



National Committee on Vital and Health Statistics (NCVHS)

Statement of Didi Davis, Director of IHE, HIMSS

Testifying on Behalf of the Integrating the Healthcare Enterprise (IHE)
Initiative and the Role of IHE in the Development of Regional Health
Information Organizations and the Future Nationwide Health
Information Network

Testimony Before the NCVHS Ad-Hoc Workgroup on the Nationwide
Health Information Network

July 27, 2006

Meeting Location:

Crowne Plaza Hotel
1001 14th Street, N.W.
Washington, D.C. 20005

ACC/HIMSS/RSNA

July 27, 2006

1. Introduction, Background and History, Current Sponsorship

Distinguished members of NCVHS and its Ad-Hoc Workgroup on the Nationwide Health Information Network, I am honored to be here today to testify on the role of IHE in the Development of Regional Health Information Organizations and the Future Nationwide Health Information Network. I will be discussing the following:

- The important role interoperability can play in transforming healthcare delivery.
- How Integrating Healthcare Enterprise (IHE) Initiative has achieved international recognition as a major interoperability initiative
- An overview of IHE's proven process for implementing multiple established standards
- The role IHE plays in the HITSP and CCHIT processes
- The role IHE should have in the development of an interoperability roadmap in conjunction with the development of RHIOs and NHIN.

My name is Didi Davis, Director of IHE for the Healthcare Information and Management Systems Society (HIMSS). HIMSS is the healthcare industry's membership organization focused on providing leadership for the optimal use of healthcare information technology (HIT) and management systems for the betterment of healthcare. HIMSS is one of the founding North American Sponsors for the IHE initiative. In my remarks today, I will share insights from all the sponsors of IHE in North America as well as from membership of the various domains that make up IHE globally.

Introduction

An essential aspect of transforming healthcare in the United States is to have interoperability across applications, systems, and settings that facilitate patient care. Interoperability enables authorized professionals and consumers to access relevant healthcare information regardless of where the patient has been seen and where the professional is located. To be effective, however, interoperability requires the widespread adoption of standards by both healthcare entities and vendors within and across medical referral regions.

The Department of Health and Human Services and its Office of the National Coordinator recognize the importance of interoperability; putting interoperability at the top of the national agenda to achieve a nationwide health information network (NHIN) based on a common framework linking regional health information organizations (RHIOs) and other health information exchanges (HIEs).

Despite the emerging consensus on the need for local, regional, and national interoperability, the task is daunting and the barriers are many. Barriers to achieving this vision include lack of effective standards, incompatibility among different IS solutions, failure to align technology solutions to process and

workflow requirements of the end user, and policies that are only now emerging related to the ownership of, access to, and the use of data.

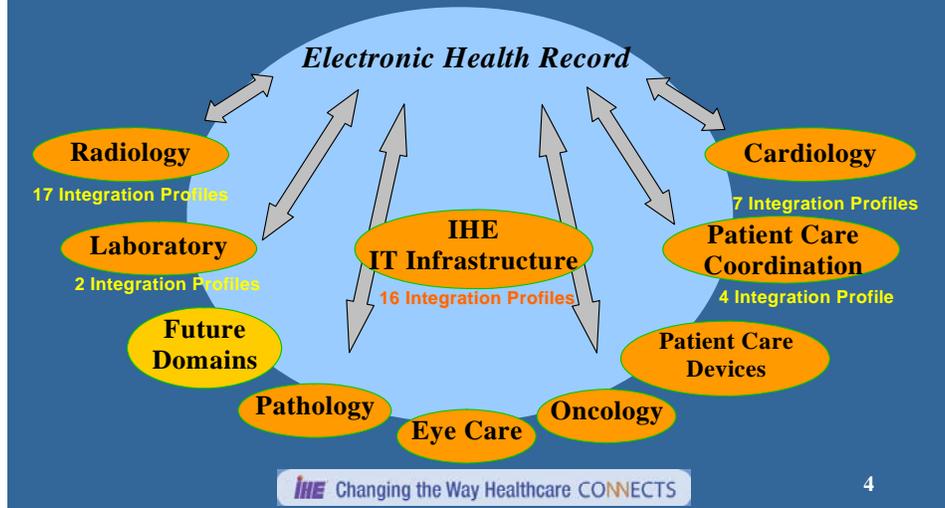
One notable initiative that has the ability and capacity to mobilize essential healthcare entities toward interoperability is “Integrating the Healthcare Enterprise” (IHE). IHE at www.ihe.net is a major multi-year global interoperability initiative including the United States, Canada, Asia and Europe. Leadership in the United States is provided by HIMSS, the Radiological Society of North America (RSNA) and the American College of Cardiology (ACC), which collectively represent over 250,000 healthcare Professionals. In pursuit of its mission, IHE brings together care providers and other healthcare professionals with representatives of the healthcare IT industry and releases its work into the public domain. IHE’s primary sponsors and domain sponsors are organizations of medical professionals who provide clinical and operational domain expertise in identifying critical integration priorities to be addressed. They oversee the work of more than 20 volunteer committees of thousands of industry professionals who define solutions to address these issues based on established information technology standards. Governance for the IHE initiative is provided by Strategic Development Committee in collaboration with the primary sponsors.

