Current Advances in Medical Device and EMR Interoperability and Integration

IHE Patient Care Device Domain (IHE-PCD)

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President, Center for Healthcare Information Research and Policy

www.iheusa.org – www.IHE.net/PCD
www.ebsloane.org
Some of the current FAQs:

Elliot B. Sloane, PhD, CCE, FHIMSS
President & Founder
Center for Healthcare Information Research and Policy

HIMSS roles:
Board of Directors, Delaware Valley HIMSS
Past Chair, HIMSS Security and Privacy Steering Committee

IHE roles (IHE = Integrating the Healthcare Enterprise, a quasi-standards body):
Co-Chair, IHE International Board of Directors
Board of Directors, IHE-USA
Co-founder, IHE-Patient Care Device Domain

Other professional roles:
Sponsor, IEEE 11073 Medical Informatics Standards
Past President, American College of Clinical Engineering
Past Board of Directors, IEEE EMBS
Past Board of Directors, ANSI/HITSP project

www.ebsloane.org &
www.ebsloane.org/HealthSystemsEngineering/
How I’ve passed my misspent youth: 40-years on “A road less followed,” or maybe “A long and winding road,” or maybe just “The long way round…”

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

10 years in publicly-traded corporation, medical device manufacturing, repairs, 24x7 rental/delivery, and med/surg/drug manufacturing and distribution
   At MEDIQ Life Support Services, from COO through CTO and CRO

13 years as a professor (10 in B-School, 3 in Biomedical Engineering and Health Information Systems)
   Third phase of my “See one, do one, teach one” journey?

“Slow and steady adult learner!” 5 yrs of undergrad biomedical engineering that was then slowly seasoned with part-time MS and PhD classes while working!
What is a Medical Device?

- FDA definition: a device, product, or contrivance (including software) that affects patient diagnosis and/or treatment
  - Examples
    - Heart monitor
    - Blood pressure monitor
    - Blood glucose monitor
    - Pacemaker
    - Suture
    - Band Aide
    - Tongue depressor!
Broad Medical Device Categories

• “Picture-based”
  – **Cardiology** (Ultrasound echocardiology, diagnostic cardiology) – *Handled by IHE Cardiology*
  – **Imaging** (CT, MR, Mammo) – *Handled by IHE-RAD*
  – **Pathology** (Cell prep, cell identification, sample management) – *Handled by IHE-Pathology*

• Numeric data based
  – **Laboratory** (Blood cell counters, assays, blood gas) – *Handled by IHE-Lab*

• Blended pictures and data
  – **Radiation Oncology** (linear accelerators, gamma knife) – *Handled by IHE-RadONC*

“EVERYTHING ELSE” – *Handled by IHE Patient Care Device Domain!*
What is a “Patient Care Device?”

• **Patient Care Devices** include
  – Medical Devices **and** Personal Health Devices

• **Medical Devices** are FDA regulated, typically solely for use under the order and control of licensed physicians
  – Almost all hospital, nursing home, and home care devices

• **Personal Health Devices** are consumer products, not claiming medical device status, and not regulated by the FDA
  – May be purchased by consumers themselves (fitness, wellness)
  – Fill an emerging telehealth gap, involving clinicians on an as-desired basis
Patient Care Devices: very different than EMR systems!

- Quantity
- Size and Mobility
- Diversity
- Nature and type of data
Sheer Quantity!

- Large teaching hospitals may have
  - 30 imaging devices/systems,
  - 20-40 cardiology devices/systems,
  - 20-30 laboratory and pathology devices/systems,
  - 4-10 radiation oncology devices/systems

- But, large teaching hospitals may have 6,000 medical devices, and large health systems (like Kaiser Permanente) may have 250,000 medical devices!

- The exact same devices are used in home care, too
  - A large teaching hospital may have >2,000 medical devices in their home-care pool, too!
Size and Mobility

- **MOST** medical devices are *stand-alone* boxes and are *mobile*!
  
  - Some medical devices (perhaps 20%) are part of large systems (e.g., centrally-computerized smart IV pump systems, and ICU patient monitors)
    
    - “Systems” may be a bit easier to integrate with EMR because a central computer can transform data

- **More and more medical devices**, like pacemakers, implanted insulin pumps, and holter monitors, are *solely mobile*, and come and go with the patient! (Maybe 3%)

**Mobility** adds “fun challenges” like wireless networking & security! e.g., OK, the patient is having a heart attack. WHERE is he/she??
Multiple Wireless Care Contexts!

