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Health Information Exchange: From Meaningful Use to Personalized Health



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Executive Overview

Studies have shown us that many consumers want more from their health information. They seek greater access to their own health records; enhanced communication with physicians, pharmacies, and clinics; and a larger role in their health management. This higher level of consumer-directed healthcare aligns with employers' goals to reduce costs associated with providing healthcare to employees as well as to promote preventive health measures and raise workforce productivity. And, of course, increased health information exchange (HIE) has significant advantages for healthcare organizations as well, helping them improve care while reducing costs.

To enable this heightened opportunity for consumer empowerment, the healthcare enterprises holding this protected health information (PHI) must first gain consumers' trust by demonstrating that their electronic data is being exchanged securely and accurately and is being made available only to those select entities—caregivers, researchers, insurance carriers, and governmental agencies among them—who are acting in their best interests.

Gaining consumers' trust and pushing forward with health information exchange are significant challenges. But they are being met head-on, by both strong federal programs and best-of-breed technologies that today are helping us approach the goal of patient-centric, cost-effective care.

Introduction

In a 2009 national survey of consumers, Deloitte found that patients have the following expectations of their healthcare providers*:

- **Security** – Patients expect their privacy and security to be protected.
- **Businesslike operation** – Patients want their healthcare providers to be “easy to work with.”
- **Dependability** – Patients want predictability and consistency.
- **Transparency** – Patients and their families want to “see” and understand what is happening to them.
- **Personalization** – Patients want their healthcare provider to know who they are and what they need as individuals.

*Source: Deloitte, *The Patient Experience: Strategies and Approaches for Providers to Achieve and Maintain a Competitive Advantage*, 2009

This study and many others have helped inform the federal government’s direction for health information technology (HIT). In late March 2011, the Office of the National Coordinator for Health Information Technology (ONC) announced an open public comment period on its Federal Health IT Strategic Plan: 2011–2015 (hereafter called “the Plan,” which is still in revision status after the collection of public comments).

The Plan reflects ONC’s strategy, developed in collaboration with other federal partners, over the next five years for realizing Congress and the Administration’s HIT agenda. ONC has established five strategic goals for HIT:

1. Achieve adoption and information exchange through meaningful use of HIT.
2. Improve care, improve population health, and reduce healthcare costs through the use of HIT.
3. Inspire confidence and trust in HIT.
4. Empower individuals with HIT to improve their health and the healthcare system.
5. Achieve rapid learning and technological advancement.

The Plan states, “The adoption and meaningful use of electronic health records (EHRs) is the unifying focal point of our strategy. **However, meaningful use is necessary, but not sufficient, to harness the power of health IT to transform healthcare over the next five years. For instance, we must continue to be attentive to implementing and enforcing privacy and security protections.**”

Discussion of the preceding sentences in bold is the focus of this paper. Accordingly, the paper will highlight the Plan’s two most directly consumer-oriented goals, numbers 2 and 3. The benefits for healthcare enterprises of optimizing HIE for consumers will be discussed, as well as how they can meet the challenges of consumer privacy, security, and empowerment through the support of five key technologies: master person index (MPI), provider directory, record locator, audit trail/consent technology, and interoperability. Because the Plan is one of the more important factors affecting the future of U.S. HIE, a number of its elements have been incorporated into this paper.

Health Information Exchange: Where We Are and What's Next

For perspective, a brief look at the Plan's current position regarding HIE is essential, then moving forward to related initiatives being discussed for the coming years.

The Plan has defined three implementation stages for HIT overall:

- **Stage 1 (2011)** – Focus on effective capturing and sharing of data, with providers demonstrating meaningful use.
- **Stage 2 (2014)** – Demonstrate health system improvement, with widespread adoption of data exchange and advanced care processes with decision support.
- **Stage 3 (2015+/-)** – Transform healthcare and population health through HIT, with improvements in care, efficiency, and population health, highlighting breakthrough examples of delivery and payment reform.

