Interoperability Symposium

February 23, 2014

Elliot B. Sloane, PhD, CCE, FHIMSS
Founder and President
Center for Health Information Research and Policy (CHIRP)

DISCLAIMER: The views and opinions expressed in this presentation are those of the author and do not necessarily represent official policy or position of HIMSS.
Elliot B. Sloane, Ph.D., CCE, FHIMSS

Has received some episodic, part-time consulting revenue from helping IHE USA and ICSA develop and deliver its Testing and Certification programs. All such activities have been disclosed to IHE USA and IHE International Board members, in accordance with its Bylaws. Aside from this revenue there are no other real or apparent conflicts of interest to report.
Learning Objectives

1. Describe emerging standards for device interoperability and data integration.

2. Identify opportunities and challenges for collaboration among clinical engineering professionals and IT professionals to implement standards.

3. Identify and define “next steps” in promoting device interoperability and data integration through collaborative efforts in your organization.
Snapshot:
This has been a very strong decade of progress for medical device interoperability!

- Very good progress is being made with standards, conformance testing, and certification
  - Leverages other prior works, such as HL7, IEEE (11073x and 802.xx), UMLS
  - Leverages USA programs on “Meaningful Use” of Electronic Medical Records
    - Extends the USA EMR Conformance Testing and Certification program that was launched in 2009.
      - ALL EMR software sold/used in the USA must be Certified under the Meaningful Use 1, 2, and, eventually 3 programs.

- IHE USA is extending the same style of product Testing and Certification for Medical Devices
  - The first medical device products were Tested and Certified for IHE conformance by IHE USA in 2013!
Over 15 years of progress!

In 1998, HIMSS and RSNA formed a new non-profit organization, devoted to nurturing “interoperability” for the healthcare community.

IHE – Integrating the Healthcare Enterprise

- Founded in 1998
  - **IHE International** converted to an independent, IRS 501(c)(3) non-profit educational organization in 2006.
  - **IHE-USA** established as a separate independent IRS 301(c)(3) non-profit educational organization in 2011.

- Still run by volunteers and donated staff resources from HIMSS and RSNA!
“Un-Interoperability:” Highest Cause of Health IT project failures

Too many “Base Standards”

Complicate eHealth Projects

Health Interoperability Standards: how can we realize the promise?
IHE Interoperability: From problems to solutions...

Base Standards

Open Profile Development

Achievable eHealth Projects

“Profiling” Organizations Have Emerged to Generate Solutions
The IHE Development Domains
17 Years of Steady Evolution 1998 – 2014

Look carefully: MOST Domains have “devices!”

- Dentistry since 2010
- Endoscopy since 2010
- Pharmacy since 2009
- Pathology since 2006
- Eye Care since 2006
- Quality Research & Public Health since 2006
- Patient Care Devices since 2005
- Mobile devices Under way for 2014!
- Surgery since 2012
- Radiation Oncology since 2004
- Cardiology since 2004
- Laboratory since 2004
- Radiation Oncology since 2004
- Patient Care Coordination since 2004
  Now including home care devices, telehealth, and PHRs

(Healthcare) IT Infrastructure since 2003

HIMSS14
ANNUAL CONFERENCE & EXHIBITION
Contributing & Participating Vendors provide SMEs

IHE Board is Global and Interdisciplinary AND User driven!
Bylaws require that the elected Co-Chairs must represent *User Segment*
David Mendelson, MD (Radiologist) & Elliot Sloane, PhD (Clinical Engineer)

26 Deployment Committee Board seats

IHE North America
- USA
- Canada

IHE Europe
- Austria
- France
- Germany
- Netherlands
- Italy
- Norway
- Spain
- Sweden
- UK

IHE Asia-Oceania
- China
- Japan
- Korea
- Australia

14 Development Domain Board seats

- Radiology
- IT Infrastructure
- Laboratory
- Cardiology
- Patient Care Coordination
- Pathology
- IT Infrastructure
- Patient Care Devices
- Eye Care
- Public Health, Quality and Research
- Pharmacy
- Radiation Oncology
- Endoscopy
- Dentistry

IHE is Primarily USER driven
Professional Societies & Gov’t agencies must be primary “sponsors”
e.g., HIMSS, RSNA, American College of Cardiology, Saudi Ministry of Health

Contributing & Participating Vendors provide SMEs
Think Globally, Act Locally

- Local Deployment with “National Extensions”
- Over 600 organizational members worldwide (see www.ihe.net/governance)

Although the USA founded IHE International, it is only now, in MU Stage 2, adopting the IHE Standards!

