Improving Patient Safety by Reporting Problems with Medical Devices



Medical Product Safety Network

Reporting Problems with Medical Devices

At the end of this session you will be able to:

1. Identify several types of medical devices
2. Explain why reporting problems with medical devices is important
3. Describe your role in promoting patient safety with medical devices
4. Describe the steps to take to report an adverse event or problem with a medical device in our hospital

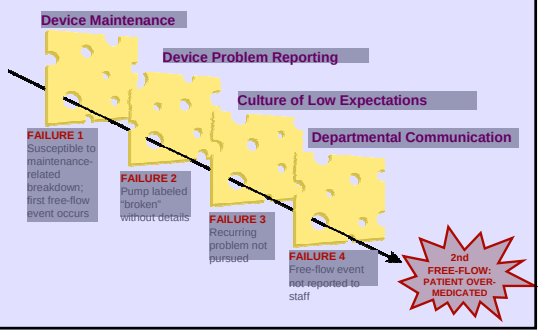
Types of Medical Devices and Examples

- **Capital Equipment**
  - cribs, bedrails, scales, wheelchairs, IV poles, infusion pumps, bathing tubs, blood pressure equipment, MRI and CAT scanners, radiology equipment
- **Instruments**
  - lab equipment, surgical staplers, glucose meters, pulse oximeters
- **Monitoring Systems**
  - cardiac, telemetry, patient call
- **Reagents**
  - laboratory solutions
- **Disposables & Accessories**
  - ventilator breathing circuits, filters
  - needles, syringes, trocars, IV catheters, IV tubing, foley catheters, feeding tubes, gloves
- **Implantable**
  - defibrillators, ventriculoperitoneal shunts
- **Computerized Medical Systems**
  - hardware
  - software versions

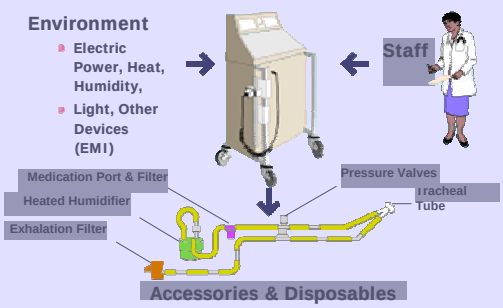
"Medical errors most often result from a complex interplay of multiple factors. Only rarely are they due to the carelessness or misconduct of single individuals."

Lucian L. Leape, M.D.
A leading patient safety expert from Harvard University

"Swiss Cheese" Model of System Failure that Can Lead to Injury



Think About the Device and its Environment



What Types of Medical Device Problems Should I Look for?

- Instructions/labeling/packaging
- Defects
- Software problems
- Failure to work as intended/malfunction
- Interactions with other devices
- Use errors
- Combinations of the above

Examples of Problems

- **Instructions/Labeling/Packaging**
  - age/weight specific usage information not provided
  - new cardiac catheterization kit changed to non-sterile outer package; staff unaware and thought entire package was sterile
  - staff discovered contaminants in the buretrol packaging

Examples of Problems (continued)

- **Defects**
  - IV pump bracket found with large crack and sharp edges
  - infant heal warmer pack leaking
  - gloves found discolored and with holes
  - nurse opened two suction catheters and discovered a knot in one

Examples of Problems (continued)

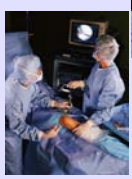
- **Software problems**
  - imaging workstation downloaded patient A's images into patient B's folder
  - CT scanner found to have a software glitch in new version
  - virus infects device operating software

Examples of Problems (continued)

- **Failure to work as intended/ malfunction**
  - open warmer bed improperly measuring patient temperature
  - stapler fired but did not cut
  - point-of-care glucose results differ from lab results

Examples of Problems (continued)

- **Interactions with other devices**
  - burns with use of orthopedic shaver and grounding pad
  - sandbag exploded inside MRI machine



Examples of Problems (continued)

- **Use Errors**
  - infusion pumps by the same manufacturer look similar but operate differently
  - otoscope and transilluminator look the same but have different light intensities
  - incorrectly positioned radiant warmer temperature sensor causes overheating

Why Reporting Medical Device Problems Is Important In Our Hospital

- Prevent future problems and protect our patients, staff, families, and visitors
- Achieve performance improvement goals
- Assist Risk Management with claims or litigation
- Provide information to manufacturers and/or U.S. Food and Drug Administration
- Impact the public health for the nation's patients and/or health care providers
- Effect changes in policies and procedures

When Do I Report?

- When you think a device has or may have caused or contributed to any of the following outcomes (for a patient, staff member or visitor):
  - Death
  - Serious injury
  - Minor injury
  - Close calls or other potential for harm

What Do We Mean by "Potential for Harm?"

- **Events that are caught before anything harmful occurred**
  - compatible connection between blood pressure cuff tubing and IV luer port
- **Important observations of a chronic problem with a device**
  - electrosurgical units used in an oxygen-rich environment
- **Problems which lead staff to develop "work-a-rounds"**
  - taping devices together, or substituting parts because of problems with a certain part
- **"Out-of-the-box" problems that are identified before use on a patient**
  - ECMO membrane found to leak prior to being used on patient

What Do I Report?

- **If there was an injury, what happened to the persons affected?**
  - second degree burn, respiratory arrest
- **What, if any, were the problems with the device(s) involved?**
  - circumcision clamp failed due to mismatched parts
- **What, if any, were the original medical procedures for which the devices were used?**
- **What, if any, were the follow-up medical procedures required because of the event?**
  - repeat surgery, antibiotics administered
- **What are the names of the manufacturers of the devices involved?**
- **What are the relevant manufacturer device identification numbers?**
  - serial, model, lot, catalog, and any other specific information
- **What did you do to solve the problem?**

How Do I Report?

Our Reporting System Involves . . .

(Customized responses would be listed below)

- *Online reporting system via hospital intranet*
- *Verbal or written reporting to supervisor*
- *Written acknowledgment to the reporter including any follow up actions*
- *Reward system for "best catches" that make patient care safer*

When You See a Device That Presents a Problem You Should . . .

(Customized responses would be listed below)

- *Attach an "out of service" tag and complete any questions to explain what happened*
- *Inform your supervisor or biomedical engineering*
- *Complete an incident report*
- *Save the device and packaging and place in a clear plastic bag*

Some Issues We've Addressed at Our Hospital

What Was Reported . . .	**What We Did . . .**
(Customized responses to appear below)	*(Customized responses to appear below)*
ECMO pump malfunction	*Found electromagnetic interference with nearby use of walkie-talkie; frequency changed; reported to MedSun*
backflow of secondary IV fluid	*consulted manufacturer; height issue enforced with IV bags; reported to MedSun*

Fostering a Climate of Patient Safety

(Customized responses would be listed below)

- *Feedback and communication*
- *Learning from errors*
- *Compliance with policies and procedures*
- *Teamwork*

If You're Not Sure What or How to Report

(Customized responses would be listed below)

- *Refer to the incident reporting section in our Policy and Procedures manual*
- *Ask your supervisor, or*
- *Call our reporting hotline at extension _____*

Your Role

- Identify actual and potential problems, adverse events, close calls with medical devices
- Report the problem or adverse event to your supervisor, according to policy and procedure
- Make sure your report includes details
- Remove the device and save the packaging

In Summary . . .

Our objectives were to:

1. Identify several types of medical devices
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Have we met them?

And Remember . . .

We can't address issues we don't know about.

Please report.