The U.S. Department of Health and Human Services (HHS) defines meaningful use in the following manner: “To achieve ‘meaningful use’ of EHR technology, providers must use the technology in a manner that improves quality, safety, and efficiency of healthcare delivery; reduces healthcare disparities; engages patients and families; improves care coordination; improves population and public health; and ensures adequate privacy and security protections for personal health information.”

In its current iteration, much of the activity related to the meaningful use initiative is to accelerate the adoption of new technologies by providers across a broad base of physicians and hospitals and to increase efficiencies and care levels within the Medicare and Medicaid programs. Eligible professionals and hospitals can receive incentive payments from Medicare or Medicaid if they demonstrate meaningful use of HIT and HIE.

However, in stage 1, HIE is intended to support improvement in care coordination as well as communication with consumers. Eligible professionals (EPs) must “provide patients with timely electronic access to their health information (including lab results, problem list, medication lists, medication allergies) within four business days of the information being available to the EP.” This gives patients a chance to review some of the content of their health records, to better follow up with care coordination activities, and to discuss the content with their providers in relation to accuracy of their health information and the sharing of this information with other care providers.

What's Ahead: Stage 2 and Beyond

The ONC HIT Policy Committee has preliminarily approved stage 2 meaningful use requirements. The proposed requirements are intended to shift the main emphasis from simple information capture and reporting toward greater interoperability, analyzing the pool of a single patient's data from different care providers, and improvements in patient decision making and outcomes. The main objective is that data more closely follow patients to the point of care—across geography and potentially disparate stakeholders such as specialists, labs, hospitals, emergency rooms, and pharmacies—and better inform critical health decisions. This greater degree of interoperability will help break down the barriers of varying health policy and technical environments among stakeholders and will enable health data to be used for secondary purposes such as population-based research.

Speaking the Same Language

Today there are new technologies and methods for exchanging data being brought to bear, specifically message infrastructure specifications. In the U.S., some of the impetus for next-generation interoperability is coming from the government's implementation of new standards and the inclusion of vocabulary in those standards.

For example, many electronic health record (EHR) vendors have tested their applications for Integrating the Healthcare Enterprise (IHE) compliance related to creating and viewing standardized medical summaries. These IHE standards include structures for how to represent a patient's summary record, including visit history—even if the patient was seen in different medical settings—lab results, medication history, and allergies, along with personal information such as name, age, address, and more. A medical summary standard chosen by the U.S. government is the HL7 standard for “templated Clinical Document Architecture (CDA)” healthcare XML documents supporting the “Continuity of Care Document (CCD)” standard internationally. It is specialized for U.S. vocabularies in the C32 government EHR document standard. Although many EHR vendors have recently offered support for IHE standards to their customers, many customers are still in the process of upgrading to the newest versions of their EHR systems.

Further, preparing for meaningful use will require practices to provide a Continuity of Care Record (CCR) and the newer CCD, essentially a summary of a patient's care, when a patient is referred out to another doctor. These documents must be flexible and must contain the most relevant and timely health information. Meaningful use will require the ability to send these electronically from one caregiver to the next. LOINC, SNOMED, RxNorm, and other data exchange standards also will be required for stage 2 meaningful use certification.

Healthcare language is continuously evolving. As interoperability standards change with healthcare language, a physician or hospital staff member electronically receiving a patient record from another caregiver will be getting a more complete and accurate picture of that patient. This is because the source and the target will be speaking the same language, not only in structure (syntactic interoperability) but also in vocabulary and terminology (semantic interoperability).

This heightened expectation for meaningful use will increase the need for HIE. The preliminary recommendations for HIE requirements in stage 2 of meaningful use have shifted from a test of HIE in stage 1 to multiple use cases that HIE will support. These use cases support the transition from simple exchange to more interoperable health records. The ONC HIT Policy Committee has recommended that the stage 2 timeline be extended. The National Coordinator for Health IT, Farzad Mostashari, has supported the recommendation. Among other things, they believe that additional time is needed for providers and vendors to prepare for the more robust measures of stage 2.

