Presentation Overview

- Overview of ECRI Institute
- Survey of the Health Technology safety landscape
- *Health Devices* evaluation research
  - Process
  - Typical findings
- Other patient safety-related efforts
- A look to the future
- Questions and discussion
Our Campus
ECRI Institute Background

For over 40 years ECRI Institute has been dedicated to bringing the discipline of applied scientific research to discover which medical procedures, devices, drugs, and processes are best.

We pride ourselves in having the unique ability to marry practical experience and uncompromising independence with the thoroughness and objectivity of evidence-based research.
Typical Problem – Close to Home
Survey of the Landscape

- Wide variety of technologies (disposables to multi-parameter interconnected instruments)
- Increasing complexity and costs of technology
- Poor planning for new technology, which results in poor implementation of technology and excess costs
- Inadequately trained users
- Lack of standardization
- Pressure to rapidly adopt new technologies
- Etc.
Medical Device-Related Safety Analyses

- Health Devices Consumer Reports-like comparative evaluations
- International problem reporting system
- Accident and forensic investigation program
- Consultation and advisory services
- Standards development and other research
- General experience
Evaluation Process

- Initial research and protocol development
- Testing and writing
- Extensive internal and external document review
- Routine interaction with manufacturers
- Finished product
Infusion Pump – Sample Findings

► No set-based free-flow protection
  ■ Unacceptable

► No dose error reduction system
  ■ Not recommended

► Poor dose error reduction system implementation
  ■ Not recommended
Other Typical Findings

- Poor human factors
- Inadequate alarms and indicators
- Failure to handle the operating environment
- Battery limitations
- Inaccurate, incorrect, or misleading specifications
- No safeguards to protect from known clinical risks
Additional Safety Research
- Top Ten List of Hazards

► Historical analysis
► Health technology-related hazards that should be on every hospital’s “to-do” list to address
► Focus on prevalence and severity of reported events
► Similar in concept to widely reported “Never Events”
► Get the word out about important and preventable safety problems
► Published in *Health Devices* (November 2007 - 2012)
A guide for prioritizing technology-related patient safety initiatives
Excellent Press Pick-up

“The Gray Sheet”

The Boston Globe

npr

Healthcare IT News

Modern Healthcare

THE WALL STREET JOURNAL.

Environment of Care News

CNN Health

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THE LIST FOR 2013

1. Alarm hazards
2. Medication administration errors using infusion pumps
3. Unnecessary exposures and radiation burns from diagnostic radiology procedures
4. Patient/data mismatches in EHRs and other health IT systems
5. Interoperability failures with medical devices and health IT systems
6. Air embolism hazards
7. Inattention to the needs of pediatric patients when using “adult” technologies
8. Inadequate reprocessing of endoscopic devices and surgical instruments
9. Caregiver distractions from smartphones and other mobile devices
10. Surgical fires
Typical Incident from Critical Care

- Ventilator-dependent patient – frequent coughing
- Coughing triggers high-pressure alarm
- Frequent response to alarm by nurse with no real problem
- Pressure alarm limit increased to minimize the number of false-positive alarms
- An accident waiting to happen
  - Patient movement crimps breathing circuit
  - Secretions clog the endotracheal tube
  - Inadequate ventilation (inhalation or expiration)
1. Alarm Hazards

Risk Factors
- Nuisance alarms
- Alarm overload & fatigue
- Defeated/misconfigured alarms
- Competing alarms
- Similar devices/designs

Prevention
- Assessment of patient care areas
- Defined protocols and user permissions
- Standardization and training
My Own Alarm Fatigue

https://www.ecri.org/blog/Lists/Posts/Post.aspx?ID=140
https://www.ecri.org/blog/Lists/Posts/Post.aspx?ID=143
An Accident Waiting to Happen
2. Medication Administration Errors Involving Infusion Pumps

- Risk Factors
  - Widespread use
  - Potent medications
  - Factor of 10 errors

- Prevention
  - Adopt dose error reduction systems
  - Develop/maintain appropriate drug libraries
  - Buy-in from staff is key
SMART PUMP ISSUES REPORTED TO ECRI INSTITUTE PSO

