

# Integrating the Healthcare Enterprise *(IHE)*

## Connecting IT and Devices to Health

INCOSE 2016



**Elliot B. Sloane, PhD, FHIMSS**

President, Center for Healthcare Information Research and Policy (CHIRP)

Co-Chair, IHE International; Board of Directors, IHE USA

**My bio?** An AAMI member for nearly 40 years, HIMSS & ACCE Fellow, and IEEE Senior Member, on a *"road less traveled,"*  
Four Decades in Health Technology and Information Systems

15 years in non-profit research, development, & independent testing, standards, and forensic investigation of medical technologies

At **ECRI Institute**, from "bench" to CIO and COO

- Worked with FDA on medical device standards
  - Computerized arrhythmia detection disclosure and apnea monitors
- Forensic investigations of patient injuries and deaths
- Breakthrough computer systems for medical device nomenclatures, "Hazard Reports," feature comparisons, product directories, medical device maintenance, and safety assurance

10 years in a publicly-traded corporation, medical device manufacturing, repairs, 24x7 rental/delivery, and medical device and drug manufacturing and distribution

At **MEDIQ Life Support Services**, from COO through CTO and CRO

Registered with FDA as device and drug manufacturer

Owned and managed a fleet of 500,000 medical devices nationwide

15+ years as a professor, consultant, businessman, and AAMI/ACCE/HIMSS/IEEE volunteer

- CHIRP's President and Founder, a non-profit focused on Medical Informatics, Health Systems Engineering, Medical Device Data Systems Research, Security and Privacy, Wireless Medical Devices, and Patient Safety
- Serve AAMI, ACCE, HIMSS, IHE, and IEEE privacy, security, standards, and education committees

Ongoing Research Professor and graduate instructor at Villanova University, PA.





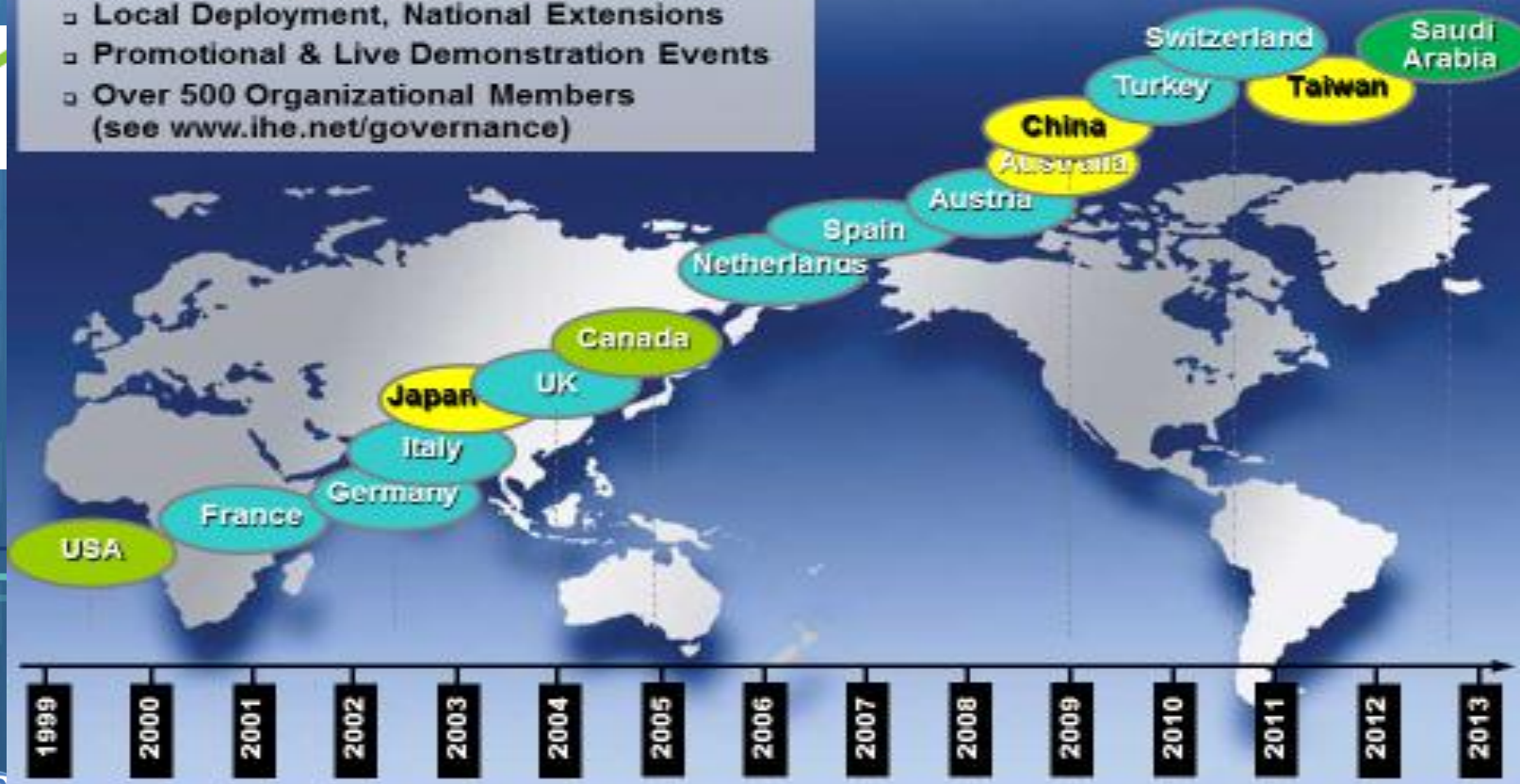
## Agenda

- IHE History
- About the US interest in EHR and IHE
- Where we are today
- Some critical success factors



