

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 morally right or wrong.
- ^ Legal decision - behavior is within legal constraints.
- ^ Many actions 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 standards to determine reasonableness; therefore:
 - ◆ ethnicity
 - ◆ legality

Standards of Care

^ Sources:

- ◆ Federal, state, local laws
 - f Clinical Laboratory Improvement Amendment
 - f Federal Drug Administration
 - f FDA Center for Devices and Radiological Health
 - f State professional boards

Link to FDA home page
<http://www.fda.gov/cdrh/index.html>

Standards of Care

^ Sources:

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

Link to AARC Clinical Practice Guidelines
<http://www.rcjournal.com/cpgs/index.cfm>

Link to AARC Ethics position statement
http://www.aarc.org/resources/position_statements/ethics_detailed.html

Medical Device Regulations

Safe Medical Device Act of 1990 (SMDA)

- ^ Administered by Federal Drug Administration, Center for Devices and Radiological Health (CDRH)
- ^ Functions
 - ◆ Defines and classifies medical devices
 - ◆ Provides rules and regulations for safety and reporting of medical device failure.

Link to FDA medical device home page
<http://www.fda.gov/cdrh/index.html>

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- increased risk from malfunction
 - ◆ Regulations on labeling, mandatory performance, post market surveillance
 - ◆ Examples- wheelchairs, infusion pumps, anesthesia devices (respiratory therapeutics)

Link to description of FDA medical device classifications
[http://www.fda.gov/Link to /cdrh/devadvice/313.html](http://www.fda.gov/Link%20to%20cdrh/devadvice/313.html)

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

Link to Medwatch healthcare professional voluntary reporting
<http://www.fda.gov/medwatch/report/hcp.htm>

Medical Device Reporting

^ Medwatch voluntary reporting-

- ◆ product quality problem
- ◆ product use error associated with FDA-regulated drugs, medical devices, etc.

Link to FDA patient safety video presentations
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/psn/index.cfm>

Medical Device Reporting

^ Emergency Care Research Institute

(ECRI)- nonprofit medical research institute

- ◆ Assess and address patient safety, quality, and risk management challenges
- ◆ Select the safest, most effective medical devices, procedures, and drugs
- ◆ 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

Link to ECRI home page
<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:

- ◆ Complete an incident report and deliver it to Risk Management within 24 hours.
- ◆ Notify whichever department is appropriate for handling the device.

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:
 - f* a monitor that operates everywhere but in one area that has a critical electromagnetic interference.
 - f* 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:
 - f* nebulizer that fails to nebulize
 - f* oxygen fuel cell that fails within its life expectancy
 - f* ventilator cabinet wheels that fail to lock

Device Misuse (human factors)

- ^ Device is operational
- ^ Use of device is not reasonably foreseeable.
- ^ Device instruction manual should describe and limit reasonable use.
- ^ Conditions for user's assumption of risk:
 - ◆ User knew risk before incident
 - ◆ User acted voluntarily
 - ◆ User acted unreasonably

Link to human factors and medical devices
<http://www.ahrq.gov/clinic/ptsafety/chap41a.htm>

Device Misuse

- ^ Examples:
 - ◆ use of Ballard catheter for tracheal gas insufflation

Device Misuse

^ Examples:

- ◆ use of blender and flowmeter to adjust oxygenation.

Device Misuse

^ Examples:

- ◆ use of oximeter finger sensor on the forehead.

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 litigation:

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

Link to definition of professional negligence
http://en.wikipedia.org/wiki/Professional_negligence

Negligence

^ Examples:

- ◆ failure to complete patient-ventilator assessments.
- ◆ failure to restock emergency equipment.
- ◆ failure to check oxygen liter flows/FIO2
- ◆ failure to ensure that manual resuscitators include masks, especially during transports.
- ◆ failure to monitor patients during treatments.

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%

Link to JCAHO sentinel events, Issue 25
http://www.jointcommission.org/SentinelEvents/SentinelEventAlert/sea_25.htm

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 - hierarchy, intimidation (13%)

Strategies to Minimize Device Accidents

- ^ Adopt safe devices - homework
- ^ Comprehensive trial evaluations

Link to reducing equipment related adverse events
http://www.brownspace.com/original_articles/equipmnts.htm

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- ^ Comprehensive trial evaluations
- ^ Comprehensive competency assurance
- ^ Ongoing clinical monitoring for proper use

Strategies to Minimize Device Accidents

- ^ Adopt safe devices- homework
- ^ Comprehensive trial evaluations
- ^ Comprehensive competency assurance
- ^ Ongoing clinical monitoring for proper use
- ^ Availability of user instruction manuals in clinical areas
- ^ Strict maintenance procedures

Responsibilities of RCPs

- ^ Management
 - ◆ Direct equipment evaluations before acquisition
 - ◆ Ensure staff competency on all equipment
 - f training
 - f monitoring (supervision)

