National Committee on Vital and Health Statistics (NCVHS)

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Testifying on Behalf of the Integrating the Healthcare Enterprise (IHE) and the IHE Quality, Research and Public Health Committee

Testimony before the NCVHS Subcommittee on Standards

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1. Introduction, Background and History, Sponsorship

Distinguished members of NCVHS and its Subcommittee on Standards, I am honored to be here today to testify on the following:

1. Current state of public health related standards; coordination of standards development activities; representation and participation by public health in standards activities; where is public health strongest and where is weakest?

2. What are the incentives and drivers for adopting and using public health data standards; what are the barriers and challenges?

3. What is the state of information exchanges of public health data from EHR systems; what are the standards being used; what are the drivers, and incentives; what are the challenges and issues?

4. What are implementation challenges from the public health agency perspective; what are the needs (technical, resources, education, etc.) to advance adoption and use of standards by public health agencies?

5. How is privacy and security covered in public health data standards? Are there privacy and security elements embedded in the standards? Is privacy and security under a different workflow process?

6. What security standards should apply to what types of data possessed by public health?

7. What interoperability standards are needed for transfer of data from electronic health records to public health?

My name is Didi Davis, President, Serendipity Health, LLC. I have 23 years experience in the healthcare industry with emphasis in the leadership, implementation, development, and management of information technology solutions and healthcare workflow requirements. I founded Serendipity Health, LLC in April 2009 to provide consulting services for the advancement and deployment of interoperable healthcare by connecting people, processes and technology. I am known nationally, as a subject matter expert for healthcare standards, interoperability design and strategy for healthcare stakeholders within hospitals, physician practices, health information exchanges and vendors deploying health information technology to improve patient safety and quality of care.

I serve on the Tennessee Healthcare Information and Management Systems Society (HIMSS) Board as the Health Information Exchange (HIE) liaison. I previously held the position as the Chief Technology Officer (CTO) for the Health Information Partnership for TN state network of networks and am currently the Chief Technology Officer for the East Tennessee Health Information Network (etHIN). I served as the Interim CEO for CareSpark, Inc.; a Health Information Exchange in Tennessee nationally known for its standards based architecture supporting public health in TN and VA. I currently serve on the IHE International Board, am one of the planning co-chairs for the Quality, Research and Public Health Domain and serve on the IHE International Testing and Tools Committee.

Prior to founding Serendipity Health, I was senior director of Informatics at the HIMSS. My responsibilities included execution and direction for the standards activities of IHE International and its related projects and committees such as the IHE North American Connectathon and the Interoperability Showcase demonstrations in the US, Europe and Asia. Prior to joining HIMSS in May 2006, I was employed by Eclipsys Corporation as Director, IT Product Strategies.

Overview/Introduction/IHE International

An essential aspect of transforming healthcare in the United States is to have interoperability across applications, systems, and settings that facilitate and impact patient care. Interoperability enables authorized professionals and consumers to access relevant healthcare information and electronically exchange it across various settings including Public Health.

The Department of Health and Human Services, Office of the National Coordinator for Health Information Technology (ONC) recognizes the importance of interoperability and has put interoperability at the top of the national agenda as part of its national strategy to support public health initiatives.

