Connectivity Issues Impacting Patient Safety

Medical Device Connectivity Conference – September 2011

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Presentation Overview

- “Back to the Future”
- Back to today
- Driving forces
- Typical first steps
- Hospital experiences
- Challenges and risks for going forward
- Evaluation findings
- Next steps
ECRI Institute

- Nonprofit healthcare research organization
- **Mission**: Enable healthcare organizations to improve patient care
- The Discipline of Science
  - Multidisciplinary staff
  - Proven methods & review processes
- The Integrity of Independence
  - Unmatched conflict-of-interest rules
  - Serving providers to help patients
Jim with the Lord Mayor of Adelaide and Carolyn Hunter from NASA - 1990
With James McCauley After 2009 “Back to the Future” Keynote
Marty McFly Crashing onto Coober Pedy Roundabout
Transport from the Crash Site
Mobile Emergency Response Hospital
Heads up display
Recovery at home – with a telemedicine link to the local hospital
Back to Today

- Lots of interoperability examples
  - Depending on how you define it
  - Localized communication, EMR, HIE?
- Examples of maturing (?) applications
  - PACS
  - Clinical lab
  - Fetal monitors and OBDMS
  - Anesthesia systems
  - ECG into data management systems (e.g., MUSE)
Other Examples Along the Technology Growth Curve (An ECRI variation)

▶ Teenage years
  ■ EMR and CPOE
  ■ Smarter infusion pumps
  ■ Ventilators and physiologic monitors (alarm integration systems)

▶ Younger (toddler [?]) years
  ■ OR integration
  ■ Third party integration

▶ Gleam in the eye
  ■ Certain decision support tools
One-third of 825 surveyed hospitals reported they have an interface between their devices and their EMR.

Physiologic monitors (24.3%), fetal monitors (19%), electrocardiographs (15.1%), and ventilators (9.3%).

Most were direct connections – 11% were using hubs.

Automatic charting was the most common driver.
Reported Interoperability Advantages

- "Real-time" data vs. many hours of delay with traditional methods
- Save nursing time from manual data entry
  - One report from a hospital through an integration vendor - claims savings of one hour per nurse per shift
- Reduces error associated with manual data entry
- Use of stored data for analytics
- Billing efficiency/accuracy and financial incentives/penalties
- Etc.

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SELECTplus quotation analyses

Typical for established technologies (e.g., infusion pumps, anesthesia machines, and ventilators)

- Hundreds (635, 488, 574) over last 2 years

Third-party integrator request

- One (from Capsule) over the last 2 years

Physiologic monitoring integrators (27)

Integration engines (6)
Recent ECRI Institute Integration-Related Hospital Discussions

► All in the early phase of adoption
► Typical initial efforts focused on patient monitors
  ■ Starting with basic functionality (e.g., only numerical data)
► Cost, complexity, lack of standardization, legacy equipment, “longer term” Meaningful Use timelines, and other priorities (e.g., EMR or CPOE implementation) were impediments
► Range of options can be daunting
► Testing a great idea – but is complex, very costly and time consuming
Questions Being Asked

- Patient monitor manufacturer’s gateway? ($$$)
- Third-party integrator’s add-on technology?
- Whose claims about system performance should we believe?
- Is it wise to use a new/unestablished vendor?
- Use a central data repository?
  - How much pre-processing is needed
- Need to hire clinical engineers with IT smarts?
- What outputs do devices actually have?
Typical Challenges

- Unplanned down time
  - Troubleshooting the cause (and dealing with vendor finger pointing)

- Need for routine data validation by clinicians

- Disruption and changes to traditional workflow
  - Clinician resistance (their lack of technical “know-how” didn’t help)
    - It won’t work if it’s not plugged in (i.e., the USB)

- Need for multiple custom interfaces

- “The experiences of this organization may not necessarily be experienced by other organizations”

- Controlling/defining costs
Example Problems from ECRI’s Files


1. When zoomed computed radiography images were exported to a PACS, measurements made by the PACS were inaccurate (Accession Nos. A9718 and A11161).

2. A PACS software error caused inaccurate processing of data from a cardiac ultrasound scanner, resulting in inaccurate display of heart wall motion abnormality scores (Accession No. A10368).

3. Reconstructed images generated by a PACS were incorrectly oriented when patients were not scanned supine and head first (Accession Nos. A10156 and A11115).

4. An anomaly between a PACS and modality caused patient data to be overwritten or matched to an incorrect patient (Accession No. A9812).

5. Sections of images from breast studies obtained by certain modalities were not displayed on a PACS (Accession No. A8325).
ECRI Institute's Health Devices Alerts Database: Percentage of Software-Related Hazards & Recalls
What Worked Well

► Collaboration
  ■ Clinical engineering, IT, nursing, vendors, etc.
► Starting small
► Negotiating power from concurrent technology purchase plans (e.g., for test bed device loaners)
► Clear integration-related help desk procedures
  ■ With pre-established roles and responsibilities
    — For clinical engineering and IT
► “Homemade” communication cables
  ■ MDDS impact?
Consumer Reports-Like Evaluation Findings
Vital Signs Monitor Evaluation

- Seven evaluated products
- Focus on EMR connectivity
- Key differentiators
  - Performance during system downtime
  - Ability to detect invalid patient IDs
  - Data associated with the correct patient ID
  - Flexibility during deployment
  - Ability to synchronize with network’s clock
Physiologic Monitor Evaluation

- Focus on connectivity and alarm performance
- Assessing products from seven vendors
- Bench testing and hospital interviews
- Interesting findings
  - Proper mapping of time fields of NIBP measurements into the EMR
  - EMR having difficulty handling patient monitoring data from multiple vendors
  - Wireless signal dropouts – required new firmware for access points to correct
  - Monitoring manufacturer not ready for ADT feeds
Help is Here (or Maybe on the Horizon)

- IHE PCD
- IEC 80001, ASTM ICE, HL7, IEEE 11073, MDDS(?)
- CE-IT Community
- Continua Alliance
- MD PnP
- ECRI Institute Interoperability Resource Center

Summary of interoperability resources in *Health Devices*, June 2011
Plans for Moving Forward

➢ Create a clear strategic vision
  ■ Driven and supported by senior leadership
  ■ Coordinated with other health technology plans

➢ Collaborate and foster relationships
  ■ Clinical engineering must be fully engaged, ideally taking on a high-level leadership role
    — Study, study, study - to become your organization’s interoperability “go to” subject matter expert and leader

➢ Make clinical work processes a priority
  ■ Actively seek clinician input and buy-in
When will we get there?

I’ll take a spin to check it out!
Thank You
Some References and Resources

► CE-IT Community
  ■ http://www.ceitcollaboration.org/

► Integrating the Healthcare Enterprise (IHE)
  ■ http://www.ihe.net/

► Medical Device “Plug and Play” Interoperability Program (MD PnP)
  ■ http://mdpnp.org/Home_Page.php

► ECRI Institute, www.ecri.org