MedSun
Medical Product Safety Network

FDA

Improving Patient Safety by Reporting Problems With Medical Devices Involving Pediatric and Neonatal Patients

Our objectives are to:

- Discuss FDA's medical device adverse event reporting, and the role of MedSun as a model for patient safety in the pediatric and neonatal patient care areas.
- Describe two types of outcomes that hospital staff are obligated to report according to the Safe Medical Device Act.
- Identify three types of medical devices, and the what, when, and how to report adverse events, and factors that contribute to device problems in the pediatric and neonatal areas.
- Explain how a series of system failures can lead to patient injury.
- Describe two ways the healthcare provider can improve patient safety by recognizing and reporting problems with medical devices, especially those involving human factors.

FDA and Patient Safety

- **FDA promotes:**
  - the safe and effective use of medical devices, drugs, biologics, foods, and cosmetics through consumer protection programs.
- **FDA's consumer protection programs are in place:**
  - to bring new products to market safely, and
  - to ensure that safe and effective products remain on the market.

FDA at a Glance

FDA is organized as follows:

1. Office of the Commissioner (OC)
2. Office of Regulatory Affairs (ORA)
3. Center for Devices and Radiological Health (CDRH)
4. Center for Drug Evaluation and Research (CDER)
5. Center for Biologics Evaluation and Research (CBER)
6. Center for Food Safety and Applied Nutrition (CFSAN)
7. Center for Veterinary Medicine (CVM)
8. National Center for Toxicological Research (NCTR)

FDA's Center for Devices and Radiological Health (CDRH)

MISSION

To promote and protect the health of the public by ensuring the safety and effectiveness of medical devices and radiological products.

VISION

To ensure the health of the public throughout the **Total Product Life Cycle.**

Medical Device Adverse Event Reporting and Patient Safety

A model for patient safety

- Reporting by health care providers, consumers, user facilities, and manufacturers
- Report information used to evaluate actual and potential problems with medical devices during clinical use

Device: Simply Defined*

An item used for the diagnosis, treatment, or prevention of disease, injury, or other condition, that is not a drug, biologic, or food.

** Actual definition of a device can be found in FD&C Act, Section 201(h).*

FDA and Patient Safety

- Capital Equipment
  - beds, bedrails, scales, isolettes, infant warmers, wheelchairs, IV poles, infusion pumps, blood pressure equipment, MRI and CAT scanners, radiology equipment
- Instruments
  - lab equipment, surgical staplers, glucose meters, pulse oximeters
  - surgical instruments
- Monitoring Systems
  - cardiac, telemetry, patient call
- Reagents
  - laboratory solutions
- Disposables and Accessories
  - ventilator breathing circuits, filters
  - needles, syringes, trocars, IV catheters, IV tubing, foley catheters, feeding tubes, gloves
- Implantable
  - defibrillators, pacemakers, hip/knee implants
- Computerized Medical Systems
  - hardware
  - software versions

What Is an Adverse Event?

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

Includes events resulting from:

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

Serious Injury or Illness

- Is life-threatening;
- Will likely result in permanent impairment/ damage to body function/ structure; and
- Requires medical or surgical intervention to preclude permanent impairment/ damage to body function/structure.

Malfunction

The failure of a device to meet its performance specifications or otherwise perform as intended.

A malfunction is reportable when it is likely to cause or contribute to a death or serious injury if it were to recur.

(Malfunctions are not required, but are encouraged to be reported by user facilities).

Types of Reporting

MEDWATCH

Voluntary (Form 3500)

- Voluntary reporting by health care professionals and consumers
- Report actual or potential product problems

Mandatory (Form 3500A)

- User Facilities
  - Report deaths and serious injury
- Manufacturers
  - Report deaths, serious injury, and malfunctions

Mandatory Reporting for User Facilities

User Facilities are required to report deaths and serious injuries.

- 1990 Safe Medical Device Act (SMDA) 11/28/90
- Effective date for User Facilities 11/28/91
- Effective date of Final Rule to implement Medical Device Reporting (MDR) 7/31/96

MDR Regulation

21 CFR 803

What Is a User Facility?

- Hospitals
- Ambulatory Surgical Centers
- Nursing Homes
- Outpatient Diagnostic Facilities
- Outpatient Treatment Facilities

Mandatory Reporting for Manufacturers

Manufacturers are required to report deaths, serious injuries, and malfunctions.

- Initial Regulation requiring MDR reporting effective 12/13/84
- Reporting requirements revised by SMDA 1990 & 1992 Amendments effective 7/31/96

MDR Regulation

21 CFR 803

What Is a Manufacturer?

