemic Interoperability. The debate continues. As we will see, the proposed definition(s) essentially address technical interoperability between computer systems.

Why is defining interoperability so important? Certainly, lack of interoperability is commonly cited as the biggest barrier to attaining the promised benefits of HIT investment. One's definition of interoperability shapes the size and scope of the problem and thus the response in terms of policy, resources and priorities.

In last fall's Request for Information, the Office of the National Coordinator for Health Information Technology (ONCHIT) offered a different perspective on interoperability as "the ability (of computer systems) to exchange patient health information among disparate clinicians and other authorized entities in real time and under stringent security, privacy and other protections. Interoperability is an essential factor in using health information technology to improve the quality and efficiency of health care in the United States." We agree with ONCHIT's definition and its reference to end users, not just systems. Interoperability is first defined by the clinical and business objectives we are trying to achieve - not by the technology capabilities. As we will discuss in this issue, defining interoperability takes us beyond systems to the real world issue of healthcare transformation and provider "interoperability."

A brief history of HIT interoperability

The emergence of departmental "best of breed" systems and local area networking in the 1980's led to both the requirement and technical opportunity to share data among systems within hospitals. This was the genesis of HL7 - developing messaging standards for use between computer systems within a hospital. HL7 Version 2.X standards were widely adopted during the 1990's and are now estimated to be in use within interfaces in over 80 percent of hospitals. However, such interfaces still require hand-tweaking at each site and specialized transformations by interface engines. These shortcomings led to the concept of "plug and play" in which computer systems would automatically communicate with each other based on compliance with standard message profiles, such as proposed by the Andover Working Group and ActiveX for Healthcare. These initiatives, which depended heavily upon vendor and user agreement on content and interaction rules, were never successful, primarily because they could not achieve a critical mass of support. Each vendor and end-user thought it had unique data requirements and in the end no consensus was reached. We will see if Integrating the Healthcare Enterprise (IHE), which uses a similar process and method, can avoid that deadlock between individual requirements and need for consensus.

The advent of the Web and extensible mark-up language (XML) in the mid-1990's refocused technical interoperability efforts to model-based, self-describing messages and documents that could be used transparently by any system. Concurrently there were two other significant business forces that impacted healthcare IT interoperability. First, the scope of the enterprise went from a single hospital to an integrated delivery system of multiple hospitals and alternative care settings. Second, the Health Insurance Portability and Accountability Act (HIPAA) Administrative Simplification, promising reduction in the complexity and cost of billing transactions, mandated the use of interoperability standards. Integrated Delivery Networks (IDNs), HIPAA and the Web crossed an interoperability boundary not clearly appreciated at the time – the boundary between different healthcare organizations. We went from the interoperability problem of dissimilar hospital-based systems with common data concepts and shared business processes inside a single enterprise, to dissimilar systems without shared data concepts or processes in multiple and potentially autonomous enterprises.

This was a profound change and forced expansion in interoperability requirements. Not only did the scope of clinical practice grow in complexity, but whole new business and organizational issues came into play. One could no longer count on internal security and controls, common policies and procedures, and a single IT and organizational authority. HL7 messaging standards were designed to facilitate sharing information and are almost devoid of security rules. Server-to-server communication assumed an internal network under a single security authority. The objective was to share not restrict. As we discussed in the June 20002 *Standards Insight*, the business problems of interoperating between enterprises surpass the technical issues. That certainly appears to be our experience with HIPAA. Use of all of the HIPAA transactions hovers around 50 percent almost ten years after the law was enacted, despite availability of existing, mandated standard transaction and code sets. The complexity of inter-enterprise business issues, policies and relationships, security and privacy not the least, continues to trump technology. Moreover HIPAA interoperability is "only" concerned with automating existing business transactions within the financial/administrative realm. HIPAA did not touch clinical practice, data and processes. Now we are talking about interoperability of ill-defined clinical transactions and changing practice patterns between autonomous health care provider organizations.

Definitions

Interoperability is defined by HL7 as "the ability of two or more systems or components to exchange information (functional interoperability) and to use the information that has been exchanged (semantic interoperability)." NAHIT uses a very similar definition of interoperability as "the ability of different information technology systems, software applications and networks to communicate, to exchange data accurately, effectively and consistently, and to use the information that has been exchanged."

There are three components of system interoperability: terminology, structure and interaction rules. All three must be supported by interoperable systems to attain semantic interoperability. Functional interoperability requires the last two components.

NAHIT also adds the Center for Information Technology Leadership (CITL) levels of interoperability as qualifiers. These levels are important because, at least in the CITL model, they determine the costs/benefits of interoperability.

- Level 1: Non-electronic data (paper, phone)
- Level 2: Machine transportable (e-mail, fax)
- Level 3: Machine organized (structured messaging without structured content)
- Level 4: Machine interpretable (structured content with semantic interoperability).

We note that all information content at all four levels can be used directly by humans. It is the computer's capability to use information that is at issue. Levels 1 and 2 exist today without any further system level interoperability. Level 3 best corresponds to the current state of the art as demonstrated by IHE. Cross-enterprise document sharing enabled by IHE, applies profiles to messaging standards for requesting and sending data and

documents between collaborating enterprise systems. This sharing does not assume, but can support, semantic interoperability by either system. The shortcoming of Level 3, as defined by the Center for Information Technology Leadership (CITL), is that such messaging would have to be manually managed and used, defeating both clerical efficiency and automated decision support. Level 4 requires semantic interoperability and only at this level do substantial benefits accrue. The CITL benefits are economic in terms of eliminating duplication and clerical effort, but the efforts/costs are dependent upon the degree of use of clinical systems.

