



DEPARTMENT OF VETERANS AFFAIRS
OFFICE OF INSPECTOR GENERAL

Office of Healthcare Inspections

VETERANS HEALTH ADMINISTRATION

Factors Contributing to the
Death of a Ventilator-
Dependent Patient at the VA
San Diego Healthcare
System

California



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Executive Summary

In summer 2018, the VA Office of Inspector General (OIG) was notified by VA Police at the VA San Diego Healthcare System (facility) of the unexpected death of a ventilator-dependent patient (Patient A) on the Spinal Cord Injury (SCI) unit. The purpose of this inspection was to evaluate factors that may have impacted or contributed to Patient A's death and follow up on the facility's response to the event.

Patient A sustained a severe SCI that prevented use of arms or legs. On the morning of Patient A's death, the assigned respiratory therapist placed an in-line Passy-Muir® Valve (PMV) on the ventilator to allow Patient A to communicate with a family member. The respiratory therapist lowered or disabled the ventilator alarms so that they would not constantly sound. The family member and an SCI nurse were present in the room when the respiratory therapist left. Sometime around 8:00 a.m., the family member left to go to work. Nursing staff interacted with Patient A on three separate occasions between about 10:00 a.m. and 12:00 p.m. When the nurse returned at 12:10 p.m., Patient A was unresponsive in bed with the ventilator tube disconnected from the tracheostomy and no ventilator alarms sounding. Because of the severity of the SCI, Patient A was not able to reconnect the ventilator tubing. The nurse reconnected the ventilator tubing to the tracheostomy while another nurse called the rapid response team. Patient A did not survive.

The OIG team could not determine what the ventilator settings were prior to the rapid response team being called, although it appears that they had been changed to the point the alarms did not sound. Shortly after Patient A's death, several facility staff inspected the ventilator and turned up the alarm settings to determine if the ventilator malfunctioned. They reportedly returned the settings to the previous levels.

The OIG team determined that the facility did not implement risk mitigation strategies to assure patient safety with the use of the in-line PMV on ventilated patients. Specifically, the facility did not have a back-up monitoring plan when the ventilator alarms were turned off, patient criteria to determine when the valve should be removed, or policies for respiratory therapy, SCI staff, and patient/family education on the use of the PMV. In addition, the facility did not have policies for constant observation of ventilator-dependent patients during in-line PMV use, policies or procedures for monitoring and documenting ventilator and alarm settings while using the PMV, a requirement for hand-off communication between respiratory therapy and SCI staff to review ventilator settings, and an expectation or policy to use anti-disconnect devices.

The OIG team was unable to find Veterans Health Administration or other patient safety alerts or advisories related to spontaneous ventilator tubing disconnects from the tracheostomy tube. However, reports about ventilator tubing "pop-off" occurrences as well as the adverse clinical outcome in this case, demonstrate that ventilator-dependent SCI patients using an in-line PMV

without anti-disconnect devices are at increased risk of dying from these spontaneous disconnects, and that risk is obviously increased when alarm settings are set low or turned off.

In addition to the issues identified above, the OIG team reviewed other concerns. These issues were not found to be directly related to the adverse clinical outcome but were problematic. At the time of Patient A's death, the SCI unit used an outdated nurse call system that required the use of a splitter to connect the ventilator to the call system. If the splitter was not connected correctly, the ventilator alarm and the nurse call alarm would sound the same and may not trigger an urgent response from nursing staff to ventilator-related issues.

The Veterans Health Administration does not require the use of ventilator tubing anti-disconnect devices, and the facility did not use them prior to Patient A's death. Therefore, none of the respiratory therapy staff had training or competency assessments related to the use of anti-disconnect devices. The OIG team also found that none of the respiratory therapy staff had training or competency assessments related to the use of the PMV, and only 16 of 25 staff folders contained documentation of completion of ventilator training. The lack of training and competencies resulted in inconsistent practices related to ventilator alarm settings and use of the in-line PMV, which could result in patient harm.

The OIG team was told that ventilator tubing can become disconnected with patient movement. Facility staff told the OIG that they reconnect the tubing quickly so do not consider this to be a patient safety concern and, therefore, did not usually submit patient safety reports. Failure to report Patient A's ventilator tubing disconnections through the patient safety reporting system resulted in facility patient safety staff being unaware of the issue; therefore, patient safety staff were unable to evaluate the incidents to determine if further investigation was needed.

The OIG team found that SCI leadership failed to follow the standard operating procedure for the management of clinical alarms. The SCI leadership committee did not review clinical alarm limits annually and did not ensure facility staff performed annual SCI unit alarm testing as part of the review.

After Patient A died, the facility closed the SCI unit to new admissions for ventilated patients while the patient's adverse clinical outcome was investigated. SCI leaders initiated interventions to ensure safe patient care including training, staff incident debriefings, and emotional support. Respiratory therapy staff completed training on the use of the ventilator, PMV, and anti-disconnect devices. The SCI unit nurse call system was upgraded and use of splitter connectors was discontinued. The facility implemented the use of ventilator anti-disconnect devices and modified documentation requirements to reflect their use. Further, respiratory therapy and nursing staff implemented a process for hand-off on SCI.

The OIG made five recommendations related to policy and training for the use of the PMV on the SCI unit and the anti-disconnect device, potential issuance of a National Patient Safety

Advisory, training related to reporting patient safety issues, and reviewing clinical alarms according to facility policies.

Comments

The Veterans Integrated Service Network and Facility Directors concurred with the OIG's recommendations and submitted acceptable action plans. (See appendixes A and B, pages 20–25 for the comments.) The OIG considers all recommendations open and will follow up on the planned actions until they are completed.



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Contents

Executive Summary	i
Abbreviations	v
Introduction	1
Scope and Methodology	5
Patient Case Summary and Sequence of Events	6
Inspection Results	9
1. Factors Contributing to Patient A’s Death	9
2. Other Concerns Identified During the Review	13
3. Facility’s Evaluation of the Sentinel Event	17
Conclusion	18
Recommendations 1–5	19
Appendix A: VISN Director Comments	20
Appendix B: Facility Director Comments	21
OIG Contact and Staff Acknowledgments	26
Report Distribution	27

Abbreviations

EHR	electronic health record
OIG	Office of Inspector General
PMV	Passy-Muir® Valve
SCI	spinal cord injury
SCI/D	Spinal Cord Injury and Disorders
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network



Introduction

In summer 2018, the VA Office of Inspector General was notified by VA Police at the VA San Diego Healthcare System (facility) of the unexpected death of a ventilator-dependent patient (Patient A) on the Spinal Cord Injury (SCI) unit. Specifically, Patient A was found unresponsive in bed with the ventilator tube disconnected from the tracheostomy, yet nursing staff reported that the ventilator alarms did not sound.¹ The purpose of this inspection was to evaluate factors that may have contributed to Patient A's death and to follow up on the facility's response to the event.