In any case, to quote from the Plan, “States will support providers by building on existing exchange activities; providing critical shared services and infrastructure such as provider directories, record locator services, and master patient indices; increasing the use of standards, services, and policies needed for widespread information sharing; and enhancing the information exchange capabilities of key trading partners including clinical laboratories, pharmacies, and public health agencies.”

The ONC State Health Information Exchange Cooperative Agreement Program is intended to ensure that every eligible healthcare provider has at least one option for HIE that meets the requirements of the Medicare and Medicaid EHR Incentive Programs, defined by the Centers for Medicare and Medicaid Services (CMS). The ONC CONNECT technology created for the Nationwide Health Information Network (now referred to as NwHIN) defines Web services for large health information organizations that want to participate in HIE. ONC's Direct Project for secure health email was developed to enhance the opportunities for small providers to participate in HIE. ONC has required grantees to describe how they will incorporate the Direct Project into their HIE deployment plans.

Security and Privacy Are Critical

Without consumers' trust that their PHI is private, secure, and to be transmitted only to those with a need to know, effective exchange of health information cannot move forward. Federal agencies and state legislatures are actively reviewing, updating, and enforcing regulations regarding data privacy and security. In addition, ONC is embarking on an outreach communication program to inform consumers of their rights regarding their PHI.

An Information Gateway Connects and Protects

Healthcare security standards, including NwHIN standards, describe an information gateway helping PHI to flow securely and connecting health information organizations to consumers, providers, hospitals, health information exchanges, public health facilities, and federal agencies.

The gateway enables interoperability of EHRs and supports the flow of patient information between systems. The following are among the number of standards that HIEs can use in their gateways:

- **NwHIN** is a set of standards, services, and policies that enable the secure exchange of health information over the Internet. The Direct Project and CONNECT are parts of NwHIN.
- **Integrating the Healthcare Enterprise (IHE)** promotes the coordinated use of established standards, such as HL7, to address specific clinical needs in support of optimal patient care.
- **The Direct Project** for secure health email is a set of international standards and national policies that enable the use of encrypted email to provide secure HIE over the Internet.
- **CONNECT** is an open-source software solution supported by numerous government agencies, academic institutions, and vendors.

The Direct Project

ONC's Direct Project has adopted standards required to enable secure email HIE at a more local and less complex level among trusted providers in support of stage 1 meaningful use requirements. Having had its first live implementation in February 2011 in Rhode Island, it is a lower-cost, secure, standards-based means of sending authenticated, encrypted information directly over the Internet to known, trusted recipients. It was designed to enable consumers and providers large and small—from individual physicians to clinics to large healthcare organizations—to effectively substitute email for facsimile as the standard for electronic health communications. An email gateway designed for the

Secure/Multipurpose Internet Mail Extensions (S/MIME) standard for email communications is needed to support and protect the secure email addresses of larger health information organizations.

Facsimile (fax) has for a long time presented numerous real-world issues for both sender and receiver, among them the cost of a dedicated phone line, privacy and security breaches, insufficient confirmations of receipt, and lack of accountability. Now, by leveraging Direct Project standards, a primary care physician can send a secure email containing a clinical summary of a patient to a referring specialist. Although Direct Project is based on older technology and doesn't eliminate workflow and security problems, it represents both a great improvement over fax technologies and an acceptable transition phase to greater adoption of more sophisticated PHI payloads and Web service technologies. It is relatively straightforward, using ordinary email routing for data transportation and S/MIME email attachment encryption for its data payload—essentially an encrypted email attachment. Yet it complements the large enterprise use cases already supported by the NwHIN Web service technologies, and it adds small, independent providers in the rural and urban “white space” to HIE use cases. By providing the opportunity to communicate standardized, structured, and coded payloads (in IHE XDM zip files) as well as scanned documents and pdf files, Direct Project standards enable the more sophisticated payloads to be automatically processed into a standardized public key directory, MPI, document registry, document repositories, traditionally structured clinical data repositories, and other electronic health record technologies.