# International Growth of IHE

- Local Deployment, National Extensions
- Promotional & Live Demonstration Events
- Over 500 Organizational Members (see [www.ihe.net/governance](http://www.ihe.net/governance))



Pragmatic global standards harmonization + best practices sharing

# Global Adoption of IHE

Year 1	(1999)
Year 2	(2000)
Year 3	(2001)
Year 4	(2002)
Year 5	(2003)
Year 6	(2004)
Year 7	(2005)
Year 8	(2006)
Year 9	(2007)
Year 10	(2008)
Year 11	(2009)
Year 12	(2010)
Year 13	(2011)
Year 14	(2012)
Year 15	(2013)

USA

France

Germany

Italy

Japan

UK

Canada

Korea

Taiwan

Norway

Netherlands

Spain

Israel

Austria

Australia

Finland

Poland

China

Sweden

Turkey

Switzerland

Saudi Arabia

Colombia

Brazil

UNDER WAY

Belgium

India

Malaysia

New Zealand

South Africa

# Where we were in 1998...

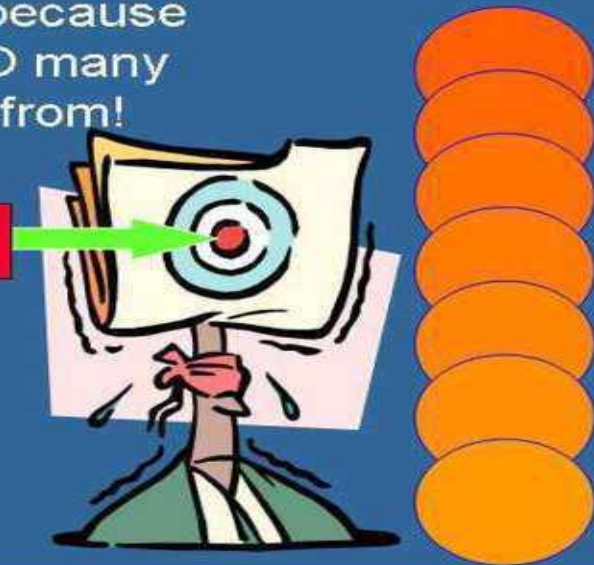
## Interoperability: Major Cause of Health IT project failures?

Base Standards



We dread  
"standards" because  
there are SO many  
to choose from!

eHealth Projects



Health Interop. Standards: Ignore & Face Consequences

# Where we finally are in 2016...



Profiling Organizations Solve Problems



# IHE Organization

IHE International is a 501(c)(3) independent non-profit organization

IHE International Elected Co-Chairs:  
David Mendelson, MD  
Elliot Sloane, PhD

IHE International Board is fairly large, with broad representation

- One member from each Global Development Domain
- One member from each National Deployment Committee
- Two At-Large members from the above communities
- Two Emeritus members from prior Board membership



- |                    |                           |                                   |
|--------------------|---------------------------|-----------------------------------|
| Anatomic Pathology | Endoscopy                 | Pharmacy                          |
| Cardiology         | IT Infrastructure         | Quality, Research & Public Health |
| Dental             | Laboratory                | Radiation Oncology                |
| Eye Care           | Patient Care Coordination | Radiology                         |
|                    | Patient Care Devices      |                                   |