Background

The facility provides medical, surgical, mental health, geriatric, SCI, and advanced rehabilitative care and is classified as a Level 1a—High Complexity facility.² The facility operates seven community based outpatient clinics. From October 1, 2017, through September 30, 2018, the facility served 84,712 patients and had a total of 272 hospital operating beds, including 134 inpatient beds, 69 domiciliary beds, 39 community living center beds, and 30 SCI beds. The facility operates several regional referral programs including cardiovascular surgery and SCI. The facility is part of Veterans Integrated Service Network (VISN) 22.

SCI and Its Management

SCI is damage to the spinal cord that can result in loss of movement or feeling. The spinal cord consists of nerves surrounded by bones, or vertebrae, that make up the spine. Vertebrae in the spine are divided into four regions—the cervical, thoracic, lumbar, and sacral regions.³ Generally, the higher the injury to the spinal cord, the more severe the resulting disability. Injuries at the cervical spine level usually cause loss of function in both arms and legs, and also result in the loss of the ability to clear one's airway or breath spontaneously, requiring the use of

¹ A tracheostomy is a surgically created hole (stoma) in the windpipe (trachea) that provides an alternative airway for breathing. A tracheostomy tube is inserted through the hole and secured in place with a strap around the neck. <https://www.mayoclinic.org/tests-procedures/tracheostomy/about/pac-20384673>. (The website was accessed March 18, 2019.)

² Veterans Health Administration (VHA) Directive 2010-018, *Facility Infrastructure Requirements to Perform Standard, Intermediate, or Complex Surgical Procedures*, May 6, 2010. The VHA Facility Complexity Model categorizes medical facilities based on patient population, clinical services offered, and educational and research missions. Complexity Levels include 1a, 1b, 1c, 2, or 3, with Level 1a facilities being the most complex and Level 3 facilities being the least complex.

³ The cervical region contains seven vertebrae located in the neck; the thoracic region contains 12 vertebrae located in the upper back; the lumbar region contains five vertebrae located in the lower back; the sacral region contains five bones fused into one and intersects with the hip bones to form the pelvis. <https://www.spine-health.com/conditions/spine-anatomy/normal-spinal-anatomy>. (The website was accessed on April 12, 2019.)

a mechanical ventilator. The National Spinal Cord Injury Statistical Center estimated in its 2016 SCI Data Sheet that approximately 282,000 people in the United States were living with SCIs, with approximately 17,000 new SCI cases each year.

SCI-Related Equipment and Alarms

Mechanical ventilation is a life-saving intervention. Ventilators can be programmed to "breathe" a set number of times per minute by blowing air into the lungs through a breathing tube connected to the tracheostomy. The Carefusion LTV® 1150 model ventilator (ventilator) generates an alarm when it detects a condition that requires immediate attention. Some of the alarms will reset themselves, such as when a patient coughs and sets off a high pressure alarm. Other alarms require action from respiratory therapy or nursing staff and will continue sounding until the problem is corrected at the patient's bedside.

- The apnea alarm sounds if the patient has not triggered a breath within the time interval set on the ventilator. This alarm should sound if the ventilator tubing is disconnected from the patient's tracheostomy.
- The high pressure alarm sounds if two consecutive breaths are limited because they reach the high pressure limit set on the ventilator. This alarm could occur if something is blocking the ventilator tube, such as secretions or a kink in the tubing.
- The low (inspiratory) pressure alarm sounds if the monitored ventilator pressure is low. A low ventilator pressure may be caused by ventilator tubing that is disconnected from the patient or the tubing is disconnected from the ventilator. It can also occur if the tracheostomy cuff is deflated.⁴

The ventilator connects to the nursing call system in order for ventilator alarms to be audible at the nursing station. The ventilator alarm is connected via a telephone jack connector from the ventilator to the appropriate port on the nursing call system (located on a panel in the wall). Prior to using the ventilator, the system should be checked to ensure the alarm is alerting at the nursing station.

The Passy-Muir® Valve (PMV) is a medical device used by tracheostomy and ventilator patients. When placed in-line with the ventilator circuit, the PMV redirects airflow through the vocal folds, mouth, and nose, enabling the patient to speak during the expiratory cycle (see Figure 1).

⁴ Tracheostomy tubes can be either cuffed or cuffless. A cuffed tracheostomy tube is used for patients requiring mechanical ventilation. When the cuff is inflated, all of the air a patient breathes is through the tracheostomy tube. When the cuff is deflated, air can flow through the vocal cords, which allows a patient to speak. <https://www.passy-muir.com/journal-2-1-trach-tube-cuff/>. (The website was accessed on April 1, 2019.)

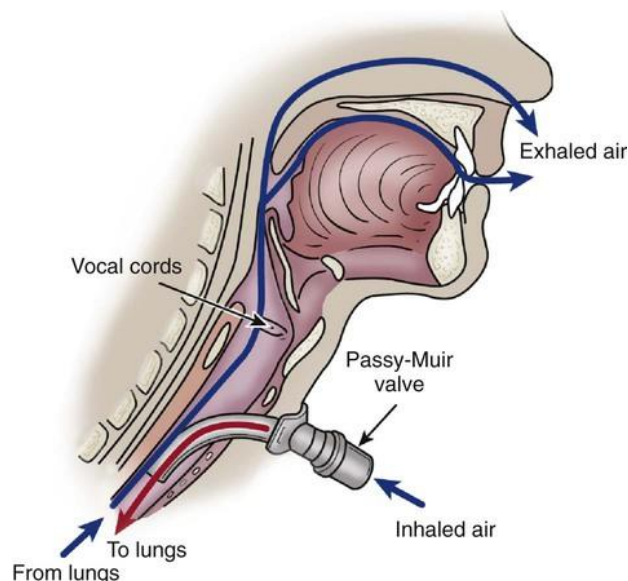


Figure 1. Illustration of Passy-Muir® Valve.

Source: The image was uploaded from

<https://nursekey.com/pulmonary-therapeutic-management>. (The website was accessed on March 27, 2019.)

Veterans Health Administration Spinal Cord Injury and Disorders System of Care

Veterans Health Administration (VHA) has established procedures and policy for the delivery of care to veterans with spinal cord injuries and associated conditions. The Spinal Cord Injury and Disorders (SCI/D) System of Care requires a full interdisciplinary team of experts to support, promote, and maintain the health and independence of individuals with spinal cord injuries. Clinical practice guidelines, supported by current medical evidence and state of the art practice, are used in the care of patients with spinal cord injuries. “The Chief, SCI Service, is responsible for incorporating [clinical practice guidelines] into the appropriate medical care settings.”⁵

VHA SCI Hub and Spoke Model

VHA's SCI/D System of Care is designed around a system of "Hub and Spokes."⁶ SCI/D Centers (called Hubs) have trained and experienced providers including doctors, nurses, social workers, therapists, psychologists, and others who specialize in the unique problems that can affect people

⁵ VHA Handbook 1176.01, *Spinal Cord Injury and Disorders (SCI/D) System of Care*, February 8, 2011. This handbook was due for recertification on or before February 29, 2016, but has not been recertified.

⁶ *Spinal Cord Injuries and Disorders System of Care*. https://www.sci.va.gov/VAs_SCID_System_of_Care.asp. (The website was accessed February 20, 2019.)

with SCI. SCI/D Centers work with other designated VA medical facilities that do not have SCI/D Centers (called Spokes) to provide care as close to the patient's home as possible.

