Abstract

Recently there has been increased focus on the need to modernize the healthcare information infrastructure in the United States.\textsuperscript{1-4} The U.S. healthcare industry is by far the largest in the world in both absolute dollars and in percentage of GDP (more than $1.5 trillion, or 15 percent of GDP). It is also fragmented and complex. These difficulties, coupled with an antiquated infrastructure for the collection of and access to medical data, lead to enormous inefficiencies and sources of error. Consumer, regulatory, and governmental pressure drive a growing consensus that the time has come to modernize the U.S. healthcare information infrastructure (HII). While such transformation may be disruptive in the short term, it will, in the future, significantly improve the quality, expediency, efficiency, and successful delivery of healthcare while decreasing costs to patients and payers and improving the overall experiences of consumers and providers. The launch of a national health infrastructure initiative in the United States in May 2004—with the goal of providing an electronic health record for every American within the next decade—will eventually transform the healthcare industry in general, just as information technology (IT) has transformed other industries in the past. The key to this successful outcome will be based on the way we apply IT to healthcare data and the services delivered through IT. This must be accomplished in a way that protects individuals and allows competition but gives caregivers reliable and efficient access to the data required to treat patients and to improve the practice of medical science.

This paper describes key IT solutions and technologies that address the challenges of creating a nation-wide healthcare IT infrastructure. Furthermore we discuss the emergence of new electronic healthcare services and the current efforts of IBM Research, Software Group, and Healthcare Life Sciences to realize this new vision for healthcare.
Introduction

Improving the state of healthcare IT has become a bipartisan top-priority issue for the United States. In his State of the Union address on January 20, 2004, President George W. Bush stated: “By computerizing health records, we can avoid dangerous medical mistakes, reduce costs, and improve care.” Also in 2004, Congressman Patrick J. Kennedy (D-RI) officially introduced the Josie King Act (also called the QUEST Act). This act is named in honor of an 18-month-old child who died as a result of preventable medical error. The bill proposes to create an IT backbone for the American healthcare industry by 2015.

There are a variety of technical challenges we face in realizing a national information infrastructure. The challenge at the forefront is to define an implementation model that simultaneously is consumer-centric and cross-institutional and supports the longitudinal healthcare and health record standards emerging around the globe. Additionally, the model needs to support the private healthcare provider model of the United States. Furthermore, the system should be scalable and capable of supporting (in the near term) the regional healthcare information organizations (RHIOs) and networks that are now emerging at the county and state levels. As the system grows, RHIOs will become interconnected through a larger national health information infrastructure (NHII) network. In a national system, RHIOs must have access to patient data regardless of where the records are physically located. Through a data federation mechanism, the RHIO will be able to bring together, on the fly, all required patient records and present them to a clinician at the point of care.

Such a model would yield a new infrastructure with unmistakable benefits. The new infrastructure would create electronic archives, thereby reducing time needed to access older records and ultimately providing better care, as patient medical histories would always be available. Insurers would benefit, too, as quality of care for their customers would improve. Pharmaceutical companies could recruit clinical trial participants more efficiently and be able to better demonstrate the efficacy and side effects of medications. Electronic services can improve patient safety, for example, by checking the accuracy and compatibility of prescriptions. Electronic access to a patient’s entire testing history can greatly reduce redundant testing. Privacy would be better protected, as only anonymous global patient identifiers would be needed. Most importantly, a true electronic health record (EHR) with summary and topical parts could be available at the point of care, based on processes that would constantly reconcile and summarize the incoming data received from all providers who have seen a given patient. The longitudinal EHR will allow personalized care for the patient based on best care practices and the patient’s individual medical circumstances; at the same time, it will give researchers the ability to leverage anonymous data for clinical research.

Toward a National Health Information Infrastructure System

Many complex regulatory and policy decisions are required to establish an NHII system. We must meet critical technical requirements while satisfying the social contract for medical care in a way that is appropriate to the United States. The key to successful implementation will be how we apply IT to the challenges of an NHII system: the system must support existing information systems and the private-provider healthcare model, be scalable, maintain patient privacy, accommodate heterogeneous data, and provide improved consumer-centric services.

The term healthcare enterprise may refer to any type of organization in the private provider model, including private practices, nursing homes, ambulatory clinics, acute care inpatient facilities, and so forth. Existing legacy and proprietary IT systems, or a lack thereof, make the task of directly linking healthcare enterprises with an NHII system daunting and unlikely to be undertaken by these institutions alone. Thus, a layered architecture approach is needed to facilitate interoperability. This approach buffers the healthcare enterprise from the difficulties of conforming to an NHII system with a standards-based RHIO (Figure 1). The RHIOs can facilitate cross-enterprise communication and cross-enterprise services among the healthcare enterprises in their jurisdiction while the enterprises themselves can continue to rely on...
local and unique infrastructures consisting of electronic medical records (EMRs), a Clinical Information System (CIS), a Picture Archiving and Communication System (PACS), and other clinical data management systems. Thus, healthcare enterprises will need to interface with just one standards-based RHIO to gain access to the NHII, a network of RHIOs.

