Preventing Medical Errors Part Two: Devices

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This Presentation is Approved for 1 CRCE Credit Hour

Learning Objectives

- Identify the responsibilities of respiratory care managers & practitioners in preventing errors associated with medical devices
- Discuss examples of medical device errors & how they could have been prevented

Medical Devices

- Number of devices at bedside has increased from 7 to 26 over previous 20 years
- Human error contributes to 90% of accidents associated with medical devices
- Respiratory care devices
  - Greater variety
  - Greater capabilities
  - Greater complexity

See links below for illustration of devices at bedside

Terminology

Definitions

- Error: failure of planned action or use of a wrong plan to achieve a goal
  - Latent errors: set the stage for future errors & usually are committed by the system
  - Active errors: have immediate consequences
    - Slips: performing a correct action incorrectly (performance)
    - Mistake: performing an incorrect action (decision-making)

Definitions

- Adverse event: an injury that was caused by medical management & that resulted in measurable disability. These may be either
  - Unpreventable, e.g. due to patient characteristic, or
  - Preventable - due to error

Definitions

- Sentinel event (Joint Commission)
  - An unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. Serious injury specifically includes loss of limb or function.
  - Not all sentinel events occur because of an error & not all errors result in sentinel events.

FYI see links below to subscribe to Joint Commission Sentinel Alerts

Causes Of Device - Associated Adverse Events

Multifactorial View

- Factors
  - Personal attributes of practitioner
  - Attributes of the system, e.g. the hospital
  - Patient attributes

Interplay of Contributing Factors

- Personal Factors
  - Health
  - Cognitive state
  - Competency
  - Professional commitment

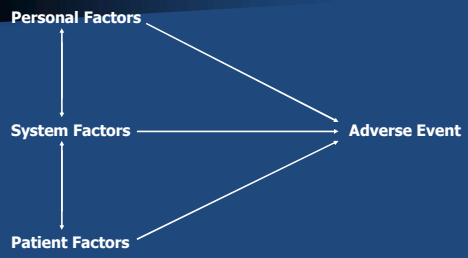
Interplay of Contributing Factors

- System Factors
  - Device design & construction
  - Physical facilities
  - Management & supervision
  - Organization culture
  - Commitment to safety

Interplay of Contributing Factors

- Patient Factors
  - Physical constitution
  - Psychological constitution
  - Illness acuity - necessity of life support
  - Comorbidities (all present conditions)

Interplay of Contributing Factors



Analysis of Adverse Events

- Root cause analysis (RCA)
  - Identifies all contributing factors
  - Aims at problem-solving, NOT reactive measures & finger-pointing
  - Aims at performance improvement by eliminating root causes
  - Eliminating root causes will prevent recurrence of event

FYI see links below for more information on root cause analysis

Medical Device Event Causes

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

Design 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

Design Defects

- Design defect
  - Examples
    - A ventilator that operates everywhere except during air transport, because of electromagnetic interference
    - An ECG monitor that displays ventricular tachycardia when the patient also has an electronic urine output monitor

Design Defects

- Design defect
  - Examples (human factor defects)
    - A ventilator that requires navigation through layers of menus to change modes
    - A monitor display that is difficult to see
    - An alarm that is easy to ignore
    - A ventilator port that permits easy misconnection

Design Defects

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

Design 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 (by manufacturer)
- Device instruction manual should describe & limit reasonable use
- Implication - liability is assumed by the user (misuser)

Device Misuse

- Examples
  - Using a nebulizer intended for a 50 PSIG source for a home compressor unit
    - Ineffective nebulization
    - Could prevent relief from exacerbations of asthma, COPD

Device Misuse

- Examples
  - Using a critical care ventilator in the home care setting
    - User manuals specify users as trained healthcare professionals
    - Home users must be informed & required to sign a waiver

Device Misuse

- Examples
  - Using a blender & flowmeter to adjust oxygenation to a nasal cannula
    - Some blenders deliver 21% at low flows (check manuals for recommended flow ranges)
    - At best, FiO_2 is unknown

Potential System Failures

- Gas sources
- Electrical power source
- Purchasing decisions
- Management
- Inadequate training

Medical Device Regulations

Safe Medical Device Act of 1990

- Administered by Federal Drug Administration, Center for Devices & Radiologic Health (CDRH)
- Functions
  - Defines & classifies medical devices
  - Provides rules & 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 links below for editorial on Device Act of 2009

Medical Device Classification

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

FYI see links below for FDA medical device safety web page

Medical Device Classification

- 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 links below for CDRH list of anesthesia devices

Medical Device Classification

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

Human Factor Engineering (HFE)

- Definition: study of the interactions between humans, machines, & complex systems
- Specific goals of HFE
  - Reduced risk of device user error
  - Easier to use (or more intuitive)
  - Reduced need for training
  - Reduced reliance on user manuals