The facility's SCI/D Center provides care to veterans and active duty personnel with SCI/D in San Diego and Imperial County California, Arizona, and Southern Nevada, and is the Hub for Prescott, Tucson, and Phoenix VA SCI/D Spoke Clinics. Additionally, the facility also provides services to veterans and active duty personnel referred from the Las Vegas and Loma Linda VA SCI/D Spoke Clinics.

Respiratory Therapy

Respiratory therapy is the care of patients with chronic and acute lung conditions. Respiratory therapists are healthcare personnel trained to diagnose lung and breathing conditions, manage ventilators and critical airway devices, and provide education to patients and families.

Respiratory therapists complete a respiratory therapy education program at the associate's or bachelor's level that is accredited by the Commission on Accreditation for Respiratory Care.

Patient Safety Alerts

VHA policy provides the following patient safety information and requirements:

Patient Safety Alerts and Patient Safety Advisories are issued by the Office of the Deputy Under Secretary for Health for Operations and Management to notify [VHA staff or facilities] when actual or potential threats to the life or health of VHA patients have been identified. Patient Safety Alerts disseminate urgent notices that require specific, mandatory, and timely action on the part of the recipient(s). Patient Safety Advisories are issued when a potential threat due to equipment design, procedural issues, or training has been identified. Patient Safety Advisories provide recommendations that are general in nature and implementation of the recommendations are subject to local conditions and judgment.⁷

⁷ VHA Handbook 1050.01, *VHA National Patient Safety Improvement Handbook*, March 4, 2011. This handbook was due for recertification on or before March 31, 2016, but has not been recertified.

Scope and Methodology

The OIG initiated the inspection on January 2, 2019, and conducted a site visit February 11–14.

The OIG interviewed the Chief of Staff, acting and former Chiefs of SCI, the SCI Nurse Manager, an SCI provider and SCI nurses, staff from Biomedical Engineering and Facility Engineering, the Chief of Pulmonary Medicine, Chief of Respiratory Therapy, respiratory therapy staff, Quality Management staff, and others with knowledge of the issues. During the site visit, the OIG toured the SCI unit. After the visit, the OIG team interviewed Patient A's family member in the presence of an attorney.

The OIG team reviewed relevant VHA and facility policies and procedures, nurse and respiratory therapy training records, committee minutes, electronic health record (EHR) documents, patient safety reports, relevant literature, and equipment manuals.

In this report, the OIG generalized the narrative and case scenario and de-identified protected patient and quality assurance information.

In the absence of current VA or VHA policy, the OIG considered previous guidance to be in effect until superseded by an updated or recertified directive, handbook, or other policy document on the same or similar issue(s).

The OIG conducted the inspection in accordance with *Quality Standards for Inspection and Evaluation* published by the Council of the Inspectors General on Integrity and Efficiency.

Patient Case Summary and Sequence of Events

Patient A, who was in their late 60s, was rendered a quadriplegic after sustaining injuries at the third cervical (C3) vertebrae after a fall in summer 2017.⁸ Patient A's medical history was significant for a tracheostomy with ventilator dependence, high blood pressure, dysphagia, placement of a gastrostomy-jejunostomy tube for nutrition, and a Stage IV sacral pressure ulcer.⁹

In fall 2017, Patient A was transferred from a non-VA nursing home to the facility due to recurrent pneumonia and right lower lobe lung collapse.¹⁰ Due to the patient's overall medical condition that included continuous ventilator support, Patient A was admitted to the intensive care unit. In early 2018, once Patient A's medical condition improved and stabilized, it was noted the patient could not return to the non-VA nursing home because of continued intravenous antibiotics and wound care needs.

In preparation for future transfer from the intensive care unit to the SCI unit, Patient A's ventilator was converted to the standard SCI ventilator.¹¹ Later that month, a speech pathologist evaluated Patient A for a PMV, and the following day, Patient A was transferred to the facility's SCI unit. While on the SCI unit, Patient A tolerated using the in-line PMV, which assisted with eating and speaking. Patient A also used a mouth-operated call bell to alert staff when assistance was needed. After an SCI physician had a formal discussion with Patient A and family members, Patient A chose a change in code status to Do Not Resuscitate.¹²

⁸ Quadriplegia is partial or complete loss paralysis of the arms, legs, and trunk due to an injury or illness of the spinal cord in the cervical (neck) region. <https://www.merriam-webster.com/medical/quadriplegia>. (The website was accessed on March 21, 2019.)

⁹ *Dysphagia* is a difficulty in swallowing. <https://www.mayoclinic.org/diseases-conditions/dysphagia/symptoms-causes/syc-20372028>. (The website was accessed on March 28, 2019.) A *gastrostomy-jejunostomy tube* is placed into the stomach and small intestine and is used for venting the stomach for air, for drainage, or for an alternate way of feeding. <https://www.cincinnatichildrens.org/health/g/gastro-jeuno-tube>. (The website was accessed on March 28, 2019.) *Pressure ulcer wounds* are classified by stages based on the depth and appearance of the wound. Stage IV indicates the wound has reached all the way to muscle, bone, and/or tendons. https://www.hopkinsmedicine.org/gec/series/wound_care.html#assessment. (The website was accessed March 28, 2019.)

¹⁰ Lung collapse, or atelectasis, occurs when the tiny air sacs (alveoli) within the lung become deflated or filled with fluid. Atelectasis can make breathing difficult. <https://www.mayoclinic.org/diseases-conditions/atelectasis/symptoms-causes/syc-20369684>. (The website was accessed April 4, 2019.)

¹¹ Carefusion® LTV 1150.

¹² A Do Not Resuscitate order is a medical order written by a doctor. It instructs healthcare providers not to attempt cardiopulmonary resuscitation (CPR) if a patient's breathing or heart stops. <https://medlineplus.gov/ency/patientinstructions/000473.htm>. (The website was accessed on March 26, 2019.)

During the SCI unit stay, Patient A experienced several episodes of non-responsiveness and transient hypoxic encephalopathy.¹³ To assess these episodes, a neurologist evaluated Patient A and recommended a magnetic resonance imaging study of the brain and cervical spine when Patient A was stable. The magnetic resonance imaging study was scheduled.

Timeline of Events on the Day of Patient A's Death

6:50 a.m. The assigned respiratory therapist documented placement of the in-line PMV and provided morning respiratory treatments. Patient A's family member and assigned SCI nurse were at the bedside. The respiratory therapist told the OIG about turning down the alarm settings after placing the PMV on Patient A but did not remember which alarms. Patient A's family member stated the respiratory therapist turned off the alarms while working with Patient A.¹⁴

7:57 a.m. The respiratory therapist documented returning to Patient A's room to address a sounding ventilator humidifier alarm, and upon leaving the room, the ventilator alarms were on and Patient A's call bell was within reach.¹⁵ Patient A's family member told the OIG team of typically leaving around 8:00 a.m. to go to work and notifying the respiratory therapist before leaving. The respiratory therapist would come to check the equipment and the family member would leave at that time.

