

Formation of a Regional Health Information Organization

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Introduction

While the Meaningful Use incentives enacted by the American Recovery and Reinvestment Act of 2009 have accelerated the adoption of electronic health records (EHR's) by healthcare providers and organizations throughout the United States, there is much progress yet to be made. Only 26.6% of hospitals have at least a basic EHR system (DesRoches, Worzala, Joshi, Kralovec, & Jha, 2012), and adoption rates for physicians were only 20% as of 2009, growing 3-6% annually (Jha, 2010). Exchange of the electronic data that does exist between the multiple providers and entities caring for a patient over time is negligible, covering less than one percent of American patients (Jha, Doolan, Grandt, Scott, & Bates, 2008; Adler-Milstein, Bates, & Jha, 2011). Without a framework for interoperability and information exchange, healthcare information systems are poorly suited to provide comprehensive clinical information when and where it's needed or to serve as the basis for clinical decision support that assists clinicians in organizing data and making critical medical decisions.

We propose the creation of a Regional Health Information Organization (RHIO) to bridge the gap between individual systems and promote the timely, accurate, bidirectional exchange of multiple types of clinical data among all of the stakeholders in our community. These stakeholders include hospitals, providers, payers, and patients, as well as labs and pharmacies. Data to be exchanged includes patient demographics, insurance information, clinical problem lists, allergy lists, medication lists, laboratory results, radiology reports, clinical care plans, and other patient health information. Several model RHIOs, as well as general studies of RHIO characteristics, challenges, and benefits, will inform our organizational and technical decisions. Standards will be based on the Office of the National Coordinator for Health Information Technology (ONC) Standards and Certification Notice of Proposed Rulemaking for Stage 2 Meaningful Use (45 CFR Part 170, available at HHS, 2012d). While we recognize that there are significant challenges to creating a RHIO, we feel that the potential benefits are compelling. Only when full and free health information exchange is achieved will health information technology realize its full potential to improve healthcare quality, safety, and efficiency and to decrease healthcare costs.

Stakeholders

There are many stakeholders in a community that are affected by the ability to exchange multiple types of clinical data. Stakeholders can play multiple roles in health information exchange as data providers, data users, and data funders (Grossman, Kushner, & November, 2008). Stakeholders that can have all these roles include hospitals, physicians, clinicians, medical groups, and community health centers. Stakeholders that can be data users and data funders include employers, commercial and public payers, state and local government agencies, and clinical researchers. In addition, ancillary providers such as labs, radiology centers, pharmacies, and pharmacy benefit managers are also involved as data providers in the health data exchange (Grossman, et al., 2008). Physicians and clinicians will be able to access health information to provide better collaboration of care and have up to date medical information on their patients. Payers would benefit from health information exchange and see savings due to a decrease in unnecessary or repeated services. Patients would have access to patient portals and their own electronic records to become more involved in their own care. Everyone in the community can potentially benefit from better interoperability and free flow of information.

Information Being Exchanged

The RHIO intends to support the bidirectional exchange of a rich variety of clinical data types sufficient to enable rapid, efficient coordination of healthcare by providers in the region. The Health Level Seven (HL7) Continuity of Care Document (CCD) (HL7, 2012) and the HITSP C32 standard (HITSP, 2012) remain very important because they were specified as required in the Meaningful Use 2011 (Stage 1) EHR Certification Criteria, and these standards will continue to be supported. A CCD consists of 17 section types containing sufficient relevant clinical and administrative data to represent the patient's basic "medical identity" at a particular instant in time. The sections include:

Required Modules	Optional Modules		
Alerts and Allergies	Advanced Directives	Immunizations	Support
Medications	Encounters	Medical Equipment	Vital Signs
Problems	Family History	Payers	
Procedures	Functional Status	Plan of Care	
Results	Healthcare Providers	Social History	

Table 1: Sections of a CCD

The full spectrum of patient care requires a more flexible and comprehensive set of data types. On March 7, 2012, ONC and CMS published a Notice of Proposed Rulemaking (NPRM) (HHS, 2012d) establishing the content exchange standards and implementation specifications required for 2014 (Stage 2) Meaningful Use certification. Section 170.205 reads in part:

The Secretary adopts the following content exchange standards and associated implementation specifications:

*(a) **Patient summary record** —(1) Standard. Health Level Seven Clinical Document Architecture (CDA) Release 2, Continuity of Care Document (CCD) (incorporated by reference in §170.299). **Implementation specifications.** The Healthcare Information Technology Standards Panel (HITSP) Summary Documents Using HL7 CCD Component HITSP/C32 (incorporated by reference in §170.299).*

The Consolidated Clinical Document Architecture (CDA) specified and codified by the Secretary of Health and Human Services incorporates the CCD and provides the additional document types that most clinicians will require for full health information exchange. The HL7 CDA Consolidation Guide (HL7, 2011) contains rules for creating nine different kinds of documents:

1. Continuity of Care Document 1.1
2. History and Physical
3. Consult Note
4. Discharge Summary
5. Diagnostic Imaging Report
6. Procedure Note
7. Operative Note
8. Progress Note
9. Unstructured Document

A CDA document is composed of headers, sections, and entries. The header provides metadata about the document itself, the body can contain documents in various human readable file formats (although re-encoded to fit into the XML structure), and entries contain machine-readable representations of clinical content (Boone, 2012). The RHIO plans to initially implement level 1 CDA where documents consist of headers and human readable body components and will progress as rapidly as feasible to level 2 CDA where the body can be structured into sections and subsections coded into standard vocabularies such as LOINC and SNOMED CT (Boone, 2012). Unfortunately it will likely take several years to ultimately progress to level 3 CDA where the entire clinical content of the document is represented in machine-readable form.