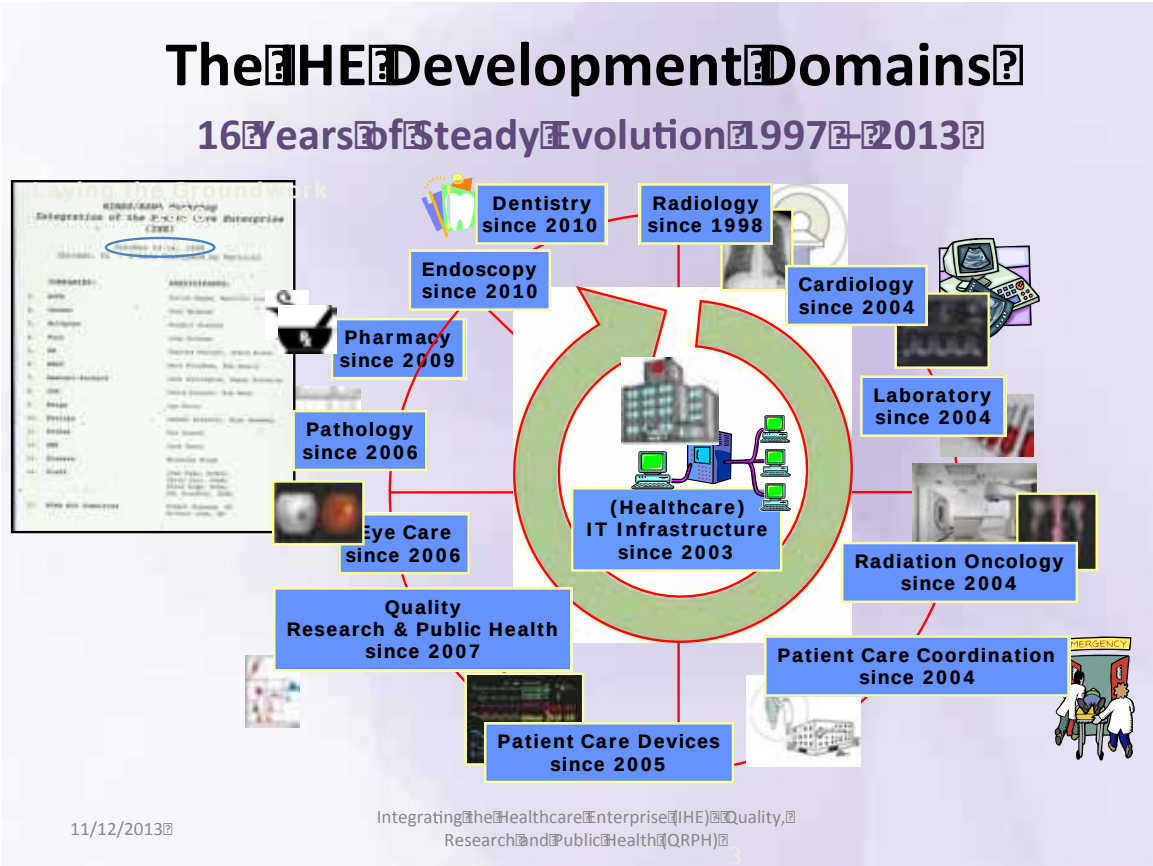
Despite the emerging consensus on the need for local, regional, and national interoperability, the task is daunting and the barriers are many. Barriers to achieving this vision including lack of effective standards, incompatibility among different IS solutions, failure to align technology solutions to 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 that includes the United States, Canada, Asia and Europe. In pursuit of its mission, IHE brings together care providers and other healthcare professionals with representatives of the healthcare IT industry. 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 volunteer committees of industry professionals who define solutions to address these issues based on established information technology standards.

They are responsible for *development* activities—i.e., support of the committees that develop and publish the IHE Technical Frameworks—in their respective domains. In addition to organizing, hosting, overseeing and providing the secretariat for these committee activities, they also are responsible for publishing the IHE Technical Framework documents the committees produce. Deployment activities (testing, demonstrations and educational activities) are lead by the regional deployment committees. IHE USA, IHE Europe and IHE Canada are examples of these deployment committees

Background and History

IHE was established in 1998 by the formation of a partnership between the Radiological Society of North America (RSNA) www.rsna.org and the Healthcare Information Management and Systems Society (HIMSS) www.himss.org. Its 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. IHE has expanded steadily to incorporate new domains, including Cardiology, Dentistry, Endoscopy, Eye Care, IT Infrastructure, Laboratory, Patient Care Coordination, Pathology, Patient Care Devices, Pharmacy, Quality, Research and Public Health, Radiology and Radiation Oncology.



These new domains have also grown the sponsorship and membership of IHE. There are currently 638 member organizations of IHE International representing over 20 countries. There are several other organizations that 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.