**IHE NORTH AMERICA**  
Canada USA

**IHE ASIA-OCEANIA**  
China Japan  
Korea Taiwan

**IHE EUROPE**  
Austria France Germany Italy  
Netherlands Norway Spain  
Sweden Switzerland UK

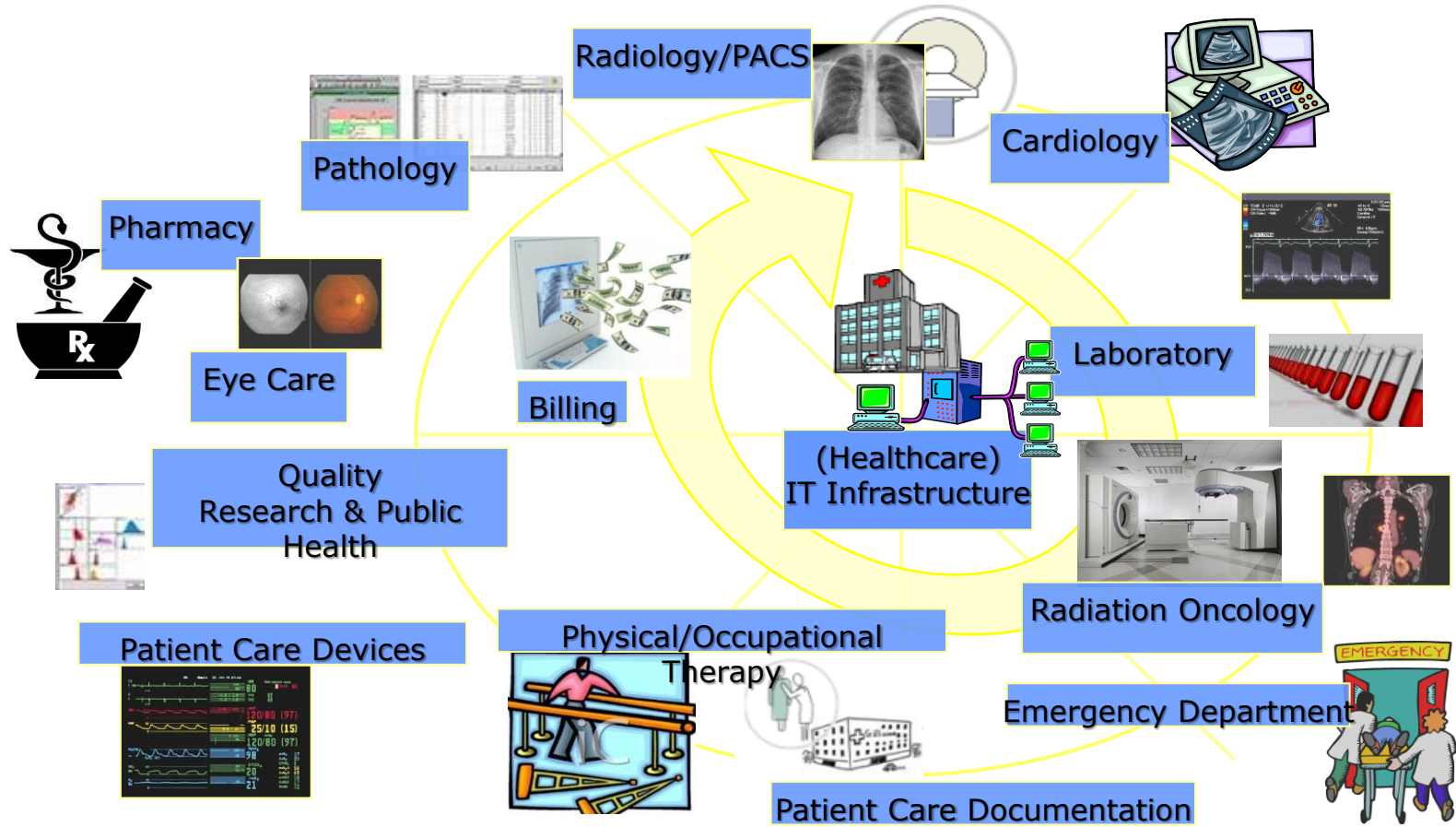
> 21 Societies Serving as Sponsors

Over 650 Contributing Vendors & Organizations



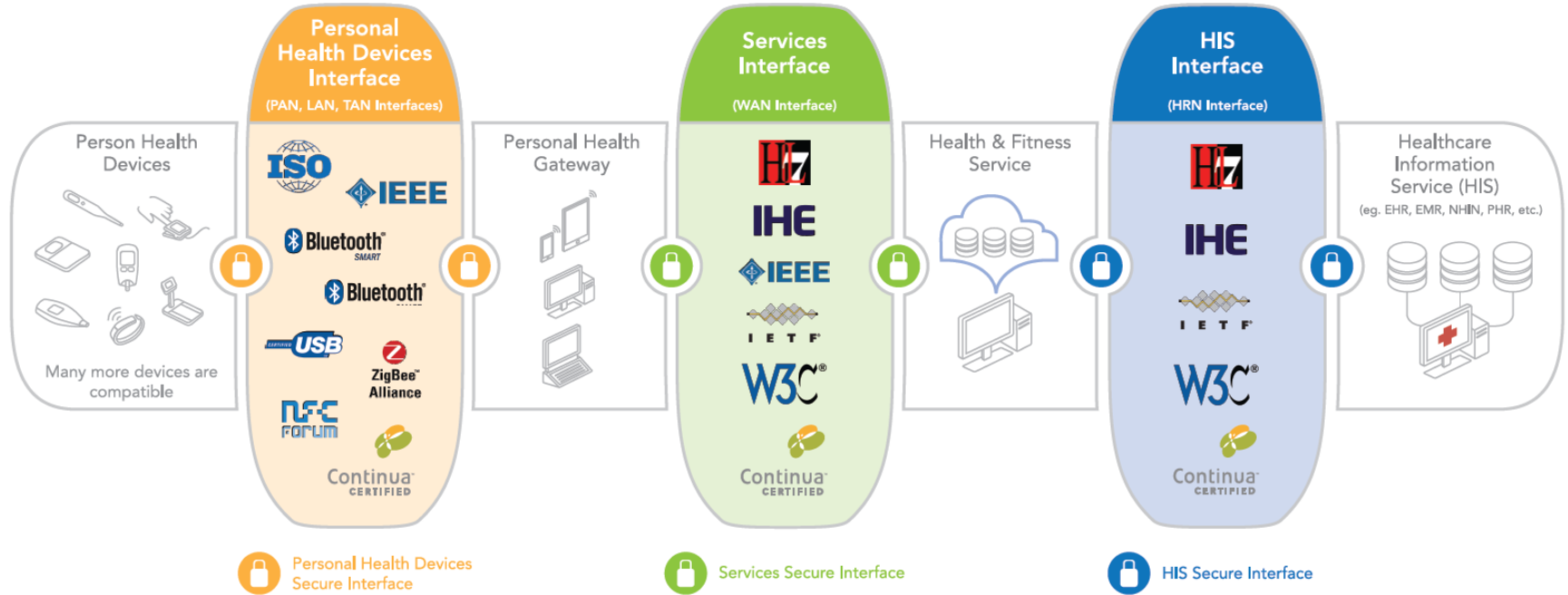


# e.g., IHE's Information Systems Domains



**Electronic Health Record System**

# Continua Health Alliance Architecture Extends IHE Connectivity into Personal Health and Home Care

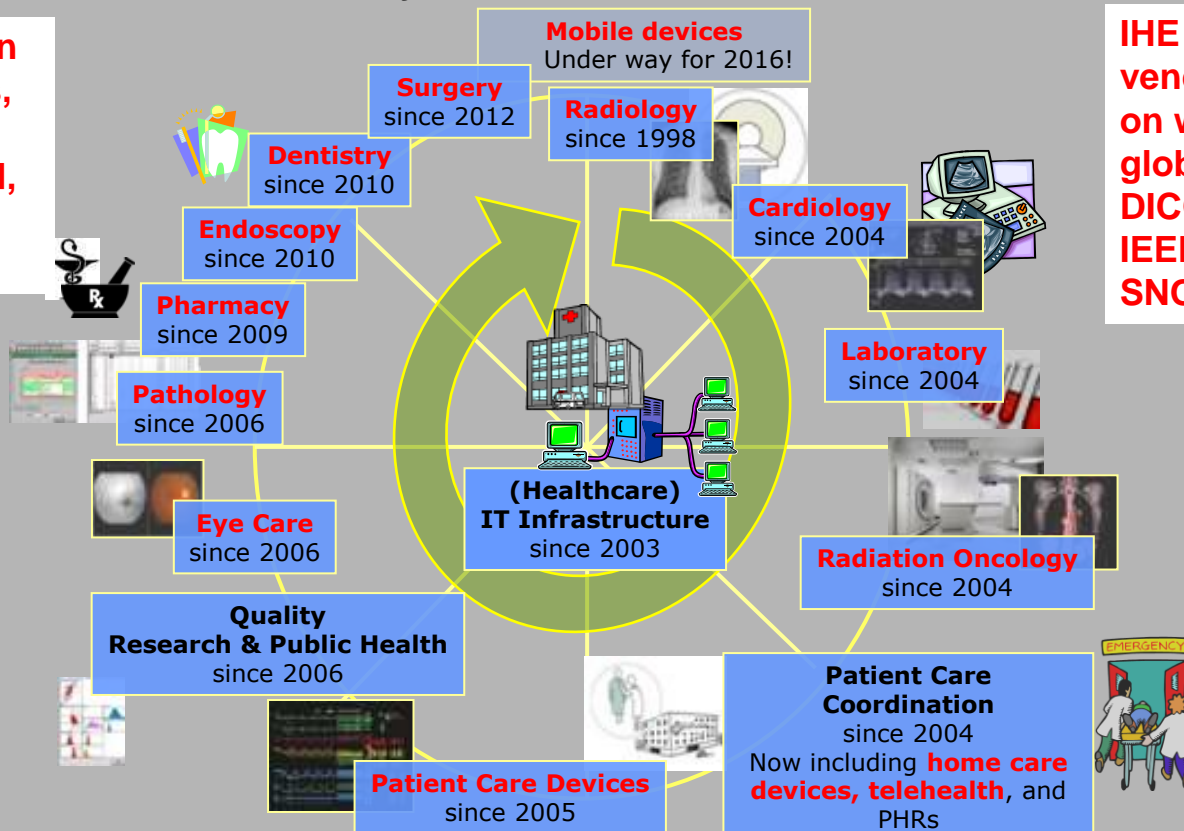


# IHE Interoperability Domains

18 Years of Steady Evolution Worldwide! 1998 – 2015

IHE reduces clinician workload and errors, enabling timely, accurate, automated, secure data capture and exchange

IHE is USER driven & vendor neutral; based on well-established global standards like DICOM, HL-7, ICD, IEEE, LOINC, SNOMED, etc.



Look carefully: **MOST** Domains capture device AND workflow data; data transfer is accurate and near-immediate.

