MedSun
Medical Product Safety Network

FDA

KidNet

The Role of Human Factors with Medical Device Use in Neonatal and Pediatric Patients

The Role of Human Factors in Medical Device Use with Neonatal and Pediatric Patients

presented by:

MedSun KidNet

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Agenda

- Welcome and Overview
- Background and Medical Device Adverse Event Reporting
- The Role of Human Factors in Medical Device Adverse Events
- Human Factors Case Studies

Objectives

- Describe medical device reporting and MedSun.
- Identify aspects of Human Factors that can have an impact on the clinical use of medical devices.
- Discuss examples of Human Factors related medical device problems.
- Explain how recognizing and reporting medical device problems involving human factors promotes patient safety.

Speakers

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Center for Devices and Radiological Health (CDRH)

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Speakers (cont'd)

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FDA, CDRH and MedSun

- **Three Centers in FDA regulate medical products:**
  - Center for Biologics Evaluation and Research (CBER)
  - Center for Drug Evaluation and Research (CDER)
  - **Center for Devices and Radiological Health (CDRH)**
    - **MedSun is located within the Division of Patient Safety Partnerships in CDRH**

Examples of Devices

- 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

CDRH's mission is:

Getting safe and effective medical devices to market as quickly as possible…

… while ensuring that devices currently on the market remain safe and effective.

We also help the public get science-based accurate information about medical devices and radiological products needed to improve health

Medical Devices, Patient Safety and Postmarket Surveillance

- **Not all devices go to market following 'clinical trials'**
  - ***10% require clinical trials prior to being approved for marketing***
    - new, high risk devices, most implantable devices
  - ***47% of devices are low risk -- 'pre-market' exempt***
    - tongue depressors, gauze, sponges, etc..
  - ***43% must be shown to be similar to another marketed device (rarely requires clinical data)***
    - ventilators, infusion pumps, oxygenators, by-pass machines, etc.

What Happens With Postmarket Information?

- **Regulatory Action**
  - Manufacturing process changes
    - New product designs
    - Improved instructions for use
  - Recall of product still on the market
- **Public Health Notification**
  - Safety Alerts, Post-market Studies
- **Education and Outreach**
  - Safety Articles in Clinical Journals
  - Safety Websites and Webcasts

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

MedSun

Medical Product Safety Network

- CDRH's newest adverse event reporting program is made up of:
  - Specially educated staff committed to detect, report, and understand medical product adverse events, focusing on medical devices
  - in 300 hospitals, large and small, academic and community, across the United States

What's KidNet?

KidNet is a MedSun specialty subnetwork that:

- Focuses on identifying, understanding, and solving problems with medical devices used in neonatal and pediatric patient populations, especially those occurring in intensive care units (NICUs and PICUs).
- Problems with medical devices used in neonatal and pediatric patients from ALL areas of the hospital are welcome and encouraged.

What is Human Factors?

Human Factors (or ergonomics) is the scientific discipline concerned with the understanding of interactions among humans and other elements of a system, and the profession that applies theory, principles, data, and other methods to design in order to optimize human well-being and overall system performance.

-Developed by International Ergonomics Association (www.iea.cc)

-Adopted by Human Factors and Ergonomics Society (www.hfes.org)

Human Factors and Adverse Events

"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 Considerations Related to Medical Devices

- **User Characteristics**
  - Instruction, familiarity with, and expectations of how a device works
- **Device Design Considerations**
  - Device-user interface, including labeling and instructions for use
- **Environment in Which the Device Is Used**
  - Light/noise intensity, time pressures, distractions

User Considerations

Device Users Expect:

- Connections or setup to be intuitive, but in reality, the design is sometimes difficult, complex, and confusing.
- New devices (or components) to operate like similar devices previously used.
- Labeling to be clear, concise, and helpful in device setup while in reality, labeling can be misleading, incomplete, or unclear on sequence of steps required for device operation or is not easily accessible.

User Considerations

Device Users also expect:

- Auditory alarms to occur in a specific sequence or sound pattern.
- Visual alarms to occur in a specific sequence or color patterns.
- Device-based treatment parameters to be consistent with prior experience (e.g., medication dose to be infused provided in standard measures, i.e., ml/hr).

Device Design Considerations

- **Visual Characteristics**
  - User should be able to clearly see device displays, labels, or markings.
  - Display screen contrast should be clear.
  - Device markings should be intuitive to the user.
- **Auditory Characteristics**
  - User should be able to easily hear or interpret device alarms (i.e., volume, frequency, tone, and sequencing of alarm sounds).
  - Warning for dangerous or critical condition should occur at an appropriate time to allow for easy correction.
- **Tactile Characteristics**
  - User should be able to feel/interpret tactile feedback from device.
  - Keypads function smoothly and easily and do not stick (bounce).
  - Appropriate connection between 2 devices locking together should be "felt."