Public Key Directory

The federal Direct Project for secure health email (www.nhindirect.org) has created the need for provider and consumer directories that hold the certificate authority public key infrastructure (PKI) certificates for Direct Project Secure/Multipurpose Internet Mail Extensions (S/MIME) communications. Generically, these are called public key directories. They have been proposed for many cross-industry uses, such as the passport data management solution proposed by the International Civil Aviation Organization (<http://www.icao.int/icao/en/atb/Index.html>).

In healthcare, the provider directory is intended to give consumers and other stakeholders the ability to locate the secure email address and its associated public key for a specific provider, in addition to any other “yellow-pages-type” information that the directory might offer. To supply up-to-date information on active public key status, the provider directory must interact regularly with one or more of the certificate authority organizations that dispense the public keys and regulate the public key status.

CONNECT: Linking Providers and Networks

Many larger healthcare entities hope to rely on CONNECT in order to support reliable, low-cost healthcare communications. CONNECT is an open-source software solution supported by numerous government agencies, academic institutions, and vendors that facilitates the implementation of HIE, both locally and at the national level. CONNECT uses NwHIN standards, services, and policies to ensure that health information organizations are compatible with other exchanges being set up throughout the country.

A CONNECT information gateway creates value in the following ways:

- **For providers** – It accelerates the implementation of meaningful use objectives through HIE, between certified and noncertified EHR modules and other health information organizations.
- **For academic medical centers** – It facilitates HIE for research and patient care purposes at a very low IT cost.
- **For clinical researchers** – It lowers the cost of obtaining and executing on consumer consent for release of health information for clinical research purposes.

In order to support providers and hospitals in meeting the short timelines of the meaningful use requirements, many health information organizations will need to use the standards being developed by NwHIN and other entities. Healthcare organizations will be able to use projects such as Direct Project and software such as CONNECT to help them meet the stage 1 requirements of meaningful use. Because meaningful use stage 2 and 3 requirements are not yet finalized, it is unclear how these initiatives might help them meet the requirements.

Benefits Across the Care Continuum

Existing and emerging HIE solutions can significantly benefit the following range of health stakeholders:

- **Patients** – They enable secure, confidential, and timely access to patient information across providers, for more efficient treatment at lower costs and higher patient involvement in their own care.
- **Providers** – They accelerate the implementation of meaningful use objectives through scalable health information data capture, data transformation, data persistence, and data retrieval Web services. They also provide a platform for collaborative, personalized, patient-centric healthcare.
- **Clinical researchers** – They ensure that optimal recruitment into clinical research is supported by consumer consent for release of health information and a complete set of phenotypic information.
- **Public health** – They enable rapid access to public health information to support public health and safety including disease prevention as well as biosurveillance and control.
- **Academia and life sciences companies** – They lower the cost and time needed to obtain consumer consent for release of health information for research purposes, thereby improving the research-dollar ROI. They also enable “cohort identification” for clinical trials and provide patient registries and a foundation for quality/efficiency research.
- **Payers** – They provide payers with key benchmark data, enabling them to perform analysis versus peers using deidentified data. They also enable payers to provide care management and population health programs and to better understand future healthcare trends and costs.

They also reduce the need for expensive contractual and technical negotiations between two providers or other business entities that are needed for communicating sensitive information over the Internet. They help provide safety, quality, and efficiency data for improved decision making.

Right Person, Right Records

A key challenge for healthcare stakeholders is identifying and exchanging the right person's data. An MPI uniquely identifies all individuals in the system, both patients and providers; standardizes core data elements, as exemplified in the following paragraph; and helps ensure that the correct record is matched to the correct patient.

According to the American Health Information Management Association (AHIMA), the following are some of the recommended core data elements for indexing and searching records:

- Internal patient identification
- Patient name
- DOB
- DOB qualifier
- Gender
- Race
- Ethnicity
- Address
- Alias/previous name
- Social Security number
- Facility identification
- Universal patient identifier (if available)
- Account number
- Admission date
- Discharge date
- Service type
- Patient disposition

In turn, document registries, also called record locator services, enable the registering and storing of documents by tracking document location. These registries also facilitate interaction between the MPI and document repositories in the query-and-response process.