Background and History

IHE’s initial work in defining the interaction of general healthcare IT and imaging systems has been widely implemented by industry and user sites and has greatly improved efficiency and information integrity in the radiology domain, and is being implemented by more than 95% of radiology vendors world-wide. IHE has expanded steadily to incorporate new domains, including Cardiology, Eye Care, IT Infrastructure, Laboratory, Pathology, Nuclear Medicine, Patient Care Coordination, Patient Care Devices and Radiation Oncology.

IHE 2006 – Nine Active Domains

Close to 200 vendors involved world-wide, 5 Technical Frameworks
51 Integration Profiles, Testing at Connectathons
Demonstrations at major conferences world-wide



Current Sponsorship

These new domains have also grown the sponsorship of IHE. Several other organizations are currently designated as domain sponsors, meaning they are responsible for support of Technical Framework development committees in their domains, but not for support of deployment-related activities. These organizations include:

- Eye Care domain: The American Academy of Ophthalmology (AAO)
- Laboratory domain: Le Groupement pour la Modernisation du Système d'Information Hospitalier (GMSIH), la Société Française d'Informatique de Laboratoire (SFIL), H.PR.I.M (Association Harmoniser et Promouvoir les Informatiques Médicales) and the Japan Association of Healthcare Information Systems Industry (JAHIS)
- Nuclear Medicine: The Society of Nuclear Medicine (SNM) and American Society of Nuclear Cardiology (ASNC)
- Patient Care Coordination domain: The American College of Physicians (ACP)
- Patient Care Devices: The American College of Clinical Engineering (ACCE)
- Radiation Oncology: The American Society for Therapeutic Radiology and Oncology (ASTRO)

In addition, a number of organizations act as affiliate domain sponsors. These organizations provide domain expertise in the development of relevant Technical Frameworks as appropriate and communicate relevant IHE developments to their

organizational membership and the segment of the healthcare IT industry that serves it.

National and regional sponsors take responsibility for *deployment* activities, including testing, demonstrations and education, to encourage adoption in their respective areas.

- IHE North America (IHE-NA)
 - IHE-USA: ACC ,HIMSS, and RSNA
 - IHE-Canada: : Infoway-Inforoute, Canadian Health Information Technology Association (CHITA), CAR and HL7 Canada
- IHE Europe (IHE-EUR): the Coordination Committee of the Radiological and Electromedical Industries (COCIR), Deutsche Röntgengesellschaft (DRG), the EuroPACS Association, European Association of Radiology (EAR) and European Congress of Radiologists (ECR), European Society of Cardiology (ESC), GMSIH, Société Française de Radiologie (SFR), and Società Italiana di Radiologia Medica (SIRM).
- IHE Japan (IHE-J): the Ministry of Economy, Trade, and Industry (METI); the Ministry of Health, Labor, and Welfare; and MEDIS-DC, JAHIS, the Japan Industries Association of Radiological Systems (JIRA), Japan Radiological Society (JRS), Japan Society of Radiological Technology (JSRT), and the Japan Association of Medical Informatics (JAMI).

Other organizations representing healthcare professionals are invited to join in the expansion of the IHE process across disciplinary and geographic boundaries.

2. IHE's Proven Process

Technical Framework Development

Because IHE focuses on the adoption of a set of existing standards around clinical needs, IHE is uniquely suited to the development of RHIOs and NHIN. There are connectivity and content standards from about 16 standards development organizations that are needed to build the NHIN. Typically, standard Implementation Guides are focused on a single standard, and standards alone do not address process and workflow issues prevalent in RHIOs. By establishing processes around a single set of existing standards that can be implemented and updated incrementally, IHE facilitates the rapid implementation of interoperable applications by providers, vendors, health plans, researchers and others.

