ECRI

Healthcare Risk, Quality, & Safety Guidance - Guidance

Ventilator Safety

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EXECUTIVE SUMMARY

Ventilators deliver positive-pressure breaths to patients who require total or partial assistance to breathe. They are used in a variety of settings for both critically ill and chronically ill patients, including operating rooms, recovery rooms, critical care units, emergency departments, nursing homes, and patients' homes. Newer ventilators offer comprehensive features for patient monitoring and assessment, as well as ventilation modes that respond to the patient's changing lung mechanics.

Ventilators incorporate monitors and alarms that alert users to changes in the status of the patient or the equipment. They also include safety features that can help with lung assessment and recruitment, patient weaning, patient monitoring, and patient-ventilator synchrony (ECRI "Evaluation Background").

Despite their life-saving capabilities, ventilators pose a number of risks to patient safety, including ventilator-associated pneumonia (VAP), ventilator-induced lung injury, acute respiratory distress syndrome (ARDS), pulmonary edema, pulmonary embolism, collapsed lung, pneumothorax, and sepsis. Such risks can emerge if staff do not follow safe and informed ventilator practices. Many of these events can be traced to inconsistent and ill-defined respiratory care protocols and to failure to use current ventilator technology. (ECRI Institute "Using Ventilator Technology")

Ventilator use has also been associated with technology-based safety concerns, such as disconnections and alarm-related problems. Many mechanical safety problems can be detected during routine ventilator checks before and during use.

Strategies to help reduce the risks associated with ventilator-associated events (VAEs) include comprehensive and ongoing education, good communication among staff, application of new ventilator technology, and model-specific ventilator training. Other strategies, such as purchasing only high-quality ventilators and accessories from reputable manufacturers, providing frequent education on the appropriate use of ventilators, and developing policies that identify which staff can perform tasks associated with ventilator use, can also help promote the safe use of ventilators.

This guidance article discusses risk management issues related to ventilators, including VAEs, disconnections, and alarms and provides recommendations to minimize the risks associated with ventilator use. Although this article focuses on ventilator safety in the critical care setting, the recommendations are applicable to use of ventilators in any type of care setting.

Action Recommendations

- Develop a comprehensive, multidisciplinary alarm management program to address potential hazards associated with ventilator alarms.
- Direct staff to confirm, during regular ventilator checks, that all alarms are active and that the alarm volume is loud enough to be heard outside the room.
- Reduce the risk of disconnections with proper alarm settings and staff involvement and education.

- Develop a written policy that identifies which staff are authorized to operate ventilators and prohibits other staff from changing ventilator settings.
- Ensure that physicians follow an accepted and documented method for calculating ventilator alarm settings, and that all clinicians responsible for ventilator settings confirm that settings derived in any other way are appropriate for the individual patient. If no standard method yet exists, adopt and document one.
- Expand and improve continuing education for physicians and respiratory therapists about proper setup of ventilators, circuits, and alarms, as well as device capabilities and ventilator best practices.
- Perform competency checks for all staff involved with ventilation practices that require demonstrations of clinical understanding and ability to operate of all ventilators used for patient care.
- Ensure that staff members who have been given authority to operate ventilators are trained in the theory of mechanical ventilation and alarms, as well as in the use of the specific ventilator models in service.
- Ensure that staff are educated on how to communicate and work with the families and caregivers of patients on ventilators, and how to educate families and patients on what to expect.

WHO SHOULD READ THIS

Clinical/biomedical engineering, Critical care, Home care, Long-term care services, OR/surgery, Patient safety officer, Respiratory therapy

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Ventilators deliver positive-pressure breaths to patients who require total or partial assistance to breathe. Used in operating rooms, recovery rooms, critical care units, emergency departments, nursing homes, and patients' homes, ventilators are microprocessor-controlled devices that receive gas (air, oxygen, or other therapeutic gas blends) from high-pressure gas sources such as wall outlets, cylinders of compressed medical gases, and/or integrated sources (i.e., air compressors, turbines). Ventilators regulate the pressure, volume, and flow of gas, as well as the fraction of inspired oxygen, and deliver gas to the patient through a flexible breathing circuit.

Ventilators incorporate monitors and alarms that alert users to changes in the status of the patient or the equipment. They also include a number of safety features that can help with lung assessment and recruitment, patient weaning, patient monitoring, and patient-ventilator synchrony (ECRI "Evaluation Background").

