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VETERANS HEALTH ADMINISTRATION

Mismanaged Mental Health Care for a Patient Who Died by Suicide and Review of Administrative Actions at the VA Tuscaloosa Healthcare System in Alabama

23-02393-250



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Mismanaged Mental Health Care for a Patient Who Died by Suicide and Review of Administrative Actions at the VA Tuscaloosa Healthcare System in Alabama

Executive Summary

The VA Office of Inspector General (OIG) conducted a healthcare inspection to evaluate allegations at the VA Tuscaloosa Healthcare System (facility) in Alabama related to the care of a patient who died by suicide six days after an appointment with mental health staff. Specifically, the OIG evaluated allegations that facility staff failed to provide the patient with adequate mental health medication management, assessment of suicide risk, and follow-up to a positive traumatic brain injury (TBI) screen.¹ The OIG also identified concerns related to staff's failure to schedule the patient's mental health and posttraumatic stress disorder (PTSD) follow-up appointments, a supervisor's oversight of a PTSD clinic social worker (social worker), and leaders' insufficient administrative actions following notification of the patient's death.

Synopsis of the Patient's Care

The patient, who was in their early twenties at the time of death by suicide in fall 2022, established care at the facility in summer 2022 (day 1).² Approximately one week later at a clinic, the patient screened positive for TBI, PTSD, and depression, and agreed to a TBI evaluation consult.³ A licensed practical nurse documented "consult order entered" and alerted a primary care nurse practitioner.⁴ That same day, the primary care nurse practitioner spoke with the patient by phone regarding the patient's positive depression and PTSD screens and the patient declined an offered walk-in mental health outpatient appointment. On day 14, the patient requested mental health treatment and the primary care nurse practitioner entered a mental health outpatient consult.

On day 16, an administrative staff member documented that the patient declined a community care referral and scheduled the patient to meet with a mental health nurse practitioner (MHNP) on day 46. During the evaluation with the MHNP, the patient reported "anger and irritability, anxiety, depression, flashbacks, intrusive thoughts, and poor sleep with nightmares." During a "Brief Suicide Risk Assessment," the patient denied feeling hopeless and thoughts of suicide.⁵

¹ The underlined terms are hyperlinks to a glossary. To return from the glossary, press and hold the "alt" and "left arrow" keys together.

² The OIG uses the singular form of they, "their" in this instance, for privacy purposes.

³ The patient was seen at a facility storefront clinic. The associate chief of staff for specialty care told the OIG that storefront clinics are locations where patients can participate in telehealth care with facility providers and in-person nurses.

⁴ The OIG team did not find a TBI consult in the patient's electronic health record.

⁵ The MHNP told the OIG about conducting a "Brief Suicide Risk Assessment" with all patients that included five questions evaluating a patient's feelings of hopelessness, suicidal ideation, plan, attempts, and psychosocial stressors and did not recall from where the assessment was obtained.

The MHNP diagnosed the patient with unspecified trauma- and stressor-related disorder and prescribed <u>mirtazapine</u> for depression and <u>hydroxyzine</u> for anxiety. The MHNP documented discussing medication effects, risks, and benefits with the patient and requested a follow-up appointment in two months. The MHNP entered a trauma-focused therapy consult with a request for the patient to be seen in one month, on day 76. An administrative staff member scheduled the patient for a PTSD evaluation appointment on day 98 and a medical support assistant (MSA) scheduled a follow-up appointment with the MHNP for day 162, almost four months later.⁶ On day 53, pharmacy staff mailed the mirtazapine and hydroxyzine to the patient.

On day 98, in an evaluation for outpatient PTSD psychotherapy, the social worker diagnosed the patient with PTSD. The patient reported "passive suicidal thoughts without any plan or intent approximately two to three weeks ago" and denied current suicidal ideation. The patient also reported access to a firearm and ammunition that were "stored in two separate locations." The social worker documented a plan for the patient to "return to the [PTSD clinic] for individual therapy." That same day, the patient completed PTSD and depression rating scales through text and electronic mail. The depression rating scale indicated "moderately severe symptoms," including thoughts of being "better off dead/hurting [your]self" several days over the prior two weeks.

Six days later, on day 104, the patient "was discovered deceased by a friend" from a firearm injury to the head.

