EHR Association Interoperability Roadmap

October 2006

Version 2

Approved by EHR Association Membership on October 10, 2006

Note: This document has been modified to reflect the name change of the organization to HIMSS Electronic Health Record Association (EHR Association). No other content has been modified.

EHR A
HIMSS Electronic Health Record Association

Table of Contents

Executive Summary

Electronic health records (EHRs) hold the potential to improve the quality and safety of patient care while increasing the efficiency and productivity of the healthcare system as a whole. Realizing this potential, however, will depend on widespread adoption of EHRs and, more importantly, on the implementation of a common foundation of standards for interoperability so that different systems can accurately and securely exchange patient data.

The HIMSS Electronic Health Record Association (EHR Association) Interoperability Roadmap provides a pragmatic, logical structure for implementation of such a foundation. Its purpose is to serve as a guide for those involved in the development of an interoperable healthcare system, from senior executives and product managers to industry analysts and policy makers.

This Roadmap is the first effort to articulate an achievable path to interoperability. The foundation we have developed identifies four levels of specificity, from high-level business use cases to the most granular technical requirements. It recognizes that progress will be incremental, identifying opportunities for immediate benefit and building on that foundation to achieve interoperability in four clearly defined phases. While these phases build on each other, they do not require that one be fully completed before beginning work on the next.

In developing this Roadmap, we have sought input from a broad range of stakeholders – experienced EHR vendors with a significant number of successful implementations, as well as healthcare providers, payers, consumers, standards development organizations, professional associations, health information technology (HIT) advocacy organizations, government organizations, and others. This breadth of perspectives ensures that anyone involved with the planning, development, and implementation of HIT – regardless of size of organization or budget – will find valuable guidance here for the requirements, services, timeline, and other facets of implementing a viable interoperable network. When the American Health Information Community (AHIC) promulgated its use cases, we found that the Roadmap was able to address them – confirming the validity of the work we have done here.

EHR Association continues to welcome feedback from stakeholders at our Web site (www.himssehra.org). Stakeholders can also review EHR Association's responses to comments that have been posted on the site.

This Roadmap recognizes both the business and technical challenges of achieving interoperability. We have utilized proven processes and existing standards; we have also taken a business-driven approach that provides sufficient flexibility for individual users to implement architecture that meets their specific business needs.

Our goal is to enable vendors, providers, and other stakeholders to align their common objectives and to engage in development that is not bounded by individual silos. Organizations that incorporate this Roadmap into organization planning and development can take advantage of the proven methodologies and detailed analysis contained here to attain needed continuity with other efforts to achieve an interoperable healthcare system.

Since the first iteration of this Roadmap was published, our members have already begun implementing various pieces of it, both within the U.S. and around the world – and demonstrating considerable success. EHR Association's vision is that this Roadmap will further mobilize the leadership of healthcare organizations, information technology vendors, and other relevant stakeholders to work toward the common goal of interoperability.

Preface

The HIMSS Electronic Health Record Association (EHR Association) was formed in 2004 to provide a collective voice with which to respond to governmental and other external initiatives affecting electronic health records (EHRs) and the creation of a nationwide health information network (NHIN). EHR Association's mission is:

- To improve healthcare by advancing the EHR industry as a whole and promoting the rapid adoption of electronic health records;
- To deliver immediate and future value to healthcare providers and patients by providing a unified voice and a forum for cooperation for the EHR vendor community; and
- To serve as leaders in standards development, EHR certification, interoperability, advancing performance and quality measures, and other EHR issues subject to an increasing number of initiatives and requests by government, payers, patients and physician associations.

EHR Association currently comprises 41 of the leading ambulatory and enterprise EHR vendors, whose customer base represents more than 90 percent of healthcare providers in the U.S. We believe that rapid, widespread adoption of EHRs will help improve the quality of patient care and the productivity of the healthcare system. Within the association, EHR vendors can work together on issues such as functional standardization, certification, and interoperability – issues that affect the adoption of EHRs across the healthcare setting. EHR Association members can reach consensus on basic principles of EHR implementation, while continuing to diverge in practice for business and competitive reasons.

One of EHR Association's first initiatives was a comprehensive response to the Request for Information promulgated by Dr. David Brailer, then head of the Office of the National Coordinator for Health IT (ONC), which included the first iteration of this Interoperability Roadmap.

In order to foster broad adoption of the Roadmap, EHR Association worked extensively both within our membership and with a wide variety of other stakeholders, including:

- Professional associations representing diverse clinical specialties, such as the American College of Cardiology (ACC), the American College of Physicians (ACP), the Radiological Society of North America (RSNA), the American Hospital Association (AHA), and the American College of Emergency Physicians (ACEP);
- HIT advocacy organizations, such as the Markle Foundation's Connecting for Health, the e-Health Initiative, and the Center for Health Transformation;
- National health information technology organizations, such as the Healthcare Information and Management Systems Society (HIMSS), Integrating the Healthcare Enterprise (IHE), and the American Health Information Management Association (AHIMA);
- National and international standards development organizations (SDOs), such as HL7, ASTM International, the Organization for the Advancement of Structured Information Standards (OASIS), and the Healthcare Information Technology Standards Panel (HITSP);
- Governmental organizations such as ONC and the American Health Information Community (AHIC); and
- Certification bodies, such as Certification Commission for Healthcare Information Technology (CCHIT) and the International Organization for Standardization (ISO).

The viability of this Roadmap is in large part due to the participation of all these diverse stakeholders. To
105 that extent, EHR Association is merely a steward, not an owner, of this process. The value of this Roadmap depends on healthcare providers and policy makers accepting and implementing the recommendations that we put forth here.

Roadmap Overview

The U.S. healthcare system is in crisis. Healthcare consumes an ever-increasing share of our gross domestic product – much of it driven by treatment for a handful of chronic diseases. Medical errors kill about 100,000 people every year[1], and may affect almost 1.5 million more[2]. Natural disasters can wipe out hundreds of thousands of medical records in the blink of an eye, jeopardizing the care of the most medically fragile members of a community. In stunning contrast to the technological advances in diagnosis and treatment that have been made over the last century, healthcare lags behind virtually every other industry in its use of information technology – and yet, IT can address all of these problems and more. Our largely paper-based healthcare system is at best inefficient and at worst actually detrimental to patient care.

In 2004, President George Bush announced the goal of having an electronic health record (EHR) for everyone in the U.S. within 10 years. To guide this effort, he established the Office of the National Coordinator for Health IT (ONC) and appointed Dr. David Brailer as its first head. ONC's role is not to mandate the use of HIT, but to use a variety of methods to encourage the formation of a nationwide health information network (NHIN) that will transform healthcare delivery.

Adoption of EHRs within a single healthcare organization can help make patient care safer and more efficient, but to have a significant impact requires robust health information exchange across the entire continuum of care. To do so, all of the disparate HIT systems in use need to be interoperable – that is, a provider must be able to securely and seamlessly access all of a patient's medical information regardless of where that information is housed.

Prerequisites for Achieving Interoperability

The path to interoperability is fraught with challenges. Some of them are technical – determining what standards should be used to achieve interoperability and implementing those standards within HIT systems. Some are cultural – encouraging both vendors and providers to share information. And some are financial – identifying sources of funding needed to acquire the technology and to establish and sustain health information exchanges.

Nonetheless, we believe that interoperability is achievable, under certain conditions outlined in this Roadmap.

Interoperability is the ability of two or more systems or components to exchange information and to use the information that has been exchanged.

Functional interoperability is the capability to reliably exchange information without error.

Semantic interoperability is the ability to interpret, and, therefore, to make effective use of the information so exchanged.

Source: IEEE Standard Computer Dictionary: A Compilation of IEEE Standard Computer Glossaries, IEEE, 1990

Stakeholder involvement

The starting point is the involvement of a wide variety of stakeholders, which has proven to be valuable in other similar efforts. For example, the Digital Imaging and Communications in Medicine (DICOM) standard for sharing images was the result of user and vendor collaboration spanning national borders, in order to achieve "out-of-the-box" sharing of images. Diagnostic imaging vendors historically used proprietary formats which allowed CT and MR images to be shared among systems supplied by the same vendor, but not between competing systems. DICOM allowed images to move from system to system, enabled hospitals to centralize storage of images to reduce costs, and led the radiology department to move toward diagnosing images on a computer screen. Significantly, DICOM was rapidly and widely adopted because

[1] *To Err Is Human: Building a Safer Health System* (2000); Institute of Medicine
[2] *Preventing Medication Errors: Quality Chasm Series* (2007); Board on Health Care Services

it was the result of a joint effort among the radiology and cardiology communities and diagnostic imaging vendors, rather than the product of government intervention.

The effectiveness of DICOM led to a desire for improving information exchange between the radiology department and other clinical IT systems in the hospital. To accomplish this, the Radiological Society of North America, the Health Information Management and Systems Society (HIMSS), the American College of Cardiology, the American College of Physicians, and other professional organizations sponsor a user-led initiative known as Integrating the Healthcare Enterprise (IHE) to create a standards-based foundation for clinical IT. IHE's interoperability showcases – held at major industry conferences – encourage competing vendors to build and demonstrate data exchange between their products via a collaborative and transparent process. IHE's scope includes radiology images, medical summaries, laboratory results, and cardiology reports – the very information that today is often still faxed, couriered, or mailed between providers at the majority of healthcare organizations in the U.S.

EHR Association's approach to interoperability is modeled on IHE's proven methodology. By working together, vendors, providers, and industry experts can drive change and improve the processes by which healthcare is delivered. EHR Association's mission is not to develop standards, but rather to help stakeholders focus their efforts, to support the work of standards development organizations such as HL7 or ASTM, and to encourage adoption of standards by our members and other stakeholders. We are also actively involved in organizations such as the Health Information Technology Standards Panel (HITSP).

While vendors and other stakeholders are not bound by EHR Association's recommendations, there are acknowledged reasons to follow a common Roadmap. Interoperability succeeds only to the extent that the majority of vendors implement a common technical foundation. In the long run, it is in the interests of vendors and other stakeholders to face ongoing challenges and make compromises for the greater good of all care providers and, in the end, patients. Achieving interoperability will require coordinated strategies that help providers achieve optimum workflow with reasonable investment, while building toward an increasingly consumer/patient centric model of healthcare. Without this, we will perpetuate the current Babel of incompatible systems that are difficult and costly to implement, and we will fail to realize the benefits that the NHIN can provide.

Phased implementation

On an undertaking of this scope, progress will necessarily be incremental. This Roadmap outlines a four-stage approach to achieving interoperability, with each phase driven by use cases that explain why information exchange is necessary. These phases build on each other and provide increasingly rich functionality to deliver the electronic health record within President Bush's requested timeframe.

