Interfacing Registries with EHRs
Draft White Paper for AHRQ Patient Registries Handbook II

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EXECUTIVE SUMMARY

Introduction

With the national commitment to invest in electronic health record (EHR) systems and to advance the evidence base in areas such as effectiveness, safety, and quality through registries and other studies, it is clear that interfacing registries with EHRs will become very important over the next few years. While in practice there may be some overlap of functionalities between these two types of systems, their roles are distinct and both are very important to the future of our health care system. This paper explores issues of interoperability and a pragmatic "building block approach" towards a functional, open-standards-based solution. An important value of this approach is that EHR vendors can implement it without major effort or impact on their current systems. While the focus of this paper is on patient registries, the same approach is applicable to clinical research studies, safety reporting, biosurveillance, public health, and quality reporting.

Background

Recent reports indicate that a small minority of U.S. physicians have implemented partial or complete EHR systems in their practices. It is expected that the passage of the American Recovery and Reinvestment Act of 2009 (ARRA) will bring about a rapid and transformative change towards adoption of these systems. ARRA sets aside approximately $19 billion in incentives to providers to adopt EHR systems that meet criteria to be established by 2010. Under ARRA, the office of the Secretary of HHS will take on a more active role in setting standards and certification criteria for EHRs with interoperability and information exchange between systems being a core goal. The creation of an interoperable health information technology (HIT) infrastructure is integral to ARRA goals including generating information on the comparative effectiveness of alternative therapies and measuring quality in the healthcare system via the "learning healthcare system" model.

Electronic health records and registry systems

An EHR is an electronic record of health-related information on an individual that conforms to nationally recognized standards and that can be created, managed, and consulted by authorized clinicians and staff across more than one health care organization. A registry is an organized system that uses observational study methods to collect uniform clinical and other data to evaluate outcomes for a population defined by a particular disease, condition, or exposure, and that serves one or more predetermined scientific, clinical or policy purposes. Registries are population-focused and designed to fulfill specific purposes that determine the methods of collecting and analyzing the data. EHRs are individual-focused with the purpose of collecting, sharing, and using health information for the benefit of that individual.

The great promise of EHRs in evidence development is in facilitating a scalable and efficient means of collecting, analyzing, and disseminating evidence through the availability of electronic rather than paper-based medical information. To the extent that EHRs capture data elements and outcomes with specific, consistent, and interoperable definitions — or to the extent that data can be found and transformed by other processes and technologies into standardized formats that match registry specifications, they avoid duplication of effort by participating clinicians and patients.

Current challenges and staged solutions

Current systems

Of the many hospitals, health care facilities, and doctor's offices that participate in studies, most have more than one data capture system. Without interoperable systems, the need to re-enter data from one system to another; train staff on new systems; and juggle multiple user names, passwords, and devices presents a high barrier to participation in registries or other studies, especially for physicians whose primary interest is patient care. The widespread implementation of EHRs that are not truly interoperable coupled with the growth in evidence development activities such as patient registries may ironically create barriers to achieving the vision of a national learning healthcare system.

To achieve broader public health goals, the need for those charged with implementing ARRA to assure both HIT adoption and implementation of open standards-based interoperability is critical. By providing mechanisms that allow for linkage between EHRs and registries, providers could link to any number of registries from their EHRs.

Interoperability

Interoperability for health information systems requires communication; accurate and consistent data exchange; and use of the information that has been exchanged. The two core constructs, around communication and content, are often called syntactic and semantic interoperability.

Syntactic interoperability is the ability of heterogeneous health information systems to exchange data. Semantic interoperability implies that the systems understand the data that has been exchanged at the level of defined domain concepts. This "understanding" requires shared data models that, in turn, depend on standard vocabularies and common data elements.

The management of patient identifiers, and the authentication and authorization of users across different healthcare applications present additional challenges. For privacy purposes, an audit trail also needs to be maintained and viewable across all the paths through which the data moves. In addition to privacy, security must also be ensured across all of the nodes in the interoperable system.

Potential Solutions

Given the lack of a holistic and definitive interoperability model, an incremental approach to the successive development, testing, and adoption of open standard building blocks towards an interoperable solution is likely the path forward. Much has been done in this area that can already provide a level of "functional interoperability." In practice, a building-block approach to the technical side of this issue allows all players in the industry to focus on specific components of interoperability; early successes can then be recognized and used to form the next step in the solution. This is a change from the earlier approaches to this issue, where the problem (and the solution) was defined so broadly that it proved overwhelming and unsupportable.

In order to visualize the technical standards for different aspects of interfacing multiple data capture systems, consider a stack where each building block is designed to facilitate one aspect of the technical interface between an EHR and a data collection system. The building blocks are modest but incremental changes that move two specific systems towards interoperability, and are scalable to different platforms.

The foundation is laid with the most basic technical components. The next block is a standard integration profile. Retrieve Form for Data Capture (RFD), was created and is maintained by Integrating the Healthcare Enterprise (IHE). It is also accepted under HITSP as TP50. Specifically, RFD/TP50 provides a method for gathering data within a user's current application to meet the requirements of an external system (e.g. a Registry). Once an EHR is RFD enabled, it can be used for multiple use-cases. RFD opens a circuit, and allows for information exchanges of different purposes including registries.

Content profiles, such as Clinical Research Data Capture (CRD), build the next level, allowing standard content defined within an EHR to be mapped into the data collection elements for the registry, eliminating duplicate entry for these defined elements. CRD allows the functional interoperability solution to leverage standardized content as it becomes defined and available within EHRs. In other words, it is an incremental approach to leveraging whatever content has been rigorously defined and resident within the EHR that is also usable and acceptable to the registry (i.e., matching some portion of its defined data elements and definitions).

As the basic components of functional interoperability are being tested and implemented, the next increment of the building block approach is to address challenges with patient privacy, digital signing, and encryption. For example, systems are needed for management and anonymization of patient identifiers across multiple systems such as EHRs and registries.