To make such a layered architecture possible, a great deal of attention needs to be directed toward the interconnection of these components. An even better scenario would be that the same technology used to connect the healthcare enterprises to the RHIOs could also be used to connect the RHIOs to the NHII system. Fortunately, these technical challenges are greatly reduced by recent advances in Web service technologies. The most important of these recent advances is the development of the Enterprise Service Bus (ESB). The Enterprise Service Bus is a scalable integration architecture that permits incremental integration or addition of new data sources and data services driven by business requirements. Each new integrated component is provided as a Web service so that the system is not limited by legacy standards or constraints. To understand the requirements for an NHII system, let us first consider the example of integration across two regional systems or RHIOs. Each institutional system emulates a community and, as such, represents much more than a single hospital or healthcare enterprise. The ESB takes a heterogeneous institution and transforms it into a single integrated (virtual) healthcare organization. A fully interconnected national system consists of a network or hierarchy of RHIOs and satellite institutions. In IBM’s research division, we are working with IBM’s Healthcare and Life Sciences Division and IBM Software Group to design a prototype multipurpose HII test bed based on ESB architecture. This prototype is discussed in more detail below.

The task of interconnecting healthcare enterprises and their respective RHIOs inherently involves privacy concerns. Data that move across enterprises will need to be de-identified according to HIPAA privacy regulations unless patient consent is secured. To comply with such regulations, an NHII system will require user and node authentication as well as transaction auditing. Many of the challenges here involve porting to and strengthening current technologies in the healthcare domain. Emerging standards, such as Integrating the Healthcare Enterprise (IHE) Audit Trail and Node Authentication (ATNA) and Enterprise User Authentication (EUA) profiles, address such security concerns.

As healthcare enterprises begin to exchange clinical information within and beyond their RHIO, it will be necessary to reconcile heterogeneous data definitions in currently use via a RHIO extraction/translation/transformation service. The job of this transformation service is to translate data from individual data sources, converting proprietary formats into a common standard (e.g., Health Level 7 [HL7] Clinical Document Architecture Release 2 [CDA R2]). By converting data to a standard format, RHIOs can exchange data nationwide. Data received in a standard format can, in turn, be converted by the receiving RHIO or healthcare enterprise to the specific data definitions used in its particular data stores. Other services and data adapters will support the most important existing standards, including those required by HL7, Digital Imaging and Communications in Medicine (DICOM), the Health Insurance Portability and Accountability Act (HIPAA), Logical Observation Identifiers, Names, and Codes (LOINC), the Systematized Nomenclature of Medicine (SNOMED), and the Clinical Data Interchange Standards Consortium (CDISC), thereby addressing the whole spectrum of biomedical care, including healthcare, public health, clinical trials, and the life sciences. This service is a critical step in developing a service that maps between different vocabularies. Until common vocabularies and terminologies are adopted, such a mapping service will be essential to extracting value from shared documents (and making them machine processable).

The final piece of a successful implementation and adoption of an NHII system is to ensure the development of new, valuable services that would otherwise not be feasible without the NHII system. Examples of some possible cross-enterprise services are outlined in Table 1.

In the future, individuals will require the ability to control and manage their own healthcare. The ESB architecture supports the creation of various Web portal–based applications to support personalized medicine as well as more efficient physician access to patient data. This paradigm change will also enable new service and utility models for the healthcare industry. Once individuals can access and control their own medical data, they can make better, more informed decisions. The availability of more complete medical data will also lead to the creation of new medical and health services, giving individuals greater
choice and control in planning their own care. Electronic data sources will provide the information necessary to understand the real outcomes of accepted medical treatments, advance medical research, and advance the science of medical care.

IBM’s IHII Reference Architecture

No one single IT vendor will be able to provide the entire technical infrastructure required for an NHII system. IBM is a founding member of an interoperability consortium (currently consisting of Accenture, Cisco, CSC, Hewlett-Packard, IBM, Intel, Microsoft, and Oracle) that formed to produce a joint response to a Request for Information (RFI) that was released during the latter part of 2004 by the U.S. Office of the National Coordinator for Health Information Technology. The RFI called for business and technical input regarding the establishment of a potential National Health Information Network (NHIN) in the United States. The consortium’s response was submitted on January 18, 2005. The IBM Research HII test bed will provide a mechanism for testing technologies and concepts such as those described in the consortium’s response.

IBM Research, in close collaboration with IBM’s Healthcare and Life Sciences Division and IBM Software Group, is in the process of developing a standards-based, ESB architecture HII system. We call this project IHII (Interoperable Healthcare Information Infrastructure) and describe its architecture and use as a test bed for vital HII solutions and services.

