FEATURE

Fighting Information Blocking in the Emerging Learning Health System

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ABSTRACT

In January 2015, the Office of the National Coordinator for Health Information Technology (ONC) released the first draft of their *Nationwide Interoperability Roadmap*. The roadmap lays out the principles, requirements and strategies for enabling and managing interoperability within what it calls the "Learning Health System" (LHS), which represents a paradigm shift in the healthcare ecosystem within which organizations operate. Within this vision, the LHS will feel less like a collection of interoperable systems and more like one large *virtual* system, providing appropriate access to data where and when it is needed–both for clinical as well as analytic purposes. Many EHR vendors are putting up barriers to access data that comes into the EHR even if the data originates within an organization – often referred to as "information blocking," which may lead to increased monetization of healthcare data. While the use by vendors of standards-based versus proprietary approaches to data access helps reduce some of these barriers, the strict use of standards by vendors does not guarantee that data will be accessible and available to the organizations that have already paid to capture and store it. This article will discuss the potential impact that the LHS will have on the development of interoperability standards within healthcare and the continuing evolution of electronic health records (EHRs) to meet this vision. This article will offer perspectives on how healthcare organizations can work to educate themselves and advocate for systems more supportive of the LHS's emerging needs.

KEYWORDS

EHR, EMR, LHS, Analytics, Interoperability, Standards, HL7, Information Blocking

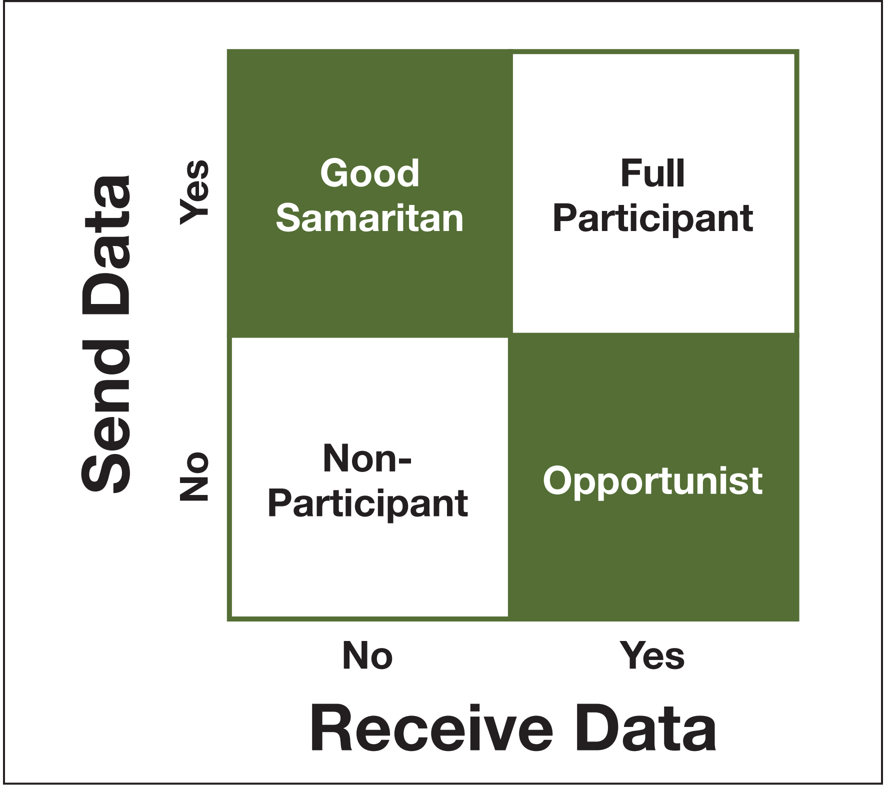
INTRODUCTION

An emerging vision for the future is that of the LHS, which represents a paradigm shift in the healthcare ecosystem within which organizations operate. Within this vision, the LHS will feel less like a collection of interoperable systems and more like one large *virtual* system providing appropriate access to data where and when it is needed – both for clinical as well as analytic purposes. Key outcomes of this LHS involve changes not only to what data will be used, but to *how* data will be used. Examples include:

- Payment models are evolving rapidly and will converge on a small number of variations. Data will be key to evaluating the success and effectiveness of these new models. This evaluation will need to take place at many levels within the LHS: the individual site/facility, the organization, at the Accountable Care Organization (ACO)/system level, and even the community level.
- Integration of data will offer the most value, both within healthcare and beyond. This includes core clinical data, administrative data including claims, and clinical quality data. Over time, more data from other domains will become integrated with core healthcare data. "Big data" will enable not only a more accurate longitudinal view of individual patients but also more robust population health analyses as well.
- The flow of data – current and retrospective – will become more pervasive in society as the demand for data will be constant and continuous. Over time, the LHS will feel less like a collection of interoperable systems and more like one large *virtual* system providing appropriate access to data where and when it is needed.
- While data systems continue to differentiate themselves in the marketplace, there is more consistent deployment of standard interfaces for getting data in and out of systems, including both the structure and content of messages. This makes the use of standards ever more important for a successful LHS.

Many EHR vendors are putting up barriers to access data that comes into the EHR even if the data originates *within* an organization which may lead to increased monetization of healthcare data. While the use by vendors of standards-based versus proprietary approaches to data access can help mitigate some of this "information blocking," the strict use of standards by vendors does not guarantee that data will be accessible and available to the organizations that have already paid to capture and store it. While software vendors should be appropriately compensated for the products and services they provide, they should not control access to a provider's data and should not impose additional services or fees on their customers to achieve this access. This article will explore perspectives around this issue.

FIGURE 1: Data Sender/Data Receiver Relationships



EVOLUTION OF CLINICAL SYSTEMS

Clinical systems – especially those in hospitals – have evolved over time. Academic medical centers were at the forefront of early system development as they had the need and the emerging informatics expertise to develop systems in-house, customized for their use. Mainframe and then mini-computers were accessible to these organizations often through the universities with which they were affiliated. MUMPS is perhaps the best example of a general-purpose programming language and supporting database environment that was developed within a major academic medical center and went on to be the basis of both commercial (*e.g.,* Epic) and open source (*e.g.,* VistA) systems in wide use today.[1]

Early approaches to hospital systems were mostly "best of breed:" various units within hospitals typically sought out the best application for their particular specialties. The primary limitation was the replication of patient data across systems, and the inability of many systems (at least in the early days) to reliably exchange data with each other. The alternative approach was a single system which enabled a more integrated view of patient data, but this often required compromise on the functionality of any particular subsystem. Many early clinical interoperability standards, like Health Level Seven (HL7) messaging, were created to facilitate this interoperability between systems *within* an institution.[2] A growing number of hospitals avoided this decision altogether by outsourcing their financial and clinical systems to companies like SMS.[3]

As clinical systems improved, and the cost of technology began to decline relative to its performance, more and better investments were made within hospitals for their core clinical systems. The Centers for Medicare & Medicaid Services (CMS) EHR Incentive Programs have provided Federal incentives (and in some cases penalties) for meaningful use of certified EHRs.[4] Mergers and acquisitions have brought a whole new set of challenges for system integration. But the real change has just started: more and more the focus is shifting to challenges of interoperability between systems in *different* organizations.

ONC'S INTEROPERABILITY ROADMAP

In January 2015 the Office of the National Coordinator for Health Information Technology (ONC) released the first draft of their *Nationwide Interoperability Roadmap*.[5] The vision described in the *Roadmap* is that of the "Learning Health System" (LHS) where, "…individuals, care providers, communities and researchers should have an array of interoperable health IT products and services that support continuous learning and improved health."[6] Central to fulfilling this vision is *interoperability,* which means that, "…all individuals, their families and their health care providers have appropriate access to electronic health information that facilitates informed decision-making, supports coordinated health management, allows individuals and caregivers to be active partners and participants in their health and care and improves the overall health of the nation's population."[7] The *Roadmap* then goes on to lay out the principles, requirements, and strategies for enabling and managing interoperability within the LHS.

The LHS represents a paradigm shift in the healthcare ecosystem within which we all operate. Through shared governance, the "rules of the road" for data sharing and data access will be collaboratively developed and agreed upon. Better, more comprehensive standards will ensure that standard terminologies are more pervasively used so that the meaning of data will be maintained from system to system, setting to setting. The LHS is data driven: stakeholders (e.g., individuals, care providers, public health, payers, researchers) both contribute and access data appropriate to their role and their "need to know." For example, a patient with a rare cancer can not only direct her health data to whichever clinicians she chooses to work on her care team, but may also use the LHS to identify other patients like her with whom she can share experiences and strategies. She can make her health data available for research – anonymously at first, but with the option of being contacted without revealing her identity should a relevant research breakthrough take place. Public health agencies receive required reports of cancer incidence in the population and can query the LHS for follow-up information on specific cases or cohorts. Clinical Decision Support Systems built on publically-accessible algorithms and ontologies assist clinicians and payers to understand the increasing complexity of medical practice and consider new techniques as they emerge.