Other efforts currently being undertaken to address these and other issues include developing the abilities to actively query a clinical data source for a variety of relevant study data such as vital signs, diagnostic results, problems and allergies, medications, and immunizations and to retrieve a protocol or

a complex set of clinical research instructions necessary to fulfill the specified requirements of the protocol.

Successful implementations of several of the aforementioned building block standards have demonstrated that functional interoperability between EHRs and registries can be achieved today.

Conclusions

Achieving EHR–registry interoperability is critical to ensuring that the massive HIT investment under ARRA does not create silos of information that cannot be joined for the public good. Such interoperability should be based on open standards that enable any willing provider to interface with any applicable registry without requiring customization by the EHR vendor. The adoption of open standards such as HITSP TP50, C76 and IHE RFD, CRD, and DSC alone would greatly enhance the ability for EHRs and registries to function together and reduce duplication of effort. "Functional interoperability" provides a goal that can be achieved in the near term with significant gains in improving workflow and reducing duplication of effort for providers and patients participating in registries. The successive development, testing and adoption of open-standard building blocks that improve functional interoperability and move us incrementally towards a fully interoperable solution is a bridging strategy that provides benefits to providers, patients, EHR vendors and registry developers today.

KEY POINTS

- Syntactic interoperability (the ability to exchange data) and semantic interoperability (the ability to understand the exchanged data) are the core constructs of interoperability and must be present for EHRs and registries to share data successfully. Full interoperability is unlikely to be achieved for some time.
- Interoperability should be based on open standards that enable any willing provider to interface with any applicable registry without requiring significant customization of either the EHR or registry.
- The successive development, testing and adoption of open standard building blocks (e.g. HITSP TP-50) is a pragmatic approach towards incrementally advancing interoperability while providing real benefits today.
- Care must be taken to ensure that integration efforts comply with legal and regulatory requirements for the protection of patient privacy.

INTRODUCTION

With a national commitment to both invest in electronic health record (EHR) systems and to advance the evidence base in areas such as effectiveness, safety, and quality through registries and other studies, it is clear that interfacing registries with EHRs will become very important over the next few years. As described below, while both EHRs and registries utilize clinical information at the patient level, registries are population focused, purpose-driven and designed to derive outcomes information defined before collecting and analyzing the data. EHRs are focused on the collection and use of health-related information on and for an individual. While in practice there may be some overlap of functionalities between the two, their roles are distinct and both are very important to the future of our health care system. This paper explores issues of interoperability and a pragmatic 'building-block approach' towards a functional, open-standards based solution. An important value of this approach is that EHR vendors can implement it without major effort or impact on their current systems. While the focus of this paper is on patient registries, the same approach is applicable to clinical research studies, safety reporting, biosurveillance, public health, and quality reporting.

BACKGROUND

In 2007, 13 percent of U.S. physicians were estimated to have adopted partial electronic health record (EHR) systems and 4 percent more complete EHR systems.[1] Other studies have found differences between the adoption rates based on practice size or 'high tech' versus 'low tech' physicians,[2,3] but on average, the reported adoption levels are fairly similar. While the adoption curve has been slower than anticipated by the healthcare community, with the passage of the American Recovery and Reinvestment Act of 2009 (ARRA), a rapid and transformative change is now likely. ARRA sets aside approximately $19 billion in incentives to providers to adopt EHR systems that meet criteria to be established by 2010.

An electronic health record refers to an individual patient's medical record in digital format. EHRs can be comprehensive systems that manage both clinical and administrative data; for example, an EHR may collect medical histories, lab data, and physician notes and assist with billing, inter-practice referrals, appointment scheduling, and prescription refills. They can also be targeted in their capabilities; many practices choose to implement EHRs that offer a subset of these capabilities, or they may implement multiple systems to fulfill different needs. According to the Institute of Medicine, there are four core functionalities of an EHR: health information and data, results management, order entry and support, and decision support.[4]

The current U.S. EHR market is highly fragmented without a dominant market leader.[5] Until recently, the term EHR was broadly applied to systems that fall within a range of capabilities. In 2004, a certification process was established by an industry coalition of the American Health Information Management Association (AHIMA), the Health Information Management Systems Society (HIMSS), and the National Alliance for Health Information Technology. The Certification Commission for Health Information Technology (CCHIT) is a private nonprofit organization with the 'sole public mission of

accelerating the adoption of robust, interoperable health information technology by creating a credible, efficient certification process'.[6] Each year, CCHIT publishes criteria against which vendors submit to a certification process. For example, approximately 26 Ambulatory EHR products qualified as CCHIT Certified for 2008.[7] While progress in standardization has been made under CCHIT, the majority of EHRs still do not meet certification criteria as set forth by CCHIT.

Even with increasing standardization of EHRs, there are many issues and obstacles to achieving interoperability (meaningful communication between systems -- as described further below) between EHRs and registries or other clinical research activities. Some of the issues identified by the Clinical Research Value Case Workgroup include issues in information interoperability and exchange; issues in confidentiality, privacy, security, and data access; and issues in regulatory compliance. For example, in terms of information interoperability and exchange, the workgroup observes that clinical research data standards are developing independently from certain standards being developed for clinical care data; that currently the interface between the EHR and clinical research data is ad hoc and can be prone to errors and redundancy; that there is a wide variety of modes of research and medical specialties involved in clinical studies making standards difficult to identify; and that there are differences among standards developing organizations around healthcare data standards and how they are designed and implemented (including some proprietary standards for clinical research within certain organizations). With respect to confidentiality, privacy, security and data access it is pointed out that secondary use of data may violate patient privacy and protections need to be put in place before data access can be automated. In the area of regulatory compliance, it is noted that for some research purposes there is a need to comply with regulations for electronic systems (e.g. 21 CFR Part 11); and other rules (e.g. Common Rule).[8]

Under ARRA, the office of the Secretary of HHS will take on a more active role in setting standards and certification criteria for EHRs with interoperability being a core goal. Specifically, ARRA designates the ONCHIT within HHS to promote the development of a nationwide interoperable HIT infrastructure; and establishes HIT Policy and Standards Committees that are comprised of public and private stakeholders (e.g., physicians) to provide recommendations on the HIT policy framework, standards, implementation specifications, and certification criteria for electronic exchange and use of health information. It is anticipated that HHS would adopt through the rule-making process an initial set of standards, implementation specifications, and certification criteria by December 31, 2009.