Model RHIOs

Three RHIO's have been selected as models for being successful in their ability to exchange clinical data with an ultimate goal of benefiting their communities. The Indiana Network for Patient Care (INPC), Massachusetts eHealth Collaborative (MAeHC), and the Rochester RHIO are all great examples of existing RHIOs that have taken the proper steps to exchange clinical data. Their success comes from having adequate funding, a critical mass of users, sufficient community involvement, and the technologies to enable efficient information flow. Table 2 summarizes key attributes for each of these RHIOs:

RHIO	HISTORY	DATA EXCHANGED	TECHNOLOGIES	FUNDING
INPC	<ul style="list-style-type: none"> • LHII launched in 1994 • IHIE formed in 2004 by civic leaders to support INPC infrastructure • Success came from ability to reach a wide range of users 	<ul style="list-style-type: none"> • From all major Indianapolis hospital systems, county and state public health departments, Indiana Medicaid and RxHub • INPC provides data from ancillary providers • Data viewed as one patient virtual medical record 	<ul style="list-style-type: none"> • D4D takes HL7 report messages from INPC repository • Files have same data structure, share the same terminology dictionary, and operate with the same software system • Medical record numbers linked through linking algorithm • LOINC consolidates patient data • Lab test codes mapped by RELMA mapping tool by extracting HL7 messages into one record per local code • Radiology images use DICOM standard • RxHub provides prescription reorders through HL7 messages 	<ul style="list-style-type: none"> • National Library of Medicine high performance computing and communication initiative • Agency for Healthcare Research and Quality and the Health Resources and Services Administration • Indiana Health Information Exchange supports INPC infrastructure
MAeHC	<ul style="list-style-type: none"> • Effort began in 2003 with the Massachusetts Chapter of the American College of Physicians • Success from promoting large-scale EHR adoption 	<ul style="list-style-type: none"> • EHR implementation allowed for clinical data exchange between clinical sites in three Massachusetts communities 	<ul style="list-style-type: none"> • Working group formed to establish technical standards and EHR vendor selection by practices and communities • Technical standards were specified to enable clinical data exchange, quality and safety initiatives, and evaluation • Standardization of key data was made possible with use of the SNOMED and ICD-9-CM • Some system features the work group focused on were friendliness, functionality, clinical decision support capability, interoperability, security, reliability, and affordability 	<ul style="list-style-type: none"> • Strong financial backing from the payer community such as Blue Cross Blue Shield of Massachusetts
Rochester	<ul style="list-style-type: none"> • Rochester RHIO was founded in 2006, is based in New York and serves a region made up of eleven counties 	<ul style="list-style-type: none"> • Rochester RHIO is based on a federated model with an MPI and twenty health care organizations exchange health data 	<ul style="list-style-type: none"> • Axolotl Analytics and business intelligence tools • Rochester RHIO's health information exchange infrastructure is supplied and supported by Optuminsight-Axolotl's Elysium Exchange 	<ul style="list-style-type: none"> • Sources of revenue are made up of payer surcharges and transaction fees from data distributors such as hospitals

Table 2: Model RHIO Characteristics

The INPC is a successful local health information infrastructure (LHII) providing community wide health data. Much of their success has come from the ability to reach a wide range of users. The LHII carries health information from all major Indianapolis hospital systems, the county and state public health departments, and Indiana Medicaid and RxHub (McDonald et al., 2005). The INPC provides data from ancillary providers such as lab, radiology, dictation, and other reports to physician offices. The INPC launched in 1994 with aid in funding from the National Library of Medicine's high performance computing and communication initiative. Additional funding was given by other agencies such as Agency for Healthcare Research and Quality (AHRQ) and the Health Resources and Services Administration (HRSA) to name a few (McDonald et al., 2005). Then in 2004 the Indiana Health Information Exchange (IHIE) was formed by civic leaders to support INPC infrastructure. The INPC developed a communitywide

clinical repository that is organized by patient (McDonald et al., 2005). The data from many institutions can be viewed as one virtual medical record for each patient. In order to comply with HIPAA regulations, the INPC implemented two rules in order to be granted access to a patient's record. The first rule is a proximity-based approach where check-in messages link a patient and provider. The second rule is called institutional privileging which grants providers access to records based on staff privileges at two or more INPC institutions (McDonald et al., 2005). These two rules exceed the HIPAA requirements.

