Finally, a standardized approach to receive medical device data into an EMR/EHR!

Introduction to the
Integrating the Healthcare Enterprise (IHE)
Patient Care Devices (PCD) Domain

DISCLAIMER: The views and opinions expressed in this presentation are those of the author and do not necessarily represent official policy or position of IHE.
Introduction

• As hospitals deploy EMRs into their most critical care areas, the need to acquire data from Medical Devices becomes increasingly evident.
  • Accurate data
    – Improved patient safety and care outcomes
    – Improved discharge decisions
    – Improved Case Management, Infection Prevention and QA
  • “Real time” data available to MD, clinicians and care managers
    – More clinically sound diagnosis and orders
    – Earlier initiative of appropriate interventions and therapies
    – Prevention of undetected patient deterioration (“failure to rescue”)
    – More “proactive” patient management (↓LOS, ↑ reimbursement)
    – Better outcomes
  • Automated Data Acquisition
    – Increased MD productivity and satisfaction
    – Increased Nursing productivity and satisfaction
    – Outcomes data warehousing
Introduction

• In a recent “Healthcare IT News” article on “5 reasons medical device data is vital to the success of EHRs”\(^1\), they make some additional points:
  – Evidence based medicine is based on data
  – Medical device data is the least error-prone
    • In many cases the data entered into the EMR is a ball-park estimate taken “around” the right time.
  – The “Empty EHR” syndrome is prevalent
    • Without device data acquisition there will holes in the progress of a patient’s care
    • Transitions of care are very important, gaps in information is bad

\(^1\)Michelle McNickle based on an interview with Shahid Shah
We have a Solution?

• Are current solutions that meet these definitions adequate?
  – Most, if not all, EMRs can connect to devices in some way.
  – We have a growing contingent of vendors (Capsule, Nuvon, iSirona, Cerner, etc.) providing device integration middleware and services.
  – Patient monitoring vendors have created interoperable systems incorporating many 3rd party devices.
  – Clinicians have developed many demonstrations and applications showing device interoperability.

• Maybe the “problem” is not a problem after all...
Problem Solved?

• Some issues with our current reality...
  – Each new device integration is a custom effort requiring months of nursing/engineering skills
    • It can cost between $6,750 and $10,000 per bed to integrate the devices, including ventilators, in a typical ICU (Moorman, 2010)
  – Clinicians desiring to use a new device must wait for their EMR vendor to develop a new driver (which may never happen)
  – The complexity of device interfacing may be hindering research which could lead to improved patient care
  – Purchasing decisions can be driven by whether an interface to specific devices exists instead of finding devices that are clinically best
Problem Solved?

• More issues with our current reality...
  – Safety issues can arise due to the sizable SW effort and on-site customization required to integrate devices
  – Costs to the Providers for system integration services are very high
  – Not all required data to accomplish a Use Case may be available
  – There can be finger pointing when trying to resolve problems
  – Too much complexity in maintaining each link in the communication chain
  – As device or system software is updated solutions break
Are Standards the Solution?

• Well, we have plenty of standards:
  – HL7
  – IEEE 11073-10101, 10xxx, etc.
  – IEEE 11073-20601, 40xxx, etc.
  – ASTM F2761 (ICE)
  – DICOM
  – ISO TC215, CEN TC251, IEC, etc.

• Standards are just a foundation
Is Interoperability the Solution?

- As discussed we already have ways of getting Medical Device data into the EMR
- Based on the evidence, we call this “**Dysfunctional** Interoperability”
- So, how do we get to a state of “**Functional** Interoperability”?
- IHE PCD is working on addressing this problem
- Healthcare providers like Baystate Health require a faster, cheaper, more dynamic method of integrating devices
IHE PCD: Simplify Specs!

Photo courtesy Jack Harrington

www.ihe.net
On the Road to Open Interoperability: From Standards to Profiles

Base Standards from SDOs

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

Profile Development

- IHE

CPs

eHealth Projects
Role of IHE PCD

• IHE PCD was formed in 2005 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 out of the box, open, interoperable solutions.
• IHE PCD’s co-sponsors are HIMSS, AAMI and ACCE.
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.
IHE Improves, Safety, Quality and Efficiency in Clinical Settings.

IHE Development Process

1. IHE Call for Proposals Opens
   - Month 1-5

2. Profile Selection by Committees

3. IHE Profiles Drafted & Revised
   - Month 6-13
   - Published For Public Comment
   - Published
   - Implementation Posted

4. Test at IHE Connectathons
   - Month 14-18
   - Publish in IHE’s Product Registry

5. IHE Technical Framework Developed

6. Demonstrate at a HIMSS Interoperability Showcase

7. Install Interoperable products in Clinical Settings worldwide
IHE PCD
From Use Cases to Profiles
IHE PCD - Profiles

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

Current PCD
Future PCD
Future Non-PCD

ACM: Alarm Communication Management
ADQ: Asynchronous Device Query
DEC: Device Enterprise Communication
IDCO: Implantable Device – Cardiac – Observation
MEM: Medical Equipment Management
PCIM: Point-of-Care Identity Management
PIV: Point-of-Care Infusion Verification
WCM: Waveform Communication Management
From Use Cases to Profiles

• The IHE process starts with an open call for Work-Item Proposals to all stakeholders.
  – The proposals are reviewed and voted on by the Planning Committee.
  – Proposals are evaluated on clinical benefit, technical feasibility and volunteer availability.