(Courtesy: Jan Wittenber, Philips Medical, ANSI HITSP/TN905)
Diversity!

- Location of use may dictate specialized versions – or configurations – of devices
  - neonatal vs. pediatric vs. adult ventilators
  - General purpose IV pump vs. narcotics/pain IV pump vs. microinfusion IV pump vs. enteral/perenteral feeding pump

- Clinical specialties may dictate variants
  - Cardiac patient monitoring may require 12-lead ECGs; most other applications suffice with 5-lead; some with 3!

“Looks like a duck, walks like a duck, quacks like a duck, but the EMR needs to know EXACTLY what kind of duck!”
Nature and type of data!

- Much medical device data is “life critical” in “near real time”
  - **Life critical**: data lost, damaged, or distorted could cause IMMEDIATE serious injury or death
  - **ALARMS** are a unique form of data; may herald serious risk
  - **Near real time**: the beat by beat, moment by moment data may be critical (unlike an episodic mammogram or a blood cell exam)
    - Accurate time stamping becomes critical
    - Much data is “movie like,” and continuous in nature
  - Units of measure are critical, are scaled differently

Is an inch of prevention worth a pound of cure?

*Not an oxymoron in medical device applications!*
Personal Health vs Medical Devices

- Often similar, but may be less precise and less frequent
  - A patient with congestive heart failure (CHF) may benefit from recording his/her weight daily, or blood pressure 2x/day
    - Infrequent measurements, not continuous, can be stored and forwarded via a cell phone or PC
  - May be much more coarse, e.g.,
    - Most personal blood pressure monitors simply record systolic and diastolic pressures via a cuff on the arm
    - Dozens of different hospital blood pressures may be measured in the vein, artery, heart, brain, periphery, or elsewhere!
Personal Health Devices

• Generally, *not life-critical*
  – IDEALLY, a home-based active patient is relatively stable
  – Chronic diseases move slowly day to day, week to week
    • The goal for a Personal Health Device is to help the patient, family member, or home care team to notice trends *before* a crisis emerges
      – Early intervention: keep patient out of the ED and ICU!

Get patient to a clinic, or get a home care aide to the patient, or get new medicines/doses to the patient!
Sometimes the lines blur!

Wide spectrum from “Personal Health Device” to Medical Device

FDA grants Proteus Biomedical 510(k) clearance

The FDA announced today that it has cleared Proteus Biomedical’s wireless, adhesive sensor technology Raisin, which can track and record a patient’s heart rate, physical activity, body position and other biometrics. Raisin then transmits the data via Bluetooth to a PC or mobile device. Proteus explains that the Raisin device is worn just like a bandaid.

Raisin, however, is just one part of the intelligent medicine system that Proteus has developed, which aims to link “sensor-based formulations of pharmaceutical products to individualized physiologic response and outcomes-based treatment systems.” The other key part of the Proteus Biomedical offering is its intelligent pill technology which embeds chips set onto pills so that medication adherence can be better tracked. Proteus and partners (including Novartis) are currently piloting the technology for cardiovascular disease.
IHE Patient Care Device Domain’s Goals

- Semantics: standardize coding clinical data across all brands/models
  - Ensure data can ALSO reliably be transported to the electronic health record (i.e., use the general-purpose IHE standards)
- Normalize the units of measurement and reporting with international standards bodies, including ISO/IEEE 11073.x, SNOMED, NLM, and others
- Tackle security, patient safety, and process efficiency opportunities whenever possible
- Make Personal Health and Medical Device data streams compatible while remaining distinct
- Accommodate integration, interdependence, and interoperability goals without increasing risks or compromising system stability
IHE-PCD is TRULY multi-disciplinary!

- Sponsored by three industry leaders:
  
  **ACCE** – American College of Clinical Engineering
  
  **HIMSS** – Healthcare Information and Management Systems Society
  
  **AAMI** – Association for the Advancement of Medical Instrumentation
The Patient Care Device Domain is concerned with use cases in which at least one actor is a patient-centric point-of-care medical device. The PCD coordinates with other IHE clinical specialty based domains such as medical imaging and lab to ensure consistency of medical device integration solutions across all IHE technical frameworks.

