Medical Devices – From Standards to Interoperability

ACCE Clinical Engineering Symposium
AAMI 2011

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Mindray North America
Co-Chair: IHE-PCD Planning Committee
Mindray

- HQ – Shenzhen, China
  - Largest Chinese medical device manufacturer
  - Listed on NYSE
  - $740 M in revenue
  - 20 years old
- US HQ – Mahwah, NJ
  - Former Datascope HQ
The Situation...

- The nation is moving quickly toward widespread (universal?) adoption of EHR/EMR based medical records.
- In this environment it is natural for clinicians to demand the automatic acquisition of data from bedside medical devices.
- Today device interfacing continues to require considerable time, effort and resources...
  - Quality and reliability is sub-optimal
- There must be a better way!!
The Situation...

• When I was (much) younger I believed that developing the appropriate Standards was all that was needed.

• Develop the Standards and They will come !!!
Are Standards Enough?
Some History...

• So we built the Standards!!
  – In the US we had the IEEE 1073 (now 11073) Working Group developing POC Medical Device Communication Standards...
  – In Europe we had CEN TC251 also working on POC Medical Device Communication Standards...

• Surprisingly these 2 groups actually talked to each other and shared some members!!
Some History...

- From this collaboration we ended up with:
  - CEN TC251 focused on Nomenclature and generated a Standard that eventually became ISO/IEEE 11073-10101.
- By the early 2000’s (after 10+++ years...) we had a set of Standards that could be used for real implementations.
Some History…

• So, what happened?
  – Almost nothing...
  – A few brave companies created some products that supposedly* complied with the Standard...
    • Philips
    • Alaris
    • Draeger
  – Very little “consumer” demand
  – No guarantee of Interoperability

*Not meant to be negative, there was just no independent way of testing compliance…
Some History…

• Why?
  – The world had moved over those 15 years.
  – HL7 became the de-facto approach for EMR connectivity.
    • Each Device Vendor had an HL7 Gateway
  – Vendors found that the 11073 Standards were quite complicated.
  – Vendors could not guarantee that 2 IEEE 11073 compliant devices would talk to each other out of the box.

• Standards are Necessary but not Sufficient !!
Plenty of Examples...

- Standards are Necessary but not Sufficient...
  - IR Remote Controls
    - All vendors use the same IR Standard, but there is no interoperability
  - Wi-Fi
    - Before the Wi-Fi Alliance was created, most 802.11b implementations would not interoperate
  - USB
    - Did not work well until Microsoft “took control” and started to manage the Drivers necessary to make it work.
- Etc.
Other Efforts...

• Integrated Clinical Environment (ICE)
  – Proposes a Framework for a Clinical Workstation using Plug and Play devices focused on Safety

• Continua
  – Focused on Personal Healthcare Devices
  – They have an ecosystem of Standards (via IEEE 11073), Plug-Fests and paths to Certification

• Prototype Regulatory Submission WG
  – How would a vendor submit an “Interoperable Device” to the FDA?
How do we get to “Interoperability”?
So, What is Interoperability?

• We use the term a lot...

• How would we define it? Some Examples:
  
  – “Interoperability means the ability of health information systems to work together within and across organizational boundaries in order to advance the effective delivery of healthcare for individuals and communities.” [HIMSS]

  – “Interoperability is the ability of different information technology information systems to communicate, to exchange data accurately, effectively, and consistently, and to use the information that has been exchanged.” [NAHIT]
Interoperability - A Definition

• From the AAMI HITI Working Group:
  – “Interoperability is the ability of two or more medical devices or clinical systems designed to communicate with one another to safely fulfill an intended purpose.”

• What this does not cover is the effort required to make the systems achieve interoperability.
  – We want to move from “Plug and Pray” to “Plug and Play”

• This introduces the concept of “Levels of Interoperability”. 
**Levels of Interoperability From Simulation Technology**

<table>
<thead>
<tr>
<th>Composability</th>
<th>Interoperability</th>
<th>Integratability</th>
<th>Assumptions &amp; Constraints understood</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level 6</td>
<td>Conceptual</td>
<td>Level 6</td>
<td>Dynamic Context understood</td>
</tr>
<tr>
<td>Level 5</td>
<td>Dynamic</td>
<td>Level 5</td>
<td>Context understood</td>
</tr>
<tr>
<td>Level 4</td>
<td>Pragmatic</td>
<td>Level 4</td>
<td>Meaning understood</td>
</tr>
<tr>
<td>Level 3</td>
<td>Semantic</td>
<td>Level 3</td>
<td>Common Format</td>
</tr>
<tr>
<td>Level 2</td>
<td>Syntactic</td>
<td>Level 2</td>
<td>Common Physical and Transport Layers</td>
</tr>
<tr>
<td>Level 1</td>
<td>Technical</td>
<td>Level 1</td>
<td>Stand-alone</td>
</tr>
<tr>
<td>Level 0</td>
<td>None</td>
<td>Level 0</td>
<td></td>
</tr>
</tbody>
</table>

### Levels of Interoperability

#### Examples

<table>
<thead>
<tr>
<th>Composability</th>
<th>Interoperability</th>
<th>Integratability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level 6</td>
<td>Conceptual</td>
<td>Model Based Interoperability</td>
</tr>
<tr>
<td>Level 5</td>
<td>Dynamic</td>
<td>Resource and Load Management</td>
</tr>
<tr>
<td>Level 4</td>
<td>Pragmatic</td>
<td>IHE PCD/Continua Use Case based Profiles, ...</td>
</tr>
<tr>
<td>Level 3</td>
<td>Semantic</td>
<td>Snomed, IHE-PCD RTM, IEEE 11073 Nomeclature, ...</td>
</tr>
<tr>
<td>Level 2</td>
<td>Syntactic</td>
<td>HL7, IEEE 11073, Continua, ...</td>
</tr>
<tr>
<td>Level 1</td>
<td>Technical</td>
<td>RS232, Ethernet, WiFi, USB, TCP/IP, ...</td>
</tr>
<tr>
<td>Level 0</td>
<td>None</td>
<td>Stand-alone</td>
</tr>
</tbody>
</table>

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Levels of Interoperability
AAMI ...