Random Sample of 100 Reports (May 2010 to March 2012)

- Concentration issue, 29
- Programming issue, 19
- Wrong rate, 8
- Weight incorrect, 8
- Wrong drug, 6
- Wrong units, 4
- Wrong dose, 1
- Secondary/piggyback physical configuration, 15
- Pump off, 6
- Not connected to patient, 4

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Networking – New Directions for Infusion Technology
5. Health IT Interoperability Failures

Risk Factors
- Device/system incompatibilities
- Interface/device misconfiguration
- Software & OS updates

Prevention
- Inventory of networked systems
- Documented risk assessment
- Change management
- Planning & contracting
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<th>Cause(s), Contributing Factors</th>
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<th>Mitigation</th>
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**PROBABILITY**

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8. Inadequate Cleaning/Disinfection of Devices

- **Risk Factors**
  - Incomplete cleaning
  - Isolation of reprocessing staff

- **Prevention**
  - Cleaning/disinfection protocols
    - Model-specific, reviewed regularly
    - Training and communication
  - Monitoring/Quality Improvement
  - Inventory to support volume
March 2005
- Headline: Monroeville Hospital urges 200 colonoscopy patients to get checked for hepatitis, HIV
- Headline: Callers flood hospital over colon tests

April 2005
- Headline: Suit claims negligence in hospital’s colonoscopies
This Issue Has Been Covered Before

FRESENIUS — MODEL 2008H HEMODIALYSIS UNITS: INADEQUATE WIRING

Hemodialysis Units [11-218]
Device: Model 2008H Hemodialysis Units
Manufacturer: Fresenius Medical Care North America
[312187], 95 Hayden Ave, Lexington MA 02420-9192

Problems: An ECRI member hospital reported overheating and device failure of the above hemodialysis units. On investigation, the hospital determined that the most likely cause of the problem was inadequacy of the crimp connections. The manufacturer acknowledged receiving other reports of the problem but offered no solution. ECRI agrees with the hospital that the cause was poor crimp quality and does not believe that this problem presents a safety hazard to the patient or the hospital.

Action Needed: (Note: Refer to the original report, cited below, for the rationale behind the following recommendations.) ECRI recommends that biomedical engineering staff be aware of the issue and do the following: (1) Check for early signs of the problem, such as discolored or deformed insulator jackets in or near the power supplies. (2) Check the power supplies in all Model 2008H units for signs of overheating. If such signs are present, remove the damaged wiring and replace the crimp connector. For further info-

Comment: ECRI recommends that this Action Item be distributed to the following departments: CCU/ICU/NCU, dialysis/ nephrology, endocrinology, and home care. Additionally, you should determine if other departments, locations, or individuals at your facility should receive this report.

Accession No.: A4989
□ None Present: □ Action Taken: ______________________

OLYMPUS — EXERA GASTROINTESTINAL ENDOSCPES WITH AUXILIARY WATER CHANNELS: REMINDER TO REPROCESS WATER CHANNEL

Gastroscopes [11-856]
Identifier: Units distributed in the U.S. and internationally
Manufacturer: Olympus America Inc Endoscopy Group
[364575], Two Corporate Center Dr, Melville NY 11747-5157

Problems: Olympus has received reports that users may inadvertently be neglecting to reprocess the auxiliary water channel found on the above endoscopes. The auxiliary water channel allows the
9. Caregiver Distractions from Smartphones

▶ Risk Factors
- Patient Care Interruption
  - Clinical messages
  - Personal use
- Interruption of Clinical Data Entry

▶ Prevention
- Mobile Device Policy
- Awareness
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Common Themes

- Awareness
- Prevention
- Mitigation

Bottom Line

Systematic Ongoing Effort

- Assessment
- Process Improvement
- Awareness Building
- Education
My Look into the Future
Safety-Related Implications – On Our Way to the Future

► Everything will be connected – everywhere
► Single points of failure can have major impact
► The new paradigm for health technology management will be complexity management
► A much needed role for professionals who can manage this complexity
► CNN Money’s prediction for clinical engineering job growth seems legitimate
When will we get there?

I’ll take a spin to check it out!
Thank You

www.ecri.org

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