Despite their life-saving capabilities, ventilators pose several risks to patient safety, including VAP, ventilator-induced lung injury, ARDS, pulmonary edema, pulmonary embolism, pneumothorax, and infection, including sepsis. Such risks can emerge if staff do not follow safe and informed ventilator practices. Many of these events can be traced to inconsistent and ill-defined respiratory care protocols and to failure to use current ventilator technology. (ECRI Institute "Using Ventilator Technology")

Ventilator use has also been associated with technology-based safety concerns such as disconnections and alarm-related problems. Many mechanical safety problems can be detected during routine ventilator checks before and during use.

Some strategies to help reduce the risks associated with ventilators include comprehensive and ongoing education, good communication among staff, application of new ventilator technology, and model-specific ventilator training. Other strategies, such as purchasing only high-quality ventilators and accessories from reputable manufacturers, providing frequent education on the appropriate use of ventilators, and developing policies that identify which staff can perform tasks associated with ventilator use, can also help promote the safe use of ventilators.

This guidance article discusses risk management issues related to ventilators, including VAEs, disconnections, and alarms and provides recommendations to minimize the risks associated with ventilator use. Although this article focuses on ventilator safety in the critical care setting, the recommendations are applicable to use of ventilators in any type of care setting.

Technology-Based Ventilator Safety Problems

Ventilator use has been associated with a number of safety concerns, including alarm-related problems and disconnections. ECRI Institute recommends that verification of proper alarm settings be included in every ventilator check.

Unsafe Ventilator Alarm Practices

Alarm management issues are one of the most common safety concerns associated with the use of ventilators. The main issues involve several common—but dangerous—practices:

ECRI RESOURCES

Clinical Alarms

- Setting improper alarm limits. Alarm fatigue is a common concern in the healthcare setting, and ventilator alarms are a significant contributor to this issue. In an attempt to address this issue, some facilities disable critical ventilator alarms, or effectively turn them off by setting them at such extreme limits that they will never be triggered. ECRI Institute considers this practice to be unsafe, as it puts patients at risk. (ECRI Institute "Unsafe")
- Display issues. Some older ventilator models do not display the alarm limits alongside the relevant measured parameter, meaning that a clinician must interact with the device to bring up the alarm limit screen so that he or she can detect an unrealistic limit setting. Additionally, some older units do not clearly indicate on their main screen that an alarm has been disabled. (ECRI Institute "Unsafe") Newer ventilators have addressed this issue, but sometimes have the opposite problem: They display too much information instead of too little, crowding the screen.
- Audibility issues. Even properly set alarms will not be effective if caregivers do not hear them. Well-meaning staff often turn down alarm volumes in an attempt to reduce the noise in the room; however, this practice can have dangerous consequences. Other factors that can prevent staff from hearing alarms include closed or partially closed room doors, long corridors, ambient noise (e.g., announcements over the public address system), and insufficiently audible alarm-volume settings (i.e., those that fail to take into account the barriers that develop as the caregiver moves farther away from the ventilator). (ECRI Institute "Ventilator

Disconnections")

For more information on alarms, see Clinical Alarms.

Ventilator Disconnections

Any complete or partial disconnection at any point along the breathing circuit—the pathway that conveys gases between the ventilator and the patient—can quickly have devastating consequences for a patient. Disconnections can occur for various reasons—for example, patients with delirium can remove the ventilator tubing, or the tubing can accidentally become partially or fully disconnected if it is not attached securely or if it is moved. If the patient is paralyzed, unconscious, disoriented, or an infant, many minutes may pass before the ventilator disconnection is detected. In those minutes, irreversible anoxic brain injury or death can occur. (ECRI "Ventilator Disconnections")

In most cases, such disconnections are detected by one or more types of alarms, allowing staff to take action and prevent harm to the patient. These alarms are critically important, not only because the consequences of a disconnection can be so severe, but also because the incidence of disconnections is relatively high. However, to be effective, such alarms must be audible and must be set to appropriate levels. ECRI Institute has investigated cases in which serious patient harm resulted from alarms that were set to inappropriate levels and thus did not activate to warn of a disconnection, or from staff not hearing the alarms that had been activating. (ECRI "Ventilator Disconnections")

Many ventilator models incorporate an automatic alarm specifically for circuit disconnections; the settings of this alarm cannot be configured by the user. However, staff must not rely on this alarm alone to warn of a disconnection, because several factors can affect whether this alarm will activate (e.g., which ventilator settings are being used, what conditions develop because of the disconnection, how the ventilator responds to such conditions). Instead, it would be better for staff to verify that user-configurable alarms are set properly—particularly the low-pressure and low-minute-volume alarms. (ECRI "Ventilator Disconnections")