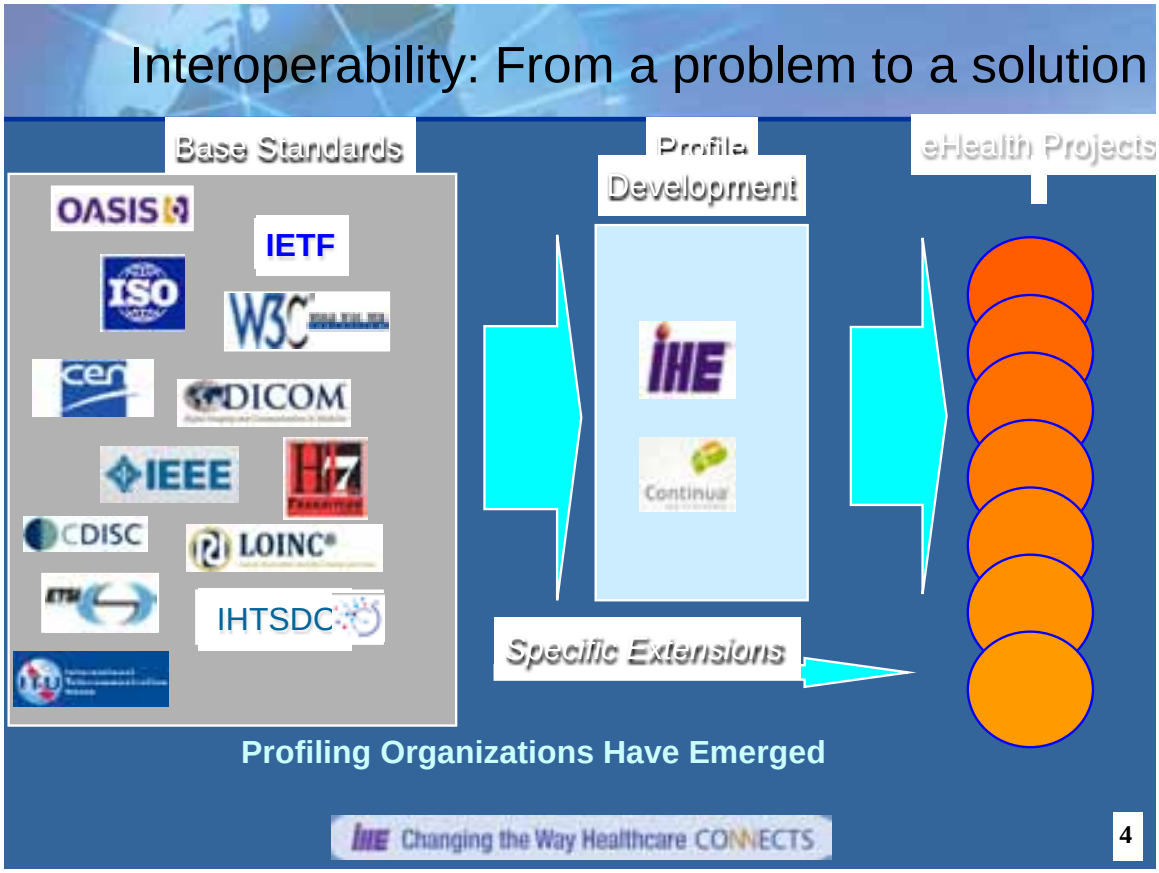
National and regional sponsors take responsibility for *deployment* activities, including testing, demonstrations and education, to encourage adoption in their respective areas. Other organizations representing healthcare professionals are invited to join in the expansion of the IHE process across disciplinary and geographic boundaries.

2. IHE International Proven Standards Adoption Process

Overview

IHE is led by healthcare professionals and industry to improve the way computer systems in healthcare share information. IHE promotes the coordinated use of established standards such as DICOM and HL7 to address integration of the information systems that support the healthcare system. IHE developed a process that is recognized by ISO Health Informatics: TR28380 Global Standards Adoption – IHE Process and Profiles. IHE has a fundamental goal to enable the interoperable exchange of data to improve the patient and provider processes. Because IHE focuses on the adoption of a set of existing standards around clinical needs, IHE is uniquely suited to the development of standards to enable more seamless exchange and the repurposed