Human Factor Engineering (HFE)

- Specific goals of HFE
  - Reduced risk of device user error
  - Easier to use (or more intuitive)
  - Reduced need for training
  - Reduced reliance on user manuals
  - Easier to read controls & displays
  - Safer connections between devices
  - More effective alarms
  - Easier repair & maintenance

FYI see links below for AHQR's human factors & medical devices

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

Medical Device Reporting

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

See links below for Medwatch healthcare professional voluntary reporting

Medical Device Reporting

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

FYI see links below for ECRI medical safety resources

Medical Device Reporting

- Steps when a medical device has been found to be defective
  - Take the device from service
  - Put the device & all its parts back in its packaging & write down its number
  - Must put some kind of notification on the device

Medical Device Reporting

- Steps when a medical device has been found to be defective
  - Notify the patient's physician
  - 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 & deliver it to Risk Management within 24 hours
  - Notify whichever department is appropriate for handling the device

FYI see links below for FDA patient safety video updates

Adverse Events With Respiratory Care Devices

Nasal Cannula

- Event: increased liter flow does not improve SPO_2
- Cause: nasopharynx obstructed with surgical gauze
- Contributing factors
  - Inadequate communication
  - Inadequate documentation
  - Inadequate patient assessment

Nasal Cannula

- Prevention
  - Comprehensive report on transfer
  - Documentation of nasal packing
  - Physical assessment of the patient

Oxygen Cylinder

- Event: pediatric patient struck in head by oxygen cylinder in MRI
- Cause: steel cylinder in MRI
- Contributing factors
  - MRI area unsecured
  - Inadequate signage
  - Inadequate staff training
  - Absence of piped-in O_2
  - Absence of nonferrous cylinders

Oxygen Cylinder

- Prevention
  - Monitoring by MRI personnel
  - Prominent signage
  - Comprehensive staff training
  - Nonferrous transport cylinders
  - Medical gas wall outlets
  - MRI - compatible devices

Up next: Video of O_2 cylinder in MRI laboratory (2 min)

Manual Resuscitation Bag

- Event: bagging worsens hypoxemia
- Cause: the manual resuscitator was connected to an air flowmeter
- Contributing factors
  - Air flowmeter attached to wall
  - Spaghetti at bedside
  - Panic mode in unit

Manual Resuscitation Bag

- Prevention
  - Air flowmeters disconnected & stored when not in use
  - All gas tubing should be labeled for applications
  - Trace tubing to source before use
  - Flow restriction device instead of air flowmeter for treatments

Manual Resuscitation Bag

- Patient exhaled during bag squeeze
- Cause: left-hander using right-handed bag
- Contributing factors
  - Purchasing failed to order left-handed bags
  - Manager hired left-handed therapist

Manual Resuscitation Bag

- Prevention
  - Fire all left-handed caregivers (equal opportunity litigation?)
  - Train left-handers to bag right-handed
  - Supply & label left-handed resuscitation bags

Endotracheal Tubes

- Event: bronchoscopy required because closed-system suction catheter tip remained in the trachea when the ETT was shortened
- Cause: catheter was in ETT when it was cut to reduce its length

Endotracheal Tubes

- Contributing factors
  - Catheter not withdrawn after suctioning
  - Visibility of catheter was minimal

Endotracheal Tubes

- Prevention
  - Catheters should be withdrawn completely after suctioning
  - Increased vigilance before cutting tube
  - Colored catheter would improve visibility

Tracheostomy Tubes

- Patient coughed & tube relocated into mediastinum - patient expired
- Cause: tube anchoring tie secured with slip knot

Tracheostomy Tubes

- Contributing factors
  - Inadequate procedure for postoperative tracheostomy care
  - Inadequate training & supervision for caregiver & residents
  - Delay in surgical intervention

Tracheostomy Tubes

- Prevention
  - Suturing new tracheostomy tubes in place
  - Strict, clear procedure for tracheostomy tube anchors
  - Comprehensive clinical training & supervision on tracheostomy procedures

Speaking Valves

- Event: patient develops respiratory failure after placement of speaking valve
- Cause: failure to deflate cuff
- Contributing factors
  - Cuffed tube in place
  - No visible indication of cuff inflation

Speaking Valves

- Prevention
  - Speaking valves should be used only with uncuffed or fenestrated tubes
  - Cuff deflation must be double-checked with syringe

Suctioning Devices

- ICU ventilator patients developed mucus retention
- Cause: patients were not suctioned
- Contributing factors
  - Hospital ran out of vacuum
  - Purchasing neglected to order vacuum cylinders
- Prevention: increase supply of vacuum (outer space?)