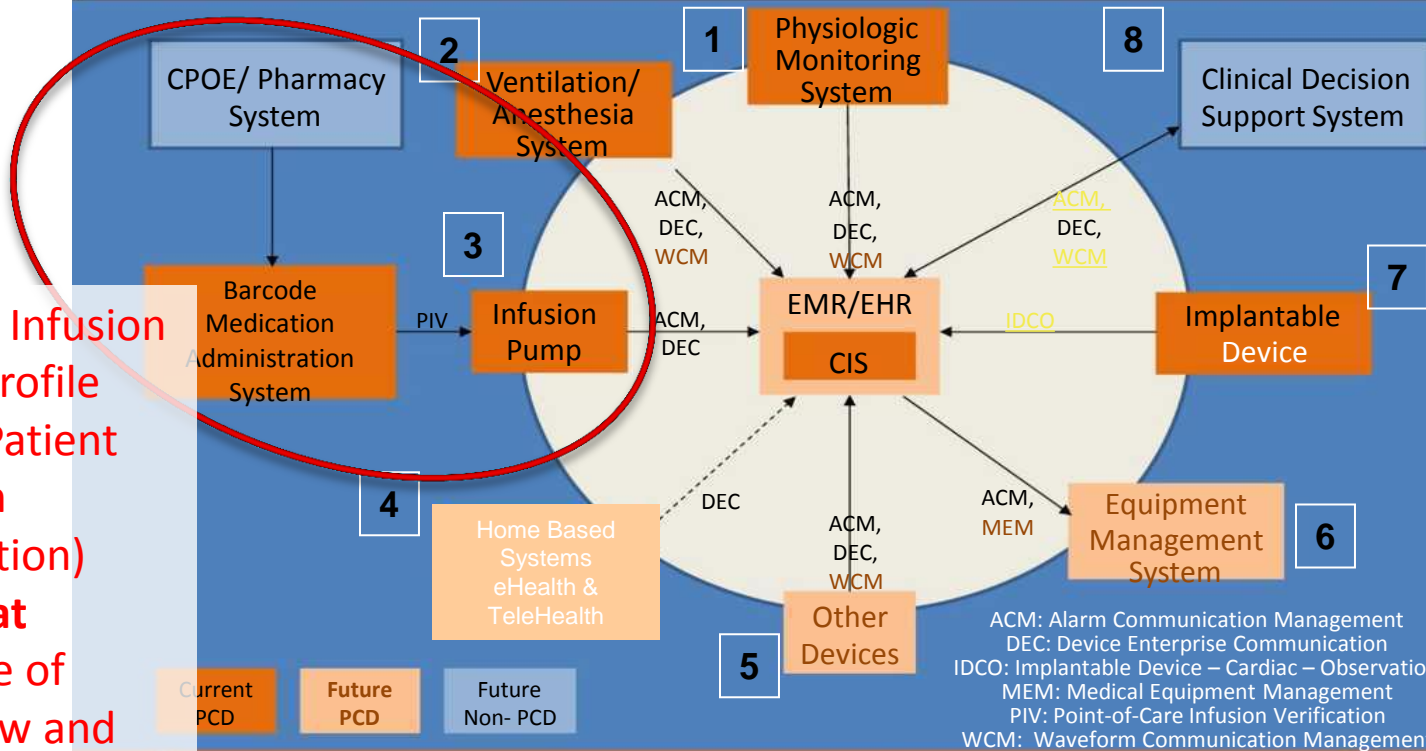
# Sample Radiology IHE Profile Themes for Workflow and Data Interoperability- Meaningful Use for the Radiologist

- Image Sharing- **XDS-i**
  - IHE XDS; Personal Health Records as a vehicle
- Radiation Exposure- **REM**
  - Aggregating and monitoring patient and population exposure
  - **ACR DIR mapping tool**
    - RadLex Playbook- vendors are interested in making this part of an IHE profile
- Radiology Reporting
- Teaching and Research- **TCE**
  - MIRC
  - CTP
- Meaningful Use Metrics Reporting for ONC/CMS

# IHE Radiology Profiles are SPECIALIZATION examples, that add useful workflow and data tools for physicians & hospitals

- PDI                    Portable Documents for Imaging
- IRWF                 Import Reconciliation Workflow
- REM                  Radiation Exposure Monitoring
- TCE                   Teaching File and Clinical Trial Export
- MAWF                Mamography Acquisition Workflow
- IOCM                 Imaging Object Change Management
- MIMA                 Multiple Image Manager/Archive

# IHE Patient Care Device Clinical Areas



The IHE Infusion Pump Profile “PIV” (Patient Infusion Verification) is a **great** example of workflow and data automation for patient safety



FREE: [http://wiki.ihe.net/index.php?title=Patient\\_Care\\_Device](http://wiki.ihe.net/index.php?title=Patient_Care_Device)

**How does IHE ensure each Profile really works?  
We test them around the world with vendors at  
“IHE Connectathons”**



1999



2016







## *Many Nations run their own national or regional IHE Connectathons.*

Each IHE Connectathon is a cross-vendor, live, supervised, and structured testing event with as many as 100 participating vendors and 600+ engineers and IT architects.

All these organizations and IT experts converge on-site in the USA, Korea, Japan, China, Australia, Europe, and, soon Colombia/Brazil, for a full week of interoperability testing and problem resolution!

Participants test their products against multiple vendors using real-world clinical scenarios contained in IHE's Integration Profiles AND the national requirements.

