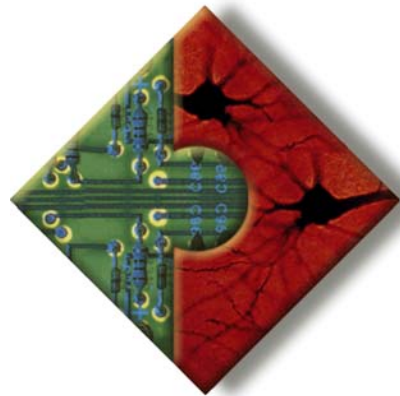




School of Biomedical Engineering, Science and Health Systems



## ***ACCE Teleconference Series***

***September 2, 1010***

# **Medical Devices and US Healthcare Reform**

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# My Bio Brief

- 35+ years in the medical technology and IT/HIT fields, as a technology/engineering expert and consumer/safety advocate
  - Biomedical and Clinical Engineering core
  - Information Systems and Sciences doctorate
- 25 years as a CIO, COO, CTO, CRO in the medical technology industry (ECRI Institute & MEDIQ, Inc)
- 10+ years in business schools, MIS, CS
- Since Nov, 2009 ***Health Systems Engineering Program Director and Research Professor*** at Drexel University, Philadelphia, USA
  - Recent NSF grant recipient for national Health IT Curriculum and Certification
  - Developing one of the early university-based Wireless Medical Device Interoperability Laboratory for teaching and research
  - Specializations: electronic health records, medical devices, privacy, security, and patient safety, wireless in healthcare, and related technical standards and policies
- Since mid-2008, **President and Co-founder of CHIRP**, a 501(c)(3) charitable agency
  - *Technology and policy research for personalized health care*



# Full Disclosure

I have no direct or indirect economic interest in, nor derive economic benefit or support from, any medical device or electronic health record software company

I hold or have held uncompensated board/member/chair roles with multiple non-profits, including ACCE, AHTF, CHIRP, IEEE EMBS, and RFID in Health Consortium, and with Standards Development Organizations including ANSI, IEEE-SA, IHE International, and IHE USA

I do provide consulting services to US gov't, the World Health Organization, and other government, educational, and non-profit agencies

I am also the founder and president of a US non-profit agency called the *Center for Healthcare Information Research and Policy (CHIRP)*

I am co-chair of the IHE International Standards program, and the EMBS Sponsor for the ISO/IEEE 11073.x Standards program



# Presentation Outline

- US Healthcare Reform
- The Role of Medical Device and Medical Device Systems
- Business as usual?



## **The 2010 Patient Protection and Affordable Care Act (PPACA) is “only” the largest of 3 Acts**

- e.g., In Act 1, medical technologies, specifically Electronic Medical Records, received over \$35 Billion in funding in the Feb 2009 Stimulus Bill (ARRA/HITECH) which turns out was only the tip of the iceberg
  - Provides funding for National Electronic Health Record for all citizens by 2015, with advanced Clinical Decision Support Systems (CDSS) in place by that time.
    - The CDSSs focus on primary care, chronic disease care, and population health, using outcomes data to reward best practices (and to punish worst practices)
  - By 2015, HITECH will also be providing funding for “Remote Monitoring” of chronic care and other patients at home and other sites



# THE “US Healthcare Reform” Act is really “Act 2”

- The PPACA brings **\$940 Billion** into healthcare in the first decade, (*\$923 B of which kicks starting in 2015!*)
  - 32 Million new insured Americans into healthcare by 2019, adding >10% to our patient pool
    - A good portion of the 32 Million will be coming from relatively poor health status, having had no safety net except for the ED for most of their lives
    - Still leaves about 19 million uninsured citizens, plus all illegal aliens, in the “ED First” crowd
  - Most “underinsurance” gaps, e.g., pre-existing conditions and Medicare medication costs, will be eliminated for the 280 Million “fully-insured” Americans by 2019



# How is Act 2 going to be accomplished?

- Significant new revenues and savings
  - e.g., the controversial 2.9% federal tax on the sale of medical devices (aside from common necessities like eyeglasses)
  - Personal and corporate payments of new health insurance taxes
  - DIFUSSION of healthcare to other points of service and to other service providers



## Nurses (and other allied health professionals) are being mobilized – and paid!

- New education and roles for nurses to be directly responsible for health care
  - Nursing-run Community Health Centers are given special privileges and roles
  - e.g., Drexel’s “11<sup>th</sup> Street Health Center”
    - <http://www.drexel.edu/11thstreet/pdf/Drexel-11thSt.Tribune.pdf>
    - Run by nurses, and delivering primary care in urban communities
  - Many more roles, authorities, and funding are defined for nurses
    - Provides nurses with direct clinical privileges to provide primary care in communities, outside of the hospital setting,
      - Creates a nursing-run public health system
    - New education for nurses to provide geriatric and other care

SEE: <http://www.aacn.nche.edu/Government/pdf/HCRsupport.pdf>



# Huge new funding coming online for Telehealth – “Act 3”

- FCC *MUST* spend up to \$400 Million PER YEAR to improve rural “deployment of broadband for healthcare”
  - These funds are from the Clinton/Gore days, from the \$1/month/cell phone taxes we have all paid for over a decade!
  - Some of those funds are implicated in the PPACA
    - e.g., CMS (“Medicare and Medicaid”) is charged with implementing an “Independence At Home” program
    - Independence at Home uses home telehealth monitoring to allow elders and patients with chronic diseases to live at home instead of Long Term Care facilities



# In fact, telemedicine and telehealth play a major role in PPACA!

- Formally, “telemedicine” is the only kind of service reimbursed by CMS today
  - A long list of CMS-reimbursed remotely-monitored physician visits is in place, but all require “audio and video telepresence” of a practitioner
    - e.g., initial intake or discharge to SNFs or LTCs can be done with telemedicine and reimbursed as if in person.
    - Telemedicine must be provided at a non-home site of service, *including nurse-managed Community Health Centers!*



# “TELEHEALTH” services are much broader, and part of PPACA

- e.g, for the PPACA ***Independence at Home*** program, home based telehealth will have to be quickly defined – and funded – by CMS!
  - You can bet that will mobilize technology AND nurses!
  - e.g., nurses (and other less costly health professionals) already play a significant role in billable “Telemedicine” services. That list includes:
    - Physician;
    - Nurse practitioner;
    - Physician assistant;
    - Nurse midwife;
    - Clinical nurse specialist;
    - Clinical psychologist,\*
    - Clinical social worker;\* and
    - Registered dietitian or nutrition professional.