- Newer members can act more quickly. e.g., Saudi Arabia just joined IHE in 2012, and is already deploying IHE Standards in 2013!

Pragmatic global standards harmonization + best practices sharing
The IHE Standards Development Lifecycle – Open, Public, Global & Local

Open, Public Ballot
- ISO Recognized Standards Development Organization
- Open source (Apache) license for any user
  - Derivative works contributed to open, public libraries
- Membership is free
  - Mandatory disclosure of any conflicts of interest OR private intellectual property (e.g., copyrights, patents) is mandatory
- Elected Board and Officers

Global & Local Specializations
- Each nation and region may form local/regional organizations
  - Use as much shared IHE framework and standards as desired
  - Local Deployment Committees develop “local specializations” to meet national regulations
  - Conduct local/regional Connectathon testing meetings, trade shows, and training, as appropriate
Install interoperable products in clinical settings worldwide.

IHE: A trusted, publicly open process.
Proven since 1998!
IHE Patient Care Device Clinical Areas

1. Physiologic Monitoring System
   - ACM, DEC, WCM

2. Ventilation/Anesthesia System
   - ACM, DEC, WCM

3. Infusion Pump
   - ACM, PIV, DEC

4. Home Based Systems eHealth & TeleHealth
   - Future PCD

5. Other Devices
   - ACM, DEC, WCM

6. Equipment Management System
   - ACM, MEM

7. Implantable Device
   - IDCO

8. Clinical Decision Support System
   - ACM, DEC, WCM

ACM: Alarm Communication Management
DEC: Device Enterprise Communication
IDCO: Implantable Device – Cardiac – Observation
MEM: Medical Equipment Management
PIV: Point-of-Care Infusion Verification
WCM: Waveform Communication Management

Current PCD: Existing Patient Care Devices
Future PCD: Planned Patient Care Devices
Future Non-PCD: Planned Non-Patient Care Devices

IHE PCD’s Shared Vision:
Affordable, compatible global patient care device interoperability standards that also links to EMRs and PHRs.

Only a single common interface would be needed per device, designed for scenarios like this:

A single common standard provides an “Enterprise Bus” solution

3 devices = 3 interfaces
500 devices = 500 interfaces (NOT 500,000 interfaces!)
Hundreds of products can communicate with PCs and PHRs!
Device Interoperability has “Arrived”
Over 25% of HIMSS’s Interoperability Showcase vendors feature medical devices, and the majority of products demonstrate IHE features and functionality.
**IHE USA Certification Framework**

Modeled after the US ONC EMR Testing and Certification Programs. This diagram shows how standards, testing, and certification fit together to assure products conform to published standards.

Standards body (Guide 7)
- IETF
- IEEE
- HL7

Accreditation
- Quality Management
- Program Management
- Competency Requirements

Certification Benefit Statement
- Trusted, credible structure
- Parallels government accreditation requirements
- Internationally recognized and accepted

ISO

Testing Organization
ISO9001:2008 • ISO17025:2005

Tools • Methodology
Testing Processes

Test Results

Certification Body
ISO17065 Guide 65

Certification Report

Certification Award/Certificate
Congratulations and thanks go to the first group IHE USA Certified Products!

Breaking from the past to help create a brighter future for healthcare delivery...

5 of the first 8 Certified products were medical devices!

The independent Testing and Certification for IHE USA was performed by 1 of 5 ONC-authorized US EMR test and certification Agencies.
SO, is the job done?
Can we all go home and declare Victory!

Well, not quite yet!

As they say, the “proof is in the pudding.”

In truth, a great deal of collaboration, and vision are needed to overcome the challenges:

Transform standards and conformant products into efficient systems of care delivery that MAKE A DIFFERENCE!

Thank you!

Elliot B. Sloane, PhD, CCE, FHIMSS
Founder and President
Center for Health Information Research and Policy (CHIRP)
Achieving Standards-based Medical Device Integration to Automate Data and Improve Patient Care Quality and Efficiency

February 23, 2014

Allen Hobbs, Ph.D. Principal Technology Consultant, Kaiser Permanente

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Conflict of Interest Disclosure

Allen Hobbs, Ph.D

Has no real or apparent conflicts of interest to report.
Learning Objectives

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2. Identify opportunities and challenges for collaboration among clinical engineering professionals and IT professionals to implement standards.

3. Identify and define “next steps” in promoting device interoperability and data integration through collaborative efforts in your organization.
Challenges to Achieving Interoperability and Integration

• Many medical device suppliers have proprietary process, technologies and approaches to system integration.

• There is variation among medical device suppliers as to the level of systems integration maturity compared to their Information Technology counterparts.