Empowering the Consumer

Anyone who has had the experience of exchanging emails with their primary physician or going online to check lab results, refill a prescription, or schedule an appointment with a specialist has seen first-hand the power and potential of this new capability.

Although consumers who have had that experience are still a distinct minority, studies have shown that many want the increased control and convenience that effective HIE offers, such as reviewing cholesterol levels over time, helping a loved one monitor glucose levels or blood pressure, and not missing work due to unnecessary visits to the doctor or pharmacy.

*Although many consumers access their banking information online daily, fewer than 10 percent use the Web to access their personal health information.**

* *Consumers and Health Information Technology: A National Survey*, April 2010, California HealthCare Foundation.

Consent Management and Audit Trails

Advances that touch upon consumers' data security, privacy, empowerment, and trust of the HIT system include audit trails tied to consent management systems. As HIE increases, consumers will rightly ask questions: "Who has access to my personal health information?" "How is it being used?" "Do I have any say in who can see it?" "Can I limit access to certain information?" Governance, risk, and compliance applications for access consent, with specialized business intelligence data marts, enable privacy officers for organizations to collect and minutely analyze healthcare transaction records for privacy breaches.

As the industry moves forward, provider enterprises and other entities exchanging health information will need a way to track and enforce patient consent, especially as data moves to more granular levels. They will also need to be able to dynamically update consent parameters as the patient makes changes. They must have the ability to monitor and track who is accessing data, which data is being accessed, and when it is being accessed. For this kind of tracking, audit trails monitored by the privacy officer are necessary to ensure that the right provider is accessing the right patient data for the appropriate use, and in many cases to inform consumers of who is accessing their data and for what purpose.

Responsibilities of Health Information Exchanges

Under the new privacy regulations, health information exchanges (HIEs) are considered "business associates" and must therefore abide by the Health Insurance Portability and Accountability Act (HIPAA). As business associates, HIEs will need to have extensive policies and procedures in place to comply with HIPAA privacy and security regulations. HIEs have the responsibility to comply not only with federal regulations but also with state regulations regarding privacy and consent. All exchanges must choose a patient consent model that abides by both federal and state laws.

According to the U.S. Department of Health and Human Services (HHS), "The proposed modifications to the HIPAA Rules include provisions extending the applicability of certain of the Privacy and Security Rules' requirements to the business associates of covered entities, establishing new limitations on the use and disclosure of protected health information for marketing and fundraising purposes, prohibiting the sale of protected health information, and expanding individuals' rights to access their information and to obtain restrictions on certain disclosures of protected health information to health plans. In addition, the proposed rule adopts provisions designed to strengthen and expand HIPAA's enforcement provisions."

A subsequent provision, yet to be finalized at this time, has recommended that "business associates of covered entities" be broadened to include HIE subcontractors. Under this rule, patients can request a modification of their data. The following two sources supply additional information:

- HHS Website
- Notice of proposed rule making (NPRM)

At this time, the following important terms are used to describe consent:

- **“Opt-in consent”** requires affirmative authorization from the patient, often through signing a standardized consent form, before a patient’s health information may be utilized for a specific “purpose of use.” A purpose of use such as “research” requires a signed patient consent by the U.S. HIPAA regulation. Although the U.S. HIPAA regulation automatically authorizes the purposes of use known as “treatment,” “payment,” and “operations” in many states, some states have elected to set a higher bar on the requirement for patient authorizations signed by patients.
- **“Opt-out consent”** requires affirmative authorization from the patient, often through signing a standardized consent form, that their health information may NOT be utilized by healthcare organizations. However, this option is also subject to local and national regulations.
- **Other, more granular models** of automated consent might also be offered that identify specific types of documents, organizations, and person roles within those organizations as attributes of access consent authorizations.

Document Repositories Help Maintain Order

Document repositories will be called upon not only to contain a database of patients’ PHI but also to help with consent management and audit trails.

