Meeting the challenges of healthcare interoperability

Introduction

President Obama's $19.2 billion HITECH Act has refocussed attention on healthcare interoperability. The legislation (Title XIII of the American Recovery & Reinvestment Act, available via http://www.whitehouse.gov) aims to have electronic health records for the whole US population by 2014. It budgets $20 million specifically for "advancing health care information enterprise integration through activities such as technical standards analysis and establishment of conformance testing infrastructure".

The Act's emphasis on adoption of "certified" electronic health records (EHRs) requires the existence of standards against which the record systems can be tested and validated. A substantially enlarged effort in healthcare interoperability standards is anticipated. What will this mean for healthcare IT in Europe?

The aim of this article is to give a brief overview of healthcare interoperability. Are international standards really necessary? How does standards development affect healthcare providers and IT vendors? I write predominantly from a UK perspective and offer a personal viewpoint not an official voice of either the NHS or HL7 UK.

What is healthcare interoperability?

In a general sense, "interoperability" simply means to be able to work together. In the case of healthcare, we need to be able to safely and securely create and convey a meaningful record of clinical knowledge, plans and actions. This could be as simple as reporting whether a biochemistry test result is normal or abnormal, or as complex as a detailed record of a hospital admission.

The US National Alliance for Health Information Technology (NAHIT) produced a widely-supported definition of healthcare interoperability (based on IEEE's wording): "the ability of different information technology systems and software applications to communicate, to exchange data accurately, effectively, and consistently, and to use the information that has been exchanged" (see http://www.nahit.org/).

Healthcare interoperability can apply at different levels, typically described as either syntactic (grammatical) or semantic (logical). Syntactic interoperability means that both the provider and consumer systems can process defined messages or records and determine whether they are correctly structured. But at this level, the systems cannot validate the logical *content* of the information. It may be quite correct in structure but contain meaningless data. Therefore, for healthcare IT the final goal is *computable semantic interoperability* – enabling software systems to interpret and validate the clinical content of an EHR or message. This complex, higher level of interoperability requires a

common information model and a robust method to link interpretable concepts to items in record structures and transactions so that *meaning* (in context) can be safely reproduced.

Why should we work to international standards for healthcare interoperability?

Standards development is sometimes portrayed as distant from the real world, a remote academic exercise practised only by learned experts as a self-perpetuating industry rather than a useful solution to pressing operational problems. And there is some truth in this view! But what is the alternative?

If we do not work to standards then we face information anarchy. We simply cannot achieve anything beyond very limited and small scale localized interoperability without at least national or preferably international standards. Citizens are mobile and major system vendors need to operate globally.

In my view there are three key arguments for standards:

- They prevent repeated reinvention of solutions for virtually identical business needs. They provide compatible ways to share information without constraining the innovative functional advantages that can give one system a competitive edge over another.

- They can act as a form of “corporate memory”, embodying the knowledge, experience and ethics of dedicated specialist teams.

- They enable integration solutions to become packaged commodities rather than bespoke developments. Multiple vendors can then offer services such as conformance testing, implementation management, training and support.

When developed with sufficient versatility, standards can allow constraints or specializations that encompass specific business requirements for localization and diversity, either by clinical specialty, healthcare domain (private/public, primary/secondary care) or national/regional realm.

In summary, we cannot envisage joined-up global, or even pan-European, healthcare without international standards for EHR interoperability.

Where are we with healthcare interoperability standards?

Internationally, there is continuing intensive work on a range of core standards. HL7 version 3 has a robust Reference Information Model (RIM). The RIM is mostly used to specify structure for records or messages, but has recently been used in software design (RIMBAA – RIM-based application architecture). HL7 also publishes the versatile and widely-adopted Clinical Document Architecture (CDA).

The European standard EN13606 for EHR communications defines an information model that is conformant with the HL7 RIM and can be mapped to CDA. EN13606 adds the important concept of clinical *archetypes* (devised by the *open*EHR Foundation), meaningful "chunks" of structured healthcare information such as observations, plans, findings or treatments. These are essentially the same as *templates* in HL7.