IHE has developed a unique development process and culture for producing its framework for interoperability combining the collaboration of the primary stakeholders in an efficient and focused manner. This process has the effect of eliminating ambiguities, reducing configuration and interfacing costs, and ensuring a higher level of practical interoperability. Key features of the process include: operating on a yearly cycle to ensure rapid and immediately applicable

steps; providing practical testing tools and information resources; employing a use-case based methodology; and analyzing standard domains to identify where overlaps and gaps exist, requiring reconciliation and/or definition.

At the micro-level, the IHE process and framework enables healthcare entities and vendors to improve access to information incrementally. At the macro-level, IHE has the potential to accelerate the migration of providers, vendors, health plans, researchers, RHIOs, and others toward the goal of an interoperable NHIN through the development of an interoperability roadmap in conjunction with the development of RHIOs and NHIN. An example of such an interoperability roadmap is proposed by the EHR Vendor Association (www.himssehrva.org). Already, the impact of the IHE process on interoperability is notable. Currently, IHE is being implemented by most EHR and HIT vendors representing over 90% of the EHR market.

The IHE initiative is both a process and a forum for encouraging integration efforts. IHE follows a defined, coordinated process for standards adoption. These steps repeat annually, promoting steady improvements in integration.

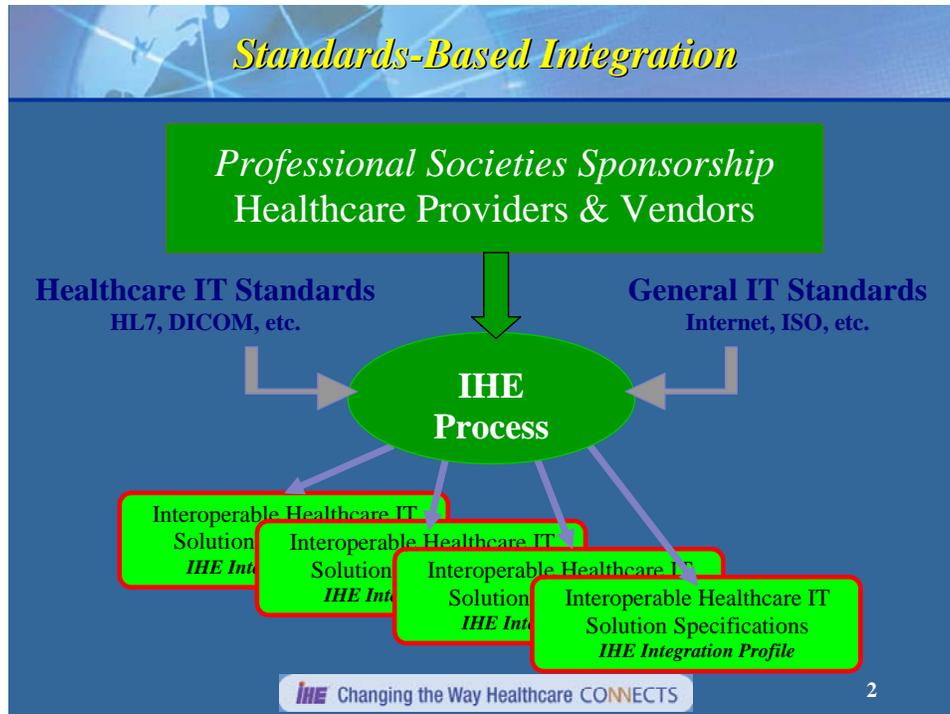
I. Identify Interoperability Problems. Clinicians and IT experts work to identify common interoperability problems with information access, clinical workflow, administration and the underlying infrastructure.

II. Specify Integration Profiles. Experienced healthcare IT professionals identify relevant standards and define how to apply them to address the problems, documenting them in the form of IHE integration profiles.

III. Test Systems at the Connectathon. Vendors implement IHE integration profiles in their products and test their systems for interoperability at the annual IHE Connectathon. This allows them to assess the maturity of their implementation and resolve issues of interoperability in a supervised testing environment.

IV. Publish Integration Statements for use in RFPs. Vendors publish IHE integration statements to document the IHE integration profiles their products support. Users can reference the IHE integration profiles in requests for proposals, greatly simplifying the systems acquisition process.