OIG Findings

The OIG substantiated that the MHNP inadequately managed the patient's medication by failing to provide the patient information about the increased risk of suicidal thoughts and behaviors for young adults prescribed mirtazapine.⁷ A <u>boxed warning</u> for mirtazapine advises to "closely monitor all antidepressant-treated patients for clinical worsening, and for emergence of suicidal

⁶ The staff member was an advanced MSA and reported responsibilities that included scheduling consults and appointments. For purposes of this report, the OIG will refer to the staff member as an MSA.

⁷ The medication the MHNP prescribed the patient, mirtazapine, includes a warning for "increased risk of suicidal thoughts or actions" in young adult patients, "especially within the first few months of treatment." At the time the MHNP prescribed mirtazapine to the patient, the patient was considered a young adult. The US Food and Drug Administration describes "young adult" as a patient 24 years old or younger. US Food and Drug Administration, "REMERON® (mirtazapine) tablets, for oral use," accessed July 13, 2023,

https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/020415s038,021208s028lbl.pdf.

thoughts and behaviors."⁸ In an interview with the OIG, when asked about the medication risks discussed with the patient, the MHNP acknowledged not discussing the risk of suicidal ideation related to mirtazapine and that pharmacy staff would mail the patient the information with the medication.⁹ The OIG would have expected the MHNP to provide information directly to the patient about the mirtazapine boxed warning given the applicability of the warning for the patient. The MHNP's failure to provide the patient education regarding the boxed warning likely resulted in the patient's insufficient awareness of the need to self-monitor for suicidal thoughts and seek supportive resources as needed.

The OIG found that the MHNP did not complete the required suicide risk screening, the Columbia Suicide Severity Rating Scale (C-SSRS), at the patient's outpatient mental health intake appointment.¹⁰ In an interview with the OIG, the MHNP reported the understanding that routine completion of the C-SSRS with patients was not required and only completed it if prompted by a reminder in a patient's electronic health record.¹¹ The MHNP's failure to complete the required C-SSRS may have contributed to an inadequate assessment of the patient's suicide risk. A suicide prevention coordinator told the OIG that mental health leaders decided not to include the C-SSRS in the outpatient mental health intake template.¹² As of March 2024, in response to an internal review, facility leaders implemented changes that included the C-SSRS in outpatient mental health intake templates.

The OIG found that the MHNP did not adequately address the need for close monitoring after initiating mirtazapine, as specified in the boxed warning.¹³ The MHNP reported to the OIG typically following up with patients newly prescribed mirtazapine in six to eight weeks. Given

⁸ US Food and Drug Administration, "REMERON® (mirtazapine) tablets, for oral use." VHA Handbook 1004.01(5), *Informed Consent for Clinical Treatments and Procedures*, August 14, 2009, amended September 17, 2021. This handbook was in place during the time of the events discussed in this report. It was rescinded and replaced by VHA Directive 1004.01(2), *Informed Consent for Clinical Treatments and Procedures*, December 12, 2023, amended May 1, 2024. Unless otherwise specified, the 2024 directive contains the same or similar language regarding informed consent discussion as the rescinded 2021 handbook. At the time of the patient's care, VHA required that "all treatment and procedures require the prior, voluntary informed consent of the patient," including "the expected benefits and known risks associated with the recommended treatment or procedure."

⁹ The interim chief of pharmacy told the OIG that when mirtazapine is mailed to a patient, it is typical practice to include an information sheet that notes the increased risk of suicidal thoughts and behaviors for young adults.

¹⁰ Assistant Under Secretary for Health for Clinical Services/Chief Medical Officer, "Eliminating Veteran Suicide: Suicide Risk Screening and Evaluation Requirements and Implementation (Risk ID Strategy)," memorandum to VISN Directors, VISN Chief Medical Officers, VISN Chief Mental Health Officer, November 13, 2020.

¹¹ VHA policy and facility procedures require the C-SSRS to be completed during outpatient mental health intake evaluations. Assistant Under Secretary for Health for Clinical Services/Chief Medical Officer, "Eliminating Veteran Suicide: Suicide Risk Screening and Evaluation Requirements and Implementation (Risk ID Strategy)," memorandum; Facility, "Suicide Risk Screening and Evaluation" (standard operating procedure), March 28, 2022.