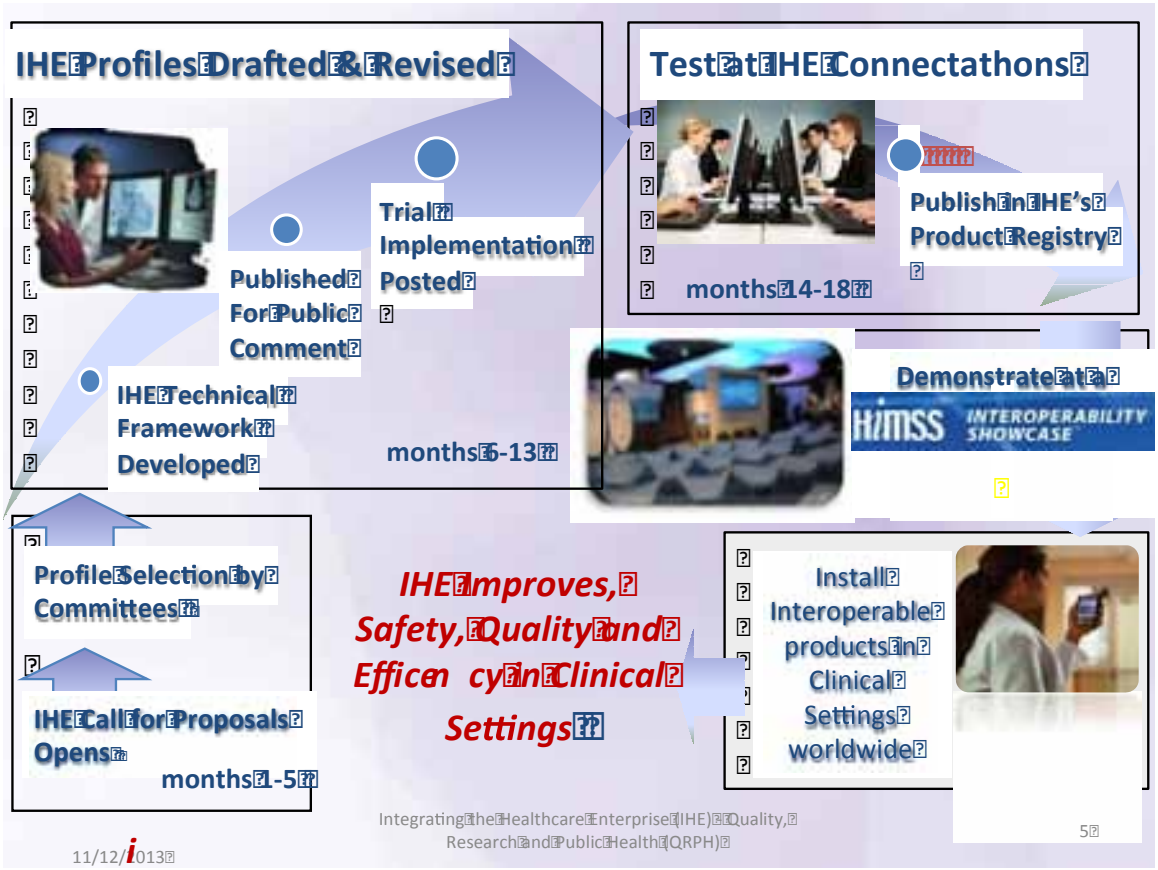
use of data such as quality reporting, research and public health reporting. By establishing processes around a single set of existing standards that can be implemented and updated incrementally, IHE facilitates the rapid implementation of interoperable applications by providers, vendors, HIEs, hospitals, researchers, public health and others.



IHE created this unique development cycle 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.

IHE brings together users and developers of healthcare information technology (HIT) in an annually recurring four-step process:

- Clinical and technical experts define critical use cases for information sharing.
- Technical experts create detailed specifications for communication among systems to address these use cases, selecting and optimizing established standards.
- Industry implements these specifications called IHE Profiles in HIT systems.
- IHE tests vendors' systems at carefully planned and supervised events called Connectathons.



3. Quality, Research and Public Health (QRPH) Domain

IHE Quality, Research and Public Health Domain (QRPH) addresses the infrastructure and content necessary to:

- Share information relevant to quality improvement in electronic patient care and health care records
- Facilitate interoperability between the healthcare system and clinical research
- Facilitate interoperability between the healthcare system and public health

Launched in 2007, the domain is sponsored by two member organizations:

- Healthcare Information and Management Systems Society (HIMSS)
- Radiological Society of North America (RSNA)

One of the first publications by the QRPH domain, in collaboration with the Public Health Data Standards Consortium (PHDSC), laid out a public health roadmap of Electronic Health Record Data. 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.

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.