ECRI Institute has investigated incidents in which the low-pressure alarm was set to a level significantly below the patient's peak inspiratory pressure. At very low settings, the alarm functionally becomes disabled, requiring a very large decrease in pressure and ventilation to activate. Similarly, ECRI Institute has observed instances in which clinicians set the low-minute-volume alarm to a level that would prevent the alarm from activating until the patient was receiving too little gas to sustain life. (ECRI "Ventilator Disconnections")

Outdated Ventilation Protocols

Outdated ventilation protocols and failure to use current ventilator capabilities can lead to preventable patient harm. ECRI Institute's Health Devices group has identified the following factors that contribute to the slow adoption of advanced ventilator technology and slow improvements in the standard of care (ECRI "Using Ventilator Technology"):

- A lack of continuing education on the appropriate use of advanced ventilator modes and device capability for patient monitoring and assessment, including both when to use them and how to use them properly
- A lack of cooperation between physicians and respiratory therapists to ensure the use of advanced ventilator modes and features
- The fact that certain advanced modes and features may be unique to specific models—which, combined with the fact that most hospitals have a mixed fleet of ventilators, can make it difficult to keep track of which ventilator and/or mode should be used for which patient condition or concern

Ventilator-Associated Pneumonia

VAP—pneumonia that develops within 48 to 72 hours or thereafter following intubation—is a serious condition that

can occur in patients on ventilators. VAP is the most common nosocomial infection in patients on mechanical ventilation, and it accounts for nearly half of all cases of hospital-acquired pneumonia. VAP rates range from 1.2 to 8.5 per 1,000 ventilator-days, and the mortality rate associated with VAP is estimated to be between 9% and 13%. (Kalanuria et al.) In addition, treating VAP can be expensive: one study found that each case of VAP can cost healthcare facilities an average of $40,144. In total, VAP costs U.S. hospitals approximately $3.09 billion to treat annually. (Zimlichman et al.)

According to the U.S. Centers for Disease Control and Prevention (CDC), VAP now falls under the classification of a ventilator-associated event. The VAE definition algorithm is intended to be used for surveillance purposes and is not intended for use in the clinical management of patients (CDC). For more information, see Centers for Disease Control and Prevention.

REGULATIONS AND STANDARDS

International Organization for Standardization (ISO) Standards for Critical Care Ventilators

In 2011, the International Organization for Standardization (ISO) published two standards affecting critical care ventilators (ECRI Institute "International Organization for Standardization"):

- Medical electrical equipment—particular requirements for basic safety and essential performance of critical care ventilators (ISO 80601-2-12)
- Medical electrical equipment—particular requirements for the basic safety and essential performance of respiratory gas monitors (ISO/DIS 80601-2-55)

Both standards are currently under review, per ISO's policy to review standards every five years.

ECRI Institute Ventilator Evaluations and Guidance

ECRI Institute's Health Devices group provides in-depth evaluations and comparative ratings on healthcare products and expert guidance on technology topics. Health Devices has written extensively on the topic of ventilator safety and has evaluated many ventilators over the years. Many of Health Devices' ventilator resources—including its February 2017 evaluation of intensive care ventilators—can be found in Ventilators: The Essentials. For more information on Health Devices, contact healthdevices@ecri.org.

These standards include requirements ECRI Institute considers necessary to ensure both safety and performance for intensive care use. ECRI Institute's Health Devices group recommends against purchasing ventilators that do not meet these standards. (For more information on Health Devices, see ECRI Institute Ventilator Evaluations and Guidance.)

Joint Commission

One of Joint Commission's National Patient Safety Goals for 2017 is an item on using alarms, including ventilator alarms, safely. The goal requires hospitals to "ensure that alarms on medical equipment are heard and responded to on time." (Joint Commission "Hospital")

In addition, Joint Commission's home care program requires organizations to provide patients with emergency maintenance, replacement, or backup of medical equipment, when needed. This includes a stipulation that the organization provides the following for ventilator-dependent patients (Joint Commission "Comprehensive"):

- A backup system that duplicates the function of the ventilator for a minimum of three times the organization's maximum response time
- A self-inflating resuscitation bag
- A spare breathing circuit

Centers for Disease Control and Prevention

In the past, surveillance by CDC's National Healthcare Safety Network (NHSN) was limited to VAP, which required radiographic evidence of pneumonia and the presence of certain symptoms. However, CDC recognized the limitations of this definition, as well as the fact that some of the most effective measures for improving outcomes of patients on mechanical ventilation do not specifically target pneumonia prevention. As a result, CDC convened a workgroup in 2011 to develop a surveillance definition algorithm "based on objective, streamlined, and potentially automatable criteria that identify a broad range of conditions and complications occurring in mechanically-ventilated adult patients." (CDC)

In 2013, CDC introduced the term "ventilator-associated events" to describe complications that can occur in patients on mechanical ventilation. VAEs are issues that cause a worsening of a patient's oxygenation after a period of stability or improvement. (ECRI Institute "Using Ventilator Technology") The VAE definition algorithm is for use in surveillance only; it is not a clinical definition algorithm and is not intended for use in the clinical management of patients (CDC).