- **Phase 1: Share Care Status Information:** Structured medical summaries support transition of care among providers.
- **Phase 2: Share Diagnostic Results and Therapeutic Information:** Adds patient-created information and emergency summaries plus e-Lab and e-Prescription, with selected coded information.

What is a digital document?

Throughout this Roadmap, the term "document" is used to mean a defined set of electronic data, rather than a traditional paper record.

A digital document is:

- Computer-processable (as opposed to a .pdf or .jpg image of the data);
- Structured data (*e.g.*, medication list, allergy list, diagnoses, etc.);
- Produced by a single source (*e.g.*, a consumer, payer, pharmacist, provider, etc.); and
- Attested by the source.

Related health record elements may be grouped by the source to form a single document.

Each electronic document includes both specific medical information about the patient plus sufficient context to provide a level of confidence in the data.

- **Phase 3: Advanced Clinical Support and Access Control:** Extends access control, exchange of continuity of care documents and dynamic queries for medications and allergies with extensively coded information.

- **Phase 4: Collaborative Care, Active Quality Reporting and Health Surveillance:** Introduces workflow-oriented collaborative services and the second generation of public health surveillance and quality reporting.

As of this writing, Phase 1 is well under way. Bringing each of the succeeding phases to availability for testing and demonstration purposes should take between one and five years, depending on the level of investment and incentives that exist. Market forces will determine when these products will be commercially available.

Coordinating technology and policy

In developing this Roadmap, we have relied heavily on the Connecting for Health Common Framework. Like health information exchange, interoperability also includes both technical and policy components.

The policy aspects of interoperability comprise "rules of the road" as to what minimum level of data should be exchanged and how and to whom that information will be made available. These aspects should be considered in the development of health information exchange use cases, and will be shaped by the groups exchanging the information.

The focus of this Roadmap is on the technology aspects of interoperability – factors such as data standards and integration profiles used to describe the structure, format, and context of the data being exchanged.

The experience of EHR Association members worldwide indicates that most of the interoperability components needed for nationwide HIT programs in clinical information are common to a high degree across national boundaries. Relatively few areas require specific national customization, and those that do can be more easily implemented as national extensions to the underlying standards, rather than as separate (and possibly competing) standards. Because diseases do not recognize national borders, surveillance for bioterrorism or epidemics such as avian flu will be more effective if systems are interoperable across those borders as well. U.S. status with various international organizations may ultimately be affected by how well we can respond to these challenges as part of a global paradigm. Further, the ability of U.S. IT vendors to compete in a global market will be fostered by harmonization of international standards.

Defining the Core Technical Foundation

This Roadmap distinguishes four levels at which a common foundation for interoperability can be defined:

- **Business level:** This encompasses health system objectives such as "chronic disease management" or "patient empowerment with a medication history." There are many ways of identifying and structuring use cases at the business level, which contributes to the challenge of creating a comprehensive list. A pragmatic approach employed by AHIC and ONC, as well as the vendor community, is to select a small – and therefore achievable – number of use cases (three or four) to scope and implement.

- **Communication Service Level:** A communication service defines a number of related means to exchange specific types of health information for the purpose of sending the information from one system to another or accessing it from a remote system. Examples of communications services are "electronic drug prescriptions," "sharing of patient's medical summaries," or "access to a patient's current allergy list." This is the level at which many development projects are already taking place around the world, and is therefore the level addressed by the Roadmap. The communication services

- **Integration profile level:** More granular than the communication service level, the integration profile level attempts to factor common interoperability building blocks in order to maximize reuse of specification and implementation methods, while allowing for evolutionary growth within a domain. Multiple standards are generally needed to define an integration profile. This is the level at which it is most practical to perform interoperability conformance testing – exemplified by IHE.

- **Base standard level:** Base standards are used across a wide range of industries to achieve fundamental IT interoperability or security management. Base standards are foundations that enable the creation of messages and documents to support any possible use case in their domain. Like the other three levels, base standards development is also use case-driven, but is faced with the significant challenge of anticipating a much greater variety of needs and market evolution. The large number of standards development organizations (SDOs) working on base standards means there is the risk of both overlaps and inconsistencies between approved standards. Because these standards are not necessarily specific to healthcare, their use in this setting requires a number of tasks that are provided at the integration profile level (*e.g.*, selection among competing standards to identify healthcare-suitable options).

  The required flexibility of base standards makes development a long-term activity with often unpredictable delivery schedules. For this reason, we recommend that standards development and integration profile development should be separate activities that operate on different schedules and consensus processes, but with strong two-way collaboration. We also recommend that SDOs offer a maintenance process that allows for approved standards to be updated with newly identified content as these standards make their way into integration profiles.

Figure 1 illustrates how these four levels support each other by adding specific technical depth as one moves from the level of business use cases (at the left side of the diagram) all the way to the most granular details needed to accomplish effective, testable and robust interoperability (at the right). This Roadmap focuses on the middle two layers, where a critical rationalization and the definition of building blocks for common solutions takes place.

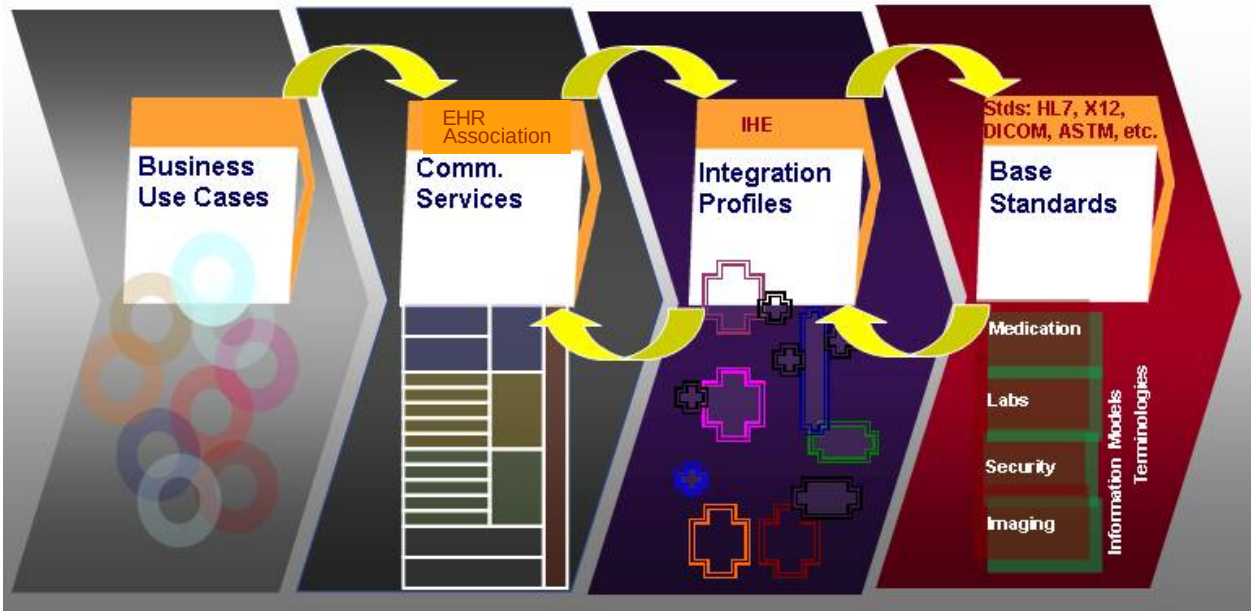

Figure 1: The Four-Level Foundation for Defining Interoperability

This Roadmap also defines essential elements and requirements of the proposed nationwide health information network (NHIN) as well as any local or regional health information organization (RHIO). These elements are:

- Utilize "thin" architecture for the core NHIN, including its sub-networks, and leverage the functionality of the edge systems that connect to it;
- Create an architecture with the necessary flexibility to support centralized or distributed data repositories within the NHIN core or any of its sub-networks without the need for multiple boundary interfaces to edge systems; and
- Simplify the infrastructure by limiting the number of core functions that are included within the NHIN and its sub-networks.

In this context, it is important to recognize that the role of the NHIN and its sub-networks is as a set of communications services that enable information to be shared or exchanged among applications such as EHRs or lab or pharmacy systems. The NHIN and its sub-networks are not applications or systems. The significance of this distinction is to ensure that the focus remains on the needs of the clinical end-users and the information they exchange.

The fact that the infrastructure is transparent with respect to clinical content is important, both because it drastically reduces the costs and operational complexity of the NHIN and of its sub-networks, and because it ensures that massive ongoing reinvestment will not be required to keep the NHIN current with constantly evolving clinical vocabularies and technologies. Building the NHIN as a thin infrastructure and allowing it to leverage the capabilities of existing edge systems (EHRs and others) will be more cost-effective than duplicating edge system functionality within the core. Thin architecture can evolve more easily, without creating additional barriers to future evolution of the edge systems. Keeping the infrastructure simple, rather than building a lot of functionality into it, means that users will be able to access the NHIN from a variety of different types of edge systems. It would not require that every provider have a full EHR in order to access the NHIN.

In this model, the functional requirements of the NHIN would focus on ensuring transparency at the boundaries between core and edge systems, and at the boundaries between edge systems. The role of the infrastructure would be to move data from one system to another, with a minimum of data actually stored within the core. This provides the necessary flexibility to support sub-networks of the NHIN (RHIOs) regardless of whether their data is centralized or distributed. This flexibility will reduce the cost of development for edge systems by avoiding a proliferation of interfaces: a vendor can rely on a single solution that will work within either a centralized or distributed environment.

Similarly, limiting the core functions of the NHIN will lead to more uniformly robust edge systems, without the need to market many different variations.

Identification of the Fundamental Requirements and Infrastructure

The phased approach of the Roadmap defines and delivers required infrastructure to facilitate cross-enterprise and constituent communication, including:

- Security and access control;
- Patient identification management;
- Persistent information management (storing/sharing aggregated records from uncoordinated sources across time, *e.g.*, medical summaries);
- Dynamic information access (direct request/response interactions to specific target systems, *e.g.*, query of immunization registry); and

- Workflow and quality (cooperative work distributed across entities, *e.g.*, ordering and results of lab tests or prescriptions).