✓ NOTE: Formed in 2005 & sponsored by ACCE, HIMSS, & AAMI
Achieving Interoperability

FIRST, we need to decide what that means!
More Expectations...

**Device Data Integration – Value propositions**

- **Integrity of data** – automatic population of all information systems – reducing medical errors
- Automated systems **save time for clinicians**
- Improved **agility** of enterprises to meet varied patient loads
- Improved **quality** of patient device data
- Automated clinical **data capture** for EHR
- **Access** to patient data across devices and systems so custom communication interfaces can be eliminated.
- Allows for **best of breed** selection
Lack of Interoperability: Highest Cause of HIT Project Failures

Health Interop Standards: How can we realize the promise?
Standards are:

- Foundational - to interoperability and communications
- Broad - varying interpretations and implementations
- Narrow - may not consider relationships between standards domains
- Plentiful - often redundant or disjointed
- Focused - standards implementation guides focus only on a single standard

Standards are Necessary but not Sufficient!!
Interoperability: From Standards to Profiles

Base Standards

- OASIS
- IETF
- ISO
- W3C
- CEN
- DICOM
- IEEE
- HL7
- CDISC
- LOINC
- IHTSDO
- ITU

Profile Organizations

- IHE
- Continua Health Alliance

Specific Extensions

Profiling Organizations Close the GAP!
Business Case for Vendors Implementing - and Hospitals Specifying - IHE Profiles

• Enables hospitals AND vendors to efficiently manage the array of integrated information systems necessary to support effective healthcare

• The alternative
  – Building site-specific interfaces
    • More expensive
    • Requires maintaining these custom interfaces for the life of the system involved.

• Integration via IHE is less costly at the start, and makes future acquisitions easier to plan and execute

• IHE Profiles give clear definitions of how the pieces fit together
• IHE Profiles come with initial unit testing done
Which begs the question...

What is Interoperability?

I’ll know it when I see it!
Dimensions of Interoperability

✓ Physical Interoperability
✓ Transport (Lower Layers) Interoperability
✓ Syntactic Interoperability
✓ Semantic Interoperability
✓ Secure Interoperability
✓ Safe Interoperability
✓ Authenticated Interoperability
✓ Certified Interoperability
Profiles Simplify Development
IHE Integration Statements

• A single page document showing what IHE Profiles and Actors and Options a product conforms to
• Conform to an actor within a profile and any options for that actor
  – Vs. conforming to a transaction or traditional HL7 spec
• Verifying conformance through Connectathon results
IHE Profile Development Process

Identify available standards (e.g. HL7, DICOM, IEEE, IETF)

Document Use Case Requirements

Develop technical specifications

Testing at Connectathons

Testing at Connectathons

IHE Demonstrations

Products with IHE

Improved safety, quality & efficiency!

Easy to integrate products

Start Here!!
IHE PCD - Profiles

- CPOE/ Pharmacy System
- Ventilation/ Anesthesia System
- Physiologic Monitoring System
- Infusion Pump
- Home Based System
- Other Devices
- EMR/EHR
- Clinical Decision Support System
- Implantable Device
- Equipment Management System

Key Abbreviations:
- 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
IHE’s *Rosetta Project* maps ALL vendor clinical coding to each other via IEEE 11073
[RTM]

Rosetta Terminology Mgmt.

ISO/IEEE 11073 Semantic Standards

Vendor Terms → Harmonized Terms

Vendor

Vendor A
Vendor B
Vendor C

RTM 1500 rows → hRTM 590 terms

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

IHE PCD Technical Framework Content

HL7 V2 Messages
HL7 V3 CDA/CCD
11073 PnP Comm
Device to Enterprise Communication

The DEC profile allows a consuming system (DOC) to receive patient clinical information including vitals, demographics, settings, and location from a reporting device/system (DOR).