Environmental Considerations

- Different brands or models of the same type of device within the same facility
- Many complex devices being used at the same time to treat critically ill patients
- Storage conditions
- Ambient noise
- Light and temperature exposure
- Patient transfers from unit to unit

Examples of Reported Human Factors Device Problems

- Unintended over-infusion of fluid via IV pump programmed to deliver 6.8 ml/hour (actual delivery of 66.8 ml/hour)
  - associated with keypad stiffness and double bounce of keys when programmed
- Luer lock misconnection
  - enteral feeding tubing connected inadvertently to IV tubing

Examples of Reported Human Factors Device Problems

- An infant fell out of an isolette, suffering a cranial injury
  - (the isolette's access panel latches did not turn in the same direction to lock)
- An infant received a burn when an otoscope was used as a transilluminator in an urgent/emergent situation
  - Otoscope and transilluminator looked the same but have different light intensities

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Human Factors Case Studies

Esophageal/Rectal Temperature Probe

- The patient was on total body cooling and during the course of her three day cooling the machine shut off three times and alarmed "check probe." The nurse was able to restart the machine without difficulty the first three times. The fourth time, the machine shut off at approximately 48 hours into cooling and alarmed "check probe." The NICU unit educator was contacted by the nurse caring for the patient after she could not get the machine to restart, who advised the nurse to replace the probe, which she did. The probe was not changed after the first three alarms because the machine was easily restarted.
- The nurse educator then contacted biomed to check the machine and probes. Together they set up their machine and used the original probe from the patient that was causing issues. Every time the educator manipulated the connection site for the probe and cable, it would shut the machine off and alarm.

Esophageal/Rectal Temperature Probe

- **Lessons Learned**
  - Important to recognize and report medical device problems – even if it means taking a suspect device out of service (tagging and sequestering).
    - tagging a device with the date and brief description of the problem – i.e. , leaks, won't power up, etc..)
    - sequestering (pulling a device out of use) until you/hospital biomeds understand what the problem is.
  - ***It can be a challenge to pull a device if staff aren't sure about where to get another one but need to go with what is in the best interest of patient safety.
  - Developing 'work-arounds' to keep a device in service not only doesn't solve the problem, it sets up a situation whereby the problem could manifest itself through injury to the patient or caregiver

Huber Safety Needle

- We had four reports of bent needles from various places in our hospital that occurred over a five month period a couple of years ago that involved a 22 gauge Huber safety needle with a Y-Injection site.

- Our first reported occurrence was a couple of years ago. A nurse encountered difficulty removing the needle after accessing the port. After the needle was removed, it was found to be bent at a 45 degree angle.

- The second reported problem (also in the same month) involved the needle being bent upon opening the package to a sterile field. A second needle was opened and placed on the field. This needle was slightly bent to one side.

Huber Safety Needle

- The third occurrence involved the nurse being unable to de-access the port using the safety feature.
- The fourth occurrence involved a port being accessed a port was accessed with the Huber safety needle, and the nurse was unable to de-access the needle from the port.
- The problem of bent needles at the 45 degree angle was reported to our hospital risk managers and then followed up by hospital staff members.

Huber Safety Needle

- **Lessons learned**
  - The problem was reported to MedSun and their follow-up with the manufacturer indicated that the firm confirmed the bent needles and inability to use the safety device on the bent needles. The manufacturer made changes to address both the bent needles and the safety feature problem. The manufacturer also provided user education and instructions for use indicating the depth and thickness of skin may cause the needle to bend.

  - Staff are eager to report problems because they “realize” that the process of reporting problems results in follow-up from the hospital, MedSun, and the manufacturer. Reports don’t go into a ‘black hole’ and can contribute in a tangible way to improved patient safety.

Infusion Pump Cassette

- The PCA pump was alarming low reservoir volume. The pump had been reporting volume administered over the course of the previous 15 hours to be at approximately 48mL total delivered. When the nurse opened the pump, she discovered the cassette/reservoir to be full. She used a syringe to determine that it contained 48mL (out of 50mL).

- A full review of the history, interviews with all nurses, and review of cassette equipment was completed. The patient experienced withdrawal symptoms and increased pain over the 15 hours prior to discovering the cassette/reservoir being full.

Infusion Pump Cassette

- It was noted that the nurse that attached the cassette originally had difficulties making the connection. At one point there was an alarm stating ‘high alarm - cassette damaged.’ However, the nurse was able to restart the pump and the pump continued to report delivery of medication with no further alarm messages.

- Unfortunately, the original cassette was discarded and not retrievable. There was nothing unusual noted by the nurse who removed it. The hospital saved the pump's log which was helpful although why the pump would show meds delivered and still have 48mL in the cassette was unknown at the time of the report.

- MedSun follow-up on this event contributed to a recall.

Infusion Pump Cassette

- **Lessons Learned:**
  - This event and the solution strategies were shared with medical surgical chain and frontline nursing staff – we thought everyone had been alerted.
  - A month later, the hospital got reports of a cluster of patients whereby meds weren't being delivered in the surgical area. We then learned that you may think something has been communicated but it may not have gotten to all affected parties. In this case, we alerted nursing staff and front line staff initially but information needed to go to the surgical staff group as well.
  - **Communicate, communicate, communicate**.

Wrap Up

References

- **CDRH Human Factors Website.** Accessed July 2012. Available at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HumanFactors/ucm124829.htm

- **MAUDE (Manufacturer and User Facility Device Experience Database).** Accessed July 2012. Available at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/ucm127891.htm

- Rich, S. (June 2008). **How Human Factors Lead to Medical Device Adverse Events.** Nursing2008. 38(6):62-3.

Device Resources

- **Medical Device Safety Website:**

http://www.fda.gov/MedicalDevices/Safety/default.htm

- **MedSun Website with links to educational materials:**

http://www.fda.gov/MedicalDevices/Safety/MedSunMedicalProductSafetyNetwork/default.htm

- **Medical Device Recalls Website:**

http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/default.htm

- **Tubing and Luer Misconnections Website**:

http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/TubingandLuerMisconnections/default.htm