Defined to include:

- Domestic Manufacturers
- Foreign Manufacturers
- Repackagers/Relabelers
- Component Manufacturers
- Hospitals Reprocessing
- Single-Use Devices

Voluntary Reporting Through the MedWatch Program

Health care professionals and consumers may report product problems or adverse events 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.
- As part of MedSun, healthcare providers can submit reports of ‘close calls’ through your MedSun representative

Demographics

Approximately 325,754 medical device adverse event reports were received in 2006:

- 95% from manufacturers
- 5% from health care practitioners and User Facilities (including those in the MedSun network)

MedSun

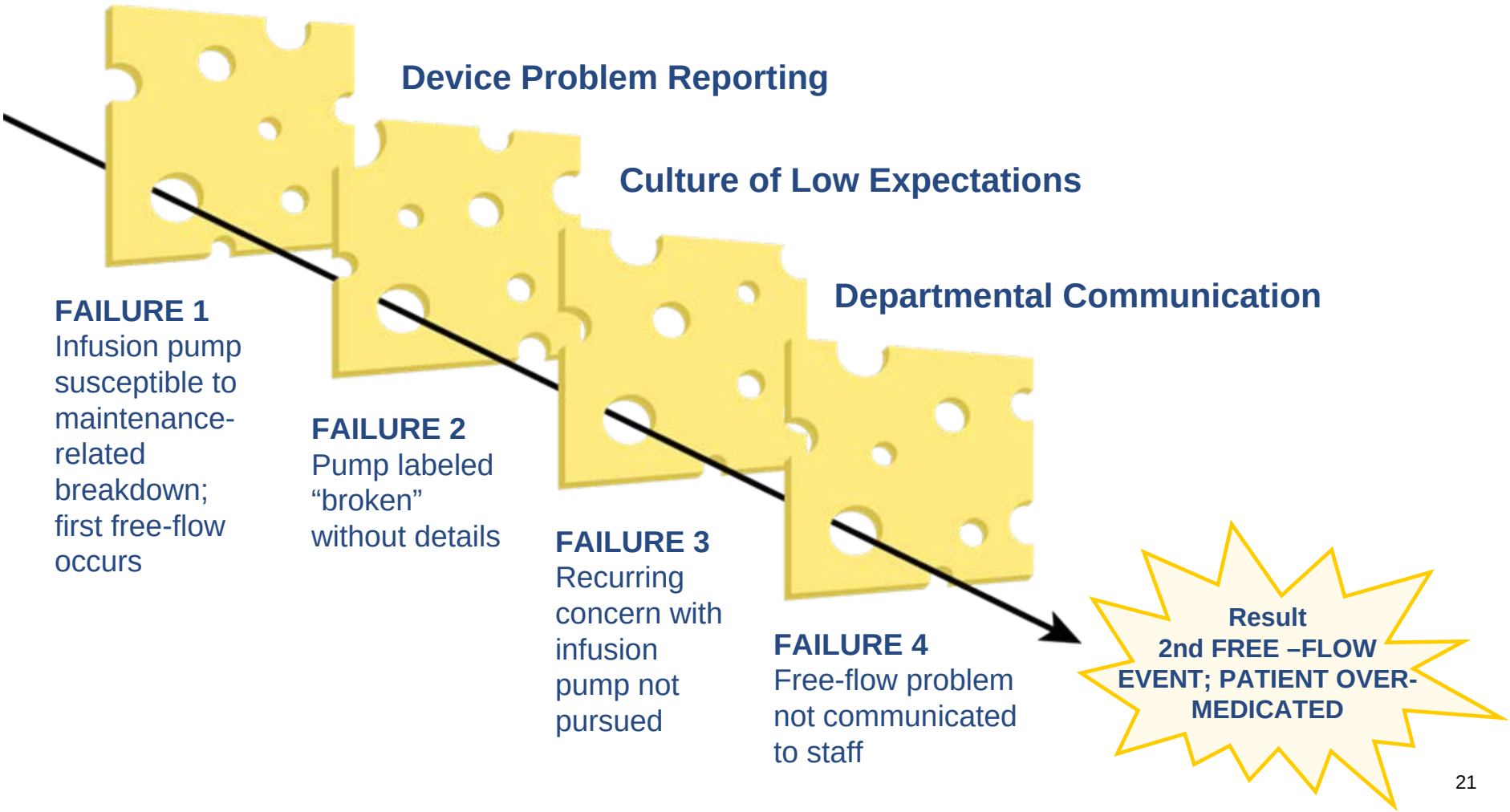
Medical Product Safety Network

- CDRH's MedSun is the newest adverse event reporting program made up of:
  - 350 hospitals, large and small, academic and community, across the United States
  - specially trained staff who detect, report, and understand medical product adverse events, focusing on medical devices and tissues

"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



What Do We Mean by "Potential for Harm"?