This is quite a vision! ONC developed a concept paper in the spring of 2014 to lay the groundwork for the *Roadmap.*[8] Within this document is a set of guiding principles (in bold below) which can be used to guide an approach to interoperability and standards:

1. Build upon the existing IT infrastructure. There is always a tension between maintaining "the old" and moving to "the new," with the understanding that here has to be some balance between the two. Clinging to existing technologies is constraining when trying to enable newer functionality, but embracing the new can be expensive and disruptive. This is true not only of technical solutions but of the underlying standards as well.

2. One size does not fit all. Solutions must be flexible since the health system itself is diverse. Different stakeholders are in different stages of deployment, so this timing lag inherently leads to a diverse landscape.

3. Empower individuals. Individuals are just one component of the ecosystem, but they are the primary target and subject of the healthcare enterprise (though at times we may be more concerned with *groups* of individuals). Empowerment is based on having *ongoing* access to one's health information, and not only the portion their provider (or payer) chooses to share with them. They must be able to access that information when they want or need it, and not when a provider deems it appropriate.

4. Leverage the market. The demand for data that evolves within the LHS should be an active driver for change and development. This demand will happen unevenly across stakeholders and clinical areas; it is important to identify and build upon opportunities as they unfold, and to influence stakeholders to consider data interoperability requirements of their initiatives.

5. Simplify. The LHS is complex: while we need to build upon simpler solutions, we need to be prepared for more complex approaches to address the more complex functionality that will need to be supported as time goes on.

6. Maintain modularity. As more complex solutions develop they will need to be modular enough to adjust to change. This implies that existing infrastructure that may be less modular will need to be replaced over time for the long-term good of the LHS. Service-oriented architectures (SOA) are key to implementing this modularity successfully. Standard interfaces need to continue to develop and be deployed with appropriate semantic standards to make them meaningful.

7. Consider the current environment and support multiple levels of advancement. The LHS will be phased in over time, and different stakeholders will deploy participating systems according to different timetables. The desires of stakeholders will vary in their interest in technology and their access to electronic information, the ability to deal with electronic systems, and the level of maturity of their data partners.

8. Focus on value. Systems must provide value to those who use them. However, it is just as important that the value generate sustainable revenue (where relevant), and that the regulatory environment remains flexible to different business models.

9. Protect privacy and security. For interoperability within the LHS to be successful, participants must feel confident that information is secured and only disclosed when appropriate. Policy harmonization across the States continues to be challenging in this area, and technical solutions will develop to overcome as many of these limitations as possible.

There will most certainly be a long period of transition from our current state to the LHS. And not all participants will behave consistently. In any data exchange relationship, a variety of roles are possible (see Figure 1). Organizations hope that data exchange partners will become full participants -- both sending data and receiving data back. But some participants may only supply data (perhaps due to a technical limitation) and are characterized as "good Samaritans." Still others may only desire to *receive* data but not contribute data; they are characterized as "opportunists." And, of course, there may also be non-participants who neither send *nor* receive data. For the LHS to be successful, organizations must consistently be *full* participants with as few barriers as possible to interoperable data. Vendors can also perform in one or more of these roles and in this way enable or hamper interoperability.

CLINICAL SOFTWARE MARKET AND INFORMATION BLOCKING

The clinical software market continues to evolve and develop. Though there are a few notable open source products, by and large the market continues to be a commercial market dominated by a small number of large players with significant market share, as well as a number of niche products with much smaller market share. According to a recent Software Advice report, in the hospital EHR market "...the biggest vendors show greater market dominance: the top 10 account for over 90 percent of the market, while the top three alone account for over half of it" (based on Meaningful Use attestation).[9] EHR systems are large, complex software products that provide rich functionality across many clinical scenarios and uses. The requirements of the EHR Incentive Programs have forced most, if not all, vendors to focus on providing and improving the functionality required to meet Meaningful Use. This includes meeting the objectives both for Stage 1[10] and Stage 2,[11] as well as the supporting clinical quality measures[12] (Stage 3 will be finalized late in 2015).