For details, see

[http://www.americantelemed.org/files/public/policy/Medicare\\_Payment\\_Of\\_Services.pdf](http://www.americantelemed.org/files/public/policy/Medicare_Payment_Of_Services.pdf)

& <https://www.cms.gov/Telemedicine/>

***Interesting to note that CMS characterizes “telehealth” as “store and forward” technologies rather than real-time medical care.***



# In short, in the 10 years from 2010-2019, FCC's "health technology" funding is huge

- \$4 Billion in rural telemedicine "pilot projects" that will greatly expand broadband's "last mile" reach to rural clinics, provider practices, and, of course, homes
  - FCC recognize this moves their (formerly) communications-only funding into medical care, and in July, '10 they signed an MOU with FDA to ensure the safety of the products and services that FCC brings to the market
    - Both "broadband and wireless" technologies
    - See:  
[http://www.fcc.gov/Daily\\_Releases/Daily\\_Business/2010/db0726/DOC-300200A2.pdf](http://www.fcc.gov/Daily_Releases/Daily_Business/2010/db0726/DOC-300200A2.pdf)



# Many of these funding sources – and regulations – “interlock”

- e.g., the current CMS telehealth reimbursement is currently restricted to underserved populations in non-urban settings
  - The FCC’s funding reinforces that emphasis
- Newly issued CMS regulations will cut through the “staff privileges” bottleneck that has locked up inter-state telehealth privileging.
  - Hospitals were required to individually “privilege” each telehealth practitioner,
    - Put the hospital and practitioners at odds with state credentialing boards
  - Under the proposed CMS regulation, hospitals will be allowed to accept the recommendations of other credible sources for each practitioner they “privilege” for CMS-reimbursable telehealth
- Reimbursement wording is shifting from “physician” to “practitioner” in many federal bills to empower – and compensate – nurses and other allied health professionals



# FCC's \$400 M/year focuses on “the last mile” to Rural America

(From the MOU)

“The goals of the FCC-FDA collaboration are to explore ways to:

Further enhance information sharing efforts in order to further ensure the safety and efficacy of **medical devices**.

Improve the efficiency of the agencies' regulatory processes in areas where their jurisdiction overlaps, such as with respect to various **medical devices** that utilize broadband and wireless technology.

Promote efficient utilization of tools and expertise for **product analysis, validation, and risk identification**.

Build infrastructure and processes that meet the common needs for evaluating broadband and wireless enabled **medical devices**.”



# Presentation Outline

- US Healthcare Reform
- **The Role of Medical Device and Medical Device Systems**
- Business as usual?



# Evolution of Medical Devices to Medical Device Systems of Systems (SoS)

- 1950's – 1970's
  - Almost all individual devices, analog I/O, no standards
- 1970's
  - Mid-1990's some single-brand SoS, like an HP or Philips Central Nursing Station or a GE PACS (RS-232 serial data interface)
- Mid-1990's on
  - Emergence of PC networks, and shift of medical device data to LANs
- 2004 onward
  - Global standards drive towards multi-vendor, multi-product interoperable device standards for flexible and complex SoS configuration/reconfiguration
- 2010 onward (eHealth, mHealth, uHealth, pHealth)
  - Global medical device and electronic health record (EHR) interoperability at the Point of Care (bedside, home, mobile)