9:58 a.m. Patient A's assigned SCI nurse documented completing an assessment and that Patient A was "tolerating PMV well this shift."

10:19 a.m. A wound care nurse documented completing Patient A's skin assessment and wound care. The wound care nurse stated that Patient A was not verbalizing but was mouthing words during skin assessment rounds.

11:30 a.m. The SCI nurse documented entering Patient A's room to administer medications but left to check whether Patient A needed to be fasting in preparation for the magnetic resonance imaging study scheduled later that day. After confirming that fasting was required, the SCI nurse returned to the room and instructed Patient A not to eat. The SCI nurse documented that Patient A verbalized understanding of the instructions. Additionally, the SCI nurse documented that Patient A's ventilator and in-line PMV were in place, and the call bell was at the patient's mouth.

¹³ Transient hypoxic encephalopathy is a transient abnormality or loss of brain function due to brain injury caused by oxygen deprivation. <https://medical-dictionary.thefreedictionary.com/hypoxic+encephalopathy>. (The website was accessed on March 28, 2019.)

¹⁴ The OIG team found no documentation of these changes in the EHR.

¹⁵ The EHR documentation reflecting the ventilator alarms were on was not consistent with the respiratory therapist's statement to the OIG that two of the alarms were turned off (the respiratory therapist did not recall which two alarms).

12:10 p.m. The SCI nurse documented returning to Patient A's room with a reminder not to eat. Upon entering the room, the SCI nurse reported hearing "air swooshing" from the ventilator tubing and discovered the ventilator tubing was disconnected from Patient A's tracheostomy tube. The SCI nurse told the OIG team that no alarm was sounding from the ventilator or the nursing call bell system. The SCI nurse immediately reconnected the ventilator tubing; but, Patient A was unresponsive and pulseless. The SCI nurse performed a sternal rub; however, Patient A did not respond.¹⁶ Another SCI nurse called the rapid response team.¹⁷

12:15 p.m. An SCI physician responded to the rapid response call and evaluated the patient. Because Patient A had a Do Not Resuscitate order, no additional interventions were performed. The time of death was documented as 12:15 p.m. Approximately 30 minutes later, the SCI physician documented informing a family member of Patient A's death.

Within an hour of Patient A's death, facility police contacted the OIG Office of Investigations to alert them of Patient A's unexpected death. The room was closed off and facility police were restricting access when the Office of Investigations team arrived. Respiratory therapy staff told the Office of Investigations team that during and after the rapid response event, they changed the ventilator alarm settings to test whether the alarms were functional. The OIG team was told that respiratory therapy staff returned the settings to pre-rapid response event levels. The OIG team was unable to determine what the ventilator alarm settings were at the time of Patient A's death; however, the ventilator event log showed no alarms for a period of about five hours prior to Patient A's death. The SCI nurse told the OIG that upon entering Patient A's room, the call bell was positioned at Patient A's mouth. The OIG team was unable to determine whether Patient A activated, or tried to activate, the nurse call bell.

¹⁶ A sternal rub is a type of painful stimulus used to assess for brain integrity and function. The rub is performed with a closed fist rubbing the knuckles forcefully across the sternum. <https://www.emsl.com/ems-products/patient-handling/articles/403668-Misinterpreting-the-results-of-a-sternum-rub/>. (The website was accessed on March 28, 2019.)

¹⁷ When a patient demonstrates signs of imminent clinical deterioration, a team of providers is called to the bedside to immediately assess and treat the patient with the goal of preventing intensive care unit transfer, cardiac arrest, or death. <https://psnet.ahrq.gov/primers/primer/4>. (The website was accessed on March 27, 2019.)

Inspection Results

Patient safety events in health care are incidents or conditions that resulted, or could have resulted, in harm to patients. The OIG team assessed multiple factors that are commonly associated with patient safety events including equipment and personnel-related issues. The OIG team found that Patient A's ventilator and its alarms were functioning properly, and SCI and respiratory therapy staffing on the day in question were adequate to care for Patient A. Further, while Patient A required total care due to the degree of injury, the patient's needs did not exceed the capabilities of the SCI or respiratory therapy staff.

While some elements of Patient A's clinical situation and needs were unique, the facility missed opportunities to strengthen policies and procedures and improve patient safety-related practices.

1. Factors Contributing to Patient A's Death

Management of Ventilator Alarms

The respiratory therapist who attached the PMV the morning of Patient A's death had done so several times in the past. As the PMV would alter the air pressure flow outside of the settings prescribed by the physician, the ventilator alarms would repeatedly sound. To prevent continuous alarming, the respiratory therapist reportedly turned the ventilator alarms low or off, which several respiratory therapy supervisors and staff described as a reasonable practice when a PMV was in place.¹⁸ However, according to the PMV manufacturer's instructions, "all alarms on the ventilator must be re-evaluated for appropriate adjustments before, during, and after use of the PMV. Since exhaled volumes are not returned to the ventilator, some alarms can be adjusted or silenced to stop unnecessary alarming. The high- and low-pressure alarms should remain intact and adjusted appropriately to detect and alert caregivers to disconnects, patient fatigue, or changes in peak airway pressures."¹⁹

¹⁸ The respiratory therapist who cared for Patient A on the day of death told the OIG team of not recalling which alarms were adjusted but stated the alarms were set to dashes. The LTV Series Ventilator Operator's Manual, August 2005, states "If a control display is set to dashes '---', it indicates that control is turned off, or is not available in the current ventilation mode." The manufacturer's review of the ventilator's alarm log on June 19, 2018, showed no alarms triggered in the five hours before Patient A's death.

¹⁹ Passy Muir Ventilator Alarms. https://www.passy-muir.com/vent_adjust/. (The website was accessed February 28, 2019.)

Risk Mitigation Measures

The Clinical Practice Guideline for Respiratory Management Following Spinal Cord Injury (Clinical Practice Guideline), developed by the Consortium for Spinal Cord Medicine and endorsed by VHA, recommends assessing the patient's ability to communicate and establishing a system so that staff can effectively interact with the patient.²⁰ The PMV facilitates this communication and enhances the patient's ability to interact with staff and family. The OIG team noted that the Clinical Practice Guideline is silent on the management of patients using the PMV. Therefore, the OIG reviewed manufacturer's guidelines and other authoritative sources to identify the recommended patient safeguards when using the PMV.

