MedSun
Medical Product Safety Network

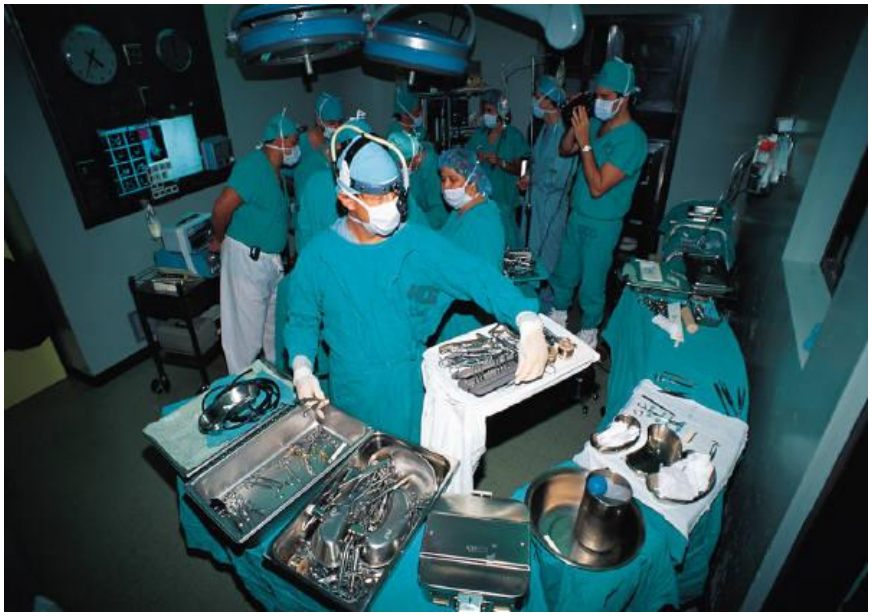
FDA

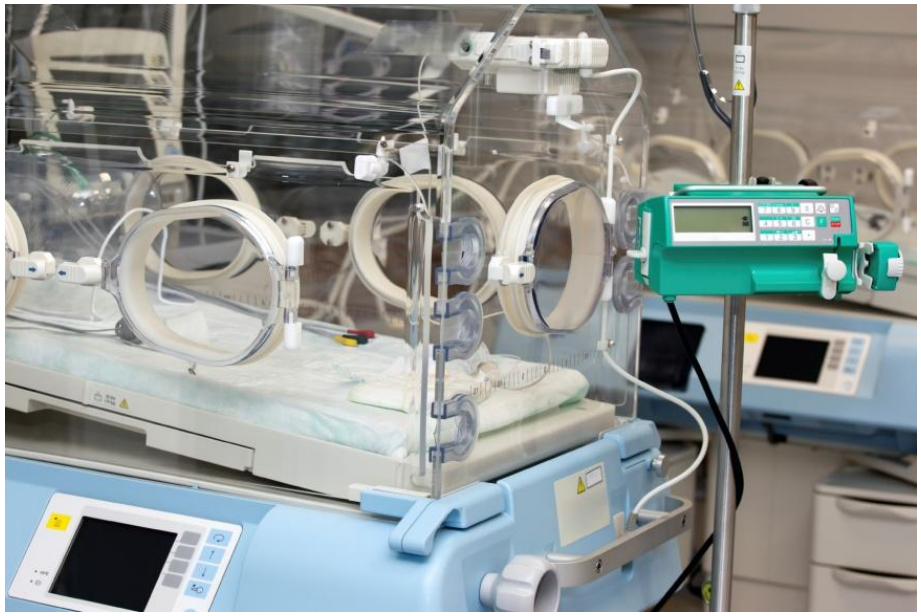
Promoting Safe Use of Medical Devices

21st Annual Nursing Recognition Day

National Institutes of Health

May 4th , 2012





Presenters

Sonia Swayze, RN, MA

sonia.swayze@fda.hhs.gov

Suzanne Rich, RN, FCN, MA, CT

Suzanne.rich@fda.hhs.gov

Center for Devices and Radiological Health

Office of Surveillance and Biometrics

Division of Patient Safety Partnerships/MedSun

Food and Drug Administration

Objectives

- **At the end of this presentation nurses will be able to:**
  - **Identify three Device Factors and three Human Factors that may contribute to medical device adverse events**
  - **Name three ways nurses can promote safe use of medical devices**

FDA Promotes Safe Use of Medical Devices

- **FDA Promotes:**
  - **The safe and effective use of medical devices, drugs, biologics, foods, and cosmetics through consumer protection programs.**
- **Medical Product Safety Programs:**
  - ***Center for Devices and Radiological Health (CDRH)***
  - **Center for Drug Evaluation and Research**
  - **Center for Biologics Evaluation and Research**

The Mission of CDRH

PRE-MARKET:
Getting safe and effective medical devices to market as quickly as possible…