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- ^ Management
 - ◆ Direct equipment evaluations before acquisition
 - ◆ Ensure staff competency on all equipment
 - f training
 - f monitoring (supervision)
 - ◆ Document preventative maintenance
 - ◆ Report adverse events
 - f facility incident reports
 - f Medwatch

Responsibilities of RCPs

- ^ RC staff
 - ◆ Assure competency on all equipment
 - ◆ Preventative maintenance and documentation
 - ◆ Routine monitoring of equipment function

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

RC Equipment Adverse Events

^ Medical gas events

- ◆ In 1977, in a new ER in Pa, a patient inexplicably became cyanotic while presumably breathing oxygen.
- ◆ A physician discovered that the oxygen outlet was actually delivering nitrous oxide.
- ◆ Mislabeled pipe connections for the anesthetic gas "may have" caused as many as five deaths in the hospital since the hospital opened its wing.
- ◆ Some 300 patients were dosed with nitrous oxide by mistake.
- ◆ This is one incident that makes a case for RC departments to analyze the output of all gas outlets.

Link to news article about nitrous oxide in emergency room
<http://www.time.com/time/printout/0,8816,915271,00.html>

RC Equipment Adverse Events

^ Medical gas events

- ◆ At a large hospital in Texas. A therapist in NICU tried to calibrate oxygen analyzers; they would calibrate at 100% only with gas from oxygen cylinders.
- ◆ the greatest FIO₂ from any outlet was 80%.
- ◆ No patient required more oxygen than 80%, so there were no injuries detected
- ◆ The bulk oxygen tank had been transfilled with liquid air, diluting the contents of the entire system.
- ◆ This is another incident that makes a case for checking the output of gas outlets.

RC Equipment Adverse Events

^ Ventilator event

- ◆ Context: A large, busy recovery room
- ◆ A fresh, postoperative patient on a mechanical ventilator began to develop dysrhythmias
- ◆ The anesthesiologist ordered medications to treat the dysrhythmias; then, an ABG, which showed lethal hypoxemia.
- ◆ The RT was called to the bedside and found a tubing disconnection from the ventilator and a nonfunctional alarm system
- ◆ The patient expired at a later date.
- ◆ Functional alarms likely would have prevented this.
- ◆ If caregivers assessed the patient, instead of only observing the monitors, he might have survived.

RC Equipment Adverse Events

^ Ventilator events

- ◆ Physician increased the control rate on a ventilator, later, informing the therapist.
- ◆ Therapist found I:E ratio nearly inverse because of adjustment; so, decreased the inspiratory time to counter this.
- ◆ No actual patient injury; but, there was risk of volutrauma from auto-PEEP and likely patient discomfort.
- ◆ Only RTs should make ventilator adjustments.

RC Equipment Adverse Events

^ Ventilator events

- ◆ RN took order for ventilator rate reduction and made the change.
- ◆ RN informed the therapist, who found that the patient's tidal volume had increased to about 1200 ml
- ◆ It was a minute volume ventilator, wherein rate changes also affect tidal volume.
- ◆ No apparent injury; but, this also makes the case for
- ◆ only RTs should make ventilator adjustments.

RC Equipment Adverse Events

^ Ventilator events

- ◆ Ventilator malfunction due to cell phone

Link to cell phones and medical devices
<http://www.newsfactor.com/perl/story/6567.html>

Summary and Review

Summary and Review

- ^ Ethical, legal decisions adhere to standards of care
- ^ Standards of care formulated by
 - ◆ government
 - ◆ agencies; e.g., JCAHO
 - ◆ professional organizations; e.g., the AARC

Summary and Review

- ^ Medical device regulations, defined by the FDA
 - ◆ classifies, regulates devices
 - ◆ provides regulations and means for reporting problems
- ^ Emergency Care Research Institute (ECRI)
 - ◆ supports evidence-based practices
 - ◆ provides for voluntary reporting of device problems

Summary and Review

- ^ Causes of device incidents
 - ◆ design defects
 - ◆ product defects
 - ◆ device misuse (human factors)

Summary and Review

- ^ Professional negligence
 - ◆ duty to patient
 - ◆ breach of duty
 - ◆ injury to patient
 - ◆ proximate cause- injury was due to breach of duty

Summary and Review

- ^ Contributing factors in ventilator deaths
 - ◆ staffing
 - ◆ communications breakdown
 - ◆ incomplete patient assessment
 - ◆ equipment problems
 - ◆ restraint failure
 - ◆ cultural factors

Summary and Review

- ^ Strategies to prevent equipment mishaps
 - ◆ adopt safe devices
 - ◆ comprehensive trial evaluations
 - ◆ competency assurance
 - ◆ clinical supervision
 - ◆ availability of reference manuals
 - ◆ preventative maintenance

Summary and Review

- ^ Responsibilities of RCPs
 - ◆ Management
 - ◆ RC staff
- ^ Equipment adverse events

References

- ^ Aikens TD. Legal and ethical issues in health occupations Chs. 7, 10, 11, 12. 2002; WB Saunders; Philadelphia.
- ^ Geddes, LA. 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.

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