The OIG identified multiple risk mitigation measures that the facility had not implemented:

- *A back-up physiologic monitoring plan in the rare instance when ventilator alarms were turned off (set to "0") due to use of the PMV.* A respiratory therapy supervisor mentioned pulse oximetry as an alternate method for monitoring, but this option was not initiated as the SCI unit did not have remote pulse oximetry capability at the time of the patient's death nor at the time of the OIG team's site visit. There was no mechanism for connecting the pulse oximeter to the nurse call system, and therefore, the pulse oximeter alarm would not be audible outside the patient's room.²¹
- *Criteria to determine when a PMV should be removed.* Passy-Muir® refers to this as "Stop" Criteria and suggests several objective measures including heart and respiratory rate, as well as breathing efficiencies.²² Patient A had orders for nursing staff to check vital signs, including heart rate, respiratory rate, and blood pressure twice a day. However, the EHR did not contain specific orders to increase monitoring of vital signs while Patient A was using the PMV, nor did the OIG team find evidence that staff were monitoring Patient A's anxiety level or ability to breathe around the tracheostomy cuff. Further, the SCI unit did not have the ability to remotely monitor Patient A's heart rate. It appeared that respiratory therapists relied on Patient A to tell them when to remove the PMV, which could result in a delay of care while the respiratory therapist was notified. In

²⁰ Consortium for Spinal Cord Medicine. *Respiratory Management Following Spinal Cord Injury: A Clinical Practice Guideline for Health-Care Professionals*, January 2005. https://pva-cdnendpoint.azureedge.net/prod/libraries/media/pva/library/publications/cpg_resmgmt.pdf. (The website was accessed on May 9, 2019).

²¹ According to a respiratory therapy supervisor, the pulse oximeter does not have a compatible phone plug for the nursing call system.

²² Passy-Muir®'s specific stop criteria included: heart rate increased more than 20 beats per minute from baseline; respiratory rate greater than 35 breaths per minute; pulse oximetry reading of less than 88 percent; oxygen concentration greater than 60 percent; Peak Inspiratory Pressure cannot be maintained at pre-cuff levels; excessive anxiety from patient; and, inefficient exhalation around the tracheostomy tube. *PMV Protocol for Cuffed Tracheostomies Tubes for Patients on Ventilators*. https://www.passy-muir.com/wp-content/uploads/2018/10/ws_pmv_protocol.pdf. (The website was accessed March 18, 2019.)

addition, this potential delay could increase the risk of complications related to increased heart rate or inadequate oxygenation.

- *Policies related to respiratory therapy and SCI staff, family, and patient education on the use of the PMV, including contraindications, cautions, and manufacturer warnings.* The Joint Commission requires staff be competent to perform their duties and that they participate in ongoing education and training.²³ None of the respiratory therapy staff had initial in-line PMV training prior to Patient A's death. The Joint Commission also requires patients receive education on their care, treatment, and services.²⁴ The OIG team found documentation of patient and family education about the PMV, but nothing related to contraindications, cautions, and manufacturer warnings. Without education, staff, patients, and family members may not recognize signs of respiratory distress and could not assure safe use of the PMV.
- *Policies for constant observation of ventilator-dependent patients during in-line PMV use.* In general, ventilator-dependent patients should not be left alone while the in-line PMV is attached unless a cuffless tracheostomy is in place.²⁵ Patients must be monitored at all times for respiratory distress while wearing the PMV regardless of whether or not ventilator alarm settings are turned down or off. Respiratory therapy staff told the OIG that when Patient A was using the PMV, they would leave the room and only conduct periodic checks. Nursing staff also told the OIG that they would not stay in Patient A's room during use of the PMV. The family member told the OIG of calling the respiratory therapist before leaving the patient; however, it was unclear whether the respiratory therapist or SCI nurse and Patient A's family member discussed the need for Patient A's constant supervision while using the PMV. The facility was unable to provide documentation that Patient A's family member was educated or trained on the expectations for monitoring and supervision of Patient A.
- *Policies or procedures for monitoring and documenting ventilator and ventilator alarm settings before, during, and after PMV use.* When the tracheostomy cuff is deflated, the patient must work harder to breathe; therefore, the ventilator settings must be changed to meet the patient's oxygen requirement. Additionally, because ventilatory pressures change with the use of the PMV, the alarm settings may need to be adjusted to prevent unnecessary alerts. The changes to ventilator and alarm settings should be monitored and documented. Documentation of ventilator settings during and after use of the PMV, as well as the length of time Patient A was on the PMV, was inconsistent.
- *A requirement for hand-off communication between respiratory therapy and nursing staff related to ventilator settings, including ventilator alarms.* A hand-off is the transfer of

²³ TJC. Human Resources standards HR.01.05.03 and HR.01.06.01.

²⁴ TJC. Provision of Care, Treatment, and Services standard PC.02.03.01.

²⁵ Patient A did not have a cuffless tracheostomy.

patient care from one caregiver or team member to another and involves the communication of patient-specific information that ensures continuity of care. The lack of hand-off communication between respiratory therapy and SCI nursing staff increased the risk of an adverse clinical event.

- *An expectation or policy for use of anti-disconnect devices despite repeated episodes of spontaneous ventilator tubing “popping off” from the tracheostomy tube.* Because the OIG team received inconsistent information about the frequency of pop-offs in the ventilator-capable units, the team could not quantify the frequency of the occurrences. In an intensive care unit setting, a spontaneous ventilator tube pop-off could immediately be remedied as the patients are under constant observation by clinical staff. VHA did not require the use of ventilator tubing anti-disconnect devices. Prior to this incident, the facility did not use these devices on ventilated patients. Patient A, who reportedly experienced several spontaneous ventilator tube pop-offs, could have benefited from the use of an anti-disconnect device.

Patient Safety Alerts

The OIG team was unable to find VHA or other patient safety alerts or advisories related to spontaneous ventilator tubing disconnects from the tracheostomy tube. However, interviewees’ reports about ventilator pop-off occurrences, as well as the adverse clinical outcome in this case, demonstrate that ventilator-dependent SCI patients using an in-line PMV without anti-disconnect devices are at increased risk of dying from these spontaneous ventilator tubing disconnects. Risk is increased when alarm settings are set low or turned off and other risk mitigation strategies are not implemented.

2. Other Concerns Identified During the Review

While the OIG did not find evidence that the issues described below were contributory to Patient A's death, significant concerns were identified.

Nurse Call System

At the time of Patient A's death, the facility was using a splitter connection to connect the ventilator alarms and the nurse call bell into the electrical system through one outlet that alarmed at the nurse's station (see Figure 2). The splitter was needed because the aging call system did not have enough wall outlets to accommodate additional components in each room.

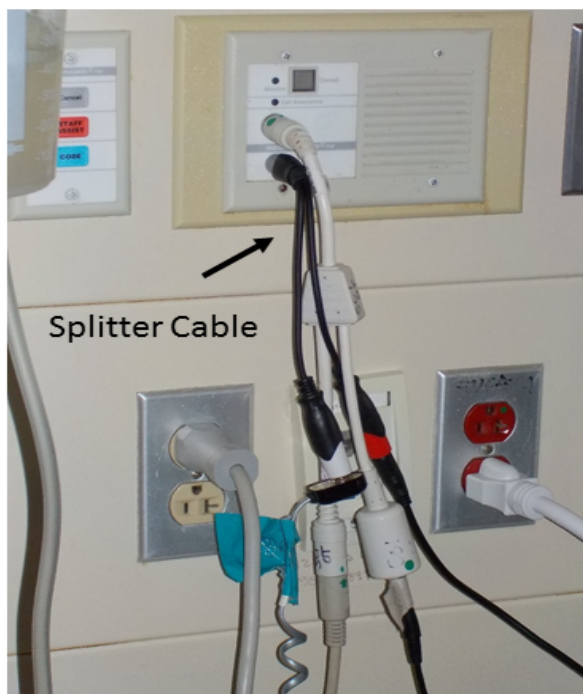


Figure 2. Picture of use of the splitter to connect the ventilator to the nurse call system. The splitter is the black cord.