POST-MARKET:
While ensuring that devices currently on the market remain safe and effective…

CDRH also provides the public with science-based information about medical devices and radiological products to improve health

Medical Device Examples

- **Capital Equipment**
  - beds, bedrails, scales, wheelchairs, IV poles, infusion pumps, lifts, bathing tubs, blood pressure equipment, MRI and CAT scanners, radiology equipment
- **Instruments**
  - lab equipment, surgical staplers, glucometers, pulse oximeters
  - surgical instruments
- **Monitoring Systems**
  - cardiac, telemetry, patient call
- **Disposables and Accessories**
  - ventilator breathing circuits, filters
  - needles, syringes, trocars, IV catheters, IV tubing, foley catheters, feeding tubes, gloves
- **Implantable**
  - defibrillators, hip/knee implants, drug-eluting stents
- **Computerized Medical Systems**
  - hardware
  - software versions

Audience Response

- Which product is not a medical device?
  - A. Sharps Container
  - B. Automatic External Defibrillator
  - C. Leeches
  - D. Tongue Depressor

Post-Market Surveillance of Medical Devices

- **The Goal of Post-market Surveillance:**
  - **To learn about the risks associated with medical devices once they are on the market**
    - **Unintended problems or a significant rise in anticipated risks**
    - **Changes in manufacturing materials, processes, staffing, or supplier/vendor**

No device is risk free !

Medical Devices Effect Patient Outcomes

- **Positive Effects**
  - Improve Patient Outcomes
    - Specialty beds; infusion pumps; monitoring devices
- **Negative Effects**
  - Unintended Consequences
    - Death or injury to patient or health care provider
    - Incorrect or delayed diagnosis and treatment
    - Device damage or contamination of equipment

What Is A Medical Device Adverse Event?

An event whereby a medical device has, or may have, caused or contributed to a death or serious injury.

Includes events involving:

- Device failure
- Device malfunction
- Use error
- Improper or inadequate device design
- Manufacturing problems
- Labeling problems

Medical Device Reporting

MedWatch

Mandatory

User Facilities

Deaths → FDA and Manufacturer

Serious injuries → Manufacturer

Manufacturers →

Deaths , Serious injuries, and Device Malfunctions → FDA

Voluntary

User Facilities

Consumers

MedSun – *one stop*

mandatory **and** voluntary reporting → reports go directly to FDA

What Is *MedSun* (Medical Product Safety Network)?

A network of Healthcare Facilities across the United States

- Large and small hospitals, teaching institutions, and community-based health-care facilities.
- Facilities trained to recognize and report in “real-time,” negative effects of devices (adverse events) involving death, serious injury, **focusing especially on close call, near miss, and potential for harm events**, directly to FDA.

Device Factors Contributing to Adverse Events at Point of Care

Packaging

- Foreign material in packaging with IV tubing connector

Defects

- Out of box problems, i.e. catheter taken from the packaging, it was bent at the distal end.

Software problems

- Imaging workstation downloaded patient A's images into patient B's folder

Device Factors Contributing to Adverse Events at Point of Care

Failure to work as intended/malfunction

- Surgical table failed to maintain position
- Implantable cardiac defibrillator (ICD) with premature battery depletion
- Safety mechanism on IV catheters/syringes failing

Interactions with other devices

- Newly installed magnetic navigation system in EP lab interacts with external defibrillator preventing defibrillator from functioning during cardioversion

Device Factors Contributing to Adverse Events at Point of Care

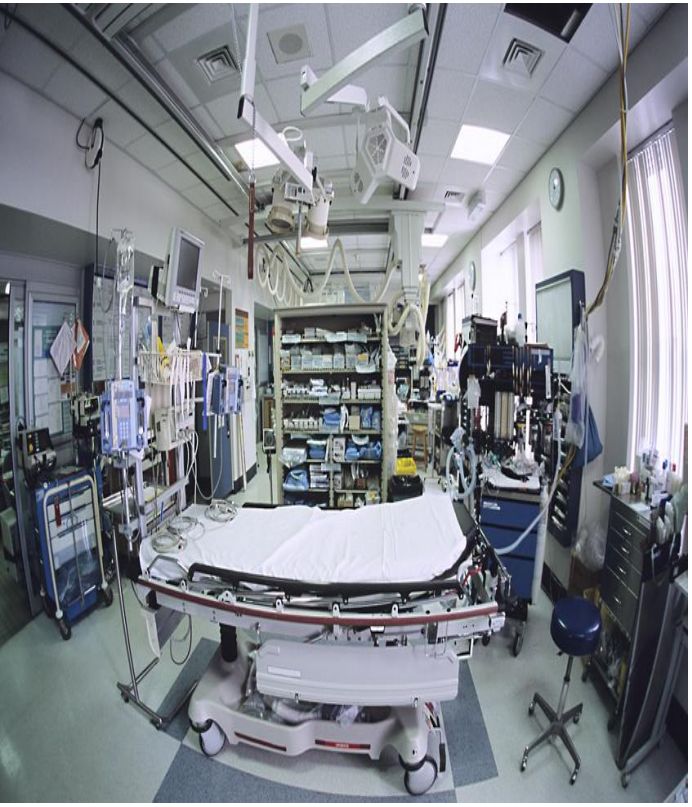
- Inability to flush IV tubing
- Catheter breakage upon removal: broken fragments remaining in patient
- Difficulty or failure to deploy vascular closure devices
- Siderails on bed fail to lock
- Leaking chest drainage system

