Testing, Conformance and Certification: How to Achieve Interoperability
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Michael H. Nusbaum, BASc, MHSA, FHIMSS
Joyce Sensmeier MS, RN-BC, CPHIMS, FHIMSS, FAAN

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Conflict of Interest Disclosure

Michael H. Nusbaum, BASc, MHSA, FHIMSS
• Consulting Fees: Program Advisor to IHE USA and ICSA Labs

Joyce Sensmeier MS, RN-BC, CPHIMS, FHIMSS, FAAN
• Has no real or apparent conflicts of interest to report.
Learning Objectives

• Differentiate testing, conformance and certification of health IT systems and devices to advance interoperability
• Evaluate lessons learned from the IHE USA Certification pilot
• Identify how the certification “ecosystem” in the US (and in other countries) can bring improved reliability, quality and rigor to the health IT marketplace
• Assess the impact of certification in contributing to an integrated and interoperable health IT environment
An Introduction to the Benefits Realized for the Value of Health IT

Value Steps

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

TOP STORY
Rural Independent Practice Named 2013 Davies Recipient
White River Family Practice located in White River Junction, Vermont has been named a 2013 Davies recipient by HIMSS.
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Read More

SATISFACTION
Patient, Provider, Staff, Other
Improved communication with patients, patient satisfaction score, and internal communication.

TREATMENT/CLINICAL
Safety, Quality of Care, Efficiency
Improved patient safety and scheduling, reduction in medical errors and readmissions.

ELECTRONIC INFORMATION/DATA
Evidence Based Medicine, Data Sharing and Reporting
Increased use of evidence-based guidelines, population health monitoring, and quality measures reporting.

PREVENTION & PATIENT EDUCATION
Prevention, Patient Education
Improved disease surveillance and patient compliance, increased immunizations, longitudinal patient analysis.

SAVINGS
Financial/Business, Efficiency Savings, Operational Savings
Increased volume, reduction in days in accounts receivable and reduced patient wait times.

Interoperability facilitates communication among patients and providers.
Clinical information at the point of care maximizes safety, quality, efficiency.
Information collected and aggregated across populations can inform decision making & improve quality outcomes.
An interoperable EHR can support patient education.
Interoperability reduces duplication, increases clinical awareness, improves care coordination.

http://www.himss.org/ValueSuite
Presentation Outline

• Introduction: a matter of Quality and Consumer Confidence
• Supporting a Healthcare System in Transformation
• Understanding Conformity Assessment
• IHE USA’s Certification Pilot: experience and results
• The Certification “ecosystem” in the USA
• The Worldwide movement towards Certified HIT interoperability
• The Value Proposition: clinicians, organizations, vendors
• Questions
Introduction: a matter of Quality and Consumer Confidence

- Interoperability is essential to quality care
- Infrastructure is still fragmented which contributes to inefficient, uncoordinated care
- Need to bridge gaps between entities, organizations, settings
- Need to understand impact on patients, end-users
- Need comparable, consistent data
- Need to support advances in EHR → Patient Care Devices → EHR integration
Consumer engagement is essential

- Portable, accessible personal health information will provide an essential foundation
- Mobile advances are an accelerator
- Growing focus on preventive care
- # of home-based devices is increasing
- Transparency of cost and quality will inform choice
Supporting a Healthcare System in Transformation

- U.S Goal: Transform healthcare through the meaningful use of health data
- Data capture → data sharing → advanced clinical processes
- Leading to:
  
  Improved Outcomes

- Requires organized structuring and effective use of information to support decision making
Need for Information Exchange in an Accountable Care Model

- Standards are foundational to development, implementation and exchange of EHRs
- Clinicians need ubiquitous access to health information to provide optimal care
- Providers, payers and public health entities must exchange health information between departments, across organizations and agencies
- Consumers need assurance that caregivers have seamless access to correct information
Interoperability: from Standards to Reality

• What would happen if standards were built into products, but without the opportunity to test and certify conformance?

• Interoperability is special… it takes [at least] “two to tango”!!

• Vendors can certainly claim “capability”, but can purchasers be assured that interoperability is baked into a specific product available for purchase?

• The solution: an independent testing and certification program based upon rigorous process and documentation protocols
Understanding Conformity Assessment

• Testing, Conformance and Certification are each part of a “Conformity Assessment” continuum

• Conformity Assessment describes “any activity to determine, directly or indirectly, that a process, product, or service meets relevant technical standards and fulfills relevant requirements” (ISO/IEC 17000)

• An international initiative, founded in international standards and guidelines

• The need for conformity assessment is primarily driven by risk

• The perception of risk associated w/ non-conformity drives the need for regulatory and market confidence

• A successful CA system provides that amount of confidence at minimal cost
Conformity Assessment can be conducted by:

- first party – seller or manufacturer
- second party – purchaser or user
- third party – an independent entity that has no interest in transactions between the 1st and 2nd parties

Components of Conformity Assessment:

- Testing
- Supplier’s Declaration of Conformity
- Certification
- Accreditation
- Surveillance
Testing by Accredited Labs
Qualified Products List based on ISO Guide 65 Certification
Supplier Declaration of Conformity
List of Declared Products
Testing by Accredited Labs
Certification Body Accredited to ISO Guide 65
Supplier Declaration of Conformity
List of Declared Products
Testing by Accredited Labs
Qualified Products List based on ISO Guide 65 Certification
Non-accredited testing
Confidence
Time, $\$, Resources
Certification
Regulation
National Institute of Standards and Technology
U.S. Department of Commerce
The Need for Certification