The new Federal oversight of EHR standards is clearly guided by the need for EHRs that benefit from the market-building impact of $19 billion in provider incentives to serve the broader public purposes for which the ARRA funds are intended. Specifically, the elusive goal that has not been satisfied in the current paradigm is the creation of an interoperable HIT infrastructure. Without interoperability, the HIT investment under ARRA may actually be counterproductive to other ARRA goals, including the ability to generate and disseminate information on the comparative effectiveness of alternative therapies and the goal of measuring quality in the healthcare system efficiently and transparently. Ideally, EHR standards under ARRA should facilitate the groundwork for what the Institute of Medicine has called the 'learning healthcare system'[9] The goal of a learning healthcare system is to transform the way evidence is generated and used to improve health and healthcare -- a system in which patient registries and

similar, real-world study methods are expected to play a very important role. As the government entities responsible for recommending HIT standards consider how best to harmonize healthcare and research systems, their recommendations on mundane issues such as standardized vocabularies, data elements, data sets and technical standards may have a far reaching impact on how transformative ARRA will ultimately be.

EHRS AND PATIENT REGISTRIES

Prior to exploring how EHRs and registries might interface, it is useful to clearly differentiate one from the other. While EHRs may assist in certain functions that a patient registry requires (e.g. data collection, data cleaning, data storage, etc) and a registry may augment the value of the information collected in an EHR (e.g., population views, quality reporting, etc.) an EHR is not a registry and a registry is not an EHR. Simply stated, an EHR is an electronic record of health-related information on an individual that conforms to nationally recognized interoperability standards and that can be created, managed, and consulted by authorized clinicians and staff, across more than one health care organization.[10] A registry is an organized system that uses observational study methods to collect uniform data (clinical and other) to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure, and that serves one or more predetermined scientific, clinical or policy purposes.[11] Registries are population focused and designed to fulfill specific purposes defined before collecting and analyzing the data. EHRs are individual focused and designed to collect, share, and use that information for the benefit of that individual.

EHRs and Evidence Development

The true promise of EHRs in evidence development is in facilitating the achievement of a practical, scalable, and efficient means of collecting, analyzing, and disseminating evidence. By digitizing information, many of the scalability constraints of patient registries and other clinical research activities can be dramatically reduced. Paper records are inherently limited because of the difficulties in systematically finding or sampling eligible patients for research activities and the effort required to re-enter information into a database. Digitizing information has the capacity to improve both of these requirements for registries, enabling larger, more diverse patient populations, and avoiding duplication of effort for participating clinicians and patients. Reducing duplication of effort only occurs to the extent that EHRs capture data elements and outcomes with specific, consistent, and interoperable definitions — or to the extent that data can be found and transformed by other processes and technologies, (e.g., natural language processing) into standardized formats that match registry specifications. In addition to enabling health care information to be more readily used for registries and other evidence development purposes, bidirectionally interoperable EHRs may also serve an efferent role of delivering relevant information back from a registry to a clinician, (e.g., natural history, safety, effectiveness, quality).

Current Challenges in a Pre-Interoperable Environment

As it turns out, data capture for research purposes in general can be challenging for physicians. Of the many hospitals, health care facilities, and doctor's offices that participate in studies, most have more than one data capture system; an estimated 17 percent have 5 or more.[12] In other words, hospitals and

practices are changing their workflow to accommodate non-harmonized research demands. As a result, data capture, especially for a registry in which a large number of patients may fit into a broad set of enrollment criteria, can be awkward and time-consuming for clinicians and their staff. Without interoperable systems, the need to re-enter data from one system to another, train staff on new systems, and juggle multiple user names, passwords, and devices presents a high barrier to participation especially for physicians whose primary interest is patient care and who are often themselves resistant to change. The widespread implementation of EHRs that are not truly interoperable (as discussed below) coupled with the growth in current and future evidence development activities, such a patient registries, may ironically create significant barriers to achieving the vision of a national, learning healthcare system. In many respects physicians are part of the problem — seeking EHRs with highly customized interfaces and database schema rather than those that may be more amenable to interoperability.

In fact, while there have been several demonstration projects (cited below), no current EHRs are fully interoperable in the core functions that would enable them to participate in the learning healthcare system that is envisioned by the IOM. This is directly related to a combination of technical and economic barriers to adoption and deployment of standards-based interoperability solutions by EHRs. There are over 40 well-established EHR vendors, many of which provide heavily customized versions of their systems for each separate client. Until now, these vendors have not had the motivation or resources to modify their systems to technically communicate with the data capture systems used for registries or clinical research. For some time, there was significant interest in adding clinical research capabilities to the already-implemented EHR systems,[13] but this so-called "Swiss Army Knife" approach did not prove to be technically or commercially effective. Issues encountered ranged from standardization of core data sets to achieving compliance with FDA requirements for electronic systems used in clinical research. And, because there is no single, national EHR, even if this were achievable, it would not meet many registry purposes, which seek data across large, generalizable populations. In recent years, the industry has primarily turned back to pursuing an open standards approach to interacting with, rather than becoming, specialized systems.[14]

Even though many EHR systems are technically uniform, in many ways due to the CCHIT EHR certification process, the actual software implementations are very different. As a result, achieving interoperability goals across the myriad of installed EHRs and current and future registries through custom interfaces is a mathematical and therefore, economic impossibility (see further below). An open standards approach seems to be the most viable. However, with few exceptions, even EHRs that have tested open standards (for interoperability) have not generally deployed these capabilities in their products largely because these standards are not yet part of certification. With the broader public health goals, the need for those charged with implementing ARRA to assure both HIT adoption and implementation of open standards based interoperability with streamlined, provider-controlled access that requires minimal customization is critical. By providing user-configurable triggers or similar mechanisms that allow for the linkage between the EHR and the registry, providers could link to any number of registries from their EHRs.