Human Factors at Point of Care

"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

Human Factors Contributing to Adverse Events at Point of Care



- **User Characteristics**
  - Familiarity with, and expectations of how a device works
- **Device-user interface**
  - Confusing set-up, assembly or operation
- **Environment in which device is Used**
  - Lighting, noise levels, time pressures, distractions

Device Factors Case Study

Defective Sterile Surgical Drape

- A sterile vascular drape with reinforced areas of instrument pouches on both sides of the opening was used during a minimally invasive aortic valve replacement.
- The femoral aortic cannula line was secured to the reinforced area with a clip. The drape tore at the clip site, pulling the cannula out. Femoral artery re-cannulation was unsuccessful. Twelve minutes of ischemic arrest led to anoxic brain injury and death.
- Follow-up with the manufacturer found that this death report and other complaints of the same device problem were all related to drapes manufactured after the firm had made changes in the reinforcement material and production process.
- Subsequent to this report, the manufacturer recalled affected device lot numbers.

Human Factors Case Study

BP tubing connection to IV catheter

- A patient went to the ER because of nausea, vomiting, and rectal bleeding. An IV catheter was placed in anticipation of a computed tomography (CT) scan, but no IV fluids or medications had been started.
- The patient also had a noninvasive automatic blood pressure (BP) cuff placed for continuous monitoring. The cuff tubing was disconnected when the patient went to the bathroom, and it was reconnected upon return.
- The patient was found “blue from the neck up.” Despite resuscitation efforts, the patient died. The BP tubing had been connected to the IV catheter and had delivered about 15 ml of air. An autopsy confirmed a fatal air embolism.

Audience Response

- **Identify these medical device adverse events as device or human factors-related:**
  - A. **Inability to flush a central venous catheter due to obstructed lumen.**
  - B. **Double bounce of IV pump programming keys resulting in over-delivery of fluid.**
  - C. **Electronic surgical sponge count machine miscounting**
  - D. **Tube-feeding line connected to suction port instead of feeding tube**

How can Nurses Promote Safe Medical Device Use?

- Create protocols to develop new skill sets to use new, evolving, and mature device technology.
- Report medical device problems/adverse events through your hospital reporting system.
- Develop position statements on medical device use in the clinical setting through nursing professional organizations.

Professional Nursing Associations Position Statements

- **What is a Position Statement?**
  - **Defines the policies, standards, and issues important to the nursing profession and serves to enhance nursing practice (ANA, 2009).**
  - **Position statements can have a positive impact on preventing and reducing medical device adverse events.**
    - **AWHONN: Fetal Heart Rate Monitoring (revised 2008)**

http://www.awhonn.org/awhonn/binarycontent.do?name=Resources/Documents/pdf/5_FHM.pdf

- **AORN: Fire Prevention in the Operating Room (2005)**

http://www.aorn.org/PracticeResources/AORN/PositionStatements

When A Medical Device Malfunctions or Fails

Tag and Sequester Malfunctioning Medical Devices

1. **R**ecognize when a device malfunctions and stop the procedure to prevent possible harm
2. **R**emove device immediately and tag it with a label describing the problem
3. **R**eport the incident to appropriate department within your facility

SAVE THE PACKAGING!!!!!

Voluntary Reporting through MedWatch

Health care professionals not in MedSun, patients, their families, and consumers may report product problems or adverse events through MedWatch by:

- **Completing the voluntary form 3500 online at http://www.fda.gov/medwatch/report/hcp.htm;**
- **Calling us at 800-FDA-1088 to report by telephone; or**
- **Downloading a copy of the form and either faxing it to us at 800-FDA-0178 or mailing it back using the postage-paid addressed form.**
  - **If you are practicing in a MedSun facility, the report will be sent to FDA via your MedSun representative**

Device Resources

- **Medical Device Safety Website:** http://www.fda.gov/MedicalDevices/Safety/default.htm
- **MedSun Website:** www.fda.gov/medsun
- **Medical Device Recalls Website:** http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm
- **Safety Tips and Articles** http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/TipsandArticlesonDeviceSafety/default.htm
- **Luer Misconnections Website**: http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm134863.htm