Defining VAEs allows a more comprehensive approach to classifying and addressing complications that can occur during mechanical ventilation. The VAE algorithm includes three definition tiers (CDC; ECRI Institute "Using Ventilator Technology):

1. Ventilator-associated condition (VAC)
2. Infection-related ventilator-associated complication (IVAC)
3. Possible ventilator-associated pneumonia (PVAP)

CDC also introduced the VAE Calculator, a web-based tool designed to help healthcare workers learn about the VAE surveillance definition algorithm and assist them in making VAE determinations. (CDC)

One study analyzed VAE data submitted to NHSN in 2014—the first full year hospitals reported events using CDC's updated VAE surveillance definitions. The study found that of 1,824 healthcare facilities reporting 32,772 location months of VAE surveillance data, pooled mean VAE incidence rates for critical care units ranged from 2.00 to 11.79 per 1,000 ventilator-days, compared with 0 to 14.86 per 1,000 ventilator-days for noncritical care units. The pooled mean proportion of infection-related VAEs ranged from 15.38% to 47.62% in critical care units. (Magill et al.)

ACTION PLAN

Address Technology-Related Ventilator Issues

Action Recommendation: Develop a comprehensive, multidisciplinary alarm management program to address potential hazards associated with ventilator alarms.

Action Recommendation: Direct staff to confirm, during regular ventilator checks, that all alarms are active and that the alarm volume is loud enough to be heard outside the room.

Action Recommendation: Reduce the risk of disconnections with proper alarm settings and staff involvement and education.

Develop an Alarm Management Program

Ventilator alarms play a key role in alerting staff to ventilator problems or changes in patient condition; however, ventilators pose some unique challenges that will require unique strategies to address. Facilities can prevent many ventilator-related mishaps by ensuring that all staff members who operate ventilators are aware of the importance of alarms and are well educated in the alarm types, uses, and settings of the ventilators functioning in the units in which they provide care.

Regardless of the steps taken to improve alarm management, it is also important to emphasize to clinical personnel that alarms cannot substitute for care and vigilance and do not obviate assessment of the patient on a regular and frequent basis.

The following strategies will help facilities develop an effective ventilator alarm management program.

Assemble a multidisciplinary alarm management committee. Initiate a comprehensive, multidisciplinary effort to address the potential hazards associated with ventilator alarm management, paying particular attention to the specific challenges with this technology. The effort should be spearheaded by an alarm management committee that includes representatives from respiratory therapy as well as other clinical personnel (e.g., nurses, pulmonologists, intensivists) who routinely address ventilator alarms and support patients on ventilators. (ECRI Institute "Missed Ventilator Alarms")

Understand how ventilator alarms are used within the facility. A successful alarm management program will require identifying where vulnerabilities lie and developing appropriate strategies to limit the hazards. To gain this understanding, facilities should first observe how the many different alarms are handled in each care area. Much can be learned by walking around, observing what happens on the care unit, and engaging frontline staff about their concerns. Facilities should also review reports of adverse events and near misses and ensure that staff feel empowered to report events and near misses involving ventilators. (ECRI Institute "Missed Ventilator Alarms") For more information on reporting adverse events, see Event Reporting and Response.

ECRI RESOURCES

Event Reporting and Response

In addition, facilities should consider collecting and analyzing alarm data to obtain a quantitative measure of the number and types of alarms that activate per device within a care area. Ventilators that are not networked in a hospital are not connected to a vendor-supplied server that would allow access to alarm data from a central location, making quantifying the number and types of ventilator alarms on these devices particularly challenging. Options that can be considered include accessing and analyzing alarm log data from individual ventilators or using third-party alarm analytics software. (ECRI Institute "Missed Ventilator Alarms")

Assess alarm volume and audibility. Examine whether environmental factors—such as the architectural layout of the care area, the presence of closed doors, or the distance of rooms from the nurses' station—or other circumstances could be hindering staff recognition of or response to ventilator alarms. (ECRI Institute "Missed Ventilator Alarms")