Ancillary reports are provided by a Regenstrief system called DOCS4DOCS (D4D). D4D takes the HL7 report messages from the INPC repository and stores them in its database by physician practice (McDonald et al., 2005). The technology used to run the INPC is a federated repository. This repository contains each institutions data in separate files on one computer where the files have the same data structure, share the same terminology dictionary, and operate with the same software system (McDonald et al., 2005). Chart medical record numbers from various institutions are linked through a linking algorithm so that providers can use the medical record number they know to access a patient's record. LOINC is used to consolidate laboratory data about one patient for use in institution flow sheets, decision support, and public health and research purposes (McDonald et al., 2005). Lab test codes are mapped by using the RELMA mapping tool by extracting HL7 messages into one record per local code (McDonald et al., 2005). Radiology images use the DICOM standard from two picture archive systems and RxHub provides prescription reorders but has them delivered as HL7 messages (McDonald et al., 2005). The INPC allows for repository data to be used for many purposes including prescribing treatments and public health and research.

The MAeHC was formed with a strategy of fully funding some community-wide demonstration projects to encourage clinical data exchange, facilitate evaluation, and generate important data and experience to promote large-scale EHR adoption in three Massachusetts communities (Goroll, Simon, Tripathi, Aczenzo, & Bates, 2008). In 2003 the Massachusetts Chapter of the American College of Physicians began the effort of establishing a collaborative to promote large scale EHR adoption (Goroll et al., 2008). A working group was formed to establish technical standards and vendor selection by practices and communities. The goal of the working group was to identify qualified vendors and give physicians the choice to select a vendor that would work well with their practice. Technical standards were specified to enable clinical data exchange, quality and safety initiatives, and evaluation (Goroll et al., 2008). Standardization of key data was made possible with use of the Systemized Nomenclature of Medicine (SNOMED) and the International Classification of Diseases (ICD-9-CM). Some system features the work group focused on were friendliness, functionality, clinical decision support capability, interoperability, security, reliability, and affordability (Goroll et al., 2008). Physician recruitment and retention in the MAeHC was strong yielding an overall participation rate of 84% in the community adopting EHRs in their practices (Goroll et al., 2008). Factors essential to the success of MAeHC EHR adoption included a strong financial backing from the payer community, intensive practice support, commitment to collective action, setting clear goals, physician leadership involvement, government support, and a community based focus (Goroll et al., 2008). Blue Cross Blue Shield of Massachusetts (BCBSMA) pledged \$50 million to support EHR implementation (Goroll et al., 2008). The collaborative was successful due to providing practices with external support at all phases of the EHR implementation. This included helping plan the implementation and redesigning the workflow through installation and training with ongoing support (Goroll et al., 2008). The MAeHC collaborative approach also helped in its success by welcoming all members of the health care community to participate allowing the physician community to take a lead role (Goroll et al., 2008).

The Rochester RHIO was founded in 2006, is based in New York and serves a region made up of eleven counties. These eleven counties are in urban areas surrounded by mainly rural communities. The Rochester RHIO is based on a federated model with a master patient index (MPI) and twenty health care organizations exchange health data (Solomon & Daniels, 2011). There are critical success factors that Rochester RHIO has implemented in order to be successful. These factors include broad community support, diverse and creative funding strategies, and the target of early adopters of EMRs. Financial sustainability has been achieved within five years due to its financial model (Kremer, 2011). The three main areas of the financial model include careful financial modeling and pre-planning, investment in campaigns to promote adoption and documenting the system's usage and value with Axolotl Analytics and business intelligence tools (Kremer, 2011). The sources of revenue received by the Rochester RHIO are made up of payer surcharges and transaction fees from data distributors such as hospitals (Solomon & Daniels, 2011). The Rochester RHIO's health information exchange (HIE) infrastructure is supplied

and supported by Optuminsight-Axolotl's Elysium Exchange (Solomon & Daniels, 2011). The Elysium EMR is made available to physicians to enable functions such as e-prescribing, clinical messaging, and other clinical applications desired at their practice (Solomon & Daniels, 2011). The Rochester RHIO is working on connecting to other RHIO's in New York including the Southern Health Link and Health e-Connections of Central New York. The primary goal of making these connections is to have the ability to query another RHIO for a patient's CCD (Solomon & Daniels, 2011). Another goal of the Rochester RHIO is implementing patient engagement strategies with the connectivity of patient kiosks and home telemonitoring devices (Solomon & Daniels, 2011). A focus on patient engagement is attributed to meeting EHR meaningful use criteria (Solomon & Daniels, 2011).

Information Flow and Architecture

Development and Deployment Hardware: The data center facility will be based on multiple clustered Production Web/HTTP Servers with shared session scope and appropriate failover management. There will be a dedicated Relational Database Management Services (RDBMS)/SQL module implemented on redundant servers and with daily backups to network attached storage. There will be a separate Development/Staging Web/HTTP and RDBMS/SQL Combined Server for development, testing, and troubleshooting/repair activities for client problems. Data transmission into and out of the RHIO will be mediated by combination router/firewall appliances implementing stateful packet inspection and stringent policies to protect against intrusions and malware. Data transmission to and from the ISP will be via carrier grade fiber optic connection capable of at least 10 Gbps data transfer rate, and a second data transfer pathway will be in place for activation in case of physical damage to the primary connection.