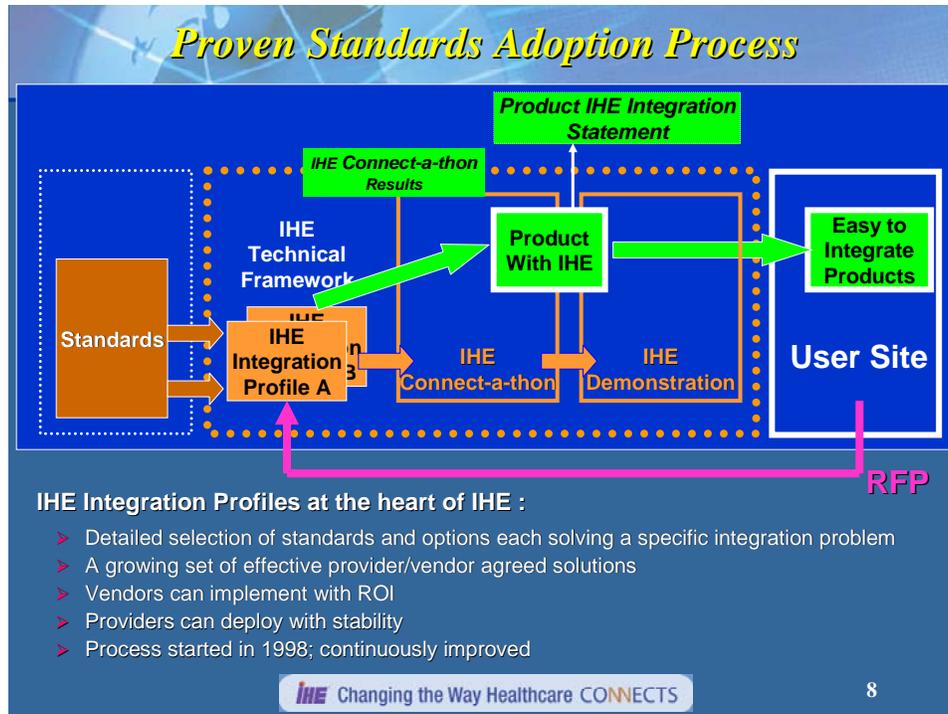
IHE defines a series of Technical Framework documents, which specify the implementation of established healthcare information standards to achieve specific clinical goals. Each use case/solution unit is known as an *Integration Profile*. IHE includes a rigorous testing process for the implementation of this framework. And IHE organizes educational sessions and exhibits at major meetings of medical professionals to demonstrate the benefits of this framework and encourage its adoption by industry and users.



The approach employed in the IHE initiative is not to define new standards, but rather **to support the use of existing standards** such as ISO, DICOM, HL7, IETF, ASTM, OASIS, and many others. These standards are incorporated as appropriate to a given healthcare domain--in an integrated manner, defining configuration choices when necessary. When clarifications or extensions to existing standards are necessary, IHE refers recommendations to the relevant standards bodies.

Connectathon

The centerpiece of the IHE testing process is the Connectathon, a weeklong interoperability testing event. The Connectathon allows participating companies to test their implementation of IHE capabilities with corresponding systems from industry peers. During the event their systems exchange information with systems from multiple vendors, performing all of the transactions required for the roles they have selected, called IHE Actors, in support of defined clinical functions, called [IHE Integration Profiles](#). IHE also organizes an international testing process that culminates in industry testing events called Connectathons that take place at least annually in North America, Europe and at multiple locations in Asia. IHE records and publishes the results of this testing. IHE also develops and distributes testing software that is used to prepare for the Connectathon and to validate implementations of IHE capabilities more generally.