The Subscribe to Patient Data (SPD) option allows the consumer to filter the data by:

- Medical Record #
- Device Class
- Update Interval

- Start & End Times
- Parameter Class
- Patient Location

The diagram illustrates the communication flow between Device Observation Reporter (DOR), Device Observation Filter (DOF), Device Observation Consumer (DOC), EMR, CIS, and CDSS.
Since Fall 2010, the IHE DEC interface can be used by Continua-WAN Personal Health Device Hubs, all IHE-PCD Medical Devices, and all IHE EHR systems!
Point of Care Infusion Verification

1. Physician’s Order
   - Infusion order sent from BCMA/EMR to Pump (PCD-03)
   - Pump may provide data to BCMA/EMR (PCD-01)

2. Nurse Review
   - Nurse confirms 5 Rights using BCMA/EMR:
     - Right Patient
     - Right Medication
     - Right Dose
     - Right Time
     - Right Route

3. Pharmacist Review and Dispensing
   - Nurse removes medication from dispensing cabinet or med room

[PIV]
IDCO profile defines sending of pacemaker and Implantable Cardiology Defibrillator data

Collect device data from:
- Device implant
- In-clinic visits
- Remote transmissions from patient’s home

Includes data for:
- Current device state
- Event/episode information
- Device-collected electrocardiograms

IDCO data transfer to EHR

Clinician views data in EHR

Company Proprietary Formats

Hospital, Other EHRs

Company Processors

Process/convert data into XML format & PDF reports

Forward raw data to company data processor systems

Collect raw Implanted Device data

Device Implant Procedure

In-clinic Follow-up

Patient Home Monitoring
Point-of-Care Identity Management

Unique identification of patients and devices at the enterprise level? Covered!

Identity capture and notification at the patient-centric point-of-care?
Patient & device association and release?
Mobile clinical context management?

The emerging Point-of-Care Identity Management (PCIM) profile aims to provide those capabilities needed to address these questions and support...

- Unique Device Identification & Notification
- Patient & Clinician Identification Notification
- Patient + Device Association
- ALL IHE device data exchanges
- Association Life Cycle Management
- Mobile & Dynamic Context Management
- ID Capture Technology Neutral:
  - Bar Code
  - RF-ID
  - Ultrasound
  - RTLS
  - ...

Medical Equipment Management

**Location Services**
- Current location
- Previous locations (Trending)
- Boundary controls (Alarm when device leaves area)

**Patch Management**
- Pending patches
- Patch history

**Battery Management**
- On A/C or D/C?
- Charge level (% of full)/Est. operating time left
- Charging / Discharging history
- Battery type and installation date
- Est. battery life

**Operational Status and Monitoring**
- Is the device currently in use
- Usage history
- Alarms – which are active, what the trigger levels, how long has the alarm been on
- Day/time of last self check and its result
- Event log recording

**Preventative Maintenance**
- Last PM
- Next scheduled PM
- Last repair time/date

**Device Configuration Management**
- Recall Management
  - Unique device identification
  - Hardware configuration (serial numbers, etc)
  - Software configuration (revision numbers, etc)
- Device Reconfiguration
  - Use profiles (NICU vs. CICU)

**Risk Management**
- Risk analysis
- Risk evaluation
- Verification of risk control measures
- Residual risks
Location Services: “Where is?”

While Location Tracking Services are being introduced into the healthcare environment at increasing rates, the ease of integration with other hospital systems has not improved. Lack of standards in this area results in integration issues and substantial development and implementation costs.

A standardized Location Tracking Profile allows for competition and technology choices while promoting consistency and interoperability for the end users.
MEDICAL DEVICE SECURITY & MGMT.

HIPAA
HITECH
FDA:
• 21 CFR 801, 803, 807, 812, 814, 820
• MDDS
IEC 80001
IHE PCD
MDS²

Cyber Protection
Configuration Management
Asset Discovery

Security
CE/IT Management

Network Access Control
Lifecycle Mgmt.
ePHI Breach Risk

Access Control
Privacy

Authentication
Key Management
Encryption
[MEM]
Medical Device Security & Mgmnt.