THE VISION OF EHR-REGISTRY INTEROPERABILITY

As EHRs become the primary desktop interface for physicians and other healthcare workers, it is clear that registries must work through the EHR for interoperability to be feasible. At the same time, the need for physicians to participate in registries to manage safety, evaluate effectiveness and to measure and improve quality of care is growing rapidly. As a result, EHRs will need to serve as an interface for more than one registry simultaneously. In considering the need for interfacing EHRs with patient registries, it is a useful construct to consider the specific purpose that the patient registry is designed for and then how an EHR that is interoperable with one or more registries might lessen the burden, barriers or costs of managing registries and other data collection programs. These potential functions can be thought of with respect to the registry purpose.

- Natural history of disease: identify patients (and alert clinicians) who meet eligibility criteria; present the relevant forms and instructions; capture uniform data; review the data prior to transmission; transmit data to the registry; receive and present information from the registry (e.g. population views).
- Effectiveness: identify patients (and alert clinicians) who meet eligibility criteria; execute sampling algorithms; present the relevant forms and instructions; capture uniform data; review the data prior to transmission; transmit data or analytics; receive and present information from the registry (follow-up schedules; registry wide results).
- Safety: identify events for reporting through triggers; capture uniform data; review the data prior to transmission; transmit data; receive and present requests for additional information; receive and present safety information from the registry.
- Quality: identify patients who meet eligibility; present the relevant forms and instructions; capture uniform data; review the data prior to transmission; transmit data to a registry for reporting; receive and present quality measure information and comparators from the registry.

In a truly interoperable system, registry-specific functionality could be presented in a software-as-service or middleware model, interacting with the EHR as the presentation layer on one end and the registry database on the other. In this model, the EHR is a gateway to multiple registries and clinical research activities through an open architecture that leverages best-in-class functionality and connectivity. Registries interact across multiple EHRs and EHRs interact with multiple registries.

INTEROPERABILITY CHALLENGES

Interoperability for health information systems requires communication; accurate and consistent data exchange; and use of the information that has been exchanged. The two core constructs, around communication and content, are often called syntactic and semantic interoperability.

Syntactic interoperability: Syntactic interoperability is the ability of heterogeneous health information systems to exchange data. There are several layers of syntactic interoperability. First, the wiring must be in place and the TCP/IP (internet) is the defacto standard. On top of this, an application protocol is needed such as HTTP or SMTP. The third layer is a standard messaging protocol such as SOAP. The

message must have a standard sequence, structure and data items in order to be processed correctly by the receiving system.

When proprietary systems and formats are used, the complexity of the task grows dramatically. For n systems, n(n-1)/2 interfaces are needed for each system to communicate with every other one.[15] For this reason, message standards are preferred. While this seems straightforward, an example portrays how, even for EHR to EHR communication, barriers still exist. Currently, the Health Level Seven (HL-7) Version 2 message standard (HL-7 v2.5) is the most widely implemented standard among EHRs, but this version has no explicit information model but rather vaguely defines many data fields and has many optional fields. To address this problem, the Reference Information Model (RIM) was developed as part of HL-7 v3, but v3 is not fully adopted and there is no well-defined mapping between v2.x and v3 messages.

Syntactic interoperability assures that the message will be delivered. Of the challenges to interoperability, this is the one most frequently solved. However, solving the delivery problem does not guarantee that the content of the message can be processed and interpreted at the receiving end with the meaning for which it was intended.

Semantic interoperability: Semantic interoperability implies that the systems understand the data that has been exchanged at the level of defined domain concepts. This "understanding" requires shared data models that, in turn, depend on standard vocabularies and common data elements.[16]

The National Cancer Institute (NCI)'s Cancer Bioinformatics Grid (caBIG) breaks down the core components of semantic interoperability into information or data models, which describe the relationships between common data element in a domain; controlled vocabularies, which are agreed upon set of standard terminology; and common data elements, which use shared vocabularies and standard values and formats to define how data are to be collected.

The standardization of what is collected, how it is collected, and what it means is a vast undertaking across healthcare. Yet, piece by piece, much work has and is currently being done although the effort is not centralized nor equally represented across different medical conditions. One effort, called the CDASH Initiative, is led by the Clinical Data Interchange Standards Consortium (CDISC) and aims to describe recommended basic standards for the collection of clinical trial data.[17] It provides guidance for the creation of data collection instruments, including recommended case report form (CRF) data points classified by domain (adverse events, inclusion/exclusion criteria, vital signs, etc.) and a core designation (highly recommended, recommended/conditional or optional). The first version of CDASH was published in October 2008, so it remains to be seen how widely this standard will be implemented in the planning and operation of registries, clinical trials and post-marketing studies, but is an excellent step in defining a common set of data elements to be used in registries, and clinical research.

Other examples of information models used for data exchange are the ASTM Continuity of Care Record (CCR) and HL7's Continuity of Care Document (CCD) which have standardized certain commonly reported components of a medical encounter, including diagnoses, allergies, medications, and procedures. The CCD standard is particularly relevant because it is one that has been adopted as part of

CCHIT certification. The Biomedical Research Integrated Domain Group (BRIDG) model is an effort to bridge healthcare and clinical research standards and organizations with stakeholders from CDISC, HL7, NCI, and the FDA. Participating organizations are collaborating to produce a shared view of the dynamic and static semantics that collectively define a shared domain-of-interest, i.e. the domain of clinical and pre-clinical protocol-driven research and its associated regulatory artifacts.[18]

Even with some standardization in the structure and content of the message, issues exist in the use of common coding systems. For any EHR and any Registry system to be able to semantically interoperate there need to be greater uniformity around which coding systems are to be used. At this time, there are some differences between coding systems adopted by EHR vendors and Registry vendors. While it is still possible to translate these coding systems and/or 're-code' them, it limits the possibility for achieving full semantic interoperability until this is achieved.