- **Events that are caught before anything harmful occurred**
  - Infant heel warmer pack found leaking
- **Important observations of a chronic problem with a device**
  - Incorrect positioning of skin temperature sensor causes overheating
- **Problems which lead staff to develop "work-arounds"**
  - Taping connections when they don't fit properly or substituting parts because of problems with a certain part
- **"Out-of-the-box" problems that are identified before use on a patient**
  - Staff discovered contaminant in buretrol packaging

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

Examples of Problems

Instructions/Labeling/Packaging

- "Non-sterile" label not easily noted on ventriculoperitoneal shunt package
- Disinfectant wipes for equipment packaged in container similar to baby wipes container
- Instructions for use: Sequence of setup unclear, incomplete, or misleading

continued…

Examples of Problems

Defects

- Metal spur found on circumcision clamp
- Foley catheter found to have no hole in tip
- Ventilator started smoking
- Gloves found discolored and with holes

continued…

Examples of Problems

Software Problems

- Imaging workstation downloaded patient A's images into patient B's folder
- Syringe pumps started shutting down on date set for preventive maintenance
- Pump not reading barcode on medication syringe because drug library had not been uploaded
- Electronic surgical sponge count machine miscounting

Examples of Problems

Failure To Work as Intended/ Malfunction

- Anesthetic in spinal trays ineffective
- Pattern of ventriculoperitoneal shunt valves leaking
- Pattern of umbilical catheters breaking
- IV pumps not infusing as programmed
- Safety mechanism on IV catheters/syringes failing

continued…

Examples of Problems

Interactions With Other Devices or Systems

- Pulse oximeter affected by fire alarm strobe light
- Luer lock misconnection, i.e., enteral feeding tubing connected inadvertently to IV tubing
- Cell phone use interferes with or creates artifact on monitoring equipment

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Examples of Problems

Use Errors/Human Factors

- Trachea perforation caused by use of stylet for intubation
- Laryngoscope blade extender left in patient after intubation
- Double bounce of IV pump programming keys
- Infusion pumps by the same manufacturer look similar but operate differently
- Otoscope and transilluminator look the same but have different light intensities

Contributing Factors Related to Device Problems

- User Considerations
- Device Design Considerations
- Environment in Which the Device Is Used

Human Factors Considerations

User expectations of device operation and communication

- User expects device (or component) to operate like similar device previously used due to general appearance
- Device labeling needs to be clearly understood by user, e.g., sequence of steps required for device operation

Device Design

- Device displays, labels, or markings need to be easily visible
- Device communication, i.e., alarms need to be easily heard
- Device tactile feedback needs to be easily 'felt' – e.g., single keypad response

Workplace

- Different brands or types of the same equipment on unit may contribute to errors – look similar but operate differently
- Maintenance and cleaning may contribute to problems with device operation - certain solvents or cleaning practices may accelerate wear and degradation of plastics interfering with device operation

Unintended Consequences

- Death or injury to patient or health care provider
- Incorrect or delayed diagnosis and treatment
- Device damage or contamination of equipment
- Device incorrectly labeled as ‘broken’ and taken out of service, creating a shortage
- Device not labeled, taken out of service, and mistakenly used

In Vitro Diagnostic Devices

Why report problems with In Vitro Diagnostic (IVD) Laboratory Devices?

- To help FDA and manufacturers ensure the safety and effectiveness of IVDs by informing them about problems seen with hospital laboratory devices.
- To improve patient safety by promoting awareness about adverse events that potentially involve IVDs.

Examples of Laboratory Medical Device Problems

- Point-of-care devices: glucose meters or blood analysis devices with erratic or erroneous results
- Inaccurate lab results
- Problems with reagents or blood tubes containing reagents

Your Role in Medical Device Patient Safety

Recognize, report, and understand device problems

- 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, especially for disposables
- Notify the manufacturer and arrange for return of the device

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

Tag and Sequester Malfunctioning Medical Devices

Stop the procedure to prevent possible harm.

Tell the responsible person about the problem.

Obtain or make a **DO NOT USE** tag.

Place device and all connected peripherals out of service with a **DO NOT USE** tag.

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 Information Is Needed for a Report?