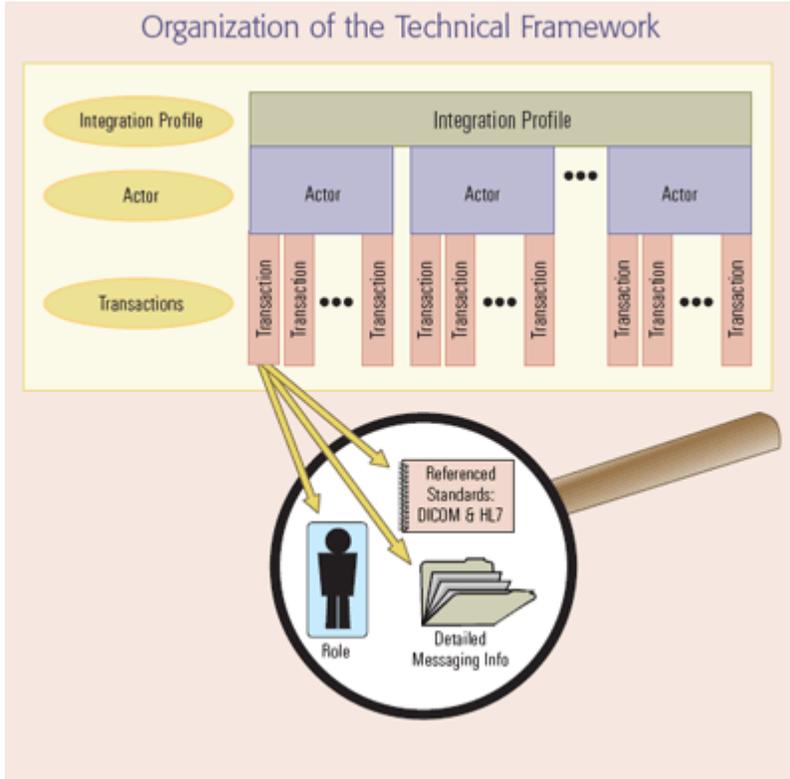


MESA Tools

An important element of the IHE testing process is the set of software tools commissioned by the sponsoring organizations. Developed by the Electronic Radiology Laboratory at the Mallinckrodt Institute of Radiology, Washington University of St. Louis, the MESA tools are designed for use by participating companies in implementing IHE capabilities in their systems and preparing for the Connectathon. Their purpose is to provide communication partners, test data and test plans to allow organizations to provide a baseline level of testing as they implement the IHE Technical Framework. These tools are made available to participants during the period of an IHE demonstration year and are then released into the public domain at the end of that cycle. The latest version of the MESA Test Tools available in the public domain can be found at www.erl.wustl.edu/mesa/index.html.

The Technical Framework — Putting Business And Technology Together

The IHE process includes an annual cycle for the deployment of a new profile within a domain that lasts approximately 18 months. The Technical Framework consists of two parts; Integration Profiles and Transactions. The Integration Profiles model the business process problem and the solution to the problem; the Transactions section defines in thorough detail the way in which current standards are used to solve the business problem defined in the Integration Profiles. Integration Profiles are based on the following modeling concepts:



An Actor. A system or part of a system that creates, manages or acts upon data.

A Transaction. A specific interaction between Actors to exchange information.

Here are a few examples of Actors and Transactions used in IHE integration profiles.

Problem	IHE Domain	IHE Integration Profile	Transaction	Actors
Managing patient identity across care settings	Infrastructure	Patient Identifier Cross-Referencing (PIX)	Patient Identity Feed	<ul style="list-style-type: none"> • Patient Identity Source • Patient Identifier Cross Reference Manager
Managing image acquisition and storage	Radiology	Scheduled Workflow (SWF)	Worklist Provided	<ul style="list-style-type: none"> • DSS/Order Filler • Acquisition Modality
Sharing electronic health records (EHRs)	Patient Care Coordination	Cross-enterprise Sharing of Medical Summaries (XDS-MS)	Register Document Set	<ul style="list-style-type: none"> • Document Repository • Document Registry
Establishing the continuity and integrity of clinical laboratory testing	Laboratory	Laboratory Scheduled Workflow	Test Results Management	<ul style="list-style-type: none"> • Order Filler • Automation Manager
Viewing high quality ECG's from any access point	Cardiology	Retrieve ECG for Display (ECG)	Retrieve ECG Document for Display	<ul style="list-style-type: none"> • Document Repository • Document Registry

Education/Demonstrations

Davis, NCVHS Testimony on Integrating the Healthcare Enterprise (IHE)

Part of the IHE process is also the educational meetings and demonstrations at the various sponsoring organizational annual meetings. Since 1999, IHE demonstrations have been held at some of the largest meetings of medical professionals in the world, including the annual meetings of the ACC, HIMSS and the RSNA.

IHE demonstrations at RSNA have focused on imaging-related capabilities and have drawn as many as 3,000 participants to hands-on demonstrations. At the RSNA 2005 Annual Meeting, 31 vendors participated in a demonstration of the Portable Data for Imaging (PDI) integration profile, showing the ability to exchange imaging studies and related clinical information via removable media. At the 2006 Annual Meeting, vendors will demonstrate the ability to exchange imaging studies, reports and related information using the Cross-enterprise Document Sharing for Imaging (XDS-I) integration profile across a RHIO-like network architecture.