Interoperability

- Level 5: Dynamic
- Level 4: Pragmatic
- Level 3: Semantic
- Level 2: Syntactic
- Level 1: Technical
- Level 0: None

Integratability

- Certification
  - Association
  - Authentication
  - Authorization
  - Discovery
  - Safety
  - Security

Increasing Capability for Interoperation
IHE PCD and Interoperability
Role of IHE PCD

- IHE PCD was formed to address issues related to integration of Point-of-Care Medical Devices:
  - With each other
  - With enterprise systems
- IHE PCD wants to “raise the bar” from the current state of integration projects to achieve out of the box interoperable solutions.
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 HIMSS & ACCE]
Profiles Simplify Development
IHE Profile Development Process

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

Start Here!!

Document Use Case Requirements

Developer technical specifications

Testing at Connectathons

IHE Demonstrations

Products with IHE

Improved safety, quality & efficiency!

Easy to integrate products
IHE PCD - Profiles

 ✓ **Current Profiles:**
   - Rosetta Terminology Management (RTM)
   - Enterprise sharing of Patient Care Data (DEC)
   - PCD Alarm Communication Management (ACM)
   - Point-of-care Infusion Verification (PIV)
   - Implantable Device – Cardiac Observation (IDCO)
   - Waveform Common Module (WCM)

 ✓ **Work in Process:**
   - Medical Device Data Query (MDQ)
   - Point-of-Care Identity Management (PCIM)
   - Medical Equipment Management (MEM)
     + Location Services
     + Cyber Security Management
IHE PCD Overview

Information Consumers:
(HIS, PHIS, CIS, EMR)

Physiological and Operational Data (PCD)

ADT, Orders

Server/Gateway

Information Reporters:
Medical Devices with Server/Gateways

Information Reporters:
Standalone Medical Devices

IHE Technical Framework

HIMSS

ACCE

AMERICAN COLLEGE OF CLINICAL ENGINEERING
Connectathon – in the dungeon...
AAMI Demonstration

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

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

AAMI: American Association for Medical Instrumentation
ACCE: American College of Clinical Engineering
HIMSS: Healthcare Information and Management Systems Society
IHE: Integrating the Healthcare Enterprise

Current PCD, Future PCD, Future Non-PCD
Let’s Go Shopping !!
The Business Case

- Enables you 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
Leveraging IHE for Purchasing

• Ask for IHE-PCD by Name!!
  – How do you get IHE Integration Profiles?
    • Specify IHE capabilities as requirements
    • State in the RFP which IHE Actors and Integration Profiles you want.
  – What do IHE Integration Profiles cost?
    • Nothing in most cases
    • Any cost should be a fraction of the overall
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...
  - [http://product-registry.ihe.net](http://product-registry.ihe.net)
  - 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</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>
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<tr>
<td>Medtronic</td>
<td>Medtronic Mainspring Connected System Gateway</td>
<td>Implantable Device Follow-up System</td>
<td>IDCO</td>
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<td>Mindray DS USA, Inc.</td>
<td>eGateway Integration Manager</td>
<td>HL7 Gateway</td>
<td>ACM, DEC</td>
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<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>
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<tr>
<td>OZ Systems</td>
<td>eScreener Plus</td>
<td>Interface</td>
<td>DEC</td>
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<td>Philips</td>
<td>Emergin</td>
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<td>Implantable Cardiac Device</td>
<td>IDCO</td>
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<td>Surgical Information Systems</td>
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<td>Periop CIS</td>
<td>ACM, DEC</td>
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<td>Anesthesia CIS</td>
<td>ACM, DEC</td>
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<tr>
<td>Welch Allyn</td>
<td>Connex VM</td>
<td>VSM HL7 Gateway</td>
<td>DEC</td>
</tr>
</tbody>
</table>
What Can You Do?

• Plan, Evaluate, Purchase IHE Conforming Devices

• In continuing discussions with vendors – at all levels
  – Push IHE Interoperability
    • Refer to lower deployment, maintenance costs
  – Encourage vendors’ active IHE participation
    • Lower development, installation, support costs
  – Refer to profiles
    • Leverage public and objective commitments

• In RFPs
  – Refer to profiles, Conformance Statements
  – Use Conformance Statements to “nail down” vendor’s representations
  – Adopt very specific language
Due to the complexity of real-world devices, Standards are only a starting point.

Achieving true “plug and play” Interoperability is still a goal and not a reality.

Supporting and Specifying IHE-PCD compliant products is a step in the right direction!
Questions???

IHE-PCD Update
Sunday 8:30 AM

Find out more at
www.ihe.net