

Ethical and Legal Issues In Clinical Practice: Medical Devices

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Objectives

- ▲ Identify the responsibilities of respiratory care practitioners and managers in adhering to regulations and preventing adverse events related to medical devices.
- ▲ Discuss examples of medical device adverse events.

Ethical and Legal Decisions

- ▲ Ethical decision- behavior is right or wrong.
- ▲ Legal decision- behavior is within legal constraints.
- ▲ Many behaviors are legal; but, are unethical
- ▲ In healthcare- breach of ethics and/or law can result in loss of practice privileges

Standards of Care

- ▲ The conduct of a professional is matched with national standards to determine reasonableness; therefore:
 - ◆ ethnicity
 - ◆ legality

Standards of Care

- ▲ Sources:
 - ◆ Federal, state, local laws
 - ▶ Clinical Laboratory Improvement Amendment
 - ▶ Federal Drug Administration
 - ▶ FDA Center for Devices and Radiologic Health
 - ▶ Pennsylvania BPOA

<http://www.fda.gov/cdrh/index.html>

Standards of Care

- ▲ Sources:
 - ◆ Agencies- Joint Commission on Accreditation of Health Care Organizations (JCAHO)
 - ◆ Clinical practice guidelines (AARC)
 - ◆ Employers' policies and procedures; e.g., job description for scope of practice.

<http://www.rcjournal.com/cpgs/index.cfm>

Causes of Medical Device Incidents

Device defects

▲ Design defect

- ◆ device meets manufacturer's specifications
- ◆ device is not safe for all reasonably foreseeable uses.

Device defects

▲ Design defect

◆ Examples:

- ▶ a monitor that operates everywhere but in one area that has a critical electromagnetic interference.
- ▶ a nebulizer that produces inappropriate particle sizes with certain medication(s).

Device defects

▲ Product defect

- ◆ device does not meet manufacturer's specifications or governmental standards
- ◆ device was defective when it left the manufacturer

Device defects

▲ Product defect

◆ examples:

- ▶ nebulizer that fails to nebulize
- ▶ oxygen fuel cell that fails within its life expectancy
- ▶ ventilator cabinet wheels that fail to lock

Device Misuse

▲ Device is operational

▲ Use of device is not reasonably foreseeable.

▲ Device instruction manual should describe and limit reasonable use.

▲ Conditions for assumption of risk:

- ◆ User knew risk before incident
- ◆ User acted voluntarily
- ◆ User acted unreasonably

Device Misuse

▲ Examples:

- ◆ use of Ballard catheter for tracheal gas insufflation
- ◆ use of oximeter finger sensor on the forehead.
- ◆ use of blender and flowmeter to adjust oxygenation.

Haynes JM. The ear as an alternative site for a pulse oximeter finger clip sensor. Respiratory Care 2007;52(6) 727-729.

Negligence

▲ Failure to conform with reasonable, prudent practice.

▲ Elements of negligence:

- ◆ duty of care
- ◆ breach of duty
- ◆ injury
- ◆ proximate cause (breach of duty caused injury)

Negligence

▲ Examples:

- ◆ failure to perform ventilator assessments.
- ◆ failure to re-stock emergency equipment.

Medical Device Regulations

Safe Medical Device Act of 1990 (SMDA)

▲ Administered by Federal Drug Administration, Center for Devices and Radiologic Health (CDRH)

▲ Functions

- ◆ Defines and classifies medical devices
- ◆ Provides rules and regulations for safety and reporting of medical device failure.

Medical Device Classifications

▲ Category I- General controls

- ◆ Least regulatory control
- ◆ Minimal potential for harm due to malfunction
- ◆ Examples- bandages, gloves, handheld instruments

Medical Device Classifications

- ▲ **Category II- Special controls**
 - ◆ Devices for which general controls are insufficient
 - ◆ Regulations on labeling, mandatory performance, post market surveillance
 - ◆ Examples- wheelchairs, infusion pumps

Medical Device Classifications

- ▲ **Category III- Devices requiring premarket approval**
 - ◆ Regulated as new devices
 - ◆ Not equivalent to existing devices
 - ◆ Examples- pacemakers, implants, some ventilators

Medical Device Reporting

- ▲ **Deaths due to devices reported within 10 days**
- ▲ **Adverse events reported to MEDWATCH:**
<http://www.fda.gov/medwatch/>

Medical Device Reporting

- ▲ **MEDWATCH voluntary reporting-**
 - ◆ product quality problem
 - ◆ product use error associated with FDA-regulated drugs, medical devices, etc.

