Top Ten Health Technology Hazards

MASHMM – July 19, 2013

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Presentation Overview

- ECRI Institute overview
- Survey of the health technology landscape
- Review of ECRI Institute’s “Top Ten” list
- Additional high profile problems
- Key measures for improving medical device-related safety
  - Hazard and recall management
  - Risk assessments
- Useful references
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
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)
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
TOP 10 HEALTH TECHNOLOGY HAZARDS FOR 2013

Most medical device hazards are avoidable. Which ones should be top priority among your patient safety initiatives?

1. Alarm hazards
2. Medication administration errors using infusion pumps
3. Unnecessary exposures and radiation burns from diagnostic radiology procedures
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From ECRI Institute’s Top 10 Health Technology Hazards for 2013
For more information, call (610) 622-8000, ext. 5891.
Multi-Media Promotions

Top Ten Hazard Video
Excellent Press Pick-up

“The Gray Sheet”

The Boston Globe

npr

Healthcare IT News

Modern Healthcare

THE WALL STREET JOURNAL.

Environment of Care® News

The Official Joint Commission Environment of Care, Emergency Management, and Life Safety News Source

CNN Health
Top 10 Health Technology Hazards

Common Themes
► Awareness
► Prevention
► Mitigation

Bottom Line
Systematic Ongoing Effort
► Assessment
► Process Improvement
► Awareness Building
► Education
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 (inhilation or expiration)
Some Questions to Ask

- Does the nurse understand the purpose of the high-pressure alarm?
- Was the nurse’s competence in ventilator use validated?
- Does the hospital have a policy for who can and cannot set ventilator alarms?
- Is there a policy on how ventilator alarms should be set?
  - If so, is it generic or does it consider specific circumstances?
  - Does the hospital have ventilator responsive-valve features, which can reduce nuisance high-pressure alarms?
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

"Alarm fatigue" blamed in hospital deaths
Boston Globe probe: More than 200 linked to alarms in past 5 years, many because so many go off, nurses often ignore them
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
2. Medication Administration Errors Involving Infusion Pumps
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
- Secondary/piggyback physical configuration, 15
- Pump off, 6
- Wrong dose, 1
- Wrong units, 4
- Wrong drug, 6
- Wrong rate, 8
- Weight incorrect, 8
- Not connected to patient, 4
- Programming issue, 19
This is Your Future and It Won’t be Easy
3. Unnecessary Exposures and Radiation Burns from Diagnostic Radiology Procedures

- **Risk Factors**
  - Incorrect protocol/configuration
  - Unnecessary studies
  - Ineffective studies

- **Prevention**
  - Promote awareness
  - Justify imaging studies
  - Optimize scanning protocols
  - Technologist training
  - Quality control
Exposure at a Young Age a Key Concern

![Image of a CT scan]

**Lifetime Cancer Risk—Incidence and Mortality from a Single CT Scan**

- **Incidence**
- **Mortality**

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4. Patient/Data Mismatches in EHRs and other Heath IT Systems

Risk Factors
- Device/system incompatibilities
- Patient association scheme
- Network outages
- Fast-track EHR implementations

Prevention
- Patient-centric EHR association
- Patient disassociation protocols
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
## HIT Risk Assessment under IEC 80001-1

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### PROBABILITY

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6. Air Embolism

**Risk Factors**
- Venous catheters
- Infusion/injection devices
- Luer connectors on air delivery devices
- Surgery/endoscopy

**Prevention**
- Departmental risk assessment
- Product assessment/selection
- CO₂ insufflation gas
7. Inattention to Pediatric Technology Needs

- Risk Factors
  - Technology designed for adults
  - Radiation exposure
  - Medication dosing errors
  - Inadequate “pediatric” inventory

- Prevention
  - Pediatric technology safety
    - Pediatric inventory protocols
    - Product assessment/selection
    - Identify/address incompatibilities
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
  - Control of contaminated devices
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

HEALTH DEVICES ALERTS

FRESENIUS — MODEL 2008H HEMODIALYSIS UNITS: INADEQUATE WIRING

Homodialysis Units [11-218]

Device: Model 2008H Hemodialysis Units

Manufacturer: Fresenius Medical Care North America

[312187], 95 Hayden Ave, Lexington MA 02420-9192

Problem: 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 but 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 infor-

Comment: ECRI recommends that this Action Item be distributed to the following departments: CCU/CICU, 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 ENDOSCOPES 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 11747-3157

Problem: 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
10. Surgical Fires

- Risk Factors
  - Surgical Environment
  - Awareness
  - Response

- Prevention
  - Training
    - Control of oxygen source
    - Control of ignition source
    - Control of fuel source
    - Response protocols
Fire Video Collaboration with the Anesthesia Patient Safety Foundation

http://www.apsf.org/resources_video_watch.php
Common Themes
- Awareness
- Prevention
- Mitigation

