Ethical and Legal Issues in Clinical Practice: Medical Devices

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This Presentation is Approved for
1 CRCE Credit Hour

Learning Objectives

- Describe the ethical and legal responsibilities of respiratory care practitioners and managers in adhering to regulations and preventing adverse events related to medical devices
- Discuss the ethical implications of examples of medical device adverse events

Ethical & Legal Decisions

Ethical and Legal Decisions

- Ethical decision – conduct is morally correct
  - Professional ethics – may be enforced and violations punished
  - Personal ethics – violations that affect reputation and conscience

Ethical and Legal Decisions

- Ethical decision – conduct is morally correct
  - Professional ethics – may be enforced and violations punished
  - Personal ethics – violations that affect reputation and conscience
- Legal decision – conduct is within legal boundaries
  - Federal, state, local laws
  - Violations punishable by civil and/or criminal authorities

Ethical and Legal Decisions

- Many actions are legal, but are unethical
- Some actions may be illegal, but perceived as ethical
- 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 published standards to determine reasonableness, therefore
  - Ethical
  - Legal

Standards of Care

- Sources
  - Federal, state, local laws
    - Clinical Laboratory Improvement Amendment (CLIA)
    - Federal Drug Administration (FDA)
    - FDA – Center for Devices and Radiological Health (CDRH)
    - State licensure or certification board

FYI see link below for the FDA homepage

Standards of Care

- Sources
  - Agencies – Joint Commission
  - Professional codes of ethics (AARC)
  - Clinical practice guidelines (AARC)
  - Employers' policies and procedures, e.g. job description for scope of practice

FYI see links below for the AARC code of ethics and professional conduct and AARC Clinical Practice Guidelines

Medical Device Regulations

Safe Medical Device Act of 1990

- Administered by Federal Drug Administration, Center for Devices (CDRH)
- Function
  - Defines and classifies medical devices
  - Provides rules and regulations for safety (including human factors)
  - Medical device failure reporting
  - Mandates device recalls

Safe Medical Device Act of 2009

- Supreme court ruling (Riegel vs. Medtronic)
  - Manufacturer cannot be sued under state law for harm caused by a device with marketing approval by the FDA
  - There are efforts underway to change the law

FYI see link below to view an editorial on device act of 2009

Medical Device Classifications

- Category I – General Controls
  - Least regulatory control
  - Minimal potential for harm due to malfunction
  - Examples: bandages, gloves, handheld instruments

FYI see link below for an overview of FDA regulation of medical devices

Medical Device Classifications

- Category II – Special Controls
  - Devices for which general controls are insufficient
  - Regulations on labeling, mandatory performance, post-market surveillance
  - Examples: anesthesia devices, which include respiratory care devices

FYI see link below for the CDRH list of anesthesia devices

Medical Device Classifications

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

CDRH Recalls

- Device recall categories
  - Class I – High risk
  - Class II – Less-serious risk
  - Class III – Low risk

CDRH Recalls

- Possible device recall actions
  - Inspect the device for problems
  - Repair the device
  - Adjust settings on the device, e.g. software upgrade
  - Re-label the device
  - Notify patients of a problem
  - Monitor patients for health issues
  - Destroy the device

CDRH Recalls

- Recalled devices of interest
  - Smiths Medical ASD, Inc., Protex Uncuffed Pediatric-Sized Tracheal Tubes (sizes 2.5, 3.0, and 3.5 mm)
  - Covidien Pedi-Cap End-Tidal CO_2 Detector
  - Respironics, Inc., SmartMonitor 2 Infant Apnea Monitor (Models 4002 and 4003)

See link below for the CDRH list of recalled devices

Medical Device Reporting

- Deaths due to devices reported within 10 days
- Adverse events reported to MedWatch

FYI see link below for MedWatch healthcare professional voluntary reporting

Medical Device Reporting

- MedWatch voluntary reporting
  - Product quality problem
  - Product use error associated with FDA – regulated drugs, medical devices, etc.

FYI see link below for an FDA video on patient safety

Medical Device Reporting

- Emergency Care Research Institute (ECRI)
  - Nonprofit medical research institute
  - Voluntary device reporting
  - Medical device safety resources

FYI see link below for ECRI medical device safety resources

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 be defective
  - If there was a patient involved in the incident, the patient's physician should be notified
  - If an employee was injured 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 your risk management within 24 hours
  - Notify whichever department is appropriate for handling the device

Causes of Medical Device Incidents

Medical Device Event Causes

- Device defect
  - Design defects
  - Product defects
- Device misuse
  - Error
  - Intentional
- Other system failure

Device Defects

- Design defect
  - The device meets manufacturer's specifications, but
  - The device is not safe for all reasonably foreseeable uses OR
  - The design has deficient human factor engineering

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)
    - A ventilator that malfunctions due to electromagnetic interference

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 with wheels that fail to lock

Device Misuse

- Device is operational
- Use of device is not reasonably foreseeable by manufacturer
- Device instruction describes and limits reasonable use

Device Misuse

- Conditions for users' assumption of ethical, legal responsibility
  - User knew risk before incident
  - User acted voluntarily
  - User acted unreasonably

Device Misuse Examples

- Using an inline suction catheter for tracheal gas insufflation

Device Misuse Examples

- Using an inline suction catheter for tracheal gas insufflation
  - Code → severe desaturation
  - Physician advanced catheter
  - Ordered therapist to attach catheter to oxygen and adjust liter flow
  - Therapist declined – obvious device misuse