- Challenge
  - Conficker
    - Malware Volume & Sophistication
  - OS Patch Deployment
    - Device Lifecycle
  - FDA, CE
    - Regulatory Mandates
  - IT, BioMed
    - Management Complexities

- On-Device PHI Exposure
- PHI Leaving on Device
- PHI Transmission Intercept
- Enterprise PHI Exposure

- Diagnostics & Specialty
- Patient Care
- Imaging

- HIS
- Archive
- EMR

- Sneakernet attack
- Device-based attack on Network
- Network attack
- Loss of System & Device Functionality

- Remedy
  - Device-based Cyber Security
    - Example: HIPS
  - Network Security Architecture
    - Example: VLAN, Firewall
  - Risk Management
    - Example: IEC 80001
  - Discovery & Compliance Management
    - Example: MDS², CMDB
Industry demonstrations: 
The proof is in the pudding!

Identify available standards (e.g. HL7, DICOM, IEEE, IETF)

Document Use Case Requirements

Develop technical specifications

Testing at Connectathons

IHE Demonstrations

Products with IHE

Improved safety, quality & efficiency!

Easy to integrate products

The proof is in the pudding!
PCD – HIMSS 2011
HIMSS ‘07

An Interoperability Breakthrough – Patient Care Devices
A Heartfelt Patient Scenario

Emergency Care → Intensive Care → Perioperative Care
25% of HIMSS ’11 Interoperability Showcase vendors featured medical devices!

Steady Growth!
PCD User Handbook 2011 Edition

FREE for download from www.IHE.net/PCD

- Overview of IHE-PCD
- **Value Propositions** for medical device interoperability
- **Advice** on how to specify IHE in technology assessment
- **Tools** to find IHE-PCD compliant products
- **Guidance** on installation testing to confirm that IHE capabilities are functioning properly
- Issues to consider when **installing and configuring** IHE-compliant system
- Identifying and addressing potential problems in order to maximize your benefit despite existing “legacy” systems

- 2011 Changes include
  - Appendix H Mapping Clinical Requirements to Purchasing Requirements
  - Consolidation of the 2 major sections into 1 section
  - Incorporation of public comments from 2010 edition
RFP Guidance (included in the manual)

How can we help?
- Standards-based approaches reduce integration headaches
- Easily identify which IHE profiles support your clinical needs
- Reduce ‘wiggle room’ for suppliers by clearly defining requirements

Right tune, wrong words?
- We help you spell out terminology support, from
  - T0: None: ad-hoc value sets for each client site
  - T1: Vendor-specific codes and value sets, consistent across all clients and sites
  - T2: Mix of vendor-specific and standard codes
  - T3: Standard codes only from certain standards
  - T4: IHE PCD Rosetta Terminology Mapping

Having trouble making heads or tails of this?
Look up specific RFP requirements by clinical function

<table>
<thead>
<tr>
<th>I want this vendor system (Sender)</th>
<th>To send this information (Requirements)</th>
<th>To another vendor system (Receiver)</th>
<th>What is my RFP language for the sending system?</th>
<th>What is my RFP language for the receiving system?</th>
<th>What is the related IHE-PCD transaction?</th>
</tr>
</thead>
<tbody>
<tr>
<td>BPOC or Pharmacy</td>
<td>Drug ID and dosing/programming information</td>
<td>Pump server</td>
<td>Shall Support PIV as the IOC</td>
<td>Shall Support PIV as the IOC</td>
<td>PCD-03 as specified by both IOC and IOR</td>
</tr>
<tr>
<td>CPOE, BPOC or Pharmacy</td>
<td>Start Order infusion</td>
<td>Medication Administration Record (eMAR)</td>
<td>Shall Support the PIV as the IOC</td>
<td>Shall Support PIV as the IOC</td>
<td>PCD-03 as specified by both IOC and IOR</td>
</tr>
<tr>
<td>Pump server</td>
<td>Intubation documentation</td>
<td>Medication Administration Record (eMAR)</td>
<td>Shall Support the PIV as the IOC</td>
<td>Shall Support PIV as the IOC</td>
<td>PCD-03 as specified by both IOC and IOR</td>
</tr>
<tr>
<td>Pump server</td>
<td>Alarm - something is wrong with this pump</td>
<td>Secondary alarm manager</td>
<td>Shall Support ACM as the AM</td>
<td>Shall Support ACM as the AR</td>
<td>PCD-04 as specified by both AR and AM</td>
</tr>
<tr>
<td>Secondary alarm manager</td>
<td>Alarm - status (e.g., accepted by a nurse)</td>
<td>Pump server</td>
<td>Shall Support ACM as the AM</td>
<td>Shall Support ACM as the AR</td>
<td>PCD-04 as specified by both AR and AM</td>
</tr>
<tr>
<td>HIS</td>
<td>Patient identification info</td>
<td>Pump server</td>
<td>Shall Support ITI-010 as the PDS</td>
<td>Shall Support ITI-010 as the PDC</td>
<td>ITI-010</td>
</tr>
</tbody>
</table>

How do I get it?
- Visit www.ihe.net/pcd/
We are Seeing Green Shoots!!