Demonstrations at the ACC Annual Scientific Sessions have focused on a variety of cardiology-specific topic areas, including report and ECG sharing in addition to workflow optimization and measurement sharing for cardiac catheterization and echocardiography. Eighteen vendors participated in the ACC 2006 Annual Meeting, Year 2 for IHE Cardiology, with more than 1,500 attendees visiting the Showcase. Future showcases will demonstrate integration profiles on electrophysiology, nuclear cardiology, and stress testing.

Demonstrations at HIMSS U.S. Conference 2006 highlighted clinical scenarios that are used to demonstrate the added interoperability between systems that are part of RHIO's that would connect to the NHIN. At the HIMSS 2006 Interoperability Showcase, 37 vendors demonstrated 48 HIT systems in a Rhio/NHIN format. 700 of the 3,000 attendees at the Interoperability Showcase created and tracked their own EHR, and 63 related education sessions were presented.

3. National HIT Strategy and IHE

NHINs and the Impact of IHE on Developing the NHIN Common Framework

All four NHIN prototype projects are planning to leverage elements of the IHE Technical Framework to connect the edge systems to the NHIN as well as solve other complex issues such as patient identifier cross referencing within a RHIO and across NHIN. The prototypes for the NHIN include the following components that IHE can accelerate deployment of to achieve an interoperable solution:

- Test patient identification and record locator services, user authentication and other technologies.

- Demonstrate the ability to communicate across organizations across the country

The NHIN contractors are utilizing portions of the Technical Framework as follows:

- **Computer Sciences Corporation** will be using IHE's Document sharing and patient identifier cross referencing profiles to communicate patient information within their RHIO's and across the 3 States in their NHIN prototype. This demonstrates the flexibility of the IHE Technical Framework since the Indiana, Massachusetts and Northern California RHIO's are all based on different models, yet can still incorporate components of IHE to facilitate interoperability.
- **IBM** will be leveraging many of the IHE profiles as the common framework to achieve interoperability.
- **Accenture** – This NHIN contractor has not stated publicly that the IHE Technical Framework will be leveraged for the NHIN implementation they are facilitating, but at least one of the other participants **CareSpark** is requiring IHE functionality for all edge systems connecting to the NHIN.
- **Northrop Grumman** is not currently leveraging IHE's Technical Framework in it's NHIN prototype, although they did participate in the IHE Connectathon and Interoperability Showcase in 2006.

Standards Harmonization in the U.S. and the Role of IHE

The Healthcare Information Technology Standards Panel (HITSP) members and experts have committed themselves to setting and implementing standards that will ensure the integrity and interoperability of health data. IHE can play a large role in the standards harmonization process within the US. At the federal level, IHE concepts were used in the original standards harmonization RFP response submitted to the Office of the National Coordinator (ONC) by 13 leading organizations including Connecting for Health Steering Group, AHIMA, Health Level Seven, e-Health Initiative and others. The award was given to American National Standards Institute (ANSI) in September 2005 which led to the creation of HITSP to address the harmonization of data standards. Many IHE experts are involved with the HITSP work and currently, HITSP is evaluating a number of IHE integration profiles for use within the Interoperability Specifications. The potential role of IHE's Technical Framework within HITSP can be summarized as follows:

- Can provide models for harmonization by:
 - Mapping of standards which have different levels of granularity
 - Preferred standards and evolution over time
- Can be referenced as Composite Transaction Packages and Components
- Can provide foundation components for architecture and context

- Can provide a proven process and expertise
 - Standards v. Implementation Guide
 - Testing
 - Demonstration
- Is being implemented in pilots such as those in Massachusetts

Certification Commission for Health Information Technology (CCHIT)

Similarly, the Certification Commission for Healthcare Information Technology is referencing IHE Integration profiles for the year 2 and year 3 certification requirements through the alignment activities being lead by the American Health Information Community (AHIC).

4. Conclusion

IHE is well positioned to provide the components necessary to lead by example and connect various HIT systems within RHIO's and across the Nationwide Health Information Network.

IHE participants promote interoperability by building systems that conform to an industry-wide framework for implementing standards. More than 200 healthcare vendors worldwide offer ready-to-integrate products to benefit healthcare enterprises of all sizes. CIOs and clinicians appreciate the positive impact IHE has made on radiology, cardiology, laboratory and enterprise infrastructure as well as powerful cross-enterprise healthcare infrastructures.