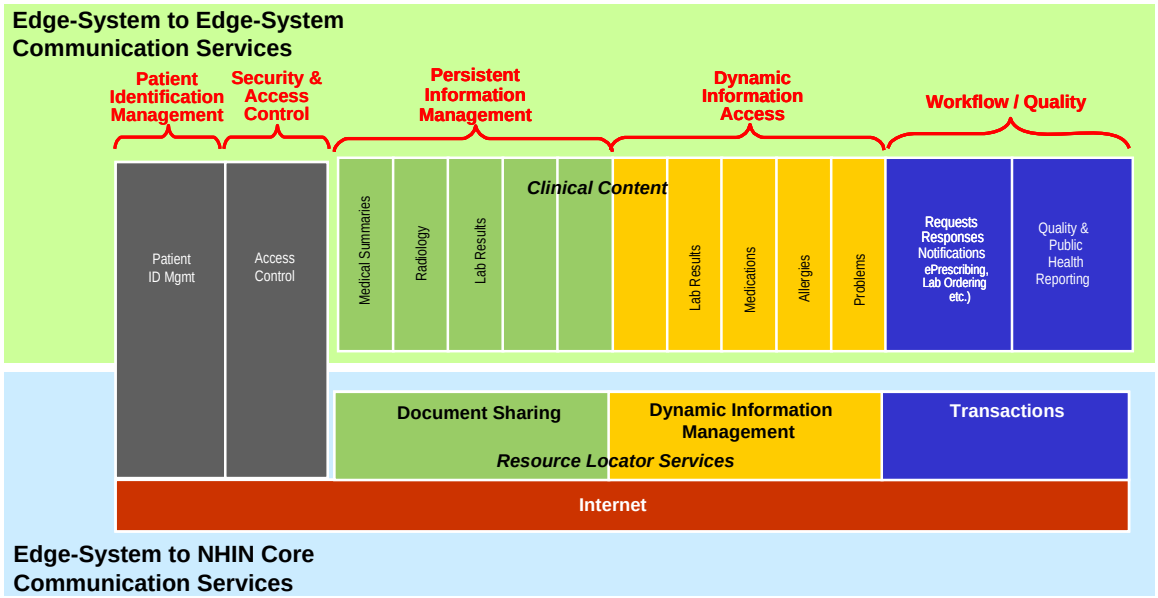

Figure 2: Roadmap Infrastructure Requirements

Of the above five functions – which have both edge-to-edge and edge-to-core components – the first two are foundational to the NHIN; without these, nothing else can be accomplished.

Once those have been established, the first priority should be persistent information management. Also referred to as ”document sharing” by analogy with the world of paper records, the fundamental characteristic of persistent information management is to allow the longitudinal aggregation of a health record with incrementally added content from uncoordinated multiple sources over time. Each electronic “document” includes both specific medical information about the patient, plus sufficient context to provide a level of confidence in the data in a form which can be both read by a provider and processed by a computer. For example, the document might list the prescribed medications associated with a recorded medical history and the known allergies at the time care was provided for the diagnosed problems. Each source is responsible for maintaining its own contribution to the record, which can include medical summaries (problems, medications allergies, etc.), radiology reports or images, laboratory results, or any other data that may be collected about the patient. All of the use cases identified to date rely on such document sharing.

Again, the structure of the NHIN needs to be flexible enough to allow persistent data to reside either in the core or in the edge systems. RHIOs should be the decision-makers about where their data is stored. In this way, the NHIN will be able to accommodate the largest variety of edge systems.

In the phased approach described above, document sharing comprises Phase 1, while dynamic queries and workflow are later priorities that are part of Phase 2. The model allows for some temporal overlap between the phases, so that some simplified areas of workflow (*e.g.*, delivery of lab results to ordering providers) could be in place before Phase 1 is completed.

Benefits of Following the Roadmap

This Roadmap offers a plan that vendors and their customers can adopt and implement in a systematic manner to incrementally advance levels of interoperability. As IT platforms evolve and progressively

become more comprehensive, vendors and providers can realize a return on their investment at each stage of the process.

A Pragmatic Solution

The Roadmap achieves complete and rich interoperability in four clearly defined phases, each providing incremental and sustainable value. While these phases build on each other, they do not require that one be fully completed before beginning work on the next. Each phase provides benefits that can be measured in terms of quality, efficiency, and cost-savings, as explained below and in Appendix I. The scenario described in the appendix is based on the example of Dr. Ernesto Africano, taken from the report "Ending the Document Game – Connecting and Transforming Your Healthcare Through Information Technology" (Commission on Systemic Interoperability, 2005).

An Implemented Solution

This Roadmap is based on proven methods and existing standardized interoperability technology. Phase 1 is fully specified and early implementations have been tested, demonstrating interoperability among more than 20 different EHR systems, ancillary IT systems, and IT infrastructure components. It was introduced into clinical use in 2005, and several regional and national projects around the world are planning deployment in 2006. Specification of Phase 2 integration profiles is under way, with testing planned for 2007. Hundreds of person-years of work have been and continue to be invested by HIT vendors (of EHRs and other systems), providers, and other stakeholders world-wide to advance the interoperability solutions presented in this Roadmap.

Benefits:
- Proven in testing, installation and use
- Additional validation through global adoption
- Global interoperability allows for diversity of markets, patient base and resources

A Collaborative Planning Process

In developing this Roadmap, EHR Association has sought input from a broad range of stakeholders – experienced EHR vendors with a significant number of successful implementations, as well as healthcare providers, payers, consumers, standards development organizations, professional associations, health information technology (HIT) advocacy organizations, government organizations, and others.

Benefits:
- Broad validity
- Meets wider scope of use and needs
- Subject matter expert input and review

Support of Government Initiatives

When AHIC promulgated its use cases, we found that the Roadmap was able to address them – confirming the validity of the work we have done here. This validation indicates that anyone involved with the planning, development, and implementation of HIT – regardless of size of organization or budget – will find valuable guidance here for the requirements, services, timeline, and other facets of implementing a viable interoperable network.

Benefit:
- Less risk of misalignment with other initiatives

Closing

No single stakeholder can achieve implementation of interoperable electronic health records. Thus, a collaborative process that actively involves and serves to unite HIT vendors, providers, standards development organizations and other stakeholders is a prerequisite to success of the NHIN. The process, as illustrated by this Roadmap, should:

- Acknowledge and access the experience of industry stakeholders in an open dialogue that values the contribution of all stakeholders;
- Utilize a pragmatic business case-oriented approach to planning; and
- Evaluate and harmonize national and private sector initiatives.

Because the development of this Roadmap is an iterative process, EHR Association continues to welcome feedback from stakeholders at our Web site (www.himssehra.org). Stakeholders can also review EHR Association's responses to comments that have been posted on the site.

What we have not included in the Roadmap is the wholesale development of more standards. We recommend instead an accepted, collaborative effort to determine where standards are needed, review existing standards, and agree which can be applied to HIT. If there are no directly applicable standards, the next step would be to expand on existing standards – including those from outside the healthcare industry. New standards should be developed only as a last resort. Our goal should be to arrive at the minimum number of standards in order to simplify the realization of interoperability.

In any transformation, both the journey and the destination are significant. EHR Association's vision of the destination is a thin, flexible, cost-effective infrastructure that leverages existing edge functionality and supports the greatest variety of edge systems. We need not – and must not – wait until we arrive there to start reaping the benefits, however. Incremental implementation of defined milestones will serve as a foundation for further achievements, ultimately hastening completion of the entire network. More importantly, incremental implementation will deliver immediate and ongoing benefits for both patients and providers in terms of both quality of care and productivity of the healthcare system.

Relation to Other Industry and Government Initiatives

In developing this Roadmap, EHR Association sought input from a broad range of stakeholders. We also recognize the contribution of thousands of technical and clinical experts who worked on the underlying integration profiles and base standards that we have referenced here.

It is therefore natural that this Roadmap is synergistic with a host of industry and government initiatives, including:

- AHIC use cases;
- Interoperability elements identified by CCHIT;
- Requirements identified by many RHIOs and health information exchanges (HIEs) in the U.S. and abroad;
- Interoperability specifications and associated constructs specified by HITSP;
- The Markle Foundation's Connecting for Health Common Framework;
- IHE Integration Profiles; and
- Base standards developed by organizations such as ISO TC215,

Technical Detail

Overview

This section of the Roadmap contains the technical detail required by consultants and technical analysts who are responsible for actual implementation of interoperable systems.

To begin this discussion, it is first necessary to explore the parameters of what is encompassed by the term "interoperability." We are concerned not with a single interface or transaction definition, but rather an entire set of protocols for the exchange of multiple types of data – such as lab data, registration data, payer claims attachment data, continuity of care documents, and personal health records. The intent of this Roadmap is to guide the development of a single standard interoperability foundation, so that healthcare organizations do not have to invest in implementing multiple platforms for each potential data exchange.

For each type of data to be exchanged, there should be a definition of what data should be included and at what level of detail (*e.g.*, unstructured text, structured documents, or coded clinical data). Because different systems may be able to accommodate different levels of structure or coded clinical data, interoperability typically implies that the standards employed are able to scale appropriately depending on the structure and level of detail or coded data provided. This capability is often referred to as "extensibility" and is intended to ensure an incremental upgrade path that minimizes disruption and cost as the use of these standards advance.

In addition to the physical transfer of data between systems, transferred data should be understood by the sending and receiving systems in exactly the same way.

Design Principles for the NHIN

The development and implementation of a nationwide interoperable HIT infrastructure must support the national goals of improving patient safety, enabling better coordination of care across care settings, and providing greater value for our investment of healthcare dollars.

The infrastructure must empower both consumers – by giving them control over their personal health records – and providers – by giving them control over the movement of data from their private space to a shared space controlled by the patient. There must be assurance that both patients and providers will be able to distinguish between patient-generated and provider-generated data.

Successful deployment of the Roadmap must take into consideration the investments providers have already made in HIT. Like designing a house remodel to use as much of the existing structure as possible, so this implementation must build on the technologies in which providers have already invested.

The NHIN should be deployed utilizing an approach that allows the incremental deployment of services so as to provide healthcare information exchange. This necessarily implies the concept of extensibility. Establishing a base set of capabilities that can be expanded over time and allowing backward compatibility with older systems, while allowing newer capabilities to be introduced, provides immediate value which builds over time. An example of this is available today with the ability to allow simple exchange of unstructured information (text), while planning to enable richer computer-consumable structured, semantic information once standards for content and vocabularies are available.

The NHIN should be deployed by encouraging the development of sub-networks, but all sub-networks must use the same common foundation of interoperability technology standards and policies. In this way, local or regional sub-networks can be established in parallel, yet seamlessly weave together to form an integrated NHIN. Sub-networks that are currently active can begin exchanging information with the nationwide network immediately; others can continue to develop and come online as they are ready. A

common foundation eliminates unnecessary dependencies and provides the greatest benefits in the least amount of time.

