

The Importance of Standards and Its Use in Healthcare



This article illustrates the current concerns and challenges faced in the healthcare industry and the needs of standards for Access of information, Quality of care and Cost reduction. It also explains the various available standards and their use in removing market barriers through case studies in building the Personal Health Record and Standards in RHIOs (Regional Health Information Organizations).

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1 Introduction

Countries around the world today have been focusing on healthcare as one of their key national agendas due to their growing aging populations and a high percentage of Chronic Disease patients.

Access the right and accurate information delivered to the right place at the right time, providing the right level of quality of care and reducing healthcare cost are the challenges faced by not only the local Government but by many of the healthcare institutions in both developed and developing countries.

Over the last 50 years, we see that the medical field has made incredible advances in increasing life expectancy dramatically, and turning many diseases that once were fatal, into chronic conditions that can be successfully managed for a lifetime.

Despite these tremendous advances in medicine, healthcare innovation is falling dangerously short of delivering consistent quality and accessing accurate information due largely to an inability to connect isolated islands of

information throughout the healthcare systems. As healthcare is an information-intensive endeavor, pervasive information disconnects are extremely costly, both economically and in terms of human life.

2 Background

In today's healthcare industry, there are goals to drive patient related information to be exchanged freely between the various systems in the continuum of care. Health-IT standards (especially for Electronic Health Records) provide the foundation for institutional data-sharing and integration of this data with home care and residential care while Personal Health Records and information platforms are a foundational enabler to extend the healthcare system into the home. Keeping in mind that Security and Privacy related challenges as well as regulatory issues will need to be addressed in the end to end delivery of information and accessibility.

In reality, in order to realise the above objective, Health Information Systems have to adhere to the same standards in order to achieve systems interoperability. Unlike other verticals such as financial industry, healthcare is still very much lagging behind when it comes to the use of interoperability standards – partially because standards don't exist, partially because too many exist and partially because they are not used or not in the consistent fashion that is needed.

As such, collaboration in the industry and the use of global standards are essential. Technological innovation and collaboration between ecosystem players will make a better and more sustainable model of care possible.

International standards are essential however, and profoundly lacking at this stage. Barriers to technology adoption remain significant in healthcare. Technology-driven quality improvement requires collaboration throughout the system and the desire for real change. The healthcare industry will make rapid gains if it can catch up to the other industries in adoption of interoperability standards, which make it possible to form the building blocks for industry-wide innovation and interaction.

Industry-wide deployment of interoperability standards will require the support of appropriate policies and regulations. These policies and regulations need to remove unnecessary obstacles and create the appropriate incentives for the deployment of standards-based and interoperable technologies.

3 Standards in Health IT

In addressing the standards in Health IT, today there are already in existence the various Standards Development Organizations (SDOs), Special Interest Groups (SIGs) and other initiatives that support the Healthcare industry.

Many SDOs are working on developing standards as well as driving its proliferation in their related industries. However, not all SDOs have been successful in propagating standards. Therefore, SDOs can and should adopt various strategies to ensure their success in both the standards development and adoption process in collaboration with the industry at large.

The healthcare system itself in different countries is also a complex network of players that are poorly connected yet intensely interdependent. It is a very complex system of hospitals, doctors, nurses, insurers and manufacturers that all try to work together in some form to improve health. Because healthcare by definition must function as a true system, the value it delivers to society cannot be created by any one piece of that system.



Hospitals alone for instance can't totally transform healthcare quality; they must work with insurers, drug companies, medical imaging providers and the government to make that happen.

We also understand that the inability to integrate the information and systems that enable care has caused the healthcare quality to fall short of the standards that are expected. Healthcare professionals also often lack the information necessary to make better decisions (clinical decision support is poor). Critical information exists in pockets throughout the system, but healthcare information isn't connected and can't move to where it is needed to deliver better and safer care (e.g. from lab to physician to pharmacy to payer to patient to caregiver).

Therefore, the real value in healthcare comes from the interactions between all the pieces of the system and how they work together. Quality improvement and greater value in healthcare can only come from better interaction throughout the system. Reducing disconnects throughout the system is in fact one of the priorities at the very heart of healthcare quality improvement today.

In order to reduce disconnects of information throughout the healthcare system, all players in the eco-systems have to adhere to same standards in order to achieve systems interoperability.

3.1 Standards are not equal to Interoperability

Standards only create the opportunity for interoperability and are not equal to interoperability.

