

#### DEPARTMENT OF VETERANS AFFAIRS

# OFFICE OF INSPECTOR GENERAL

Office of Healthcare Inspections

VETERANS HEALTH ADMINISTRATION

Mismanagement of a Patient at the Tomah VA Medical Center in Wisconsin

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## **Executive Summary**

The VA Office of Inspector General (OIG) conducted a healthcare inspection at the request of Congressman Ron Kind regarding allegations related to the care of a patient at the Tomah VA Medical Center (facility) who subsequently died at another VA medical center from a presumed anoxic brain injury. The allegations included over-sedation, failed oxygen delivery, insufficient alcohol withdrawal management, incomplete electronic health record (EHR) documentation, and lack of communication with the patient's family. The inspection also evaluated OIG-identified concerns related to medication management, airway management training, the facility's review of the patient's cardiopulmonary resuscitation, alcohol withdrawal assessment, restraint use and training, the patient's transfer to another facility, the facility's response to identified deficiencies, oversight of one of the physicians involved in the patient's care, and the institutional disclosure process.

As discussed below, facility physicians did not address the patient's abnormal electrocardiogram and did not prescribe an adequate medication regimen to address the patient's <u>delirium tremens</u> effectively. Nursing staff did not complete all required Clinical Institute Withdrawal Assessment for Alcohol (CIWA) scales.<sup>2</sup> Further, a physician improperly ordered the patient's restraints and nursing staff failed to obtain the patient's full vital signs while the patient was in restraints.

## Synopsis of the Patient's Spring 2019 Episode of Care

The patient initiated primary care services at the facility in spring 2008, and from fall 2011 through summer 2018, the patient received intermittent mental health treatment for <u>alcohol use</u> <u>disorder</u>, anxiety, attention-deficit disorder, <u>posttraumatic stress disorder</u>, and sleep disturbance.<sup>3</sup>

On day 1, at approximately 11:00 a.m., the patient presented to the facility's Urgent Care Clinic and reported having a seizure prior to coming to the facility. An electrocardiogram was done at 11:09 a.m. The patient also reported drinking a half liter of vodka daily and the patient's blood alcohol level that was ordered shortly after arrival was undetectable. Following evaluation of the

<sup>&</sup>lt;sup>1</sup> The underlined terms are hyperlinks to a glossary. To return from the glossary, press and hold the "alt" and "left arrow" keys together.

<sup>&</sup>lt;sup>2</sup> S. Jesse et al., "Alcohol withdrawal syndrome: mechanisms, manifestations, and management," *Acta Neurologica Scandinavica* 135, (2017): 4-16. The CIWA revised version is referred to as CIWA-Ar. In this report, the OIG refers to CIWA-Ar as CIWA. Elizabeth C. Perry, "Inpatient Management of Acute Alcohol Withdrawal Syndrome," *CNS Drugs* 28, (April 30, 2014): 401-410. The Clinical Institute Withdrawal Assessment for Alcohol (CIWA) is a nurse-administered questionnaire that evaluates the severity of a patient's withdrawal symptoms. A score less than 10 indicates mild withdrawal, 10–18 indicates moderate to severe withdrawal, and greater than 18 indicates risk for major complications if left untreated.

<sup>&</sup>lt;sup>3</sup> The patient did not respond to facility staff's outreach in late 2018 and the patient's EHR did not include any contacts from late 2018 until day 1 2019.

patient, a nurse practitioner consulted with a physician (consulting inpatient physician) who recommended contacting another VA medical center for a "seizure evaluation." The patient refused a transfer to another VA medical center and agreed to admission to the facility's inpatient medical unit. At approximately 2:00 p.m., the nurse practitioner placed an admission order with an alcohol abuse diagnosis.

An inpatient unit physician (admitting physician) ordered a <u>lorazepam</u> injection and <u>diazepam</u> tablets at dosages dependent upon the CIWA scale score, and vital signs to be taken every four hours while the patient was awake. Upon the patient's arrival to the inpatient medical unit at approximately 3:30 p.m., a day nurse completed a CIWA assessment with a score of 2 that did not require intervention.

Approximately three hours later, a second day nurse completed a CIWA that resulted in a score of 15, indicating "severe withdrawal (impending delirium tremens)." The patient received lorazepam intravenously. The admitting physician documented that the patient had made statements to nursing staff such as, "there are lasers on the floor" and nursing staff were concerned that the patient might leave the facility.

At approximately 8:00 p.m., the second day nurse administered intramuscular <u>haloperidol</u> and documented that the patient was placed on a "Director's Hold," and the admitting physician placed an order for staff to observe the patient continuously.<sup>5</sup> At approximately 10:30 p.m., the consulting inpatient physician documented that the patient appeared confused with likely delirium tremens and a provider at another VA medical center accepted the patient for further care.

On day 2, at approximately 12:30 a.m., staff placed the patient in <u>four-point restraints</u>. The consulting inpatient physician placed a transfer order and documented that the "Specialized services/care" to address the patient's alcohol withdrawal with delirium were not available at the facility.

At 1:20 a.m., a night nurse documented that while obtaining the patient's oxygen saturation, the "patient went limb [sic]" and the consulting inpatient physician started cardiopulmonary resuscitation. Emergency medical services (911) was called and approximately 10 minutes later,

<sup>&</sup>lt;sup>4</sup> In an interview with the OIG, the Chief of Acute Care clarified that the facility does not offer neurology services for inpatients.

<sup>&</sup>lt;sup>5</sup> The Wisconsin state statute addressing emergency detention is found in Chapter 51 of the State Alcohol, Drug Abuse, Developmental Disabilities and Mental Health Act. Wis. Stat. Ann. § 51.15 (2020), accessed March 19, 2020, <a href="https://docs.legis.wisconsin.gov/statutes/statutes/51">https://docs.legis.wisconsin.gov/statutes/statutes/51</a>. Facility Policy MCM PCS-SW-17, *Emergency Detention*, *Probable Cause and Commitment Proceedings*, February 22, 2018, is consistent with Wisconsin law. According to the facility's policy, there are two mechanisms for an emergency detention under Chapter 51 depending on where the patient is located in the facility. If the patient is an inpatient on an acute medical unit, the VA police must initiate the emergency detention consistent with the criteria outlined in the policy. A "Director's Hold" is initiated by the treatment provider after a patient has threatened to leave the facility and the provider considers the patient to be a danger to self or others.

the non-VHA emergency medical services arrived and the patient's pulse returned.<sup>6</sup> The paramedics performed an <u>endotracheal intubation</u> on the patient and the patient was transported to a non-VHA facility by helicopter at approximately 2:45 a.m.

On day 3, the patient was transferred from the non-VHA hospital to another VA medical center and was admitted to that VA medical center's hospice unit on day 25. The patient died eight days later. On the death certificate, a hospice attending physician documented cause of death as anoxic brain injury "due to or as a consequence of" alcohol use disorder, cardiopulmonary arrest, and delirium tremens. The OIG acknowledges that the patient's deterioration could be attributed to a broad diagnostic differential. However, based on the patient's documented history and clinical presentation as discussed above, the OIG believes the most likely cause of the patient's clinical deterioration was <a href="https://www.hypoxemia">hypoxemia</a> caused by cardiac arrest secondary to haloperidol administration.

#### **OIG Findings**

The OIG did not substantiate staff over-sedated the patient. To the contrary, the OIG found that the admitting and consulting inpatient physicians did not prescribe an adequate benzodiazepine medication regimen to address the patient's delirium tremens effectively. Early and adequate benzodiazepine dosing may have halted progression of the patient's alcohol withdrawal. Further, the physicians' failure to treat the delirium tremens with adequate benzodiazepine dosing, review the patient's abnormal electrocardiogram prior to haloperidol administration, or transfer the patient to a higher level of care earlier likely contributed to the patient's respiratory suppression and cardiac arrest.

The American Heart Association recommends electrocardiogram monitoring for patients who may be at risk for arrythmias resulting from a prolonged QTc interval.<sup>8</sup> QT is an electrocardiogram measurement that reflects electrical activity in the lower chambers of the heart and can identify abnormal cardiac functioning.<sup>9</sup> QTc is a calculated measurement that factors in a patient's heart rate to determine the corrected QT interval.<sup>10</sup> In a patient with a prolonged QTc

<sup>&</sup>lt;sup>6</sup> Facility Policy MS-03, *Emergency Services*, March 7, 2017, requires staff to respond to medical emergencies by calling "911," non-VHA as necessary for non-VHA emergency service assistance. The emergency medical services personnel who responded to the patient's medical emergency included a lead paramedic, a second paramedic, and an emergency medical technician. The lead paramedic completed the documentation. The administrative staff canceled the scheduled transport service.

<sup>&</sup>lt;sup>7</sup> Sandeep Grover and Abhishek Ghosh, "Delirium Tremens: Assessment and Management," *Journal of Clinical and Experimental Hepatology* 8, (December 2018): 460-470.

<sup>&</sup>lt;sup>8</sup> Kristen E. Sandau et al., "Update to Practice Standards for Electrocardiographic Monitoring in Hospital Settings: A Scientific Statement from the American Heart Association," *Circulation* Vol. 136, November 2017, accessed February 17, 2021, <a href="https://www.ahajournals.org/doi/full/10.1161/cir.000000000000000527">https://www.ahajournals.org/doi/full/10.1161/cir.00000000000000527</a>.

<sup>&</sup>lt;sup>9</sup> Pieter G. Postema and Arthur A.M. Wilde, "The Measurement of the QT Interval," *Current Cardiology Reviews* 10, (2014): 287-294.

<sup>&</sup>lt;sup>10</sup> Postema, "The Measurement of the QT Interval."

interval, the administration of medication such as haloperidol may precipitate a fatal cardiac arrhythmia.<sup>11</sup>

The OIG found providers did not review the patient's day 1, electrocardiogram that reflected a prolonged QTc or monitor the patient's cardiac function prior to and after the administration of haloperidol. Further, an internal review of the patient's care identified staff's failure to document the patient's electrocardiogram results but facility leaders did not propose corrective actions related to this deficiency. Facility providers' failure to review, document, and monitor the patient's electrocardiogram to assess cardiac risk before prescribing haloperidol may have contributed to the patient's respiratory suppression and cardiac arrest.

The Veterans Health Administration (VHA) requires inpatient facilities (such as the facility), without a code team or an emergency department to ensure Out of Operating Room Airway Management (OOORAM) providers (Level 1 providers) are available to perform basic airway management and assess the need for a higher level of airway expertise. <sup>13</sup> If needed, Level 1 providers access a higher level of airway management based on facility processes. <sup>14</sup> Facility providers, who were Level 1 OOORAM providers, were not trained to perform endotracheal intubation. According to facility policy, staff were instructed to contact 911 emergency medical services as needed to perform intubation. <sup>15</sup>

The OIG substantiated that a non-VHA paramedic (lead paramedic) observed and documented in the emergency medical services record that the patient's flow of oxygen was not active at the time the emergency medical services participated in the patient's cardiopulmonary resuscitation. Facility staff involved in the patient's cardiopulmonary resuscitation were unable to recall whether the patient was receiving oxygen. As the <u>magnetic resonance imaging</u> study performed after transfer to a non-VHA hospital was interpreted to be "normal," the ultimate cause of the patient's brain injury was undetermined but likely due to metabolic, toxic, or <u>hypoxic ischemic encephalopathy</u>. <sup>16</sup> The OIG found that facility leaders and staff reported lack of knowledge about the patient's failed oxygen delivery and did not include the lead paramedic's documentation in a review of the patient's care. <sup>17</sup> The OIG concluded that inclusion of emergency medical services'

<sup>&</sup>lt;sup>11</sup> Postema, "The Measurement of the QT Interval."

<sup>&</sup>lt;sup>12</sup> Grover, "Delirium Tremens;" Jesse, "Alcohol withdrawal syndrome." The lack of recognition of the patient's prolonged QT may indicate an absence of a standardized approach to electrocardiogram interpretation.

<sup>&</sup>lt;sup>13</sup> The Chief of Staff reported to the OIG that the facility's "core emergency response team" is considered a rapid response team and not a code team. Facility Policy MS-03; VHA Directive 1157(1), *Out of Operating Room Airway Management*, June 14, 2018, amended on September 19, 2018. A Level 1 OOORAM provider is trained to provide basic airway management to patients experiencing a medical emergency.

<sup>&</sup>lt;sup>14</sup> VHA Directive 1157(1).

<sup>&</sup>lt;sup>15</sup> Facility Policy MS-03.

<sup>&</sup>lt;sup>16</sup> An autopsy was not performed and therefore the cause of encephalopathy was undetermined.

<sup>&</sup>lt;sup>17</sup> The Chair, Emergency Services Committee told the OIG team that the Emergency Services Committee did not review emergency medical services documentation as part of its process.

documentation in facility leaders' reviews may identify systemic root causes and performance deficiencies in patient care.

During its review of actions staff took during the patient's cardiopulmonary arrest, the OIG found that four inpatient medical unit providers, including the admitting physician and inpatient consulting physician, did not have current OOORAM training at the time of the patient's care. <sup>18</sup> The OIG was unable to determine if the consulting inpatient physician's lapse in OOORAM training contributed to the patient's failed oxygen delivery because facility leaders were not aware of the emergency medical services documentation and therefore the cause for the oxygen flow cessation was not evaluated.

Nursing staff failed to complete all required CIWAs, which may have contributed to an incomplete understanding of the patient's alcohol withdrawal progression and an increased risk of an adverse clinical outcome.<sup>19</sup>

The OIG found that the inpatient consulting physician's restraint order did not include the rationale for restraint use, the type of restraint, and clinical indication for restraint use as required by facility policy.<sup>20</sup> Further, the OIG concluded that if the patient's delirium tremens had been adequately managed with benzodiazepine medications, the use of restraints may have been avoided. The OIG also concluded that nursing staff's failure to obtain full vital signs as required likely resulted in a diminished understanding of the patient's subsequent respiratory deterioration.<sup>21</sup>

The OIG found that inpatient medical unit nurses did not receive restraint training from October 1, 2018, through July 2019. The OIG concluded that the lack of restraint training likely contributed to the nurses' failures to (1) verify that the physician's order included the specific type of restraint and (2) obtain full vital signs as required may have prevented staff from recognizing the patient's subsequent respiratory deterioration. Given that restraints are rarely used on the inpatient medical unit, the OIG would expect nursing staff to receive ongoing training to promote competency and currency.

The OIG found that facility staff initiated the patient's transfer to a higher level of care after the patient's condition deteriorated and necessitated emergency medical services. The OIG would have expected staff to pursue transfer to a higher level of care upon determination of the need for an emergency detention and prior to the patient's rapid deterioration on the day of admission.

<sup>&</sup>lt;sup>18</sup> The facility's Director, Performance Improvement, provided the OIG with documents containing the physicians' OOORAM training information.

<sup>&</sup>lt;sup>19</sup> For purposes of this report, the OIG defines harm in terms of an adverse clinical outcome such as cardiac arrest and need for a higher level of care.

<sup>&</sup>lt;sup>20</sup> Facility Policy PCS-03, Restraint and Seclusion Use, June 30, 2017.

<sup>&</sup>lt;sup>21</sup> Facility Policy PCS-03.

After the patient's spring 2019 discharge from the inpatient medical unit, the Chief of Staff received staff complaints about the admitting physician's lack of involvement in the management of the patient including prolonged response time to concerns about the patient's respiratory status. The OIG determined that facility leaders took appropriate actions regarding staff complaints about the admitting physician's behavior and performance during the patient's episode of care. The OIG found that the 2018 focused professional practice evaluation (FPPE) for the admitting physician was not completed.<sup>22</sup> The OIG determined that the incomplete FPPE was not identified until June 2019 likely due to staff's failure to ensure adequate FPPE tracking.

The OIG did not substantiate that facility staff failed to document information about the non-VHA emergency medical services provided to the patient. The OIG found that facility staff documented the non-VHA emergency medical services care in response to the lead paramedic's request.

The OIG substantiated that facility leaders and staff did not communicate with the patient's family upon initiation of the emergency detention. However, state law and facility policy do not require next of kin notification in the emergency detention process.<sup>23</sup> Although a police officer completed the form as required by emergency detention form (ME-901), the OIG found that facility policy erroneously advised the "treating provider, VA Police Officer, or medical center designee" may complete an ME-901, which is specific to a law enforcement officer.<sup>24</sup> An adverse event may warrant institutional disclosure, which is a formal process for facility leaders and clinicians to inform the patient or patient's personal representative that an adverse event occurred and includes specific information about the patient's rights and recourse.<sup>25</sup> The OIG found that facility leaders did not conduct an institutional disclosure with the patient's family timely or in person and did not provide a relevant update, as required by VHA.<sup>26</sup>

The OIG made 10 recommendations to the Facility Director related to facility staff's education regarding the management of alcohol withdrawal and delirium tremens, providers' consideration of underlying cardiac risk prior to haloperidol administration, a comprehensive review of the

<sup>&</sup>lt;sup>22</sup> VHA Handbook 1100.19, *Credentialing and Privileging*, October 15, 2012. When management determines a need for a privileged provider's performance to improve, a FPPE provides a structured opportunity for improvement. FPPE is an oversight process that "evaluates the privilege-specific competence of the practitioner who does not have documented evidence of competently performing the requested privileges of the facility."