Truth be told, Stage 1 and Stage 2 Meaningful Use are not terribly focused on interoperability; there are public health reporting requirements defined, as well as requirements for patients to "view, download, and transmit" their own health data (with more emphasis by most vendors on "view and download" rather than "transmit"), and some requirements to support the transition of care from one facility to another. But as the market for EHR systems becomes more saturated, vendors need to look for other sources of revenue than just core system deployment. One such target is interoperability: It is not uncommon for EHR vendors to charge each customer for each interface they deploy.[13,14] Likely, many interfaces are identical since they are connecting the EHR to many of the same destinations (like statewide public health registries).

Access to data locked within EHR systems is often controlled by the EHR vendor, so increasingly hospitals find that they are not as much in control of their own data as they might think.[15,16] This is often the case even for data flowing into an EHR from *within* the organization, like data from a pharmacy dispensing system or an infusion pump. These specialized systems continue to be external to the EHR but the EHR relies on regular feeds of data from these systems and devices to update the patient's clinical record. Standards are being defined to allow this information to flow more freely. If an infusion pump vendor can support a single interoperability standard between the pump and other systems, the pump can interface with *any* system that supports the same standard. And it is logical to assume that if an organization generates the data in one system it should have access to that data in any system to which it transmits that data *within* the organization.

Well, not so fast. Many EHR vendors are putting up barriers to access data that comes into the EHR even if the data originates within the organization.[17] There are several reasons for this strategy. First, EHR systems have complex databases and data models which often grow and expand by accretion. In some cases systems grow by absorbing other systems within them as vendors purchase systems and sub-systems from other vendors and then incorporate them into their products. Access to this data can become increasingly challenging, especially for *ad hoc* use, and off-the-shelf tools for accessing data from databases rarely work easily with EHRs. The health IT standards community has recognized this problem. ONC launched the Standards and Interoperability (S&I) Framework initiative in 2011 to help meet some of the challenges posed by Meaningful Use within the standards community.[18] Several years later the Data Access Framework (DAF) was initiated to select a set of standards that would support query/response transactions between EHR systems within and between organizations.[19] By adopting a consistent set of standards, two systems that use these standards should be able to interoperate regardless of their underlying architecture or source. By demanding that EHR vendors support these emerging standards "out of the box," hospitals and ancillary system vendors should ensure access to their own data without incurring additional charges. DAF has begun by focusing on a limited data set (the data set required for Meaningful Use transactions) and some of the underlying standards are immature, but EHR vendors must start heading in the right direction. HL7's Argonaut Project is working to accelerate the part of DAF that is based on the Fast Healthcare Interoperability Resources (FHIR).[20]

In April 2015, ONC issued a Report to Congress addressing the issue of health information blocking.[21] In this report, ONC defined three necessary criteria for information blocking to be considered to have taken place: First, there has to be some *interference* with authorized access; second, this interference must have been done *knowingly*; and third, there cannot be any *reasonable justification* for the blocking.[22] ONC goes on to identify a number of typical practices which – depending on the specific circumstances – could be considered information blocking, including vendor contract terms or pricing policies that appear to block the flow of information in some excessive way.[23] The tricky part is in deciding which practices are reasonable and which are unreasonable. The current regulatory framework for EHR systems under the CMS EHR Incentive Programs does not provide the necessary policy framework for completely managing this problem. In addition, while there is a growing set of anecdotal data, there is very little empirical data that helps us understand the extent or impact of this problem.

ONC has proposed some additional steps to help alleviate information blocking, including further constraining standards to enable interoperability rather than hamper it; promote greater transparency in the pricing, features, and limitations of EHRs; and establish governance rules that discourage the creation of artificial barriers.[24] These steps may help but they will not likely go far enough to eliminate information blocking. At a minimum, ONC needs to make the reporting of information blocking easier so that a larger base of data can be built to characterize the extent of the problem and its impact on healthcare organizations and citizens. But here's the real problem: Interoperability should result from a compelling business case, not regulation or incentives. Incentives cannot overcome the lack of a compelling business case to cooperate and not compete when it comes to healthcare data.