# IHE Profiles Selected for the Saudi eHealth Exchange

- **Confirmed for the following Use Cases (Admin, Lab, Imaging)**
    - Patient Identifier Cross-exchange (PIX)
    - Patient Demographic Query (PDQ V3)
    - Audit Trail and Node Authentication (ATNA)
    - Consistent Timing (CT)
    - Basic Patient Privacy Consents (BPPC)
    - Cross-Enterprise User Assertion (XUA)
    - Cross-Enterprise Document Sharing (XDS)
    - Cross Enterprise Sharing of Scanned Documents (XDS-SD)
    - XDS-Imaging (XDS-I)
    - Sharing Laboratory Reports [XD-LAB]
  - **Under review for the following use case (Medical Summaries, Immunization, Referral, Medications)**
    - Medical Summaries [MS]
    - Community Medication Prescription and Dispense [CMPD]
    - Pharmacy Prescription Document. [PRE]
    - Pharmacy Pharmaceutical Advice Document [PADV]
    - Pharmacy Dispense Document [DIS]
    - Immunization Content [IC]
- iEHR Display Integration for Provider.



# There are now cross-national and cross-state IHE initiatives

- Cross-state (sort of an ATM network of networks model)
  - The Interoperability Working Group (IWG) has formed a 20-state consortium to build IHE-based Health Information Exchanges to allow medical data to flow inter- and intra-state
  - The Sequoia project is a similar project that crosses the VA and DoD security and interfaces with IHE-based data
- Cross-National
  - The epSoS program with the European Commission is a demonstration of 15-nation EU health data transport
  - The Trillium Project crosses US, EU, and Latin American borders

# Agenda

- IHE History
- **About the US interest in EHR and IHE**
- Where we are today
- Some critical success factors



# SO, how about our US of A?

## History and context for US's National Electronic Health Record (EHR) Initiatives



- **President George W. Bush** Executive order, 2004
  - Goal: electronic health records for each citizen
    - Created HHS ‘Office of National Coordinator’
    - Tasked ONC with National Strategic Plan
  - 2006 Executive Order requiring ALL new federal software purchases must be compliant
- **President Barak Obama** ARRA-HITECH, 2009 (Huge economic development investment to re-boot US economy from recession)
  - Goal: Certified EHR software adoption incentives
    - Penalties for security and privacy lapses
  - 2015 MACRA law, extending the clout of Medicare, VA, DoD, and CHIP, requiring EHR-based “pay for value”



# Current state of US interoperability

- “Majority” of primary care physicians and hospitals
  - **ARE** now using EMR software
    - Advances in ePrescribing, structured and coded documents, exchanging problem lists and allergies to coordinate care, and replacing paper
  - **BUT**, many frustrating limitations, flaws
    - Data are internally standardized, but loosely
    - Very limited interoperability between parties
      - No national Health Information Exchange standards
    - VERY substantial ongoing privacy breaches
    - Financial incentives are unaligned
    - WAY too little automation; hard work for all



Anyone in hospitals has heard about “Meaningful Use” or MU; which is driven by the 2009 ARRA-HITECH Act.



**MU 1 and 2 were scaffolds; MU 3 is an on-ramp to broader interoperability**

- Fortunately, a lot of MU 3 looks like an updated version of the IHE Profiles that were “baked into” the ANSI/HISTP Standards (2005-2010) (Google ANSI HITSP to find the libraries.”

***i.e., Industry knows a lot about those standards!***

**Selecting and using these software tools will take leadership, insight, and vision, because they will cause business process re-engineering.**



# Meaningful Use is DEAD?

## *Long live MACRA!*

- YES, in early January CMS announced “Meaningful Use” is ending.
  - *A week later, CMS and ONC explained “not really...”*

