ECRI Institute

- Non-profit 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
UNIQUELY QUALIFIED:

- U.S. Agency for Healthcare Research and Quality Designations
  - Evidence-Based Practice Center
  - Patient Safety Organization (PSO)

- Renowned Evaluator of Healthcare Technology
  - Physical testing, human factors assessment, and life cycle cost analysis
  - Accident and forensic investigations
  - Comparative effectiveness research
Top 10 Health Technology Hazards

Common Themes
- Awareness
- Prevention
- Mitigation

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

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EMERGENCY PROCEDURE
EXTINGUISHING A SURGICAL FIRE

Fighting Fires ON the Surgical Patient
Review before every surgical procedure.

In the Event of Fire on the Patient:
1. Stop the flow of all airway gases to the patient.
2. Immediately remove the burning materials and have another team member extinguish them.
   If needed, use a CO₂ fire extinguisher to put out a fire on the patient.
3. Care for the patient:
   __Resume patient ventilation

https://www.ecri.org/surgical_fires
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9. Caregiver Distractions from Smartphones

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

Prevention
- Mobile Device Policy
- Awareness
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

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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
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
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

<table>
<thead>
<tr>
<th>#</th>
<th>Hazard</th>
<th>Hazardous Situation</th>
<th>Cause(s), Contributing Factors</th>
<th>Harm</th>
<th>Initial Risk</th>
<th>Mitigation</th>
<th>Reference</th>
<th>Residual Risk</th>
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### SEVERITY

- **Catastrophic**
  - Improbable: Yellow
  - Remote: Red
  - Occasional: Red
  - Probably: Yellow
  - Frequent: Red

- **High**
  - Improbable: Yellow
  - Remote: Red
  - Occasional: Red
  - Probably: Yellow
  - Frequent: Red

- **Medium**
  - Improbable: Yellow
  - Remote: Red
  - Occasional: Red
  - Probably: Yellow
  - Frequent: Red

- **Low**
  - Improbable: Yellow
  - Remote: Red
  - Occasional: Red
  - Probably: Yellow
  - Frequent: Red

- **Negligible**
  - Improbable: Yellow
  - Remote: Red
  - Occasional: Red
  - Probably: Yellow
  - Frequent: Red
4. Patient/Data Mismatches in EHRs

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

Prevention
- Patient-centric EHR association
- Patient disassociation protocols
3. Unnecessary/excessive Radiation Exposure

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

Prevention
- Promote awareness
- Justify imaging studies
- Optimize scanning protocols
- Technologist training
- Quality control
2. Medication 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
- Secondary/piggyback physical configuration, 15
- Wrong drug, 6
- Wrong rate, 8
- Weight incorrect, 8
- Wrong units, 4
- Wrong dose, 1
- Pump off, 6
- Not connected to patient, 4
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
Taking Action - Alarms

- Form Team
  - Sponsorship
  - Team Leaders
  - Safety Champions

- Assess
  - Identify Care Areas
  - Inventory Equipment
  - Inventory Alarms

- Plan & Implement
  - Policies
  - Training
  - Follow-up Assessment

ECRI Institute
The Discipline of Science. The Integrity of Independence.
Last Year’s No. 1 Hazard: Leo

- Incidents
  - Dismantled suction canister
  - Repeatedly removed SP0₂ probe
  - Pulled monitor to crib and reset alarms

- Prevention
  - Unstoppable
Top Ten Health Technology Hazards 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

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Health Technology Hazard Self-Assessment Tool - View Single Facility Results

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<tr>
<th>Survey Topics</th>
<th>Assessed Risk Level (Low - High)</th>
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<td>(01) - Alarm Hazards</td>
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<tr>
<td>(02) - Medication Errors Using Infusion Pumps</td>
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<td>(03) - Unnecessary Radiation Exposures</td>
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<td>(04) - Patient &amp; Data Association Error in EMRs</td>
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<td>(05) - Device &amp; Health IT Interoperability Failures</td>
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<td>(06) - Air Embolism Hazard</td>
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<td>(07) - Inattention to Needs of Pediatric Patients</td>
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<td>(08) - Endoscope and Instrument Infection Risks</td>
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<td>(09) - Digital Distractions with Smart Phones</td>
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<td>(10) - Surgical Fires</td>
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![Chart showing assessed risk level for Hospital A and Hospital B]

- Survey potentially affected departments on relevant hazards.
- 7 to 12 yes/no questions on each hazard.
- Aggregate results to identify high impact safety initiatives.
- Contact
  
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Thank You