Using the same technical foundation for interfacing all edge systems among multiple sub-networks provides economy of scale (*i.e.*, reuse of software, as well as drastically reduced integration, training and maintenance costs) and allows healthcare providers, vendors and other users of healthcare information to focus their resources on providing healthcare delivery innovation in the foreground of the healthcare delivery process. This allows stakeholders to utilize their skill sets in the areas of most benefit – their core competencies.

The EHR Association Interoperability Roadmap must allow for the incremental development and deployment of a first set of healthcare information exchange services, using recognized best practices for interoperability standards selection, profiling and integration. This delivers immediate benefits, and creates a foundation for further development, with the flexibility needed to allow for product development schedules, rates of diffusion into the provider base, and interdependencies with other standard deployment efforts.

Implementation of standards-based interoperability, such as that used by IHE, allows for:

- Identification of critical workflows and use cases to provide immediate benefit;
- Identification of requirements for the information exchange protocol to support the specified workflows; and
- Prevalence and widespread adoption of these workflows in a plug-and-play environment, ensuring those EHRs and other edge systems can be integrated predictably and at lower costs.

This Roadmap contemplates demonstration of the possible NHIN infrastructure services through the use of industry showcases in which a variety of stakeholders participate. These events serve as collaborative forums where industry stakeholders can interact with each other, the government, and the public to showcase progress.

Finally, this Roadmap provides a market-driven focus on health information exchange. The exchange must serve a relevant purpose – one that provides a value to multiple stakeholders with respect to adoption of health information technology. This approach guides our efforts in the direction of the very real problems that must be solved in order to accelerate adoption of health information technology. If a use case does not provide enough value to expend effort and resources to implement, then the market will not adopt it. This has been proven via the experience of EHR Association members, their customers, and their patients.

Common Foundation

The EHR Association Interoperability Roadmap distinguishes two levels of interfacing between edge systems (see Figure 3:

- The edge system and the NHIN core infrastructure (which includes all the sub-networks and the backbone that will link them together), similar to the way a home PC interfaces over the internet using TCP/IP; and
- Peer edge systems performing information exchange where the NHIN core is transparent to the applications running on these systems, similar to the way a home PC browser interfaces with a remote web server with no interference of the underlying network.

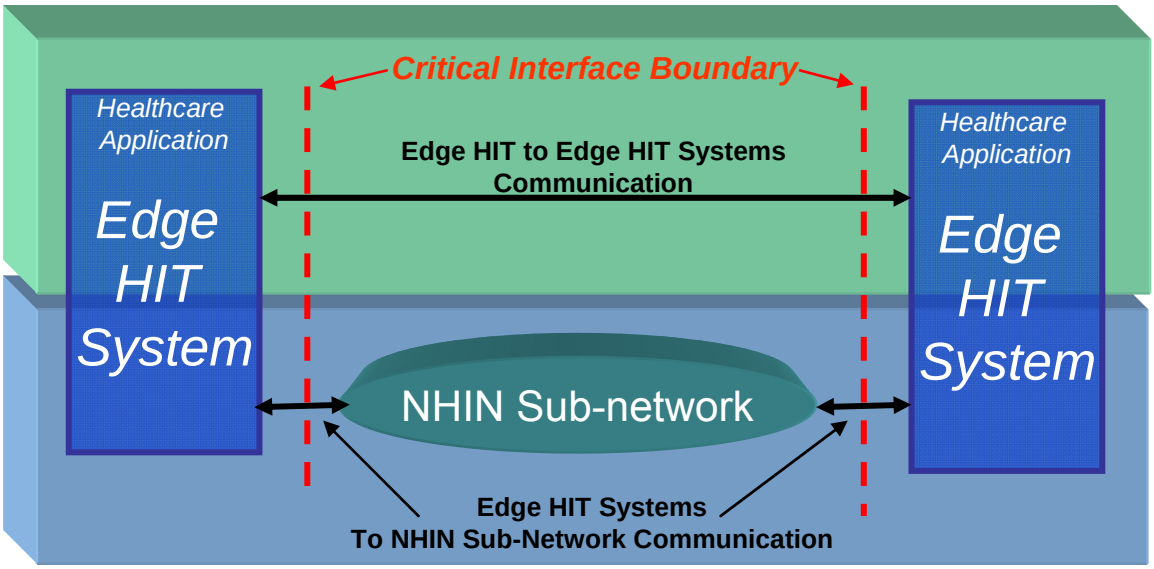

Figure 3: Two Levels of Edge System Interfacing

This provides the ability to evolve the information exchange content at the end-to-end level, without requiring any evolution of the NHIN core. It is a critical element aimed at allowing a stable and cost-effective infrastructure of the NHIN core as increasingly richer and more specialized content is exchanged.

Enabling a Broad Range of Architectures

The Interoperability Roadmap has been designed to support different architectures and configurations. Indeed, there are a number of factors (such as operational costs, scale of health information exchange, trust policies, technology evolution, disaster recovery, etc.) that will influence specific architectural deployment of these communication services. In particular, EHR Association recognizes that different approaches will co-exist in the design of NHIN core. However, maintaining the same set of communication services at the boundary between the edge HIT Systems and the NHIN core will ensure that the majority of systems that need to be interfaced are minimally affected by such architectural and configuration flexibility. Edge systems will number in the many thousands, whereas the NHIN core are expected to number in the hundreds or fewer.

The communication services of this Roadmap have the following characteristics:

- Stored persisted information is supported in the following models:
  - entirely decentralized (*i.e.* supported by the edge systems);
  - entirely centralized model (*e.g.* central core repository); or
  - any mix of the above.

- All systems that conform to the edge boundary communications requirements are supported as edge HIT systems, including systems delivered through web access (*i.e.*, applications shared by several users generally accessed through simple web browsers). All variants of application delivery (*e.g.* thick or thin clients) are supported as part of the edge HIT systems. Edge HIT systems may or may not use network infrastructures to interface their users. In terms of communication services, there is no difference between a web-based, remotely hosted doctor's EHR and an EHR system installed in a clinic. Edge HIT systems may range from small single doctor offices to large distributed IDNs. The inner structure of edge HIT systems is not constrained by the network but their communication with the health information network is explicitly defined.

- Record location services are part of the core infrastructure. These will not contain patient clinical information, only minimal meta-information about the location of patient-related records. This meta-information may be as minimal as:
    - "Existence of information" in a location (*e.g.*, edge HIT system or repository). This is what Connecting for Health has developed with its record locator service (RLS).
    - High-level information about a "dynamic communication service" where information for a patient may be accessed.
    - "Generic attributes" of a shared document (*e.g.*, a lab report or a medical summary published by a location at a specific time, but not the test results values) for a patient, and the pointer where this document may be accessed. This is what IHE has developed with the Cross-Enterprise Document Sharing (XDS) Integration profile.

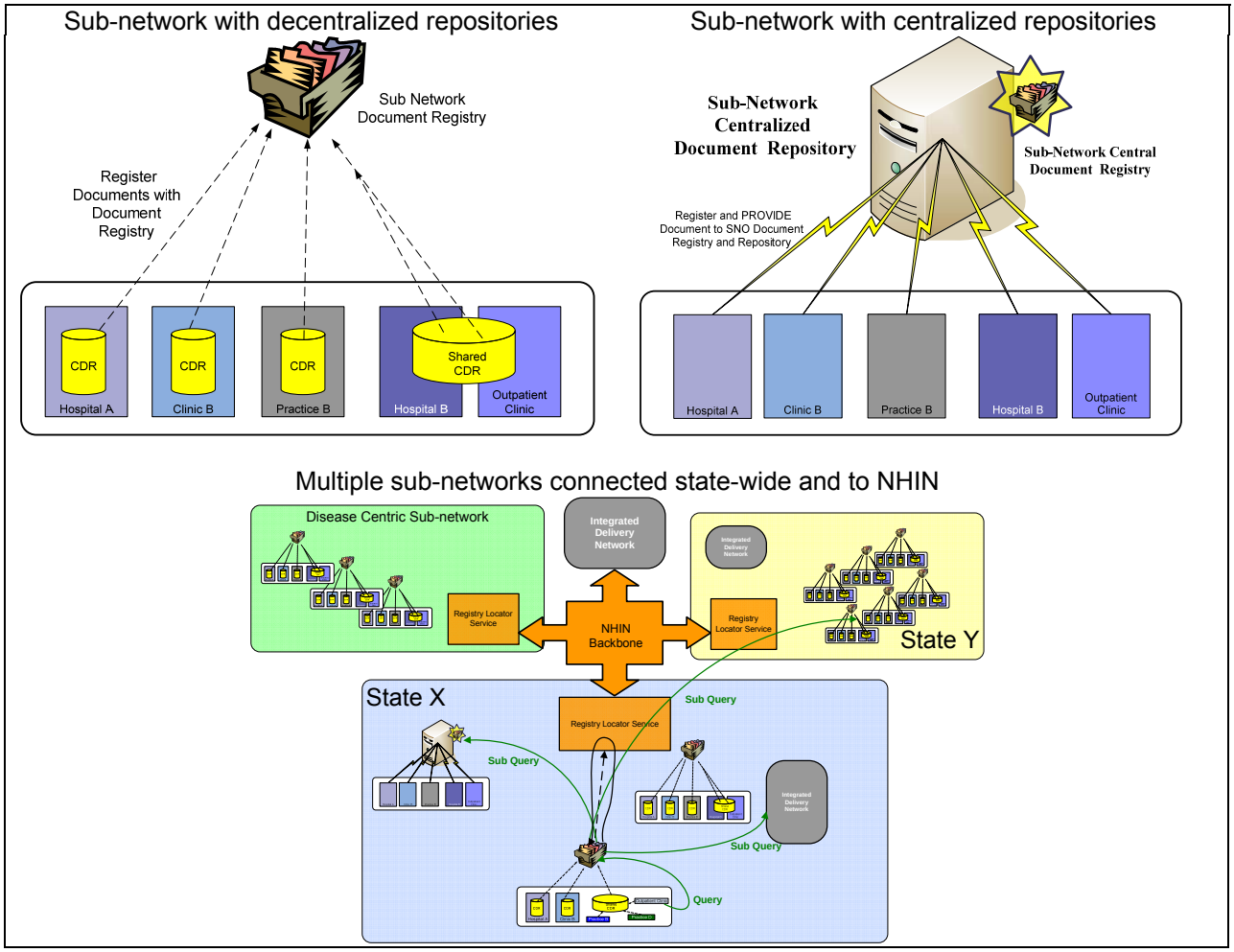

Figure 4: Examples of Implementation Architecture Models

EHR Association believes that all three approaches are needed. Distinguishing record location services actors from repositories actors in defining integration profiles is critical to allow for both centralized and decentralized architectures.