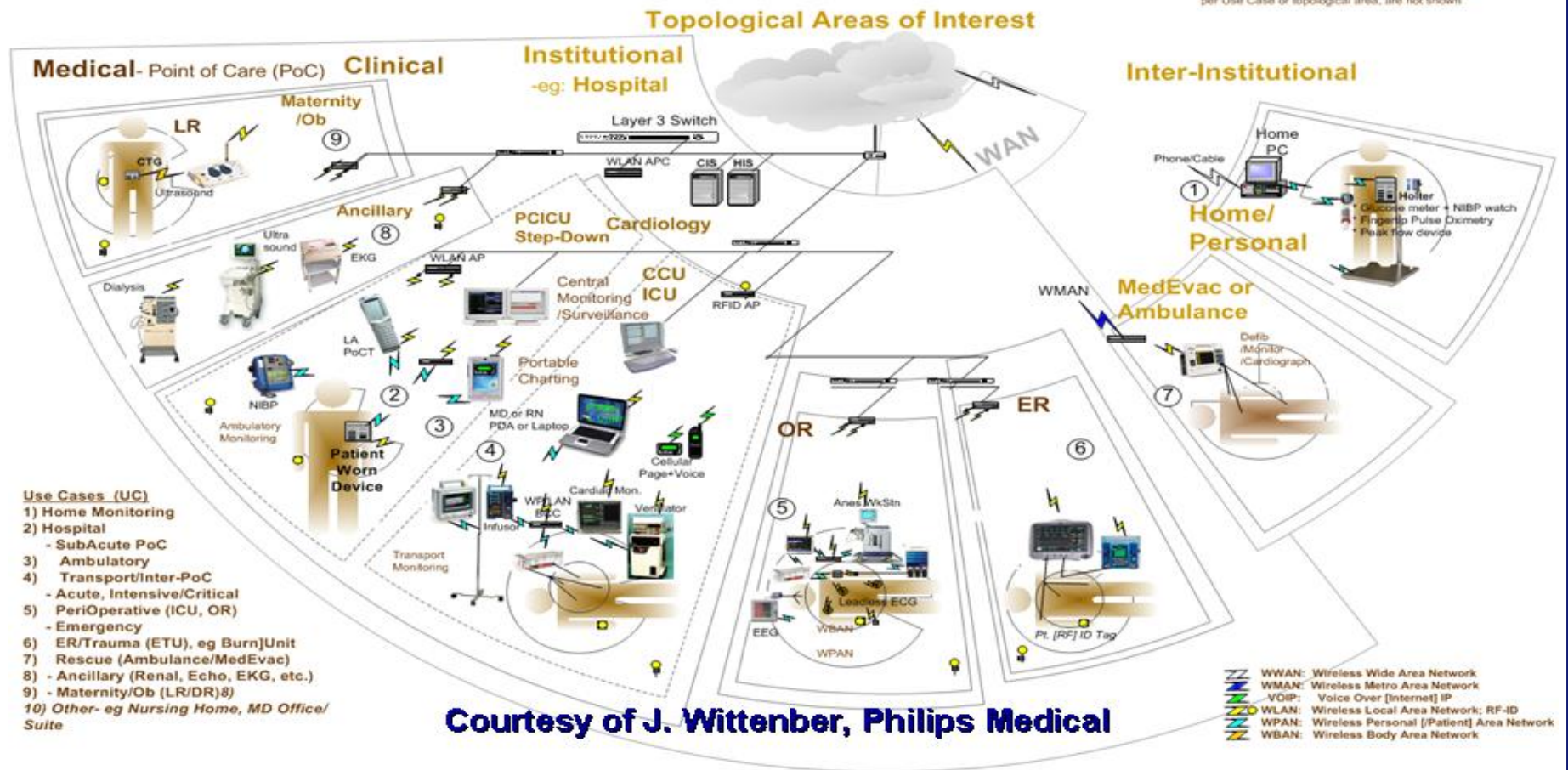
# A Wireless Medical Systems Map

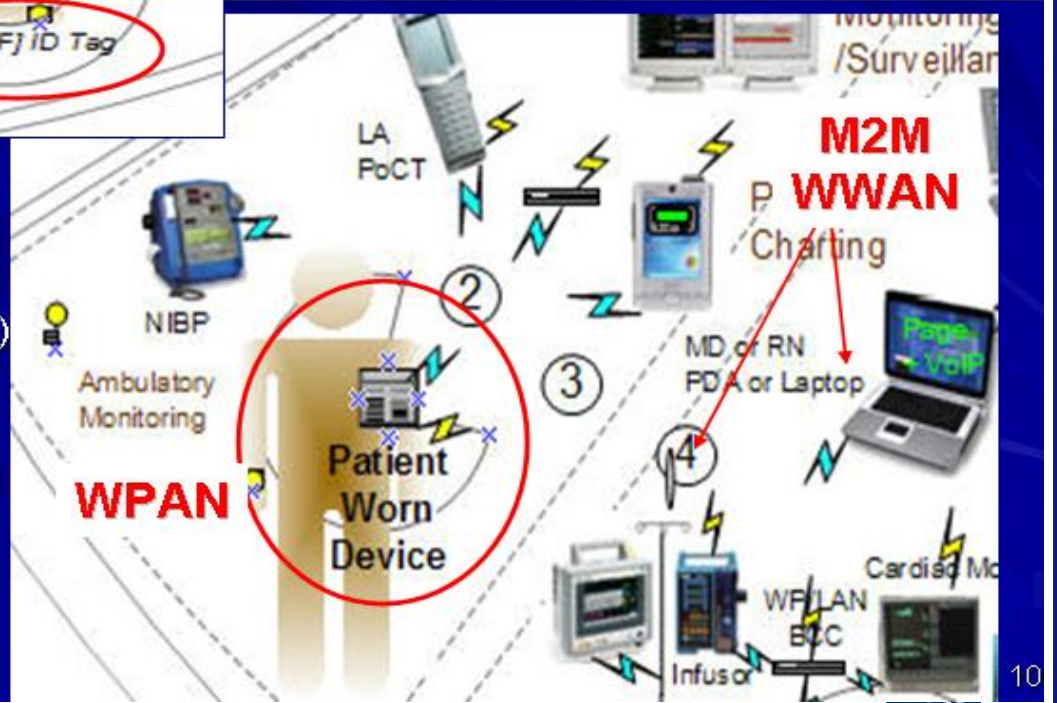
Medical Device Semantics and Communication Modalities Use Cases

IEEE 11073.x and IEEE 802.x Standards At Work

22July10 Rev 4a

Note:  
1) Drawings are intended to be representative of devices; do not take literally!!  
2) Scaling factors, eg number of AP's or PWD's, etc., per Use Case or topological area, are not shown





### Wireless medical system networks

- Body Area Network (ZigBee)
- Personal Area Network (Bluetooth)
- Wide Area Network (Wi-Fi)
- Metropolitan Area Network
  - Cellular
  - Wi-Max (4G)
  - 3G



# Common elements of the Medical Device SoS environment

- Today, almost 100% Ethernet (IEEE 802.3) and/or WiFi (IEEE 802.11 a/b/g/n) based
  - Rapidly evolving to wide- and metropolitan-area networks (WAN and MAN) for mobile health (mHealth) using IEEE 802.11n/m, 3G and 4G cellular
- Rapid global uptake of ISO/IEEE 11073.x medical device semantic interoperability standards for data structure and content
- Rapid global uptake of open-source Integrating the Healthcare Enterprise (IHE) Electronic Health Record *AND* IHE Patient Care Device (IHE-PCD) data interchange standards