Device Misuse Examples

- Pediatric physicians using a blender and flowmeter to adjust oxygenation for neonates with nasal cannulae
  - Alternately adjusting FiO_2 and liter flow, e.g. FiO_2 = 30%, 0.5 L/min
  - Blender user manual states that blender is inaccurate at flows less than 5 L/min
  - Analysis of FO_2 by RCP found that FiO_2 was room air at low flows

Device Misuse Examples

- Pediatric physicians using a blender and flowmeter to adjust oxygenation for neonates with nasal cannulae
  - RCPs questioned practice, then analyzed FO_2
  - Blender user manual confirmed RCP's questioning the practice
  - Harm to patients?
  - Practice should have been questioned and investigated at outset

Device Misuse Examples

- Using a pulse oximeter finger sensor on the forehead
  - Sensor was not a reflective sensor and was misused to obtain any number
  - SPO_2 readings were artifactually high
  - Documentation of SPO_2 was inaccurate for numerous patients

Device Misuse Examples

- Using a pulse oximeter finger sensor on the forehead
  - AARC and AACN Clinical Practice Guidelines state to use sensor at intended site
  - Harm
    - Multiple arterial punctures
    - Failure to detect hypoxemia

Reference: 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)

FYI see link below for the definition of professional negligence

Negligence

- Common examples
  - Failure to verify physician's orders
  - Failure to complete patient-ventilator assessments
  - Failure to restock emergency equipment
  - Using malfunctioning devices on patients

Contributing Factors in Deaths/Injuries with Long-term Ventilation

Note: As with almost all adverse events, there were multiple contributing factors pertaining to deaths/injuries in these cases, explaining percentages in excess of 100%

FYI see link below for Joint Commission sentinel events, Issue 25

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%)
- Institutional culture: hierarchy, intimidation (13%)

Minimizing Device Accidents

Strategies to Minimize Accidents

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

FYI see link below for information on reducing equipment-related adverse events

Responsibilities of RCPs

- Management
  - Evaluate equipment before acquisition
  - Ensure staff competency on all equipment
    - Training
    - Monitoring (supervision)
    - Appropriate clinical assignment
  - Document preventative maintenance

Responsibilities of RCPs

- Management
  - Report adverse events
    - Facility incident reports
    - MedWatch and/or ECRI

Responsibilities of RCPs

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

Responsibilities of RCPs

- RC staff
  - Ensure self-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

- In 1977, in a new ER in Pennsylvania, a patient became cyanotic while on a non-rebreather mask
- Physician discovered that the O_2 outlet delivered N_2O
- Mislabeled pipe connections for the N_2O "may have" caused as many as five deaths in the hospital
- 300 patients were mistakenly given N_2O
- RC departments are responsible for analyzing output of all gas outlets

FYI see link below for a news article about nitrous oxide in emergency rooms

Medical Gas Events

- At a medical center, a NICU therapist could calibrate O_2 analyzers to 100% ONLY with gas from oxygen cylinders
- The greatest FiO_2 from any outlet = 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
- Another incident that supports checking the output of gas outlets

Ventilator Event: Recovery Room

- Post-op patient on a ventilator developed dysrhythmias
- Anesthesiologist ordered medications for dysrhythmias, then an ABG, which showed lethal hypoxemia
- The RT was called to the bedside and found a disconnection and a nonfunctional alarm
- Functional alarms likely would have prevented this
- Assessing the patient, instead of only observing the monitors, would prevent this

Ventilator Events

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

Ventilator Event

- 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 that only RTs should make ventilator adjustments

Ventilator Event

- Ventilator malfunction due to cell phone??
- Current cell phones do not interfere with medical devices
- Never text while driving or while intubating

FYI see link below for info on cell phones and medical devices

Summary & Review

Summary and Review

- Ethical, legal decisions adhere to standards of care
- Standards of care formulated by
  - Government
  - Agencies, e.g. Joint Commission
  - Professional organizations, e.g. AARC
  - Individual institutions, departments

Summary and Review

- Medical device regulations, defined by the FDA
  - Classifies, regulates devices
  - Provides regulations and means for reporting problems
  - Provides mechanism for recalls
- Emergency Care Research Institute (ECRI)
  - Supports evidence-based practice
  - Provides for voluntary reporting of device problems

Summary and Review

- Causes of device incidents
  - Design defects
  - Product defect
  - Device misuse (negligence)
- Professional negligence
  - Duty to patient
  - Breach of duty
  - Injury to patient
  - Proximate cause – injury was due to breach of duty

Summary and Review

- Joint Commission Sentinel Alert on contributing factors in ventilator deaths
  - Staffing
  - Communications breakdown
  - Incomplete patient assessment
  - Equipment problems
  - Restraint failure
  - Institutional cultural deficiencies

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 RC management
  - Considering safety before money
  - Evaluating equipment before acquisition
  - Ensuring staff competency on all equipment
  - Supervision
  - Appropriate staffing

Summary and Review

- Responsibilities of RC staff
  - Ensuring self-competency
  - Participating in equipment evaluation
  - Routine monitoring
  - Removing malfunctioning devices from service
  - Reporting risks
- Examples of equipment misadventures
  - Medical gases
  - Ventilators

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.
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