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. Planning has begun for the next IHE North America Connectathon--to be held in January 27 – 31, 2014 in Chicago, IL. IHE deployment committees organize international testing events that culminates in industry connectathon testing events that take place 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.

Testing Tools

An important element of the IHE testing process is the set of open source software tools supported by various organizations found at the hyperlink in this sentence. IHE has developed a growing body of software tools to facilitate testing and implementation of IHE Integration Profiles in healthcare information technology systems. These tools are available for download and licensed by their developers for free use. A profile-by-profile Index to Pre-Connectathon Test Software is available here.

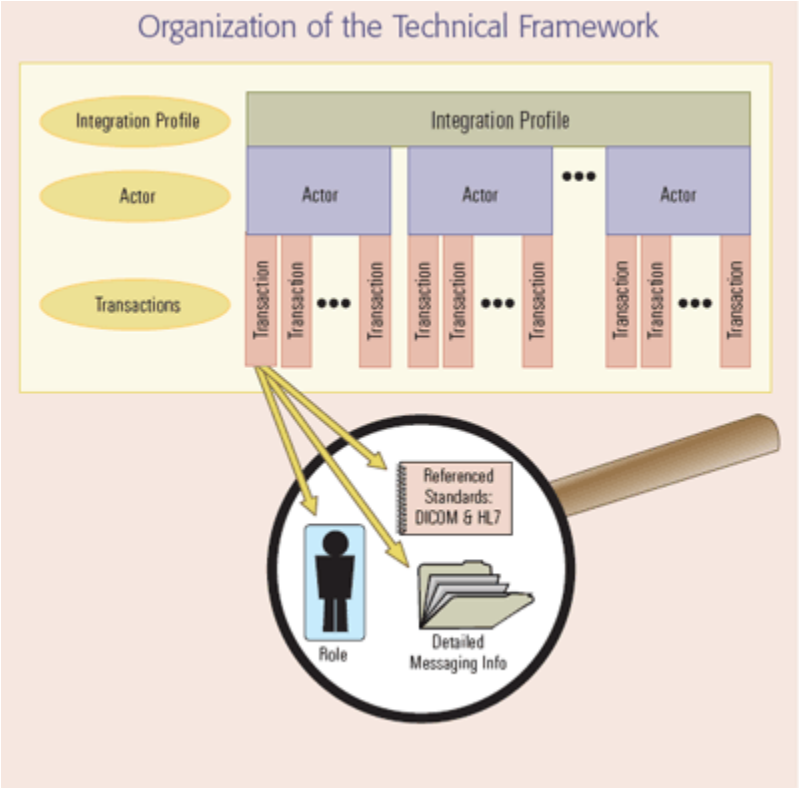
4. THE TECHNICAL FRAMEWORK — PUTTING BUSINESS AND TECHNOLOGY TOGETHER

The IHE Technical Frameworks are a detailed set of reference documents that guide systems developers and integrators in implementing standards to achieve IHE integration capabilities. The Technical Frameworks define standards-based transactions among systems, generically known as *IHE Actors* that support specific workflow and integration capabilities, known as *Integration Profiles*. Technical Frameworks are published in all active IHE domains.

Domain	Start	Profiles
Radiology	1998	29
IT Infrastructure	2003	33
Cardiology	2004	10
Laboratory	2004	10
Radiation Oncology	2004	10
PCC	2004	20
PCD	2005	9
QRPH	2006	14
Eye Care	2006	7
Anatomic Pathology	2006	3
Pharmacy	2009	5
Dentistry	2010	1
Surgery	2013	0

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	• Patient Identity Source • Patient Identifier Cross Reference Manager
Managing image acquisition and storage	Radiology	Scheduled Workflow (SWF)	Worklist Provided	• DSS/Order Filler • Acquisition Modality
Sharing electronic health records (EHRs)	Patient Care Coordination	Cross-enterprise Sharing of Medical Summaries (XDS-MS)	Register Document Set	• Document Repository • Document Registry
Establishing the continuity and integrity of clinical laboratory testing	Laboratory	Laboratory Scheduled Workflow	Test Results Management	• Order Filler • Automation Manager
Viewing high quality ECG's from any access point	Cardiology	Retrieve ECG for Display (ECG)	Retrieve ECG Document for Display	• Document Repository • Document Registry

5. Current IHE Quality, Research, and Public Health Publications (Profiles)

Symbol Key

The Profiles listed here may be in one of three states:

- ● - Final Text – stable (profile has been tested at two separate connectathon events with no significant changes or actor/transaction additions.
- ○ - Trial Implementation - frozen for trial use; changes permitted prior to Final Text
- ○ - Retired/Deprecated - no longer recommended or maintained by IHE

○ [BFDR] Birth and Fetal Death Reporting describes the content and format to be used within the pre-population data part of the Retrieve Form Request transaction from the RFD Integration Profile.