SNOMED CT provides a foundation for clinical terminology content expressed in a rich and flexible ontology comprising over 300,000 distinct concepts and over a million relationships between them. At the archetype or template level, data items ("fields" in the information model) can be "bound" to specific constrained ranges or value lists of clinical terms. For example, a "blood pressure" archetype might be constrained to a particular set of SNOMED CT terms related to whether the patient was standing or sitting, the diastolic and systolic values, the type of instrument used or other specified clinical parameters. The idea is that archetypes and templates can be re-used across multiple clinical domains and provide a level of modelling that is meaningful to care providers who are not IT experts.

The global organization *Integrating the Healthcare Enterprise* (IHE) originated in the radiology field but has extended into a range of clinical domains. IHE develops and maintains *profiles* of specific use cases, defining particular uses of HL7 messaging and DICOM image workflow. IHE operates on a vendor self-certification basis, where suppliers publish their own compliance statement indicating the IHE profiles that they support. IHE compliance is demonstrated by participation in the annual Connectathons, valuable opportunities for suppliers to work together (interoperate!) to show end-to-end information flow for particular operational scenarios.

There is also work in progress on summary patient records at various levels. For example in Scotland there is the Emergency Care Summary (ECS), in England the Summary Care Record (SCR) and in Europe the EPSOS project is in its early stages.

However, current *operational* EHRs in the UK are mostly islands of information – GP clinical systems, departmental hospital systems and a small minority of hospital-wide information systems. There has been excellent progress in electronically transferring patient records between GP systems, but this is so far limited to a subset of vendor systems. Most current healthcare interoperability in Britain still uses a mixture of loosely defined international standards (for example, various flavours and interpretations of HL7 v2), some international profiles (for example, IHE radiology workflow profiles) and, predominantly, locally devised or proprietary solutions. Furthermore, due to the gulf between GP and hospital EHR maturity there is yet no interoperability at the semantic level between primary and secondary care, as there is no significant content with which to interoperate. The only nationally defined and supported information standard for electronic communication from hospitals to GPs in England is the EDIFACT-based method for sending laboratory results.

How do interoperability standards affect on the vendor market?

In England, the rigorous approach adopted for conformance certification to national specifications has raised the entry level of investment for vendors wishing to supply products compliant with national systems.

However, much healthcare activity is outside the current scope of national systems so many smaller vendors are still active for departmental systems or corporate systems with only local integration. Such solutions can use less rigorous standards, such as flavours of HL7 v2 or proprietary integration methods, but this adds to the costs per implementation. There are many opportunities for systems integrators at the local hospital level due to the predominance of applications that are not standards-based.

What is the likely European impact of the Obama HITECH investment?

If the American programme follows the anticipated path of building upon usage of HL7 v3 CDA, SNOMED CT and IHE, then this will support and enhance the work already done by the national programmes in Canada and England, among others.

In particular, global vendors who have already participated in standards development will be well placed to take part in the American projects.

The Obama investment should also increase the drive for cooperation between standards development initiatives, as already seen in accords such as the collaboration agreement between HL7 and IHTSDO, the not-for-profit organization that owns and promotes SNOMED CT.

One key factor will be whether the American programme centrally manages its own conformance testing or opens this to the market. If specifications used for certification are close to the international standards (with minimal realm-specific modifications) and the process can be delegated to authorized testing centres, it is possible that the financial entry level for vendors need not be prohibitive for niche or startup companies.

Either way, it seems likely that the HITECH Act will further polarize the market between major global vendors and niche suppliers of specialized systems or integration as a commodity.

Conclusions

There is no question that standards are essential for effective healthcare interoperability. The incentives and mandates from national programmes give the impetus that is needed for widespread adoption of standards. In turn, the widespread adoption matures the standards. And, ultimately, patients will benefit from the improvements in care made possible by safe and reliable production and transmission of their healthcare information.