It is critical that these principles be applied to the definition of the communication services (see next section) to ensure their greater flexibility in a variety of current and evolving deployment architectures. See Figure 4 for illustrations of the three deployment models.

Security & Reliability

Ensuring privacy and building trust

Any health information exchange will be only as secure as its weakest link. Extending healthcare information outside the boundaries of an enterprise or even a single EHR system brings with it vast threats. Thus, it is vital that privacy protections be designed into both the NHIN and the systems it interconnects, spanning both the infrastructure and the edge systems.

Securing healthcare data is more complex than general IT security. In healthcare, the assets to be protected are the safety and privacy of both patients and caregivers. In most cases, both assets can be protected simultaneously, but in emergency situations the need for privacy may be secondary to (and conflict with) the need for safety. This tension cannot be resolved through technology alone; it requires a balance of technology with policies and procedures.

In addition, security breaches in other industries can be remediated, where breaches in healthcare cannot. If financial information is revealed, a consumer can close the accounts that have been compromised and open new ones. Healthcare information, however, cannot be changed or revoked.

The ultimate solution for protecting patient information would be to give the patient complete power over when and by whom the data is used, with case-by-case access control. The standards and technology to implement this level of control will likely take five to ten years to mature. In the meantime, this Roadmap proposes a multi-year plan that will protect privacy, ensure accountability, and promote patient safety.

- State-of-the-art security technology can now enable access controls that prevent unauthorized individuals from gaining access to any system storing or providing access to the patient health record (EHR or the NHIN or any of its sub-networks). Clinical users have unfettered access to ensure that the patient receives treatment, but this access must be carefully tracked to provide accountability.

- Over the next one to three years we expect to have access controls based on functional role and broadly defined objects, which can be shared across organizational boundaries. This will ensure that those who have proper clinical credentials will have access to the types of information they need to best treat the patient. Defined roles will be controlled at a high functional level, and objects will be controlled at the report, view, results, or study level. Critical to this level of control is standards-based user identity and permissions that can be uniformly enforced across the NHIN, its sub-networks, and participating edge systems.

- In years three through six, RHIO-level access controls should recognize the role of the treating clinician. This role is assigned to individuals that have a treatment relationship to the patient and thus should gain access to that patient's information. Currently this level of access control is somewhat available in single-organization EHR systems; extending it to the core and its edge systems would be a significant gain.

- In years seven through 10, RHIO-wide access controls will place more control into the patient's hands. The patient and providers will have strong identifiers and dynamic relationships that can be used to bind the patient's access control directives to each use. Built into this system will be fail-safe mechanisms to ensure that the critical patient data is available in case of emergencies.

Enabling reliability, availability and recoverability

This Roadmap has been designed to support architectures that can meet the performance requirements of a paperless healthcare environment. A complete response to enabling reliability, availability and recoverability would encompass a broad range of design issues – not just interoperability – and is thus beyond the scope of this effort. We have, however, outlined critical elements covering not only normal operations but also a variety of degraded modes, to ensure that software and hardware maintenance do not have a negative impact on continued operations.

The separation of responsibilities between the NHIN and the edge systems makes the NHIN simpler – and therefore more reliable – and requires less frequent upgrades. Shifting the burden of clinical data awareness to the edge systems, however, also shifts the problem of reliability and availability to those systems. Both NHIN and edge systems are necessary to maintain reliable access to patient records.

The document registry, clearly part of the NHIN infrastructure, is a central component that needs to meet high-performance and availability objectives. These can be achieved with reasonable ease by using the classic Internet server techniques (redundant hardware, fail-over configurations, redundant network path with rerouting, etc.) typical of a search engine service. The document registry should be designed to reference any type of digital document with any type of information content, so extension of content will not require upgrade of the registry or reconfiguration. Finally, from a performance standpoint, simplicity of the registry content (about 20 attributes per document) will ensure rapid response, even with significant query traffic. In cases where there is no relevant document, it is a particularly important requirement that users experience less than two seconds response time. This is critical for care providers so that patient care may proceed quickly and with the confidence that no relevant information exists in another system. It is important to note that the definition of XDS registry attributes ensures that queries are sufficiently discrete and filling errors minimized.

One or more document repositories, considered edge systems, need to be in an environment similar to the NHIN document registry, regardless of the chosen level of centralization or decentralization. One of the critical characteristics of XDS document repositories is their extremely simple functionality: store any digital document (regardless of content), place it in a file, assign a URL, and provide the digital document back unchanged in response to a single transaction for document retrieval. Such a simple document repository will need little software development and highly reliable implementations are available today. The decision to implement document repositories as shared edge systems (managed or not by the RHIO) or a dedicated system co-located with (or implemented within) the source HIT systems, is left to RHIO policy. This is one of the reasons that led EHR Association to select the IHE XDS document sharing approach for the Interoperability Roadmap

Cross-Enterprise Document Sharing

Cross-Enterprise Document Sharing (XDS) will use the concepts of document repositories and document registries. These are distinct entities with separate responsibilities:

- The repository is responsible for storing documents in a transparent and persistent manner and responding to document retrieval requests.
- The registry is responsible for storing information about the documents so that documents of interest for the care of a patient may be easily found, selected and retrieved irrespective of the repository where they are actually stored.

XDS is document-content neutral. It will support any type of document without regard to content and format, allowing this integration profile to be able to handle documents in a wide variety of commonly accepted formats for medical records.

IHE IT Infrastructure Technical Framework Supplement 2004-2005 Cross-Enterprise Document Sharing (XDS)

In the case of dynamic access services, achieving an acceptable level of availability and reliability will be a much more difficult challenge, as information sources will require regular upgrades to source repositories and database schema when new types of clinical data are made available. Therefore, use of such services is recommended only in later phases of the Roadmap.

Workflow and quality communication services require different analyses. Indeed, in many cases only two edge systems are engaged in workflow communications (*e.g.* the generator of a lab order and a laboratory performing the lab work). In some cases, three parties may be participating (*e.g.* a prescribing system, an intermediary when the target pharmacy is not known at the time of prescribing and a pharmacy). Availability and reliability in these cases is primarily constrained by the specific edge systems supporting an instance of the workflow.

Roadmap Communications Services Model

In a previous section we articulated the building blocks of an interoperability foundation. Within that foundation, there are information services that will support the hundreds of use cases that can be developed. We have organized these services into five major categories, which demonstrate the incremental implementation of interoperability. (*See* Figure 5.)

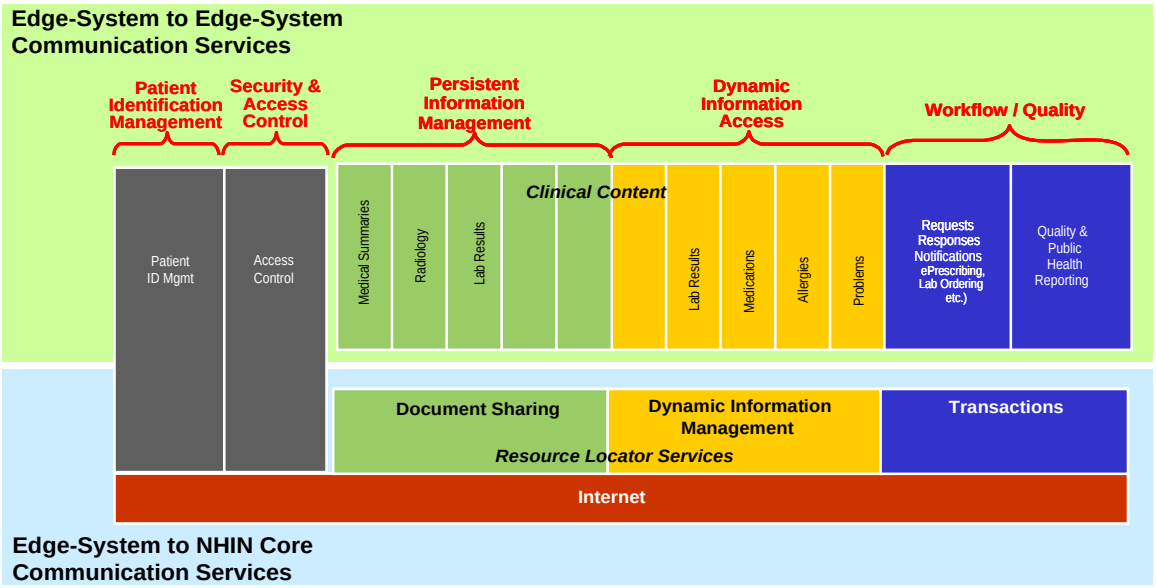

Figure 5: Interoperability Target – Roadmap Communications Service Model

Each of these five categories represents a set of services that supports a specific mode of health information exchange, as described below. Within each category, each service may operate between edge systems (upper section) or between an edge system and the NHIN infrastructure (lower section).

Security and Access Control. This category does not comprise clinical information; rather, it provides the means to secure health information as it is exchanged and stored, such as user authentication, encryption, audit trail, access control, edge-system authentication and information access consent. Robust security is fundamental in gaining the trust of consumers and patients to share their information.

Patient Identification Management. This category comprises the necessary information exchange services to properly identify consumers and care providers as they exchange health information (*e.g.*, services to link patient identifiers). The category will be enriched in the future with vocabulary management services.

Persistent Information Management. The fundamental characteristic of this set of services is to allow the longitudinal aggregation of an individual patient's health record by incrementally adding content from uncoordinated multiple sources over time. Each contribution represents one part of the whole truth about a patient's health. Each source is responsible for "persisting" its own contribution to the patient's record – although the information may be maintained either in the edge system or in the NHIN core.

These services allow providers to share a collection of closely related health information (*e.g.*, the prescribed medications associated with a recorded medical history, and the known allergies at the time care was provided for the diagnosed problem) as a single document. The authoring source – a physician office, hospital, or pharmacy, for example – is responsible for providing the necessary context for the information, so that it can be accurately interpreted by any receiver within the healthcare system. The content that can be managed by these services covers the entire spectrum

from medical summaries (including problems, medications, allergies, etc.) to radiology reports or images and laboratory results, to future types of information such as genetic profiles.