Identify and implement strategies for reducing the alarm load. Using the information collected during the steps listed above, analyze the most frequently occurring alarms for each care area and categorize them as follows (ECRI Institute "Missed Ventilator Alarms"):

- Alarms that are clinically actionable—for example, low-pressure alarms (which could signify a disconnection or leak) or low-volume alarms
- Alarms that are not clinically actionable—for example, transient high-pressure alarms caused by a patient coughing

Once this analysis is complete, facilities should work with frontline staff to identify and implement appropriate strategies for reducing the number of nonactionable alarms in each care area. For example, the appropriate use of ventilator modes to promote better synchrony between the patient and the ventilator can be an effective strategy for reducing unnecessary alarms. (ECRI Institute "Missed Ventilator Alarms")

Identify and implement strategies to improve staff awareness of and response to ventilator alarms. Investigate whether staffing levels or staff deployment can be adjusted to improve responsiveness to the needs of

patients on ventilators. For example, in ECRI Institute's experience, assigning respiratory therapists to a specific care area, rather than having them float between multiple care areas, leads to the best alarm and patient response. (ECRI Institute "Missed Ventilator Alarms")

Facilities may also consider enhancing notification of ventilator alarms with secondary notification pathways. Several alternatives are available, but each has limitations. Alternatives include the following (ECRI Institute "Missed Ventilator Alarms"):

- Using the nurse call system as a means of alerting users to the presence of certain (but not necessarily all) ventilator alarms. The ventilator alarms that can be communicated in this manner will depend on the capabilities of the ventilator model and the nurse call system.
- Integrating ventilators with patient monitoring systems to allow notification of ventilator alarms via the associated central stations and ancillary displays.
- Using ancillary alarm notification/alarm integration systems to send specific alarms to end-user communication devices. These systems can also be used to configure delays so that self-correcting conditions do not add to the alarm load. For example, configuring a delay for high-pressure alarms could reduce the number of alarms staff receive for transitory conditions such as a patient cough.

With any of the above approaches, it is important to test the systems before implementation to examine whether and how each alarm is communicated to the clinician and to understand the type of information (e.g., alarm type, priority level, patient) that is and is not being communicated. (ECRI Institute "Missed Ventilator Alarms")

Perform routine ventilator checks. Many safety problems can be detected during routine ventilator checks. Consistently perform checks before and during ventilator use, and include the following in the checks:

- Verification of alarm activation
- Verification of proper alarm settings
- Confirmation of proper patient/circuit connections
- Verification that alarm volume is loud enough to be heard outside the room—if alarms are not loud enough, consider using a remote alarm system

Reduce the Risk of Disconnections

The following steps can be taken to minimize the problems associated with ventilator disconnections (ECRI Institute "Ventilator Disconnections"):

- Develop and document a policy on setting ventilator low-pressure and low-minute-volume alarms to levels that are appropriate for detecting disconnections. An appropriate low-pressure alarm setting is 5 to 7 cm H_2O below the patient's peak inspiratory pressure. The low-minute-volume alarm should be set no more than 15% below the patient's required minute volume. Facilities may customize these values, or these values may be adjusted as appropriate for each patient. Inform clinicians involved with caring for patients on ventilators of this policy and of the role of the low-pressure and low-minute-volume alarms in detecting disconnections.
- Instruct all clinicians to confirm that low-pressure and low-minute-volume alarm settings derived in any other way (e.g., default settings, settings made using the "autoset" feature available on some ventilators) are within the appropriate range.
- Purchase only high-quality, easy-to-grasp tubing, connectors, and artificial airways from reputable manufacturers. With lower-quality equipment, fit is often imprecise, resulting in a connection that cannot be tightened adequately or that is difficult to assemble or take apart. Materials management staff should work with clinical and biomedical engineering personnel to choose equipment of good quality.

- Involve frontline clinical staff in purchasing decisions for ventilator accessories, and have them evaluate proposed purchases for snug-fitting, well-made connections.
- Familiarize all staff with the visual and audible alarms on new ventilators before the units are put into service.
- Provide frequent education on the proper setup of ventilation circuits and the proper setup and use of alarms.
- Direct nurses to examine the breathing system to verify that all circuit connections are secure after the patient has been moved (e.g., repositioned in bed, returned to the unit after a transport).
- Assess whether alarms can be adequately heard in the areas where the ventilator will be used. Be sure to consider any potential barriers that may develop in those areas (e.g., closed or partially closed doors, ambient noise).
- If an ancillary alarm notification system is to be used for remote ventilator alarm annunciation: Establish clear clinical and technical needs and expectations for the notification system, and thoroughly test the system before purchase, during acceptance testing, and when software changes are made to either the ventilator or the ancillary notification system. Examine whether and how each alarm is communicated to the clinician via the ancillary system, considering the type of information that is communicated (e.g., alarm type, priority level). Also examine whether adequate warning is provided when communication between the ventilator and the ancillary system becomes disrupted (e.g., an interface cable becomes unplugged); staff should be trained to identify and address the circumstances that could cause such disruptions.