Medical Device Reporting

- ▲ **Emergency Care Research Institute (ECRI)**
 - ◆ Assess and address patient safety, quality, and risk management challenges
 - ◆ Select the safest, most effective medical devices, procedures, and drugs

Medical Device Reporting

- ▲ **Emergency Care Research Institute (ECRI)**
 - ◆ Procure healthcare technology in the most cost-effective manner
 - ◆ Develop evidence-based health coverage policies
 - ◆ Align hospital and health facility capital investments with strategic technology needs

<http://ecri.com/Pages/default.aspx>

Medical Device Reporting

- ▲ Steps when a medical device has been found to be defective:
 - ◆ Put the device and all its parts back in its packaging and write down its clinical engineering number or serial number.
 - ◆ Put some kind of notification on the device or packaging so people are aware it is defective and should not be used.

Medical Device Reporting

- ▲ Steps when a medical device has been found to be defective:
 - ◆ If there was a patient involved in the incident, the patient's physician should be notified.
 - ◆ If an employee was involved in the incident, the employee should be referred to Occupational Health.

Medical Device Reporting

- ▲ Steps when a medical device has been found to be defective:
 - ◆ Fill out an incident report and deliver it to Risk Management within 24 hours.
 - ◆ Notify whichever department is appropriate for handling the device.

Contributing Factors in Deaths/Injuries With Long-Term Ventilation

Note: There were multiple contributing factors pertaining to deaths/injuries in these cases; explaining percentages in excess of 100%

Contributing Factors

- ▲ Staffing
 - ◆ Inadequate orientation/training process (87%)
 - ◆ Insufficient staffing levels (35%)
- ▲ Communication breakdown
 - ◆ Among staff members (70%)
 - ◆ With patient/family (9%)

Contributing Factors

- ▲ Incomplete patient assessment
 - ◆ Room design limits observation (30%)
 - ◆ Delayed or no response to alarm (22%)
 - ◆ Monitor change not recognized (13%)

Contributing Factors

- ▲ Equipment
 - ◆ Alarm off or set incorrectly (22%)
 - ◆ No alarm for certain disconnects (22%)
 - ◆ Alarm not audible in all areas (22%)
 - ◆ No testing of alarms (13%)

Contributing Factors

- ▲ Restraint failure (13%)
- ▲ Distraction (22%)
- ▲ Cultural (13%)

http://www.jointcommission.org/SentinelEvents/SentinelEventAlert/sea_25.htm

Strategies to Minimize Device Accidents

- ▲ Adopt safe devices- homework
- ▲ Comprehensive trial evaluations
- ▲ Comprehensive competency assurance
- ▲ Availability of user instructions
- ▲ Ongoing clinical monitoring for proper use
- ▲ Maintenance procedures

Responsibilities of RCPs

- ▲ Management
 - ◆ Evaluate equipment before acquisition
 - ◆ Ensure staff competency on all equipment
 - ▶ training
 - ▶ monitoring (supervision)
 - ◆ Document preventative maintenance

Responsibilities of RCPs

- ▲ Management
 - ◆ Report adverse events
 - ▶ facility incident reports
 - ▶ Medwatch

Responsibilities of RCPs

▲ RC staff

- ◆ Assure competency on all equipment
- ◆ Preventative maintenance and documentation
- ◆ Routine monitoring of equipment function
- ◆ Remove nonfunctioning equipment from service
- ◆ Document and report adverse events to management
- ◆ Report any potential risks from equipment

RC Equipment Adverse Events

▲ Medical gas events

- ◆ Nitrous oxide piped into oxygen lines in emergency room
- ◆ Bulk oxygen tank transfilled with air
- ◆ Oxygen cylinder placed in MRI
- ◆ Non-rebreathing mask connected to air flowmeter

RC Equipment Adverse Events

▲ Ventilator events

- ◆ Ventilator tubing disconnected from circuit with inadequate alarm system
- ◆ Physician made erroneous adjustment
- ◆ Nurse made erroneous adjustment
- ◆ Pacemaker malfunction due to electric signal from ventilator
- ◆ Ventilator malfunction due to cell phone
- ◆ Ventilator malfunction during change from AC to battery power

References

- ▲ Aikens TD. Legal and ethical issues in health occupations Chs. 7, 10, 11, 12. 2002; WB Saunders; Philadelphia.
- ▲ Geddes, L.A. Medical device accidents with illustrative cases. 1998; CRC Press; Boston.
- ▲ Haynes JM. The ear as an alternative site for a pulse oximeter finger clip sensor. Respiratory Care 2007;52(6) 727-729.