Data Model: The RHIO will employ a Federated (Decentralized) Data Model. The current political and economic climate in the healthcare industry suggests that most healthcare organizations will insist on maintaining possession and control of their own data. Although a Centralized Model where data is collected from client sources and aggregated into one large combined clinical data repository can leverage economies of scale and provide faster access to data, concerns about the large initial financial and organizational investment in transferring data and about data security, accessibility, and ownership would likely deter the majority of healthcare providers from joining a RHIO that utilized this model (HIMSS, 2009a). A Federated Model where data is stored locally at the point of creation provides better assurance that data is current and accurate and mitigates client concerns over storage, access, and ownership of data. In addition, there is no single point of failure which can cripple the system. A federated model does bring its own set of challenges including patient record matching, harmonization of client standards for data storage and display, methodology for locating and retrieving large volumes of data across organizational boundaries, delays in data retrieval, proper authentication of authorized users, and concerns about patient privacy, security, and informed consent (HIMSS, 2009a; HIMSS, 2009b; Scalise, 2006; Hurd, 2008). Proven working examples of how these problems have been solved are discussed elsewhere in this paper, and federated systems are much easier to implement in stages as clients are added, so this has become the dominant model in first generation health information exchange.

Patient Record Matching: One of the most fundamental problems in establishing communication between electronic health records is uniquely identifying the patients whose data is contained (and often duplicated) in different EHR systems. Matching patient specific data from the different providers to produce properly linked data sets is fundamental to the quality and integrity of the communication process and of the information provided to RHIO clients (Clyde and Salkowitz, 2006). The MPI's of the RHIO's client organizations will be merged into a single enterprise master patient index (EMPI) which establishes a unique identifier for each patient, avoids duplication of records, and protects against incorrectly associating one patient's data with another patient's identifier. Unless this process is completed successfully, there is a risk of transmitting inaccurate data to care providers thus creating liability and risk, increasing costs and inefficiencies, and undermining the credibility of the system (Clyde and Salkowitz, 2006; HIMSS, 2009b). Although the MPI's of the component local organizations may share identifying fields, even the most carefully designed rule sets for deterministic matching of database fields will produce too many false positive and false negative results in the matching process. This has led to the use of complex statistical methods to develop probabilistic matching algorithms which have significantly higher sensitivity and specificity (Clyde and Salkowitz, 2006; Baksi, 2009; Karmel et al., 2010).

Many proprietary commercial implementations of these matching algorithms are available (HIMSS, 2009b; HIMSS, 2009c), but there is lack of scientific data on their reliability and performance. Besides the lack of scientific studies to determine which algorithm best reduces false positives and false negatives, there is also no information on the parameter settings and configurations programmed by the application vendors (HIMSS, 2009c). Finally, these solutions are very expensive, often priced at \$100,000 and up (HIMSS, 2009b). The other option is to develop an in-house solution based on one of the open source systems available (HIMSS, 2009b). This allows the RHIO IT staff to adjust configuration parameters based on local experience with matching accuracy and to develop an understanding of the product at a very fundamental level which should allow better technical support by local staff. This solution will likely be less expensive, although it will have some costs such as IT staff time and some level of support from experts in the product code. A few national vendors (e.g. QuadraMed Corporation, IBM Initiate Systems) appear regularly on the KLAS Research (KLAS, 2011) list of top ranked EMPs, and the RHIO plans to survey a number of the customers using these products to determine whether the value and accuracy of a commercial system are sufficient to justify the cost.

Record Locator Service: A second major service that the RHIO must provide is a system to determine what medical data exists for each patient and where that primary source data is located. The EMPI will contain pointers to each patient's record locations at all institutions belonging to the RHIO. The record locator service (RLS) will accept queries for the location of patient records, determine the matching patient in the EMPI, and return the record location(s) to the requesting system (HHS, 2012c; HIMSS, 2009b). The participating clinicians will expect the system to operate in a synchronous request-response mode optimized to return results in real time. The RLS and EMPI must be capable of processing additions, deletions, and updates of patient information. Even though the RLS communicates data locations rather than actual data, the service must communicate securely and maintain an audit log, must implement or interface with a patient consent manager so that even record locations are not shared unless appropriate patient consent is verified, and must implement or interface with a provider identification engine to ensure that record locations and ultimately protected health information are only shared with properly authenticated requesters (HIMSS, 2009b; Markle Foundation, 2012).

