MedSun Educational Training Program

"Improving Patient Safety by Reporting Problems with Medical Devices"
INSTRUCTOR GUIDE and SCRIPT

GENERAL VERSION

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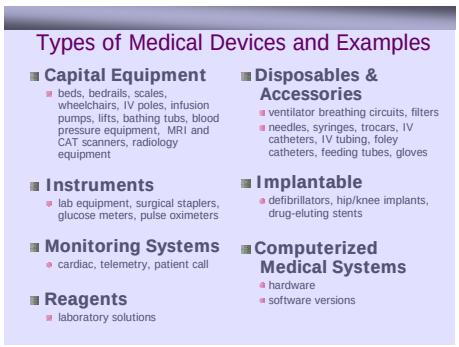
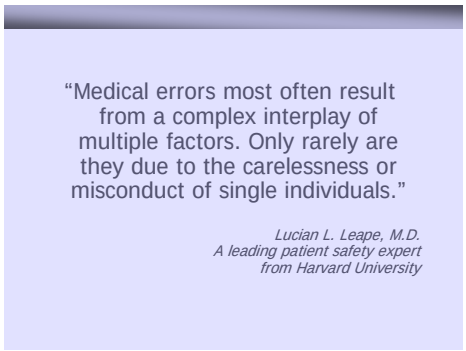
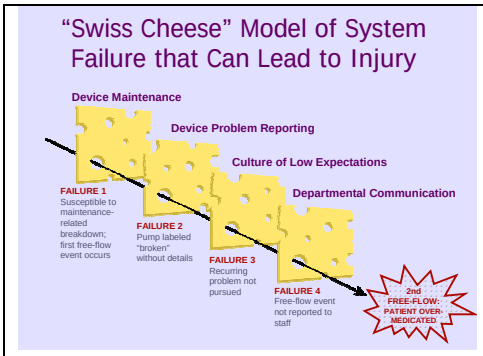
SLIDE #	SCRIPT
1. 	**DISPLAY SLIDE # 1** **Welcome participants**. **STATE**: For the next 10 minutes we'll be talking about improving patient safety in our hospital. As you may know, our hospital is involved in a project called MedSun, which is a device-reporting project with the FDA. MedSun involves many other hospitals that are working with FDA to ensure patient safety by reporting adverse events involving medical devices.
2. 	**DISPLAY SLIDE # 2** **STATE:** Our goal for the session is to 1)increase awareness of incidents that potentially involve a medical device or technology and 2) encourage our staff to report it quickly. **READ OBJECTIVES ON SLIDE**: At the end of the session you will be able to: ° Identify several types of medical devices ° Explain why reporting problems with medical devices is important ° Describe your role in promoting patient safety with medical devices ° Describe the steps to take to report an adverse event or problem with a medical device in our hospital **CLARIFY AND CONFIRM AS NEEDED**

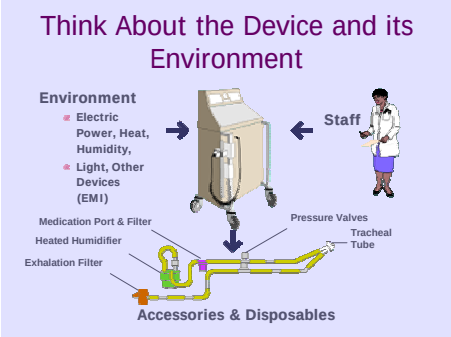
3.  	**DISPLAY SLIDE # 3** **EXPLAIN:** This slide lists types of medical devices in some general categories that you may be familiar with or work with on a daily basis. Some devices you may not realize are considered medical devices by the FDA such as laboratory solutions or computer software. This list is not all-inclusive but gives you some idea of the spectrum of devices. As you may know, devices can be anything from a q-tip and tongue depressor to a sophisticated scanner or hi tech heart lung machine. It's important to note here that regardless of how the simple the device may be, it can still be problematic and contribute to an adverse event for a patient.
4.  	**DISPLAY SLIDE # 4** **STATE:** This next slide is a quote from Dr. Lucien Leape from Harvard that reads, " Medical errors most often result from a complex interplay of multiple factors. Only rarely are they due to the carelessness or misconduct of a single individual." This quote addresses the complexity of a medical error and the challenges of determining what happened, who's involved and why. The kinds of adverse events we're discussing with devices falls under the general category of medical error.
5	**DISPLAY SLIDE # 5** **EXPLAIN:** This slide is a modified version of the "Swiss Cheese" model developed by James Reason, a well-known safety expert. It depicts a trajectory of



harm (shown here as the black arrow) that moves through a hole or breaks-downs in systems where the cumulative effects of failures result in harm to a patient. Also, it can be described as a domino effect that continues because no intervention occurs. It's important to note here that in isolation, each hole or failure in and of itself may be okay but as a process of successive failures the result can be serious harm or even death for a patient.