# International Adoption of IHE

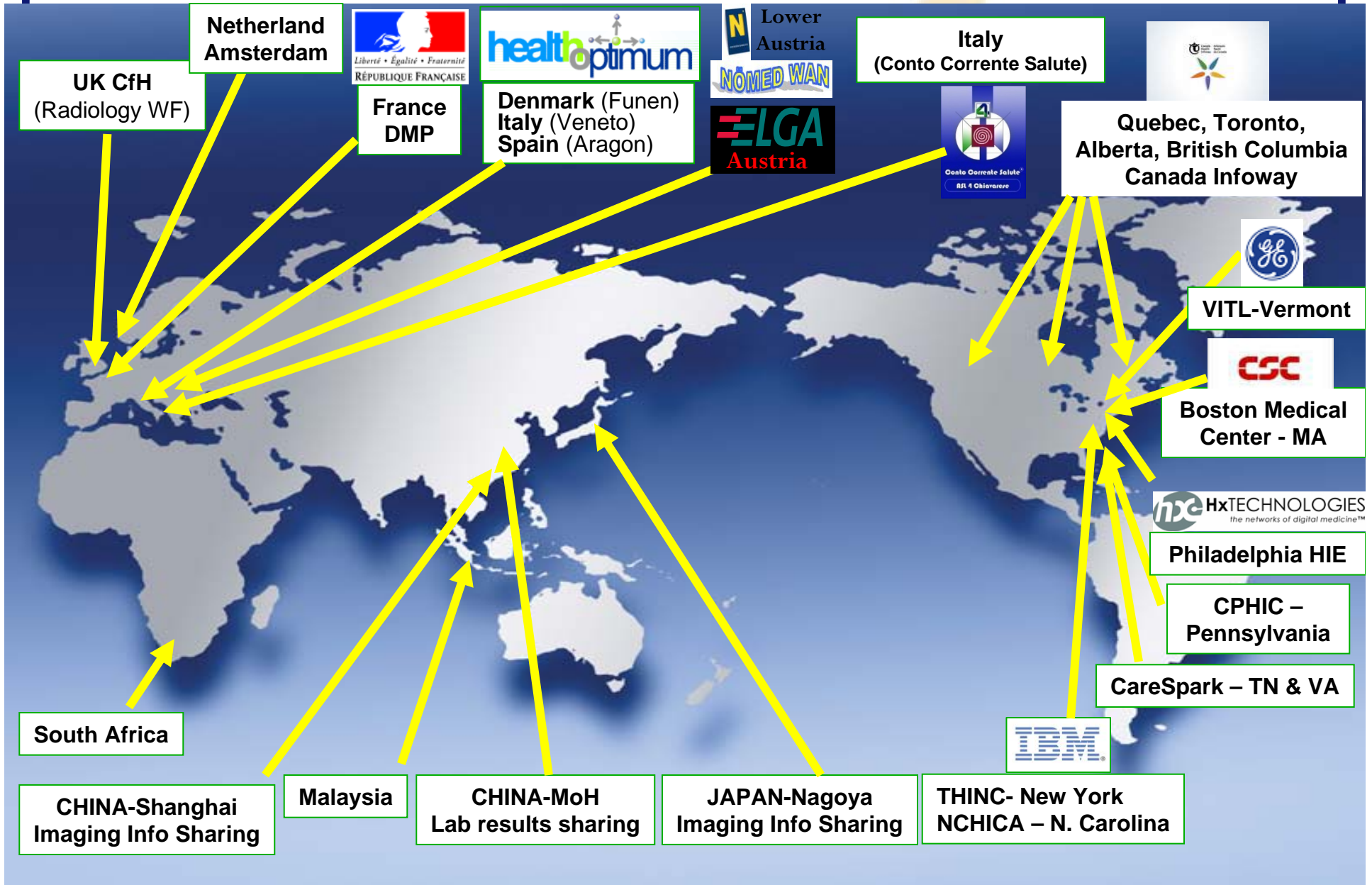
- Local Deployment, National Extensions
- Promotional & Live Demonstration Events
- Over 300 Organizational Members (all stakeholders)



Pragmatic global standards harmonization + best practices sharing



# National and Regional Projects Use IHE Profiles





# Interoperability: From a Problem to a Solution

## Base Standards

Logos for Base Standards organizations: OASIS, IETF, ISO, W3C, cen, DICOM, IEEE, HI7, CDISC, LOINC, IHTSDO, ITU.

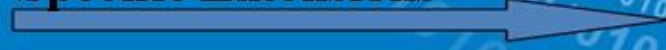
## Profile Development

Logos for Profile Development organizations: IHE, Continua Health Alliance.