Data repositories will store multiple types of data, clinical and administrative. To protect a patient’s PHI, the use of the data in clinical data repositories (CDRs) must be controlled through “consent engines” that contain information relating to which information a patient has consented to share and with whom. A key capability for an HIE is to ensure that before any data is sent to a requester, there is appropriate consent for its release.

To ensure that clinical data maintains the same meaning it had at the source as it does when received by a requester, the HIE must ensure what is called *semantic interoperability*. Ensuring semantic interoperability—consistent meaning of the data across multiple organizations—the HIE must include technology standards that will map to a common set of terminology. Alternatively, the HIE can provide a “mapping engine” that translates data from one standard to another while ensuring that the meaning is maintained.

Bringing It Together: Integration

Interoperability of healthcare systems is a challenge mainly because of rapidly growing expectations. Information exchanges, public health reporting, and in-hospital integration needs are placing increasing pressure on already stretched IT resources. Integration solutions must provide the advanced transformation and coding capabilities needed. Comprehensive support for communication protocols and message formats enables a mapping and translating mediator between virtually any systems.

Health Information Exchange: Truly Two-Way

Today there are new instances of the use of HIE for consumer-directed care that are especially interactive and timely. In some locations, individuals can now send blood-sugar or heart-related data from mobile devices to a caregiver and receive not only advice but also immediate changes in medications and treatment if needed, either for maintaining health or for preventing a more serious situation.

This data falls into the category of “device-generated data.” In addition, the ONC recognizes “patient-generated insights,” which are individuals’ observations and perceptions about their own health or care. These could come in the form of surveys, health journal entries, online blog entries, or any number of other media. This latter form of data will be valuable to the health system in measuring and rewarding for healthcare quality. Data of both types can become part of the patient’s EHR.

Toward Personalized Healthcare

The secure sharing of health data across networks can help providers move toward a model of personalized healthcare whereby they can better meet patients’ expectations for transparency and privacy and securely utilize longitudinal patient information, such as disease states or reactions to certain medicines, to provide higher-quality care.

In addition to the significant operational and business efficiencies that providers can realize over time through secure, effective HIE, their ability to offer patients more personalized care will also improve. Because more vital patient information will be shared between stakeholders—including physicians, labs, clinics, hospitals, and the patients themselves—caregivers will have a more complete, more accurate picture of their patients’ health history. This should mean smarter medical decisions as well as fewer errors, unnecessary tests, and prescriptions.

This increased data liquidity can also support translational research by more quickly getting critical data to and from the point of care and establishing the consent management needed to deliver care that is more personalized.

Conclusion

Health information exchange has the potential to improve the quality, coordination, and efficiency of healthcare. If handled correctly, it can also help achieve the necessary level of trust among consumers. Complying with meaningful use criteria and achieving HIE with other healthcare entities is a daunting challenge for any organization. Nevertheless, today’s products, initiatives, and best practices have shown that the challenge can be met and that the benefits—including improved security and privacy, enhanced care, and consumer empowerment, as well as increased efficiencies for enterprises—are all attainable. Ultimately, when such efforts are well thought out, strategies are well designed, and implementations are successful, we as a country and consumers of healthcare services will benefit from better outcomes and greater quality of life.

About the eHealth Initiative

Since 2001, the eHealth Initiative (eHI) has represented the multiple and diverse stakeholders who are improving healthcare through the use of health information technology (HIT). The mission of the eHealth Initiative is to drive improvement in the quality, safety, and efficiency of healthcare through information and technology. eHI is the only national organization that represents all of the stakeholders in the healthcare industry.

About Oracle's Global Health Sciences Division

Oracle is a leading strategic software, hardware, and service solutions provider to the health sciences industry. By offering innovative products and services that deliver the most compelling business value, Oracle helps healthcare providers and life science and medical device organizations become the most successful in the world. Oracle's comprehensive industry solutions focus on meaningful use and quality management, accountable care, enterprise performance management, governance and compliance, and personalized healthcare. Oracle partners with health sciences industry leaders—including 9 of the top 10 hospitals and all of the top 20 life sciences companies—to help prevent and cure disease, enhance quality of life, and accelerate insights for better health.

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