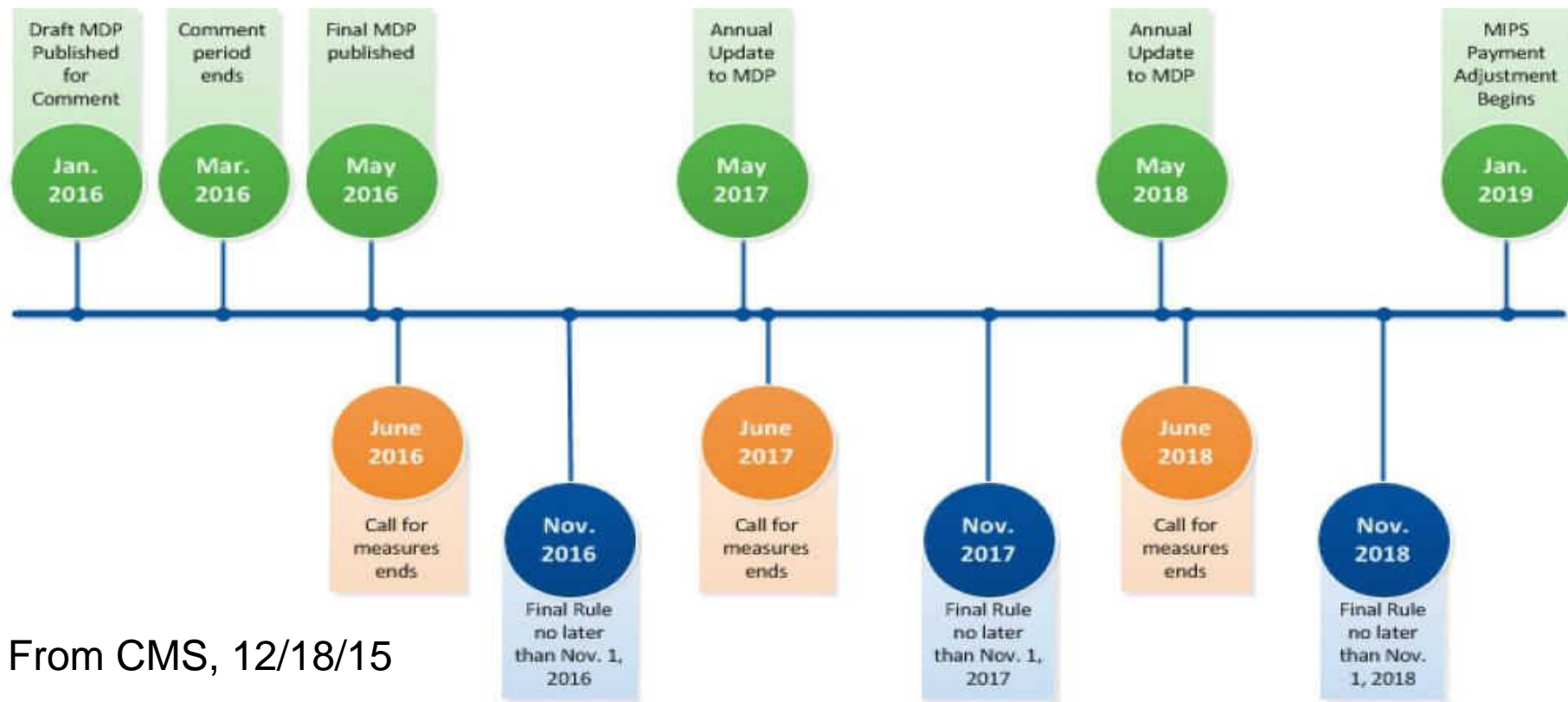
From CMS’s December 18, 2015 publication, MACRA was explained:

The passage of the Medicare Access and Children’s Health Insurance Program (CHIP) Reauthorization Act of 2015 (MACRA)<sup>3</sup> supports the ongoing transformation of healthcare delivery by furthering the development of new Medicare payment and delivery models for physicians and other clinicians. Section 102 of MACRA<sup>4,1</sup> requires that the Secretary of Health and Human Services develop and post on the CMS.gov website “a draft plan for the development of quality measures” by January 1, 2016, for application under certain applicable provisions related to the new Medicare Merit-based Incentive Payment System (MIPS) and to certain Medicare alternative payment models (APMs).



# Time keeps on slippin', slippin', slippin' into the future! *(Here's the new MACRA timeline.)*

Figure 1: Key Dates in the Measure Development Plan



# A rose by any other name...

SO, in their December, 2015 document, CMS explained that MACRA will look like this:

## Merit-Based Incentive Payment System

Beginning in 2019,<sup>vi</sup> CMS will apply a positive, negative, or neutral payment adjustment to each MIPS EP based on a composite performance score across four performance categories<sup>vii</sup>:

- Quality
- Resource use
- Clinical practice improvement activities
- Meaningful use of certified electronic health record (EHR) technology

**OK;** MU is dead! ***BUT,*** after 2019, CMS payments depend on **"*Meaningful use of certified health record (EHR) technology*"**



# Another critical factor in the US: *Industry collaboration, partnership, & transformation for Certified products!*



Working with industry and standards groups that ONC knows and trusts.

*Ultimately takes load off vendors, buyers, and regulators!*



## Critical success factor:

### ***Device data automation is in sight!***

- HIMSS, RSNA, IHE, HL7, DICOM, IEEE collaborations
  - Since 1998
  - Large number and variety of products, brands
    - Vendor neutral, IHE Rosetta Terminology mapping, coordinated by NIST
  - Many product's EHR interfaces are tested, some even certified, worldwide