Interoperability of standards requires market viable use cases which comprise of a standard or a collection of standards in order to drive proliferations. Industry players can also come together to develop and agree on Interoperability Guidelines or Profiles that describe how to use the Standards to achieve interoperability which includes interoperability compliance testing (whether formal and/or informal). Last but not least, promoting the standards and its use in the form of marketing, educating the community and institutions, or evangelising in conferences and seminars.

Standards and interoperability are in many ways the key to unlocking the collaboration so needed in the complex healthcare network. Many of the issues that the healthcare system faces, high cost and uneven quality, are due to the isolated islands of information caused by a lack of standards and interoperability. As we have seen in other industries, standards are the building blocks of innovation and lead to increased interaction, improving information access and reducing cost.

3.2 Collaboration and International Standards are Essential

Technological innovation and collaboration between ecosystem players will make a better and more sustainable model of care possible. International standards are essential, however, and profoundly lacking at this stage. As we see, barriers to technology adoption remain significant in healthcare.

Technology-driven quality improvement requires significant collaboration throughout the system and the desire for real change. Despite the recognised quality improvements and long-term cost savings, technology implementation challenges can be significant and barriers to adoption run the gamut from initial cost outlays, cultural issues, process differences, regulatory issues, and certainly, interoperability standards.

To compound matters further, a system had been created in which incentives are grossly misaligned, making poor quality unthinkable good for business in certain instances. Many healthcare systems, for instance, pay for medical visits and procedures but do not reward for quality, therefore creating incentives for volume but not for quality improvement.

The success of digital health will hinge largely on the ability of the healthcare and technology industries to lead fundamental change, collaborate steadily toward common building blocks and establish greater expectations for technology adoption.

The healthcare industry will make rapid gains if it can catch up with other industries in the adoption of interoperability standards, which makes it possible to form the building blocks for industry-wide innovation and interaction.

International standards organisations and consortia supply the framework on which interoperability will develop in healthcare. Industries such as financial services and manufacturing long ago successfully deployed interoperability standards to radically improve productivity and increase profits.

Although the task to drive interoperability standards in healthcare seems extremely complex and the incentives to drive change and improve quality are misaligned, the overall benefits derived from greater interoperability through international standards are significant. Interoperability in healthcare is the primary means by which we can save lives and save money, even as the burden intensifies.

International interoperability standards will require the development of public policy, incentives and regulations, without which interoperability will not naturally emerge. Solid standards policy is essential to increasing interoperability in ways that make it possible to deliver better health at less cost.

The following two cases show how standards can be used in both Personal Health Record and Regional Health Information Organizations across a country like the USA.

4 Case: Personal Health Record

Personal Health Records (PHR) is a way for individuals to maintain control over their health care information. The Connecting for Health report from the Markle Foundation defines PHR as "an electronic application through which individuals can access, manage, and share their health information in a secure and confidential environment. It allows people to access and coordinate their lifelong health information and make appropriate parts of it available to those who need it"¹. To date most efforts in the PHR space have been proprietary and limited to patient-sourced information. Additionally, Electronic Health Record (EHR) systems are extremely varied preventing interoperability with PHR solutions not provided by the EHR vendor.

One of the efforts currently ongoing to address the fundamental issue of PHR definition is taking place within HL7 where a workgroup is developing conformance criteria for PHR. This work should allow a common framework for understanding basic functionality that should be part of any offering to consumers.

¹ Connecting Americans to their Healthcare, Connecting for Health, Markle Foundation, July 2004.



The E31 Committee on Healthcare Informatics of ASTM has created a standard called the Continuity of Care Record (CCR). The CCR is "a core data set of the most relevant administrative, demographic, and clinical information facts about a patient's healthcare, covering one or more healthcare encounters"². This is an XML standard making it platform-independent. Though not designed specifically as a PHR standard, the sections of the CCR include data ideally suited for the PHR including demographics, insurance information, family history, immunisation history, medications, problem list, etc. The CCR allows inclusion of both textual (human readable) as well as coded data where appropriate allowing for semantic interoperability. A large number of EHR vendors have already included code within their systems to allow both the generation of CCR as well as the consumption of CCR data. The work of the committee continues to refine the standard through clinically relevant additions and modifications to meet the needs of the healthcare industry.

Another ongoing effort that will be pertinent to PHR is the development of a PDF (portable document format) for healthcare, tentatively called PDF/H. The workgroup, under the auspices of the standards development organisation AIIIM, intends to leverage existing features of the PDF format for security, protection of data integrity, and cross-platform portability and add to these the special features that will be required to transport medical information in usable forms. The PDF format allows rendering of XML using appropriate transformations into an easily viewable document utilising the freely-distributed Adobe® Reader®. PDF forms allow data entry for patient-sourced or editable data. The data can be consumed via transformation back to XML or as a printout that could include text data as well as 2D barcodes which contain semantic XML information. These features would allow individuals to maintain their secure information and share it as they choose in a fashion that could be consumed by any physician with a compatible EHR system.