The collection of uniform data, including data elements for risk factors and outcomes, is a core characteristic for patient registries. If a functionally complete, standard 'dictionary' existed, it would also greatly improve the value of the information contained within the EHR. But, while tremendous progress has been made in some areas such as cancer[19] and cardiology,[20] the reality is that full semantic interoperability will not be achieved in the short term.

Beyond syntactic and semantic interoperability, there are other issues that require robust, standardized solutions. One of the key issues is managing patient identifiers among different healthcare applications. Different healthcare entities, even departments within institutions, may use different identifiers for the same patient. Consider the example of a longitudinal patient registry that begins with a hospital admission but moves to follow-up in an ambulatory practice with a different EHR and a different identifier. There are several specific solutions, such as master patient indexes, patient record pointers, and patient controlled access mechanisms, but none is universal.

A second issue is how best to authenticate users across multiple applications. A third issue is permission or authorization management. At a high level, how does the system enforce and implement varying levels of authorization? A healthcare authorization is specific to authorized purposes. A particular patient may have provided different authorizations to disclose information differently to different registries interacting with a single EHR at the same time, and, the specificity of that permission needs to be retained in some way linked with the data as it transits between applications. For privacy purposes, an audit trail also needs to be maintained and viewable across all the paths through which the data moves. In addition to privacy, security must also be ensured across all of the nodes in the interoperable system.

PARTIAL AND POTENTIAL SOLUTIONS

Achieving true, bidirectional interoperability for all of the required functions for EHRs and patient registries to function seamlessly with one another is unlikely to be accomplished for many years. However, as noted above, the ARRA investment requires that a level of interoperability be achieved so that silos of information within proprietary informatics systems are not created that make it difficult or

impossible to conduct large registries or other evidence development research across diverse practices and populations. Given the lack of a holistic and definitive interoperability model, an incremental approach to the successive development, testing, and adoption of open standard building blocks towards an interoperable solution is likely the path forward. In fact, much has been done in the area of interoperability and if fully leveraged can already provide at least a level of 'functional interoperability' that could significantly ameliorate this potential problem.

From an EHR-registry perspective, functional interoperability could be described as a standards-based solution that achieves the following requirements:

> *The ability of any EHR to exchange valid and useful information with any registry on behalf of any willing provider at any time in a manner that improves the efficiency of registry participation for the provider and the patient and does not require significant customization to the EHR or the registry system.*

What constitutes 'useful' information exchange includes both general activities (e.g., patient identification, accurate/uniform data collection and processing), and specific additional elements depending on the purpose of the registry (e.g., quality reporting). Such a definition implies an open standards approach where participation is controlled by the provider/investigator. To be viable, such a model would require that EHRs 'certify' to meet open standards for basic functional interoperability (the requirements advance over time), but have the opportunity to further differentiate their services by how much they can improve the efficiency of participation.

While the goal of functional interoperability likely requires the creation and adoption of effective open standards, there have been several approaches to partially addressing these same issues in the absence of a unified approach. HIT systems, including some EHRs, have been used to populate registry databases for some time. The Society of Thoracic Surgeons (STS), the American College of Cardiology (ACC), and others utilize models that are based on a central data repository that receives data from multiple conforming systems on a periodic basis through batch transfers. Syntactic interoperability is achieved through a clear specification that is custom programmed by the HIT systems vendor. Semantic interoperability is achieved by the publication of specifications for the data collection elements and definitions on a regular cycle and incorporation by the systems vendors. Each systems vendor pays a fee for the specifications and for testing their implementation following custom programming. In some cases, an additional fee is levied for the ongoing use of the interface by the systems vendor. Periodically, as data elements are modified, new specifications are published and the cycle of custom programming and testing is repeated. While there is incremental benefit to the provider organizations by not having to use multiple systems to participate in these registries, the initial and periodic custom programming efforts and the need to support custom interface requirements makes this approach not scalable. Furthermore, participation in one registry actually makes participation in other similar registries more difficult since the data elements are customized and not usable in the next program.

The American Heart Association's Get With the Guidelines℠ program uses a web services model for similar purpose. The advantage of the web services model is that the data are transferred to the patient

registry database on a transactional basis (immediately). But, the other drawbacks in custom programming and change management still apply. This program also offers an open standards approach through IHE RFD[21] or HITSP TP50 (described below), but few EHR vendors have adopted the standard and are not yet enabling their clients to participate via this approach.

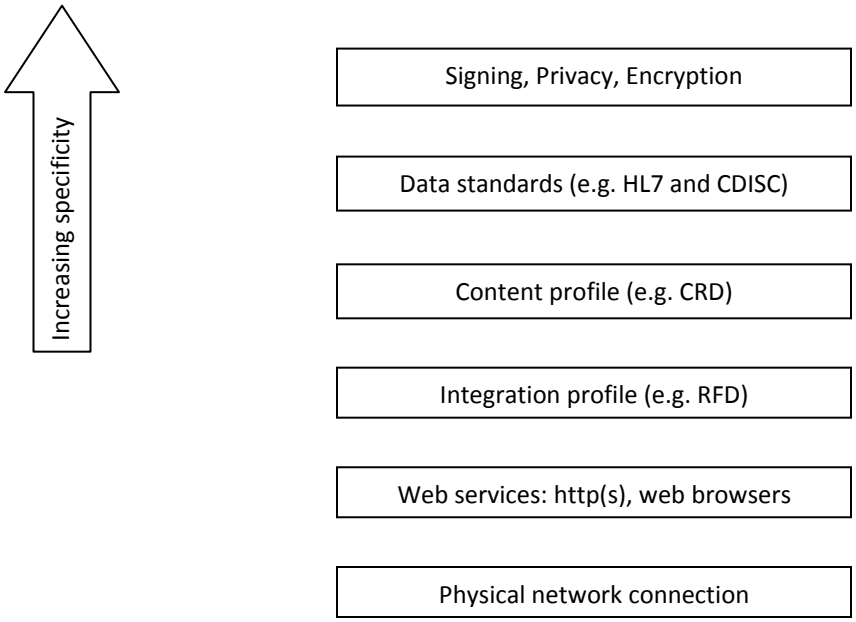
Momentum Towards a Functional Interoperability Solution