<sup>&</sup>lt;sup>23</sup> Wis. Stat. Ann. 8 51.15(10); Facility Policy PCSW-SW-17, *Emergency Detention, Probable Cause and Commitment Proceedings*, February 22, 2018.

<sup>&</sup>lt;sup>24</sup> Wisconsin Form ME-901, *Statement of Emergency Detention by Law Enforcement Officer*, May 2014; Facility Policy PCSW-SW-17.

<sup>&</sup>lt;sup>25</sup> VHA Directive 1004.08, *Disclosure of Adverse Events to Patients*, October 31, 2018. Adverse events are "untoward diagnostic or therapeutic incidents, iatrogenic injuries, or other occurrences of harm or potential harm directly associated with care or services delivered by VA providers." An adverse event may lead to an adverse clinical outcome.

<sup>&</sup>lt;sup>26</sup> VHA Directive 1004.08. See report section, *Deficiencies in the Institutional Disclosure Process*, for additional information.

patient's cardiopulmonary resuscitation event to determine potential causes of failed oxygen delivery, consideration of systemic root causes and performance deficiencies, OOORAM workgroup outcome, staff adherence to CIWA protocol, restraint management and training, compliance with inpatient unit admission criteria, emergency detention processes, and institutional disclosure procedures.<sup>27</sup>

# OIG Comments to the Responses from the Veterans Integrated Service Network and Facility Directors

The purpose of this healthcare inspection was to review allegations related to the care provided to a patient at the facility and evaluate the management of the patient's condition. While the patient was treated at other hospitals after the facility, this healthcare inspection was focused on the care the patient received at the facility. The OIG team conducted a thorough inspection and wrote an accurate report that identified factual deficiencies in care at the facility. It is of significant concern to the OIG that the patient was admitted for treatment of potentially severe alcohol withdrawal symptoms despite the facility staff's limited resources and capability to provide care for this condition. The facility did not have the capability to treat delirium tremens that requires a higher level of care such as specialized inpatient or intensive care unit settings. Further, the limitations of facility staff's out of operating room airway management capabilities necessitated emergency medical services to arrive on site to perform an endotracheal intubation on the patient. The OIG hopes that facility leaders thoroughly address the care deficiencies identified including facility staff's (1) failure to review the patient's electrocardiogram; (2) inadequate treatment and assessment of alcohol withdrawal; (3) administration of haloperidol in spite of the patient's prolonged QTc interval; (4) failed oxygen delivery; (5) improper restraint management and inadequate training; and (6) delayed transfer of the patient to a higher level of care. Additionally, facility leaders were not aware of the failure in oxygen delivery to the patient and did not review non-VHA emergency medical services documentation. The exclusion of the emergency medical services' documentation in reviews may result in the omission of significant information, such as failed oxygen delivery for a patient. The OIG concluded that the inadequate management of the patient's alcohol withdrawal and the patient's cardiac arrest at the facility contributed to the patient's poor outcome and subsequent death.

<sup>&</sup>lt;sup>27</sup> On October 15, 2020, the Chief of Staff charged a workgroup to review the VHA OOORAM directive "to ensure that Tomah VAMC meets all standards and has processes in place." In January 2021, the Chief of Staff expressed the hope of having the changes in place by the end of February 2021.

Despite the concerns expressed by the Veterans Integrated Service Network and Facility Directors, they concurred with recommendations 1, 2, and 4–9, and concurred in principle with recommendations 3 and 10. An acceptable action plan was provided (see appendixes A and B). The OIG will follow up on the planned actions until they are completed.

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for Healthcare Inspections

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# **Abbreviations**

CIWA Clinical Institute Withdrawal Assessment for Alcohol

EHR electronic health record

FPPE focused professional practice evaluation

mg milligram

OIG Office of Inspector General

OOORAM Out of Operating Room Airway Management

VHA Veterans Health Administration

VISN Veterans Integrated Service Network



## Introduction

The VA Office of Inspector General (OIG) conducted a healthcare inspection at the request of Congressman Ron Kind regarding the care of a patient at the Tomah VA Medical Center (facility) who subsequently died at another VA medical center from a presumed <u>anoxic brain injury</u>.

#### **Background**

The facility, part of Veterans Integrated Service Network (VISN) 12, provides services including primary care, outpatient mental health, and inpatient acute medicine and psychiatry. The Veterans Health Administration (VHA) classifies the facility as level 3, low complexity. From October 1, 2018, through September 30, 2019, the facility served 25,795 patients and had a total of 291 hospital operating beds, including 21 inpatient beds, an 80-bed domiciliary, 180-bed community living center, and a 10-bed Compensated Work Therapy/Transitional Residence area. The facility operates four community-based outpatient clinics throughout Wisconsin and serves patients in mid-western Wisconsin and eastern Minnesota. The facility is affiliated with the Medical College of Wisconsin.

#### Request for Review, Allegations, and OIG Concerns

On February 20, 2020, Congressman Ron Kind, on behalf of constituents, requested the OIG review the facility staff's care of a patient who died in spring 2019.

Specifically, the OIG reviewed the following allegations regarding the patient's care:

- 1. Over-sedation, failed oxygen delivery, and insufficient alcohol withdrawal management;
- 2. Incomplete electronic health record (EHR) documentation about the non-VHA emergency medical services; and
- 3. Lack of communication with the patient's family.

During its evaluation of the allegations, the OIG identified multiple concerns related to medication management, airway management training, the facility's review of the patient's cardiopulmonary resuscitation, alcohol withdrawal assessment, restraint use and training, the patient's transfer to another facility, the facility's response to the identified deficiencies,

<sup>&</sup>lt;sup>1</sup> The VHA Facility Complexity Model categorizes medical facilities by complexity level based on patient population, clinical services offered, educational and research missions, and administrative complexity. Complexity levels include 1a, 1b, 1c, 2, or 3. Level 1a facilities are considered the most complex and Level 3 facilities are the least complex. "Facility Complexity Model," VHA Office of Productivity, Efficiency and Staffing, accessed October 6, 2020, <a href="http://opes.vssc.med.va.gov/Pages/Facility-Complexity-Model.aspx">http://opes.vssc.med.va.gov/Pages/Facility-Complexity-Model.aspx</a>. (This is an internal VA website not publicly accessible.)

oversight of one of the physicians involved in the patient's care, and the institutional disclosure process.

# **Scope and Methodology**

The OIG opened the inspection on February 25, 2020. At the request of the Acting Facility Director, the virtual site visit was postponed until June 29 through July 16, 2020, due to the facility's response to the coronavirus (COVID-19) pandemic.<sup>2</sup>

The OIG team interviewed the complainants; VHA Fire Department Program Manager; VISN 12 and facility leaders; facility staff knowledgeable about the patient's care or related procedures; a physician consultant; and emergency medical services personnel involved in the patient's care.<sup>3</sup>

The OIG team reviewed applicable VHA and facility policies and procedures and relevant provisions of Wisconsin State law related to commitment, inpatient medical unit, Clinical Institute Withdrawal Assessment for Alcohol (CIWA) protocol, credentialing of health care professionals, Out of Operating Room Airway Management (OOORAM), restraint use, emergency services, fire department services, cardiopulmonary resuscitation, inter-facility transfers, disclosure of adverse events, patient safety, and management of health records.<sup>4</sup>

The OIG team reviewed facility-provided nursing restraint education completion dates and OOORAM training records from October 1, 2018, through August 26, 2020, for inpatient medical unit nurses. The OIG team also reviewed meeting minutes for the Medical Staff Executive Committee, Emergency Services Committee, Peer Review Committee, and the Mental Health Executive Committee, as well as documentation related to the patient's EHR, police reports, issue brief, and the non-VHA emergency medical service documentation. Additionally, the OIG team reviewed the EHRs of 14 patients who experienced medical emergencies at the facility between October 1, 2018, and September 30, 2020.<sup>5</sup>

<sup>&</sup>lt;sup>2</sup> The site visit was conducted virtually due to the COVID-19 pandemic. World Health Organization, "WHO Director-General's opening remarks at the media briefing on COVID-19 - 11 March 2020," accessed November 10, 2020, <a href="https://www.who.int/dg/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---11-march-2020">https://www.who.int/dg/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---11-march-2020</a>. Merriam Webster, "Definition of pandemic," accessed November 10, 2020, <a href="https://www.merriam-webster.com/dictionary/pandemic">https://www.merriam-webster.com/dictionary/pandemic</a>. A pandemic is a disease outbreak over a wide geographic area that affects most of the population. The World Health Organization, "Naming the Coronavirus Disease (COVID-19) and the Virus that Causes It," accessed November 10, 2020, <a href="https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/naming-the-coronavirus-disease-(covid-2019)-and-the-virus-that-causes-it. COVID-19 is caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), a newly discovered coronavirus.

<sup>&</sup>lt;sup>3</sup> Facility leaders consulted with a physician from Louis Stokes VA Medical Center, Cleveland, Ohio, regarding the CIWA protocol.

<sup>&</sup>lt;sup>4</sup> For purposes of this report, the OIG notes that an adverse event can lead to an adverse clinical outcome.

<sup>&</sup>lt;sup>5</sup> The facility provided the OIG with the names of 19 patients reported to have had medical emergencies during the review period. The OIG found that 5 of the 19 patients did not have medical emergencies during the review period.

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 substantiates an allegation when the available evidence indicates that the alleged event or action more likely than not took place. The OIG does not substantiate an allegation when the available evidence indicates that the alleged event or action more likely than not did not take place. The OIG is unable to determine whether an alleged event or action took place when there is insufficient evidence.

Oversight authority to review the programs and operations of VA medical facilities is authorized by the Inspector General Act of 1978, Pub. L. No. 95-452, 92 Stat. 1105, as amended (codified at 5 U.S.C. App. 3). The OIG reviews available evidence to determine whether reported concerns or allegations are valid within a specified scope and methodology of a healthcare inspection and, if so, to make recommendations to VA leaders on patient care issues. Findings and recommendations do not define a standard of care or establish legal liability.

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**

The patient was in their 30s at the time of death in spring 2019.<sup>6</sup> The patient initiated primary care services at the facility in spring 2008. From fall 2011 until summer 2018, the patient received intermittent mental health treatment for <u>alcohol use disorder</u>, anxiety, attention-deficit disorder, <u>posttraumatic stress disorder</u>, and sleep disturbance.<sup>7</sup>

On day 1 at approximately 11:00 a.m., the patient presented to the facility's Urgent Care Clinic and reported having had a seizure prior to coming to the facility. An electrocardiogram was completed at 11:09 a.m. The patient reported drinking a half liter of vodka daily and the patient's blood alcohol level was undetectable. A nurse practitioner described the patient as "lethargic, falls asleep during conversation," and having "garbled speech." The nurse practitioner ordered a computed tomography scan of the head and blood tests. The nurse practitioner consulted with a physician (consulting inpatient physician) who recommended contacting another VA medical center for a "seizure evaluation." The patient refused transfer to another VA medical center and agreed to admission to the facility's inpatient medical unit. The nurse practitioner documented that the patient "was more awake and speech was clearer at the time of admit" and at approximately 2:00 p.m., placed an admission order with an alcohol abuse diagnosis.

An inpatient unit physician (admitting physician) completed a history and physical exam at approximately 3:15 p.m., and documented that the patient did not "think the seizure activity could be alcohol related, since [patient] has been drinking for years and this is the first such episode." The admitting physician documented that based on blood test results of liver functioning, "I definately [sic] think that drinking is a problem," and ordered a lorazepam injection and diazepam tablets at dosages dependent upon the CIWA score, and vitals to be taken every four hours while the patient was awake. 9

Upon the patient's arrival to the inpatient medical unit, at approximately 3:30 p.m., a day nurse completed a CIWA assessment with a score of 2 due to observed tremors that did not require intervention. Approximately three hours later, a second day nurse completed a CIWA that resulted in a score of 15, indicating "severe withdrawal (impending delirium tremens)," and the patient received lorazepam 2 milligrams (mg) intravenously. The admitting physician documented that the patient had made statements such as, "there are lasers on the floor" to

<sup>&</sup>lt;sup>6</sup> The OIG uses the singular form of they (their) in this instance for the purpose of patient privacy.

<sup>&</sup>lt;sup>7</sup> The patient did not respond to facility staff's outreach in late 2018; the patient's EHR did not include any contacts from late 2018 until day 1.

<sup>&</sup>lt;sup>8</sup> In an interview with the OIG, the Chief of Acute Care clarified that the facility does not offer neurology services for inpatients.

<sup>&</sup>lt;sup>9</sup> Elizabeth C. Perry, "Inpatient Management of Acute Alcohol Withdrawal Syndrome," *CNS Drugs* 28, (April 30, 2014): 401-410. The CIWA is a nurse-administered questionnaire that evaluates the severity of a patient's withdrawal symptoms.

nursing staff and was concerned that the patient might leave the facility. The admitting physician contacted a psychiatric provider and anticipated that the patient would be evaluated the next day.

At approximately 8:00 p.m., the second day nurse administered 2.5 mg of intramuscular haloperidol and documented that the patient was placed on a "Director's Hold" and the admitting physician placed an order for staff to observe the patient continuously. The patient became increasingly agitated and exhibited visual hallucinations and delusions. The nursing assistant observing the patient documented that the patient fell multiple times and required "constant redirection." At approximately 10:30 p.m., the consulting inpatient physician documented that the patient appeared confused with likely delirium tremens and a provider at another VA medical center accepted the patient for further care. A nurse administered intramuscular haloperidol and diphenhydramine and intravenous lorazepam as ordered.

The nursing assistant documented the patient's increased agitation and aggression, and that the patient was attempting to hit staff. At approximately 11:30 p.m., VA police were called to assist with the patient's aggression. On day 2 at approximately 12:30 a.m., staff placed the patient in <u>four-point restraints</u>. The consulting inpatient physician placed a transfer order and documented that the "Specialized services/care" to address the patient's alcohol withdrawal with delirium were not available at the facility. An administrative staff member scheduled a transport service to transfer the patient to a higher level of care.<sup>11</sup>

At 12:45 a.m. the patient's <u>oxygen saturation</u> level was 84 percent, an oxygen mask was applied, and 10 minutes later the patient's oxygen saturation was documented at 91 percent. At 1:07 a.m., the patient's oxygen saturation was 82 percent and nursing staff documented that the consulting inpatient physician changed the patient's oxygen mask to a <u>venturi mask</u>.

At 1:20 a.m., a night nurse documented that while obtaining the patient's oxygen saturation, the "patient went limb [sic]" and the consulting inpatient physician started cardiopulmonary resuscitation. Emergency medical services (911) was called and approximately 15 minutes later,

<sup>&</sup>lt;sup>10</sup> The Wisconsin state statute addressing emergency detention is found in Chapter 51 of the State Alcohol, Drug Abuse, Developmental Disabilities and Mental Health Act. Wis. Stat. Ann. 8 51.15 (2020), accessed March 19, 2020, <a href="https://docs.legis.wisconsin.gov/statutes/statutes/51">https://docs.legis.wisconsin.gov/statutes/statutes/51</a>. Facility Policy MCM PCS-SW-17, *Emergency Detention*, *Probable Cause and Commitment Proceedings*, February 22, 2018, is consistent with Wisconsin law. According to the facility policy, there are two mechanisms for an emergency detention under Chapter 51 depending on where the patient is located in the facility. If the patient is an inpatient on an acute medical unit, the VA police must initiate the emergency detention consistent with the criteria outlined in the policy. A "Director's Hold" is initiated by the treatment provider after a patient has threatened to leave the facility and the provider considers the patient to be a danger to self or others.

<sup>&</sup>lt;sup>11</sup> Between approximately 12:30 a.m. and 12:45 a.m., administrative staff documented that two of five transport services were available to transport the patient, with estimated arrivals at the facility in approximately 55 minutes and the other over seven hours later.

the non-VHA emergency medical services personnel arrived and the patient's pulse returned. 12 The paramedics performed an <u>endotracheal intubation</u> on the patient and the patient was transported to a non-VHA facility by helicopter at approximately 2:45 a.m. Approximately 10 hours later, staff at the non-VHA facility obtained a <u>magnetic resonance imaging</u> study of the patient's head that revealed a "normal exam of the brain."

On day 3 the patient was transferred from the non-VHA hospital to another VHA medical center and on day 25, was admitted to the VHA medical center's hospice unit. The patient died eight days later. On the death certificate, a hospice attending physician documented cause of death as anoxic brain injury "due to or as a consequence of" alcohol use disorder, cardiopulmonary arrest, and delirium tremens. The OIG acknowledges that the patient's deterioration could be attributed to a broad diagnostic differential. However, based on the patient's documented history and clinical presentation as discussed above, the OIG believes the most likely cause of the patient's clinical deterioration was <a href="https://www.hypoxemia">hypoxemia</a> caused by cardiac arrest secondary to haloperidol administration.

# **Inspection Results**

#### 1. Over-Sedation and Failed Oxygen Delivery

The OIG did not substantiate staff over-sedated the patient. To the contrary, the OIG found that the admitting and consulting inpatient physicians did not prescribe an adequate benzodiazepine medication regimen to address the patient's delirium tremens effectively. Early and adequate benzodiazepine dosing may have halted progression of the patient's alcohol withdrawal. Further, the physicians' failure to treat the delirium tremens with adequate benzodiazepine dosing or transfer the patient to a higher level of care earlier likely contributed to the patient's respiratory suppression and cardiac arrest.