- **If there was an injury, what happened to the person(s) affected?**
  - blisters noted; respiratory arrest
- **What, if any, were the problems with the device(s) involved?**
  - umbilical catheter found leaking
- **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?

Use the Reporting System for Your Hospital:

- Know Policy and Procedures
- Complete documentation/forms
- Report to MedSun representative who will submit a report online

What Happens to Medical Device Adverse Event Reports Submitted to MedSun?

MedSun Report Process

- Adverse Event Review
- Adverse Event Evaluation
- Reviewers Make Recommendations
- FDA analysts talk to manufacturers

Adverse Event Reviewers

The MedSun review staff relies on the clinical knowledge, expertise, and experience of a staff of health care professionals with backgrounds in:

- nursing
- biology
- biomedical engineering
- radiology
- public health
- medicine
- chemistry
- dentistry

Adverse Event Evaluation

- Reports are triaged to identify immediate or potential risk to public health.
- Reports are then reviewed against other data to identify newly emerging device-related problems.
  - FDA regulatory data such as premarket submissions (PMA or 510k), labeling and instructions for use, and product recalls
  - Literature reviews, third-party data
  - Previously submitted adverse event reports
    - similar problems with similar devices
    - similar problems with other manufacturers
    - similar patient or use scenarios

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Adverse Event Evaluation

- Reviewers may request additional information individually or work with other CDRH components to obtain data for a reported event:
  - by contacting the manufacturer, user facility, or voluntary reporter by telephone, fax, or letter; or
  - by working with other CDRH Offices to arrange:
    - a manufacturing facility inspection;
    - a user facility visit; and/or
    - consultation with other FDA Centers.

Reviewers Make Recommendations

All data related to the adverse event are reviewed to determine if further FDA action is needed. Outcomes of adverse event evaluation include:

- Education and Outreach
  - Articles in peer-reviewed clinical journals and newsletters (e.g., *MedSun News*)
  - Conferences, partnerships with professional organizations, (e.g., ESU workshop at 2004 MedSun National Conference)
- Research
  - Postmarket studies
  - Surveys (e.g., MedSun)
  - Registries (e.g., American College of Cardiology)

continued…

Reviewers Make Recommendations

All data related to the adverse event are reviewed to determine if further FDA action is needed. Outcomes of adverse event evaluation include:

- Public Health Notification
  - Safety Alerts, CDRH Web postings
- Regulatory Action
  - Recalls, seizures
  - Standards development

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FDA

FDA U.S. Food and Drug Administration
Department of Health and Human Services

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

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Questions?

FDA > CDRH > Medical Device Safety > Public Health Notifications > Precautions in Using the Reintroduced Vapotherm® 2000i [Respiratory Gas Humidifier] System

FDA Public Health Notification: Precautions in Using the Reintroduced Vapotherm® 2000i [Respiratory Gas Humidifier] System

(You are encouraged to copy and distribute this notification.)

Date: February 1, 2007

Previous Publications:

December 20, 2005 (http://www.fda.gov/cdrh/safety/122005-vapotherm.html)
October 27, 2005 (http://www.fda.gov/cdrh/safety/102705-vapotherm.html)

Dear Health Care Practitioner:

Vapotherm, Inc. has reintroduced the 2000i [Respiratory Gas Humidifier] System. This system was recalled in 2005 due to possible contamination with *Ralstonia* spp. cultures.

Syringe Pump

- A pediatric patient was found holding a syringe of medication, while standing in the patient's crib. The syringe of medication had been properly placed in the syringe pump, even though the patient was able to pull on the tubing, reaching the syringe and removing it from the pump. CDRH follow up with the manufacturer in late 2006 resulted in the firm promising creation and availability of a lock box in early 2007 to prevent this event from recurring, in spite of this being the sole event of this type.

continued. . .

Syringe Pump

- This summer, we received another report from a MedSun KidNet hospital that describes a similar event.
- Telephone follow-up with the manufacturer indicates that although the lockbox project had been delayed, they've been working diligently to complete it. Receipt of the report has underscored the firm's commitment to get the issue addressed and anticipates this will be completed by early 2008.

Extracorporeal Membrane Oxygenator (ECMO)

- An adverse event report stated that a small amount of blood was noted at the base of the oxygenator and under the outer wrapper. The event occurred during patient transport to the facility. The user facility states the device age is one day. Follow-up with the manufacturer confirmed that the device leaked as reported. A corrective action plan to address the problem has been implemented by the manufacturer.