Significant momentum is already building towards adopting open standard building blocks that incrementally will lead to functional interoperability solutions. For example, the EHR Clinical Research Value Case Workgroup has focused its use cases on two activities: the ability to communicate study parameters (e.g. eligibility information, CRFs) and the ability to exchange a core dataset from the EHR.[22] Others in the standards development community have taken a stepwise approach to create the components for a first generation functional interoperability solution. As described below, this solution has already overcome several of the key barriers to creating an open, scalable, model that can work simultaneously between multiple EHR systems and registries. Some of the issues that have been addressed through these efforts include: flexibility in presenting a uniform data collection set that can be modified from time to time without custom programming by the EHR vendor; the ability to leverage existing, standardized EHR data to populate portions of the data collection set; and the ability to submit the data on a transactional basis to a registry, clinical trial or other data recipients in a standard format.

Building-Block Approach

A building-block approach to the technical side of this issue is an effective and pragmatic way to build in increments, and allow all players in the industry to focus on specific components of interoperability; early successes can then be recognized and used to form the next step in the solution. This is a change from the earlier approaches to this issue, where the problem (and the solution) was defined so broadly that complete semantic interoperability seemed to be the only way to solve the problem; this proved overwhelming, and unsupportable. Instead, a working set of industry-accepted standards and specifications that already exist can focus tightly on one aspect of interfacing multiple data capture systems, rather than considering the entire spread of issues that confound the seamless interchange between healthcare and research systems.

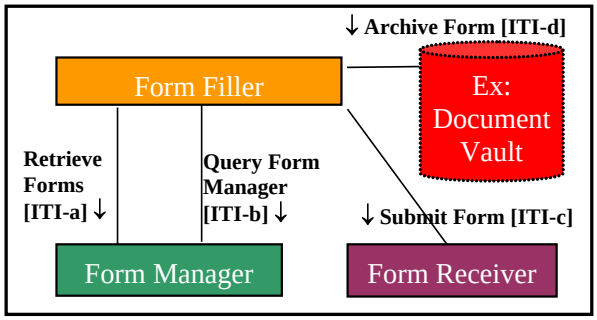
There are many different standards focused on different levels of this interface, and several different key stakeholders that create, work with, and depend on these standards. A useful way to visualize these technical standards is to consider a stack where each building block is designed to facilitate one aspect of the technical interface between an EHR and a data collection system. The building blocks are modest but incremental changes that move two specific systems towards interoperability, and are scalable to different platforms.



This theoretical stack starts with the most basic technical components as the ground layers. Physical network connections, followed by web services, secure hypertext transfer protocol (https) using secure socket layer (SSL) communications protocol, and web browsers, create the foundation of the interoperability structure. These standard technologies are compatible across most systems already, as part of the World Wide Web.

A standard integration profile, Retrieve Form for Data Capture (RFD), sits as the base of specific interoperability for health care data transfer and takes advantage of the Web standards as a way to integrate between EHRs and registry systems. RFD is a generic way for systems to interact. In a sense, RFD opens a circuit or provides a 'dial tone' to allow an EHR to exchange information with a registry or other clinical research system. RFD was created and is maintained by Integrating the Healthcare Enterprise (IHE). It is also accepted under HITSP as TP50. Specifically, RFD provides a method for gathering data within a user's current application to meet the requirements of an external system (e.g. a Registry). In RFD, as the diagram below shows, this is accomplished by retrieving a registry or other data collection form from a source (Form Manager), displaying it within the EHR system (Form Filler) to allow completion of the form (with data validation checks) either through direct user entry or automated population from the EHR database, and then returning an instance of the data back to the registry system (Form Receiver). Of importance, the EHR initiates the transaction.

Once an EHR is RFD enabled, it can be used for multiple use-cases. RFD opens a circuit, and allows for information exchanges of different purposes including registries and clinical trials, quality initiatives, safety, and public health reporting.



Content profiles such as Clinical Research Data Capture (CRD) build the next level, allowing standard content defined within an EHR to be mapped into the data collection elements for the registry, eliminating duplicate entry for these defined elements. CRD and the Drug Safety Content (DSC) profiles managed by IHE build upon the IHE RFD integration profile. Correspondingly, HITSP C76 or Case Report Pre-Populate Component (for Drug Safety) leverages the HITSP TP50 retrieve form for data capture transaction package.

CRD allows the functional interoperability solution to leverage standardized content as it becomes defined and available within EHRs. In other words, it is an incremental approach to leveraging whatever content has been rigorously defined and resident within the EHR that is also usable and acceptable to the registry (i.e., matching some portion of its defined data elements and definitions). To the extent that these data reside in a common format, they can be used for auto-population of the registry forms without custom programming. CRD leverages the Continuity of Care Document (CCD), an HL7 standard that is also a current requirement for CCHIT EHR certification. In this scenario, the CCD is generated by the EHR to populate a case report form. Only the relevant data from the CCD are used by the registry as is determined by the registry system that is presenting the form. Alternatively, CRD specifies that CDASH, a CDISC standard for data collection elements, may optionally be used as the content message to pre-populate the case report form.

The Next Increment

As the basic components of functional interoperability are being tested and implemented, more attention is focusing on the next increments of the building block approach. The important challenges to be addressed include: patient identification/privacy protection, the potential and appropriate use of digital signatures, other related and emerging profiles such as querying the EHR for existing data [Query for Existing Data (QED)] and transferring process related study information as captured in the study protocol [Retrieve Protocol for Execution (RPE)]. More extensive work in data mapping and the development of use cases around content are also needed.