Source: The OIG Office of Investigations' photo taken at the facility SCI unit, on the day of Patient A's death.

When using the splitter connection, the facility's Engineering Service staff had to remove the outside panel of the call system in the patient's room and "flip a switch" that allowed the call system to recognize the difference between the ventilator alarm and a patient call alarm. On occasion; however, this process was problematic. For example, in 2016, a ventilated SCI patient was to be transferred from the intensive care unit to the SCI unit. In preparation for this transfer, SCI staff contacted Engineering Service to change the switch so that the call system would recognize the ventilator alarm. Engineering staff reported they completed the switch change and the patient was transferred. However, upon arrival, nursing staff discovered that the nursing call

system was not set up properly, and the ventilator alarm would not work correctly. As a result, the patient had to be transferred back to the intensive care unit until the issue could be resolved. Also, in 2018, it was reported that the ventilator alarm in a patient's room was not sounding properly to the nursing station.

While the OIG found no evidence that use of the splitter was contributory in this case, after Patient A's death, a new call system was installed in the SCI unit. The new call system has separate ports for the ventilator and the patient's nursing call system, eliminating the need for a splitter.

Respiratory Therapy Competencies

The U.S. Office of Personnel Management defines a competency as “a measurable pattern of knowledge, skills, abilities, behaviors, and other characteristics that an individual needs to perform work roles or occupational functions successfully.”²⁶ The American Association for Respiratory Care, along with the Commission on Accreditation for Respiratory Care and the National Board for Respiratory Care, determined that competency related to mechanical ventilation, including alarm parameters, and the use of airway devices should be obtained prior to entry into professional practice. The OIG team reviewed the competency documentation for the 25 respiratory therapy staff who were employed at the facility at the time of the OIG on-site visit. Of the 25 staff folders reviewed, 16 contained documentation of completion of ventilator training, and none contained evidence of in-line PMV or anti-disconnect device training prior to the event. The folders also did not contain assessments of respiratory therapy staff competence in initial ventilator, in-line PMV, and anti-disconnect devices prior to the event. As of February 2019, 24 of 25 respiratory therapy staff completed the refresher ventilator training, 23 of 25 completed the in-line PMV training, and 22 of 25 completed the anti-disconnect device training. The deficiencies in training and competencies resulted in inconsistent practices related to ventilator alarm settings and use of the in-line PMV, which could result in an adverse clinical outcome.

²⁶ The U.S. Office of Personnel Management is the chief human resources agency and personnel policy manager for the Federal Government. <https://www.opm.gov/about-us/>. (The website was accessed on April 2, 2019.)

Identification of Patient Safety Issues Prior to the Event

VHA requires staff to report unsafe patient conditions according to local policy, even if the condition has not yet resulted in an adverse clinical outcome.²⁷ The facility uses the Joint Patient Safety Reporting system to electronically enter information about patient safety concerns. The report of events is the primary mechanism through which the root cause and contributing factors of system vulnerability(s) can be mitigated to prevent future events.

The facility's preliminary investigation revealed that Patient A's ventilator tubing disconnected from the tracheostomy on more than one occasion. The OIG team found no evidence that SCI and respiratory therapy staff submitted Joint Patient Safety reports for these ventilator pop-offs. Facility staff told the team that ventilator tubing can disconnect when a patient moves. When the tubing disconnects, staff would immediately reconnect the tubing. The OIG team reviewed the patient safety reports submitted from December 2014 through January 2019 and found five incident reports submitted for ventilator alarms related to faulty cords/incorrect connector or other unidentified cause, two for ventilator alarms related to incorrect alarm settings by respiratory therapy, and three for tubing disconnects.²⁸ Only one patient event report related to this adverse event was entered for Patient A.

Failure to report Patient A's ventilator tubing disconnections through the formal Joint Patient Safety Reporting system resulted in the facility's patient safety staff being unaware of these issues. This failure resulted in the patient safety staff being unable to evaluate the incidents to determine if further investigation was needed. As a result, the facility missed an opportunity to implement corrective actions.

Policy for Management of Clinical Alarms

In April 2013, The Joint Commission issued a Sentinel Event Alert related to the safety of alarm systems.²⁹ This alert identified several contributing factors to many of the alarm-related events, which included absent or inadequate alarm systems, improper alarm settings, alarms not audible in all areas, and alarm signals inappropriately turned off. Additionally, in 2014, The Joint Commission included the safety of clinical alarms as part of the National Patient Safety Goals.³⁰ This guidance requires facilities identify the most important alarm systems to be managed based

²⁷ VHA Handbook 1050.01.

²⁸ Per available documentation, each of these ten incidents were referred to the Chief of Respiratory Therapy, SCI nurse manager, or the appropriate section chief for review.

²⁹ Sentinel Event Alert is a newsletter published by The Joint Commission that identifies specific types of sentinel and adverse events, such as an adverse clinical outcome. The publication describes the event, common causes, and recommended actions to reduce the risks and prevent future occurrences.

³⁰ National Patient Safety Goals were established by The Joint Commission in 2002 to help accredited organizations address specific areas of concern regarding patient safety.

on the risk to patients if the alarm signal is not attended to or if it malfunctions, establish policies and procedures for managing the identified alarms, and educate staff about the proper operation of alarm systems for which they are responsible.

The facility policy for management of clinical alarms requires that each unit develop their own clinical alarm standard operating procedure.³¹ The SCI unit has a standard operating procedure for the management of clinical alarms; however, the OIG team found implementation to be inconsistent.³²

According to the SCI unit standard operating procedure, the SCI leadership committee approves clinical alarm default settings for the unit. Additionally, the SCI leadership committee must “review alarm limits annually, approve when and who can change alarm limits, and determine when alarms are not clinically necessary.”³³ The OIG team reviewed SCI leadership committee minutes from January 2018 through December 2018 and did not find evidence that clinical alarm default settings, alarm limits, when and who can change alarm limits, or when alarms can be disabled were reviewed. As part of an annual review, facility staff were required to test the alarms to determine whether alarms were working and audible. The OIG team reviewed annual alarm testing results on the SCI unit for 2016 and 2019, but the facility did not provide evidence of alarm testing for 2017 and 2018. Without appropriate clinical alarm review and testing, system leaders could miss opportunities to identify malfunctioning clinical alarms or staff alarm fatigue, which increases the risk of patient harm.

³¹ Facility Memorandum 11-90, *Effective Use of Clinical Alarm Systems*, June 17, 2017.

³² Facility Spinal Cord Injury Service Policy 34, *Clinical Alarms and Minimizing Alarm Fatigue on the SCI/D Unit*, March 2014.

³³ Spinal Cord Injury Service Policy 34.