○ [CRD] Clinical Research Document describes the content pertinent to the clinical research use case required within the Retrieve Form for Data-Capture (RFD) pre-population parameter.

○ [CRPC] Clinical Research Process Content specifies content, which is appropriate to help automate the sharing of information among systems during the clinical research process using the transactions from the Retrieve Process for Execution (RPE) profile. Using the transactions from the Retrieve Process for Execution (RPE) profile, CRPC will improve the recruitment for, setup, and performance of clinical studies.

○ [DEX] Data Element Exchange leverages the concept of a metadata registry to add mapping metadata to an annotated data capture form at the point of form design instead of the exchange of data instances.

○ [DSC] Drug Safety Content describes the content pertinent to the drug safety use case required within the Retrieve Form for Data-Capture (RFD) pre-population parameter.

○ [EHCP] Early Hearing Care Plan communicates care plan content and instructions to care providers (as jurisdictionally directed by the Public Health EHDI Program) to assist early detection, documentation and intervention for hearing loss.

○ [HW] Healthy Weight captures and communicates information for managing and monitoring healthy weight among clinical and public health surveillance systems.

○ [NANI] Newborn Admission Notification Information describes the content needed to communicate a timely newborn admission notification to public health to be used by Early Hearing Detection and Intervention (EHDI) screening programs.

- [PRPH-Ca] Physician Reporting to a Public Health Repository – Cancer Registry defines the data elements to be retrieved from the EMR and transmitted to the cancer registry or to a healthcare provider.
- [QME-EH] Quality Measure Execution-Early Hearing describes the content needed to communicate patient-level data to electronically monitor the performance of early hearing-loss detection and intervention (EHDI) initiatives for newborns and young children.
- [RSP] Redaction Services redacts data from a document in a user's current application to meet the requirements for exporting to an external system.
- [RM] Research Matching publishes research process definitions to EHR systems to match patients and investigators with appropriate research studies.
- [RPE] Retrieve Process for Execution enables a healthcare provider to access a process definition, such as a research protocol and to execute automated activities, without leaving an EMR session.
- [VRDR] Vital Records Death Reporting defines a Retrieve Form for Data Capture (RFD) content profile that will specify derivation of source content from a medical summary document. by defining requirements for form filler content and form manager handling of the content.

IHE QRPH 2013 – 2014 (Year 8) Proposals Under Consideration

The 2013_2014 IHE QRPH annual cycle began in October 2013. The process for the development of the IHE integration profiles includes committee meetings to discuss and assemble the documentation. This includes convening the Planning and Technical Committees.

The QRPH Domain received 8 proposals at the kick off meeting to year 8 for the domain. The 8 brief profile proposals were discussed during the planning committee meeting held in October 2013. The Planning Committee reviewed and discussed the profile submissions. The Planning Committee's final recommendation resulted in the selection of 4 profile proposals being voted on and ranked in priority order. This information has been reviewed by the Technical Committee in a series of weekly conference calls. These discussions are to help inform the scope and body of work the committee will undertake in the coming development cycle. The current proposed work including whitepapers can be found here.

IHE QRPH Profile Cycle Stages	Participation Status	Open Date	Close Date	Learn More
Planning Committee Call for Proposal	Open	Week of July 29, 2013	September 29, 2013	http://wiki.ihe.net/index.php?title=Profile_Proposal_Process
Planning and Technical Profile Selection	Member Only	October 9-10, 2013	December 2013	http://wiki.ihe.net/index.php?title=Quality,_Research_and_Public_Health_Planning_Committee
IHE Profiles drafted in IHE Technical Committee	Member Only	January 2014	May 2014	http://wiki.ihe.net/index.php?title=Quality,_Research_and_Public_Health_Technical_Committee
New QRPH Profile Work Public Comment	Open	June 2014	July 2014	http://wiki.ihe.net/index.php?title=Public_Comment_Process
QRPH Trial Implementation Published	Open	N/A	August 2014	http://www.ihe.net/Technical_Frameworks/#qrph
IHE USA Connectathon Registration	Open	September 23, 2013	October 18, 2013	http://www.iheusa.org/Events.aspx
IHE USA Connectathon & Conference (1/29)	Open	January 27, 2014	January 31, 2014	http://www.iheusa.org/Events.aspx
IHE Europe Connectathon	Open	April 2014	April 2014	http://www.ihe-europe.net/connectathon/65/connectathon