Develop Ventilator-Related Policies and Procedures

> **Action Recommendation: Develop a written policy that identifies which staff are authorized to operate ventilators and prohibits other staff from changing ventilator settings.**
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> **Action Recommendation: Ensure that physicians follow an accepted and documented method for calculating ventilator alarm settings, and that all clinicians responsible for ventilator settings confirm that settings derived in any other way are appropriate for the individual patient. If no standard method yet exists, adopt and document one.**

Facilities should develop a written ventilator policy that identifies which staff members are authorized to operate ventilators (e.g., respiratory therapists, pulmonologists) and that prohibits other staff from changing ventilator settings. Staff members who have been given authority to operate ventilators should be trained in the theory of mechanical ventilation and alarms, as well as on the use of the specific ventilator models in service.

The policy should highlight the following:

- The role all alarms play in protecting the patient
- The importance of setting all alarms to appropriate parameters
- The fact that no alarm should be disabled at any time
- The importance of the minute-volume and low-pressure alarms—these alarms are misused more than any others, even though they play a vital role in detecting disconnections of the breathing circuit

The ventilator policy should also outline an accepted and documented method for physicians to follow to calculate ventilator alarm settings. It should also require clinicians responsible for ventilator settings to confirm that settings derived using any other method are appropriate for the individual patient. If the facility has not yet instituted a standard method for calculating ventilator alarm settings, one should be adopted and documented.

According to the American Association for Respiratory Care (AARC), policies and procedures for ventilator alarms should do the following:

- Be evidence-based
- Include clinical targets
- Include directives regarding permission to modify alarm settings
- Identify the time required to respond to alarms
- Establish a list of parameters that require monitoring
- Identify competency assessment intervals
- Identify the alarm priority level designation

Offer Ventilator-Related Continuing Education and Perform Competency Checks

Action Recommendation: Expand and improve continuing education for physicians and respiratory therapists about proper setup of ventilators, circuits, and alarms, as well as device capabilities and ventilator best practices.

Action Recommendation: Perform competency checks for all staff involved with ventilation practices that require demonstrations of clinical understanding and ability to operate of all ventilators used for patient care.

Action Recommendation: Ensure that staff members who have been given authority to operate ventilators are trained in the theory of mechanical ventilation and alarms, as well as in the use of the specific ventilator models in service.

Promote Continuing Education

Expanding and improving continuing education for physicians and respiratory therapists about device capabilities and ventilation best practices are essential to ensuring patient safety. ECRI Institute has found that many best practices, strategies, and advanced ventilator modes and features that have been developed to help reduce ventilator-induced lung injury and other VAEs are often not used to their full advantage in hospitals, putting patients at risk (ECRI Institute "Failure to Appropriately Operate").

To help reduce the risk to patients, risk managers should ensure the following (ECRI "Failure to Appropriately Operate"):

- Physicians and respiratory therapists are given access to education and training resources available from organizations such as AARC, the National Heart, Lung, and Blood Institute (NHLBI) ARDS Network, the Association for the Advancement of Medical Instrumentation (AAMI), and CDC. See Resource List for more information.
- The facility has adopted standardized terminology or other methods to clarify ventilation modes and features for all ventilators at the facility. Because ventilator manufacturers do not apply consistent terminology to their device modes and features, staff may be confused about device operation or about the physiologic benefits associated with particular ventilation modes and settings. Training staff on the terminology used in the facility can help minimize the confusion.
- Clinicians are educated about device features that may assist with patient care and promote healing. This can be done in coordination with clinical experts from ventilator manufacturers.
- Clinicians are provided with information about best practices for patient ventilation, including the use of lung-protective strategies, optimal setting of alarms, effective use of respiratory monitoring capabilities, and use of advanced ventilation modes and features.

Encourage Collaboration and Communication

Poor understanding of complex ventilation modes, features, and functions (e.g., advanced ventilation modes, device features) on the part of respiratory therapists and physicians has likely hindered the widespread adoption of more effective ventilation techniques. Encouraging physicians and respiratory therapists to collaborate and communicate about ventilation features and best practices can help promote these advanced techniques and thereby improve patient safety.