Data Integration, Terminology Standards and Transmission: The third and final major component of RHIO architecture is application software that actually executes the exchange of clinical data. The RHIO will implement an integration engine to translate data between formats, adjust for differences in coding structures and data sets at its various members, and transmit data from sending to receiving systems (HIMSS, 2009b). The integration engine will utilize the standard terminologies, document structures, and transmission standards specified in the recent NPRM defining the standards required for 2014 (Stage II) Meaningful Use certification (HHS, 2012d). The standard terminologies specified in Section 170.207 of the rule include ICD-9/10 for diagnoses, SNOMED CT for problem lists and medical terms, LOINC for laboratory results, CPT-4 for procedures, RxNORM for medications, and CVX for immunizations. Section 170.205 of the rule adopts HL7 Clinical Document Architecture Release 2 and HL7 Continuity of Care Document as the required forms for patient summary records and HL7 2.5.1 as the standard for many other types of electronic transmissions. As specified in Section 170.314 of the proposed rule data transport between the RHIO and member servers will be managed by secure hypertext transfer protocol (https) and will support S/MIME encoding. Also in compliance with the ONC proposed rule and in order to support transport specifications under the Direct Project (The Direct Project, 2010), the RHIO will support External Data Representation (XDR) and Cross Enterprise Document Media Interchange (XDM) for direct messaging. ONC believes that these transport standards will open HIE to clinicians who need simplified data transmission scenarios and make it possible for patients to view, download, and transmit a copy of their summary care record to the destination of their choice.

Data Security, Privacy, and Integrity: Data will be encrypted by an NIST-certified encryption algorithm as specified in the ONC proposed rule, and the selected patient record matching algorithm will be certified to produce a false positive rate low enough to comply with the HIPAA standards. The RHIO will maintain a provider index and management system based on the National Provider Index (NPI) numbers of its participants to assure that protected health information is only shared with authorized users for legitimate purposes. Server to server identification will be managed by X.509 digital certificates and encryption as specified in the ONC proposed rule.

In regard to patient privacy, the RHIO had to choose between an opt-in model where providers are responsible for obtaining explicit written consent from patients regarding what protected health information may be included in a RHIO and with whom it may be shared versus an opt-out model where

patient information is assumed to be included in the data exchange unless the patient explicitly requests that this information be excluded. Dr. John Halamka (2012), Co-chair of the Health Information Technology Standards Committee and of the Massachusetts HIT/HIE Advisory Committee, argues strongly for an "Opt in consent to disclose at each institution. This means that no data is exchanged between organizations until the patient consents to the release of information from the sending institution (the place where the data was generated). This consent stays in force until a patient revokes it." Because consent has been given at the sending institution, there is no burden on receiving institutions to repeat the consent process. This model has been implemented in the New England Healthcare Exchange Network and is incorporated in the design of the statewide healthcare data exchange being built in Massachusetts. Dr. Halamka says "Opt in to disclose is straightforward to implement and support. It's easy to enforce and audit." The RHIO will adopt an opt-in consent policy, and patient consent information will be maintained in an embedded consent management application (e.g. Heinze et al., 2011).

Organizations joining the RHIO will be required to sign a Data Use and Reciprocal Support Agreement or DURSA, a comprehensive agreement creating a legal framework of mutual responsibilities based on existing law for the electronic exchange of health information (HHS, 2012f). The DURSA builds upon legal requirements which are ready to bind each of the participants individually and describes the mutual responsibilities, obligations, and expectations that will "create a framework for safe and secure health information exchange, and are designed to promote trust among participants and protect the privacy, confidentiality, and security of the health data that is shared (HHS, 2012f)." Such agreements are already being tested in the Phase II Trial Implementations of the Nationwide Health Information Network (NHIN) and the specified privacy and security standards are available at the NHIN website (HHS, 2012a; HHS, 2012e). The areas addressed include access consent policies, authorization frameworks, messaging platforms, and many others.

Architecture Model: Figure 1 on page 18 provides a graphical representation of the proposed architecture, showing the data ownership and information flow between primary stakeholders (hospitals, physicians, health plans, and patients) and the standards governing the data exchange.

Standards

Standards are essential to system interoperability and data exchange, and adopting standards for the representation and transmission of health information will allow our organization to build a comprehensive, effective RHIO. As discussed in the Information Flow and Architecture section of this paper, the ONC has proposed standards for the "Meaningful Use" of EHRs. The ONC recommends widely used health care standards for clinical observations and laboratory test data, medications, digital images, problem lists, discharge diagnoses, immunization reports, and transmission of patient records. Other standards cover patient demographic data, data security and encryption, and quality reporting (U.S. HHS, 2012c; HHS, 2012d). The standards specified by ONC are recommended by leading standards organizations such as Health Level Seven and Integrating the Healthcare Enterprise. ONC's endorsement will likely lead to rapid universal adoption of these standards by EHR users, so it will be vital for our RHIO to support them as we implement our system for the free exchange of electronic health data.

The ONC recommends LOINC for clinical observations and laboratory test data, which are important parts of a patient's health record. Leading national laboratories including Quest Diagnostics, LabCorp, and LifeChem use LOINC codes. Healthcare providers such as the U.S. Veteran's Administration (VA), the U.S. Navy, and the Kaiser Permanente health care network use LOINC as their laboratory data standard (Huff et al., 1998). Successful local and regional HIEs such as the INPC have been using LOINC for years (McDonald et al., 2005). LOINC's ONC recommendation and widespread adoption make it the best choice for our RHIO's laboratory testing and clinical observation standard.