Potential uses of standards in the PHR area are illustrated in the use case below.

Jane Wilkins brings her son Jason to see his paediatrician, Dr Smith. Jason will be starting school in the fall and Jane will need to provide his immunisation records. After performing a preschool exam and updating any necessary immunisations, Dr Smith completes the charting in his EHR. The EHR software is then used to create XML using the ASTM Continuity of Care Record (CCR). It also contains a tool allowing this XML to be transformed to portable document format (PDF). Dr Smith securely emails the document to Jane who is able to store the information in Jason's personal health record. The PDF contains an immunisation record formatted for printing as a paper form that is acceptable by the school district. This form includes a 2D barcode containing coded data regarding the immunisations which the school district can electronically store using their barcode reader. This exchange of electronic information will allow Jane to provide accurate information to Jason's school without the need to repeatedly fill out paper forms by hand.

5 Case: Standards & RHIOs (Regional Health Information Organizations) in US

RHIOs or Regional Health Information Organization's, are inter or intra-state organisations with a collective business objective of deploying rich, patient health information exchanges, in order to support improved healthcare delivery. The intent of these exchanges is to deliver a more complete patient information record to each RHIOs participant, using patient consent policies, controls and governance, on a secure and standards-based regional health information network.

² Standard Specification on Continuity of Care record (CCR), ASTM E2369, Published December 2005.

In the US, there are now more than 140 RHIO-type organisations already formed, who are working collectively – both outside of and across their traditional 4-walled boundaries – to improve the quality, safety and efficiency of healthcare delivery. The majority of participants in RHIO activities today (hospitals and healthcare organisations), plan to be a part of a health information network within the next 5-7 years.

"Data converted to Information, presented as Knowledge"

RHIO organisations have developed in the last year as a result of the need for greater information access and availability, which is believed to be the best way in which we can begin to drive down the escalating cost of healthcare delivery here in the US.

The saying that "all healthcare is local" is one of the driving forces behind the concept of a RHIO. Each RHIO will manifest itself as local information exchange using an 'overlay network' to carry and share regional patient information via the Internet. They will use secure, Internet-based transport and traditional client or peer connection protocols like VPN, SSL and SOAP (for XML) in order to communicate between machine interfaces or via Portals.

Whether a given RHIO is based on a peer-to-peer or shared data information model is an individual RHIO decision, but the drivers for developing these models are very consistent. RHIOs are expected to provide a way for Patients, their PCPs, Specialists, Dentists, Regional Care Providers, Large IDN', Pharmacies and Insurance plans to all have a deeper and richer view of any individual patients health history. This will inevitably allow all parties to make better informed decisions about the patient's healthcare delivery – at any given time – through ubiquitous access and availability of information.

We've arrived at this point because of the lack of a national health information network here in the US. Other countries are in fact moving much faster than the US in this space and in many cases, have the ability to specify technology, standards and even healthcare vendor applications in more of a top-down fashion via their internal Ministries of Health.

Alternately, the US Healthcare system has been built up over many, many years as a commercially funded and driven system. Individual providers made independent vendor and technology decisions that were best suited for them.

The disparity in system acquisition and deployment (across providers), has always been a differentiator here in the US. It afforded each care delivery provider to be competitive in their own market or market segment. It also provided them with a way to purchase products and services from a single vendor in order to quickly integrate and expand their healthcare delivery offerings using that vendor's solution.

The downside to this individual vendor selection process was that providers actually limited their ability to horizontally integrate with others (across the industry). While clinical vendor solutions all tended to follow the same standards body treadmill, the problem was that each vendor tended to be on differing versions of those standards at any given time.

This limited any one provider's ability to openly extend their clinical systems to any other provider – without complex and costly custom development work, software and system interfaces, and IT investment. This industry



misalignment was a double-edged sword; it allowed each vendor to differentiate, but at the same time it created a significant technology gap between providers and their ability to share information.

This has increasingly led to higher healthcare delivery costs, lab and test redundancy, and incomplete or inaccurate views into patient information and histories. As a result, recent mandates by HHS & ONCHIT require the building of an interoperable and extensible National Electronic Health Record system to solve this problem. This forces the industry to embrace information exchange, common standards adoption and is the reason why the need for, RHIOs have come into existence.