3. Facility's Evaluation of the Sentinel Event

The facility immediately initiated an investigation into the sentinel event as required.³⁴ Sentinel events are a type of adverse clinical outcome defined by The Joint Commission as occurrences involving “death, permanent harm, [or] severe temporary harm and intervention required to sustain life.”³⁵

The OIG was informed that the facility closed the SCI unit to new admissions for ventilated patients for about 10 days until SCI leaders implemented interventions to ensure safe patient care. The interventions for SCI staff included staff support and training.

Patient A's death was a traumatic event for many employees, and the facility conducted multiple staff debriefings on the incident and offered mental health/emotional support to staff.

As a result of the investigation, the facility initiated the following actions:

- Training respiratory therapy staff in use of the LTV 1150 ventilator, in-line PMV with a ventilator-dependent patient, and ventilator anti-disconnect devices
- Upgrading the nurse call system
- Discontinuing use of splitter connectors
- Implementing use of anti-disconnect devices
- Updating the facility's Respiratory Therapy Service EHR documentation flowsheet to include documentation of use of an anti-disconnect device
- Creating a process for the respiratory therapist to “hand-off” patient- and equipment-specific information to nursing staff taking care of a patient before the respiratory therapist leaves the patient's room³⁶
- Completing an institutional disclosure with members of Patient A's family³⁷

Overall, the OIG team determined that the facility responded promptly and appropriately to this patient's adverse clinical outcome.

³⁴ VHA Handbook 1050.01, *National Patient Safety Improvement Handbook*, March 4, 2011, page 8. This handbook was scheduled for recertification on or before the last working date of March 2016 and has not been recertified.

³⁵ https://www.jointcommission.org/sentinel_event_policy_and_procedures/ (The website was accessed on April 4, 2019.)

³⁶ The hand-off includes the patient's ventilator status, functionality of the ventilator alarms, and confirmation that the call bell is working.

³⁷ VHA Directive 1004.08, *Disclosure of Adverse Events to Patients*, October 31, 2008. An institutional disclosure of adverse events is “a formal process by which VA medical facility leader(s), together with clinicians and others as appropriate, inform the patient or the patient's personal representative that an adverse event has occurred during the patient's care that resulted in, or is reasonably expected to result in, death or serious injury, and provide specific information about the patient's rights and recourse.” For the purposes of this report, an adverse event is an adverse clinical outcome.

Conclusion

The OIG team was unable to determine what the ventilator alarm settings were at the time of Patient A's death; however, use of a potential life-saving ventilator alarm system outside of the manufacturer's guidelines, coupled with intermittent patient supervision, created substantial risk for Patient A. The facility did not have measures in place to mitigate that risk, which may have contributed to the patient's death. Specifically, the facility did not have a plan for physiologic back-up monitoring or patient supervision when ventilator alarms were turned down or off due to use of the PMV.

The assigned respiratory therapist turned the ventilator clinical alarms either low or off after placing the in-line PMV on Patient A. Respiratory therapy supervisors and staff stated this was not an unreasonable practice. However, per the PMV manufacturer's instructions, while some alarms can be deactivated, the high- and low-pressure alarms should remain active to alert caregivers to disconnects, patient fatigue, or other clinical issues. Further, the facility did not have policies or procedures related to PMV education and training for relevant caregivers, monitoring of ventilator and alarm settings, hand-off requirements related to PMV use between respiratory therapy and SCI nursing staff, or use of anti-disconnect devices.

The OIG team identified other issues that may not have contributed to the adverse clinical outcome but that were still concerning. At the time of Patient A's death, the facility was using a nurse call system that required the use of a splitter to connect the ventilator and the call bell. Prior to the event, none of the respiratory therapy staff had initial training on the PMV or the anti-disconnect device. However, as of February 2019, all but two of the respiratory therapists completed the PMV training and all but three completed the anti-disconnect training.

Respiratory therapy and SCI nursing staff did not submit reports through the Joint Patient Safety Reporting system when Patient A's ventilator tubing became disconnected, which prevented patient safety staff from evaluating the risk to patient safety. Also, the SCI unit had a standard operating procedure on the management of clinical alarms but did not consistently follow it. The SCI leadership committee did not discuss clinical alarm settings or determine when clinical alarms could be disabled. While the OIG team reviewed 2016 and 2019 SCI annual alarm testing results, the facility did not provide evidence of alarm testing for 2017 and 2018.

The facility took appropriate actions immediately after Patient A's death. The facility closed the SCI unit to new admissions for ventilated patients while the patient's adverse clinical outcome was investigated and SCI leaders implemented multiple interventions to ensure safe patient care.

Recommendations 1–5

1. The VA San Diego Healthcare System Director ensures that a policy is developed, staff is trained, and compliance is monitored related to the use of the Passy-Muir[®] Valve on the Spinal Cord Injury unit to include
 - a) Staff education on ventilator alarm settings when an in-line Passy-Muir[®] Valve is used,
 - b) Documentation and monitoring of ventilator settings before, during, and after Passy-Muir[®] Valve use,
 - c) Documentation of length of time the Passy-Muir[®] Valve is in place,
 - d) Back-up plan for monitoring patients on a Passy-Muir[®] Valve,
 - e) Patient supervision while using the Passy-Muir[®] Valve, and
 - f) Patient and family education on the safe use of the Passy-Muir[®] Valve.
2. The VA San Diego Healthcare System Director ensures that a policy is developed for the use of ventilator anti-disconnect devices, that staff are trained, and that compliance is monitored.
3. The VA San Diego Healthcare System Director confers with the National Center for Patient Safety to determine if a National Patient Safety Advisory should be issued regarding a potential deficit in training for staff who care for ventilated patients in non-intensive care unit settings.
4. The VA San Diego Healthcare System Director ensures that Spinal Cord Injury and respiratory therapy staff are provided refresher training regarding issues to report to the Patient Safety program.
5. The VA San Diego Healthcare System Director ensures that Spinal Cord Injury leadership reviews clinical alarms annually and ensures that the review is discussed and documented in Spinal Cord Injury Leadership Committee minutes.

Appendix A: VISN Director Comments

Department of Veterans Affairs Memorandum

Date: June 25, 2019

From: Director, Desert Pacific Healthcare Network (10N22)

Subj: Healthcare Inspection—Factors Contributing to the Death of a Ventilator-Dependent Patient at the VA San Diego Healthcare System, California

To: Director, VA OIG Office of Healthcare Inspections Rapid Response Team (54RR00)
Director, GAO/OIG Accountability Liaison (GOAL) Office (VHA 10EG GOAL Action)

1. I have reviewed and concur with the findings, recommendations, and action plans as submitted. The action plans will be followed through to completion and sustainment.
2. If you have any questions, please contact the VISN 22 Acting QMO, Terri Elsholz, at (480)397-2782. Thank you.

(Original signed by:)

Michael W. Fisher
Director, Desert Pacific Healthcare Network (10N22)

Appendix B: Facility Director Comments

Department of Veterans Affairs Memorandum

Date: June 24, 2019

From: Director, VA San Diego Healthcare System (664/00)

Subj: Healthcare Inspection—Factors Contributing to the Death of a Ventilator-Dependent Patient at the VA San Diego Healthcare System, California

To: Director, Desert Pacific Healthcare Network (10N22)

1. In response to the report received as a result of the OIG Healthcare Inspection initiated in June 2018 and site visit conducted at VA San Diego Healthcare System, February 11–14, 2019, the implementation plans address the findings and recommendations. (See “*Comments to OIG’s Report for Recommendations #1-5*”)
2. I have reviewed and concur with the findings, recommendations, and action plans as submitted. The action plans will be followed through to completion and sustainment.