## eHealth Projects



## Specific Extensions



**Profiling Organizations Have Emerged**



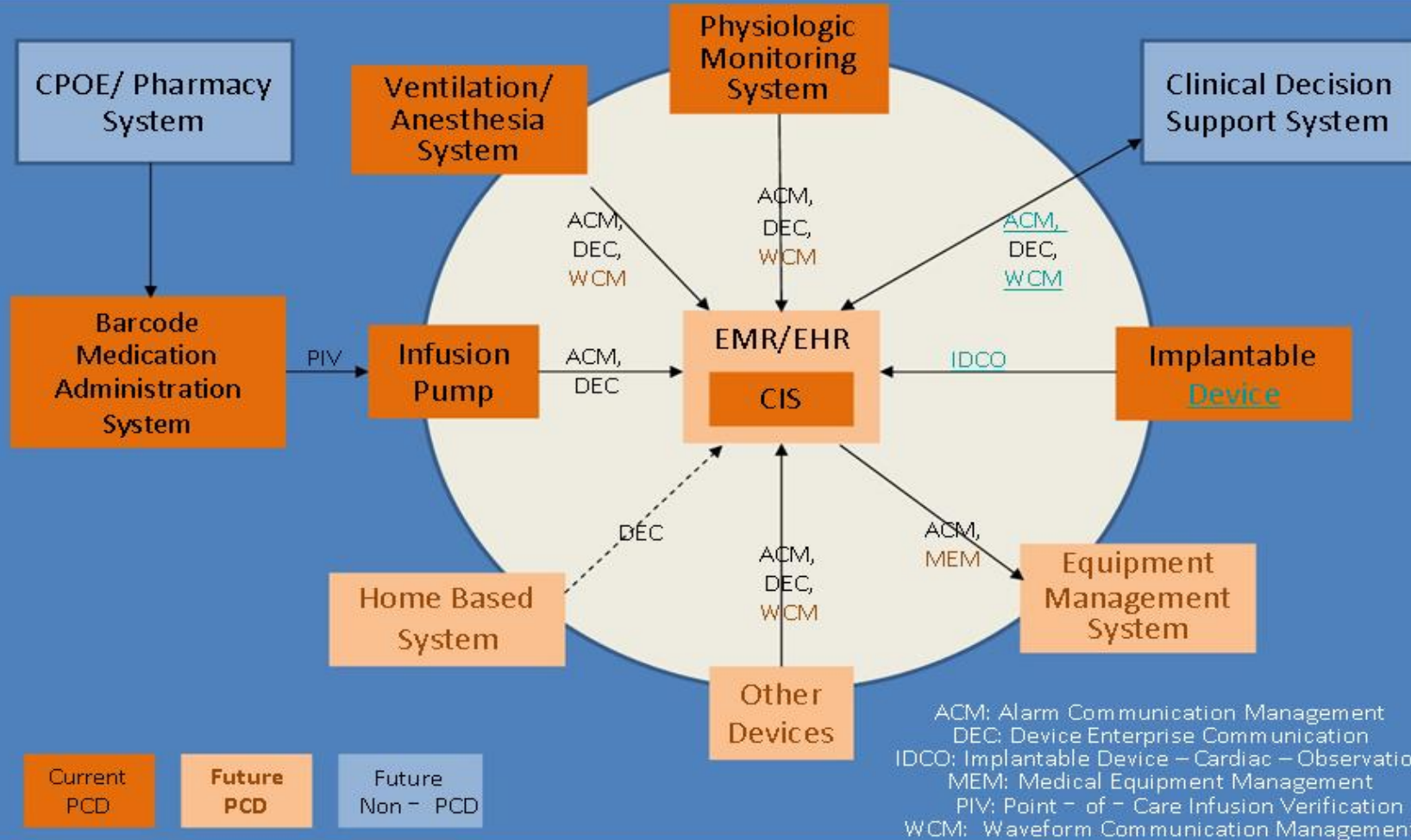


# Disclosure

- I will give you more details about the IHE-PCD SoS framework because I do not directly participate in and am not a member of the Continua Alliance program, nor the ASTM Integrated Clinical Environment program (ASTM F2671-2009)
  - I cannot and do not formally speak for or represent their views
- I consider them partners in our IHE and IEEE efforts to improve patient care, and recommend that you read Bridget Moorman's AAMI article as one source of more complete details
  - [http://www.continuaalliance.org/static/cms\\_workspace/132-138\\_IT\\_WorldMA2010.pdf](http://www.continuaalliance.org/static/cms_workspace/132-138_IT_WorldMA2010.pdf)



# IHE PCD – Profile Overview

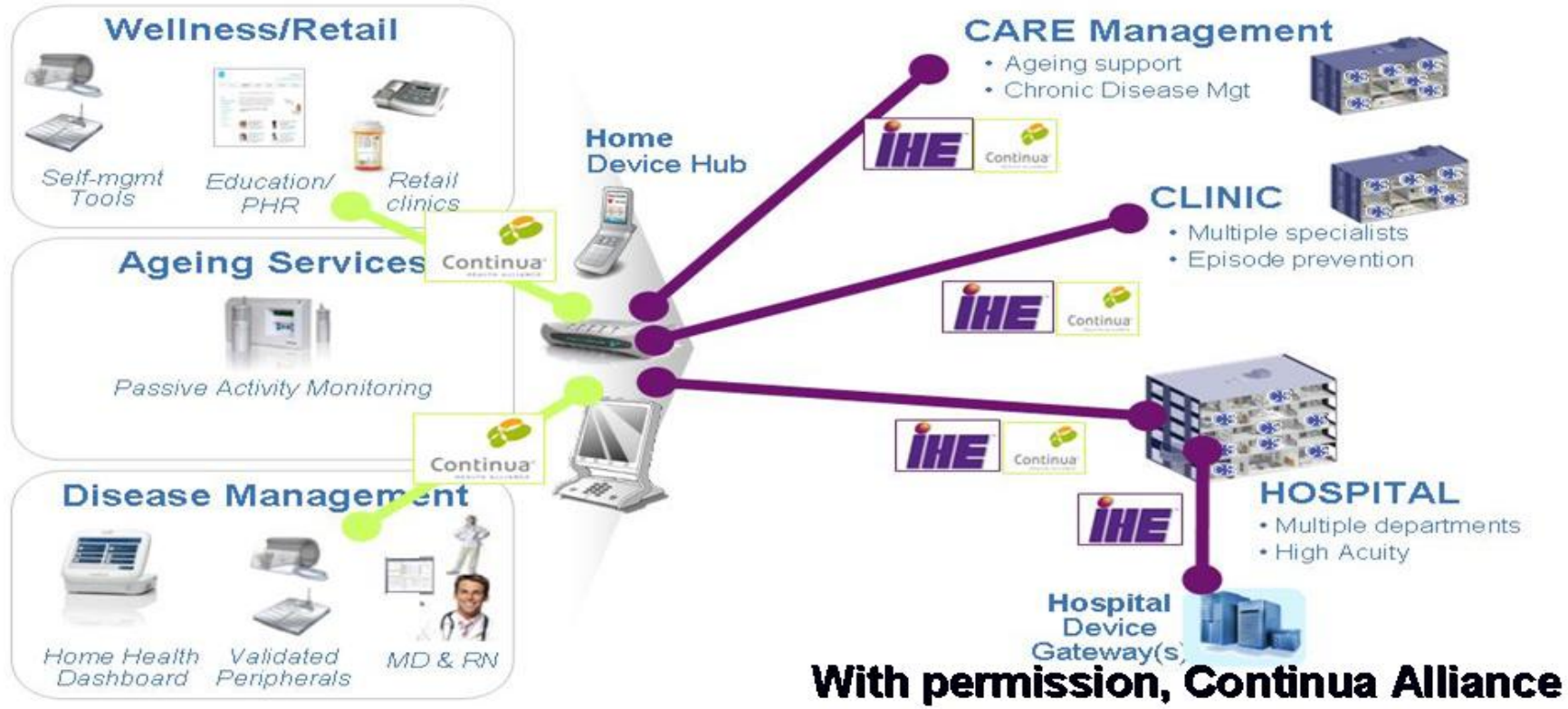




Beginning this Fall, a single data interface architecture can be used by all Continua Personal Health Devices, all IHE-PCD Medical Devices, and all IHE EHRs!

### Home health – Key connection Standardized

IHE and CONTINUA have agreed to support the a single common IHE DEC profile for feeding home device data and clinical device data into health records





