Ethical and Legal Issues in Clinical Practice: Medical Devices

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http://www.geocities.com/jonesapjr/index.html

Learning Objectives:
- Describe the functions of standards of care in guiding ethical and legal decision-making in clinical practice.
- Recognize the functions of agencies that regulate medical devices.
- Distinguish among specific causes and contributing factors of adverse events involving medical devices.
- Describe strategies for preventing adverse events involving medical devices.
- Discuss the responsibilities of respiratory care personnel pertaining to adverse events involving medical devices.
- Examine 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 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 boards

FYI - link to the FDA home page
http://www.fda.gov/default.htm

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 - Link to AARC code of ethics and professional conduct
http://www.aarc.org/resources/position_statements/ethics_detailed.html
FYI - Link to AARC Clinical Practice Guidelines
http://www.rcjournal.com/cpgs/index.cfm

Medical Device Regulations

Safe Medical Device Act of 1990

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

Functions
- 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 - click to download editorial on device act of 2009
http://content.nejm.org/cgi/reprint/360/15/1550.pdf
**Medical Device Classifications**

<table>
<thead>
<tr>
<th>Category I - General controls</th>
</tr>
</thead>
<tbody>
<tr>
<td>Least regulatory control</td>
</tr>
<tr>
<td>Minimal potential for harm due to malfunction</td>
</tr>
<tr>
<td>Examples - bandages, gloves, handheld instruments</td>
</tr>
</tbody>
</table>

FYI - Link to FDA medical device classifications
http://www.qrasupport.com/FDA_MED_DEVICE.html

<table>
<thead>
<tr>
<th>Category II - Special controls</th>
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</thead>
<tbody>
<tr>
<td>Devices for which general controls are insufficient</td>
</tr>
<tr>
<td>Regulations on labeling, mandatory performance, post-market surveillance</td>
</tr>
<tr>
<td>Examples - anesthesia devices, which include respiratory care devices</td>
</tr>
</tbody>
</table>

FYI - Link to CDRH list of anesthesia devices

<table>
<thead>
<tr>
<th>Category III - Devices requiring premarket approval</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regulated as new devices</td>
</tr>
<tr>
<td>Not equivalent to existing devices</td>
</tr>
<tr>
<td>Examples - pacemakers, implants, some ventilators</td>
</tr>
</tbody>
</table>

**CDRH recalls**

<table>
<thead>
<tr>
<th>Device recall categories:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class I........high risk</td>
</tr>
<tr>
<td>Class II........less-serious risk</td>
</tr>
<tr>
<td>Class III.......low risk</td>
</tr>
</tbody>
</table>

**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

**Recalled devices of interest**

- Smiths Medical ASD, Inc., Portex Uncuffed Pediatric-Sized Tracheal Tubes (sizes 2.5, 3.0, and 3.5 mm)
- Covidien Pedi-Cap End-Tidal CO2 Detector
- Respironics, Inc., SmartMonitor 2 Infant Apnea Monitor (Models 4002 and 4003)

Click for CDRH list of recalled devices
http://www.fda.gov/MedicalDevices/Safety/RecallsCorrectionsRemovals/ListofRecalls/default.htm
Medical Device Reporting

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

FYI - 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.

FYI - Link to FDA patient safety video presentations (bookmark?)
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/psn/index.cfm

Medical Device Reporting

- Emergency Care Research Institute (ECRI)
  - nonprofit medical research institute
  - voluntary device reporting
  - medical device safety resources

FYI - Link to ECRI medical device safety resources
https://www.ecri.org/PatientSafety/Pages/safetyresources_pages_default.aspx

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 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

- Product defect
  - device does not meet manufacturer’s specifications or governmental standards
  - device was defective when it left the manufacturer

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

- Examples:
  - a 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 by manufacturer
- Device instruction describes and limits reasonable use.

Device misuse

- Conditions for user’s 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 FIO2 and liter flow, e.g., FIO2 = 30%, 0.5 L/min
  - blender user manual states that blender is inaccurate at flows less than 5 L/min
  - analysis of FIO2 by RCP found that FIO2 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 FO2
  - 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.
  - SPO2 readings were artifactually high.
  - Documentation of SPO2 was inaccurate for numerous patients.


**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 - Link to definition of professional negligence
http://en.wikipedia.org/wiki/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 - Link to JC sentinel events, Issue 25
http://www.jointcommission.org/sentinel_event_alert_issue_25_preventing_ventilator-related_deaths_and_injuries/
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%)

- **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 - Link to reducing equipment-related adverse events
http://www.brownspath.com/original_articles/equipevnts.htm

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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**
- Ensure self-competency on all equipment
- Preventive 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

Responsibilities of RCPs

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

RC Equipment Adverse Events

- In 1977, in a new ER in Pa, a patient became cyanotic while on a nonrebreathing mask.
- Physician discovered that the O2 outlet delivered N2O.
- Mislabeled pipe connections for the N2O "may have" caused as many as five deaths in the hospital.
- 300 patients were mistakenly given N2O
- RC departments are responsible for analyzing output of all gas outlets.

FYI - Link to news article about nitrous oxide in emergency room
http://www.time.com/time/printout/0,8816,915271,00.html
### Medical gas events
- At a medical center. A NICU therapist could calibrate O2 analyzers to 100% ONLY with gas from oxygen cylinders.
- The greatest FIO2 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
- Postop 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 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 for 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.

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**Summary & Review**

FYI - Link to cell phones and medical devices
http://www.medicalnewstoday.com/articles/64865.php
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., the 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 defects
- 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

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