The OIG substantiated that a non-VHA paramedic (lead paramedic) observed that the patient's flow of oxygen was not active at the time the emergency medical service participated in the patient's cardiopulmonary resuscitation. The OIG found that facility leaders and staff reported lack of knowledge about the patient's failed oxygen delivery and did not include the lead paramedic's documentation in a review of the patient's care. The OIG concluded that inclusion of the emergency medical services lead paramedic's documentation in the facility leaders'

<sup>&</sup>lt;sup>12</sup> Facility Policy MS-03, *Emergency Services*, March 7, 2017, requires staff to respond to medical emergencies by calling "911," as necessary for non-VHA emergency service assistance. The emergency medical service personnel who responded to the patient's medical emergency included a lead paramedic, a second paramedic, and an emergency medical technician. The lead paramedic completed the documentation. Facility administrative staff canceled the scheduled transport service.

<sup>&</sup>lt;sup>13</sup> Sandeep Grover and Abhishek Ghosh, "Delirium Tremens: Assessment and Management," *Journal of Clinical and Experimental Hepatology* 8, (December 2018): 460-470.

reviews may have identified systemic root causes and performance deficiencies that contributed to the failed oxygen delivery in the patient's care.

## **Ineffective Medication Management**

An appropriate benzodiazepine regimen to treat delirium tremens is 4 mg of intravenous lorazepam every 10 minutes until the patient is lightly sedated or scores below an 8 on the CIWA. If delirium persists after 16 mg, an administration of 8 mg intravenous lorazepam "is to be administered." On day 1, over approximately five hours, the patient exhibited persistent hallucinations and increasing aggression. During this time, nurses administered 10 mg of haloperidol and 4 mg intravenous lorazepam, a significantly lower benzodiazepine dosage than is considered appropriate in the treatment of delirium tremens. The consulting inpatient physician documented the patient's "likely" delirium tremens and described concern to the OIG that using benzodiazepines would over-sedate the patient or worsen the patient's confusion. The consulting inpatient physician explained that the decision to prescribe haloperidol was to avoid over-sedation with benzodiazepines. Based on recommended protocols and the patient's symptoms, the OIG would have expected the consulting inpatient physician to order additional and higher doses of benzodiazepines to treat the patient's delirium tremens. Further, the providers did not initiate intravenous rehydration, as would be expected to manage alcohol withdrawal. <sup>16</sup>

The OIG found that the admitting and consulting inpatient physicians did not prescribe an adequate benzodiazepine medication regimen to address the patient's delirium tremens effectively. The Early and adequate benzodiazepine dosing may have halted progression of the patient's alcohol withdrawal and further, the physicians' failure to treat the delirium tremens with adequate benzodiazepine dosing or transfer the patient to a higher level of care earlier likely contributed to the patient's respiratory suppression, cardiac arrhythmia, and subsequent presumed anoxic brain injury. The patient is a subsequent presumed anoxic brain injury.

The OIG recognizes that ideally, the appropriate medication regimen would be administered in an intensive care unit and maintains that the patient should have been transferred after the patient's 6:25 p.m. CIWA score was 15 and indicated "severe withdrawal (impending delirium tremens)," and the patient was exhibiting psychotic symptoms. If transfer was not possible, the medication should have been administered with significantly increased monitoring including the physician at the bedside. See discussion of delayed transfer below.

<sup>&</sup>lt;sup>14</sup> Grover, "Delirium Tremens."

<sup>&</sup>lt;sup>15</sup> Grover, "Delirium Tremens."

<sup>&</sup>lt;sup>16</sup> Grover, "Delirium Tremens."

<sup>&</sup>lt;sup>17</sup> Grover, "Delirium Tremens."

<sup>&</sup>lt;sup>18</sup> Grover, "Delirium Tremens."

#### Failure to Review the Patient's Electrocardiogram

The OIG found that the patient had an abnormal electrocardiogram that was not reviewed prior to administration of haloperidol, a medication that can affect cardiac rhythm.<sup>19</sup> Facility staff's failure to review, document, and monitor the patient's electrocardiogram to assess cardiac risk before prescribing haloperidol may have contributed to the patient's respiratory suppression and cardiac arrest.

The American Heart Association recommends electrocardiogram monitoring for patients who may be at risk for arrythmias that result from a prolonged QTc interval.<sup>20</sup> QT is an electrocardiogram measurement that reflects electrical activity in the lower chambers of the heart and can identify abnormal cardiac functioning.<sup>21</sup> QTc is a calculated measurement that factors in a patient's heart rate to determine the corrected QT interval.<sup>22</sup> The administration of haloperidol in the presence of a prolonged QTc interval may lead to cardiac arrhythmias, including ventricular fibrillation, and death.

Although haloperidol should be avoided in the treatment of delirium tremens due to an increased risk of seizures and death by cardiac arrhythmia, the OIG did not find evidence that providers reviewed the patient's abnormal electrocardiogram or considered obtaining another electrocardiogram prior to the administration of haloperidol.<sup>23</sup>

On day 1, the Urgent Care Clinic nurse practitioner ordered an electrocardiogram for <u>tachycardia</u> that identified abnormalities that included a prolonged QTc interval.<sup>24</sup> The nurse practitioner did not document the electrocardiogram abnormality. Both the admitting physician and consulting inpatient physician ordered haloperidol for the patient. In an interview with the OIG, the nurse practitioner did not recall bringing the patient's electrocardiogram to the attention of a physician.

In an interview with the OIG, the admitting physician reported informally consulting with a mental health nurse practitioner who recommended intramuscular haloperidol for the patient's psychotic symptoms. The admitting physician told the OIG that the mental health nurse practitioner did not recommend an electrocardiogram and the patient was not complaining about chest pain. In an interview with the OIG, the admitting physician acknowledged not considering

<sup>&</sup>lt;sup>19</sup> Grover, "Delirium Tremens." The lack of recognition of a patient's prolonged QT may indicate an absence of a standardized approach to electrocardiogram interpretation.

<sup>&</sup>lt;sup>20</sup> Kristen E. Sandau et al., "Update to Practice Standards for Electrocardiographic Monitoring in Hospital Settings: A Scientific Statement from the American Heart Association," *Circulation* Vol. 136, November 7, 2017, accessed February 17, 2021, <a href="https://www.ahajournals.org/doi/full/10.1161/cir.0000000000000527">https://www.ahajournals.org/doi/full/10.1161/cir.00000000000000527</a>.

<sup>&</sup>lt;sup>21</sup> Pieter G. Postema and Arthur A.M. Wilde, "The Measurement of the QT Interval," *Current Cardiology Reviews* 10, (2014): 287-294.

<sup>&</sup>lt;sup>22</sup> Postema, "The Measurement of the QT Interval."

<sup>&</sup>lt;sup>23</sup> Grover, "Delirium Tremens;" S. Jesse et al., "Alcohol withdrawal syndrome: mechanisms, manifestations, and management," *Acta Neurologica Scandinavica* 135, (2017): 4-16.

<sup>&</sup>lt;sup>24</sup> Postema, "The Measurement of the QT Interval." A normal QTc interval is less than 450 milliseconds.

an electrocardiogram. Additionally, the consulting inpatient physician reported not being aware of the patient's electrocardiogram and because an electrocardiogram was typically obtained upon a patient's admission, did not consider ordering one for the patient.

The OIG found providers did not review the patient's abnormal electrocardiogram or monitor the patient's cardiac activity prior to and after the administration of haloperidol, a medication that can affect cardiac rhythm. Further, an internal review of the patient's care identified staff's failure to document the patient's electrocardiogram results but facility leaders did not identify corrective actions related to this deficiency. Facility staff's failure to review, document, and monitor the patient's electrocardiogram to assess cardiac risk before prescribing haloperidol may have contributed to the patient's respiratory suppression and cardiac arrest.

#### Failed Oxygen Delivery

The OIG substantiated that a lead paramedic observed and documented in the emergency medical services record that the patient's flow of oxygen was not active at the time the emergency medical services personnel participated in the patient's cardiopulmonary resuscitation. Facility staff involved in the patient's cardiopulmonary resuscitation were unable to recall whether the patient was receiving oxygen.

#### Background

#### Out of Operating Room Airway Management

VHA requires inpatient facilities (such as the facility) without a code team or an emergency department to ensure OOORAM providers (Level 1 providers) are available to perform basic airway management and assess the need for a higher level of airway expertise.<sup>25</sup> If needed, Level 1 providers access a higher level of airway management based on facility processes.<sup>26</sup> Facility providers, who are Level 1 OOORAM providers, are not trained to perform endotracheal intubation.<sup>27</sup> According to facility policy, staff are instructed to contact 911 emergency medical services as needed.<sup>28</sup>

## **OIG Findings**

On day 2, at 12:45 a.m., the consulting inpatient physician applied oxygen and the patient's oxygen saturation improved. Approximately 20 minutes later, the patient's oxygen saturation

<sup>&</sup>lt;sup>25</sup> The Chief of Staff reported to the OIG that the facility's "core emergency response team" is considered a rapid response team and not a code team. Facility Policy MS-03; VHA Directive 1157(1), *Out of Operating Room Airway Management*, June 14, 2018, amended on September 19, 2018. A Level 1 OOORAM provider is trained to provide basic airway management to patients experiencing a medical emergency.

<sup>&</sup>lt;sup>26</sup> VHA Directive 1157(1).

<sup>&</sup>lt;sup>27</sup> VHA Directive 1157(1).

<sup>&</sup>lt;sup>28</sup> Facility Policy MS-03.

decreased and the consulting inpatient physician applied a different mask. At 1:20 a.m., a night nurse documented that the consulting inpatient physician started cardiopulmonary resuscitation. The emergency medical services personnel arrived approximately 10 minutes later and the lead paramedic documented that the "oxygen was not turned on for the [bag valve mask]. The tubing was connected to the wall, but oxygen was not on." The lead paramedic described to the OIG noticing that "the oxygen hadn't been turned on" and making a "statement that the oxygen was off, or the oxygen wasn't on." The lead paramedic reported, "I didn't ask how long it was disconnected…Or how long it had been turned off." The lead paramedic did not recall if facility staff responded.

In an interview with the OIG, the other paramedic recalled the lead paramedic "requesting that oxygen be turned on," but could not recall who turned it on. The emergency medical technician told the OIG that "at one point it became known that the oxygen was plugged into the oxygen tree in the wall, but the valve was never opened," and did not recall whether one of the ambulance crew "turned it on or instructed someone to turn it on." In interviews with the OIG team, facility staff involved in the patient's cardiopulmonary resuscitation were unable to recall whether the patient was receiving oxygen.

The OIG determined that it was possible that the patient's oxygen was not operational for approximately 20 minutes before the lead paramedic identified that it was not flowing. Given facility staff's reported lack of knowledge about the patient's failed oxygen delivery, the OIG was unable to determine how the oxygen was turned off. The OIG found that VA facility leaders and staff reported lack of knowledge about the patient's failed oxygen delivery and did not include the lead paramedic's documentation in a review of the patient's care. The incomplete EHR documentation is discussed later in the report.

Although the patient died from presumed anoxic brain injury, the non-VHA <u>magnetic resonance</u> <u>imaging</u> obtained 10 hours after transfer from the facility did not indicate damage from a lack of oxygen. The OIG consulted with two <u>radiologists</u> from the non-VHA facility who confirmed that the patient's magnetic resonance imaging did not reflect damage from a lack of oxygen. The ultimate cause of the patient's brain injury was undetermined, but likely due to metabolic, toxic, or a hypoxic ischemic encephalopathy.<sup>29</sup>

# Insufficient Internal Review of Patient's Cardiopulmonary Resuscitation Event

VHA requires staff to measure resuscitation performance and outcomes, and each facility must have a committee responsible "for ensuring the review of each resuscitative episode of care under the facility's responsibility."<sup>30</sup> The facility's Emergency Services Committee provides

<sup>&</sup>lt;sup>29</sup> An autopsy was not completed and therefore the cause of the patient's encephalopathy was unable to be clarified.

<sup>&</sup>lt;sup>30</sup> VHA Directive 1177, Cardiopulmonary Resuscitation, August 28, 2018.

guidance for emergency services, including reviews of cardiopulmonary resuscitation episodes to identify "errors or deficiencies in technique or procedure," "lack of availability or malfunction of equipment," appropriateness of interventions, clinical or patient care issues that "may have contributed to the occurrence of a cardiopulmonary event," and "delays in the initiation of [cardiopulmonary resuscitation]."<sup>31</sup>

VHA requires facilities to complete internal reviews for all adverse events, such as a <u>root cause analysis</u>, peer review, or management review.<sup>32</sup> A root cause analysis must include interviews with individuals who were involved in the adverse event.<sup>33</sup> VHA requires peer reviews of health care professionals for quality management purposes that are also used for individual practice or system improvement.<sup>34</sup> "A management review is any review conducted for purposes other than confidential quality assurance" and allows for personnel actions.<sup>35</sup>

A facility release of information clerk scanned the lead paramedic's documentation, entitled "Fee Basis," into the patient's EHR on day 10. The Nurse of the Day, who was present at the patient's cardiopulmonary resuscitation event, reported to the Emergency Services Committee that oxygen was provided to the patient. On day 12, the Emergency Services Committee reviewed the event. In an interview, the Chair, Emergency Services Committee told the OIG team that the Emergency Services Committee did not review emergency medical services documentation as part of its process.

In an interview with the OIG, the Director, Performance Improvement reported not being aware of the lead paramedic's documentation and that the documentation would have been reviewed if available for the Emergency Services Committee. On September 15, 2020, the VISN 12 Director informed the OIG that there had not been a requirement for the Emergency Services Committee to review paramedics' notes, but since learning about the paramedics' documentation of the patient's oxygenation issue, the facility was directed to establish a process for paramedic documentation to be reviewed.

In late spring 2019, the facility conducted a root cause analysis and peer reviews of relevant staff. The Patient Safety Manager told the OIG team that the emergency medical service documentation was not available for the root cause analysis team. The Risk Manager told the OIG team that emergency medical service documentation is "not usually looked at during a peer review" because reviews focus on the episode of care.

<sup>32</sup> VHA Handbook 1050.01, *VHA National Patient Safety Improvement Handbook*, March 4, 2011. An adverse event is an unexpected negative outcome associated with an episode of healthcare.

<sup>34</sup> VHA Directive 1190, *Peer Review for Quality Management*, November 21, 2018.

<sup>&</sup>lt;sup>31</sup> Facility Policy MS-03.

<sup>&</sup>lt;sup>33</sup> VHA Handbook 1050.01.

<sup>&</sup>lt;sup>35</sup> VHA Directive 1190. Management reviews, also referred to as unprotected peer reviews, are not protected by 38 U.S.C. 5705.

Further, the OIG determined that the scanning of emergency medical services' documentation in the EHR was not routinely completed. Two of the 14 EHRs of facility inpatients (including the patient) who received emergency medical services between October 1, 2018, and September 30, 2020, included scanned emergency services documentation.

The OIG concluded that the inclusion of emergency medical services' documentation in facility leaders' reviews may identify systemic root causes and performance deficiencies in patient care. The OIG suggests that facility leaders consider routine scanning of emergency medical services documentation.

#### Deficiencies in Airway Management Training

The OIG was unable to determine if the consulting inpatient physician's lapse in OOORAM training contributed to the patient's failed oxygen delivery because facility leaders were not aware of the patient's failed oxygen delivery and therefore the cause for the oxygen flow cessation was not evaluated.

VHA requires inpatient facilities, such as the facility, without a code team or an emergency department to ensure Level 1 OOORAM providers are available to perform basic airway management and assess the need for a higher level of airway expertise. <sup>36</sup> If needed, Level 1 providers access a higher level of airway management based on facility processes such as contacting 911 emergency medical services. <sup>37</sup> Facility policy required all inpatient unit medical providers to have training every two years on insertion of an airway device. <sup>38</sup>

The Director, Performance Improvement, provided the OIG with documentation that indicated that the four inpatient medical unit providers including the admitting physician and inpatient consulting physician did not have current OOORAM training at the time of the patient's care. The Director, Performance Improvement, forwarded information from the facility's medicine service that explained that the training deficiencies were due to the turnover of clinical and administrative leaders and the implementation of a different type of airway device in the summer of 2019. Additionally, the information included that as of November 2020, OOORAM training was up-to-date and oversight was provided by the Chief of Acute Care.

Additionally, the OIG learned in May 2019, the then-Acting Director, Performance Improvement, notified the facility Acting Director and Chief of Staff that the facility policy erroneously identified the facility as exempt from the VHA OOORAM directive. On September 9, 2019, the Chief of Acute Care determined that the facility policy and practice were in compliance. On September 30, 2020, the OIG requested the Director, Performance Improvement,

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<sup>&</sup>lt;sup>36</sup> The Chief of Staff reported to the OIG that the facility's "core emergency response team" is considered a rapid response team and not a code team. Facility Policy MS-03; VHA Directive 1157(1).

<sup>&</sup>lt;sup>37</sup> VHA Directive 1157(1). A Level 1 OOORAM provider is trained to provide basic airway management to patients experiencing a medical emergency.

<sup>&</sup>lt;sup>38</sup> Facility Policy MS-03.

provide OOORAM training records for the consulting inpatient physician. On October 6, 2020, the Director, Performance Improvement informed the facility Acting Director and Chief of Staff that the consulting inpatient physician had not received OOORAM training for four years, and that the facility was out of compliance with the VHA OOORAM directive.