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Significant Deployments for IHE QRPH

- The Clinical Data Interchange Standards Consortium (CDISC) has put a lot of emphasis on the QRPH work in the area of Clinical Research. CDISC has initiated one ITI and five QRPH profiles. This work, which CDISC 'brands' as Healthcare Link, has been carefully coordinated with the Office of Scientific Coordination of the FDA. At the request of FDA, additional security was added by integrating three ITI security profiles: Cross Community Access (XUA), Audit Trail and Node Authenticaton (ATNA), and Consistent Time (CT). The resulting nine profiles provide a starting point for EHR-enable clinical research.

- European Electronic Health Records for Clinical Research (EHR4CR) project has accepted QRPH research profiles for clinical study execution, based on the 6-month internship which brought a French student to the states to study and recommend the use of these profiles.

- In the US, CDC supports state Early Hearing Detection and Intervention (EHDI) programs for planned pilot projects.

    - North Dakota and Oregon have completed testing pilots for CDA. Vendors involved were Epic, Oz Systems and Orion Health. CDC, Public Health Standards Data Consortium (PHSDC), NIST, State of North Dakota, State of Oregon, Oregon Health and Science University Hospital, Sanford Health and Trinity Health organizations were involved.

- In the US, The Department of State Health services Texas EHDI program has deployed **Newborn Admission Notification Information (NANI)**. The Department of Health in Maryland is deploying NANI through its Health Information Exchange (HIE) for EHDI and Critical Congenital Heart Disease Screening and Birth Conditions reporting. North Dakota EHDI is implementing NANI through the State HIE. The Newborn Screening

Program in Indiana has implemented NANI to enable their hospitals to send newborn notification messages to the State.

- Retrieve Form for Data Capture (RFD) and Clinical Research Data (CRD) has been implemented in the following sites:

  1. Paris George Pompidou hospital, under Dr. Christel Daniel

  2. Hamamatsu Hospital in Japan, Dr. Michio Kimura

  3. Five sites in the US:

- OPUS in Carrolton GA using Greenway and Outcome Sciences. Contact Jason Colquitt, Greenway Medical.

- NextGen study, using Greenway and Nextrials. Contact Jim Rogers, Nextrials

- Diabetes disease registry, Outcome Sciences. Contact Dan Levy, Outcome Sciences.

- S001 study, Cerner and Eli Lilly. Contact Jane Griffin, Cerner.

- Florida hospital, various investigator initiated studies. Contact Susan Mitchell, Florida Hospital.

- **Drug Safety Content (DSC)** was implemented in the drug safety reporting project called ASTER,at Brigham and Women's hospital in Boston with CRIX, Cerner, and Pfizer. Contact Michael Ibara, Pfizer.
  - This project was written up in the Wall Street Journal, and was published at pharmacoepidemiology and drug safety 2010; 19: 1211–1215, Linder et al/. 2009 – The ASTER project used DSC to send individual case safety reports from physicians at Brigham and Women's hospital to the FDA. See summary at www.CDISC.org.
- SALUS Project (Scalable, Standard based Interoperability Framework for Sustainable Proactive Post Market Safety Studies) includes this profile in their article describing an initial implementation of their Semantic Framework project to achieve interoperability between the clinical research and the clinical care domains.

- **Physician Reporting to a Public Health Repository - Cancer Registry (PRPH-Ca)** An Implementation Guide developed and published by the US Centers for Disease Control uses PRPH-Ca as the base document. It was adopted as part of the US Department of Health and Human Services Meaningful Use Stage 2 optional requirements in August 2013. Reporting using this specification begins 1/1/2014. Kentucky and Missouri are alpha testing the receipt of this reporting. Vendors are able to certify this option and can be found on the Certified Health IT Product List (CHPL).

