

Medical Device Accident Investigation

Northeastern Healthcare Technology Symposium
Sturbridge, MA – October 8, 2008
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copy of presentation will be at www.nesce.org

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Incident Investigation

- Pre-incident Preparation
 - Develop the right relationships
 - Establish authority
 - Prepare the organization
 - Train those on the front line
 - Train those in support roles
 - Have outside support lined up
 - Prepare your response kit (“tool-box”)
 - Practice responding

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Incident Investigation

Clinician Response

- **Ensure the Safety** and continued treatment of the patient.
- **Replace the Device** involved in the incident as soon as possible. Replace all involved disposable accessories such as electrodes, catheters, or tubing sets provided that the patients condition can tolerate the change-over. Disposables often contribute to the event and should be retained and evaluated as well.
- **Impound** the equipment, all disposables and packaging for disposables, by placing small items in a plastic bag clearly labeled: “IMPOUNDED - DO NOT DISCARD OR TAMPER”. Affix the bag to any large device in question.
- **Secure** the impounded items in a locked room until the Clinical Engineer or other authorized investigator arrives to document and investigate the incident.
- **Document** all applicable information in complete accordance with the hospital incident policy. Include information concerning device settings, treatments in progress, other devices in use at the time including Control Numbers or serial numbers.
- **Notify** the appropriate person in the hospital to commence an investigation.
- **Expect** the Clinical Engineer or other agent to contact the involved staff and to evaluate the equipment. Interviews are not for the purpose of finding a scapegoat: they are to collect information so problems related to device defect or unsafe equipment can be quickly resolved.
- The Clinical Engineer will provide a written report to the hospital contact and/or safety committee in a timely manner. The hospital is then responsible to pursue appropriate actions to rectify, document, and prevent similar occurrences.

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Incident Investigation

- Arrive with the right tools (tool box)
- Document the overall scene – layout
- Document environmental issues
- Document the arrangement of the people and their roles
- Document the settings, connections and nearby but apparently uninvolved equipment

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Incident Investigation

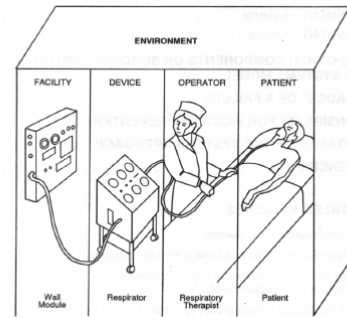


Figure 1-1

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Incident Investigation

- Photograph everything – a good camera is important & a microscope
- Test the equipment – against know standard
- Do not fix the equipment – spoliation is bad
- Write the report – nothing but the facts
- Develop your opinions separately

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Incident Investigation

- Work with & report to Risk Manager
- Do things by the book – follow policies and procedures
- A lawsuit could develop and unproven opinions and conclusions will become facts in the mind of opposing lawyers

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Incident Investigation

- Using outside consultants
- Work with the Risk Manager
 - Know your limitations
 - Anticipate where the process will end up
 - You can't write a report that comments on your activities (PM, repair, recall mgt)
 - An independent outside expert that supports your position is a strong ally

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Incident Investigation

● In Retrospect

- If you have good well thought out policies and procedures
- If you inspect and repair equipment, manage recalls and safety issues according to policies and procedures
- If you work closely with Risk Management during incident investigations
- If you know when to step aside and use an outside expert
- Things will go well for CE.

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Root Cause Analysis

- Process for identifying the basic or causal factors in performance variation
- Focuses primarily on systems and processes, not individual performance
- No assignment of blame
- Find the factors that enabled the event to occur

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Root Cause Analysis

● Reactive – probe the reason for problems that already occurred

- To prevent recurrence
- To create an action plan for improvement
- To probe near-misses

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Root Cause Analysis

● Proximate Causes

- Superficial
- Obvious
- Immediate
- Special causes

● Underlying Causes

- Causes that lead to the proximate cause
- Common causes

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Root Cause Analysis

- Do not solve problems by eliminating special causes or proximate causes
- Probe, understand and address underlying common causes or root causes
- Ask the question Why? Why? Why? to get to the root cause.