Is the Healthcare Industry really all that different? The term 'Mission Critical' in the healthcare industry, does take on a whole new meaning, versus the more traditional IT definition. If you were to lose your financial information through fraud or theft at your bank, it would be an inconvenience to you initially, but you would eventually rebuild and recover. Theft or fraud with regard to patient healthcare information has a much longer impact and exposure element associated with it. A single incident, may damage a patient for life.

In addition, a transaction gone bad in the financial, retail or commercial services industry may impact the individual in an adverse way for some period of time, but not having all of the right healthcare information, presented to the right caregiver, at the right place and time, can be life threatening or worse.

The good news for RHIOs is that their formation is happening at the right inflection point within the industry and within the right life cycle of the Internet itself. The drivers may be governmental, local employer cost driven or even healthcare plan related, but the healthcare industry can now benefit from much of the work already done in other industries - if they choose to do so.

Applying lessons learned from the past, RHIOs can benefit from interoperability implementations across industries like the commercial sector. There, we've already solved some of the more complex information modelling, electronic data exchange, network robustness and data security issues which plagued them at the start of the Internet. Today for example, manufactures deploy robust and resilient B2B networks, with reliable messaging protocols, data persistence and common information exchange formats for supply chain, customer orders, financial and purchasing transactions - using the robustness and resiliency of the Internet.

In the financial services industry (for example), they have worked together across industry segments, to implement a secure, reliable and auditable business process model for stock clearing between disparate financial institutions. This business process model uses industry agreed upon (secure) XML exchange formats, Internet-based messaging protocols, full audit and government compliance capabilities, to solve what was a multi-week transaction problem in a just few days.

Building RHIOs: the new P2Pi Health Internet; (Patient to Provider, Payer or Pharmaceutical Health Internet)

In order to actually build 140+ regional health information networks here in the US, RHIOs must focus their architectural and engineering resources towards a set of fundamental objectives for creating these overlay health information exchanges. These recommendations are not intended to include policy-based considerations within the RHIO itself like, patient consent models, RHIO governance, profit/non-profit status and business transaction services. Rather, these architectural principles are intended to be guidelines which we hope RHIOs will follow in order to ensure the deployment of a standards-based and robust interoperability network.

This will ultimately allow them to grow and prosper for the long-term and therefore, we suggest the following:

1)Simplify Interoperability

Ideally, RHIOs should work with vendors to deliver platform-based exchange architectures and ingredients in order to address the current disparities with regard to information access. A platform is a set of technologies which delivers an experience to the RHIO participant. Therefore, a platform is not just hardware, but it's also software, services and ultimately the content, delivered on that platform, which drives the overall user experience.

Therefore, RHIOs should strive - even initially - to deliver a complete experience. To achieve this, they will have to standardise on a set of platform technologies and services which are utilised by all participants. Semantic normalisation and interoperability of the patient's data - in whatever form - has to include all parties as both viewers of the information and contributors to it, via this platform-level approach.

To achieve this, RHIOs will have to normalise the conversation between entities. This means that choices have to be made with regard to the RHIO exchanges Reference Information Model (RIM) and document exchange principles. RHIOs should deploy proven and secure Internet information exchange methods which utilise message-based protocols (for resiliency and robustness), XML as a default exchange document language and web services where possible, for extensibility.

They must require all platform-based, machine to machine participants to exchange information in a standard XML form. Specific forms can be built for specific process requirements like, prescription histories, patient CCRs, Lab Summaries, e-Prescribing, Claims Inquiries etc., but in the end, all participants should exchange information within the 'cloud' using a common set of elements and attributes.

This latter point allows for a number of unique capabilities to emerge within the RHIO architecture, like the use of WS-Addressing, Routing, Encryption and Attachments for efficient and secure document transaction. Any platform decision must also have the ability to protect, de-crypt, process, audit and manage the XML transaction at the edge (on the providers network) and in the cloud (at the RHIO or virtual RHIO).

By using a standard XML exchange format and Reference Information Model, all entities facing the cloud will be able to speak the same language - whether that conversation is based upon HL7 v2.x, HL7 v3, HL7 CDA, DICOM, ASTM CCR, HIPAA TS, NCPDP, CDISC or other. The point here is to normalise the 'language exchange' and business process workflows between all RHIO participants to minimise the need to transform every single conversation in two directions and in multiple x formats.

2)Deploy technologies which exemplify Reed's Law

The value is the network (Metcalf's Law) but increasingly, the exchange of information and knowledge between peers across the network (Reed's Law) are what will ultimately drive down the cost of healthcare delivery.