The goals of this project are to

• Provide an implementation of the solidified and emerging standards for clinical documents and clinical document exchange across enterprises,
• Demonstrate a Web service architecture that provides for scalable integration of healthcare information across the distributed healthcare enterprise, and
• Illustrate a replicable methodology for healthcare data and application integration from the RHIO to the NHII scale.

The IHII architecture is based on several emerging healthcare standards, the most prominent of which is the IHE Cross-Enterprise Document Sharing profile (XDS). XDS outlines architectural components and transactions needed to execute tasks involved in clinical document sharing, such as generating and assigning RHIO-level patient IDs, registering and storing shared clinical documents, and querying those documents. Components of the XDS architecture are:

• Patient Identifier Cross-Referencer—generates, assigns, and manages RHIO-level patient IDs
• Registry—shared document registry
• Repository—storage of shared documents
• Document Consumer—provides query and retrieval interfaces to Registry and Repository
• Document Source—provides an interface to load shared documents

Also, the architecture of the IHII test bed conforms to the transaction standards outlined in XDS. These transactions will be supported internally within the IHII system by the new Service-Oriented Architecture (SOA) integration model. SOA enables flexible connectivity of applications and resources by representing them as services, each with a standardized interface. These services exchange standardized data structures known as Service Data Objects, or SDOs. Utilizing this model, participants in a regional network can make use of services that are accessible via a common ESB. Messaging and pub/sub (publish-subscribe) communication models are also supported. This allows rapid integration of new and existing services and the staged, incremental development of a system on a full national scale.

Furthermore, IHII builds upon the XDS components with critical services needed for interoperability. Services currently under development include:

• User Interface (UI)—provides connections to the Document Consumer and Document Source from partner UI applications and Web portals
• Healthcare Collaborative Network (HCN)—provides security and privacy services, message-level data translation, and management and transmission services
• Data Transformation—provides document-level translation services
Clinical Terminology—a service that translates among and enhances data by adding codes from controlled vocabularies such as LOINC, SNOMED-CT, and ICD-9

Summarization—prototype of a service to be used in mining the IHII infrastructure to create patient EHRs

With the HII test bed, we can explore many more of the advanced services (such as those in Table 1) enabled by a nationwide health information infrastructure. Each of these IT services can be built around reusable technology components according to the framework depicted in Figure 2. This proposed architecture was one of four selected for prototype for a U.S. National Health Information Network. This contract comes from the U.S. Department of Health and Human Services.

Conclusion

The time is right to begin the work to transform our national healthcare infrastructure through the proper application of IT. The escalating cost of, demand for, and error rate of our current healthcare system dictate that a significant change in the infrastructure must take place during this decade, when demand will be accelerated by the aging of the baby-boomer generation. We must achieve this rapid change in a cost-effective way that does not violate the social contract between individuals and caregivers, and we must get it right the first time. To maximize the chance of success, we can take advantage of the latest Web service technologies to create a scalable system. In such a system, both existing and new data sources and IT services can be added incrementally as required by a new, evolving infrastructure. With proper application of technology, we have the opportunity to turn a revolution in healthcare into a renaissance of medicine that provides better, safer, and more efficient care for all.

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References

17. HL7 functional model, http://www.hl7.org,
Figure One

Layered Architecture Approach
Figure Two

IBM IHII Reference Architecture
Table One

Services Enables by a Modern NHII

<table>
<thead>
<tr>
<th>Patient Services</th>
<th>Payer Services</th>
<th>Provider Services</th>
<th>Public Services</th>
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<tbody>
<tr>
<td>Patient billing and insurance management—utilizing X12 and CPT (Current</td>
<td><strong>Clinical terminology</strong>—a service that translates among and enhances data by</td>
<td><strong>Master person identification</strong>—a service that correlates the various IDs of</td>
<td><strong>Clinical trial recruitment applications</strong>—online, enhanced</td>
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<td>Procedural Terminology) standards</td>
<td>adding codes from controlled vocabularies such as LOINC, SNOMED-CT, and ICD-9</td>
<td>the same patient and assigns an anonymous global patient ID when needed</td>
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<td><strong>Enterprise patient healthcare information location</strong>—a service to identify,</td>
<td><strong>Data integration services/EHR virtualization</strong>—the ability to assemble a</td>
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<td><strong>Public health applications</strong>—including biosurveillance, epidemic simulation,</td>
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<td>on the fly, the actual location of an identified consumer’s data. It includes an</td>
<td>composite health record from the partial records contained in disparate EHRs</td>
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<td>and anonymized population health trend data and studies</td>
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<td>index of consumers and references to their data.</td>
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<td><strong>Patient insurance/coverage eligibility/claims support services</strong></td>
<td><strong>Data transformation</strong>—a service that translates among standard clinical</td>
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<td>document formats and from proprietary document formats to standard ones</td>
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<td>send electronic reminders to patients to take their medications.</td>
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... and countless additional services