Facilities may want to consider implementing regular group meetings between physicians and respiratory therapists to share knowledge about issues such as treatment protocols that incorporate best practices for the mechanical ventilation of patients and which ventilation modes and features should be used based on the patient's condition. The group can also discuss the technological capabilities of ventilators in the facility's current fleet and regularly assess newly introduced ventilator configurations, modes, or features to determine whether their use could help improve patient care. (ECRI "Failure to Appropriately Operate")

Perform Competency Checks

According to AARC, approximately 9% of changes to mechanical ventilator settings were performed by healthcare providers who had no competency training regarding the specific functions of the ventilator in use. AARC's position statement on prehospital ventilator management competency advocates regular competency evaluations of prehospital providers of mechanical ventilation and recommends that facilities verify that all personnel trained to set up, install, and make setting adjustments have formal training in the basics of mechanical ventilation, as well as competency specific to the ventilator(s) in use. (AARC)

Competencies in the care of patients on mechanical ventilation should be validated for all members of the care team, including temporary and agency staff. Other health professionals who may provide care and treatment to patients (e.g., occupational therapists, physical therapists, speech-language pathologists) should also receive an orientation on specific safety concerns related to ventilators (e.g., alarms, disconnections).

VAP Bundles

Several organizations have released VAP "bundles" to help hospitals reduce the incidence of hospital-acquired VAP. The Institute for Healthcare Improvement (IHI) defines a bundle as "a structured way of improving the processes of care and patient outcomes: a small, straightforward set of evidence-based practices—generally three to five—that, when performed collectively and reliably, have been proven to improve patient outcomes." (IHI)

In 2014, Joint Commission Resources (JCR) reported that its Partnership for Patients Hospital Engagement Network (HEN) aimed to reduce the incidence of VAP in its hospitals. Using a bundle of best practices, JCR HEN hospitals managed to achieve an 86% reduction in VAP from the baseline rate. The VAP bundle included the following (JCR HEN):

- Elevation of the head of the bed
- Daily "sedation vacations"
- Peptic ulcer disease prophylaxis
- Deep-vein thrombosis prophylaxis
- Daily oral care with chlorhexidine

In addition to implementing the VAP bundle, JCR HEN hospitals engaged in monthly group webinar learning sessions focused on reducing VAP. During the sessions, groups completed SWOT (strengths, weaknesses, opportunities, and threats) analyses and developed a cause-and-effect diagram that the hospitals used with their VAP improvement teams; reviewed literature and protocols related to delirium avoidance and early mobility; and shared stories and successes on group calls to promote sharing across hospitals. (JCR HEN)

Another study found that the risk of developing VAP fell 97.6% and the expected time until VAP occurred was nearly 3.5 times longer in patients who received the following bundle (Curtin):

- Maintaining endotracheal tube cuff pressures between 20 and 25 cm H_2O
- Keeping the head of the bed elevated between 30° and 45°
- Providing mouth care every two hours or every four hours

Additionally, a study implemented by the Johns Hopkins Armstrong Institute for Patient Safety and Quality focused on applying a multifaceted intervention to improve adherence to evidence-based practices, unit teamwork, and safety culture. Researchers provided training to quality improvement teams in 56 intensive care units at 38 hospitals in Maryland and Pennsylvania between October 2012 and March 2015. Interventions included elevating the head of the bed; using subglottic secretion drainage endotracheal tubes; administering proper oral care and chlorhexidine mouth care; and conducting daily spontaneous awakening and breathing trials. Implementing the interventions reduced the total number of VAEs to 4.58 (down from 7.34) cases per 1,000 patient ventilator-days; this represents a 38% reduction. (Rawat et al.; Zimmerman)

Provide Education and Support to Families of Patients on Mechanical Ventilation

> **Action Recommendation: Ensure that staff are educated on how to communicate and work with the families and caregivers of patients on ventilators, and how to educate families and patients on what to expect.**

For families and caregivers, seeing their loved one receiving mechanical ventilation can be distressing. An upfront discussion about why the patient is on ventilation and how the treatment is helping the patient can go a long way in addressing these concerns. Staff should be trained on how to communicate information to the patient and/or the patient's family effectively. Strategies include the following:

- Explain to family members what you are doing and the reason and need for multiple assessments and procedures such as x-rays and laboratory testing (Parker).
- Communicate desired outcomes and the patient's progress toward those outcomes to help family members actively participate in the patient's care (Parker).
- Discuss the potential complications associated with mechanical ventilation and the strategies the facility is taking to reduce them. Doing so may keep families engaged in preventing ventilator complications. (Johns Hopkins)
- Educate families on the process for transitioning to postacute care, and describe the support the facility will offer the patient.
- Discuss any end-of-life issues with the family, including advance directives that may exist for the patient.