Education, Demonstrations, Implementations and Other Events

- All these demonstrations highlight QRPH's CRD and DSC profiles along with ITI's RFD infrastructure profile:
  - 2007 – 2009 CDC Public Health Information Network (PHIN) Interoperability Showcases

  - 2011 - National Center for Public Health Informatics (NCPHI) – National HIT Week Demonstration sponsored by HIMSS

    - 2009 – 2012 - CDISC Demonstrations – US, Budapest, Latvia, Japan, Brussels, China and UK
    - 2011 - 2012 Drug Information Association (DIA) Interoperability Showcases
    - 2008 - 2013 IHE International Educational Webinar Series
- BFDR
    - Has been tested at 3 IHE USA Connectathons, 2011- 2013 and demonstrated at the HIMSS Interoperability Showcases 2011-2013
    - CDC Public Health Informatics Conference and Interoperability Showcase, 2011
    - National Association for Public Health Statistics and Information Systems annual meeting 2013
- EHDI
    - Has been tested at 3 IHE USA Connectathons 2011- 2013 and demonstrated at the HIMSS Interoperability Showcase 2011-2013
    - CDC Public Health Informatics Conference and Interoperability Showcase, 2011

IHE Integration Statements

IHE Integration Statements are documents prepared and published by vendors in the Product Registry to describe the intended conformance of their products with the IHE Technical Framework. They identify the specific IHE capabilities a given product is designed to support in terms of the key concepts of IHE: Actors and Integration Profiles.

6. Conclusion

As the only organization dedicated specifically to implementation of standards-based solutions to meet the interoperability needs of the healthcare system, IHE is uniquely positioned to provide the building blocks necessary to lead by example and connect various HIT systems within Public Health and across various clinical care settings.

IHE participants promote interoperability by building systems that conform to an industry-wide framework for implementing standards. More than 300 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.

QRPH Trends

- Public Health Reporting continues to trend up in the US with the linkage to the S&I Public Health Reporting Initiative and current pilots underway in Minnesota, Utah, Oregon, North Dakota, Delaware, New York, and California.
- The average time for drug development (molecule to product) is 17 years. EHR enabled research through cooperation between CDISC and IHE International hopes to improve this time to market.
- In the US, the Office of the National Coordinator (ONC) Structured Data Capture (SDC) initiative is reaching out to the IT Infrastructure,(ITI) and Quality Research and Public

Health (QRPH) to leverage existing profiles Retrieve Form for Data Capture (RFD) and Data Element Exchange (DEX). A number of IHE-related pilots are under development, including three from the Structured Data Capture (SDC) Public Health Tiger Team (EHDI, Cancer Surveillance and Communicable Disease Reporting).

- Regenstrief and IHTSDO are working together to link LOINC and SNOMED CT vocabularies.
- HL7 and QRPH have piloted a joint comment period for Healthy Weight. Recommendations from the pilot are still being reviewed to determine how to improve future joint comment periods.
- In the US, four of the quality measures that was developed as part of the EHDI Profile (now QMD-EH) were endorsed by the National Quality Forum (NQF). One of these measures, Hearing screening prior to hospital discharge (EHDI-1a), was adopted for the US Phase II Meaningful Use**.**

Summary of Future Plans:

- QRPH intends to work with Regenstrief and IHTSDO to continue to link LOINC and SNOMED CT vocabularies.
- Support PCC and ITI domains with joint development of content, pre-population data and other such profiles to enhance the QRPH offering to optimize workflows for new electronic reporting initiatives.
- The domain member organizations will support educational outreach through specific webinars. These webinars will be geared toward stakeholders such as vendor implementers, providers involved in public health reporting, etc.

On behalf of IHE QRPH and the IHE International Board, I'd like to thank NCVHS for allowing me the opportunity to represent the IHE initiative in North America. I have provided my insight and expertise regarding the various ways IHE is being leveraged to provide the building blocks for an interoperable public health architecture. This includes edge systems as these are where the biggest improvement for patient care and safety can be realized within the clinician workflow. The IHE process can be leveraged to accelerate standards adoption and deployment to achieve a truly interoperability patient care experience with ubiquitous flow of health related data.