Medications play a significant role in acute care and chronic disease management. Many patients take multiple prescription drugs regularly, forcing clinicians and pharmacists to try to keep track of allergies and drug interactions in order to avoid adverse drug events (ADEs). The ONC recommends RxNorm for this medication management. Large health care providers such as the VA and the U.S. Department of Defense (DOD) have used RxNorm to exchange patient health information. RxNorm supports clinical decision support for drug therapies and offers many support tools (Nelson et al., 2011). RxNorm's ONC recommendation and proven data exchange capability make it the right choice for our RHIO's EHR medication terminology standard.

The ONC recommends the ICD-9/10 standard for discharge diagnosis coding. As of October 1, 2014, CMS will require that Medicare beneficiaries' diagnoses be coded in ICD-10 to be eligible for payment, and for practical purposes all other health care payers are converting to this system also. Since ICD-10 is the required code set for billing and reimbursement, supporting the same terminology for all diagnostic coding in our organization makes sense. ICD-10 (over 68,000 codes) incorporates much greater clinical detail than ICD-9 (13,000 codes). This additional granularity brings many benefits, including more accurate billing with fewer rejected claims, improved quality, safety, and efficacy of care, better data for operational and strategic planning, better data to support clinical research and public health efforts, and better data to support resource monitoring, policy decisions, and design of healthcare delivery systems (North Carolina Healthcare Information and Communications Alliance, Inc., 2010). ICD-10 is a global standard promoted by the ONC and CMS: it is the best solution for our diagnosis coding.

SNOMED CT is the ONC-recommended standard for problem lists. The extent and completeness of the terminology, which has over 300,000 entries and has been cross-mapped to ICD-10, make it possible to code clinical concepts in a standard format that supports interoperability while still maintaining a high level of granularity and detail. Distributing this data across a wide spectrum of providers and settings will provide more complete, accurate information for the patient at each time and point of care allowing more effective diagnosis and treatment. Eliminating the need for repeated data entry will reduce transcription errors and potentially allow staff to be transferred to more productive activities. The availability of more timely, accurate data can improve organizational planning and resource management, enhance the use of embedded clinical decision support, and enable better subsequent use of the data for clinical research, service planning, and epidemiology (Canada Health Infoway, 2012). The addition of the ONC recommendation makes SNOMED CT an obvious choice for use by our RHIO.

Digital imaging provides clinicians with valuable information related to patients' conditions and diagnoses. We will use DICOM as our organization's digital imaging standard, as recommended by the ONC and based on its virtual universal use in hospitals worldwide. DICOM allows providers to display, store and retrieve, print, and exchange digital medical images while providing related workflow management capabilities (Hebda & Czar, 2009). Our RHIO will adopt DICOM in order to optimize digital imaging information exchange with the hospitals and other health care providers serving our community.

The ONC recommends HL7 Table 0292, CVX (HHS, 2012b), for meaningful use immunization reporting. CVX supports many programs, including immunization information systems/registries, vaccine tracking, and adverse event reporting for all current, historical, or forthcoming vaccines in the U.S. Mandated provider reporting to state and federal agencies supports population-level public health surveillance and education initiatives, as well as provider-level vaccine management and administration. As recommended by the ONC, our RHIO will implement CVX to exchange of immunization-related patient information.

Adopting the ONC-recommended standards for our RHIO serves two purposes. First, we will better serve our community by developing an interoperable HIE infrastructure connecting health care providers and entities locally and regionally. Second, we will be able to "on ramp" seamlessly to the Nationwide Health Information Network (NHIN), which the federal government is developing "...to provide a secure, nationwide, interoperable health information infrastructure that will connect providers, consumers, and others involved in supporting health and healthcare. This critical part of the national health IT agenda will enable health information to follow the consumer, be available for clinical decision making, and support appropriate use of healthcare information beyond direct patient care so as to improve health (HHS, 2012a)." Various government (e.g. CMS, the DOD, and the VA) and private (e.g. Kaiser Permanente and the Marshfield Clinic) healthcare organizations are exchanging patient data as part of the trial implementation phase of the initiative (HHS, 2012e). Adopting the ONC-proposed standards for patient health information collection and exchange will enable our RHIO to collaborate with partnering healthcare providers and networks in achieving the meaningful use of EHR's and support national efforts to improve the accessibility and portability of patient health information.

RHIO Challenges

The challenges facing RHIO's are complex. There are four main areas presenting challenges: financial, organizational, technical, and data privacy and security. Financial challenges still represent the most critical barrier to RHIO success. In a survey of RHIO's by Adler-Milstein, Bates, and Jha (2009), lack of funding was the most frequently identified barrier to long-term sustainability. Only 41% of operational RHIO's were able to cover operating costs with revenue from participants in the data exchange, and it took these RHIO's an average of 25 months to reach that level of financial stability. Only 28% of the remaining RHIO's reported that they ever expected to accomplish this goal. A follow-up survey by the same authors (Adler-Milstein, Bates, and Jha, 2011) again found that only 33% of operational RHIO's were financially viable, and only 40% of those that were not expected to become so in the future. The majority of RHIO's were still at least partly dependent on the \$548 million in grant funding provided by ONC through the State Health Information Exchange Cooperative Agreement Program. Recent communications from ONC to the state agencies administering these funds indicate that federal support for HIE is short-term and that rapid development of sustainable business models will be required. Yet the major portion of the financial benefits of HIE accrue to payers and patients, making it difficult to convince hospitals and physicians that they should pay all the costs through RHIO entrance fees and service charges (Adler-Milstein, Bates, and Jha, 2011).