IHE and the NHIN

IHE has defined a common framework to deliver the basic interoperability needed for local and regional health information networks. It has developed a foundational set of standards-based integration profiles for information exchange with these interrelated efforts:

1. Cross-Enterprise Document Sharing (XDS) support for document content interoperability. This supports a standards-based EHR across clinical encounters and care settings.
2. A security framework for protecting the confidentiality, authenticity and integrity of patient care data.
3. Cross-domain patient identification management to ensure consistent patient information and effective searches for EHRs.
4. A “thin” NHIN should build upon the peer-to-peer model using existing Internet technologies, which allows the healthcare market to utilize and expand upon proven standards and technologies.
5. By utilizing existing Internet technologies, a “thin” NHIN fosters increased competition, innovation and resource utilization since efforts are focused on providing healthcare specific solutions.

6. The NHIN Common Framework specifically defines two levels of interfaces between End-Point Systems (e.g. EMR, Patient Portal, Acute Care Information System, Payor Systems, etc.). See Figure 1.
7. The first level of interfacing is between the End-Point system and the NHIN sub-network.
8. The second level of interfacing is where Peer Entities perform information exchange, i.e., the NHIN should be transparent.

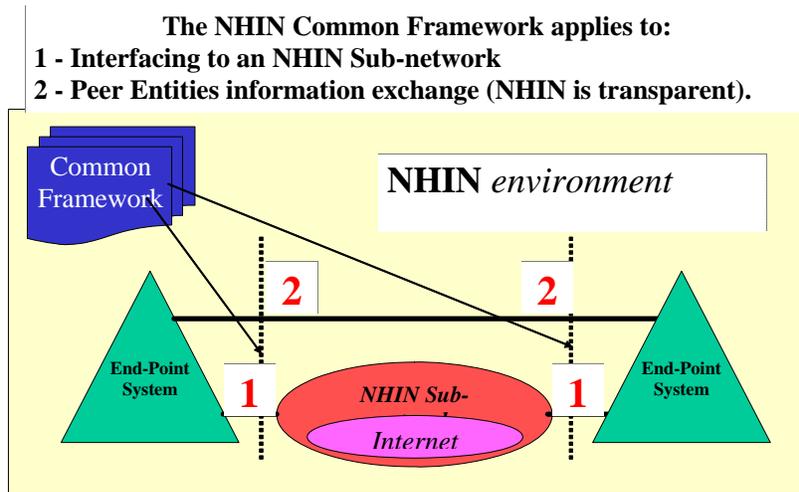
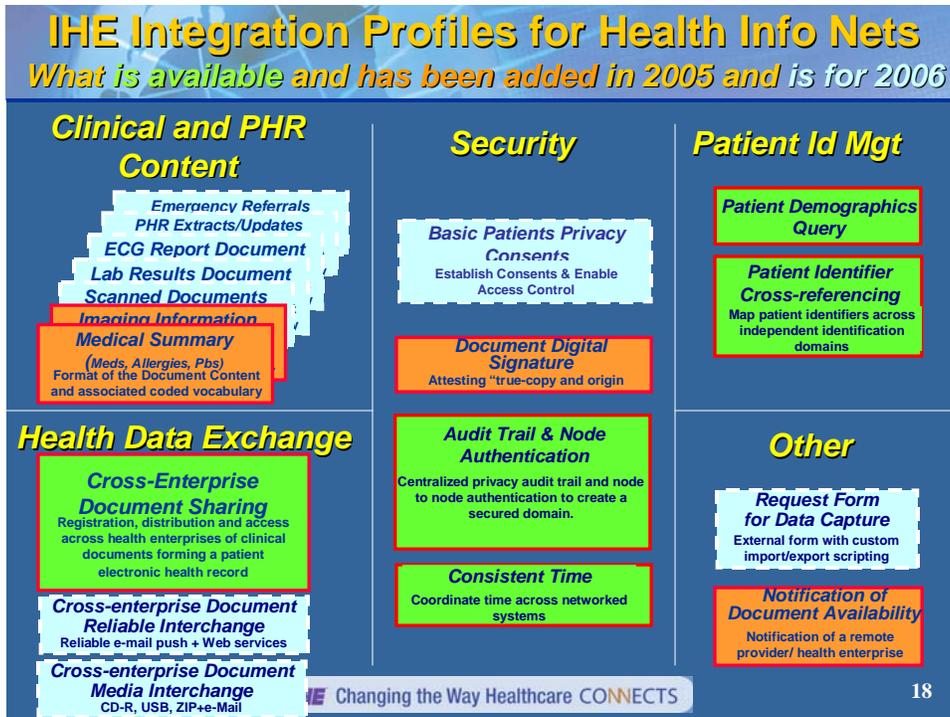