On October 15, 2020, the Chief of Staff charged a workgroup to review the VHA OOORAM directive "to ensure that Tomah VAMC meets all standards and has processes in place by December 31, 2020." In January 2021, the Chief of Staff told the OIG that credentialing and privileging and training for OOORAM will be the responsibility of the Chief of Staff. The Chief of Staff also reported pursuing formal assignment of an OOORAM trainer through the Medical Executive Staff Committee. The Chief of Staff noted that VHA training for OOORAM trainers has been suspended due to the COVID-19 pandemic. The Chief of Staff expressed the hope of having the changes in place by the end of February 2021.

The OIG was unable to determine if the consulting inpatient physician's lapse in OOORAM training contributed to the patient's failed oxygen delivery because the cause of the oxygen flow cessation was not identified.

# Deficiencies in Evaluation and Management of Alcohol Withdrawal

Nursing staff failed to complete all required CIWAs which may have contributed to an incomplete understanding of the patient's alcohol withdrawal progression and an increased risk of an adverse clinical outcome.<sup>39</sup>

## Background

Alcohol withdrawal may occur "within several hours to a few days" of an abrupt discontinuation of prolonged, excessive alcohol use and must include a minimum of two symptoms such as sweating, increased pulse rate, hand tremor, auditory or visual hallucinations, agitation, and seizures. <sup>40</sup> The likelihood of alcohol withdrawal increases with the quantity and frequency of alcohol use. <sup>41</sup>

The revised version of the CIWA scale is the most widely used tool for the evaluation of a patient's alcohol withdrawal symptom severity.<sup>42</sup> The CIWA evaluates the severity of a patient's

<sup>&</sup>lt;sup>39</sup> For purposes of this report, the OIG defines an adverse clinical outcome in terms of an event such as cardiac arrest and need for a higher level of care.

<sup>&</sup>lt;sup>40</sup> Diagnostic and Statistical Manual of Mental Disorders. "Substance Related and Addictive Disorders," accessed August 12, 2019,

https://dsm.psychiatryonline.org/doi/full/10.1176/appi.books.9780890425596.dsm07#BABJAEHE.

<sup>&</sup>lt;sup>41</sup> Diagnostic and Statistical Manual of Mental Disorders. "Substance Related and Addictive Disorders,"

<sup>&</sup>lt;sup>42</sup> Jesse, "Alcohol withdrawal syndrome." The CIWA revised version is referred to as CIWA-Ar. For purposes of this report, the OIG will refer to the CIWA-Ar as CIWA.

withdrawal symptoms and requires patient participation.<sup>43</sup> Frequent CIWA administration is necessary to assess a patient's alcohol withdrawal symptoms effectively.<sup>44</sup>

Treatment for mild symptoms of alcohol withdrawal (CIWA score less than 10), including anxiety, insomnia, tremor, headache, and heart palpitations, may include intravenous rehydration and supportive care.<sup>45</sup>

Moderate to severe alcohol withdrawal (CIWA score of 10–18), including seizures, requires inpatient monitoring, hourly assessment, and treatment with <u>benzodiazepine</u> medications to avoid progression to <u>delirium tremens</u>, the most severe form of alcohol withdrawal.<sup>46</sup> If untreated, severe withdrawal symptoms may progress to delirium tremens in one third of patients.<sup>47</sup>

Delirium tremens, a medical emergency that occurs in three to five percent of patients treated for alcohol withdrawal and results in death rates of one to four percent, should be managed in an inpatient or intensive care unit setting. AB Diagnosis requires the presence of both delirium and severe alcohol withdrawal symptoms. AP For patients with delirium tremens, the most common causes of death are due to complications from seizures, excessively high body temperature, and cardiac arrhythmias. The primary treatment goals for patients diagnosed with delirium tremens are to reduce agitation and seizure risk, and treat the alcohol withdrawal.

Benzodiazepines are the preferred treatment for moderate to severe alcohol withdrawal, including delirium tremens.<sup>52</sup> Benzodiazepines are categorized as short acting (such as <a href="lorazepam">lorazepam</a>) and long-acting (such as <a href="diazepam">diazepam</a>), based on the duration of the medication effect.<sup>53</sup>

<sup>&</sup>lt;sup>43</sup> Perry, "Inpatient Management of Acute Alcohol Withdrawal Syndrome." "The maximum possible score is 67. A score less than 10 indicates mild withdrawal, 10–18 indicates moderate to severe withdrawal, and any score greater than 18 may indicate a patient is at risk for major complications if not treated." Jesse, "Alcohol withdrawal syndrome."

<sup>44</sup> Jesse, "Alcohol withdrawal syndrome."

<sup>&</sup>lt;sup>45</sup> Perry, "Inpatient Management of Acute Alcohol Withdrawal Syndrome;" Jesse, "Alcohol withdrawal syndrome."

<sup>&</sup>lt;sup>46</sup> Perry, "Inpatient Management of Acute Alcohol Withdrawal Syndrome;" Jesse, "Alcohol withdrawal syndrome."

<sup>&</sup>lt;sup>47</sup> Perry, "Inpatient Management of Acute Alcohol Withdrawal Syndrome."

<sup>&</sup>lt;sup>48</sup> Grover, "Delirium Tremens;" Marc Schuckit, "Recognition and Management of Withdrawal Delirium (Delirium Tremens)," *The New England Journal of Medicine*, 371, no. 22, (November 2014): 2109-2113.

<sup>&</sup>lt;sup>49</sup> Grover, "Delirium Tremens;" Schuckit, "Recognition and Management of Withdrawal Delirium (Delirium Tremens)." Delirium is characterized by rapid-onset, fluctuating disturbances in attention, awareness of the environment, clarity of thought, agitation, and the sleep-wake cycle.

<sup>&</sup>lt;sup>50</sup> Grover, "Delirium Tremens;" Schuckit, "Recognition and Management of Withdrawal Delirium (Delirium Tremens)."

<sup>&</sup>lt;sup>51</sup> Grover, "Delirium Tremens;" Schuckit, "Recognition and Management of Withdrawal Delirium (Delirium Tremens)."

<sup>&</sup>lt;sup>52</sup> Perry, "Inpatient Management of Acute Alcohol Withdrawal Syndrome;" Jesse, "Alcohol withdrawal syndrome;" Grover, "Delirium Tremens;" Schuckit, "Recognition and Management of Withdrawal Delirium (Delirium Tremens),"

<sup>&</sup>lt;sup>53</sup> Jesse, "Alcohol withdrawal syndrome."

One of the most common regimens for severe alcohol withdrawal is the administration of high doses of a long-acting benzodiazepine to quickly achieve sedation, such as diazepam 10–20 mg every one to two hours until sedation is achieved, with an average of three doses required.<sup>54</sup> Another regimen, symptom triggered dosing, uses either short- or long-acting benzodiazepines with CIWA administration hourly and then every four hours when scores are less than 8.<sup>55</sup>

Antipsychotic medications, including <u>haloperidol</u>, should be avoided in delirium tremens, particularly in the early stages due to an increased risk of seizures and death by cardiac arrhythmia.<sup>56</sup> If the severity of psychotic symptoms or agitation warrants the use of haloperidol, an electrocardiogram should be completed prior to administration to evaluate risk factors for arrhythmia, including a prolonged QTc interval.<sup>57</sup>

#### **OIG Findings**

At the time of the patient's care, the available standard order set included an option for either oral diazepam or intravenous lorazepam medication with dosage based on the CIWA score. Facility nurses needed to determine whether to administer the oral or intravenous benzodiazepine medication. For example, a nurse could administer every two hours either diazepam 10 mg by mouth or lorazepam 2 mg intravenous for a patient who scored 11 to 15 on the CIWA. Additionally, the standard order set required obtaining vital signs every four hours while the patient was awake.

The admitting physician initiated the CIWA standard order set upon the patient's admission to the inpatient medical unit. At 3:25 p.m., a day nurse obtained vital signs and a CIWA score of 2 due to observed tremors that per the standard order set did not require intervention. Approximately three hours later, the patient's CIWA score was 15, "severe withdrawal (impending delirium tremens)," and staff administered an initial benzodiazepine dose intravenously. The patient was agitated, appeared to be visually hallucinating, and lacked mental clarity or awareness of the environment. Approximately four hours later, a staff member obtained vital signs and the consulting inpatient physician documented "patient appears confused with likely [delirium tremens]" and requested the patient's transfer to a higher level of care. At approximately 11:30 p.m. the patient scored a nine on the CIWA and a nurse administered 1 mg of lorazepam intravenously.

<sup>&</sup>lt;sup>54</sup> Grover, "Delirium Tremens;" Jesse, "Alcohol withdrawal syndrome."

<sup>&</sup>lt;sup>55</sup> Grover, "Delirium Tremens;" Jesse, "Alcohol withdrawal syndrome."

<sup>&</sup>lt;sup>56</sup> Grover, "Delirium Tremens;" Jesse, "Alcohol withdrawal syndrome."

<sup>&</sup>lt;sup>57</sup> Grover, "Delirium Tremens."

<sup>&</sup>lt;sup>58</sup> A standard order set is a collection of orders that a licensed independent provider prescribes to streamline and standardize a regularly utilized treatment protocol.

Based on the patient's report and symptoms, the OIG team estimated that the patient's last alcohol use was likely more than 12 hours prior to arrival at the facility. <sup>59</sup> The patient presented with symptoms of severe alcohol withdrawal including fluctuating states of consciousness and elevated temperature and heart rate. Despite the patient's history of alcohol use and the patient's alcohol withdrawal symptoms, the OIG found that a CIWA was not performed until more than four hours after the patient's presentation to the Urgent Care Clinic. The nurse practitioner could not recall whether a CIWA was administered in the Urgent Care Clinic prior to the patient's care. The consulting inpatient physician reported that a CIWA was not routinely administered in the Urgent Care Clinic because patients were usually still intoxicated at the time of presentation.

Nursing staff failed to administer a CIWA every two hours as indicated by the order set. Nurses administered a CIWA at approximately 6:30 p.m. but failed to administer the CIWA until five hours later, four hours beyond the time indicated by the patient's initial CIWA score. At approximately 7:30 p.m., nursing staff documented the patient's hallucinations, agitation, and inappropriate behavior. Based on the patient's high CIWA score, administered medications, and deteriorating condition, the OIG would have expected nursing staff to complete a CIWA prior to 11:30 p.m.

#### Improper Restraint Use

The OIG found that the inpatient consulting physician's restraint order did not include the rationale for restraint use, the type of restraint, and clinical indication for restraint use as required by facility policy. Further, the OIG team concluded that if the patient's delirium tremens had been adequately managed with benzodiazepine medications (as discussed above), the use of restraints may have been avoided.

Restraint is used in a medical setting to limit a patient's movement to prevent self-harm or harming others including medical personnel. Restraints may be used to prevent a patient's movement during surgery or removal of medical tubes and intravenous lines, and to control or prevent harmful behavior due to mental health symptomatology.<sup>61</sup> When restraints are needed, the least restrictive restraint should be used, and restraint removal should occur immediately when no longer necessary.<sup>62</sup> The use of restraints should be avoided in delirium tremens as it

<sup>&</sup>lt;sup>59</sup> National Institute on Alcohol Abuse and Alcoholism, "Alcohol Alert: Alcohol Metabolism," accessed March 11, 2020, https://pubs.niaaa.nih.gov/publications/aa35.htm.

<sup>&</sup>lt;sup>60</sup> Facility Policy PCS-03, Restraint and Seclusion Use, June 30, 2017.

<sup>61</sup> Medline Plus, "Use of Restraints," accessed March 3, 2020, <a href="https://medlineplus.gov/ency/patientinstructions/000450.htm">https://medlineplus.gov/ency/patientinstructions/000450.htm</a>. Common types of physical restraints are belts and soft wrist restraints which are used to restrict freedom of movement and are designed to prevent injury to the patient or others.; American Psychiatric Nurses Association, "APNA Position on the Use of Seclusion and Restraint," accessed June 5, 2019, <a href="https://www.apna.org/i4a/pages/index.cfm?pageid=3730">https://www.apna.org/i4a/pages/index.cfm?pageid=3730</a>.

<sup>&</sup>lt;sup>62</sup> American Medical Association, "Use of Restraints," accessed June 5, 2019, <a href="https://www.ama-assn.org/delivering-care/ethics/use-restraints">https://www.ama-assn.org/delivering-care/ethics/use-restraints</a>.

may increase agitation.<sup>63</sup> Treatment focused on the reduction of agitation associated with delirium tremens likely reduces seizure and mortality risk.<sup>64</sup>

The Joint Commission requires that restraint orders be consistent with facility policy and restraint use occur only when clinically justified or "when warranted by patient behavior that threatens the physical safety of the patient, staff, or others." Facility policy requires a licensed independent provider, selected nurse practitioners, and physician assistants to enter a restraint order that includes clinical justification within one hour of restraint application to the patient and complete an EHR templated progress note. The frequency of staff's assessment and observations of a patient depends on whether the restraint is used for medical/surgical or behavioral health management.

VA police officers cannot employ therapeutic containment restraint techniques.<sup>68</sup>

Facility policy requires that when VA police respond to a behavioral emergency, they "will only intervene when requested" or the situation "has escalated beyond the capacity" for clinical staff to manage.<sup>69</sup>

#### Improper Restraint Orders, Application, and Assessment

The OIG determined that the inpatient consulting physician improperly ordered the patient's restraints and nursing staff failed to obtain the patient's full vital signs as required by facility policy. The OIG was unable to determine if nursing staff or VA police applied four-point restraints to the patient because of inconsistent documentation and statements to the OIG.

<sup>63</sup> Grover, "Delirium Tremens."

<sup>&</sup>lt;sup>64</sup> Grover, "Delirium Tremens;" Perry, "Inpatient Management of Acute Alcohol Withdrawal Syndrome."

<sup>&</sup>lt;sup>65</sup> The Joint Commission, *Standards Manual*, PC.03.05.01, The Joint Commission *Standards Manual*, PC.03.05.05, "The hospital initiates restraint or seclusion based on an individual order." VHA Handbook 1160.06, *Inpatient Mental Health Services*, September 16, 2013.

<sup>&</sup>lt;sup>66</sup> Facility Policy PCS-03.

<sup>&</sup>lt;sup>67</sup> Facility Policy PCS-03.

<sup>&</sup>lt;sup>68</sup> "Therapeutic Containment Trainer Requirements," VHA Prevention and Management of Disruptive Behavior Program, accessed December 1, 2020,

https://dvagov.sharepoint.com/sites/VHAPMDB/PMDB%20Wiki%20Pages/Therapeutic%20Containment%20Train er%20Requirements.aspx (This is an internal VA website not publicly accessible). "Therapeutic containment is a specialized manual restraint technique designed by VA for use in special clinical circumstances requiring immediate physical containment of violent patients who are causing harm or about to cause harm to themselves or others in a clinical setting." Acting Deputy Under Secretary for Health for Operations and Management Memorandum, "VHA Prevention and Management of Disruptive Behavior (PMDB) Program: VA Police Roles and Responsibilities," March 16, 2015.

<sup>&</sup>lt;sup>69</sup> Facility Policy MH-26, *Behavioral Emergency Response Protocol (BERP)*, July 28, 2017. "A behavioral emergency is behavior of any person whether patient, beneficiary, volunteer, visitor, or employee in the form of a physical attack, threat, or harassment which endangers the physical well-being or life of patients or staff, or threatens destruction of property."

<sup>&</sup>lt;sup>70</sup> Facility Policy PCS-03.

Medical literature suggests that restraints may increase agitation in patients experiencing delirium tremens. Facility leaders told the OIG that a restraint order would include the type of restraint applied, such as restraints applied to two or four extremities. On day 2 at approximately 12:15 a.m., the consulting inpatient physician entered an order that stated "restraints please." The consulting inpatient physician documented that the restraint was indicated for "behavioral health reasons" including the "patient swinging at staff." Nursing staff documented that four-point restraints were applied to the patient although the consulting inpatient physician did not specify restraint type in the order or related EHR documentation. A nurse told the OIG that VA police officers who responded to staff's request for assistance suggested four-point restraints because they could not control the patient.

Facility policy requires nursing staff to document an assessment and observation of the patient every 15 minutes when restraints are applied to a patient for behavioral health management. Facility staff are required to use the "Behavioral Health Restraint/Seclusion Flowsheet" that guides documentation of the patient's vital signs, restraint level, and an assessment of the patient's circulation. Using an untitled form or nursing note, nursing staff documented the patient's location, behavior, and observation in line of sight every 15 minutes including restraint level and assessment of the patient's circulation. However, the OIG found that nursing staff did not obtain patient's vital signs when the restraints were applied and failed to obtain the full set of vital signs that included temperature, pulse, respiration, and blood pressure in three restraint management notes. Specifically, nursing staff failed to obtain the patient's blood pressure in two of the three applicable assessments and temperature and respiration in all assessments. Given the risk of a patient's suffocation while in restraints, the assessment of respiratory rate is critical to monitor risk of respiratory failure.