Patient identification/privacy protection:

Patients within the context of clinical care are identified by a patient identifier usually referred to as a medical record number. When those patients participate in a registry, they will also have a patient

identifier within the context of those programs. In some cases, where explicit authorization has been obtained, the medical record number may be shared across programs and can be used as a common identifier that links the patient across systems. In other cases, there is a need to anonymize the patient identifier. In the latter situation, infrastructure can be deployed to create unique anonymized patient identifiers that serve to protect the patients' identity and facilitate secure patient identity management [e.g. Patient Identifier Cross-Referencing (PIX)].[23]

Beyond anonymizing, it also may be desirable to maintain a cross-referencing of patient identifiers or aliases across multiple systems so that the medical record number within the EHR can be linked back to the identifier within the registry or clinical trial without revealing the patient identity. Pseudonymization is a procedure by which all person-related data is replaced with one artificial identifier that maps one-to-one to the person.[24] Pseudonymization allows for additional use cases where it is necessary to link a patient seen in different settings (such as linking back to source records for additional information or monitoring).[25]

Digital signatures:

Certain registry purposes (such as regulatory reporting) require electronic signatures, such as when the clinician or investigator attests to the completeness and accuracy of information being submitted for a research purpose. The current paradigm is the physical or electronic signature of a paper or electronic CRF by the investigator. The potential and appropriate use of digital signatures may further broaden the set of use cases by which EHRs may be utilized for secondary purposes. Other approaches to facilitating identity management, signing, and verification such as Private Key Infrastructure (PKI) provide advantages in terms of non-repudiation and detection to tampering. In the next wave of the interoperability effort, it will be important to define those scenarios that will require the strength of an enhanced digital signature.

Other related and emerging efforts:

As the building blocks of interoperability develop, additional flexibility will be gained as the registry and EHR can more fully communicate in a common language to both request more clinical data and to provide the EHR with more information on the workflow requirements of the registry or other study protocol. These requirements point to other work being done to address these issues. Below are two examples from IHE profiles:

- Query for Existing Data (QED) – This integration profile allows a clinical data consumer such as a registry, clinical trial, or quality reporting system to query a clinical data source for a variety of relevant study data such as vital signs, diagnostic results, problems and allergies, medications, and immunizations. With this model, the registry data consumer plays an active role in querying an EHR for real-time clinical information relevant to the study protocol.
- Retrieve Protocol for Execution (RPE) – This profile intends to allow an EHR to retrieve a protocol or a complex set of clinical research instructions necessary to fulfill the specified requirements of the protocol. The objective of this effort is to leverage existing standards such as the Trial Design Model and efforts underway by the CDISC and HL7 standards organizations to further advance these definitions. The availability of these definitions and a set of transactions

defined by RPE will provide an EHR with content which may be used to identify patients for a research program based on defined inclusion/exclusion criteria, or manage the patient visit schedule and appropriate case report forms or assessments which need to be completed in the appropriate sequence, or even assist with other clinical activities such as ordering protocol specified tests or labs.

Data mapping and constraints:

While the efforts described above continue to expand the use of electronic medical record data for a variety of secondary purposes, it is clear that clinical and research teams, standards, and terminologies, need to be further harmonized to maximize the benefits of information sharing across the variety of clinical and research systems. Effectively and efficiently managing this requires that harmonization efforts are furthered among vendors and among standards organizations. It also requires that use cases continue to be honed and explicitly defined so that new clinical document *constraints* can be applied as necessary for each specified use case. Use cases will range across study types and across purposes including drug safety, biosurveillance, public health, and so forth. Each clinical document constraint should strive to capture and deliver the necessary information to fully support the level of information sharing required by the scenario that maximizes the efficiency of the clinical care/research workflow, and the value of previously collected relevant data.

What Has Been Done

A number of efforts have demonstrated successful implementations of several of the aforementioned building block standards for the purpose of achieving functional interoperability for registry purposes that have included safety, effectiveness, and quality measurement. In one case, a registry focused on effectiveness in pain management was made interoperable with a commercial EHR using RFD communication.[26] In a second case, the **A**dverse Drug Event **S**pontaneous **T**riggered **E**vent **R**eporting (ASTER) project,[27] interoperability was achieved for the purpose of reporting adverse event information to the Food and Drug Administration (FDA). In a third case, a commercial EHR was made interoperable with a quality reporting initiative for the American College of Rheumatology (ACR)[28] and to a Physician Quality Reporting Initiative (PQRI) Registry for reporting data to the Centers for Medicare and Medicaid Services.[29] In each case, both the registry and the EHRs were able to exchange useful information and to decrease the effort required by the participating physicians.

Distributed Networks

It should be noted that the models of interoperability discussed above presume that data is shared between a distributed EHR and a patient registry (or another recipient such as a regulatory authority or a study sponsor). Alternative models may leave all data within the EHR but execute analyses in a distributed fashion and aggregate only results. To effectively accomplish distributed analyses requires either semantic interoperability or the ability to map to a conforming database structure and content, and the sophistication of a large number of EHR systems to run those types of queries in a manner that does not require providers to customize or program their systems. Several groups are advancing these concepts (e.g., i2b2.org) and they may eventually prove to be very suitable for particular registry purposes (e.g., safety or public health surveillance). To our knowledge, they have not yet been subject

to the rigors of a standard setting process, but they do provide an interesting alternative or complementary framework for further investigation.

CONCLUSIONS

Achieving EHR–registry interoperability will be increasingly important as adoption of EHRs and the use of patient registries for many purposes both grow significantly. It is also critical to ensuring that the massive HIT investment under ARRA does not create silos of information that cannot be joined for the public good. Such interoperability should be based on open standards that enable any willing provider to interface with any applicable registry without requiring customization or permission by the EHR vendor. Interoperability for health information systems requires accurate and consistent data exchange and use of the information that has been exchanged. While we remain a long way from full semantic interoperability, a great deal of useful work has and is being done. For example, the adoption of open standards such as HITSP TP50, C76 and IHE RFD, CRD, and DSC alone greatly enhance the ability for EHRs and registries to function together and reduce duplication of effort. 'Functional interoperability' provides a goal that can be achieved in the near term with significant gains in improving workflow and reducing duplication of effort for providers and patients participating in registries. The successive development, testing and adoption of open standard building blocks that improve functional interoperability and move us incrementally towards a fully interoperable solution is a bridging strategy that provides benefits to providers, patients, EHR vendors and registry developers today.