¹² An administrative officer reported to the OIG that the leader who had been in the associate chief of staff, mental health position in 2018 was no longer employed by the VA at the time of this inspection. The suicide prevention coordinator described serving as the facility's suicide prevention program manager.

¹³ US Food and Drug Administration, "REMERON® (mirtazapine) tablets, for oral use."

that the mirtazapine was newly prescribed to the patient and included a boxed warning for close monitoring, the OIG would have expected the MHNP to plan follow-up contact with the patient sooner to assess the patient's response to the medication. The OIG determined that the MHNP's failure to closely monitor the patient after initiating mirtazapine prevented a timely evaluation of worsening symptoms or emerging adverse medication effects, including suicidal thoughts and behaviors. The lack of close monitoring could also result in a failure to assess medication effectiveness for mental health symptoms and provide necessary adjustments to the treatment.

The OIG found that MSA staff did not initiate scheduling of the patient's follow-up appointment within two business days as required by the Veterans Health Administration (VHA), and scheduled the patient's appointment approximately two months later than the MHNP's requested return date.¹⁴ Further, the MSA did not consult with the MHNP as expected by supervisory MSAs when unable to schedule the patient's appointment as requested by the MHNP. The OIG concluded that MSA staffing vacancies may have contributed to staff's failure to initiate timely scheduling efforts and ultimately not scheduling the patient's follow-up appointment until approximately four months after the patient's initial visit with the MHNP.

The OIG substantiated that the social worker failed to sufficiently assess the patient's suicide risk, conduct <u>lethal means safety counseling</u> with the patient, and consult with the patient's prescriber due to having the perception of the patient as not being at risk for suicide.¹⁵ The social worker's failure to thoroughly evaluate the patient's suicide risk and conduct adequate lethal means safety counseling may have contributed to the social worker's underestimation of the patient's suicide risk and the patient's immediate access to the means to engage in suicidal behavior. The social worker's lack of notification to the MHNP about the patient's worsening depression symptoms hindered the MHNP's monitoring of the patient's medication response and contributed to a failure to address the patient's suicide risk.

The OIG found that staff failed to arrange follow-up PTSD treatment for the patient due to a lack of a formal consult and documentation process in the PTSD clinic, as required by VHA.¹⁶ During the patient's PTSD evaluation, the social worker documented a plan for the patient to return to the PTSD clinic for individual psychotherapy and sent a supervisory social worker an instant message to contact the patient to schedule a follow-up appointment. Staff did not contact the patient after the PTSD evaluation to confirm a follow-up plan. The lack of a follow-up plan may

¹⁴ VHA, "National Return To Clinic (RTC) Order Standard Operating Procedure (SOP)," last updated September 7, 2022.

¹⁵ For purposes of this report, the OIG uses the term prescriber to refer to a healthcare provider with authority to prescribe mental health medication.

¹⁶ Assistant Under Secretary for Health for Clinical Services/Chief Medical Officer (CMO), "Standard Operating Procedures for Outpatient Mental Health Consults," memorandum to the VISN Director, VISN CMOs, VISN Chief Mental Health Officers, October 7, 2021.

have led to uncertainty for the patient about the accessibility of treatment to address PTSD-related concerns.

The OIG also determined that the supervisory social worker provided inadequate oversight of the social worker, who was hired approximately six weeks prior to conducting the patient's PTSD evaluation. The supervisory social worker reported consulting with the social worker as needed but not providing formal supervision because the social worker was a licensed independent provider.¹⁷ Given the supervisory social worker's awareness of the social worker's minimal experience working with PTSD patients, the OIG would have expected the supervisory social worker to ensure adequate oversight of the social worker's specialized PTSD care provision. The supervisory social worker's lack of oversight may have contributed to a failure to identify the social worker's inadequate suicide risk assessment and lethal means safety counseling for the patient and consequently, an underestimated and unmitigated suicide risk.

The OIG substantiated that facility staff did not submit a consult for TBI evaluation following the patient's positive TBI screen, as required.¹⁸ Staff involved in the patient's care and the facility TBI coordinator provided conflicting information to the OIG about who was responsible for submitting a TBI consult following a patient's positive TBI screen. The OIG concluded that the primary care nurse practitioner failed to ensure a consult was submitted due to a lack of knowledge about providers' responsibilities following a positive TBI screen. Failure to facilitate a TBI evaluation for the patient may have hindered the patient's access to TBI treatment.