Let's look at the model in the context of a problem involving an infusion pump. We begin with an infusion pump that's not maintained and prone to break-down – a free flow event happens. The problem is not reported completely or in detail for the biomedical department, the tag only says, "broken, " the hospital's culture is one in which staff expect that device problems will always exist and nothing gets fixed well anyway, nor are they even communicated among departments, so free flow happens again and the result is catastrophic. You can apply this model to any potential for harm from a device that can easily slip through the holes.

6.

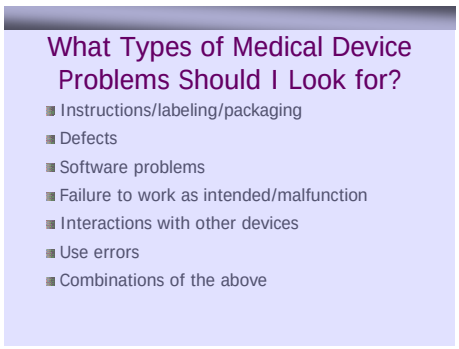


DISPLAY SLIDE # 6

EXPLAIN:

We know of the interface between devices and patients, but it's important to consider the device in its many interfaces as well. The device shown here is a ventilator. When an adverse event occurs, it's important to consider all characteristics of the

- **Environment:** such as the power source, lighting, and other devices, and the
- **Peopl**e involved: who may be the patient,

	device-operator, or visitors, and any ◦ **Accessories and disposables**: attached such as filters, valves, ports, and tubing, etc. Any or many of these aspects of the adverse event may be the reason or a contributing factor and warrants further investigation to determine what may have happened.
7. 	**DISPLAY SLIDE # 7** **What Types of Medical Device Problems Should I Look for?** **STATE:** This is a list of broad categories or ways to classify possible causes of adverse events. Some of what is listed here may remind you of problems you've had or times you have questioned a device as the reason for a problem. Let's briefly run through the list here and we'll cover more detail with examples in the next several slides from actual MedSun reports. **NOTE TO INSTRUCTOR**: read the list and move to next slides. ◦ **Instructions/labeling/packaging** ◦ **Defects** ◦ **Software problems** ◦ **Failure to work as intended/malfunction** ◦ **Interactions with other devices** ◦ **Use errors** ◦ **Combinations of the above**

8.

Examples of Problems

- **Instructions/Labeling/Packaging**
  - dialysis bag pin not clearly labeled so fluid did not infuse
  - new cardiac catheterization kit changed to non-sterile outer package; staff unaware and thought entire package was sterile
  - Salem sump tube package discovered contaminated

DISPLAY SLIDE #8

NOTE to instructor: **Briefly** describe the examples on each slide. It's important to maintain a steady pace as you move through these next few slides to keep within the time frame. **Spend approximately 1 minute per slide**.

Instructions/Labeling/Packaging

- Dialysis pin was not clearly labeled so the staff person didn't know to release the pin for the fluid to infuse
- New cardiac cath kit outer package was changed to non-sterile but staff weren't aware and assumed it was all sterile
- Staff discovered contaminants in the packaging for a Salem sump tube

9

Examples of Problems
(continued)

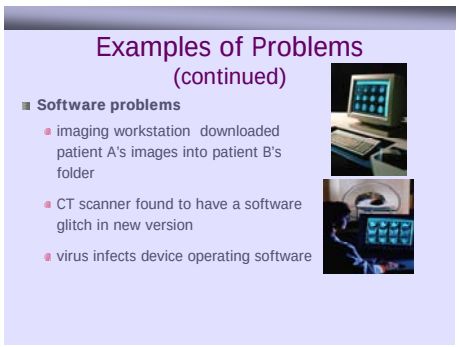
- **Defects**
  - IV pump bracket found with large crack and sharp edges
  - ventilator started smoking
  - gloves found discolored and with holes
  - gastric pH capsule failed to transmit results to external receiver

DISPLAY SLIDE # 9

Defects

- A biomedical engineer was notified of a large crack & sharp edges on an IV pump bracket that resulted in a cut on a patient's hand
- Smoke was noticed coming from a ventilator
- Gloves were found discolored and had holes in them
- We've also had a few reports that a new gastric pH capsule failed to transmit results to an external transmitter

10.

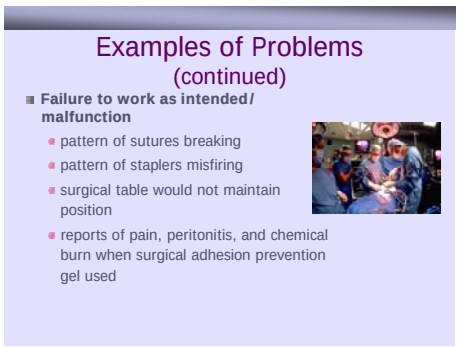


DISPLAY SLIDE # 10

Software Problems

- Some examples of medical computer software problems included an imaging workstation that downloaded patient A's images into patient B's folder and
- A CT scanner was found to have a glitch in the newer version that caused invalid dates to appear
- A virus from a hospital information system infected software used for operating a medical device

11.