• Vendors are starting to release IHE compliant product...
  – ~20 devices/systems announced so far
  – We expect ~30 devices by end of ’11

• Typically a search of Integration Statements on the IHE web site will give you a list...

  – Some vendors are having internal issues getting the appropriate web sites set up.
### We are Seeing Green Shoots!!

<table>
<thead>
<tr>
<th>COMPANY</th>
<th>SYSTEM</th>
<th>SYSTEM TYPE</th>
<th>PCD PROFILES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amcom</td>
<td>Commtech Messenger</td>
<td>Event Notification Middleware</td>
<td>ACM</td>
</tr>
<tr>
<td>BIOTRONIK SE &amp; Co. KG</td>
<td>Home Monitoring Service Center</td>
<td>Implantable Cardiac Device Observer System</td>
<td>IDCO</td>
</tr>
<tr>
<td>B Braun</td>
<td>Outlook Infusion Pump</td>
<td>Infusion Pumps</td>
<td>DEC, ACM, PIV</td>
</tr>
<tr>
<td>B Braun</td>
<td>Space Infusion System</td>
<td>Infusion Pumps</td>
<td>DEC, ACM, PIV</td>
</tr>
<tr>
<td>B Braun</td>
<td>DoseTrac Infusion Management Software</td>
<td>&quot;Gateway&quot; software</td>
<td>DEC, ACM, PIV</td>
</tr>
<tr>
<td>Capsule</td>
<td>Datacaptor</td>
<td>Interface System</td>
<td>DEC</td>
</tr>
<tr>
<td>Cerner</td>
<td>CareAware iBus</td>
<td>Interface System</td>
<td>PIV, DEC, ACM</td>
</tr>
<tr>
<td>Epic</td>
<td>EpicCare Inpatient and associated modules</td>
<td>EMR/EHR</td>
<td>DEC, PIV,ICDO</td>
</tr>
<tr>
<td>Medtronic</td>
<td>Medtronic Mainspring Connected System Gateway</td>
<td>Implantable Device Follow-up System</td>
<td>IDCO</td>
</tr>
<tr>
<td>Mindray DS USA, Inc.</td>
<td>eGateway Integration Manager</td>
<td>HL7 Gateway</td>
<td>ACM, DEC</td>
</tr>
<tr>
<td>Mindray DS USA, Inc.</td>
<td>A5</td>
<td>Anesthesia machine</td>
<td>ACM, DEC</td>
</tr>
<tr>
<td>Nuvon</td>
<td>VEGA™</td>
<td>Interface System</td>
<td>DEC</td>
</tr>
<tr>
<td>OZ Systems</td>
<td>eScreener Plus</td>
<td>Interface</td>
<td>DEC</td>
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<tr>
<td>Philips</td>
<td>Emergin</td>
<td>Alarm Manager</td>
<td>ACM</td>
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<tr>
<td>Philips</td>
<td></td>
<td>HL7 Gateway</td>
<td>DEC</td>
</tr>
<tr>
<td>St. Jude Medical, Inc.</td>
<td>Merlin.net MN5000</td>
<td>Implantable Cardiac Device Observer System</td>
<td>IDCO</td>
</tr>
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<td>Surgical Information Systems</td>
<td>SIS Periop</td>
<td>Periop CIS</td>
<td>ACM, DEC</td>
</tr>
<tr>
<td>Surgical Information Systems</td>
<td>SIS Anesthesia</td>
<td>Anesthesia CIS</td>
<td>ACM, DEC</td>
</tr>
<tr>
<td>Welch Allyn</td>
<td>Connex VM</td>
<td>VSM HL7 Gateway</td>
<td>DEC</td>
</tr>
</tbody>
</table>
IHE PCD is helping inspire innovation and competition!