The OIG was unable to determine if nursing staff or VA police applied four-point restraints to the patient because of staff's inconsistent documentation and statements to the OIG. The facility Chief of Police told the OIG that VA police are permitted to apply handcuffs but not medical restraints to patients. However, the facility Chief of Police told the OIG that "there isn't any written guidance prohibiting officers from applying medical restraints." A VA police officer completed a police report and stated, "I assisted and gave guidance to the medical staff applying the soft restraints to [the patient]." <sup>76</sup> Both night nurses documented that the VA police placed the

<sup>&</sup>lt;sup>71</sup> Grover, "Delirium Tremens."

<sup>&</sup>lt;sup>72</sup> Facility Policy PCS-03.

 $<sup>^{73}</sup>$  Restraint level is a numeric assignment that refers to the type of restraint applied such as 1 – seclusion, 2 – 2-point restraints, and 4 – 4-point restraint. Facility Policy PCS-03.

<sup>&</sup>lt;sup>74</sup> Facility Policy PCS-03.

<sup>&</sup>lt;sup>75</sup> American Nurse, *When and how to use restraints*, January 13, 2015, accessed on June 9, 2021, https://www.myamericannurse.com/use-restraints/.

<sup>&</sup>lt;sup>76</sup> A facility human resources officer informed the OIG that the VA police officer separated from the VA on March 14, 2020, and the OIG was unable to interview the VA police officer.

patient in four-point restraints. However, in interviews with the OIG, one night nurse reported that nursing staff placed the restraints while the police restrained the patient and the other night nurse did not recall who placed the restraints. In an interview with the OIG, the Deputy Chief of Police reported speaking with the VA police officer about police not being allowed to place restraints.

The inpatient consulting physician's order did not include the rationale for restraint use, the type of restraint, and clinical indication for restraint use as required by facility policy. The OIG concluded that if the patient's delirium tremens had been adequately managed with benzodiazepine medications (as discussed above), the use of restraints may have been avoided. The OIG also concluded that nursing staff's failure to obtain full vital signs as required likely resulted in a diminished understanding of the patient's subsequent respiratory deterioration.

#### Inadequate Restraint Training

VHA requires staff to be trained and competent in restraint use available in their care settings.<sup>78</sup> Facility policy required staff to be competent to apply, monitor, and provide care to a patient in restraints and that staff receive "ongoing" restraint training.<sup>79</sup> Inpatient medical unit nurses did not receive ongoing restraint training, as required by facility policy.<sup>80</sup>

On day 2, following staff's application of restraints to the patient, inpatient medical unit staff requested an inpatient mental health nurse provide "further clarification regarding restraints." The inpatient mental health nurse documented "provider called [inpatient mental health unit] stating needing further clarification regarding restraints." The inpatient mental health unit nurse documented that the patient was in four-point restraints with "irregular respirations" and "suggested to provider to elevate the head of bed." Further, the inpatient mental health nurse documented demonstrating to the inpatient medical unit nursing staff "regarding assuring restraints are secure but not impeding circulation." Nursing staff failed to obtain the full set of vital signs for the patient during the restraint episode, as discussed above.

From October 1, 2018, through July 23, 2019, none of the 15 inpatient medical unit nurses completed restraint training. <sup>81</sup> Between July 24, 2019, and September 21, 2019, all inpatient medical unit nurses received restraint training. The Associate Chief Nurse, Acute Care and Outpatient Care told the OIG that the organizational improvement analyst provided inpatient medical unit nurses training approximately every "year-and-a-half or two years." The organizational improvement analyst told the OIG that training is done at the request of the

<sup>78</sup> VHA Handbook 1160.06, *Inpatient Mental Health Services*, September 16, 2013.

<sup>&</sup>lt;sup>77</sup> Facility Policy PCS-03.

<sup>&</sup>lt;sup>79</sup> Facility Policy PCS-03. Facility policy does not define "ongoing."

<sup>80</sup> Facility Policy PCS-03.

<sup>&</sup>lt;sup>81</sup> This time period includes the time of the patient's care at the facility. According to the Acting Associate Director of Patient Care Services, 1 of the 15 inpatient unit nurses separated from the facility in early July 2019.

inpatient medical unit nurse manager and there was no formal schedule for inpatient medical unit staff restraint training. In August 2020, the organizational improvement analyst told the OIG about the development of a video resource on restraints and plans to provide restraint training "more regularly."

The OIG found that inpatient medical unit nurses did not receive restraint training from October 1, 2018, through July 2019. The OIG concluded that the lack of restraint training likely contributed to the nurses' failures to (1) verify that the physician's order included the specific type of restraint and (2) obtain full vital signs as required may have prevented staff from recognizing the patient's subsequent respiratory deterioration. The OIG would expect inpatient medical unit nursing staff to receive ongoing training to promote competency and currency.

## **Delayed Transfer**

The OIG found that facility staff initiated the patient's transfer to a higher level of care after the patient's condition had deteriorated and necessitated emergency medical services. The OIG would have expected staff to pursue transfer to a higher level of care upon determination of the need for an emergency detention and prior to the patient's rapid deterioration on day 1.

Patients in need of services not available at the facility may be offered transfer to a facility capable of providing that service. If a patient refuses transfer, the provider must document why the transfer was proposed, the patient's stated rationale for refusal, and a description of a discussion of the risks and benefits of the transfer.<sup>82</sup>

On day 1, after presenting in the Urgent Care Clinic with complaints of seizure-like activity, the admitting physician recommended the patient be transferred to another VA medical center for a neurology evaluation but the patient refused transfer. A discussion of the risks and benefits of that recommendation and possible outcomes of declining transfer was not documented. The admitting physician documented that the patient did not want to have a seizure alone, and therefore agreed to admission to the facility. The admitting physician admitted the patient for alcohol detoxification at approximately 2:00 p.m.

Later on day 1 at approximately 10:30 p.m., the consulting inpatient physician noted the patient was "confused with likely [delirium tremens]," documented a plan to transfer the patient to another VA facility, and noted that a provider had accepted the patient for transfer. At approximately 12:30 a.m., the consulting inpatient physician placed an order for the patient to be transferred and a facility medical administrative assistant began contacting ambulance companies for transport. The medical administrative assistant called five ambulance companies to arrange ground transport and at 12:45 a.m., scheduled with one of the five ambulance companies and arranged an estimated time of arrival in 55 minutes. At 1:20 a.m., the patient went into cardiac arrest. At approximately 1:30 a.m., the emergency medical services' paramedics arrived at the

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<sup>&</sup>lt;sup>82</sup> Facility Policy HAS-22, *Inter-Facility Referral and Transfer Policy*, July 17, 2018.

facility and participated in the resuscitation event. At 1:36 a.m., the consulting inpatient physician requested the medical administrative assistant to cancel the ambulance ground transport and arrange air transport to a closer non-VHA facility. At approximately 2:45 a.m., the patient was transferred to the non-VHA facility by air ambulance.

An internal review completed by the facility indicated that one of the underlying causes of the outcome was that a patient requiring a higher level of care was allowed to refuse transfer and be admitted. As a result, the facility revised its policy on admission criteria to include direction that "in the event of a patient refusing transfer to an outside medical facility when deemed clinically appropriate by the treating provider, the Associate Chief of Staff for Medicine or Chief of Staff must be contacted, and care discussed for further guidance."<sup>83</sup>

#### Facility Leaders' Response to Identified Deficiencies

Following the patient's care, facility leaders updated the CIWA protocol and reported that nursing staff received training. <sup>84</sup> The OIG determined that facility leaders took appropriate actions regarding staff complaints about the admitting physician's behavior and performance during the patient's episode of care. However, the OIG found that a facility leader failed to complete a focused professional practice evaluation (FPPE) for the admitting physician in 2018, and it was not identified until June 2019, likely due to facility leaders' failure to ensure adequate FPPE tracking.

The Associate Chief Nurse, Acute Care and Outpatient Care told the OIG that before the patient's inpatient medical unit admission, CIWA education included training in new employee orientation and providing alcohol withdrawal management for a patient with an assigned preceptor on the inpatient medical unit.

The Chief of Acute Care reported to the OIG having pursued consultation with a subject matter expert (physician consultant) at another VA medical center to modify the facility's alcohol withdrawal protocol that contained "a lot of variance." The Chief of Staff confirmed that at the time of the patient's admission in spring 2019, the CIWA protocol was based on symptoms rather than administering high doses of a long-acting benzodiazepine to quickly achieve sedation. The Chief of Staff told the OIG that following the patient's inpatient medical unit admission, facility staff worked with the physician consultant to revise the CIWA order set. In early 2020, facility leaders established new alcohol withdrawal management protocols. The

<sup>83</sup> Facility Policy MS-06, Admission Criteria for Acute Medicine Unit, January 17, 2020.

<sup>&</sup>lt;sup>84</sup> Facility Policy MS-25, *Clinical Institute Withdrawal Assessment for Alcohol, revised (CIWA-Ar) Protocol*, January 6, 2020; Patient Care Services Standard Operating Procedure for Nursing Procedure, *Symptom Triggered CIWA-Ar Protocol*, February 5, 2020.

<sup>&</sup>lt;sup>85</sup> Grover, "Delirium Tremens;" Jesse, "Alcohol withdrawal syndrome." The administration of high doses of a long-acting benzodiazepine demonstrated superior efficacy.

<sup>86</sup> Facility Policy MS-25; Patient Care Services Standard Operating Procedure for Nursing Procedure.

facility Nurse Educator reported that since the establishment of new policies, inpatient medical unit nurses received training to include simulation training.

#### Oversight of Admitting Physician

When internal reviews identify patterns of failures to meet standards of care, management may initiate an FPPE to determine whether administrative personnel actions or changes in privileges are warranted. In May 2018, facility leaders recommended initiation of an FPPE for the admitting physician. The Chief of Acute Care did not complete the assigned review of 20 EHRs within 90 days for the admitting physician's FPPE, and told the OIG "I believe [the FPPE] was" completed. However, the admitting physician's information was not included in the facility's FPPE tracking documentation. The OIG was unable to determine why the FPPE was not completed due to the absence of a documented explanation.

After the patient's discharge from the inpatient medical unit, the Chief of Staff received staff complaints about the admitting physician's lack of involvement in the management of the patient including prolonged response time to concerns about the patient's respiratory status.

In late spring 2019, facility leaders initiated a management review regarding the physician's management of the patient's care and allegations of unprofessional behavior. The physician who reviewed the patient's care recommended a pharmacist and an intensivist review the care. The VISN 12 Acting Chief Nursing Officer told the OIG that because an intensivist was considered a higher level of care than was provided by the facility, and therefore not considered a peer, that review was not completed. The Chief of Staff informed the OIG that a pharmacist serves on the facility peer review committee and that the pharmacist "would evaluate as a part of that committee."

The OIG found that the May 2018 FPPE was not completed and a new FPPE was initiated in June 2019. The Chief of Acute Care told the OIG that in June 2019, the admitting physician was reassigned from the inpatient medical unit to the Urgent Care Clinic. In September 2019, the Associate Chief of Staff for Medicine provided a written counseling to the admitting physician.

On October 2, 2019, the Chief of Staff reported a delay in completing the May 2019 FPPE due to the admitting physician's extended leave and a 90-day extension was granted. On November 6, 2019, the Chief of Acute Care reported the FPPE was completed and closed.

The OIG determined that facility leaders took appropriate actions regarding staff complaints about the admitting physician's behavior and performance during the patient's episode of care. The OIG found that the 2018 FPPE for the admitting physician was not completed. The OIG

<sup>&</sup>lt;sup>87</sup> VHA Handbook 1100.19, *Credentialing and Privileging*, October 15, 2012. When management determines a need for a privileged provider's performance to improve, a FPPE provides a structured opportunity for improvement. FPPE is an oversight process that "evaluates the privilege-specific competence of the practitioner who does not have documented evidence of competently performing the requested privileges of the facility."

determined that the incomplete FPPE was not identified until June 2019 likely due to staff's failure to ensure adequate FPPE tracking.

#### 2. Incomplete EHR Documentation

The OIG did not substantiate that facility staff failed to document information about the non-VHA emergency medical services provided to the patient. The OIG found that facility staff documented the non-VHA emergency medical services care in response to the lead paramedic's request. Further, review of the non-VHA emergency medical services' documentation revealed the patient's failed oxygen delivery prior to the emergency medical services arrival.

VHA requires a patient's EHR note contain "accurate, relevant, timely, and complete" information. 88 However, VHA does not provide guidance regarding documentation requirements or expectation for care provided to inpatients by non-VHA emergency medical services.

The recorder, responsible to document the patient's cardiopulmonary resuscitation event, told the OIG team that facility staff were not responsible to document the paramedics' actions but did so during this patient's care because the paramedics requested it. 89 In interviews with the OIG, the VISN 12, Deputy Chief Medical Officer and three facility leaders did not know or were uncertain if facility staff were required to document actions taken by the non-VHA emergency medical services during a cardiopulmonary resuscitation. Two other facility leaders told the OIG that the expectation would be for staff to document the care provided by the non-VHA emergency medical services. Further, the Associate Chief Nurse, Acute Care and Outpatient Care told the OIG that "it's common knowledge that whoever the recorder is documents" the events.

The OIG determined that staff documented non-VHA emergency medical services' intervention at the request of the lead paramedic's request. The OIG found that 2 of the 14 EHRs of facility inpatients (including the patient) who received emergency medical services from October 1, 2018, through September 30, 2020, included facility staff EHR documentation regarding actions of the emergency medical service. Through review of the non-VHA emergency medical services' documentation, the OIG substantiated the patient's failed oxygen delivery prior to the emergency medical services arrival. The OIG concluded that facility leaders and staff's lack of review of the non-VHA emergency medical services' documentation for this patient contributed to an incomplete understanding of the circumstances of this patient's care and condition. Given the additional identified information, the OIG recommends that facility leaders conduct a

<sup>88</sup> VHA Handbook 1907.01, Health Information Management and Health Records, March 19, 2015.

<sup>&</sup>lt;sup>89</sup> Facility Standard Operating Procedure ESC-03, *Emergency Services*, August 15, 2018. A staff member, referred to the recorder, is assigned to complete the Medical Emergency Worksheet, which includes the times and interventions of a medical emergency including a cardiopulmonary resuscitation event.

comprehensive review including all documentation and staff interviews to fully address any performance or systemic deficiencies.

## 3. Communication with the Patient's Family

The OIG substantiated that facility leaders and staff did not communicate with the patient's family upon initiation of the emergency detention. However, state law and facility policy do not require next of kin notification in the emergency detention process. The OIG concluded that facility staff generally adhered to state law and facility policy in the placement of the patient's emergency detention although the OIG found a deficiency in the facility policy related to the emergency detention process. The OIG also found that facility leaders did not conduct a timely institutional disclosure with the patient's family or in person and did not provide a relevant update, as required by VHA.

### **Involuntary Commitment and Emergency Detention**

Involuntary commitment is the process whereby individuals who are a danger to themselves or others may be temporarily detained and placed in a hospital setting for mental health evaluation and treatment. 93 Involuntary admissions at a VHA facility must be managed according to state law 94

#### Wisconsin Law and Facility Policy

Under Wisconsin law, an individual may be placed on an emergency detention by a law enforcement officer or attending provider (treatment director) if the individual meets certain criteria that includes mental illness, drug dependence, developmental disability, and is reasonably believed to be unable or unwilling to cooperate with voluntary treatment. The individual should be provided with specific rights that include but are not limited to the right to counsel and the right to contact immediate family. The

In Wisconsin, a law enforcement officer must complete a Statement of Emergency Detention by Law Enforcement Officer (Form ME-901), that includes a detailed emergency detention statement that the law enforcement officer has cause to believe that the patient "evidences

<sup>&</sup>lt;sup>90</sup> Wis. Stat. Ann. 8 51.15(10); Facility Policy PCSW-SW-17, *Emergency Detention, Probable Cause and Commitment Proceedings,* February 22, 2018.

<sup>&</sup>lt;sup>91</sup> Wisconsin Form ME-901, Statement of Emergency Detention by Law Enforcement Officer, May 2014; Facility Policy PCSW-SW-17.

<sup>&</sup>lt;sup>92</sup> VHA Directive 1004.08, *Disclosure of Adverse Events to Patients*, October 31, 2018.

<sup>93</sup> VHA Handbook 1160.06, Inpatient Mental Health Services, September 16, 2013.

<sup>94</sup> VHA Handbook 1160.06.

<sup>&</sup>lt;sup>95</sup> Wis. Stat. Ann. 851.15(10). A treatment director must be a fully licensed physician or licensed psychologist who actively assumes clinical responsibility for the emergency service.

<sup>&</sup>lt;sup>96</sup> Wis. Stat. Ann. 8 51.15(10).

behavior which constitutes a substantial probability of physical harm to self or to others."<sup>97</sup> Facility policy requires staff to contact the VA police for emergency detention of a patient admitted to a mental health or medicine unit, or a community living center.<sup>98</sup> The police are to collaborate with Northwest Connections to initiate an emergency detention.<sup>99</sup>

Consistent with Wisconsin law, facility policy also allows an attending provider (treatment director) to initiate emergency detention when an inpatient "threatens to leave and the attending provider considers that patient to be dangerous to himself/herself or others." Facility policy refers to this emergency detention process as a "Director's Hold." State law and facility policy require the staff member to complete a Form ME-902, Statement of Emergency Detention by Treatment Director. 102

Additionally, facility policy requires the staff member who completes the Forms ME-901 or ME-902 to (1) present the emergency detention statement, (2) read the patient his or her rights, and (3) obtain the patient's signature acknowledging receipt of the notice. <sup>103</sup>

The OIG found that facility policy erroneously advised the "treating provider, VA Police Officer, or medical center designee" to complete Form ME-901, which requires completion by a law enforcement officer. <sup>104</sup> As will be discussed below, the OIG found that a VA police officer completed the patient's Form ME-901, as required. <sup>105</sup> However, the OIG determined that this facility policy inaccuracy could result in an unauthorized staff member's completion of the Form ME-901.