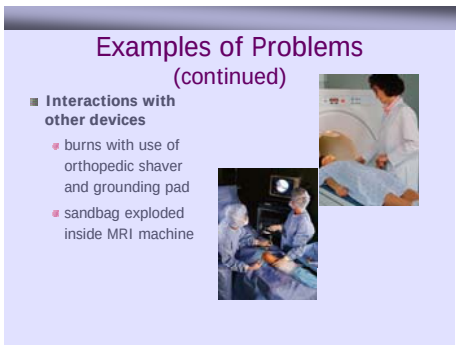
DISPLAY SLIDE # 11

STATE: Some examples of . . .

Failure to work as intended/malfunction include:

- A pattern of sutures breaking
- A pattern of staplers misfiring
- Surgical table that would not maintain position and although did not result in patient injury, the table and patient dropped several inches toward the floor
- Another example is reports of pain, peritonitis, and chemical burns after a surgical adhesion prevention gel was used in surgery

12.

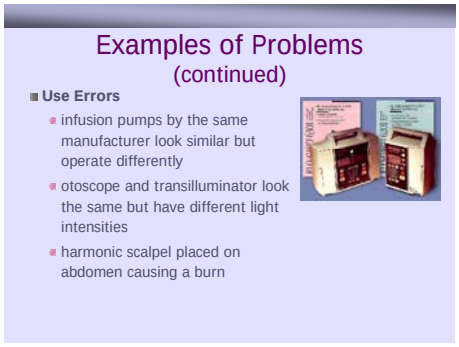


DISPLAY SLIDE # 12

Interactions with other devices includes:

- Burns with use of an orthopedic shaver and grounding pad where the voltage potential between them was higher than expected
- A sandbag exploded inside a MRI machine and was found to have metal pellets inside that staff were unaware of

13.



DISPLAY SLIDE # 13

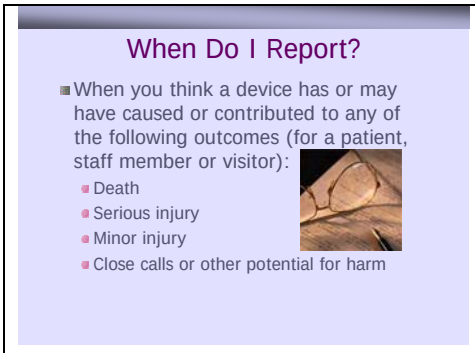
STATE: In looking at . . .

Use Errors, we've had reports about

- Infusion pumps that are made by the same manufacturer and look similar but operate differently so misprogramming of a medication occurred
- An otoscope and a transilluminator (used for locating veins for an IV) look the same but have different light intensities; staff took the otoscope and it resulted in a burn to a child
- A harmonic scalpel placed on an abdomen caused a burn

STATE: It's important to note here that although you may think of these examples solely as "use error" they may be the result of a poorly designed device so it's important to report it to us.

14.  	**DISPLAY SLIDE # 14** **STATE:** So let's talk specifically about our hospital and. . . **"Why Reporting Medical Device Problems is Important in Our Hospital. It will, most importantly, . . . "** (Read slide) ◦ 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 nations' patients and/or healthcare providers ◦ Effect changes in policies and procedures
15.	**DISPLAY SLIDE # 15** **STATE:** So you may ask. . .

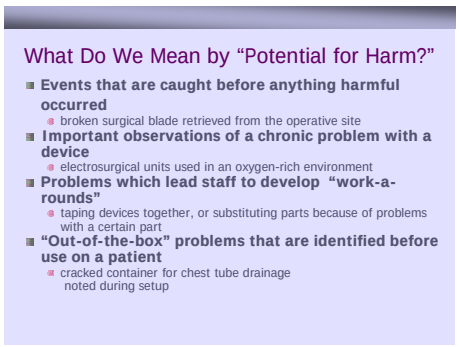


"When Do I Report?"

When you think a device has **caused** or **contributed** to any of the following outcomes for a patient, a staff member, or a visitor:

- Death
- Serious injury
- Minor injury, or
- Close calls or other potential harm

16.



DISPLAY SLIDE # 16

STATE: Next, let's look closely at . . .