Bite Block

- Laryngoscopy done because caregivers suspected aspiration of portion of oropharyngeal airway
- Cause: bite-block created by cutting oropharyngeal airway

Bite Block

- Contributing factors
  - Inadequate shift report
  - Tribalism - RCP was not consulted
- Prevention
  - Improved shift report
  - Communication among tribes

Oximetry

- Event: patient requires multiple punctures due to disagreement of blood gas & pulse oximeter
- Cause: inaccurate oximetry because sensor was misused
- Contributing factors
  - Inadequate instruction & supervision of caregivers
  - Tribalism - MD & RN did not believe RCP

Oximetry

- Prevention
  - Oximeter sensors should be used in accordance with recommendations
  - Physician & RN should trust RCP
  - Strong medical direction to support RCP

Adverse Events With Mechanical Ventilators

Sentinel Events - Contributing Factors

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

FYI see links below for ventilator sentinel event alert

Sentinel Events - Contributing Factors

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

Sentinel Events - 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%)

Sentinel Events - Contributing Factors

- Restraint failure (13%)
- Distraction (22%)
- Cultural (13%)
  - Hierarchy
  - Intimidation

Current Ventilator Issues

- Alarms
  - Discerning among alternative devices
  - Excessive activations - 'crying wolf'
- Displays, e.g. visibility
- Layers of menus to adjust controls
- Modes that self-adjust ventilation parameters

Mechanical Ventilation

- Event: patient in intermediate unit disconnected from ventilator & expired
  - Alarms were adjusted & functioning
  - ECG technician notified caregivers of dysrhythmias

Mechanical Ventilation

- Cause: disconnect (cough?)
- Contributing factors
  - Patient was located in corner room, distant from station
  - Patient was in a unit where RCP was not assigned full-time

Mechanical Ventilation

- Contributing factors
  - Patient was located in corner room, distant from station
  - Patient was in a unit where RCP was not assigned full-time
  - Caregivers were unfamiliar with mechanical ventilation
  - Ventilator had alarmed frequently
  - Tribalism - caregivers did not believe ECG technician

Mechanical Ventilation

- Prevention
  - Continuous ventilation only in unit with dedicated RCP
  - Clinical training on mechanical ventilation for caregivers
  - Immediate response to alarms & monitors
  - Improved communication, including listening

Mechanical Ventilation

- Event: ventilator patient with severe COPD developed respiratory distress due to air-trapping
- Cause: physician increased the control rate on a ventilator & did not decrease the inspiratory time or notify RCP

Mechanical Ventilation

- Contributing factors
  - Unfamiliarity of physician with interactions of ventilator controls
  - Inadequate communication
  - Tribalism - chiefs do whatever
  - Inadequate medical direction

Mechanical Ventilation

- Prevention
  - Ventilator adjustments only by RCPs
  - Training for physicians on interactions of ventilator controls
  - Prompt communication to RCPs for all ventilator adjustments
  - Medical director to enforce policies

Accidents Waiting to Happen

- Poorly located ventilator patients
- Untrained personnel adjusting ventilators (too many chefs)
- Other equipment located in front of ventilators
- Procedures, unwritten, unclear, uncommunicated
- Variety of ventilators, monitors

Accidents Waiting to Happen

- Inadequate RCP competency assurance
- Inadequate respiratory care orientation for other caregivers
- Air flowmeters in wall outlets
- Spaghetti at the bedside
  - Medical gas tubing
  - Suction tubing
- Any others at your place?

General Preventive Measures

Strategies to Minimize Accidents

- Adopt safe devices
  - Homework - research on devices
  - Safest, rather than cheapest
- Standardization of devices
- Comprehensive trial evaluations with structured input from staff
- Comprehensive competency assurance

Responsibilities of RCPs

- Management
  - Evaluate equipment before acquisition - structured staff evaluation
  - Ensure staff competency on all equipment & applications, e.g. ventilator modes
    - Training
    - Monitoring (supervision)
  - Documented preventive maintenance

Responsibilities of RCPs

- Management
  - Report adverse events
  - Root cause analysis of adverse events

Responsibilities of RCPs

- RC staff
  - Assure competency on all devices
  - Preventative maintenance & documentation
  - Routine monitoring of device function
  - Removing malfunctioning equipment from service (includes labeling)
  - Document & report adverse events to management
  - Report any potential risks

Summary & Review

Summary & Review

- Definitions
  - Errors - active & latent
  - Sentinel events
- Multifactorial event factors
  - System factors, including devices
  - Personal factors
  - Patient factors
- Root cause analysis - solve the problems

Summary & Review

- Causes of device incidents
  - Device defects
    - Product defects
    - Design defects, including HFE
  - Device misuse - examples
  - System factors

Summary & Review

- Medical device regulations
  - CDRH device classifications & recalls
  - Goals of human factor engineering
  - Medical device reporting

Summary & Review

- Examples of adverse events with respiratory care devices
- Sentinel events with ventilators & contributing factors
- Examples of ventilator events
- General preventive measures
  - Respiratory care management
  - Respiratory care staff

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