The contractual relationship between the parties engaged in exchange of this type of information is very simple and robust:

- The *source* of a set of documents (a provider, a patient, a pharmacy, etc.) preserves the information at the time it is made available for sharing. The source is and will remain the steward of the document's content and accuracy.
- The *infrastructure* preserves the documents as they are created at a point in time, and makes them available upon authorized requests. It supports replacement/addendum upon request by the original source.
- The *consumer* (patient or subject of care) or any other care/service provider may access an attested copy of any document, and choose to use any part of each one of these documents with knowledge of the context described in each document.

Persistent information management vs. dynamic information access:

A family physician and a cardiologist each prescribe specific medications for the same patient for different conditions. The pharmacy creates a list of medications as they are dispensed, and the health plan maintains its own list as claims are received (which may lag the other lists by a few weeks). The patient is also taking over-the-counter medication, which is not reflected on any of the other lists.

Issuing a dynamic query to each of these sources will provide a series of snapshots that represent where each source is in the midst of its respective workflow, but that – taken individually – do not accurately represent the patient's overall medication status. In this case, it may be more useful to aggregate the data using persistent information management.

Dynamic Information Access. The fourth category of communication services provides the means to query a remote HIT system for current clinical information, such as known allergies or medication lists. Unlike a request for persistent information, a later query may result in different information being provided, or the information may have different relevance depending on the source's role in the health system.

Dynamic information access is commonly used in environments such as acute care facilities, where the various sources of information and care provider teams have well-established workflows. It is most appropriate for use cases where the most timely and up-to-date information is needed and can be accessed from a single source (*e.g.*, a query of a statewide immunization registry). On the other hand, in environments with multiple sources of data, the use of dynamic queries may be prone to misinterpretation and are therefore not suitable for general deployment.

For dynamic information access, the contractual relationship among the parties depends on the role of the information source:

- The *source* of information (a provider, a personal health record, a pharmacy, etc.) provides a snapshot of specific information at the time the request is received.
- The *infrastructure* conveys the request and the response and should not aggregate information from multiple sources, which would jeopardize the effective use of the information by mixing information from different sources.
- The *consumer* (patient or subject of care) or any other care/service provider obtains response(s) to a specific request, but access to the context of this information may require multiple queries with independent results that are not easy to link.

Workflow and Quality. The last category of communication services provides the means to engage in cooperative work between communicating entities. The main focus is no longer the sharing of or access to health information, but the execution of distributed work in the context of specific workflows – for example, ordering a set of lab tests and receiving results as those lab tests are performed;

issuing a request for a prescription and receiving confirmation that the prescription has been dispensed by a pharmacy; issuing a notification of a biosurveillance-related event to a public health agency; or reporting a set of quality metrics to a performance management agency.

This category of communication services is specific to a precise set of tasks that require timely coordination among a well-defined set of partners who have agreed to be responsive to such transactions. For this type of service only the conclusions of the workflow need to be recorded, rather than the form and context of the information itself. The contractual relationship among the parties to this type of information exchange is specific to each workflow. It binds the parties for the duration of the workflow which, by definition, has an agreed-upon conclusion.

Underlying these five categories of services is a layer which we have simply called "Internet." This oversimplification is intended to convey that generally available standard telecommunication and media interchange IT infrastructures (e.g. CD-R, a smart card, or a USB key) can be used to effect the exchange of information. This layer will not be further discussed in the Roadmap.

Finally, in the background of the figure we have introduced the distinction between edge HIT systems (*e.g.* EHR systems, pharmacy systems, imaging center systems, PHR Systems, etc.) and core infrastructure (a sub-network of a broader nationwide health information network). Edge HIT systems are primarily focused on delivering direct healthcare services to consumers, whereas health information sub-networks are intended to support the effective communications of among those edge HIT Systems.

For each category of communication services, the upper level of the diagram indicates those exchanges where the infrastructure is transparent and communication involves peer-to-peer interaction among edge systems. The lower level indicates the areas where the core infrastructure and the edge systems cooperate.

Structuring the target services is not a theoretical exercise. It is critical to ensure that commonality of communication services is maximized across a wide range of use cases that are known today and will be identified in the future, as well as to ensure consistency within each one of the categories of communication services.

Implementation Phases

This section provides more detail on the four implementation phases identified to provide incremental progress – and benefits – toward achieving interoperability. Figures illustrating the content of each phase are based on the health information exchange services described above. Detailed specifications for each phase are contained in Appendix I.

Phase 1: Share Care Status Information

Since the first iteration of this Roadmap, considerable progress has been made on sharing care status information.

We identified persistent document sharing as the starting point for this phase, because it would have the highest chance of adoption by both patients and providers.

In January 2006, a successful implementation and testing of this first phase was completed at the IHE North America Connectathon. This test, involving more than 120 vendor systems under supervision of IHE, confirmed the validity of the services selected, their ease of integration in existing products, and the positive support of non-EHR vendors – who have an equally important role to play in delivering IT infrastructure, systems integration, and other factors critical to the implementation of interoperability.

The sharing of imaging information (medical images and reports) was also accomplished in this first phase. This reflects the maturity and high-level of standardization reached by medical imaging (DICOM),

as confirmed by most national IT projects around the world that are successful in deploying the imaging component of their national program (UK, Canada, etc.).

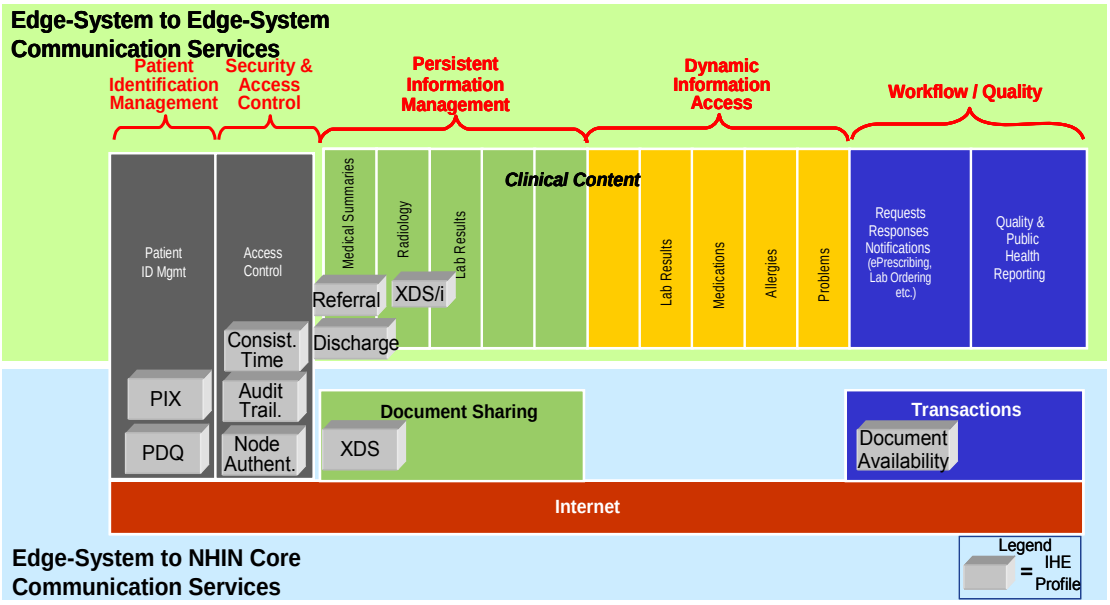

Figure 6: Roadmap Phase 1 Achievements (2005-2006)

By the end of 2006, all of the integration profiles and supporting standards for Phase 1 will be finalized, based on feedback received from implementers at the IHE Connectathon. Product implementation will then be possible, but other factors beyond the responsibilities of EHR vendors – such as the maturity of the markets that will build sub-networks, nationwide program priorities, and availability of incentive programs – will determine the extent to which implementation actually occurs. We expect that EHR vendors will be responsive to any RHIO projects that align their interoperability strategy with this first phase of the Roadmap.

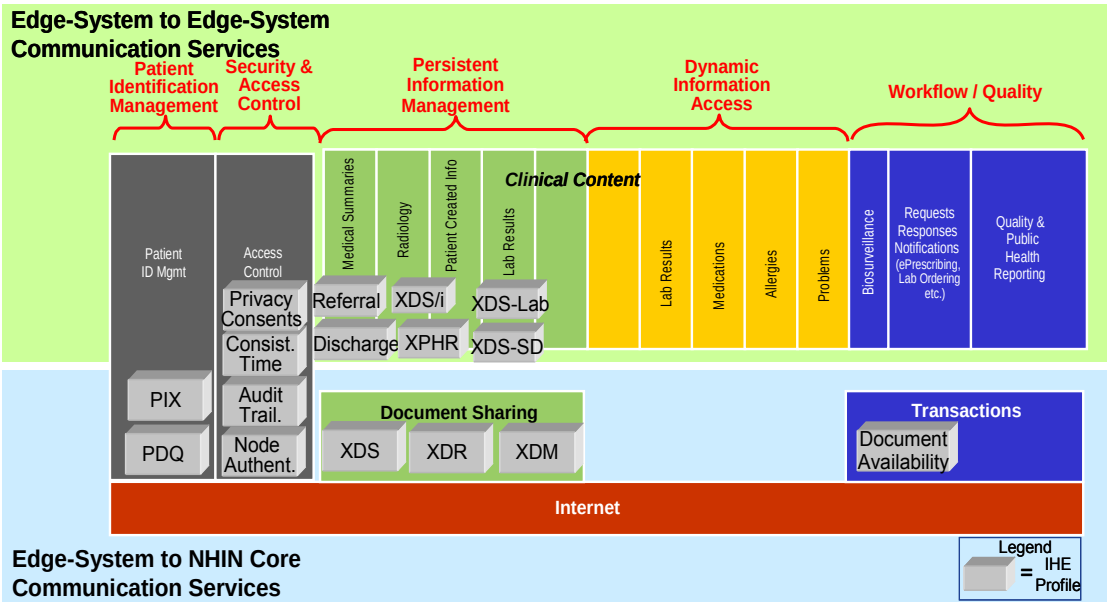

Figure 7: Roadmap Phase 2 (2006-2007)

Phase 2: Share Diagnostic Results and Therapeutic Information

Phase 2 was defined in early 2006 as a series of realistic and evolutionary steps building on the achievements of Phase 1. Trial implementation specifications have been developed, along with integration profiles and resolution of some standards gaps. Final specifications are expected in 2007, following testing at an IHE Connectathon. Product release could be available as early as 2007 or 2008, depending on market conditions.

Phase 2 further expands the breadth of document content with laboratory reports and consumer-created persistent health information (updated medication lists, patient identified allergies, etc.).