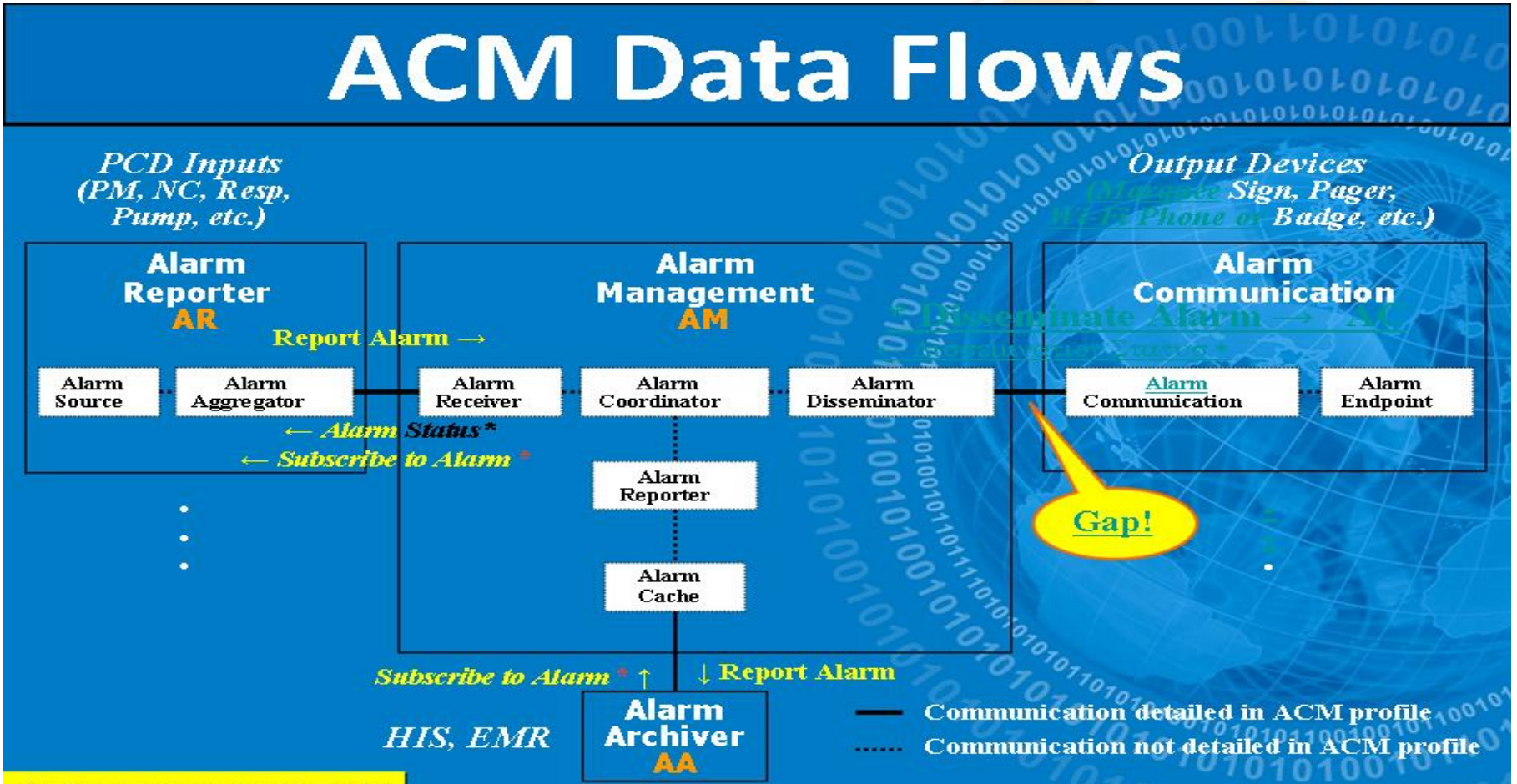
## IHE-PCD and Continua “live” in two different but overlapping worlds

- *Continua* – **Personal Health Devices** non-regulated personal appliances, non-life-critical settings like home, car, gym, simple data sets
  - Personal wellness status, chronic illness home care
- *IHE-PCD* – Full-on clinical devices and applications, from home chemotherapy through intensive care, implanted devices, and surgery
  - Becoming MUCH more mobile, including relative acute care management at the home
- *Both products must co-exist in the home, with overlapping missions, different price-points*



e.g., IHE (and ASTM-ICE) have to tackle life-critical, real time Alarm Communication Management