Bottom Line
Systematic Ongoing Effort
- Assessment
- Process Improvement
- Awareness Building
- Education

THE LIST FOR 2013
1. Alarm hazards
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Other Notable Hazards – From Previous Lists

- Burns during electrosurgery
- Fiberoptic light-source burns
- Misconnection of blood pressure monitors to IV lines
- Ferromagnetic objects in the MRI environment
A Scary User-Related Problem

Spermatic Cord Damage from Electrosurgery
Safety Alerts Management: An Escalating Burden

ECRI Institute Medical Device Safety Alerts

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Hazard and Recall Management

As part of ECRI Institute's mission to improve patient safety, since 1977 we have published Health Devices Alerts to inform healthcare professionals about medical device hazards and recalls.

ECRI Institute has published over 50,000 Health Devices Alerts Action Items and Abstracts since then.

In 2003 ECRI Institute introduced its “Alerts Tracker” service to facilitate the electronic distribution and tracking of its notices.
An Effective Safety Alerts Program

- Captures Complete Alerts Information
- Promotes Staff Involvement
  - Individualized Alert Distribution
  - Communication and Information Sharing
- Closed Loop Process
- Reporting to Support Program Management
  - Sponsorship and Awareness
  - Process Management
  - Accountability
  - Detailed Documentation of Specific Alerts
Top 10 Health Technology Hazards

Common Themes
- Awareness
- Prevention
- Mitigation

Bottom Line
Systematic Ongoing Effort
- Assessment
- Process Improvement
- Awareness Building
- Education
Medical Technology Safety Survey

- Routine assessment of how you are doing
- Focus on technologies with a high-level of concern (e.g., among the Top Ten)
- Establish a checklist for regular (e.g., annual) walk-through
- Examples
  - Infusion pump set-based free-flow protection
  - Observation of clinical alarm settings
  - Misconnection possibilities
  - Follow-through on known hazards and recalls
ECRI Institute’s Top 10 Hazards Self-Assessment Tool

- Allows facilities to quickly estimate their vulnerability
- Provides a simple tool to send out and manage short surveys for selected staff
- No need to analyze survey results – automatically done by the application based on question weightings developed by our topic experts
- Dashboard allows you to view relative risk bar graphs for each hazard surveyed
- Confirm that your patient safety initiatives are helping to address recognized hazards
- Pick and choose which hazards to examine – from just one or two up to all 10
Survey results appear in bar graph format for each hazard - showing your specific risk.
Printable Summary Report

ECRI Institute’s
2013 Top 10 Technology Hazard Self Assessment Tool
Plymouth Hospital Summary Report

Plymouth Hospital has chosen to use ECRI Institute’s Top 10 Technology Hazard Self Assessment Tool to prioritize the organization’s vulnerabilities. The tool helps healthcare facilities to prioritize their technology safety initiatives. The tool highlights technology safety hazards that ECRI believes warrant particular attention in the opening year. Throughout each year, ECRI Institute engineers, clinicians, and safety analysts evaluate health technology hazards, including technology malfunctions, staff training in technology safety, and policy adherence. Key focus areas include reviewing the literature, speaking with clinicians and clinical engineers, as well as technology problem reports and device interactions.

The following survey measures outcomes for the risk level assessed for each topic. The survey is an important tool for self-assessment and a guide to starting discussions that can be used to assess the vulnerabilities of the organization to specific technology hazards.

For more comprehensive understanding of the hazards, readers are encouraged to refer to the 2013 Top 10 Technology Hazards report and any additional ECRI Institute reports. Topics from the 2013 list that were not assessed in this report are listed in the report appendix.

Top Risk Factors

The following survey measures outcomes for the risk level assessed for each topic.

Survey (EHR, Wireless, Wired, NUC, PACU)

Risk Level: Moderate Risk

Assessed Date: 12/18/2013

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The Discipline of Science. The Integrity of Independence.
General Recommendations

- Pay close attention to appropriate technology selection and use
- Establish safety-related device selection criteria
- Plan for user training during technology acquisitions
- Conduct ongoing training and check for proficiency
- Plan for new technology at the right time and for the right reasons
- Monitor for ongoing risks, take appropriate steps to reduce risk, and document actions taken
Thank You
Useful References

- Top 10 Hazard Resource Center – www.ecri.org
- Top 10 Health Technology Hazards for 2013: Key Patient Safety Risks and How to Keep them in Check. *Health Devices*, November 2012
- Top 10 Technology Hazards for 2012: Key Technology Risks to Keep in Check. *Health Devices*, November 2011