### Patient's Emergency Detention

The patient was alert and oriented when presented to the Urgent Care Clinic on day 1. Upon admission to the inpatient medical unit, the patient signed the "Patient Rights and Responsibilities" and a form, "Designee for Patient Personal Property," that designated the recipient of the patient's personal property in the event of death during admission. <sup>106</sup> The patient's completed form included a family member's name and contact information, although

<sup>99</sup> Facility Policy PCSW-SW-17. Northwest Connections provides an Emergency Mental Health Services program to contracted counties in Wisconsin that is a "collaborative effort between those county partners, service providers and law enforcement" with the goal to provide the least restrictive response to crisis situations.

<sup>97</sup> Wisconsin Form ME-901; Facility Policy PCSW-SW-17.

<sup>98</sup> Facility Policy PCSW-SW-17.

<sup>&</sup>lt;sup>100</sup> Facility Policy PCSW-SW-17; Wis. Stat. Ann. 8 51.15(10).

<sup>&</sup>lt;sup>101</sup> Facility Policy PCSW-SW-17.

<sup>&</sup>lt;sup>102</sup> Facility Policy PCSW-SW-17; Wisconsin Form ME-902.

<sup>&</sup>lt;sup>103</sup> Facility Policy PCSW-SW-17.

<sup>&</sup>lt;sup>104</sup> Wisconsin Form ME-901; Facility Policy PCSW-SW-17.

<sup>&</sup>lt;sup>105</sup> Facility Policy PCSW-SW-17.

<sup>&</sup>lt;sup>106</sup> VA Form 10-10118, Designee for Patient Personal Property, November 2014.

the name itself appeared crossed out. The patient's EHR did not include an advance directive or durable power of attorney, but the family member was listed as next of kin. For "Family History," the admitting physician documented that the patient "doesn't talk to them." In an interview with the OIG, the Urgent Care Clinic nurse recalled asking the patient "was there anybody that we needed to call" and the patient "declined."

At approximately 6:00 p.m., the patient "had significant change in activity level with auditory/visual hallucinations" and then attempted to leave the facility. At 7:20 p.m., the admitting physician documented a plan to contact VA police to "work on holding [patient] here for [patient's] inability to care for self." In an interview with the OIG, the admitting physician confirmed that the police came to prevent the patient from leaving.

At 7:22 p.m., a VA police officer obtained approval from Northwest Connection staff for an emergency detention of the patient. A nursing assistant documented the patient's behavior over almost four hours starting at 7:32 p.m. that indicated the patient's loss of connection with reality. At approximately 8:00 p.m., the VA police officer completed Form ME-901 to place the patient on emergency detention and documented that the rights were read to the patient and initialed each of the rights, including the right to contact immediate family or an attorney.

Approximately five hours following the initiation of the emergency detention, at approximately 1:20 a.m. on day 2, the patient experienced a cardiopulmonary resuscitation event and did not regain consciousness. The consulting inpatient physician called the patient's family and the patient was transferred to a non-VHA facility.

The OIG found that facility staff followed Wisconsin law and facility policy requirements to initiate the patient's emergency detention. The OIG found that although the police officer provided the patient with a list of patient rights, it is unlikely that the patient comprehended the information in a meaningful way and therefore could not pursue action, such as family contact or legal counsel. Given the patient's condition, the OIG would have expected facility staff to contact family sooner.

#### **Deficiencies in the Institutional Disclosure Process**

The OIG found that facility leaders did not conduct an institutional disclosure with the patient's family timely or in person and did not provide a relevant update, as required by VHA.<sup>108</sup>

An adverse event may warrant institutional disclosure, which is a formal process for facility leaders and clinicians to inform the patient or patient's personal representative that an adverse event occurred and includes specific information about the patient's rights and recourse. <sup>109</sup> VHA

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<sup>&</sup>lt;sup>107</sup> Wisconsin Form ME-901; Facility Policy PCSW-SW-17.

<sup>&</sup>lt;sup>108</sup> VHA Directive 1004.08.

<sup>&</sup>lt;sup>109</sup> VHA Directive 1004.08. Adverse events are "untoward diagnostic or therapeutic incidents, iatrogenic injuries, or other occurrences of harm or potential harm directly associated with care or services delivered by VA providers."

requires institutional disclosures occur in person, if possible, and occur "as soon as reasonably possible and generally within 72 hours." Facility staff must document the reason if the institutional disclosure cannot occur in person. The disclosure of an adverse event may not always be "a singular event, but may involve a series of conversations," particularly if additional information is learned regarding the event. 112

The Chief of Staff informed the OIG that the institutional disclosure was not conducted earlier because they "[were] very unclear at the start of [the patient's] care" "exactly what [the patient's] health status was going to be" and the need to consult with the VA Office of General Counsel. On day 14, the Director, Performance Improvement, after consultation with the then Facility Director, advised the facility's Chief of Staff to conduct an institutional disclosure and consult with the Office of General Counsel prior to "discussing with the family." On day 27 the Chief of Staff emailed a VA Office of General Counsel attorney to follow up on a "previous discussion" regarding an institutional disclosure given that the patient was not expected to regain consciousness and was transferred for end-of-life care.

The Chief of Staff and two other facility leaders conducted an institutional disclosure with the patient's family by telephone on day 38, five days after the patient's death and 11 days after consultation with the Office of General Counsel. The Chief of Staff documented the following "Discussion points of the adverse event:"

- Admission "for presumed alcohol withdrawal upon [patient's] declining transfer" to another facility
- "Progressive confusion and agitation over the course of the evening"
- "Several ambulance companies declined dispatch"
- "Cardio-pulmonary arrest"
- "Ground ambulance cancelled at that point for airlift to [non-VHA facility]"

Given that the disclosure was focused on the patient's care at the facility days 1 and 2, the OIG would have expected facility leaders to complete an institutional disclosure with the patient's family earlier.

The Chief of Staff failed to document the reason for completing the disclosure by telephone and told the OIG that a telephonic institutional disclosure was made at the direction of the then-Acting Director, Performance Improvement, to the Chief of Staff's administrative staff. In an

<sup>111</sup> VHA Directive 1004.08.

<sup>&</sup>lt;sup>110</sup> VHA Directive 1004.08.

<sup>&</sup>lt;sup>112</sup> VHA Directive 1004.08.

<sup>&</sup>lt;sup>113</sup> The VISN Director reported having been the Facility Director until assuming VISN Acting Director responsibilities on April 29, 2019, and being appointed VISN Director in March 2020.

interview with the OIG, the Director, Performance Improvement, recalled that the family requested the institutional disclosure occur by telephone. However, the patient's family reported to the OIG that an in person meeting was not offered.

Institutional disclosures are intended to be ongoing, allowing for communication of new information about the incident as it is obtained.<sup>114</sup> The Chief of Staff told the OIG that changes were made to the CIWA protocol as a result of a review of the patient's care. However, facility leaders did not inform the patient's family regarding changes made to the CIWA protocol subsequent to the patient's care.

<sup>&</sup>lt;sup>114</sup> VHA Directive 1004.08.

### **Conclusion**

The OIG did not substantiate staff over-sedated the patient. To the contrary, the OIG found that the admitting and consulting inpatient physicians did not prescribe an adequate benzodiazepine medication regimen to address the patient's delirium tremens effectively. Early and adequate benzodiazepine dosing may have halted progression of the patient's alcohol withdrawal. Further, the physicians' failure to treat the delirium tremens with adequate benzodiazepine dosing, review the patient's abnormal electrocardiogram prior to haloperidol administration, or transfer the patient to a higher level of care earlier likely contributed to the patient's respiratory suppression and cardiac arrest. The OIG acknowledges that the patient's deterioration could be attributed to a broad diagnostic differential. However, based on the patient's documented history and clinical presentation as discussed above, the OIG believes the most likely cause of the patient's clinical deterioration was hypoxemia caused by cardiac arrest secondary to haloperidol administration.

On day 1, the patient had an electrocardiogram for tachycardia that identified abnormalities that included a prolonged QTc interval that facility staff did not document. Additionally, the OIG found providers did not review the patient's abnormal electrocardiogram or monitor the patient's cardiac activity prior to and after the administration of haloperidol, a medication that can affect cardiac rhythm. Further, an internal review of the patient's care identified staff's failure to document the patient's electrocardiogram results; however, facility leaders did not identify corrective actions related to this deficiency. Facility staff's failure to review, document, and monitor the patient's electrocardiogram to assess cardiac risk before prescribing haloperidol may have contributed to the patient's respiratory suppression and cardiac arrest.

The OIG substantiated that the lead paramedic observed and documented in the emergency medical services record that the patient's flow of oxygen was not active at the time the emergency medical services participated in the patient's cardiopulmonary resuscitation. Facility staff involved in the patient's cardiopulmonary resuscitation were unable to recall whether the patient was receiving oxygen. The OIG concluded that the inclusion of emergency medical services' documentation in facility leaders' reviews may identify systemic root causes and performance deficiencies in patient care. The OIG found that facility leaders and staff reported lack of knowledge about the patient's failed oxygen delivery and the lead paramedic's documentation. The ultimate cause of the patient's presumed anoxic brain injury was undetermined but likely due to metabolic, toxic, or hypoxic ischemic encephalopathy. 118

<sup>&</sup>lt;sup>115</sup> Grover, "Delirium Tremens."

<sup>116</sup> Grover, "Delirium Tremens."

<sup>117</sup> Grover, "Delirium Tremens;" Jesse, "Alcohol withdrawal syndrome."

<sup>&</sup>lt;sup>118</sup> An autopsy was not performed and therefore the cause of encephalopathy was unable to be clarified.

During its review of actions staff took during the patient's cardiopulmonary arrest, the OIG found that four inpatient medical unit providers including the admitting physician and inpatient consulting physician did not have current OOORAM training at the time of the patient's care. The OIG was unable to determine if the consulting inpatient physician's lapse in OOORAM training contributed to the patient's failed oxygen delivery because facility leaders were not aware of the emergency medical services documentation and therefore the cause for the oxygen flow cessation was not evaluated. On October 15, 2020, the Chief of Staff charged a workgroup to review the VHA OOORAM directive "to ensure that Tomah VAMC meets all standards and has processes in place." In January 2021, the Chief of Staff expressed the hope of having the changes in place by the end of February 2021.

Nursing staff failed to complete all required CIWAs which may have contributed to an incomplete understanding of the patient's alcohol withdrawal progression and an increased risk of an adverse clinical outcome.

The OIG determined that the inpatient consulting physician improperly ordered the patient's restraints and nursing staff failed to obtain the patient's full vital signs as required by facility policy. The OIG was unable to determine if nursing staff or VA police applied four-point restraints to the patient because of inconsistent documentation and statements to the OIG. The OIG also concluded that nursing staff's failure to obtain full vital signs as required likely resulted in a diminished understanding of the patient's subsequent respiratory deterioration.

The OIG found that inpatient medical unit nurses did not receive restraint training from October 1, 2018, through July 2019. The OIG concluded that the lack of restraint training likely contributed to the nurses' failures to (1) verify that the physician's order included the specific type of restraint and (2) obtain full vital signs as required may have prevented staff from recognizing the patient's subsequent respiratory deterioration. Given that restraints are rarely used on the inpatient medical unit, the OIG would expect nursing staff to receive ongoing training to promote competency and currency.

The OIG found that facility staff initiated the patient's transfer to a higher level of care after the patient's condition deteriorated and necessitated emergency medical services. The OIG would have expected staff to pursue transfer to a higher level of care upon determination of the need for an emergency detention and prior to the patient's rapid deterioration on the day of admission.

After the patient's discharge from the inpatient medical unit, the Chief of Staff received staff complaints about the admitting physician's lack of involvement in the management of the patient including prolonged response time to concerns about the patient's respiratory status. The OIG determined that facility leaders took appropriate actions regarding staff complaints about the

<sup>&</sup>lt;sup>119</sup> The facility's Director, Performance Improvement, provided the OIG with documents containing the physicians' OOORAM training information.

<sup>&</sup>lt;sup>120</sup> Facility Policy PCS-03.

admitting physician's behavior and performance during the patient's episode of care. The OIG found that a facility leader failed to complete an FPPE for the admitting physician in 2018. The OIG determined that the incomplete FPPE was not identified until June 2019 likely due to facility leaders' failure to ensure adequate FPPE tracking.

The OIG did not substantiate that facility staff failed to document information about the non-VHA emergency medical services provided to the patient. The OIG found that facility staff documented the non-VHA emergency medical services care in response to the lead paramedic's request.

The OIG substantiated that facility leaders and staff did not communicate with the patient's family upon initiation of the emergency detention. However, state law and facility policy do not require next of kin notification in the emergency detention process. Although a police officer completed the form as required by emergency detention form (ME-901), the OIG found that facility policy erroneously advised the "treating provider, VA Police Officer, or medical center designee" may complete an ME-901. 122

Institutional disclosures are intended to be ongoing, allowing for communication of new information about the incident as it is obtained. The OIG found that facility leaders did not conduct an institutional disclosure with the patient's family timely or in person and did not provide a relevant update, as required by VHA. 124

Wis. Stat. Ann. 8 51.15(10); Facility Policy PCSW-SW-17.

<sup>&</sup>lt;sup>122</sup> Wisconsin Form ME-901; Facility Policy PCSW-SW-17.

<sup>&</sup>lt;sup>123</sup> VHA Directive 1004.08.

<sup>&</sup>lt;sup>124</sup> VHA Directive 1004.08.

### Recommendations 1–10

- 1. The Tomah VA Medical Center Director ensures that providers receive education regarding the management of alcohol withdrawal and delirium tremens, and monitors compliance.
- 2. The Tomah VA Medical Center Director makes certain providers consider patients' underlying cardiac risk prior to the order of haloperidol.
- 3. The Tomah VA Medical Center Director conducts a comprehensive review of the patient's cardiopulmonary resuscitation event to determine potential causes of failed oxygen delivery including systemic root causes and performance deficiencies, and consults with the appropriate Human Resources and General Counsel Offices to determine whether any personnel action is warranted and takes action.
- 4. The Tomah VA Medical Center Director implements actions recommended by the Out of Operating Room Airway Management workgroup, and monitors compliance.
- 5. The Tomah VA Medical Center Director evaluates staff adherence to the Tomah VA Medical Center Policy MS-25, Clinical Institute Withdrawal Assessment for Alcohol, revised (CIWA-Ar) Protocol and the Standard Operating Procedure for Nursing Procedure, Symptom Triggered CIWA-Ar Protocol, and takes action to ensure compliance.
- 6. The Tomah VA Medical Center Director ensures inpatient medical unit providers and nursing staff compliance with patient restraint management, as required by to the Tomah VA Medical Center Policy, PCS-03, *Restraint and Seclusion Use*.
- 7. The Tomah VA Medical Center Director monitors provider compliance with Tomah VA Medical Center *Policy MS-06, Admission Criteria for Acute Medicine Unit.*
- 8. The Tomah VA Medical Center Director consults with the Office of General Counsel to ensure the Tomah VA Medical Center Policy *PCS-SW-17 Emergency Detention* is consistent with Wisconsin law.
- 9. The Tomah VA Medical Center Director strengthens processes for staff to consider next of kin or family notification in the emergency detention of patients who may not comprehend their legal rights.
- 10. The Tomah VA Medical Center Director ensures compliance with institutional disclosure procedures, as required by the Veterans Health Administration.

## **Appendix A: VISN Director Memorandum**

#### **Department of Veterans Affairs Memorandum**

Date: August 2, 2021

From: Director, VA Great Lakes Health Care System (10N12)

Subj: Healthcare Inspection—Mismanagement of a Patient at the Tomah VA Medical Center in

Wisconsin

To: Director, Mental Health Programs, Office of Healthcare Inspections (54MH00)
Director, GAO/OIG Accountability Liaison Office (VHA 10BGOAL Action)

- Thank you for the opportunity to review the Draft Report: Healthcare Inspection— Mismanagement of a Patient at the Tomah VA Medical Center in Wisconsin. I offer my sincere condolences to the family of this Veteran. The loss of this Veteran has significantly impacted our staff as well and reinforced our commitment to learning from this experience.
- 2. As the former facility director at Tomah VAMC, I understand the lengths providers went through to gain this Veteran's trust over the many years they provided [the Veteran]care. Urgent Care and medical providers understood that a higher level of care was most appropriate for treatment of this Veteran early on in [the Veteran's] care and despite multiple attempts, staff were unable to influence [the Veteran] in receiving care at any other facility besides Tomah. At that point, there was a very tough decision to make. Instead of watching the Veteran leave the facility against medical advice, the Tomah staff respected [the Veteran's] wishes to stay at the Tomah VAMC where[the Veteran] felt most comfortable despite the difficult situation it put them in. It is often very hard to do the right thing, but the staff strongly felt the need to continue to try and help this Veteran to the best of their ability in a hospital setting. This situation was suboptimal but based upon the circumstances, was considered in the best interest of the Veteran at the time.
- 3. It is unfortunate that we do not know the full impact of this Veteran's entire care journey outside of the Tomah VAMC since most of the care received by this Veteran did occur external to Tomah VAMC. Focusing only on the short time the Veteran was at Tomah VAMC does not reflect the complex and lengthy medical care this Veteran was provided.
- 4. Like all healthcare facilities, there is room for improvement in order to provide safe, quality care for positive patient outcomes. I will ensure that the recommendations presented in this report are completed and sustained. As with the other VISN 12 facilities, Tomah VA is committed to providing excellent care and continues to focus on process improvement. They were able to overcome opioid issues with a 55% reduction in opioids prescribed over the past 4 years. Tomah VA is the flagship for VISN 12 for Whole Health. The trust score of Veterans receiving care at both Tomah VA and Madison VA has placed them in the top 10 out of 140 VAMCs across the enterprise.
- 5. I appreciate the opportunity to respond and concur with the Tomah VA Medical Center Director.