**Lower clinician workload and stress,  
increase productivity and performance,  
reduce waste and errors!**

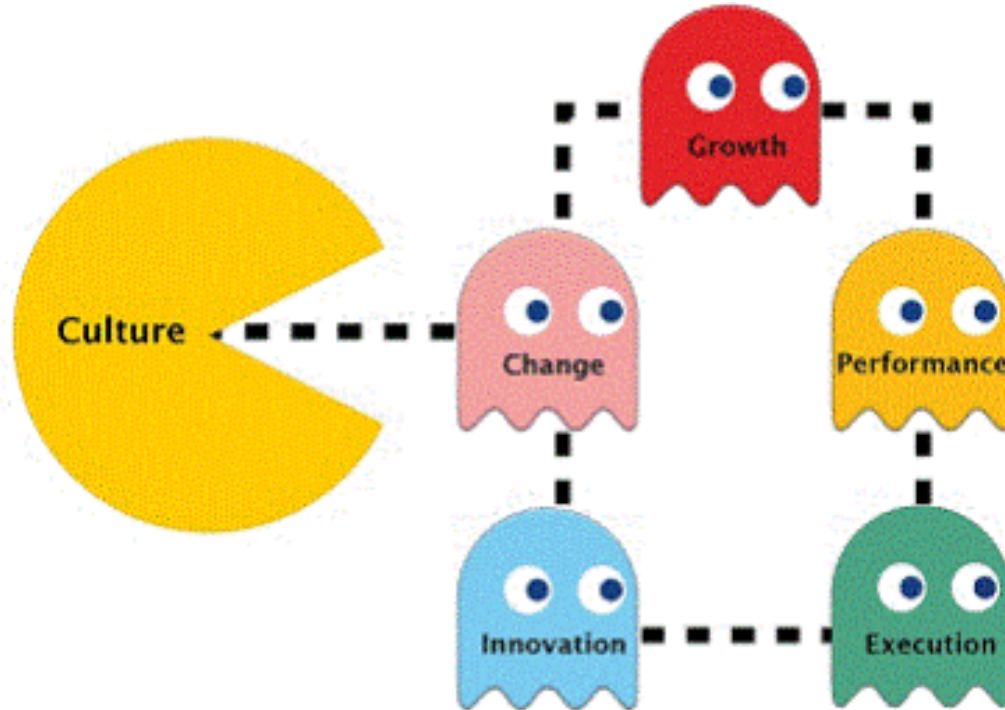


## What does this mean for Emergency Medicine?

- Advanced hospitals, like Kaiser Permanente, ARE already integrating medical device data from the home to the hospital, and ARE already integrating Electronic Health Record data for each of their patients
  - BUT, they are doing it manually, only using fragments of IHE when mandated by government.
- MOST other hospitals are wholly dependent on government requirements to cajole them to integrate their own data from department to department, LET ALONE data from nearby hospital competitors.

**WHY?**

# Culture eats Strategy for breakfast, lunch, and dinner!



**AAMI, INCOSE, ACCE, IHE, etc MUST work together to remove the technical barriers, but cannot ignore the cultural ones.**



## How can IHE help Emergency Care?

- First Responders (EMTs) could have immediate access to ALL relevant patient data, including diseases, meds, advanced directives.
- The ED could have immediate access to all EMT data AND all relevant patient data from sources NEAR, FAR, and the patient's own personal health record.
- ALL device data could be posted directly to the patient record automatically, needing clinician's verification one time, AND all data could be shown in graphic formats to speed context, interpretation
- All workflow tasks could be automated UNLESS clinical or operational conditions override.
- IT and communication could make data available at clinician's fingertips.
- Hospital operations could be allocated to match realtime demand.



The US government PAID for this specification nearly 10 years ago!



Free for the asking: Google "HITSP First Responder"

December 18, 2008

Version 2.0

# HITSP Emergency Responder Electronic Health Record Interoperability Specification

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HITSP/IS04



EMENTATION





# Conclusion



**AAMI has made FANTASTIC progress under Mary Logan and Carol Herman, becoming a thought and standards leader in the integration of “health technologies,” especially in the USA.**

**It is a challenge to transform the culture of clinical engineering and biomed, too!**

# Management of Complex Clinical System

Chapter 6 in:

Roberto Miniati | Ernesto Iadanza | Fabrizio Dori

## CLINICAL ENGINEERING

From Devices to Systems

Elliot B. Sloane

RESEARCH FACULTY, VILLANOVA UNIVERSITY CENTER FOR ENTERPRISE EXCELLENCE IN TECHNOLOGY, VILLANOVA, PA, USA; EXECUTIVE DIRECTOR, CENTER FOR HEALTHCARE INFORMATION RESEARCH AND POLICY, OSPREY, FL, USA

### Introduction

On September 8, 2015, the left General Electric jet engine on a British Airways Boeing 777 airliner departing from Las Vegas to England caught fire on take-off. The fire badly damaged the left wing, too, but the pilot and crew were able to abort the take-off and safely guide the jumbo jet to a place where all passengers and crew safely evacuated (British Airways Las Vegas plane fire: Eyewitnesses describe blaze).

Is this Boeing 777 incident relevant to Management of Complex Clinical Systems? In three words: "Yes, VERY relevant," because this incident illustrates how highly refined and effective the aviation industry's design, manufacturing, and maintenance have become. As we will discuss in this chapter, modern patient care systems have very similar profiles of complexity and risk. The clinical engineering profession needs to learn from, and adapt and incorporate,

Educating my colleagues is a HUGE undertaking. I began with AAMI in 2001; most still do NOT want to change.

*To that end, I just wrote a new chapter on the topic for Elsevier, painting the path towards systems engineering and ICT.*

Much more to come!



# Nothing stays the same, except change itself!

Heraclitus of Ephesus c. 535 BC – 475 BC



Take a careful look in the mirror.

*We have been all about INNOVATION  
since the beginning!*

**So, be careful what you wish for, but  
be relentless in pursuing it...**



## Review

- IHE History
- About the US interest in EHR and IHE
- Where we are today
- Some critical success factors



# Thank You!

**Elliot B. Sloane, PhD, CCE, FACCE, FHIMSS**

- **President**, Center for Healthcare Information Research and Policy, and
- **Co-Chair**, IHE International

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# Questions?

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