(Original signed by:)

Cynthia Abair, Associate Director
for Robert Smith, MD
Director, VA San Diego Healthcare System

Comments to OIG's Report

Recommendation 1

The VA San Diego Healthcare System Director ensures that a policy is developed, staff is trained, and compliance is monitored related to the use of the Passy-Muir[®] Valve on the Spinal Cord Injury unit to include

- a) Staff education on ventilator alarm settings when an in-line Passy-Muir[®] Valve is used,
- b) Documentation and monitoring of ventilator settings before, during, and after Passy-Muir[®] Valve use,
- c) Documentation of length of time the Passy-Muir[®] Valve is in place,
- d) Back-up plan for monitoring patients on a Passy-Muir[®] Valve,
- e) Patient supervision while using the Passy-Muir[®] Valve, and
- f) Patient and family education on the safe use of the Passy-Muir[®] Valve.

Concur.

Target date for completion: July 19, 2019, July 31, 2019, September 27, 2019

Director Comments

1. SCI Policy # 28 on Management of Ventilator Dependent Patients on the SCI Unit was revised on 7/10/18, to include a) annual competency of RT [Respiratory Therapy] and RN [registered nurse] on use of the Passy-Muir Valve and LTV 1150 ventilator 2) active hand-off communication between RT and RN for patients on ventilator 3) responsibilities of RN and RT related to securing cables connecting to wall and bed, ventilator and call light alarms set and audible from nurses station, communication of RT and RN phone numbers on patient's communication board.

Education Completed:

- All SCI Staff completed in-service education on the LTV Ventilator and use of the in-line Passy-Muir Valve between July 3, 2018–July 21, 2018.
 - Patient and Family education regarding the Passy-Muir Valve was created and implemented, including signage which is posted at the bedside, on July 3, 2018.
 - A Nursing Practice Alert was sent to all SCU Nursing and RT staff on June 29, 2018, describing the new hand-off communication tool to be used for patients on ventilators.
2. SCI Policy # 28 on Management of Ventilator Dependent Patients on the SCI Unit will be revised to include a) staff education on ventilator alarm settings when an in-line Passy-

Muir Valve is used, b) documentation and monitoring of ventilator settings before, during and after Passy-Muir Valve use, c) documentation of length of time the Passy-Muir Valve is in place, d) back-up plan for monitoring patients on a Passy-Muir Valve, e) patient supervision while using the Passy-Muir Valve, and f) patient and family education on the safe use of the Passy-Muir Valve.

- **Target Date:** The Revised SCI Policy #28 will be completed and approved by SCI Leadership and the Section Chief of Pulmonary Medicine approval by July 19, 2019.

Following approval, a Nursing Practice Alert will be sent to all SCI Nursing staff regarding revised SCI Policy #28 on Management of Ventilator Dependent Patients. This will cover: a) staff education on ventilator alarm settings when an in-line Passy-Muir Valve is used, b) documentation and monitoring of ventilator settings before, during and after Passy-Muir Valve use, c) documentation of length of time the Passy-Muir Valve is in place, d) back-up plan for monitoring patients on a Passy-Muir Valve, e) patient supervision while using the Passy-Muir Valve, and f) patient and family education on the safe use of the Passy-Muir Valve.

- **Target Dates:**

- I. Nursing Education will be completed by July 31, 2019.
 - II. The Respiratory Therapist Chief will educate all Respiratory Therapy staff on the revised Policy #28 by July 31, 2019.
1. Respiratory Therapy Policy “Use of the Passy-Muir Valve in Mechanically Ventilated Patients” was completed on June 20, 2019.
 2. SCI Policy # 28 on Management of Ventilator Dependent Patients will be part of Annual Ventilator Skill Training for all SCI staff between August 12, 2019–September 27, 2019.

Recommendation 2

The VA San Diego Healthcare System Director ensures that a policy is developed for the use of ventilator anti-disconnect devices, that staff are trained, and that compliance is monitored.

Concur.

Target date for completion: July 31, 2019

Director Comments

1. Respiratory Therapy (RT) implemented the use of an anti-disconnect device on August 16, 2018.
2. RT staff completed initial competency training on the user of the anti-disconnect device between July 4, 2018–July 10, 2018.

3. Audits were conducted by RT monthly for 6 months through March 2019, to ensure compliance with use and effectiveness of the anti-disconnect device.
4. A revised RT Policy “Anti-Disconnect Device Policy” was completed on June 20, 2019.
5. Annual updated Competency has been developed for training staff on use of the Anti-Disconnect Device. RT Staff will complete training by July 31, 2019.

Recommendation 3

The VA San Diego Healthcare System Director confers with the National Center for Patient Safety to determine if a National Patient Safety Advisory should be issued regarding a potential deficit in training for staff who care for ventilated patients in non-intensive care unit settings.

Concur.

Target date for completion: July 5, 2019

Director Comments

1. The VA San Diego Healthcare System (VASDHS) Patient Safety Manager contacted the National Center for Patient Safety (NCPS) on August 3, 2018, to discuss the potential need for a Patient Safety Alert related to the Anti-Disconnect Device.
2. A Patient Safety Bulletin regarding the Anti-Disconnect Device was shared with VISN 22 facilities on August 16, 2018.
3. The VASDHS Patient Safety Manager will confer with NCPS to determine if a Patient Safety Alert should be issued regarding a potential deficit in training for staff who care for ventilated patients in non-intensive care settings. This will be completed by July 5, 2019.

Recommendation 4

The VA San Diego Healthcare System Director ensures that Spinal Cord Injury and respiratory therapy staff are provided refresher training regarding issues to report to the Patient Safety program.

Concur

Target date for completion: October 4, 2019

Director Comments

1. The VASDHS Patient Safety Manager will create refresher training for SCI and Respiratory Therapy staff regarding issues to report to the Patient Safety Program,

including but not limited to, near miss/close call events, and how to report them using the Joint Patient Safety Reporting System.

2. Training will be conducted with all SCI and Respiratory Therapy staff by October 4, 2019.

Recommendation 5

The VA San Diego Healthcare System Director ensures that Spinal Cord Injury leadership reviews clinical alarms annually and ensures that the review is discussed and documented in Spinal Cord Injury Leadership Committee minutes.

Concur.

Target date for completion: January 31, 2020, February 28, 2020

Director Comments

1. SCI Leadership completed a review of clinical alarms on January 29, 2019. The next clinical alarm reviews will be conducted in January 2020. The results of the clinical alarm reviews will be discussed and documented during SCI Leadership Committee meeting.
 - **Target dates:**
 - I. Complete clinical alarm audit by January 31, 2020.
 - II. Results of clinical alarm audits in SCI will be discussed and documented during the SCI Leadership Committee meeting by February 28, 2020.

OIG Contact and Staff Acknowledgments

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