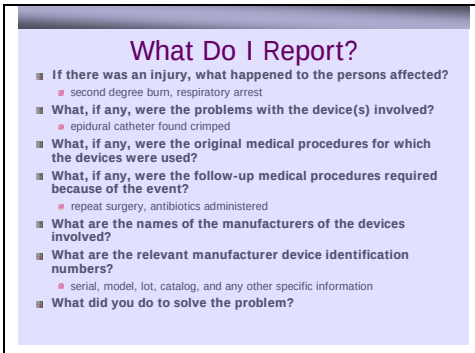
"What Do We Mean by "Potential for Harm?"

- **Events that are caught before anything harmful occurred**
- **Important observations of a chronic problem with a device**
- **Problems which lead staff to develop "work-a-rounds"**
- **"Out-of-the-box" problems that are identified before used on a patient**

17.

DISPLAY SLIDE # 17

STATE: We've looked at **when to report**, let's focus now on **what to report**. This information is



so valuable because it's focused on getting complete information initially and possibly from the staff person who may have been directly involved. Then the effort is made to have a complete report and it's expedites any follow up steps.

What Do I Report?

- **If there was an injury, what happened to the persons affected?**

STATE: was it a burn, or did the patient arrest

- **What, if any, were the problems with the device(s) involved?**
-

STATE: for example, was the epidural catheter found crimped

- **What, if any, were there original medical procedures for which the device were used?**

- **What, if any, were the follow up medical procedures required because of the event?**

STATE: was repeat surgery needed, or antibiotics administered

- **What are the names of the manufacturers of the devices involved?**

- **What are the relevant manufacturer device identification numbers?**

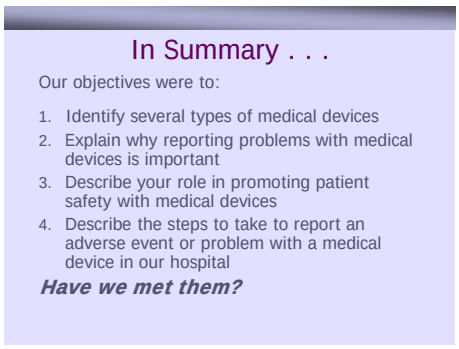
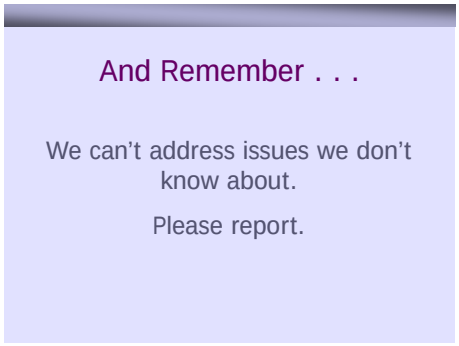
STATE: what are the serial numbers, or model, catalog and lot numbers, or any other device information. And, finally. . . .

- **What did you do to solve the problem?**

(discuss idea of pocket card here)

18. 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*	**DISPLAY SLIDE # 18** **STATE:** And lastly, **How Do I [you] Report?** **Our Reporting System Involves. . .**
19. 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*	**DISPLAY SLIDE # 19** **When You See a Device That Presents a Problem, You Should. . .**
20. Some Issues We've Addressed at Our Hospital **What Was Reported . . .** *(Customized responses to appear below)* ▪ *ECMO pump malfunction* ▪ *bed alarm not audible* ▪ *backflow of secondary IV fluid* **What We Did . . .** *(Customized responses to appear below)* ▪ *Found electromagnetic interference with nearby use of walkie-talkie; frequency changed; reported to MedSun* ▪ *Found defective lot; returned to manufacturer; reported to MedSun* ▪ *consulted manufacturer; height issue enforced with IV bags; reported to MedSun*	**DISPLAY SLIDE # 20** **STATE:** We've listed **Some Issues We've Addressed here at Our Hospital** With device problems and the actions we took to solve them. We hope this will reinforce with everyone the importance of reporting what you've seen so we can intervene and prevent any harm to patients, staff, and visitors to our hospital. READ SLIDE **What Was Reported. . .** **What We Did. . .**

21. **Fostering a Climate of Patient Safety** *(Customized responses would be listed below)* ▪ *Feedback and communication* ▪ *Learning from errors* ▪ *Compliance with policies and procedures* ▪ *Teamwork*	**DISPLAY SLIDE # 21** **STATE:** Here's what we need to do as an organization to **"Foster a Climate of Patient Safety"** **STATE:** We need to • Provide **feedback and communication** about adverse events and close calls • **Learn from our errors** • **Comply with our policies and procedures** • And promote and exhibit **teamwork**
22. **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* _____	**DISPLAY SLIDE # 22** **If You're Not Sure What or How to Report. . .**
23. **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	**DISPLAY SLIDE # 23** **STATE:** And, **Your Role. . .** is to. . .

24.  	**DISPLAY SLIDE # 24** **In Summary** **NOTE to Instructor:** Read slide
25.  	**DISPLAY SLIDE # 25** **And Remember. . . .** **We can't address issues we don't know about. Please report.**