The OIG found that facility staff did not inform facility leaders about closure of an incomplete root cause analysis action item. Facility mental health leaders reported to the patient safety manager that it was not feasible to complete one of the identified action items due to a staffing shortage. The patient safety manager suggested closing the action item and the acting associate chief of staff, mental health agreed. The patient safety manager reported mental health leaders were responsible to provide that information to the leadership team. However, the patient safety manager routinely provided updates to facility leaders; therefore, the OIG would have expected facility leaders to be notified regarding the closure of the incomplete action item. The lack of communication regarding the closure of an incomplete action item diminished facility leaders' awareness of barriers to address system vulnerabilities and improve quality of care.

The OIG determined that the Peer Review Committee failed to address two system issues identified during the peer review process. The OIG concluded that a lack of Peer Review Committee documentation to reflect discussions and tracking of actions to resolution may have

¹⁷ A licensed independent provider is an individual "permitted by law" and the VHA to "provide patient care services independently, i.e. [that is], without supervision or direction, within the scope of the individual's license and in accordance with individually granted clinical privileges." VHA Directive 1110.02, *Social Work Professional Practice*, July 26, 2019.

¹⁸ VHA Directive 1184, Screening and Evaluation of Post 9-11 Veterans for Deployment Related Traumatic Brain Injury, January 3, 2022.

contributed to gaps in communication and follow-up, and consequently a failure to mitigate identified patient safety risks.

The OIG found that the suicide prevention coordinator failed to complete the required Behavioral Health Autopsy Program Family Interview Tool—Contact Form after notification of the patient's death.¹⁹ In an interview with the OIG, the suicide prevention coordinator reported not contacting the patient's family because facility staff who had contact with the patient's family reported that outreach would upset the family. Further, the OIG found that VHA leaders did not provide written guidance related to criteria or processes for suicide prevention program staff to determine when not to contact family. The absence of written VHA guidance regarding when not to contact family members likely contributed to the suicide prevention coordinator's failure to seek consultation regarding the decision and document the rationale in the Family Interview Tool-Contact form. The suicide prevention coordinator's failure to seek consultation resulted in incomplete consideration of the family member's potential need for resources to support grief management and the offer for the family member to participate in the family interview process.

Additionally, the OIG found that facility leaders did not conduct an institutional disclosure based on an erroneous understanding of requirements. Given facility leaders' failure to adequately consider conducting an institutional disclosure and the OIG-identified care deficiencies, facility leaders should consider an institutional disclosure.

The OIG made 1 recommendation to the Under Secretary for Health to consider establishing written guidance regarding the Behavioral Health Autopsy Program family interview process. The OIG made 13 recommendations to the Facility Director related to a review of the patient's care; boxed warning patient education; suicide risk screenings; outpatient mental health scheduling; lethal means assessment and safety planning; PTSD clinic consultation, scheduling, and supervision; TBI evaluation; and root cause analysis, peer review, Behavioral Health Autopsy Program, and institutional disclosure processes.

¹⁹ The suicide prevention coordinator is expected to contact the next of kin to inform them about the Behavioral Health Autopsy Program family interview process, offer the opportunity to participate, and document the family member's interest in participating in an interview on a Family Interview Tool-Contact form. VHA, *Suicide Prevention Program Guide*, November 2020, updated December 2022. For purposes of this report, the OIG refers to the next of kin as *family member*; VHA Directive 1160.07, *Suicide Prevention Program*, May 24, 2021.

VA Comments and OIG Response

The Under Secretary for Health and the Veterans Integrated Service Network and Facility Directors concurred with the recommendations and provided acceptable action plans (see appendixes A, B, and C). Based on information provided, the OIG considers recommendation 14 closed. For the remaining open recommendations, the OIG will follow up on the planned actions until they are completed.