6.	If you have any questions, please feel free to reach out to the VISN 12 Quality Management Officer
	and/or the Tomah Performance Improvement Director.

(Original signed by:)

Victoria P. Brahm, RN, MSN, VHA-CM Network Director

## **Appendix B: Facility Director Memorandum**

#### **Department of Veterans Affairs Memorandum**

Date: August 2, 2021

From: Director, Tomah VA Medical Center (676/00)

Subj: Healthcare Inspection—Mismanagement of a Patient at the Tomah VA Medical Center in

Wisconsin

To: Director, VA Great Lakes Health Care System (10N12)

1. Thank you for the opportunity to review the Office of the Inspector General (OIG) draft report "Mismanagement of a Patient at the Tomah VA Medical Center in Wisconsin."

- 2. We extend our condolences to the family and friends of this patient and are deeply saddened by this loss. We fully expected a positive recovery following care at the Tomah VAMC and grieve for this patient whom we had cared for over the previous 11 years. Our staff had developed a relationship with this patient, and we appreciate the trust placed in our staff to provide care. The loss of this patient impacted our staff and reinforced our commitment to learning from this experience. As health care professionals, we find it difficult to accept the loss, especially as our staff were heavily invested in providing quality care during this complex admission.
- 3. The urgent care and medical providers were right to help this patient. The staff understood [the patient's] healthcare needs and tried early in this episode of care to convince the patient to transfer to a hospital that had all the services required. When the patient insisted on staying, they respected the right to refuse transfer and upheld their professional and ethical obligation to provide the patient with all the medical care that they could. Tomah VAMC is a Level 3 complexity facility without an emergency department or intensive care unit; and our staff cared for this patient to the best of their ability. Despite widespread prior communication to Veterans about the differences between an emergency department and urgent care, staff were still unable to convince this patient to seek a higher level of care. I am proud of the healthcare staff at Tomah who compassionately treated this patient even though the healthcare needs were more complex.
- 4. We would like to note that the patient's entire course of care was not discussed in the report; in fact, three different healthcare facilities provided care for this patient for [a 32-day period in spring 2019]. The report addressed the first approximately 14 hours of care and, with the exception of citing the normal MRI at a local health system, omitted the health care events that occurred during two helicopter transfers, the time at the local health system and at another VAMC. Without a comprehensive review of this patient's entire course of care, we do not know the effects of care received at the other facilities.
- 5. Tomah VAMC continues its commitment to providing high reliability health care and upholding Veteran trust. The OIG has reviewed the Tomah VAMC in two Comprehensive Healthcare Inspection Program (CHIP) reviews since 2015. In both reviews, the Tomah VAMC did very well overall, with two recommendations in 2017 and four recommendations in 2020. In addition, the February 2020 Commission on Accreditation of Rehabilitation Facilities International (CARF) Accreditation Report for the Tomah VAMC, which oversees substance abuse care, praised the medical center for its provision of 'excellent' mental health services to Veterans.
- 6. Since 2015, the medical center has made a positive impact in patient care through, among others, the adoption of a whole health system of care, appropriate reductions in opioid prescribing, and

- improvements in the acute care standardized mortality ratio. As a result of these efforts, Veteran trust of the Tomah VAMC was 94.1% (time period 5/24/2021-6/23/2021, in the top 10 nationally), indicating Veterans are satisfied with the care they receive and prefer to stay within our system.
- 7. In addition to the acute medical unit, where this patient received care, the facility operates an 11-bed acute mental health unit and an 80-bed residential rehabilitation treatment program (RRTP) unit. The facility has an intensive outpatient treatment program for substance use disorder. In FY 2021, the RRTP treated 114 unique patients for substance use disorders, with most of these patients being treated for alcohol use disorder. In addition, the acute medical unit had 113 admissions for alcohol-related diagnoses in FY 2021.
- 8. We thank the OIG team for their recommendations which identified areas for improvement. We have been actively working to improve care for Veterans with alcohol withdrawal since the completion of our internal reviews. We concur with recommendations 1-2 and 4-9. We concur in principle with recommendations 3 and 10. The leadership team at the Tomah VAMC is committed to implementing corrective actions and will diligently pursue all measures to ensure safe, high-quality care for the Veterans that we serve.

(Original signed by:)
Karen Long, MS

### **OIG Comments to Responses from the VISN and Facility Directors**

The purpose of this healthcare inspection was to review allegations related to the care provided to a patient at the facility and evaluate the management of the patient's condition. While the patient was treated at other hospitals after the facility, this healthcare inspection was focused on the care the patient received at the facility. The OIG team conducted a thorough inspection and wrote an accurate report that identified factual deficiencies in care at the facility. It is of significant concern to the OIG that the patient was admitted for treatment of potentially severe alcohol withdrawal symptoms despite the facility staff's limited resources and capability to provide care for this condition. The facility did not have the capability to treat delirium tremens that requires a higher level of care such as specialized inpatient or intensive care unit settings. Further, the limitations of facility staff's out of operating room airway management capabilities necessitated emergency medical services to arrive on site to perform an endotracheal intubation on the patient. The OIG hopes that facility leaders thoroughly address the care deficiencies identified including facility staff's (1) failure to review the patient's electrocardiogram; (2) inadequate treatment and assessment of alcohol withdrawal; (3) administration of haloperidol in spite of the patient's prolonged QTc interval; (4) failed oxygen delivery; (5) improper restraint management and inadequate training; and (6) delayed transfer of the patient to a higher level of care. Additionally, facility leaders were not aware of the failure in oxygen delivery to the patient and did not review non-VHA emergency medical services documentation. The exclusion of the emergency medical services' documentation in reviews may result in the omission of significant information, such as failed oxygen delivery for a patient. The OIG concluded that the

adequate management of the patient's alcohol withdrawal and the patient's cardiac arrest a e facility contributed to the patient's poor outcome and subsequent death.		

## **Facility Director Response**

#### **Recommendation 1**

The Tomah VA Medical Center Director ensures that providers receive education regarding the management of alcohol withdrawal and delirium tremens, and monitors compliance.

Concur.

Target date for completion: July 31, 2021; all training completed by July 1, 2021, will report on compliance through Leadership Quality Council in July 2021.

#### **Director Comments**

The Tomah VA Medical Center Director will ensure that providers receive education regarding the management of alcohol withdrawal and delirium tremens and will monitor compliance.

Initial education to providers was completed January 7, 2020. 13/13 (100%) of acute medical and urgent care providers received education. A Talent Management System (TMS) module was developed for future training (item # 4570187). Re-education was completed by July 1, 2021. 16/16 (100%) of acute medical and urgent care providers received education. The Chief of Staff will report to Leadership Quality Council where the Medical Center Director is the Chair. The Medical Center Director will ensure the number of providers current with education regarding the management of alcohol withdrawal and delirium tremens (numerator) equals ninety percent or greater as compared to the number of total providers assigned said education (denominator).

#### **OIG Comment**

The OIG considers this recommendation open to allow time for the submission of documentation to support closure.

#### **Recommendation 2**

The Tomah VA Medical Center Director makes certain providers consider patients' underlying cardiac risk prior to the order of haloperidol.

Concur.

Target date for completion: Completed June 8, 2021

#### **Director Comments**

To immediately address provider consideration of patients' underlying cardiac risk, the Chief of Pharmacy was directed to modify the ordering menu for antipsychotic medications to create a clinical decision support tool to help providers evaluate cardiovascular risk before ordering antipsychotics. The modified ordering menu has been implemented.

#### **OIG Comment**

The OIG considers this recommendation open to allow time for the submission of documentation to support closure.

#### **Recommendation 3**

The Tomah VA Medical Center Director conducts a comprehensive review of the patient's cardiopulmonary resuscitation event to determine potential causes of failed oxygen delivery including systemic root causes and performance deficiencies, and consults with the appropriate Human Resources and General Counsel Offices to determine whether any personnel action is warranted and takes action.

Concur in principle.

Target date for completion: August 31, 2021

#### **Director Comments**

Following this event, the Tomah VA Medical Center Director directed the Chief of Staff to review the process utilized by the Emergency Services Committee to review cardiopulmonary resuscitation events. The Emergency Services Committee has implemented changes to their review process. In addition, a Root Cause Analysis (RCA) and reporting of event as a Sentinel Event to Joint Commission were conducted on this event. Peer reviews were completed, reviewed by Peer Review Committee, and used for quality improvement.

The Tomah VA Medical Center continues to review this case to identify any further opportunities for improvement. The OIG based their conclusion that this patient's oxygen was not operational on documentation from an outside source. Of note, the information was not brought to the attention of VA personnel neither during nor after the event. Documentation from the VA medical record shows that VA staff were monitoring oxygen status of the patient up to the time of the witnessed cardiac arrest, and at that time, CPR was initiated immediately. A supraglottic device had been placed by VA staff prior to the arrival of the outside ambulance company, and outside provider documentation showed that a bag valve mask was in use upon their arrival. The Medical Center Director has launched a management review specifically targeted at the alleged failure of oxygen delivery and, upon conclusion, will review for and direct appropriate action.

#### **Recommendation 4**

The Tomah VA Medical Center Director implements actions recommended by the Out of Operating Room Airway Management workgroup, and monitors compliance.

Concur.

Target date for completion: July 31, 2021

#### **Director Comments**

Upon direction from the Tomah VA Medical Center Director, the Chief of Staff chartered a Rapid Process Improvement Workgroup-- Out of Operating Room Airway Management (OOORAM) in October 2020. Various items that resulted from that workgroup are already completed to include revision of local policy, designation of OOORAM providers, assignment of appropriate TMS trainings, evaluation of OOORAM competency, inclusion of OOORAM compliance in OPPE, and development of a process for obtaining ambulance run sheets from the local ambulance service provider.

As of June 7, 2021, 20/20 (100% of identified Level 1 OOORAM providers have completed both the TMS and competency portions of training. The Chief of Staff oversees provider education and will report to Leadership Quality Council where the Medical Center Director is the Chair. The Medical Center Director will ensure the number of providers current with education and competency regarding Level 1 OOORAM (numerator) equals ninety percent or greater as compared to the number of total providers assigned said education and competency (denominator).

#### **OIG Comment**

The OIG considers this recommendation open to allow time for the submission of documentation to support closure.

#### **Recommendation 5**

The Tomah VA Medical Center Director evaluates staff adherence to the Tomah VA Medical Center Policy MS-25, *Clinical Institute Withdrawal Assessment for Alcohol, revised (CIWA-Ar) Protocol* and the Standard Operating Procedure for Nursing Procedure, Symptom Triggered CIWA-Ar Protocol and takes action to ensure compliance.

Concur.

Target date for completion: December 31, 2021

#### **Director Comments**

The Tomah VA Medical Center Director has directed the Associate Director for Patient Care Services and the Chief of Staff to evaluate staff adherence to MS-25 *Clinical Institute Withdrawal Assessment for Alcohol, revised (CIWA-Ar) Protocol* and the Standard Operating Procedure for Nursing Procedure, Symptom Triggered CIWA-Ar Protocol.

Compliance is demonstrated as the number of assessments and interventions documented per policy in the medical records of Veterans who were treated for alcohol detoxification in the acute medical unit (numerator) equaling ninety percent or greater as compared to the total number of

expected assessments and interventions per policy in the medical records of Veterans treated for alcohol detoxification in the acute medical unit (denominator).

The Associate Director for Patient Care Services and Chief of Staff will report monthly through the Leadership Quality Council. As the Chair, the Medical Center Director will ensure continued reporting until six consecutive months of compliance has been demonstrated.

#### **Recommendation 6**

The Tomah VA Medical Center Director ensures inpatient medical unit providers and nursing staff compliance with patient restraint management, as required by the Tomah VA Medical Center Policy, PCS-03, *Restraint and Seclusion Use*.

Concur.

Target date for completion: February 28, 2022

#### **Director Comments**

The Tomah VA Medical Center Director ensures staff compliance with patient restraint management as required per Medical Center Policy, PCS-03, *Restraint and Seclusion Use*, which is now Medical Center Policy MH-36, *Restraint and Seclusion Use*.

There have been no restraint events on the acute medical unit since December 2020. The Chief of Staff will report compliance through Leadership Quality Council as the number of restraint episodes on the acute medical unit demonstrating adherence to PCS-03/MH-36 *Restraint and Seclusion* (numerator) equals ninety percent or greater as compared to the total number of restraint episodes on the acute medical unit (denominator). As the Chair, the Medical Center Director will ensure continued reporting until six months of consecutive compliance has been reached or until six consecutive months of monitoring have occurred with no events meeting criteria to be considered in the denominator.

#### **Recommendation 7**

The Tomah VA Medical Center Director monitors provider compliance with Tomah VA Medical Center Policy MS-06, *Admission Criteria for Acute Medicine Unit*.

Concur.

Target date for completion: January 31, 2022

#### **Director Comments**

The Tomah VA Medical Center Director monitors compliance with Medical Center Policy MS-06, *Admission Criteria for Acute Medicine Unit*, through active monitoring of all urgent care visits and admissions to acute medicine. The Chief of Staff will report compliance monthly

through the Leadership Quality Council. Evidence of compliance will be demonstrated as the number of refusals for transfer of a higher level of care documenting discussion with the Chief of Staff or Associate Chief of Staff for Medicine (numerator) equals ninety percent or greater as compared to the total number of refusals for transfer to a higher level of care (denominator). As the Chair, the Medical Center Director will ensure continued reporting until six months of consecutive compliance has been reached or until six consecutive months of monitoring have occurred with no events meeting criteria to be considered in the denominator.

#### **Recommendation 8**

The Tomah VA Medical Center Director consults with the Office of General Counsel to ensure the Tomah VA Medical Center Policy PCS-SW-17, *Emergency Detention*, is consistent with Wisconsin law.

Concur.

Target date for completion: August 31, 2021

#### **Director Comments**

The Tomah VA Medical Center Director ensures policy PCS-SW-17, *Emergency Detention*, is consistent with Wisconsin Law. The Office of General Counsel was consulted, has reviewed this policy, and has provided recommendations for improvement. Upon the direction of the Medical Center Director, the Chief of Social Work has reviewed the recommendations and will revise PCS-SW-17, *Emergency Detention*. Closure will be requested once the final draft has been published.

#### **Recommendation 9**

The Tomah VA Medical Center Director strengthens processes for staff to consider next of kin or family notification in the emergency detention of patients who may not comprehend their legal rights.

Concur.

Target date for completion: August 31, 2021

#### **Director Comments**

The Tomah VA Medical Center Director has directed the Chief of Social Work to evaluate the process for staff to consider next of kin or family notification in the emergency detention of a patient who may not comprehend their legal rights. The Chief of Social Work will review and revise PCS-SW-17, *Emergency Detention*. Closure will be requested once the final draft has been published.

#### **Recommendation 10**

The Tomah VA Medical Center Director ensures compliance with institutional disclosure procedures, as required by the Veterans Health Administration.

Concur in principle.

Target date for completion: Completed May 27, 2021

#### **Director Comments**

The Tomah VA Medical Center Director has reviewed VHA Directive 1004.08, *Disclosure of Adverse Events to Patients (published October 31, 2018)*, and concurs in principle with the findings regarding the institutional disclosure contained in this report. Of note, according to paragraph 9.a.2. on page 17 of the directive, "Institutional disclosure must be initiated as soon as reasonably possible and *generally* (italics added for emphasis) within 72 hours". The same paragraph also states that "disclosure may be delayed allowing for a thorough investigation of the facts provided." In addition, paragraph 9.d on page 17-18 for the directive states that "Institutional disclosure *ideally* (italics added for emphasis) needs to be made face-to-face with the patient or patient's personal representative". Lastly, the directive does not mandate ongoing updates to the patient/representative, especially in instances of facts uncovered pursuant to USC 5705 quality assurance activities. In this instance, the reviews that occurred were 5705 protected and thus not able to be released to the patient's family.

Events like this patient's case prompt us to re-examine our processes to ensure that they are robust and consistent with VHA and local guidance. The medical center has revised and enhanced the templated note that it uses for institutional disclosure. This template will guide the discussion to ensure all elements of the Directive are covered.

#### **OIG Comment**

The OIG considers this recommendation open to allow time for the submission of documentation to support closure.