End-of-life care. If resuscitation is unlikely, healthcare organizations and their providers must inform families of the benefits and risks of care at the end of life and help them make informed decisions for the patient. To do so, providers must receive appropriate training and education to prepare them to lead such discussions. Patients' and family members' decisions must be communicated to all members of the care team to ensure that their decisions are followed. For more information, see the guidance articles Patient Self-Determination Act and Patient-Centered Care. See also the guidance articles Communication and Setting Realistic Expectations.

ECRI RESOURCES

Patient Self-Determination Act

Patient-Centered Care

Communication

Setting Realistic Expectations

Home Ventilation: A Safety Guide for Caregivers

Home care. Healthcare facilities should be prepared to educate families and caregivers of patients who will receive mechanical ventilation at home. For many home care clients and family caregivers, the safe use of medical devices and other technology in the home poses a particular challenge. The use of health literacy strategies can aid staff in educating and engaging clients. In addition, to help clients and caregivers improve safety when using medical technology in the home, ECRI Institute and the Healthcare Technology Foundation have created resources for clients and family caregivers addressing several health technologies, including a brochure on home ventilation.

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RESOURCE LIST

ECRI Resources

- Guidance: Clinical Alarms

- Guidance: Communication
- Guidance: Event Reporting and Response
- Guidance: Patient Self-Determination Act
- Guidance: Patient-Centered Care
- Guidance: Setting Realistic Expectations
- Guidance: Top 10 Health Technology Hazards for 2016
- Guidance: Top 10 Health Technology Hazards for 2017
- Guidance: Ventilators: The Essentials (available to Health Devices members)
- Tool: Home Ventilation: A Safety Guide for Caregivers

Additional Resources

Agency for Healthcare Research and Quality (AHRQ)

(301) 427-1104

https://www.ahrq.gov/

- Toolkit to improve safety for mechanically ventilated patients

American Association for Respiratory Care

(972) 243-2272

http://www.aarc.org

- Care of the ventilator circuit and its relation to ventilator-associated pneumonia
- Prehospital ventilator management competency [position statement]
- Safe initiation and management of mechanical ventilation [white paper]

Association for the Advancement of Medical Instrumentation

(703) 525-4890

http://www.aami.org

- National Coalition for Alarm Management Safety

Association for Professionals in Infection Control and Epidemiology (APIC)

(800) 650-9570

http://www.apic.org/

- Guide to the elimination of ventilator-associated pneumonia

Centers for Disease Control and Prevention

(800) 232-4636

https://www.cdc.gov

- Frequently asked questions: ventilator-associated events
- Surveillance for ventilator-associated events
- Ventilator-associated event calculator

Institute for Healthcare Improvement

(866) 787-0831

http://www.ihi.org

- How-to guide: prevent ventilator-associated pneumonia

International Organization for Standardization (ISO)

+41 22 749 01 11

https://www.iso.org/home.html

- Medical electrical equipment—particular requirements for basic safety and essential performance of critical care ventilators [ISO 80601-2-12]
- Medical electrical equipment—particular requirements for the basic safety and essential performance of respiratory gas monitors [ISO/DIS 80601-2-55]

Joint Commission

(630) 792-5800

http://www.jointcommission.org

- Best practices on reducing VAPs
- Ventilator-associated pneumonia (VAP)

National Heart, Lung, and Blood Institute (NHLBI) ARDS Network

http://www.ardsnet.org/ [organization no longer exists, but resources still available]

- Tools

Society for Healthcare Epidemiology of America

(703) 684-1006

https://www.shea-online.org

- Strategies to prevent ventilator-associated pneumonia in acute care hospitals: 2014 update

TOPICS AND METADATA

Topics

Alarm Management
;
Technology Management
;
Culture of Safety

Caresetting

Hospital Inpatient
;
Assisted-living Facility
;
Hospice
;
Home Care
;
Trauma Center
;
Emergency Department

Clinical Specialty

Critical Care
;
Geriatrics
;
Home Care
;
Pulmonary Medicine

Roles

Allied Health Personnel
;
Clinical Practitioner
;
Nurse
;
Patient/Caregiver

Information Type

Guidance

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