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Abbreviations

BHAP	Behavioral Health Autopsy Program		
CID	clinically indicated date		
C-SSRS	Columbia Suicide Severity Rating Scale		
EHR	electronic health record		
FIT-C	Family Interview Tool-Contact		
MHNP	mental health nurse practitioner		
MSA	medical support assistant		
OIG	Office of Inspector General		
PRC	Peer Review Committee		
PTSD	posttraumatic stress disorder		
RTC	return to clinic		
TBI	traumatic brain injury		
VHA	Veterans Health Administration		
VISN	Veterans Integrated Service Network		



Introduction

The VA Office of Inspector General (OIG) conducted a healthcare inspection to evaluate allegations related to the care of a patient who died by suicide six days after an appointment with mental health staff at the VA Tuscaloosa Healthcare System (facility) in Alabama. Specifically, the OIG evaluated allegations that facility staff failed to provide the patient with adequate mental health medication management, assessment of suicide risk, and follow-up to a positive <u>traumatic brain injury</u> (TBI) screen.¹

Additionally, the OIG identified concerns related to

- staff's failure to schedule the patient's mental health and <u>posttraumatic stress disorder</u> (PTSD) follow-up appointments,
- a supervisor's inadequate oversight of a PTSD clinic social worker (social worker), and
- leaders' insufficient administrative actions following notification of the patient's death.

Background

The facility, part of Veterans Integrated Service Network (VISN) 7, includes the Tuscaloosa VA Medical Center and the Selma VA Clinic. Specialty care is also offered through telehealth services at remote sites in Demopolis, Hamilton, Fayette, and at the University of Alabama. The facility offers a range of services including inpatient and outpatient mental health and primary care. The facility operates 43 inpatient mental health unit beds and a PTSD residential rehabilitation treatment program. The facility is affiliated with the University of Alabama School of Medicine.

Prior OIG Reports

In June 2022, the OIG reported that facility leaders failed to fill staffing vacancies, including a psychiatrist position. As of February 2023, the OIG closed the related recommendation to the Facility Director to identify "difficult to fill" positions and develop a plan for addressing the staffing challenges.²

A February 2023 OIG report identified deficiencies related to the facility patient safety program and leaders' oversight. The OIG recommended that the VISN Director evaluate the role of a

¹ The underlined terms are hyperlinks to a glossary. To return from the glossary, press and hold the "alt" and "left arrow" keys together.

² VA OIG, *Failure of Leaders to Address Safety, Staffing, and Environment of Care Concerns at the Tuscaloosa VA Medical Center in Alabama*, Report No. 21-03201-185, June 29, 2022.

patient safety subcommittee in tracking action plans after deficiencies are identified.³ The recommendation was closed as of January 2024.

A March 2024 OIG Management Advisory Memorandum identified unclear policy and inconsistent application regarding institutional disclosures. The OIG requested the Under Secretary for Health to "reinforce to VHA staff the indications for institutional disclosure."⁴

Allegations and Related Concerns

On April 6, 2023, the OIG received allegations that

- a mental health nurse practitioner (MHNP) provided inadequate medication management;
- a social worker failed to
 - o sufficiently assess for suicide risk,
 - o mitigate <u>lethal means</u> access, and
 - o consult with a prescriber regarding the patient's suicidal ideation; and
- staff failed to address the patient's positive TBI screen.⁵

During evaluation of the allegations, the OIG identified additional concerns related to the MHNP's inadequate suicide risk assessment; staff's failure to schedule the patient's mental health and PTSD follow-up appointments; a supervisor's failure to provide sufficient oversight of the social worker; and leaders' insufficient actions following the patient's death, including partial completion of quality management reviews and the Behavioral Health Autopsy Program (BHAP).

Scope and Methodology

The OIG initiated the inspection on June 12, 2023, and conducted a virtual site visit July 24–31 and August 7–17, 2023.

The OIG team interviewed facility staff and leaders familiar with the patient's care and relevant processes, the Director of the Veterans Health Administration (VHA) Center of Excellence for

³ VA OIG, <u>Deficiencies in the Patient Safety Program and Oversight Provided by Facility and VISN Leaders at the</u> <u>Tuscaloosa VA Medical Center in Alabama</u>, Report No. 22-00031-67, February 27, 2023.

⁴ VA OIG, *Institutional Disclosure Policy Requirements Should Be Clarified*, Report No. 23-02386-91, March 13, 2024.

⁵ For purposes of this report, the OIG uses the term prescriber to refer to a healthcare provider with authority to prescribe mental health medication.

Suicide Prevention and Program Coordinator of Field Operations, and a family member of the patient.

The OIG reviewed the patient's electronic health record (EHR); relevant VHA directives, handbooks, and memoranda; and facility policies, standard operating procedures, and organizational charts.