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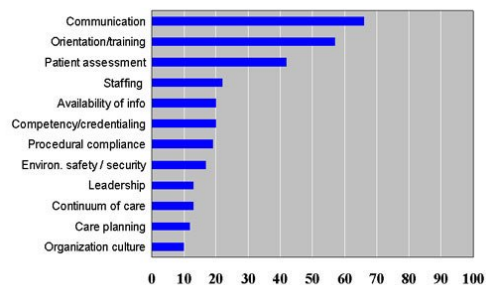
Root Cause Analysis

- Mechanical breakdown of a piece of equipment in surgery -> problem with organization's PM activities
- Intoxicated employee -> organization's screening and hiring practices
- Equipment failure causes death -> lack of policy related to tracking and follow through on recalls and alerts

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JCAHO Sentinel Events

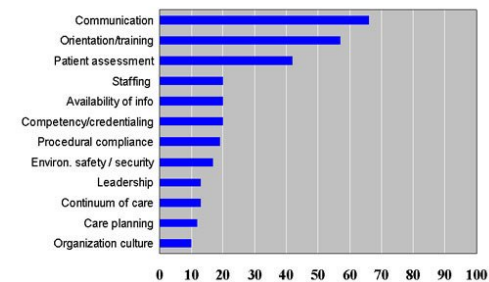
Root Causes of Sentinel Events
(All categories; 1995-2004)



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JCAHO Sentinel Events

Root Causes of Ventilator Events
(1995-2004)



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JCAHO 2007 Patient Safety Goals

- Goal 1 Improve the accuracy of patient identification.
- Goal 2 Improve the effectiveness of communication among caregivers
- Goal 3 Improve the safety of using medications.
- Goal 7 Reduce the risk of health care-associated infections.
- Goal 8 Accurately and completely reconcile medications across the continuum of care to prevent medication errors.
- Goal 9 Reduce the risk of patient harm resulting from falls.
- Goal 10 Reduce the risk of influenza and pneumococcal disease in institutionalized older adults.
- Goal 11 Reduce the risk of surgical fires.
- Goal 12 Implementation of applicable National Patient Safety Goals and associated requirements by components and practitioner sites.
- Goal 13 Encourage patients' active involvement in their own care as a patient safety strategy.
- Goal 14 Prevent health care-associated pressure ulcers (decubitus ulcers).
- Goal 15 The organization identifies safety risks inherent in its patient population.

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Resolved Patient Safety Goals

- Goal 4 - Wrong Site-Wrong Side Surgery
- Goal 5 - IV Pump Free Flow
- Goal 6 – Clinical Alarm systems

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Analyzing Events

- **Retrospective**
 - Root Cause Analysis
 - Get to the root of the problem, not the apparent, surface or proximate cause (special cause)
 - Ask - why, why, why
- **Prospective**
 - Failure Modes and Effects Analysis
 - Analyzes what could go wrong, the likelihood it will go wrong and the effect if it did.

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High Risk Equipment

- Anesthesia Machines -- Added Vaporizers
- Outdated Anesthesia Machines
- Anesthetizing Locations Outside the Operating Room
- Anesthesia Vaporizer Calibration
- Heated Humidifiers
- Infant Ventilators
- Continuous Oxygen Monitoring
- Electronic Infusion Devices
- Tourniquets in Surgery
- Creation of Oxygen-Enriched Atmospheres
- Medical Air Systems
- Electrosurgical Units
- Reusable Electrosurgical Electrodes and Cables
- Laparoscopic Instruments
- Infant Radiant Warmers
- Outdated Incubators
- Outdated Cribs

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Never Events – National Quality Forum

- **Surgical Events**
- Surgery performed on the wrong body part
- Surgery performed on the wrong patient
- Wrong surgical procedure on a patient
- Retention of a foreign object in a patient after surgery or other procedure
- Intraoperative or immediately post-operative death in a normal healthy patient
- **Product or Device Events**
- Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the healthcare facility
- Patient death or serious disability associated with the use or function of a device in patient care in which the device is used or functions other than as intended
- Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a healthcare facility
- **Patient Protection Events**
- Infant discharged to the wrong person
- Patient death or serious disability associated with patient disappearance for more than four hours
- Patient suicide, or attempted suicide resulting in serious disability, while being cared for in a healthcare facility

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Never Events – National Quality Forum

- **Care Management Events**
- Patient death or serious disability associated with a medication error
- Patient death or serious disability associated with a hemolytic reaction due to the administration of ABO-incompatible blood or blood products (transfusion of the wrong blood type)
- Maternal death or serious disability associated with labor or delivery on a low-risk pregnancy while being cared for in a healthcare facility
- Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in a healthcare facility
- Death or serious disability (kernicterus) associated with failure to identify and treat jaundice in newborns
- Stage 3 or 4 pressure ulcers acquired after admission to a healthcare facility
- Patient death or serious disability due to spinal manipulative therapy
- **Environmental Events**
- Patient death or serious disability associated with an electric shock while being cared for in a healthcare facility
- Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by toxic substances
- Patient death or serious disability associated with a burn incurred from any source while being cared for in a healthcare facility
- Patient death associated with a fall while being cared for in a healthcare facility
- Patient death or serious disability associated with the use of restraints or bedrails while being cared for in a healthcare facility

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Break Time

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