# ACM Data Flows



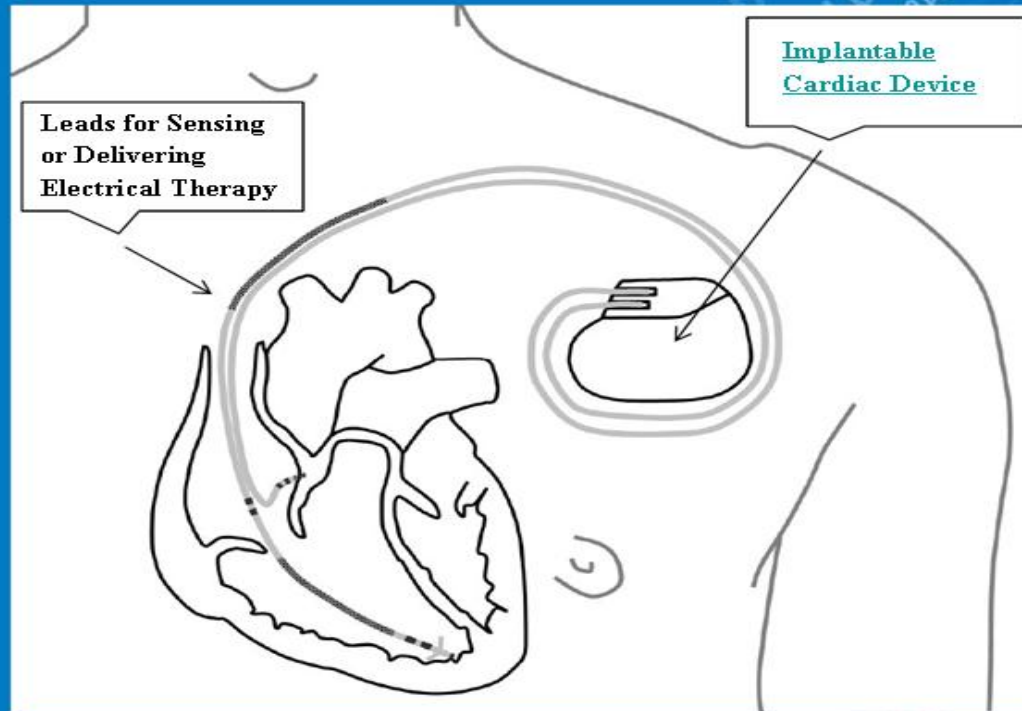
\*Note: Implementation TBD





e.g., IHE-PCD has to tackle implants

# Implantable Cardiac Devices





# Profiling has emerged as a POWERFUL enabler

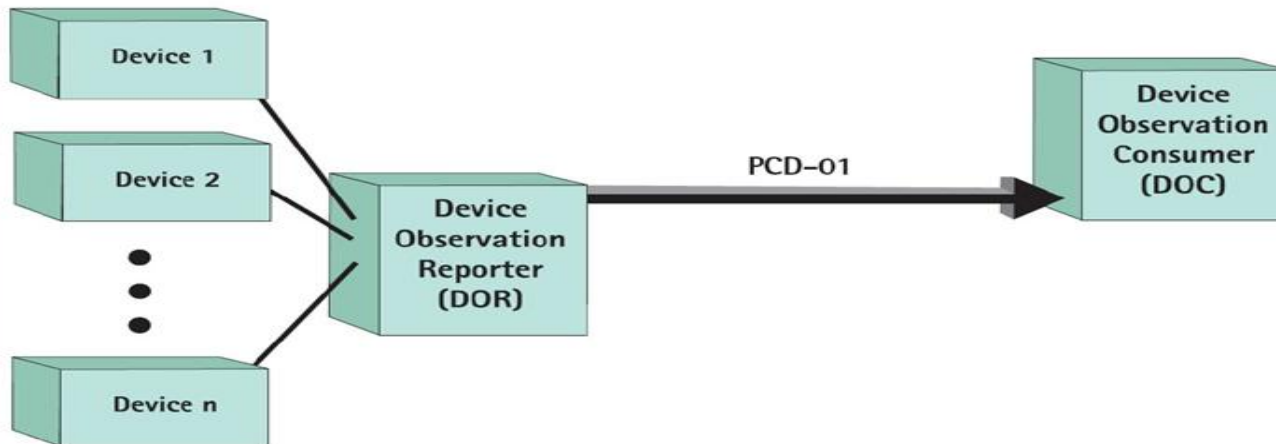
- IHE's and Continua's "Integration Profiles" take myriad "base standards" such as DICOM, ICD9/10, HL7, or IEEE and "**CONSTRAINS THE OPTIONALITIES**"
  - e.g., Each base standard has a different (or many different) coding choices and data structure locations for Date and Time
  - An Integration Profile **specifies the SOLE option** to be used for each standard AND **specifies a SOLE Global Standard** for "Universal Timekeeping" (typically "internet time")



e.g., IHE-PCD and the **Continua-WAN** profile have adopted the same “DEC” profile to enable interoperability

## Device to Enterprise Comm. (DEC)

The Device to Enterprise Communication (DEC) profile allows a consuming device to receive patient clinical information including vitals, settings, demographics and location from a reporting device.



*Look for new Continua-WAN products this Fall/Winter*



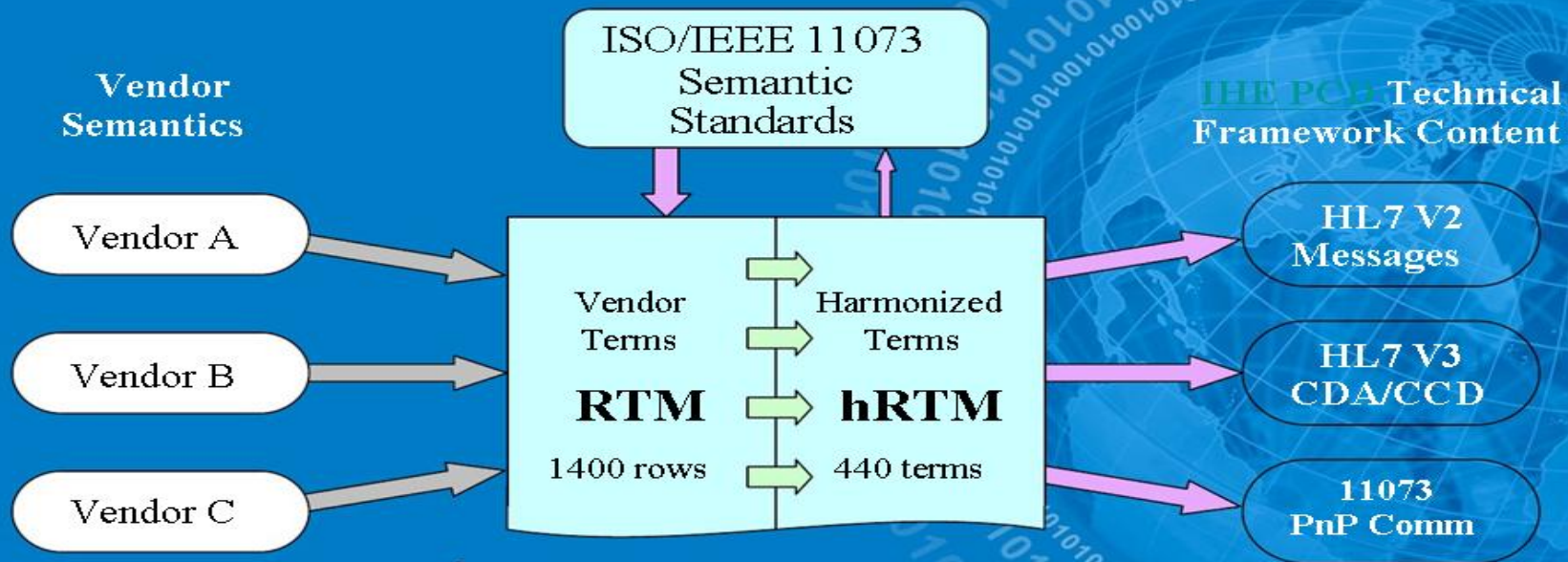
# The **GREAT** news?

- With Continua, ASTM-ICE, and IHE-PCD working together, all of our work can converge in ways that intersect the global trend for interoperable Electronic Medical Records!
- The GLOBAL leadership to ensure the inclusion of all of our good works in the international ISO and HL7 frameworks goes to the near single-handed expert leadership of Todd Cooper, by the way.
  - You have NO idea how much work that guy does for YOU!



# What's "inside the box?" The EMBS IEEE 11073.x standards are foundational to both Continua and IHE

## Rosetta for Semantic Interoperability



- Open consensus process
- Observation identifiers *and* co-constraints
- New terms incorporated into standards
- hRTM used for conformance testing



# IHE's *Rosetta Project* maps ALL vendor clinical coding to each other via IEEE 11073

## Rosetta for Semantic Interoperability

### PCD ROSETTA PROJECT

Named after the Rosetta Stone, the PCD Rosetta Project maps existing and proprietary vendor parameters and units-of-measure for virtually all physiological measurements to the ISO/IEEE 11073-10101 vital signs nomenclature and related standards such as UCUM.



This will facilitate real-time interoperability between devices and systems, including EHR systems using the IHE PCD-01 Technical Framework.

This level of collaboration for the common good is open to all vendors in the IHE PCD.