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, as amended, 5 U.S.C. §§ 401–424. 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, who was in their early 20s at the time of death by suicide in fall 2022, received military mental health care in spring 2022 and then established care at the facility in summer $2022.^{6}$

Mental Health Assessments and Care During Military Service

During a military annual health assessment in 2019, the patient denied suicidal thoughts and mental health concerns. In an early 2021 pre-deployment health assessment, the patient denied receiving mental health care within the prior year and reported drinking three to four alcoholic drinks two to four times per month. Over nine months later, in fall 2021, the patient completed a post-deployment health assessment and reported having nightmares, being constantly on guard,

⁶ The OIG uses the singular form of they, "their" in this instance, for privacy purposes.

watchful or easily startled, and being "bothered a little" by difficulty sleeping, headaches, and pain. The patient denied thoughts of being better off dead or self-harm in the prior month and reported having three to four alcoholic drinks monthly or less.

Approximately six months later, in spring 2022, the patient presented to a military mental health clinic with complaints of anxiety; racing thoughts; lethargic mood; reclusive behavior; low motivation and energy; and feelings of shame, helplessness, and guilt. The patient reported receiving a Driving While Impaired charge the month prior and drinking four or more alcoholic drinks two to four times per month.⁷ The patient expressed interest in psychotherapy and was scheduled for an appointment.

Approximately three weeks later, the patient, referred due to the Driving While Impaired charge, completed a substance use assessment at the military clinic. The patient reported blackouts from drinking while deployed and daily drinking of four or more mixed drinks during parts of 2021. The patient denied "current concerns" regarding alcohol use, described having nightmares, flashbacks, and anxiety since deployment, and denied suicidal ideation. The social worker recommended substance abuse treatment and noted the patient's scheduled psychiatry and social work appointments.⁸ The patient separated from the military in summer 2022.

Mental Health Assessments and Care at the Facility

In summer 2022 (day 1), the patient completed an application for health care at the facility and was given information on how to schedule with a clinic.⁹ Approximately one week later, the patient presented to the clinic for "labs to be drawn for an upcoming appointment." A licensed practical nurse documented that the patient described recent difficulty with memory lapses, irritability, headaches, nightmares, avoidance behaviors, hypervigilance, feeling numb or detached, guilt, and feelings of depression nearly every day. The patient screened positive for TBI, PTSD, and depression, and negative on alcohol use and suicide risk screens. The patient agreed to a TBI evaluation consult and the licensed practical nurse documented "consult order entered" and alerted a primary care nurse practitioner.¹⁰ That same day, the primary care nurse practitioner spoke with the patient by phone regarding the patient's positive depression and PTSD screens. The patient denied suicidal ideation and reported knowing how to manage

⁷ North Carolina Law Addressing Impaired Driving, N.C. Gen. Stat. Ann. § 20–138.1. Under North Carolina law, a person commits the offense of impaired driving if the person has an alcohol concentration of 0.08 [percent] or higher while operating a vehicle.

⁸ The OIG did not find evidence in the patient's EHR regarding whether or not the patient completed the recommended substance abuse treatment or attended the scheduled psychiatry and social work appointments.

⁹ The patient was referred to a facility storefront clinic. The associate chief of staff for specialty care told the OIG that storefront clinics are locations where patients can participate in telehealth care with facility providers and inperson nurses.

¹⁰ The OIG team did not find a TBI consult in the patient's EHR.

symptoms from "some of therapy [the patient] received." The patient declined an offered walk-in mental health outpatient appointment, "was given Crisis Hotline number," and was scheduled for a virtual primary care appointment in one week.

On day 14, during the primary care appointment, the patient reported headaches, chronic lower back pain, joint pain, depressed mood with no suicidal ideation, and alcohol use of two to three drinks per week. The patient's laboratory results from the previous week were unremarkable except for elevated <u>cholesterol</u>. The patient requested mental health treatment and the primary care nurse practitioner entered a mental health outpatient consult with a clinically indicated date (CID) of a week later (day 21).¹¹ On day 16, following the primary care nurse practitioner's request for outpatient mental health treatment for the patient, an administrative staff member documented that the patient declined a community care referral and scheduled the patient to meet with the MHNP on day 46. On day 42, during a case management phone screening, a social worker documented that the patient was not "experiencing a medical and/or mental health crisis," and did not identify needs related to access to health care, benefits, or "social concerns."