One vendor from China has designed, built, and is selling “IHE-PCD-native” anesthesia and monitoring products to US and global markets already!
Testing and Verification

- Identify available standards (e.g. HL7, DICOM, IEEE, IETF)
- Document Use Case Requirements
- Develop technical specifications
- Testing at Connectathons
- IHE Demonstrations
- Products with IHE
- Improved safety, quality & efficiency!
- Easy to integrate products
Medical Device Interoperability
Using ‘Profiles’ To Advance Rigorous Testing

Validation
- Test Management
- Test Services
- Test System Development Components
- Test Harness
- Test Resources
- Test System Instance

Specification Constraints
- Standards Profile
- Domain Framework
- Terminology/Nomenclature
- Test Case/Value(s)

Based on Use Case(s)

Message
- E.g., HL7 V2

User / Device

Report

Assertions
- HL7 v2 Standard Message Definition
- HL7 v2 Standard Value Sets
- ISO/IEEE 11073 Nomenclature
- IHE-PCD TF Message Transaction Test Assertions
- IHE-PCD TF Message Transaction Value Set Constraints
- Harmonized Rosetta Terminology Mapping Constraints
- Test Case Specific Test Assertions
- Conformance Profile (XML)
- Table Library (XML)
- Validation Context File (XML)
- Validation Context File (XML)

Testable Assertions:
IHE-PCD Validation Requirements Used by NIST Test Tools

Patient Care Devices (PCD)
Medical Device Interoperability
IHE-PCD Test Environments and Services

Services
- HL7 V2 Message Validation
- Report

Test Management
- HL7 V2 Message Validation Test Case
- Results HL7 V2 Message Validation Report

Test Execution
- Test Harness (Java Code)

Registry/Repository

Instance Test Environment
E.g., IHE-PCD Conformance Testing of an HL7 V2 IHE-PCD Message using a NIST Web Application Client

Isolated System Test Environment
E.g., IHE-PCD Functional Behavior Conformance Testing using a NIST Web Application Client and Test Agents

Test Artifacts
- Conformance Profile
- HL7 Tables
- Device Test Agents
- ISO/IEEE 11073/Rosetta Terminology

Services
- HL7 V2 Message Validation
- HL7 V2 Message Generation

Test Management
- IHE-PCD Client Test Scenario
- Results HL7 V2 Message Validation Reports

Test Execution
- Test Harness (Java Code)

Vendor

System Under Test

Router/Logger/Proxy

Patient Care Devices (PCD)
Connectathon – “in the dungeon...”
Patient Devices on the Connectathon Floor
IHE: Working to ensure medical technologies help us continue to improve healthcare one breath at a time!

**Meaningful Miracles:** Amelia was under 10 oz at birth!

**Fla. preemie gets OK to leave hospital**

MIAMI (AP) — Parents of one of the world’s smallest premature babies got to take her home Wednesday for the first time since she was delivered last fall.

Amillia Sonja Taylor has known only an incubator for a bed at Baptist Children’s Hospital since she was delivered in October after less than 22 weeks in the womb.

“The baby is healthy and thriving and left Baptist Children’s Hospital today after four months in our neonatal intensive care unit,” hospital spokeswoman Liz Latta said.

Amillia, who was just 9 1/2 inches at birth and weighed less than 10 ounces, will still require oxygen at home and a developmental specialist will follow up with her and her parents to track her neurological development.

The infant now weighs about 4 1/2 pounds and is just over 15 1/2 inches long.

Amillia Taylor Turns 2!

The world’s most premature baby ever is celebrating a very special birthday.

2009

Amillia Taylor, born at just 21 weeks and weighing only 10 ounces, turned 2 years old yesterday.

Her proud parents told Local 10’s Laurie Jennings that Baby Amillia now weighs a healthy 26 pounds and is 26 1/2 inches tall.

2 yrs later, she was 26 lbs!

**Forward, ever forward...**
IHE: Putting devices to work everywhere
Innovative collaboration between providers, CMS, and EMR and device manufacturers strive to put this country’s money into Patient Care and Wellness, not wasted time and energy.
Questions???

Find out more at [www.IHE.net/PCD](http://www.IHE.net/PCD) & ASK downstairs during the TOUR!
Thank you for spending the day with us today!

I’d be happy to hear from you!

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