• There is variation in methodology as to how medical devices are integrated in networked or connected environments to assure sustained and successful interoperability and integration of services over the long term.
Opportunities to Achieving Interoperability and Integration

• Define clear mutually shared technical infrastructure and operational requirements among health care organizations and medical device suppliers to assure sustainable interoperability and integration.

• Develop a Medical Device Interoperability Maturity Model.

• Apply Risk Management for IT- networks incorporating medical devices.

• Implement responsibility agreements between responsible organizations, Information technology suppliers and medical device manufacturers.
Establishing Connected Environments with Interoperability & Integration Requirements

- Capture IT requirements that are aligned for interoperability and integration 3-5 years and beyond.
- Provide a catalogue of requirements with key internal stakeholders to share with medical device manufactures.
- Create and provide integration roadmaps to medical device manufactures.
- Evaluate “must have” requirements to RFP Go/No Go criteria for implementation.
KP Proposed Interoperability Maturity Model for Medical Devices

• The following diagrams provide a proposed Interoperability Maturity Model for Medical Devices.

• We would like to receive any comments you may have in joint discussion regarding relevance and adoption to your clinical environments.
Next-Generation Medical Devices and Systems must go well beyond Clinical functions to include complex Network Transactions and System Lifecycle Management functions as well.

ITIL conformance will be a key success factor (Stage 3)
Addressing Maturity Model Risk Management for IT networks incorporating medical devices

ISO/IEC 80001 consists of the following parts, under the general title Application of risk management for IT-networks incorporating medical devices:

- Part 1: Roles, responsibilities and activities
- Part 2-1: Step-by-step risk management of medical IT-networks – Practical applications and examples
- Part 2-2: Guidance for the disclosure and communication of medical device security needs, risks and controls
- Part 2-3: Guidance for wireless networks
- Part 2-4: Application guidance – General implementation guidance for Health Care Delivery Organizations
- Part 2-5: Application guidance – Guidance on distributed alarm systems
- Part 2-6: Application guidance – Guidance for responsibility agreements
This Technical Report provides practical guidance to Responsible Organizations on establishing Responsibility Agreement between all stakeholders involved, namely the Responsible Organization, the Medical Device manufacturer(s), and the IT supplier(s).

- Types of Responsibility Agreements are proposed.
- Technical requirements are recommended for project phases.
- Roles and Responsibility Charting (RACI) methodology is suggested to map stakeholders to project phase metrics.
Additional Standards to Help Achieve Higher Interoperability Maturity Model Stages

- Integrating the Health Enterprise (IHE) – Technical Framework and Integration Profiles for the Patient Care Device Domain (IHE-PCD)

- Continua Health Alliance for personal health care devices and home care delivery

- ISO / IEEE 11073 Medical Device & Personal Health Data (PHD) Semantic Interoperability Standards

- Integrated Clinical Environment (ICE) Management

- HL7 FHIR Device-focused Resources
Proposed Benefits for Achieving Interoperability and Integration Through Collaboration

- Increase the number of optimized ready biomedical systems in connected environments - Secure, Scalable, Networked, Available, Manageable, Interoperable.
- Reduce the cost of integration through clear mutually shared requirements and guidelines for responsibility agreements.
- Reduce integration cycle time leveraging standards through a Medical Device Maturity Model.
Future Trends to Consider

• Impact of “Internet of Things” (IoT) on health care delivery in an emerging hyper-connected world.
  • The world population is expected to be 7.6 billion by 2020
  • 25 billion devices are expected to be connected by 2015
  • 50 billion devices are expected to be connected by 2020
  • 6.6 devices are expected to be connected per person by 2020

• 21st Century Cyber – Physical Systems
  • Effective and Reliable Integration and Interoperability
  • Trust, Security and Privacy

• U.S. Critical Infrastructure Protection for the Health Care Sector
  • Inter-dependencies among sectors
  • Mitigating “cascade failure” and disruption of healthcare services
How do you achieve standards-based medical device integration to automate data and improve patient care quality and efficiency?

- Define clear mutually shared technical infrastructure and operational requirements and standards among health care organizations and medical device suppliers to assure sustainable interoperability and integration.
- Develop a Medical Device Interoperability Maturity Model.
- Implement responsibility agreements between responsible organizations, Information technology suppliers and medical device manufacturers
Questions?

Thank You!
Medical Device Interoperability: Whither health care providers?