- Supplies additional rigor through a formal testing framework
- Supplies assurance that the capabilities are reliably implemented into the actual purchased product
- Supplies assurance that the products will perform as advertised to advance the goal of interoperability
IHE USA Certification

• Purpose
  – To advance IHE USA’s mission to improve our nation’s healthcare by promoting the adoption and use of IHE and other world-class standards, tools and services for interoperability
  – Ensure products that leverage advanced IHE interoperability capabilities are delivered to the marketplace

• Process
  – Reviewed by an independent body using ISO methods and standards, the industry’s highest level of quality for testing and certification
  – Makes sure that everything examined in the process is verified, documented, repeatable and traceable.
IHE USA Certification Framework
How do standards, testing, and certification fit together?

Accreditation
• Quality Management
• Program Management
• Competency Requirements

Standards Requirements
ISO
Standards body (Guide 7)
• IETF
• IEEE
• HL7

User Defined
• ONC
• NIST
• IHE USA

“Scheme”

Testing Organization
ISO9001:2008 • ISO17025:2005

Tools • Methodology
Testing Processes

Test Results

Certification Body
ISO17065 Guide 65

Certification Report

Certification Award/Certificate

Certification Benefit Statement
• Trusted, credible structure
• Parallels government accreditation requirements
• Internationally recognized and accepted
ICSA Labs & IHE USA: Partners in Testing & Certification

- A trusted institution since 1989
- 20+ Years Security & Privacy Testing Experience - One of the oldest and most extensive certification programs in security
- ANSI Accredited ONC-Authorized Certification Body
  - Certifying EHR Technology tested to meet federal clinical, interoperability, privacy and security requirements
- Analyst Expertise in HIPAA Compliance, Meaningful Use Regulations and Required Standards
- NVLAP Accredited Test Lab for Health IT
Review of the IHE USA 2013 Certification Pilot

• 8 vendors participated in the testing and certification pilot that kicked off at the 2013 NA Connectathon.

• 4 additional vendors chose to be “supportive partners”, providing peer services to certification candidates to support the program.

• More than 40 “testable units” (product-profile-actor) were tested during the Connectathon week.

• Certification Testing Analysts closely observed and documented the results of each “testable unit”.

• “Scenario Testing” was introduced to better model end-to-end interoperability.
Congratulations to the first group IHE USA Certified Vendors!
Certification Pilot: Key Findings

1. Connectathon Testing vs. Certification Testing
2. The Certification “ecosystem”
3. Configuration Issues
4. Training Considerations
5. Peer/Scenario Testing
6. Development of Test Data
7. Strengthen Documentation
8. Test Sequencing and Connectathon Alignment
9. Test Management Tools
10. Certification-specific Test Tooling
11. Expanded Communications
The Certification “ecosystem” in the USA

• National recognition of the importance of Certification
• Organic growth of certification programs, each designed to fulfil a specific purpose
• Recognition that a confused marketplace is unhealthy
• Economic viability and sustainability
  – Minimize vendor burden
  – Eliminate redundant process
• Willingness to harmonize programs & design a system of reciprocity where appropriate
The Worldwide movement towards Certified HIT interoperability

National/Regional Certification Programs
• Certification in the USA
• Certification in Canada
• Conformity Assessment in Europe

International Certification Frameworks
• IHE International Conformity Assessment Framework
The Value Proposition: Clinicians

• Decreased risk of error during transfer of care
• Improved quality of care, timely delivery
• Decreased cost by eliminating redundancy
• Improved workflow and accuracy with timely, accessible clinical data
• Allows for clinician collaboration and early intervention
The Value Proposition: Organizations

- Information exchange provides a mechanism to validate deployed systems
- Enhances ability to automate interaction with external partners, decreasing cost
- Reduces manual intervention, increasing productivity and streamlining operations
- Improves the quality and efficiency of healthcare delivery
- And ultimately, it improves patient outcomes and population health
The Value Proposition: Vendors & Customers

• Extends ability to differentiate products in the marketplace
• Clear communication of product capabilities in the marketplace
• Tying testing to specific products will lead to more reliable and complete interoperability for vendors and their customers in real clinical settings
• Certification maintenance and surveillance will ensure that products that are certified continue to deliver the tested functionalities in the market
A Recap of the Benefits Realized for the Value of Health IT

Certification facilitates the achievement of Interoperability, which in turn ensures the right information is available at the right time to the right people so the right decisions can be made and the health status of populations is improved.

- Strategic Guidance from HIMSS Board of Directors
Resources

• Interoperability for Dummies, IHE Edition
  Now Available | Get Your Copy!

• IHE Profiles and Certification Drive Interoperability
  A Whitepaper | Get Your Copy!
Questions?

Thank You!

Michael H. Nusbaum, BASc, MHSA, FHIMSS
President, MH Nusbaum & Associates Ltd.
michael@mhnusbaum.com ● (250) 384-0001

Joyce Sensmeier MS, RN-BC, CPHIMS, FHIMSS, FAAN
President, IHE USA
jsensmeier@himss.org ● (708) 955-4377