The information value proposition

We have been defining interoperability in terms of "system," which is our historical framework, without reference to end-users, workflow and organizations. Information systems, even interoperable systems, do not of themselves deliver patient care, effect organizational transformation or create value. Note that interoperability is manifested through computer system functions that are valued by end users, which seamlessly deliver external information to the internal system. Hence the HL7 EHR system functional model lists interoperability as an infrastructure function that supports the direct and supportive care functions. Thus while CITL tries to tease value from interoperability/data exchange itself, benefits are actually realized through the use of computer systems at the interconnected nodes.

There are three levels of potential IT value:

- Automating data and documentation
- Supporting optimized workflow and processes (doing things right)
- Providing decision support (doing the right thing)

System interoperability can support all three levels. However, most of our experience and capability is at the first level through data messaging. While automating documentation is a necessary condition, it has not been sufficient to drive adoption of clinical or EHR systems. For much of the last 30 years, the goal of IT developers was to replicate the manual, paper-based system on computers, creating highly configurable systems that could be adapted to individual clinician's preferences. We have invariably found that when automating documentation is the goal, there is limited payback for clinicians, particularly physicians. Whatever personal and organizational benefits accrue downstream, physicians and nurses found entering data to be too time consuming and constraining compared to paper. Thus "automating the chart" has never been widely adopted, and if automating the EHR were all we were about today, it too would have failed to gain traction. After all the seminal Institute of Medicine (IOM) study on computerizing the patient record was published in 1991 and only in the last few years has there been real movement. The real question here is why?

The answer lies somewhere within the following key points. First, in 1999 the IOM began its campaign to improve patient safety and second the wide variability in clinical practice and processes, which results in the errors, was also recognized as a great source

of waste and increased costs. HIT, particularly in terms of clinical information systems, was seen as a means for enabling workflow standardization, formalizing processes and improving decision making. This created the emphasis by the Leapfrog Group and others on computerized physician order entry as a mechanism for reducing errors and improving outcomes. The electronic health record is the building block of any comprehensive IT solution. The reason for implementing EHR systems is not to replicate fractured, error-prone paper-based system but to structure workflow and standardize processes. The comprehensive set of functions listed in the HL7 EHR system functional model goes well beyond automating documentation to enhance workflow and enable decision support.

EHR system implementations are not just IT projects but clinical transformation projects. They are changing how clinicians work, and directing behavior towards evidence based practice not adapting the system to clinician preference. Such transformation projects are difficult because they require clinicians and provider organizations to change how they work and deliver care. Yet it is clinical transformation, not administrative simplification, that yields the break-through improvements in effectiveness and efficiencies.

The value of interoperability

With this value proposition as perspective we come to back to the definition of interoperability and its importance. Interoperability is an enabler of higher order system functions which in turn enable end-users to create value. The value of interoperability is embedded in higher level system and business values. If our experience with EHR systems is indicative, then interoperability should be directed at support for transforming clinical care not reducing clerical costs. Defining interoperability only in terms of technology and systems and not in terms of end users' value proposition creates an unbounded problem. If interoperability means that all EHR systems can semantically interoperate with all other EHR computer systems then interoperability is an insurmountable barrier within any actionable planning horizon. If interoperability is defined as semantic support of a patient-centric record across all care settings at all times, we have a huge problem in alternative care domains and organizations. If interoperability is defined as support for a set of minimum functions, say e-prescribing, e-results and e-reminders, among primary care providers, we have significantly narrowed the problem and we can begin to craft the standards and profiles to move forward now.

This definition is of no small significance in setting forth the technical requirements upon which we want standards developers and vendors to implement. HL7 has in Version 3 developed a comprehensive, albeit abstract, model of healthcare information - the product of a decade of work by some of the brightest minds in healthcare informatics. However, Version 3 still requires implementation guides, agreed to terminologies and yet to be defined interaction rules, the so-called dynamic model. Moreover, its semantics must be fully adopted at the point of data entry to avoid very complex issues of post-coded entries. Tying interoperability to end-to-end standardization, although theoretically correct, is impractical to implement. This so-called rip and replace approach would require adoption of new EHR systems that use standards not yet available. Delaying the internal benefits of EHR systems to improve care while waiting for those that seamlessly

connect to other provider systems would not make sense. Certainly most of the transformational value of EHR systems is achieved through internal system use, even if external data must be manually managed.

Interoperability should be defined in terms of value to stakeholders, particularly the end-user provider organizations who must accept the costs. The definition should start at the relationships and interactions between providers and the impacted internal functions that require interoperability with external systems. In a white paper in February 2004, available on the author's Web site, I looked at the dimensions of interoperability, the inside and outside the firewall problem. I recommended that we separate the technical solutions based on business requirements. For better or worse the current generation of provider-centric EHR systems is built from a core vendor's solution and only "interoperate/interface" at their edges, e.g., with departmental systems using HL7 Version 2 and interface engines. Over time more advanced standards, such as HL7 Version 3, will open these systems to more components, modules and "best of breed" solutions but that is a battle none can fight today. No, the focus of interoperability should be in the inter-enterprise space beyond the firewall. This is the problem that must be solved: sharing minimum data sets of high value while maintaining security and privacy. It is not that interoperability is "dumbed down" but rather applied deeply to narrow problem sets, e.g., e-prescribing. Sharing a limited but growing set of data, documents and processes will force evolution of internal systems.

Thus the just in time approach, which CCHIT proposes to use to define interoperability, is sound if their choice of "use cases" is based on the end user value proposition and not derived from vendor offerings. CCHIT must define what functions need to interoperate and then place those functions on a roadmap within a timeframe. The work of the HL7 EHR Technical Committee's interoperability project should help identify what functions need interoperability and provide a more global road map. Finally, the National Health Information Network (NHIN) proposed by ONCHIT can point us to future, comprehensive interoperability standards that are aligned with transformed clinical practice and realigned incentives.

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