### PCD ROSETTA PROJECT

Creating common terminology for device connectivity

<b>Neuromonitoring</b>	<b>Gas Delivery</b>
<b>Respiratory</b>	<b>Gas Monitoring</b>
<b>Cardiovascular ECG</b>	<b>Cardiovascular Hemo</b>
<b>Blood Chemistry</b>	
<b>Urine Output</b>	<b>Infusion Pumps</b>
<b>Temperature</b>	<b>Transcutaneous</b>
<b>Patient Demographics</b>	





# IHE Rosetta Project

- Now over 400 columns of vendor-specific mappings of clinical variables and globally-harmonized UCUM units of measurements
  - e.g., Every brand of ECG monitor, EHR, or IV pump can “know” the kinds of data that other branded products might send, and can therefore translate that information correctly
  - This is **ESSENTIAL** for life-critical data preservation, interpretation, and, ultimately, closed-loop multi-vendor systems



# The ISO/IEEE 11073 Standards began a long, long time ago

- They've come of age today, now formulated as semantic interoperability standards instead of an "electrical medical information bus"
- FYI, The IEEE 11073 standards are all chaired by Todd Cooper, too! (Next time you see him, remember to thank him heartily, please, for that thankless task.)



## All IHE and IHE-PCD profiles are FREE to download and use

- [www.IHE.net](http://www.IHE.net) and [www.IHE.net/PCD](http://www.IHE.net/PCD)
  - The IHE-PCD profiles are a joint product of ACCE, HIMSS, and IHE
    - IHE International and IHE USA are now independent non-profit agencies, incorporated in IL, and filing for 501(c)(3) status with the IRS
- Continua Alliance is also a non-profit agency, and its profiles are proprietary and require membership in the Community or direct purchase
- ASTM, HL7, and IEEE 11073.x standards must be purchased for use
- Happily, the complex IEEE 802.x Communications Standards ARE available for free, 6 months after they are published!
  - <http://standards.ieee.org/getieee802/>



# Presentation Outline

- US Healthcare Reform
- The Role of Medical Device and Medical Device Systems
- **Business as usual?**



# Business as Usual? I don't think so!

## Many new opportunities are emerging

- In order to meet the US Health Reform goals, flexible, multi-vendor interoperable medical device solutions must finally be deployed
  - These are needed to facilitate telemedicine, eHealth, and mHealth as well as acute care, in-hospital uses
  - *Human data entry will be minimized, freeing up valuable physician, nurse, and caregiver time AND reducing errors!*
- Asset management (procurement, deployment, maintenance) should become easier as more interoperable products come to market



# Electronic Medical Records REALLY get put to use!

- The Electronic Medical Record systems will begin to share timely and accurate data regionally and nationally
  - **Personalized Health and Wellness, Pervasive Healthcare (pHealth), and Ubiquitous Healthcare (uHealth) can emerge.**
  - **Personal, national, and global quality of care, clinical outcomes, and overall population health will become easier to see and manage in real time!**



# So, in short, CE opportunities and responsibilities *SHOULD* grow

- More healthcare technologies, including EMRs/EHRs, than ever are going to be deployed
  - New regulations, standards, and services are going to emerge this decade!
  - ACCE should move to the forefront of those policy decisions to support the engagement of AAMI, HIMSS, and others.



# Consequences and Challenges

- Interoperable systems are relatively complex and have many hidden interdependencies
  - When one system or sub-system fails, many systems may fail too
  - Risk assessment and risk acceptance strategies need to emerge for planning and commissioning such systems
    - The ICT exposures, for example, are significant. Consider, e.g., if a single virus or worm enters such systems!
    - Wireless, though it provides essential mobility and point of care interventions, is vulnerable to interference and privacy breaches



# There are many System of Systems Engineering (SoSE) Challenges

- e.g., Verification and Validation of SoS is relatively new field of research
- “Emergent Behaviors,” i.e., unanticipated human-system interactions and effects are a new class of “unintended consequences” that DEFINE SoSE research
  - e.g., people with complex implants are now traveling on airplanes and are being asked to shut off their wireless interfaces!
- Clinical Engineering needs a whole new toolkit!
  - ICT- and SoS-aware actionable strategies, toolkits, and checklists need to be written, tested, published, and adopted by our profession ASAP!



# New Medical Device SoSE Challenges

- Regulation is going to be tough.
  - Where does the medical device end? The box itself, the interface, the network, the sub-system? Who/what is regulated?
  - Software engineering comes to the forefront, including Software Development Life Cycles (SDLC) including Agile and Extreme methods, Change Management, and State Machine Programming
  - IEC 80001 is a Risk Management strategy that harnesses the hospitals and the vendors together, but who is really responsible??
  - Security management of homogeneous, open, interoperable, and interdependent systems is going to present challenges!
    - On the other hand, relatively autonomous sub-systems might be more robust... *but only if designed that way.*



# Help take on another challenge: Facilities for Wireless Medical System and Interoperability Testing are needed

This field will continue to evolve, and contemporary teaching and research resources do not exist.

***I am building a baseline Wireless Medical Device Interoperability Laboratory (aka “sandbox”) this winter at Drexel University’s School of Biomedical Engineering, Science and Health Systems.***

Quite frankly, MANY more are needed around the country to support R&D in this important area properly.

We will be glad to collaborate with YOU to help you set up your own!



# Presentation Review

1. US Healthcare Reform
2. The Role of Medical Device and Medical Device Systems
3. Business as usual? ***“I don’t think so!”***



# HUGE funding and policy changes for primary healthcare and telemedicine are arriving NOW

- More professionals and more of the public will receive incentives to ***use medical technologies*** to improve healthcare safety, efficacy, quality, and cost-effectiveness

**CE's have to lead, follow, or simply  
get out of the way!**

**ACCE needs to get to the Policy Table at FCC,  
FDA, and HHS/ONC, among others!**



# This is New Golden Age of Clinical Engineering!!

- If you don't have the right skills,
  - Get cracking and *get them pronto!!!*
    - The world is not going to wait around.
    - Don't wait for another invitation...
- A great, and free, resource for medical device interoperability is the HITSP Technical Note 905 (TN905), available for download at [www.HITSP.org](http://www.HITSP.org)!
  - HITSP has “gone dark” for now, but the online resources live on!



# Resources

- [www.CEITCollaboration.org](http://www.CEITCollaboration.org)
- [www.ContinuaAlliance.org](http://www.ContinuaAlliance.org)
- [www.HITSP.org](http://www.HITSP.org)
- [www.IHE.net](http://www.IHE.net)
- [www.IHE.net/PCD](http://www.IHE.net/PCD)
- <http://standards.ieee.org/getieee802/>



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**I will be glad to send you a copy of this presentation.**

**Thank you.**