The communication services added in Phase 2 rely on approved standards, as well as standards close to finalization and committed integration profile development in IHE. EHR Association will continue to work with SDOs, particularly HL7 and ISO TC215, to build upon the successes in Phase 1 by delivering high quality implemented and tested integration profiles. We will also coordinate with nationwide initiatives in the U.S. (such as HITSP) and elsewhere to ensure that the integration profiles are globally acceptable. If national extensions are required, they will be designed into the global foundation.

Phase 3: Advanced Clinical Support and Access Control

Phase 3 enters into the broad coding of exchanged information, either via document sharing or in cases where dynamic access to selected sources is more efficient. A widely available and more advanced user access control may also be introduced, providing increased flexibility to consumers in managing access permission to their own health information.

This third phase adds the following Communication Services:

- **Security:** User access control – Extend existing authentication mechanisms to include role and content specific rules using Security Assertion Markup Language (SAML) as the basis for the profile. Currently, there is no common definition of authentication and role provision among EHR systems.
- **Security:** Consumer Permissions – Enable consumers to opt in or opt out of the exchange of health information and control which types of data are available to which user roles. SAML may also be the basis of this profile.
- **Document Sharing:** HL7 CDA and ASTM CCR – Harmonization of the ASTM CCR into HL7 CCD as an addition to XDS-MS. This would add structured vocabularies and content for vital signs, immunizations, etc.
- **Document Sharing:** Consumer data for disease management of the top 10 chronic diseases account for 80% of health plan costs (e.g., diabetes, asthma). Engaging patients and providers in an interactive process has resulted in dramatic decreases in the cost of caring for these diseases as well as improvements in patient satisfaction and quality of life.
- **Dynamic Information Access:** Medication List Management – Create and maintain an active medication profile based upon ordering providers, dispensing pharmacies and health plan claims data. Reduce unknown drug interactions from multiple providers as well as reducing fraud and abuse.
- **Dynamic Information Access:** Allergy List Management – Create and maintain an active allergies and sensitivities list for use by providers and pharmacies which can be combined with Dynamic Medication List Management to improve patient safety in the prescribing process. Allergic reactions are the number six reason for reported adverse drug events.

- **Workflow**: Radiology Orders and results – Like laboratory orders and results, an integration profile for diagnostic imaging orders and results would reduce implementation costs and improve interoperability between EHR systems and diagnostic imaging centers.

- **Quality:** Performance Reporting (standards to be defined) – The impact on physician workflow for recording, reporting, and measuring clinically related quality metrics for pay-for-performance or other qualitative or quantitative initiatives can be greatly reduced by using a standardized data exchange/reporting integration profile between aggregating entities and providers.

Phase 4: Collaborative Care, Active Quality Reporting and Health Surveillance

Through Phase 3, the Roadmap addresses basic information exchange and the main ancillary services. In Phase 4, the level of IT capability across the healthcare system gives rise to additional key workflows that will be possible:

- **Dynamic Information Access**: Medication List (PHR to EHR) – Patients' over-the-counter (OTC) medications are rarely documented in any provider's EHR. Connecting the consumer PHR to the Dynamic Medication List will improve the quality of care and reduce adverse drug effects that these OTC medications often cause.

- **Dynamic Information Access:** Problem List Management – Create and maintain an active problem list which is shared among providers and other appropriate providers. Problem lists can be critically important in reducing adverse drug events.

- **Workflow**: Referrals to consulting physicians and consultation reports – Similar to Laboratory and Diagnostic Imaging workflow profiles, consult order and reports integration profile would reduce costs and improve interoperability between EHR systems.

- **Workflow**: Order signature by MD, for orders entered by HomeCare/VNA. Unlike Diagnostic Imaging and Laboratory, orders for home care patients are often originated or suggested by the in-home provider and then officially signed by the responsible physician. An integration profile addressing this workflow would reduce the need for physicians to transcribe or re-enter orders for this setting of care.

- **Workflow**: Bed Availability Checking – Physician offices often must call a hospital prior to patient admission to determine bed availability, especially for non-urgent procedures. An integration profile between hospital bed management systems and physician office EHR systems would reduce costs and improve workflow.

- **Workflow**: Orders for Durable Medical Equipment – When physicians write orders for durable medical equipment or medical supplies, these orders must be printed and faxed to the supplier and/or patient. An integration profile connecting EHR systems and suppliers would reduce costs and improve workflow.

- **Workflow**: Public Health Outbreak alert notification – Once the flow of data into public health organizations is improved, it will be necessary to improve the notification and case management system for tracking and treating affected patients. An integration profile between public health organizations and physician EHR systems will improve general notifications of possible outbreaks as well as identification of specific patients who may need to be treated and tracked. It is expected that by 2010, a significant share of bio-surveillance may be performed by data mining (through registry traversing) at regular intervals (hourly, daily), newly contributed patient summaries, abnormal diagnosis frequencies, lab result values, etc.

Testing

Integrating multiple healthcare IT systems to achieve workflow integration is typically a high-cost and time-consuming activity, typically done at the customer's site. IHE pioneered a detailed and effective

implementation and testing process to promote the adoption of standards-based interoperability by vendors and users of healthcare information systems. The process culminates in the Connectathon, a weeklong interoperability-testing event.

The testing process starts with test participants reviewing the clinically defined use-cases, called an integration profile. Test criteria are created and an independent test environment developed for implementers to internally test their interoperability solution. This public domain test environment, the MESA test tools, provides a universal test bench for participants, with a successful internal test of their application required before attending the Connectathon.

During the Connectathon, systems exchange information with complementary systems from multiple vendors, performing all of the transactions required for the roles they have selected, called IHE Actors, in support of defined clinical use cases, or Integration Profiles. Thousands of vendor-to-vendor connections have been tested overall, and tens of thousands of transactions passed among the systems tested. This process provides for a highly efficient and transparent verification of an interoperability solution, which minimizes integration time at the customer site. The effectiveness of this process is evidenced by the recognition in the industry of radiology IT systems, which provide the most efficient and reliable integration compared to other healthcare IT platforms – due in large part to radiology IT involvement in IHE since its inception eight years ago.

Collaboration

EHR Association members are actively engaged in national and global efforts to provide interoperability solutions, and many of the proposed Roadmap services that are in place or under advanced development reflect the existing collaborative efforts of standards development organizations, professional societies, the vendor community, public sector organizations and country-specific initiatives.

At the 2005 HIMSS Conference IHE Cross-Enterprise Showcase, 14 companies – including seven EHR Association members – demonstrated the document-sharing health information exchange concept using medical summary information, lab reports, static text reports (.pdfs), and structured information. The product demonstrations focused on use cases that would enable plug-and-play interoperability with the types of clinical information that patients and clinicians utilize in typical medical settings.

In the spring of 2005, 16 European vendors participated in the IHE-Europe Connectathon for cross-enterprise information exchange. The IHE Cross-Enterprise Document Sharing (XDS) profile and associated integration profiles achieved connectivity between inpatient and ambulatory EHR systems (including products from different EU countries) that had not previously communicated.

Also in 2005, the first federated health information exchange using the XDS profile was launched in a region of Italy that serves 5 million lives.

At the 2006 HIMSS Conference, the Patient Care Coordination team (comprising 23 HIT vendors and the Department of Veterans Affairs, along with clinicians representing multiple disciplines) demonstrated fundamental medical summary profiles to support outpatient referrals and inpatient discharge use cases. The team had been launched only nine months earlier, in April of 2005.

The HIMSS 2006 IHE Showcase also demonstrated services identified in this Roadmap to ensure the security and privacy of health information exchanged, as well as services that provide basic building blocks to support clinical messaging and exchange of other clinical data such as medical imaging information. Substantial demonstrations of other Roadmap services enabling health information exchange to enhance quality, patient safety, and workflow efficiency in cardiology and radiology have been featured at the 2006 ACC and RSNA conferences.

These implementations and user-supervised testing activities have removed most of the technical gaps for building information exchange to accelerate and enhance the AHIC use cases. The EHR Association

Interoperability Roadmap is also complementary to the health information exchange initiatives underway in Canada, France, and other EU and Asian countries, with regional deployments slated for 2006 and 2007. The deployment of these Roadmap services in several countries, in addition to the growing global vendor support, provides powerful and relevant proof statements for government policy makers and regional health information organizations in the United States.

The underlying interoperability building blocks of this Roadmap have been recognized by the Global Health IT Summit organized in Japan in September 2005, to which Dr Brailer and other leaders of nationwide projects contributed by engaging the International Standards Organization (ISO) and its partner standards development organizations to accelerate the efficiency of delivering more readily applicable standards. As a follow-up, ISO TC 215 has asked IHE to establish a liaison and is proposing to endorse the IHE process and the existing IHE Integration Profiles as ISO Technical Reports. The EHR Association strongly supports these healthcare-professional led collaborative efforts involving standards development organization, HIT vendors and nationwide initiatives, and recommends that integration profile development should continue to be conducted as a global activity by expanding the IHE initiative.

Standards selection

There are myriad standards development organizations (SDOs) involved in the development of base standards for HIT. These SDOs include HL7, ASTM, DICOM, SNOMED, LOINC, ICD, IETF, OASIS, W3C, IEEE, ISO, NCPDP, and ANSI. Increasingly, national leadership has recognized the need for consistent standards to achieve interoperability. As of this writing, HITSP is establishing a process for responding to standards harmonization requests to support recognized business use-cases, resulting in establishing the specific interoperability specifications used in one or multiple use-cases. The roadmap may provide guidance to stakeholders collaborating with HITSP on potential interoperability specification priorities.

1090 ## *Appendix I: Benefits of Roadmap Implementation*

Current Status				
Use Case	***Interoperability Level[3]***	***Roadmap Services Utilized***	***Quality and Effectiveness Benefits***	***Cost Saving/ Financial Benefits***
Dr. Ernesto Africano, a specialist in a solo practice, uses an electronic health record (EHR) system in his solo office. The system helps him keep track of his patients' progress, saves him time, and ensures that patient records are legible and easy to share with his patients' primary care doctors after they come to see him. He still has to maintain paper charts, however, because of the volume of information he receives via fax and "snail mail."	Level 2 – Machine Transportable Data Exchange (email and fax)	None	• Makes patient charts more legible and easily accessible • Provides clinical decision support to reduce adverse events and improve patient safety • Shortens revenue cycle by supplementing charts with tools to support immediate clinical documentation and billing processes • Improves productivity and staff satisfaction through streamlined workflow • Provides management reporting to improve practice operations and quality	Annual net return: $22 billion[4]

[3] Walker, Jan; Pan, Eric; Johnson, Douglas; Alder-Milstein, Julia: Bates, David: Middleton, Blackford. "The Value Of Health Care Information Exchange And Interoperability". Health Affairs, 19 January 2005.
[4] *Ibid*.