## **Appendix C: Letter From Office of General Counsel**



General Counsel Washington, DC 20420

August 23, 2021

The Honorable Michael J. Missal Inspector General Department of Veterans Affairs 810 Vermont Ave, NW Washington, DC 20420

Dear Mr. Missal,

I write to you with questions and concerns about the draft report issued by your office entitled Mismanagement of a Patient at the Tomah VA Medical Center in Wisconsin. I have reviewed the report as well as the response to the draft dated August 2, 2021 from the Network Director.

First let me be unequivocal in emphasizing that the Secretary and I value and support the independence of your office. As the Secretary has said on several occasions, he believes the OIG plays a central role in identifying issues that need to be addressed and in improving the functioning of the Department. This letter in no way is meant to undermine that independence or to interfere with the important work that the OIG performs. The OIG's work in helping understand why as well as how mistakes have been made is an important part of ensuring VHA can continue its improvement as a high reliability organization.

I write now to bring to your attention some aspects of the referenced Draft Report that I would ask you to review to ensure we have the best opportunity to learn from this tragic episode so as to ensure something like it does not happen again. We feel strongly that we owe that to the Veterans we serve, and especially to the families of the nation's Veterans.

Our principal concern about the Draft Report is the implication that the tragic death of the patient was in some way "caused" or hastened by [the patient's] treatment at Tomah. Related to and central to that concern is the complete lack of information or analysis of what happened to the patient in the 30 days after [the patient] left the Tomah facility until [the patient] tragically passed. The Draft Report is sprinkled with words and phrases such as "likely" or "may have caused" conditions and complications that, the Report implies, led to [the patient's] death. We do not believe that the Tomah facility's care can in any way, even by implication, be associated with the patient's death, and it is important to understand what occurred in the subsequent 30 days

2.

The Honorable Michael J. Missal Mismanagement of a Patient at the Tomah VA Medical Center

in several other medical facilities where [the patient] was apparently treated by many other medical professionals.

Further concerning is the lack of information or recognition in the Draft Report about the excellent care the Tomah facility provided to the patient for eleven years prior to these tragic events in [spring] 2019; information about how the Tomah staff did its best for the twelve hours after the patient entered the facility on [a day in spring] 2019; and any discussion about how the Tomah staff repeatedly tried without success to convince the patient to allow transfer to another more appropriate facility.

The Tomah staff, and the rest of health care employees of VHA, are dedicated to helping Veterans 24 hours per day. Under these circumstances, we think it is unfair to leave the implication that the patient's treatment at the Tomah facility contributed to [the patient's] death. We would ask you to review the Draft with these points in mind and perhaps add language to make clear, if appropriate, that the OIG is not implying any causal relationship between the Tomah facility's care and the tragic events that occurred over a month later.

Again, we value the contribution made every day by the OIG and the willingness to have open and frank discussions that you especially have championed. We stand ready to answer questions or discuss any aspect of this letter.

Sincerely,

#### **OIG Comments to the Letter from the Office of General Counsel**

The General Counsel's response reiterates some of the points already addressed in the OIG's response to both the VISN and facility leaders. This healthcare inspection was focused on reviewing allegations of inadequate care during the patient's spring 2019 inpatient admission at the facility. The patient's history of outpatient care in the years prior was not relevant to that evaluation. Similarly, the patient's care at other facilities does not weigh into the assessment of that episode of care, for which the OIG identified serious deficiencies and recommended corrective action. VA in its response has concurred with those recommendations.

The General Counsel's letter takes issue with the OIG's conclusion that the most likely cause of the patient's clinical deterioration was hypoxemia caused by cardiac arrest secondary to haloperidol administration. The letter argues that this conclusion is speculative and fails to consider the patient's treatment at other facilities in the following 30 days. This argument ignores the significant evidence the OIG developed concerning the patient's care at Tomah, including evidence from a responding paramedic regarding a lack of oxygen administration to the patient during a cardio-pulmonary emergency. The CIGIE Quality Standards for Inspection and Evaluation require the OIG to "analyze and interpret the evidence to determine whether it sufficiently and appropriately supports inspection findings and provides a reasonable basis for conclusions."

The evidence the OIG reviewed supports the conclusions documented in the report. The OIG acknowledged that the ultimate cause of the patient's brain injury was undetermined; however, the medical records and interviews with the patient's facility providers provided ample evidence to support a medical opinion as to contributing factors to the patient's deteriorating condition and ultimate death. These included facility staff's inadequate treatment of alcohol withdrawal; failure to review the patient's electrocardiogram; administration of haloperidol when contraindicated; failed oxygen delivery; and delayed transfer of the patient to a higher level of care.

Tomah staff were afforded ample opportunities to provide information to the OIG to explain their treatment decisions, but did not provide adequate evidence to contradict the OIG's findings or to support their decision not to initiate the transfer of the patient to a higher level of care facility immediately after the patient's CIWA score was assessed at a 15. However well-intentioned, the patient was admitted for treatment of potentially severe alcohol withdrawal symptoms despite the facility staff's limited resources and capability to provide appropriate care. The inability of facility staff to perform an endotracheal intubation of the patient after the cardiac arrest is itself evidence of this misjudgment.

The OIG recognizes and applauds the dedication of VHA staff in caring for veterans. However, the role of the OIG is to assess that care, identify areas of concern, and make recommendations for improvements. When the OIG determines that the care provided could be improved, it will

clearly state that in its reports. The OIG hopes that facility leaders thoroughly address deficiencies identified in the report.	the care

## **Glossary**

To go back, press "alt" and "left arrow" keys.

adverse event. A harmful occurrence directly associated with facility care or services. 125

against medical advice. A term used when a patient chooses to leave a hospital contrary to the recommendation of the physician or treating provider. 126

alcohol use disorder. A pattern of alcohol use within the previous year that leads to significant impairment or distress characterized by drinking larger quantities or for longer periods of time than intended, craving for alcohol, ongoing alcohol use despite recurring problems at home, socially or at work, needing increasing amounts of alcohol to be intoxicated, or experiencing symptoms of alcohol withdrawal. 127

anoxic brain injury. Complete lack of oxygen delivery to the brain that frequently results in poor neurological outcomes. 128

antipsychotic medication. A class of medications originally used to manage symptoms of psychosis including delusions (idiosyncratic, fixed, false beliefs) and hallucinations, now used more broadly to treat mood disorders and other conditions. 129

arrhythmia. A problem with the rate or rhythm of the heartbeat. If left untreated, the heart may not be able to pump blood to the rest of the body, resulting in long term damage to end organs. 130

benzodiazepine. A medication prescribed for treatment of anxiety disorders and alcohol withdrawal, among other uses. 131

<sup>125</sup> VHA Handbook 1050.01.

<sup>&</sup>lt;sup>126</sup> Marilynn Bartley, "Case Study: Against Medical Advice," Journal of Trauma Nursing 21, (November/December 2014): 314-318.

<sup>127</sup> Diagnostic and Statistical Manual of Mental Disorders, "Substance Related and Addictive Disorders," accessed March 9, 2020, https://dsm.psychiatryonline.org/doi/full/10.1176/appi.books.9780890425596.dsm07#BABJAEHE.

<sup>&</sup>lt;sup>128</sup> Cerebral Hypoxia Information Page, National Institute of Neurological Disorders and Stroke, (March 27, 2019) accessed December 14, 2020, https://www.ninds.nih.gov/disorders/all-disorders/cerebral-hypoxia-information-page.

<sup>&</sup>lt;sup>129</sup> National Institute of Mental Health. "Mental Health Medications," accessed February 26, 2020, https://www.nimh.nih.gov/health/topics/mental-health-medications/index.shtml#part 149857.

<sup>&</sup>lt;sup>130</sup> National Heart, Lung, and Blood Institute, "Arrhythmia," accessed March 9, 2020, https://www.nhlbi.nih.gov/health-topics/arrhythmia.

<sup>131</sup> National Institute of Mental Health, "Mental Health Medications," accessed February 26, 2020. https://www.nimh.nih.gov/health/topics/mental-health-medications/index.shtml#part 149857.

cardiopulmonary arrest or sudden cardiac arrest. The abrupt loss of heart function and breathing. 132

cardiopulmonary resuscitation. A procedure designed to restore normal breathing after cardiac arrest. 133

computed tomography scan. A type of scan that uses an x-ray beam to create cross-section images of the body to create a three-dimensional view of the body area. 134

**delirium**. A confused and disoriented mental state which is typically temporary and responsive to treatment <sup>135</sup>

delirium tremens. The most severe form of alcohol withdrawal and a medical emergency that should be managed in an inpatient or intensive care unit setting. Delirium tremens is characterized by fluctuating levels of consciousness, cognition, and agitation, abnormal vital signs, hallucinations, seizures, and agitation. The estimated rate of death for delirium tremens is one to four percent with cardiac arrhythmias, high fever, or complications from seizures as the most common causes of death. 136

diazepam. A benzodiazepine medication. Intravenous, intramuscular, or oral diazepam can be used in the treatment of alcohol withdrawal. 137

diphenhydramine. An antihistamine medication that can be used to induce sedation and treat some of the motor-related side effects of antipsychotic medications. 138

disulfiram. A medication which used in combination with alcohol causes unpleasant symptoms, including headache and vomiting; may be prescribed as an alcohol deterrent in the treatment of chronic alcoholism. 139

<sup>132</sup> Mayo Clinic, "Sudden cardiac arrest," accessed April 5, 2021, https://www.mayoclinic.org/diseasesconditions/sudden-cardiac-arrest/symptoms-causes/syc-20350634. For purposes of this OIG report, the term cardiopulmonary arrest, cardiac arrest, and sudden cardiac arrest are considered to refer to the cessation of heart and respiratory functions.

<sup>&</sup>lt;sup>133</sup> Medline Plus. "CPR," accessed March 3, 2020, https://medlineplus.gov/cpr.html.

<sup>&</sup>lt;sup>134</sup> Medline Plus. "CT Scan," accessed September 30, 2020, <a href="https://medlineplus.gov/ency/article/003330.htm">https://medlineplus.gov/ency/article/003330.htm</a>.

<sup>&</sup>lt;sup>135</sup> Medline Plus. "Delirium," accessed December 14, 2020, https://medlineplus.gov/delirium.html.

<sup>&</sup>lt;sup>136</sup> Grover, "Delirium Tremens."

<sup>&</sup>lt;sup>137</sup> Prescribers' Digital Reference. "Diazepam – Drug Summary," accessed March 2, 2020, https://www.pdr.net/drug-summary/Valium-diazepam-2100.1196.

<sup>&</sup>lt;sup>138</sup> Prescribers' Digital Reference. "Diphenhydramine hydrochloride – Drug Summary," accessed December 17, 2020, https://www.pdr.net/drug-summary/Diphenhydramine-Hydrochloride--diphenhydramine-hydrochloride-1140.

<sup>&</sup>lt;sup>139</sup> Prescribers' Digital Reference. "Disulfiram – Drug Summary." accessed December 4, 2020. https://www.pdr.net/drug-summary/Antabuse-disulfiram-681.

**encephalopathy.** Any diffuse disease of the brain that alters brain function or structure such as bacteria, virus, toxin, or metabolic cause. 140

**endotracheal intubation.** A procedure in which a tube is placed in the windpipe through the mouth or nose to keep the airway open and to support breathing.<sup>141</sup>

**four-point restraints.** Restraint of all extremities (arms and legs), typically used for violent patients who pose a danger to themselves or others. 142

**haloperidol.** A conventional antipsychotic medication used in treatment of psychotic symptoms including delusions and hallucinations and may also be used to treat agitation in an inpatient setting. Haloperidol can increase the risk of cardiac arrhythmia and should be used with caution and increased monitoring in patients already at risk for cardiac arrhythmias including patients with alcohol use disorder. <sup>143</sup>

**hypoxemia.** A below-normal blood oxygen level that is a sign of breathing or circulation problems. <sup>144</sup>

**hypoxic ischemic encephalopathy.** A central nervous system (the brain and spinal cord) disease of adults that results from an extensive injury due to profound loss of cerebral blood supply or low oxygen.<sup>145</sup>

**lorazepam.** A benzodiazepine medication. Intravenous, intramuscular, or oral lorazepam is often used in the treatment of alcohol withdrawal. 146

**magnetic resonance imaging**. The most frequently imaging used of the brain and spinal cord to help diagnosis many conditions including stroke, tumors, and brain injury.<sup>147</sup>

<sup>&</sup>lt;sup>140</sup> National Institute of Neurological Disorders and Stroke, "Encephalopathy," accessed February 25, 2021, <a href="https://www.ninds.nih.gov/Disorders/All-Disorders/Encephalopathy-Information-Page">https://www.ninds.nih.gov/Disorders/All-Disorders/Encephalopathy-Information-Page</a>.

<sup>&</sup>lt;sup>141</sup> Medline Plus, "Endotracheal Intubation," accessed March 3, 2020, <a href="https://medlineplus.gov/ency/article/003449.htm">https://medlineplus.gov/ency/article/003449.htm</a>.

<sup>&</sup>lt;sup>142</sup> American Nurse, *Choosing the right restraint*, January 13, 2015, accessed March 11, 2020, <a href="https://www.myamericannurse.com/choosing-restraints/">https://www.myamericannurse.com/choosing-restraints/</a>.

<sup>&</sup>lt;sup>143</sup> Prescribers' Digital Reference, "Haloperidol – Drug Summary," accessed March 3, 2020, https://www.pdr.net/drug-summary/Haldol-haloperidol-942.

<sup>&</sup>lt;sup>144</sup> Mayo Clinic, "Hypoxemia," accessed June 15, 2021, https://www.mayoclinic.org/symptoms/hypoxemia/basics/definition/sym-20050930.

<sup>&</sup>lt;sup>145</sup> S. Yang et al., "Prognostic value of magnetic resonance imaging performed during the subacute phase in adult patients with hypoxic-ischemic encephalopathy for long-term neurological outcomes," Journal of Stroke and Cerebrovascular Diseases 29, (2020): 1-18.

<sup>&</sup>lt;sup>146</sup> Prescribers' Digital Reference, "Lorazepam – Drug Summary," accessed on March 2, 2020, <a href="https://www.pdr.net/drug-summary/Ativan-Injection-lorazepam-996.5972">https://www.pdr.net/drug-summary/Ativan-Injection-lorazepam-996.5972</a>.

<sup>&</sup>lt;sup>147</sup> Mayo Clinic, "MRI," accessed February 24, 2021, <a href="https://www.mayoclinic.org/tests-procedures/mri/about/pac-20384768">https://www.mayoclinic.org/tests-procedures/mri/about/pac-20384768</a>.

Out of Operating Room Airway Management. A type of emergent airway management that is performed outside of an operating room, such as insertion of a tube or alternative airway device. 148

**oxygen saturation.** A measurement of how much oxygen is present in the blood and deliverable to other organs. Oxygen saturation is measured by a noninvasive device placed on a person's finger. Resting oxygen saturation less than 95 percent is considered abnormal.<sup>149</sup>

**posttraumatic stress disorder.** A disorder that may affect people after exposure to a potentially life-threatening event or serious injury. Symptoms last longer than one month and must be severe enough to interfere with interpersonal relationships and or work, including re-experiencing symptoms, avoidance symptoms, arousal symptoms, and changes in thoughts or mood. 150

radiologist. A physician specializing in advanced imaging technology to support accurate diagnosis and treatment. 151

root cause analysis. A focused review to determine underlying system vulnerabilities that contributed to an adverse event or close call. 152

tachycardia. A heart rate above 100 beats per minute not caused by exercise or stress. If untreated, serious health complications may occur, including stroke or cardiac arrest. 153

ventricular fibrillation. Disorganized electrical activity originating from the lower chambers of the heart. The disorganized activity can be life-threatening as the heart muscle is unable to contract and pump blood. 154

venturi mask. A device that allows a precise concentration of oxygen delivery to a patient. 155

<sup>148</sup> VHA Directive 1157.

<sup>&</sup>lt;sup>149</sup> "Pulse Oximetry," Yale Medicine, accessed December 14, 2020, <a href="https://www.yalemedicine.org/conditions/pulse-">https://www.yalemedicine.org/conditions/pulse-</a> oximetry.

<sup>150</sup> Diagnostic and Statistical Manual of Mental Disorders, "Post-traumatic Stress Disorder," accessed February 27, 2020, https://dsm.psychiatryonline.org/doi/full/10.1176/appi.books.9780890425596.dsm07#BABJAEHE.

<sup>151</sup> Mayo Clinic, "Radiology," accessed February 24, 2021, https://www.mayoclinic.org/departmentscenters/radiology/sections/overview/ovc-20469630.

<sup>&</sup>lt;sup>152</sup> VHA Handbook 1050.01.

<sup>&</sup>lt;sup>153</sup> Mayo Clinic, "Tachycardia – Symptoms and Causes," accessed December 4, 2020, https://www.mayoclinic.org/diseases-conditions/tachycardia/symptoms-causes/syc-20355127.

<sup>154</sup> Mayo Clinic, "Ventricular Fibrillation," accessed February 19, 2021, https://www.mayoclinic.org/diseasesconditions/ventricular-fibrillation/symptoms-causes/syc-20364523.

<sup>155</sup> U.S. Food and Drug Administration, Code of Federal Regulations, Subchapter H - Medical Devices, Part 868 -Anesthesiology Devices, Subpart F – Therapeutic Devices, Sec. 868,5600, "Venturi mask," accessed March 3, 2020, https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=868.5600.

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