Fire Alarm Strobe Light Interference with Pulse Oximetry

- An example of a collaborative follow-up effort between CDRH, ECRI, and the pulse oximetry manufacturer to understand a reported problem.

Fire Alarm Strobe Light Interference with Pulse Oximetry

- An event was reported that a hospital's NICU experienced fire alarm strobe light interference with their pulse oximetry when a fire strobe light activated during a fire drill resulting in:
  - Pulse oximetry readings being unavailable
  - The report indicates when the fire alarm strobe light stopped, measurement of pulse oximetry resumed
  - The fire alarm strobes were about 5 ft. from the pulse oximetry sensor

Devices Involved

Physiologic Monitor

Fire Alarm Strobe

Typical neonatal sensor & placement (disposable / adhesive sensor)

Reusable clip-style sensor
Better at blocking ambient light
(Not an option for neonates)

Failure Analysis Results

- The manufacturer is relatively certain interference is due to the high intensity light emitted from the strobe (75 candela).

  Note: A typical candle's light intensity is 1 candela.

- Slight chance that interference could be a result of EMI (electromagnetic interference)

Manufacturer Actions

- Submitted a “Request for Improvement”
- Clarified wording in product documentation
  - Earlier documentation stated that “high levels of ambient light” may cause interference.
  - Current documentation states…

CAUTION Injected dyes such as methylene blue, or intravascular dyshemoglobins such as methemoglobin and carboxyhemoglobin may lead to inaccurate measurements.

Interference can be caused by:

- High levels of ambient light or strobe lights or flashing lights (such as fire alarm lamps). (Hint: cover application site with opaque material.)
- Electromagnetic interference.
- Excessive patient movement and vibration.

Hospital Options to Consider

1. **Continue with the current situation & alert clinicians in advance of fire drills to monitor patient status carefully during the test**
2. **Cover pulse oximetry sensors with a tightly-weaved, opaque material for the period of the fire alarm test**
   - Clinicians should provide input as to any potential clinical consequences
   - Further testing needed to find a material that proves impenetrable to the strobe light

Hospital Options to Consider

3. **Placement of fire alarm strobes could be re-evaluated.**
   - All applicable fire codes and building codes must still be met.

4. **The strobe comes in two colors: white and red. The hospital uses the strobe emitting white light. The manufacturer indicates that it may be possible that the model emitting red light could minimize interference effects.**
   - Thorough testing is required to verify this option's viability before investing in any capital costs or labor.

Lessons Learned

- If a patient care unit is being built, or renovated, keep fire alarm strobe interference in mind during the design phase
  - e.g. distance of the strobe from pulse oximetry
- Consider buying a fire alarm strobe that has multiple intensity settings
  - e.g. switch between different candela settings
- Before installation, consider testing different strobe light colors with pulse oximetry
  - e.g. strobe lights can come in various colors such as white, red, blue, green, or amber

Conclusion

Why Reporting Medical Device Problems Is Important In Your Hospital:

- Prevents future problems and protects patients, staff, families, and visitors.
- Achieves staff performance improvement goals and is one of the many ways hospital staff can contribute to patient safety.
- Assists Risk Management with claims or litigation.
- Facilitates changes in policies and procedures.

continued…

…and

- Has an impact on public health for the nation's pediatric patients and health care providers by:
  - **Creating a climate of patient safety by recognizing, reporting, and understanding adverse events or close calls with medical devices; and**
  - **Serving as a patient advocate by providing information on adverse events and potential problems to FDA and manufacturers for further action.**

Questions and Answers

Device Resources

- MedSun:
  http://www.medsun.net
- Center for Devices and Radiological Health:
  http://www.fda.gov/cdrh
- MAUDE:
  http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM
- Patient Safety News Link:
  www.fda.gov/psn
- Medical Device Safety Website (links to recalls, safety tips and articles):
  http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfTopic/medicaldevicesafety/mds.cfm?page=4&sort=1
- Recalls/Withdrawals/Field Corrections:
  http://www.fda.gov/cber/recalls.htm#06

Laboratory Device Resources

- OIVD Web Site: www.fda.gov/cdrh/oivd/
- 510(k) Database
- CLIA Database
- Recall Database
- In Vitro Device News
- Safety Tips for Laboratorians

Tissue and Cells Resources

- CBER home page:
  http://www.fda.gov/cber

- Tissue-Related Documents:
  http://www.fda.gov/cber/tissue/docs.htm

- Human Cell and Tissue Establishment Registration (HCTERS) Public Query Application:
  https://www.accessdata.fda.gov/scripts/cber/CFAppsPub/tiss/index.cfm