Individual hospitals are not the only users of EHR data. As payment reform continues to take hold, ACOs will increasingly aggregate data from across organizations and EHR systems to understand the movement and outcomes of their patients. But only a small number of ACOs – typically the largest ones – have been able to establish data warehouses to facilitate their "big data" analytics. Without a more affordable market for these products, smaller ACOs are left to fend for themselves. With or without sophisticated products, ACOs often end up spending a significant portion of their IT budgets just on the interfaces required to collect data – what former National Coordinator for Health IT Farzad Mostashari refers to as a "tax" from EHR vendors on hospitals just to make their own data available.[25]

Because product-specific solutions are often required to gain access to this EHR data, EHR vendors often feel justified in charging incrementally for the tools and strategies that are required; this is another source of supplemental revenue as the number of new license sales declines due to market saturation. And EHR vendors also feel they can charge for features that some customers may not want and justify the price they charge by making these features available. While it is expected that vendors will amortize their research and development costs through the sale of their software and services to many customers, there is a limit to the degree this can be done legitimately. We run the risk that health data in the U.S. will become monetized as access to data itself – even data within an organization – will carry an ever-increasing price tag. Within a hospital especially there are issues of safety and often urgency that should not be susceptible to artificial barriers for data access. More and more, hospitals will engage third party data consumers to assist in aggregating, analyzing, and sharing data with other organizations, patients, and appropriate government authorities whether they are public health agencies collecting surveillance data or CMS collecting quality measure reports. ONC can try to combat information blocking through its various policy levers, incentives, and disincentives – and we should support those efforts – but the lack of collective agreement on even defining the problem will only enable limited success.

ARE STANDARDS ENOUGH?

Standards make access to data easier, especially between disparate systems and different organizations. Standards help prevent vendor "lock in" and, thus, help protect organizational investments in interoperability. While participation in standards development activities in the U.S. is largely open to anyone, the hidden truth is that these efforts can become dominated by large vendors who can afford to pay their representatives to attend, while smaller companies and other stakeholders – like hospitals, provider organizations, public health agencies, and even individuals – cannot afford the time to attend and, therefore, have less of an influence on the outcome. The net result of this is that the standards development process can become overly influenced by these vendors and their particular agendas. The use of standards for interoperability is certainly preferable to proprietary approaches, but standards can be bent to accommodate the proprietary interests of those who are helping to define them. Even the strict use of open standards by vendors does not guarantee that data will be accessible and available to the organizations that have already paid to capture and store it. Vendors continue to promote that "special sauce" that they feel differentiates their products from those of their competitors.

Standards are not enough. Vendors need to resist the temptation to monetize data as pressure for new sources of revenue escalate. The vision of the LHS cannot be achieved with structural, technical, or undue financial barriers to data sharing. Vendors should compete on the merits of the functionality they provide, not the opportunism of the data locked within systems they provide. The need for improved functions and features within healthcare systems is so dramatic that there is plenty of opportunity for future revenue. But healthcare organizations need to bear their share of the burden as well. Participation in standards development – directly, through associations, or through other organizations – is essential to ensure that one's interest, needs, and perspectives are taken into account. As the LHS evolves, so, too, must its component organizations evolve.

So what can organizations due to promote their interests in this area? Here are some suggestions:

- *Participate* in standards development. As the need for interoperability increases, our reliance on solid standards that achieve their intended purposes becomes paramount. If you don't trust your vendors enough to represent your interests in the standards community do it yourself!
- *Insist* that your vendors develop and provide standards-based products. Standards help prevent vendor lock-in, even in the world of large EHR systems.
- *Educate* decision makers about the broader health data landscape and the impact of current systems deployments on the future direction of the LHS. Health IT is at the core of what drives many enterprises and supports the clinical and research missions directly. It must be thought of by leadership as a strategic asset and managed accordingly.
- *Consider* all your options when it comes to health information exchange (HIE). While vendor-based HIE may be strongly encouraged by your EHR vendor as the simplest way to achieve interoperability with other organizations, there are usually other options – including community- or state-based systems – that may provide more flexibility, serve a wider variety of trading partners, and prevent your data from feeling captive to any one vendor.
- *Complain* to ONC when you feel a vendor or another organization is unfairly or unnecessarily blocking access to information. ONC must begin to build a stronger base of data first to understand and then to combat this problem.
- *Organize* with your colleagues – through vendor user group forums, organizations like HIMSS, and other professional or industrial membership groups – to present a more unified front to the vendor community to promote *your* interests in a more interoperable future. **JHIM**

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