The Joint Commission

Sentinel Event Alert

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Preventing ventilator-related deaths and injuries

As of January 2002, the Joint Commission has reviewed 23 reports of deaths or injuries related to long term ventilation--19 events resulted in death and four in coma. Of the 23 cases, 65 percent were related to the malfunction or misuse of an alarm or an inadequate alarm; 52 percent were related to a tubing disconnect; and 26 percent were related to dislodged airway tube. A small percentage of the cases were related to an incorrect tubing connection or wrong ventilator setting. None of the cases were related to ventilator malfunctions. As the percentages indicate, ventilator-related deaths and injuries are often related to multiple failures that lead to negative outcomes. The majority of the cases occurred in hospital Intensive Care Units (ICUs), followed by long term care facilities and hospital chronic ventilator units.

Root causes

Root cause analysis of the 23 cases reveals the following contributing factors:

Staffing	
Inadequate orientation/training process	87 percent
Insufficient staffing levels	35 percent
Communication breakdown	
Among staff members	70 percent
With patient/family	9 percent
Incomplete patient assessment	
Room design limits observation	30 percent
Delayed or no response to alarm	22 percent
Monitor change not recognized	13 percent
Equipment	
Alarm off or set incorrectly	22 percent
No alarm for certain disconnects	22 percent
Alarm no audible in all areas	22 percent
No testing of alarms	13 percent
Restraint failure (escape)	13 percent
Distraction (environmental noise)	22 percent
Cultural (hierarchy/intimidation)	13 percent

In addition, several organizations found that during the use of low airway pressure alarms only, some ventilators did not always respond to tubing disconnects at all levels of the airflow circuit. For example, the disconnected airway tube may fall into the bedding or against the patient's body, ventilation cycling continues and the ventilator continues to receive indications of correct air pressure.

Risk reduction strategies

Both the Food and Drug Administration (FDA) and the American Association of Respiratory Care (AARC) have published guidelines for testing and evaluating ventilators. The FDA's Draft Reviewer Guidance for Ventilators (1) covers continuous ventilators, critical care ventilators, and electrically powered home care ventilators. The AARC is a professional membership association of respiratory therapists that focuses primarily on respiratory therapy education and research. The AARC Clinical Practice Guideline-Patient-Ventilator System Checks (2) cover the breadth of respiratory care procedures, including guidelines related to care of patients using mechanical ventilator support.

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"The AARC has long held that death and injury due to faulty alarms, inadequate alarm systems, alarm misuse, and airway disconnect are avoidable," says Sam Giordano, executive director of the AARC. "The key are an informed and alert caregiver team." The AARC recommends that health care organizations undertake efforts to assure that:

> *disconnect is avoidable. The key are an informed and alert caregiver team."*
> *--**Sam Giordano**, executive director, American Association of Respiratory Care*

- Professionals responsible for application, adjustment and monitoring of ventilators, alarm systems and airways, possess relevant education, and have undergone validated competency testing.
- Systems are in place to check ventilator and monitoring system performance before and during clinical use.
  All devices and systems are maintained according to manufacturers' specification. This includes medical gas systems.
- A tracking system is in place to identify, analyze and remedy all ventilator-related incidents that lead to serious injury or death.
  Protocols for the application and discontinuance of mechanical ventilation are in place.
- A mechanism is in place to track outcomes of all ventilator patients.
- Organized, periodic, ventilator-related continuing education is accessible to those professionals responsible for the many components of care directed to ventilator patients.

The AARC recommendations are in-line with the following risk reduction strategies identified by Joint Commission-accredited organizations that experienced a sentinel event related to ventilators:

1. Improve and expand staff orientation and training on ventilators.
2. Upgrade alarms and monitoring systems on ventilators.
3. Institute team training.
4. Establish new processes for alarm testing and verification of alarm settings.
5. Establish new or redesigned alarm response procedures.
6. Redesign rooms or units to improve observation of patient and ventilator.
7. Improve and expand preventive maintenance on ventilators.
   Recommendations

Joint Commission makes the following recommendations to help prevent ventilator-related deaths and injuries:

1. Review orientation and training programs for job-specific, ventilator safety-related content and include in competency assessment process.
2. Review staffing process to ensure effective staffing for ventilator patients at all times.
3. Implement regular preventive maintenance and testing of alarm systems.
4. Ensure that alarms are sufficiently audible with respect to distances and competing noise within the unit.
5. Initiate interdisciplinary team training for staff caring for ventilator patients.
6. Direct observation of ventilator-dependent patients is preferred in order to avoid over dependence on alarms.

Resources

1. Food and Drug Administration, Draft Reviewer Guidance for Ventilators, http://www.fda.gov/cdrh/ode/500.pdf
2. American Association of Respiratory Care, AARC Clinical Practice Guideline-Patient-Ventilator System Checks, http://www.aarc.org/

Published for Joint Commission accredited organizations and interested health care professionals, Sentinel Event Alert identifies specific sentinel events, describes their common underlying causes, and suggests steps to prevent occurrences in the future.

During the on-site survey of accredited organizations, Joint Commission surveyors assess, for consultative purposes, the organization's familiarity with and use of Sentinel Event Alert information. Accredited organizations are expected to:

- Review and consider relevant information, if appropriate to the organization's services, from each Sentinel Event Alert.
- Consider information in an alert when designing or redesigning relevant processes.
- Evaluate systems in light of information in an alert.
- Consider standard-specific concerns.
- Implement relevant suggestions or reasonable alternatives or provide a reasonable explanation for not implementing relevant changes.

At this time, Joint Commission has placed a moratorium on using the organization's response to Sentinel Event Alert recommendations as the basis for scoring standards.

Setting the Standard for Quality in Health Care
The Joint Commission
Sentinel Event Hotline (630) 792-3700