In addition, ONC has started shifting the focus of HIE away from RHIO's and supporting direct point-to-point data exchange models such as The Direct Project or alternative Internet-like architectures developed by the President's Council of Advisors on Science and Technology (PCAST) (Lenert, Sundwall, and Lenert, 2012). These new models open an avenue for private corporations to begin building networks that compete with RHIO's. Because such private networks are not obligated to provide any specific service profile or maintain universal connectivity, they can focus on the most profitable part of the market and avoid the onerous tasks necessary to provide the comprehensive level of data exchange required to improve the quality of care. Meanwhile, the technically difficult and expensive job of creating and maintaining Enterprise Master Patient Indices, Record Locator Services, and the other necessary infrastructure for full and free data exchange falls to RHIO's which are expected to operate for the good of the community like public utilities, albeit without the monopoly status afforded to electric power, telephone, or postal services (Lenert et al., 2012). If this trend continues, it may become impossible to build a sustainable model for a RHIO.

RHIO's face multiple organizational challenges (First Consulting Group, 2006). At inception, the RHIO must define a common vision and purpose for its participants and recruit an articulate CEO with the political skill to keep the project moving forward. It must establish an effective governance structure and legal status consistent with its vision and purpose and develop the necessary technology and infrastructure to actually support patient information exchange. It must deliver common services in a way that protects its participants and overcomes factors related to competitiveness that may impede providers from joining (Adler-Milstein, DesRoches, & Jha, 2011). It must develop a sustainable business model that can show explicit benefits and value for its stakeholders and a fee structure that accurately reflects the value that each stakeholder receives from participating. It must execute an agreement on data sharing (DURSA) and develop change management procedures to help its participants integrate the new system into their clinical workflows.

Among the technical challenges, as discussed in the Information Flow and Architecture section of this paper, is the process of establishing unique patient identifiers and accurate record matching. A study by the E-HIM Workgroup on Patient Identification in RHIO's (2006) examines and reviews three categories of record linking. Level I is deterministic matching of selected data elements, which unfortunately is not highly accurate. The second level enhances deterministic tools with additional logic such as subjective weighting or scoring systems, fuzzy logic, or rules-based algorithms. The third and most advanced level utilizes sophisticated mathematical and statistical algorithms such as probabilistic matching, bipartite graph theory, machine learning, and neural networks (E-HIM Work Group, 2006). While implementing the more advanced record matching solutions increases accuracy and efficiency, it burdens the RHIO with a more complex system to develop and maintain. A second major technical challenge is the implementation of the terminology and messaging standards specified in the recently released Stage 2 Meaningful Use certification requirements, as well as working diligently with members to enforce the use of agreed-upon standards while still providing specialized interface capabilities to allow communication with member systems whose implementations do not follow the standards optimally.

In an era of strict HIPAA regulations and potential penalties, maintaining the privacy and security of protected health information is a major challenge to the success of RHIOs. The vast majority of American health care providers and patients are very concerned about the privacy and security of electronic health records. Patients worry that release of such information to unauthorized individuals could result in embarrassment, fraud or identity theft, discrimination in employment or access to credit, and several other potentially serious consequences. The Markle Foundation Survey on Health in a Networked Life 2010 (Markle Foundation, 2011) found that more than 80% of doctors and patients interviewed said that data privacy safeguards were important. In addition, 79% of patients said that it was very important to them that policies be in place allowing individual patients to be able to review who has had access to their health information and to be able to make informed choices about how their information is collected, shared, and used. Dimitropoulos, Scheffler, and Posnack (2010) randomly surveyed 1847 English speaking adults and found that 70% were very concerned or somewhat concerned about the privacy of health information exchange and that this could constitute a barrier to the adoption of HIE. So it is likely that in the long run HIE organizations will have to adopt policies which convince patients that serious, strong data privacy and security safeguards are in place in order to persuade them to participate.

RHIO's must work hard to address these concerns. A study conducted in 2007 by the California HealthCare Foundation (CHF, 2007) found that there are four questions which a RHIO must answer continually in order to be effective and considered a trustworthy business associate in the local healthcare community. These questions are:

- Who will have access to the patient information?
- Which information will be accessible?
- What are acceptable purposes of the exchange?
- What circumstances allow the users to be able to access the information?

The questions asked in the CHF study form an excellent framework for the RHIO to utilize as a foundation for privacy and security objectives in the organization. The "minimum necessary" language, found in HIPAA, is a good basis to define what information will be accessible. The question of access to the patient information is governed by the DURSA. Secure access will be provided to the clinicians directly involved in patient care and other necessary staff members in their organizations, and there will also be language governing secondary access to information for other purposes such as research. The information to be exchanged, as discussed at length in the Information Being Exchanged section of this paper, will be full and free except as limited by patient consent and system access and audit controls.