Fig 1: Common Framework, key to interoperability for a thin NHIN

What are the “minimum but essential” network functional requirements for the initial roll out of the NHIN

We recommend organizing the functional requirements for the initial roll-out of the NHIN around the interoperability use cases for which IHE Integration Profiles have been defined. These somewhat are more specific and generic than the ONC use cases, although they would support them.



18

The Health Data Exchange Focuses on Document Sharing.

Many standards have emerged over the past three years which recognize that sharing of information between independent organizations will not leverage the tightly coupled model used today in highly integrated hospital. These models use very specific messages which will be exchanged point-to-point, even over a shared NHIN message switching infrastructure. Except for tightly coupled trading partners such as an ordering physician and the direct supporting laboratory, sharing documents that include a broad self-defining context will be paramount to ensuring trust among the care providers. By document, IHE means electronic document or information objects that may be highly structured and coded with vocabularies, such as HL7 CDA. The three fundamental document content-neutral infrastructure services are: Document Sharing (Document locator and distributed/centralized document repositories), Document Reliable Interchange (Not sharing but single target destination), and Document Media Interchange. In some cases consumers will expect to receive an integral electronic copy of all their shared documents on a physical media device. This would support moving from one RHIO to another before the NHIN is fully connected, while conveying the content of a PHR to a non-connected physician office.

Second, a variety of NHIN-wide standardized coded document content should be defined. This standardization of specific document content has the merit to address, in a step-wise manner, the extension and evolution of the shared clinical content. Eight types of content have been defined by IHE, beginning with a general purpose medical summary, historical laboratory and radiology reports and images, PHR extracts, emergency referrals, etc.

Third a solid security foundation can be provided by IHE which addresses the required elements: node authentication, consistent time, audit trail, encryption, document digital signature, and basic consent for information sharing. Consent content is not defined, but can be identified and enforced to allow for granular consent policies (not blanket ones) to be established and enforced.

Fourth, Patient Identity management is also necessary where the linkage of multiple patient identifiers and selective access to patient demographics query allows the sharing of information without a national identifier.

IHE expects that other categories of NHIN services will emerge over time. The message switching between edge systems supporting pre-selected trading partners is likely to form the second information exchange service after document sharing. The distribution of lab results to ordering providers is expected to be specified in 2007 by building upon the excellent work started by ELINCS.

Functions that would be ‘minimum but essential’ for linking specific edge systems to the network?

It has been IHE’s experience that the edge system applications are generally varied. However, the communication services expected from the NHIN or RHIO are very generic. This may not be obvious at first, but a careful analysis of the “communication” requirements, clearly distinguished from that of the “user perceived functionality” is critical, and a source of confusion that NCVHS should be careful to avoid. For example, document sharing between edge systems, does not mean that the user interface will display a lists of documents. The question from the user may be for the trending of CBC test results from the last 6 months, while the edge system interaction with the NHIN may be to query for laboratory reports for the last 6 months, retrieve those within the application, and extract only the requested subset of CBC tests.

Advantages of using IHE in RHIO and NHIN development

- The IHE Technical Framework provides a solid technical foundation and accelerates RHIOs and NHIN pilot development
- IHE is standards-based, open, multi-vendor, provider-led.
- Clinical scenarios will be enabled by the standards-based IHE technical framework.
- The public-domain detailed specifications called integration profiles ensure that standards are implemented in a consistent manner by different IT companies as they incorporate interoperability into their products.
- Yearly progress, validation testing is built in and backed by a proven process.
- Implementation by many vendors.
- IHE welcomes NHINs’ technical architects’ active involvement.

Lastly, I'd like to thank NCVHS for providing me the opportunity to represent the IHE initiative in North American and discuss my insights and expertise regarding the various ways IHE is being leveraged to provide many components for an interoperable NHIN architecture. The IHE process can be leveraged to accelerate standards adoption and deployment to achieve a truly interoperable patient care experience.