Appendix I: Relevant Entities in Health Information Technology Standards

The Clinical Data Interchange Standards Consortium, or CDISC, is a multidisciplinary non-profit organization that is focused specifically on medical research, and works toward developing and supporting global, platform-independent data standards that enable information system interoperability. It is a membership organization made up of more than 170 academic research centers, global biopharmaceutical companies, technology and service providers, and IRBs.[30] CDISC has established standards to support the acquisition, exchange, submission and archival of clinical research data and metadata, such as case report tabulation data definitions, submission data, and operational data modeling; these standards are intentionally vendor-neutral, platform-independent and freely available.[31] CDISC has formed key partnerships with other standards bodies, vendors and research groups to further the creation and use of these and other industry standards. CDISC's Healthcare Link project is a board-approved initiative that specifically focuses on the mission of interoperability between healthcare and clinical research.[32]

Health Level Seven, or HL7, is an American National Standards Institute (ANSI) -accredited organization that produces specifications and protocols for clinical and administrative health care data. HL7 is a global organization with corporate and individual membership consisting of providers, vendors, payers, consultants, and government groups. Like CDISC, HL7 does not develop software, but instead creates specifications. HL7's original specification was a messaging standard that enables disparate healthcare applications to exchange keys sets of clinical and administrative data.[33] This standard defines the structure and content of the messages that are exchanged between systems in either batch mode, which facilitates transfer of a collection of individual messages labeled by a single header, or interactive mode, which transmits a single message. HL7 then extended this idea to a Clinical Document Architecture (CDA), which is designed to support standards for storing and retrieving file-level information, such as electronic health records.[34] The Reference Information Model (RIM) then specifies the details, results, and contexts of clinical informatics by defining subject areas, classes, attributes, use cases, and trigger events, such as a follow-up clinical visit.[35] HL7 also houses important specifications and tools relating to electronic documentation of standards, for example, the Continuity of Care document (CCD).

The Healthcare Information and Management Systems Society, or HIMSS, is an industry membership organization that focuses on knowledge sharing, advocacy and collaboration among its members. HIMSS is a long-standing advocate of using information management systems to improve health care, and represents a large portion of the industry (over 20,000 individuals and 350 corporations).[36] HIMSS plays a critical role in this discussion through the HIMSS Electronic Health Record (EHR) Association, and also through its role in partnering with two other key standards groups: HITSP and IHE.

The HIMSS Electronic Health Record Association (EHRA) is a trade association specifically made up of Electronic Health Record (EHR) companies. This Association is a key player in the interoperability

discussion. The HIMSS EHR Association focuses on creating interoperable EHRs in hospital and ambulatory care settings, by providing a forum and structure for EHR leaders to work toward standards development, interoperability, the EHR certification process, performance and quality measures, HIT legislation, and other EHR issues.[37]

IHE, or Integrating the Healthcare Enterprise, is an initiative sponsored by HIMSS that is designed specifically to bridge the gap between existing standards and the implementation of integrated systems. IHE does this by creating Profiles, which specify precisely how standards are to be used in integration implementations. It is important to note that IHE does not develop standards; instead, it provides a link point between the standards that exist and the problems among the industry that need to be solved. The initiative is focused on eliminating ambiguities, reducing configuration and interfacing costs, and ensuring a higher level of practical interoperability for users and developers of health care information technology as they implement standards-based communication between systems and then perform tests to determine that the implementation conforms to the specifications.[38] Standards from different organizations that achieve the same goal can be inserted into an IHE profile and IHE will then produce technical specifications that can be used by developers and vendors to build products that are compliant with those standards. IHE's value has been recognized by other standards organizations, particularly CDISC, because of its practical approach. For example, IHE has defined a simple 4-step process that carries a specific problem from problem definition, through implementation and testing, to the real world:

1. Identify interoperability problem
2. Specify Integration profiles
3. Test systems at Connectathon (an annual weeklong interoperability-testing event); demo at HIMSS Interoperability Showcase
4. Implement in real world

The Healthcare Information Technology Standards Panel (HITSP) serves as a partnership between the public and private sectors with the purpose of identifying a widely accepted set of standards for interoperability of health care applications. HITSP is funded by HHS, administered by ANSI, and tightly partnered with HIMSS; Federal agencies are mandated to use interoperability standards that have been harmonized by HITSP.[39]

The Certification Commission for Health Information Technology (CCHIT) is a private nonprofit organization with the 'sole public mission of accelerating the adoption of robust, interoperable health information technology by creating a credible, efficient certification process'.[40] It is divided into workgroups that address the standards for specific functional areas such as ambulatory care, behavioral health, personal health records, and cardiovascular care. Since being recognized as a certifying body by the U.S. Department of Health and Human Services in 2006, it remains the only Federally approved organization to certify health IT products and systems.[41]

Group	Year Est.	# Members	Mission	Relevant Standards/ Specifications
CDISC	2000	>170 (corporate)	Develop and support data standards	CDASH
HL7	1987	>2200 (individuals)	Produce specifications and protocols for clinical and administrative health care data	CDA, RIM, CCD
HIMSS	1961	>350 (corporate), >22,000 (individuals)	Knowledge sharing, advocacy and collaboration	
EHRA	2004	~40 (corporate)	Creating interoperability between existing EHRs	EHRA Interoperability Roadmap
IHE	1997	>230 (organizations)	Provide a link point between the standards that exist and the problems among the industry that need to be solved	RFD, CRD
HITSP	2005	>550 (corporate and organizations)	Partnering with public and private sectors to achieve standards to support interoperability among healthcare software applications	TP50, C76
CCHIT	2004	26 products certified under 08 CCHIT ambulatory EHR criteria	Defines the requirements for an EHR to be certified in the US	CCHIT certification criteria (available at www.cchit.org/certify)

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