Acceptable purposes of the exchange will certainly include the primary use of data for clinical treatment. However, the secondary use of the data such as in clinical research, measuring performance of health professionals, population health studies, pharmaceutical studies, and marketing analysis is problematic. The HIE Framework established by the ONC states, "Individuals should be provided a reasonable opportunity and capability to make informed decisions about the collection, use, and disclosure of their individually identifiable health information" (HHS, 2008). In light of this statement by the ONC, the opt-in consent system our RHIO is implementing will provide our patients with sufficiently granular control over what information can be exchanged and for what purposes. The consent process will also notify patients of the "break the glass" provisions for accessing prohibited data needed for emergency care when a patient is too incapacitated to change his consent decision.

RHIO Benefits

While there are many challenges to the success of RHIO's, they can provide significant benefits to patients, providers, and the communities in which they operate. The 2006-2007 HIMSS HIE Steering Committee (2007) projected/found that the enhanced data exchange enabled by RHIO's confers benefits including decreased risk of medical errors (less manual data entry and more complete information available for physicians at the point of decision-making), increased quality of care through incorporation of clinical decision support systems and evidence-based best practices, increased provider efficiency and reduction of wasteful duplication of laboratory and radiologic testing, increased patient access to healthcare data (which should motivate patients to adopt healthy living habits and increase patients' stake in their healthcare outcomes), and increased opportunities for secondary use of data in clinical research and public health initiatives. These benefits depend on the RHIO's "potential capability to quickly and

automatically locate and retrieve most relevant electronic health records for a patient. This capability could be thought of as a public service-like function, readily available to all authorized providers but not necessarily economically viable to create or self-supporting (Lenert, Sundwall, and Lenert, 2012).”

Yet a financial analysis suggests RHIOs do create enough value to be self-supporting. As we look at the points of data exchange between family physician practice groups, radiology, laboratories, surgery centers, pharmacies, specialty physician practices, hospitals, long-term care centers, and payers, the cost savings resulting from these benefits will be tremendous. An article published in *Health Affairs* presents the results of a quantitative study of literature focused on the levels of interoperability of HIEs and their projected financial impact. The study divided HIE capability into four levels. Level 1 (Nonelectronic data) makes no use of IT to share information. Everything is handled by paper-based records, mail, or telephone. Level 2 (Machine-transportable data) allows the transmission of non-standardized information. Level 3 (Machine-organizable data) allows the transmission of structured messages containing non-standardized data; this requires interfaces that can translate incoming data (HL-7 messages). Level 4 (Machine-interpretable data) allows the transmission of structured messages containing standardized and coded data (automated exchange of coded data from lab results to EMR's) (Walker et al, 2005).

A higher level of interoperability results in greater financial benefit. The summary of the overall study projects the following annual savings, focusing on Level 4 capability of HIEs. Data exchange between outpatient providers and laboratory services saves \$87.81 per person, with a national benefit of \$31.8 billion. HIE between ambulatory and acute care settings and radiology services is projected to have a national benefit of \$26.2 billion. Data exchange between outpatient providers and pharmacies is projected to have a national benefit of \$2.71 billion. HIE between providers is projected to have a national benefit of \$13.2 billion. Data exchange between providers and public health entities is projected to have a national benefit of \$195 million. Finally, data exchange between providers and payers is projected to have a national benefit of \$20.1 billion. Even taking the costs of establishing and running a HIE into account, the cost savings are huge. The study provides a net benefit analysis projecting that over a ten year period, the national savings associated with the implementation of Level 4 interoperability HIE would be \$337 billion (Walker et al., 2005).

Other research supports Walker et al.'s projections of the financial benefits of RHIO's. Frisse et al. (2011) studied all Emergency Department (ED) encounters over a 13-month period in which HIE was accessed in all major EDs in Memphis, Tennessee. Although HIE was only accessed in 6.8% of ED visits across the 12 EDs studied, it led to a statistically significant decrease in hospital admissions and decreases in head CT use, body CT use, and laboratory test ordering. This resulted in a net cost savings of \$1.07 million over 13 months. If 6.8% utilization saved \$1.07 million, then 100% utilization could potentially save up to \$14.5 million per year in this one community alone. The significant quality and financial benefits of HIE justify the further expansion of RHIO's such as the one we propose in this paper.

Conclusion

It is widely accepted that the implementation of health information technology will lead to improved quality and safety in patient care, more widespread use of clinical decision support and best practices, better cost efficiency in the healthcare system, and the accumulation of enormous volumes of medical care data in structured form that can serve as the basis for research which develops the next generation of best practices. None of this will happen if medical information remains trapped within the narrow boundaries of disparate healthcare organizations. The full and free information sharing enabled by organizations such as RHIO's is indispensable for accomplishing the goals for which health information technology was designed.

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Figure 1 RHIO Architecture