Todd Cooper
Executive VP – Interoperability Trust

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Conflict of Interest Disclosure

Todd Cooper
Has no real or apparent conflicts of interest to report.
Learning Objectives

• Review the challenges around achieving standards-based seamless medical device interoperability
• Present research on the potential impact of seamless medical device interoperability on health care delivery
• Identify a key missing piece to the business model and discuss current efforts to finish the puzzle.
An Introduction to the Benefits Realized for the Value of Health IT

http://www.himss.org/ValueSuite

Value Steps

Health IT creates five kinds of value of benefit to patients, healthcare providers and communities.

Medical interoperability can have a significant impact on safety, quality of care and affordability – lowering the cost of healthcare!

- **S**atisfaction
  - Patient; Provider; Staff; Other
  - Improved communication with patients, patient satisfaction score, and internal communication.

- **T**reatment/Clinical
  - Safety; Quality of Care; Efficiency
  - Improved patient safety and scheduling. Reduction in medical errors and readmissions.

- **E**lectronic Information/Data
  - Evidence Based Medicine; Data Sharing and Reporting
  - Increased use of evidence-based guidelines, population health reporting, and quality measures reporting.

- **P**revention & Patient Education
  - Prevention; Patient Education
  - Improved disease surveillance and patient compliance. Increased immunizations. Longitudinal patient analysis.

- **S**avings
  - Financial/Business; Efficiency Savings; Operational Savings
  - Increased volume. Reduction in days in accounts receivable and reduced patient wait times.

http://www.himss.org/ValueSuite
Historical reasons for not realizing seamless medical device interoperability?

- Vendors use proprietary technology to lock-in / control market share
- Easier for vendors to stick with proprietary solutions than change to standards.
- Lack of standardized technology
- Regulatory burden makes open standards-based interoperability (hard enough just getting your own tech to the field)
- Health care delivery doesn’t demand it
- Public policy doesn't demand it
What is the cost of dysfunctional interoperability?

Analysis coordinated by West Health Institute finds medical device interoperability could save more than $30 billion a year

www.westhealth.org/institute/interoperability
Over $30 Billion estimated saving from Medical Device Interoperability

**Estimated Savings from Medical Device Interoperability**

- Increased clinician productivity secondary to decreased time spent manually entering information: $12.3B
- Increased capacity for treatment secondary to shortening length of stay: $17.8B
- Reduced cost of care secondary to avoidance of redundant testing: $3B
- Quality improvement through reduction of adverse events due to safety interlocks: $2B
- Avoided development testing and integration costs based on use of commonly adopted standards: $1B

"The Value of Medical Device Interoperability," West Health Institute, March 2013
Observations …

- There are plenty of standards and technologies!
- Lack of medical device interoperability is a business model problem, not a technology problem
- Most advocacy organizations dominated by vendors
Where are the health care providers?!
Center for Medical Interoperability
Launched 9/18/2013

Created to advance the safety, quality and affordability of U.S. healthcare delivery by driving rapid, widespread, sustained interoperability of medical technology.
Led by Hospitals & Health Systems

✓ The **Board of Directors** for the Center for Medical Interoperability will consist of *chief executives* who represent the different types and sizes of *hospitals* across the nation. This includes non-profit, investor owned, federal government, and public hospitals and health systems. The Board will insure that all types of hospitals are considered in order to drive rapid, widespread, sustained interoperability of medical technology.

✓ A **Technical Advisory Committee** (TAC) consisting of hospital **CTOs / CIOs / CMIOs** will set the direction of all **Center technical campaigns**. Efforts will advance interoperability across the full continuum of data flow (device-device, device-EHR, EHR-EHR, EHR-HIE)
Neutral environment for health system stakeholders to identify technical solutions

Develop common standards-based architectures, specifications and reference designs

Steward protocols for testing and certifying that requirements are fulfilled

Facilitate trust through medical grade solutions, best practices, tooling & education

www.MedicalInteroperability.org
Engaging all stakeholders ...

The **Center for Medical Interoperability** will create momentum to achieve medical interoperability by empowering hospitals and health systems to drive ecosystem alignment.

**Healthcare Delivery**
Clear and consistent requirements for interoperability

**Standards Adoption**
Making it easy for manufacturers to adopt standards and specifications

**Policy & Regulatory**
Aligned with regulatory pathways

- Architecture, Specifications & Reference
- Protocols for Testing & Certification
Health care providers taking control of their interoperable technology will break the chicken & egg conundrum, save $B’s annually, and drive rapid, widespread and sustained interoperability!

Value Steps

Medical interoperability can have a significant impact on safety, quality of care and affordability – lowering the cost of healthcare!
Questions?

Thank You!

Todd Cooper
Executive VP – Interoperability Trust
Todd@Center4MI.org