• So far most accepted proposals are related to enterprise connectivity (as contrasted with Point of Care).
  – Vendor gateways (MDDS) to enterprise systems are easier to modify than regulated devices.
    • Profiles are typically developed in 18 months or less.
    – Some vendors are starting to implement PCD profiles directly in point-of-care medical devices.
Use Cases to Profiles

• Use Case:
  – **Time synchronization** across multiple devices and systems

• Profile:
  – [CT] Continuous Time, based on NTP

• Use Case:
  – **Reporting of device data** (heart rate, infusion volume, airway pressure, etc.) to consuming systems such as EMRs

• Profile:
  – Also adopted by Continua for WAN reporting.
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
Rosetta Terminology Mapping [RTM]

- ISO/IEEE 11073 Semantic Standards
  - Vendor Terms
  - Harmonized Terms

- RTM (1500 rows) → hRTM (590 terms)

- Vendor Semantics
  - Vendor A
  - Vendor B
  - Vendor C

- IHE PCD Technical Framework Content
  - HL7 V2 Messages
  - HL7 V3 CDA/CCD
  - 11073 PnP Comm

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

✓ **Completed Workitems:**
  - 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 Content Module (WCM)

✓ **Work in Process:**
  - Event Communication (EVT)
  - Asynchronous Data Query (ADQ)
  - Point-of-Care Identity Management (PCIM)
  - Device Point-of-care Integration (DPI)
  - Medical Equipment Management (MEM)
    - + Maintenance Management Systems
    - + Cyber Security Management
IHE PCD:
From Profiles to Release
NIST Testing Tools

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)

Assertions
- HL7 Message Definitions
- Value Set Constraints
- IEEE / Rosetta Nomenclature
- Test Case Specific Assertions

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

Message E.g., HL7 V2

User / Device

Report
PCD – HIMSS 2011
# IHE PCD Compliant Commercially Available Systems (as of January 2012)

<table>
<thead>
<tr>
<th>COMPANY</th>
<th>SYSTEM</th>
<th>SYSTEM TYPE</th>
<th>PCD PROFILES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accent on Integration, Inc. (AOI)</td>
<td>Accelero Connect®</td>
<td>Medical Device Integration</td>
<td>DEC</td>
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<tr>
<td>Amcom</td>
<td>Messenger</td>
<td>Alarm Manager</td>
<td>ACM</td>
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<td>BIOTRONIK SE &amp; Co. KG</td>
<td>Home Monitoring Service Center</td>
<td>Implantable Cardiac Device Observer System</td>
<td>IDCO</td>
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<td>B Braun</td>
<td>DoseTrac Infusion Management Software</td>
<td>Gateway software</td>
<td>DEC, ACM, PIV</td>
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<td>Carefusion</td>
<td>CGW</td>
<td>Gateway</td>
<td>DEC</td>
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<tr>
<td>Cerbera</td>
<td>CareAware iBus</td>
<td>Enterprise Device Connectivity Platform</td>
<td>DEC, PIV</td>
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<tr>
<td>Epic</td>
<td>EpicCare Inpatient and associated modules</td>
<td>EMR/EHR</td>
<td>DEC, PIV,IDCO</td>
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<td>HL7 Gateway</td>
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<td>Mindray DS USA, Inc.</td>
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<td>Anesthesia machine</td>
<td>DEC</td>
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<tr>
<td>Nuvon</td>
<td>VEGA™</td>
<td>Interface Overlay Architecture &amp; Appliances</td>
<td>DEC</td>
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<td>OZ Systems</td>
<td>eSP™</td>
<td>Interface</td>
<td>DEC</td>
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<td>IntelliSpace Event Management</td>
<td>Alarm Manager</td>
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<td>Philips Healthcare</td>
<td>Philips IntelliVue and Philips IntelliBridge SC200</td>
<td>Monitoring central station and gateway</td>
<td>DEC</td>
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<td>Welch Allyn</td>
<td>Connex VM</td>
<td>Vital Signs Monitor</td>
<td>DEC</td>
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Conclusion

• The current environment of “Dysfunctional Interoperability” is not desirable.

• Users and vendors need a roadmap which allows us to achieve “Open Interoperability”.
  – Prioritized Use Cases
  – Assessment of Current Standards
  – Profiles of Standards to achieve Use Cases
  – Ecosystem for rigorous conformance and certification testing based on “complete and computable” representations of standards
  – Incentives for vendors to offer and providers to demand compliant medical devices.

• IHE PCD is making real progress towards attaining this goal.