(Appendix I, con't.)

Phases 1 and 2				
Use Case	***Interoperability Level***	***Roadmap Services Utilized***	***Quality and Effectiveness Benefits***	***Cost Saving/ Financial Benefits***
Many primary care practices have EHRs, and the hospital, labs, and pharmacies are increasingly electronic. Using the latest version of EHR software, Dr. Africano is able to send and receive patient medical record information electronically when primary care physicians refer patients to him. He can manage most patient prescriptions electronically, receive patient lab results immediately, and populate his EHRs automatically with information he needs to make patient care decisions. Dr. Africano is able to provide better patient care because the system guides his decision-making with clinical alerts as to best evidence-based practice when he places orders and recommends treatments. He can rapidly obtain aggregated views of patient histories, scan through images, and identify key information for more detailed assessments of specific findings because this information is stored and received in a semi-structured form. He is now able to scan the remaining paperwork into the patients' chart because it is more affordable, making his office paperless.	Level 3 – Machine Organizable Data – structured messages with nonstandardized data requiring interfaces, translation, and mapping between different formats and vocabularies	Security and Access Services • Patient identity • Authentication Persistent Information Access • Medical summaries • Referrals • Discharge summaries • Laboratory results • Imaging results Workflow Services • e-Prescribing (on-line transmission of prescription and refills) • Notification of information availability	• Improves patient care decision making and reduces duplicate tests by providing a complete view of patient information across all sources • Uses advanced decision support to reduce adverse events and support implementation of evidence-based care interventions • Streamlines workflow to coordinate and manage care services across settings • Improves patient compliance and satisfaction • Encourages collaboration and team-based care by increasing data sharing	Annual net return: $24 billion[5]

[5] *Ibid*.

(Appendix I, con't.)

Phases 3 and 4				
Use Case	***Interoperability Level***	***Roadmap Services Utilized (Phase 2 +items below)***	***Quality and Effectiveness Benefits***	***Cost Saving/ Financial Benefit***
The most recent version of Dr. Africano's EHR system enables a more patient-centric design for office practice because patients schedule their appointments on-line and supply medically related information from their personal health record before they arrive at the office. This, in combination with the ability to view encounter information from other providers, has led to more time with patients. Patients are able to access their care plan and instructions through their personal health records. Dr. Africano can place radiology orders electronically and follow patients in real-time when they're admitted to the nearby community hospital. The EHR gives him better capabilities to monitor the quality of care with decision support at the point of care, as well as with reports that show various quality measures of patient populations. As a byproduct of using the EHR to care for patients and document their care, the quality measures required by insurance companies' pay-for-performance programs are captured and passed to Dr. Africano's billing system for automated reporting. The EHR also automatically captures and reports most surveillance data needed for public health surveillance and reporting.	Level 4 – Machine Interpretable Data – structured messages with standardized and coded data using same format and vocabularies	Security and Access Services • Patient directed access Persistent Information Service • Patient-created information • Patient interaction/updates Dynamic Information Services • Dynamic queries for meds/allergies/problems, available to follow time-critical patient care Workflow & Quality • Quality reporting and on-line connection to specific labs • Advanced biosurveillance	• Accommodates more growth in patient volume • Improves quality of care for complex problems • Increases patient involvement in care process • Offers open access to appointment scheduling • Decreases cost of compliance auditing • Provides population management capabilities • Enables reimbursement for virtual encounters • Supports "pay for performance" programs	Annual net return: $87 billion[6]

1100

[6] Ibid.

Appendix II: Roadmap Standards and Integration Profiles

This Appendix provides a detailed specification of the Integration Profile supporting each Communication Service. It also identifies the standards on which these Integration Profiles rely.

1105 **EHR Association Interoperability Roadmap Phase 1**

Patient Identification Management			
Communication Service Use Case	***Base Standard***	***Integration Profile (IP)***	***Availability and Implementation Readiness***
Patient identifier cross-referencing and Patient demographics query. Patient/consumer identification between Edge HIT systems and master patient indexes (MPI).	HL7 V2.5 (evolving to HL7V3 in 2006-2007)	-IHE PIX Integration Profile -IHE PDQ Integration Profile	Final IHE IP (ITI Tech Framework V2.0) Connectathon 2005: > 20 implementations tested. US-CCHIT selected, Canada, France, Italy.
Identification and Security			
Communication Service Use Case	***Base Standard***	***Integration Profile (IP)***	***Availability and Implementation Readiness***
Audit trail, node authentication and transport encryption Establish a solid security foundation among the communicating edge HIT and infrastructure systems.	IETF RFC 8366 (approved by HL7, DICOM and ASTM) IETF – TLS X.509 certificates	IHE ATNA Integration Profile	Final IHE IP (ITI Tech Framework V2.0) Connectathon 2005: > 12 implementations tested. France, Italy
Consistent Time System clock synchronization	IETF NTP	IHE CT Integration Profile	Final IHE IP (ITI Tech Framework V2.0) Connectathon 2005: > 12 implementations tested.

1110 (Appendix II, con't.)

Persistent Information Management			
Communication Service Use Case	***Base Standard***	***Integration Profile (IP)***	***Availability and Implementation Readiness***
Cross-enterprise document sharing Infrastructure to publish a source persisted set of documents in a repository and reference them in a registry. Sources may query for specific documents, and retrieve them through their reference from repositories.	ISO-OASIS ebXML Registry Service	-IHE XDS Integration Profile	Final IHE IP (ITI Tech Framework V2.0) 2005 Connectathon > 30 implementations tested. US-CCHIT selected, Canada, France, Italy.
Cross-Enterprise Sharing of Medical Summaries. Sharing of health summary information for physicians referral and hospital discharge.	HL7 CDA Rel 2. HL7 Care Record Summary HL7 V3 Meds, Allergies, Pbs.	-IHE XDS-MS Content Profile	Developed in 2005. IHE Patient care Coordination Technical Framework 2006 Connectathon > 12 implementation tested.
Cross-Enterprise Sharing of Imaging Information. Sharing of imaging reports and images studies among imaging facilities and care providers.	DICOM images and structured reports Text and PDF	-IHE XDS-I Integration Profile	Developed in 2005. IHE IP in trial implementation 2006 Connectathon > 30 implementation tested. US CCHIT, Canada.
Workflow & Quality			
Notification of Document Availability Notifying a remote entity that one or more specific documents having been made available may be of interest.	Internet e-mail W3C DSG	-IHE NAV Integration Profile	Developed in 2005. IHE IP in trial implementation 2006 Connectathon > 5 implementation tested.

EHR Association Roadmap Phase 2 Additions

Building on 2005-2006 Phase 1 Success

1115

Patient Identification Management			
Communication Service Use Case	***Base Standard***	***Integration Profile (IP)***	***Availability and Implementation Readiness***
Patient identifier cross-referencing and Patient demographics query. Patient/consumer identification between Edge HIT systems and master patient indexes (MPI).	HL7 V3.0	-IHE PIX Integration Profile Extension -IHE PDQ Integration Profile Extension	IHE ITI Tech Framework Supplement for Trail Implementation – Seot 2006 Leverages Canada & Netherlands experience
Federation of XDS Domains	HL7 V2.X-V3.0	Connecting for Health RLS- IHE XDS Federation	White Paper - Sept 2006. Prototyping NHIN Contract and 2007 HIMSS Showcase
Persistent Information Management			
Communication Service Use Case	***Base Standard***	***Integration Profile (IP)***	***Availability and Implementation Readiness***
Cross-Enterprise Document Interchange Point to point interchange, either on physical storage media (CD or USB), or through document sets secured e-mail "push".	*Candidate Stds:* 9660 CD or USB. E-mail, S-MIME	IHE Cross-Enterprise Document Media Interchange (XDM) IHE Cross-Enterprise Document Reliable point-to-point Interchange (XDR)	IHE IT Infrastructure Technical Framework Supplements for Trial Implementations -Sept 2006.
Sharing of Patient Created Summaries. Support consumers' ability to input and share their own health information with other healthcare entities.	*Candidate Stds:* HL7 CDA Rel 2, HL7/ASTM CCD, HL7 V3 Meds, Allergies. ASTM CCR.	-IHE XPHR Content Profile	IHE Patient Care Coordination – Supplement for trial implementation - August 2006.
Sharing of Laboratory Reports. Share laboratory results (sets of laboratory tests ordered and have been performed and validated). See Note	*Candidate Stds:* HL7 CDA Rel 2. HL7 V3 Lab	-IHE XDS-Lab Sharing of Laboratory Report Content Profile	IHE Laboratory XDS-Lab Supplement for trial implementation
Sharing of Scanned Documents. Sharing of scanned paper documents with other healthcare entities.	*Candidate Stds:* HL7 CDA Rel 2. PDF	IHE XDS-Scan Docs	IHE IT Infrastructure Technical Framework Supplements for Trial Implementations -Sept 2006.
Claims Attachments of Scanned Documents	*Candidate Stds:* HL7 CDA Rel 2. PDF HL7 V3 Lab	Claim Attachments NPRM – Should be a compatible subset of XDS-Lab and XDS Scan.	To be developed in 2006/2007 by HL7 Claim Attachment

(Appendix II, con't.)

Dynamic Information Access			
Query Immunization Registry	HL7 V2.5	Multiple Integration Profiling efforts non coordinated	Profiling incomplete and Connectathon testing needed.
Workflow & Quality			
e-Prescribing	*Candidate Stds:* NCPDP Script 8.1	MMA NCPDP Implementation Guide	Pilot implementation in progress. Connectathon testing needed.
Ordering and real-time receipt of Lab Results This Communication Service addresses the on-line ordering of laboratory work (on some sample) and the real-time sending of results (partial or complete). See Note.	*Candidate Stds:* HL7 V2.5	IHE Lab Scheduled Workflow convergence with ELINCS 2.x and HITSP Lab Message	To be developed in 2006/2007. IHE may prototype ELINCS IHE Connectathon testing.
Bio surveillance Lab Notifications	*Candidate Stds:* HL V2.5 Lab	See above	Needs Connectathon testing
Bio Surveillance Info Entry	*Candidate Stds:* HTPP+XFORMS	IHE Request Form for Data Capture	IHE IT Infrastructure Technical Framework Supplements for Trial Implementations -Sept 2006.
Clinical Trial Capture	*Candidate Stds:* HTPP+XFORMS	IHE Request Form for Data Capture	IHE IT Infrastructure Technical Framework Supplements for Trial Implementations -Sept 2006.