ECRI Institute Overview

- ECRI Institute is an independent, not-for-profit, research organization.
- For 40 years we have dedicated ourselves to:
  - Bringing the discipline of applied scientific research to discover which technologies and patient care approaches are best.
- We are one of only a handful of organizations designated as:
  - Collaborating Center of the World Health Organization
  - Evidence-based Practice Center by the AHRQ (U.S. Agency for Healthcare Research and Quality)
- The only Consumer Reports-like evaluator of healthcare technology.
Physiologic Monitoring Systems

- A system that continuously monitors invasive and non-invasive physiologic parameters.

- The system can consist of:
  - Bedside monitor
  - Telemetry unit
  - Central station
  - Associated network components (e.g., switches, servers, antenna system)
What can physiologic monitoring systems connect to?

- It varies depending on the care area
  - ADT
  - EMR
  - Anesthesia/perioperative documentation systems
  - Sleep Lab documentation systems
  - ECG data management systems
  - LIS
  - PACS

Often via third-party integrators.
Hospital Interviews

► Wide range of facilities
  ■ Teaching hospitals
  ■ 200 bed hospitals

► Wide range of vendors
  ■ Physiologic monitoring system vendors
  ■ EMR vendors

► Wide range of input
  ■ Clinical Engineering (CE)
  ■ IS departments
  ■ Nursing
One size fits all?

Hospitals can have very different connectivity solutions

- Physiologic monitoring system vendor
- EMR vendor
- Third-party integrator
- Date of the installation
- Hospital-specific decision factors (e.g., workflow, resources)
User Experience – Rate of Adoption

**EMR / ADT**

- Less connectivity than might be expected
  - Many competing priorities
- Currently, some facilities have:
  - Just an ADT feed
  - Just an EMR export
  - Both an ADT and EMR interface
- Experience is typically a year or less
  - Specifically with physiologic monitoring connectivity to the EMR
User Experience – Rate of Adoption

Clinical Access to Data at the Bedside

- Fairly rare to date
- Planned as a future project
- Preferred feature
- Some clinicians love it
  - Feature as an icon on EMR system
Connectivity Project Management

Drivers:

- HITECH Act
- Efficient clinician workflows
- Improved patient safety

Goals:

- Want clinicians to trust the technology
- Want the process to be as seamless for clinicians as possible
- Want the project to be a success with minimal hiccups
Connectivity Project Management

Approaches:
- Pilot is typical
- “Big bang” method
- Staggered approach

Project becomes more challenging if:
- Connecting two different physiologic monitoring systems to a single EMR
- Connecting one or more physiologic monitoring systems to multiple EMRs
User Experience – Project Management

- EMR project timelines are extremely tight
  - Creation of interfaces
  - Testing
- Training for clinicians is a priority
- Generally speaking, good support from vendors
- Go-live is “intense” for CE and IT staff
- Highlights the need for good collaboration between CE and IT departments
User Experience – Lessons Learned during Projects

- Ensure consistency in data
  - Nomenclature
  - Units
  - Mapping of fields

- Understand how the times associated with different measurements are handled
  - NIBP measurement vs. NIBP time posting into the EMR
Areas to Consider

- Patient association / patient disassociation
- Patient transfer
  - Single patient record
  - Avoid gaps in the data
- Validation of data
Change Management

- All changes must be assessed, approved, and implemented in a controlled manner

- Includes:
  - New software applications
  - New network appliances
  - Security changes
  - Planned upgrades
  - Planned maintenance
  - Hardware, firmware, or software upgrades
Software Management

- Convergence intermingles medical software with nonmedical software
  - Increases the likelihood of interference between different software coding elements
- The more integrated systems become, the more one part of the system can affect the whole
- Understand the hierarchies of software
  - Will an upgrade to a medical device affect data exchange into an information system?
Understanding Software Issues

- Potential large source of error
  - Difficult to test for all software defects
  - Numerous lines of code
  - Hard to anticipate every work flow or clinical process
- Despite good V&V, many software anomalies are found after public release of the product
Software Changes

Software revisions required to:

- Upgrade to a desired feature or enhancement
- Support desired interoperability between systems
- Revision level no longer supported
  - Medical device manufacturer
  - EMR vendor
- Fix a known problem
User Experience – Software Management

- Change management is crucial
  - One change can cause other parts of the system to fail or perform in unexpected ways
  - 1-3 issues can arise with one software upgrade
- Testing before implementation is critical
- Several hospitals mentioned that software revision levels were being discussed
  - EMR vendors may only support certain medical device revision levels
Software-Based Hazards and Recalls

- ECRI Institute’s *Health Devices Alerts* database contains hazard and recall information since 1982
- Searched “active” & “completed” action items
- Search parameter = *software*
- Past 15-year trend
ECRI Institute's *Health Devices Alerts* Database: Percentage of Software-Related Hazards & Recalls
- A17054 – Critical priority
  Mindray – V Series Patient Monitors: System Database Corruption May Occur, Potentially Causing Monitor to Reset and Lead to Temporary Loss of Monitoring

- A16058 02 – High priority
  GE – Model 3000, Model 4000, and Model 5000 DASH Patient Monitors Used with LA-4137 Wireless LAN Cards: Patient Monitoring, Vital Signs Data, and Alarms May be Lost

- H0150 – High Priority
  Patient Data from Philips IntelliVue Monitors May Appear on Wrong XDS Remote Display

- Main target audience is the healthcare facility
- Risk management is required for the life cycle of the medical IT-network
IEC 80001-1’s Three “Key Properties”

- Risk management should be applied to address the balance of the key properties
  - Safety
  - Effectiveness
  - Data and system security

Obtain from:
http://www.aami.org/publications/standards/80001.html
User Experience - Problem Resolution

- Troubleshooting problems is more difficult
  - More points of failure
  - More vendors to deal with
  - Finger pointing
- Typically, hospital staff need to solve the issue with input from vendors
- Need the vendors to know their technology inside and out
Physiologic Monitoring Connectivity: More than just Interfaces

- Connectivity involves much more than just technology
- System of systems
- Brings CE-IT collaboration to the forefront
- Highlights the need for:
  - Good policies and procedures
  - Good contracts
  - Good relationships with vendors
  - Good understanding of clinical work processes
Connectivity: Final Thoughts

- Very few facilities with more advanced interoperability
- Generally speaking, clinicians are satisfied with medical device integration project outcomes and view connectivity as having a positive effect on their daily work processes.
- In part, connectivity provides data to permit health facilities to measure their performance. Creating baseline measurements are key to continued process and quality improvement.
Industry Initiatives

- 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 Resources

- April 2012 issue of *Health Devices*

- October 2011 issue of *Health Devices*

- September 2011 issue of *Health Devices*
  - Vital Signs Monitoring Systems: A Look at Seven Monitors and Their Connectivity Solutions [Evaluation]