A RHIO's success will be measured in the final analysis on its ability to engage all entities - both large and small - to enhance, extend and exchange information in an effective way. Therefore, RHIOs must deploy technologies which enhance business processes, not detract or derail from what already exists within the region.

Large provider organisations, IDNs, Payers and Pharmacy gateways, already have the IT expertise and capability to integrate RHIO gateway platforms into existing environments. Small doctors (PCPs), mid-cap providers and some retail pharmacies, have very limited resources to do the same.

Many current solutions being proposed to RHIOs involve the use of a portal for access by RHIO participants. While we acknowledge that a portal interface needs to be provided for access to each patient's electronic health record - by the patient in particular, a portal alone adds significant burden to many smaller RHIO business participants.

Small doctors for example, are already burdened with multi-part workflows for patient retention, scheduling, insurance inquiry, billing and financial management. Requiring that same doctor to duplicate patient workflow (input) via a portal interface, places undue burden on an already taxed segment of the market.

To accelerate RHIO information exchange (value), RHIOs will have to look at platform-level solutions which fit into existing PCP workflows and systems which are already in place. These platforms and services - provided by the RHIO - should allow these smaller RHIO business entities to both inquire and extend information from their existing systems in a seamless and natural way - as opposed to an out-of-process, web-only solution.

There are ISV vendors today who offer solutions to this problem in the form of virtual print driver technologies for mapping existing PCP system data and reporting formats to XML documents for exchange within the RHIO. Technologies like these - though simplistic - will go a long way towards information participation and input by all.

3) Support legacy systems, current and evolving standards in healthcare data representation

In order to support the largest breadth of use cases and to provide a bridge between the current (state) as-is healthcare exchange model and any proposed to-be models, RHIOs must utilise legacy interoperability technologies which exist elsewhere in other industries and have millions of proven transactions associated with them.

Like the agreements forged within RosettaNet back in the 1990's, RHIOs have an opportunity to develop agreed upon exchange formats and technologies which provide a bridge to today's clinical solutions, but also provide a pathway to next generation standards deployment of SOA4HL7, HL7 CDA (Health Level 7 Clinical Document Architecture), ASTM CCR (Continuity of Care Record). If we assume that the healthcare industry - like other industries before it - will adopt a true service-oriented and federated workflow model within each RHIO, then RHIOs may benefit from this upfront analysis.

Collectively working towards common, document-based exchange architectures which are built upon proven business and industry standards, RHIOs will be able to lay the foundation for future growth and implementation as these industry standards continue to evolve and perhaps, converge. Alternately, if RHIOs choose to build their architectures with rigid (and custom) adaptor interfaces to each and every participating entity, then they will incur additional cost burden twice. Initially upfront as the RHIO deployment model is developed and then after the fact, as these standards develop further later on. RHIO structural development budgets will not be able to support continuous IT development spirals. Upfront analysis with regard to the design and deployment of flexible and agile platform-based architectures will be essential to the long-term sustainability of a RHIO.

In the final analysis, RHIOs can really learn from past missteps within the industry. Hindsight always has the benefit of 20/20 and here, RHIOs are no different. We've heard many naysayers talk about the eventual failure of RHIOs based on the CHIN outcomes of the 1990s. The fact remains that both the healthcare industry, technology in general and the standards bodies themselves, have advanced considerably in the last five to ten years. Remember that in the mid-1990s, the web itself, corporate networks, clinical data, information and access security, message-based exchange methods and even web-portal technologies, were all nascent and in some cases, completely unproven in size and scale.

These technologies have matured greatly - along with vendor products, standards application and the availability of proven solutions. RHIOs should take advantage of current state technology (T) or even T+1, for the architectural choices that they make and to collectively move the industry forward as a whole.

"If not RHIOs, then who? If not now, then when?"

6 Conclusion

Standards and interoperability are in many ways the key to unlocking the collaboration so needed in the complex healthcare network. Many of the issues that the healthcare system faces, high cost and uneven quality, are due to the isolated islands of information caused by a lack of standards and interoperability. As we have seen in other industries, standards are the building blocks of innovation and lead to increased interaction, improving information access and reducing cost.

As a building block for interoperability, standards are an essential aspect of healthcare system infrastructure. That's why it is essential for policy makers, regulators and industry leaders to come together to remove policy barriers to standards development worldwide (e.g., licensure, liability, reimbursement, etc.) and create new policies and incentives to advance harmonisation.

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