Four days later (day 46), in a mental health evaluation, the MHNP documented that the patient complained of "anger and irritability, anxiety, depression, flashbacks, intrusive thoughts, and poor sleep with nightmares." The patient described anxiety at bedtime and hearing "screams" from combat deployment "almost nightly." The patient reported uncharacteristic lack of motivation, having "failed myself as a good person," and occasional alcohol and cannabis use with increasing anxiety over the prior year. During a "Brief Suicide Risk Assessment," the patient denied feeling hopeless and thoughts of suicide.¹² The MHNP diagnosed the patient with <u>unspecified trauma- and stressor-related disorder</u>. The MHNP prescribed <u>mirtazapine</u> for depression and <u>hydroxyzine</u> for "social and testing anxiety" and "discussed effects of meds [medications]/management including risks vs [versus] benefits, SEs [side effects]" with the patient.

The MHNP requested a follow-up appointment in two months and entered a trauma-focused therapy consult with a CID one month later, on day 76.

Another administrative staff member scheduled the patient for a PTSD evaluation appointment on day 98, approximately a month after the CID. A medical support assistant (MSA) scheduled a

¹¹ VHA defines CID as "the date care is deemed clinically appropriate" by a provider. VHA Directive 1232(4), *Consult Processes and Procedures*, August 24, 2016, amended December 14, 2021. In 2022, VHA replaced clinically indicated date with "patient indicated date" that is defined as "the date the health care provider and Veteran agree is clinically indicated for care." VHA Directive 1230, *Outpatient Scheduling Management*, June 1, 2022.

¹² The MHNP conducted a "Brief Suicide Risk Assessment" that included five questions evaluating the patient's feelings of hopelessness, suicidal ideation, plan, attempts, and psychosocial stressors. The MHNP told the OIG about conducting the assessment with all patients and did not recall where the assessment was obtained.

follow-up appointment with the MHNP for day 162, almost four months later.¹³ On day 53, pharmacy staff mailed the mirtazapine and hydroxyzine to the patient.

On day 98, in a screening evaluation for admission to outpatient PTSD psychotherapy, the social worker diagnosed the patient with PTSD. The patient reported "passive suicidal thoughts without any plan or intent approximately two to three weeks ago" and denied current suicidal ideation. The patient also reported access to a firearm and ammunition that were "stored in two separate locations." During the appointment, the patient reported "seldom alcohol use" and "occasional marijuana use." The patient agreed to PTSD treatment, and the social worker documented a plan for the patient to "continue follow-up with MH [mental health] Provider for Medication Management" and "will return to the [PTSD clinic] for individual therapy."

That same day, the patient completed PTSD and depression rating scales through text and electronic mail. The PTSD rating scale indicated that the patient "may meet the criteria for a PTSD diagnosis." The depression rating scale indicated "moderately severe symptoms," including thoughts of being "better off dead/hurting [your]self" several days over the past two weeks. The social worker documented that the symptoms made it difficult for the patient to "work, take care of things at home, or get along with others," and noted, "The patient reported some symptoms of depression; symptoms are not consistent with a major depressive episode."

Six days later, on day 104, the patient "was discovered deceased by a friend" from a firearm injury to the head.

Inspection Results

1. Inadequate Medication and Suicide Risk Management

The OIG substantiated that the MHNP inadequately managed the patient's medication by failing to provide information about the increased risk of suicidal thoughts and behaviors associated with mirtazapine. The OIG also found that the MHNP did not complete the required suicide risk screening during the patient's initial mental health evaluation. Additionally, the MHNP did not closely monitor the patient after prescribing the medication, as advised by the United States Food and Drug Administration.¹⁴

The OIG also found that MSA staff did not initiate scheduling of the patient's follow-up appointment within two business days as required by VHA, and scheduled the patient's

¹³ The staff member was an advanced MSA and reported responsibilities that included scheduling consults and appointments. For purposes of this report, the OIG will refer to the staff member as an MSA.

¹⁴ United States Food and Drug Administration, "REMERON® (mirtazapine) tablets, for oral use," accessed July 13, 2023, <u>https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/020415s038,021208s028lbl.pdf</u>.

appointment approximately two months later than the MHNP's requested return date.¹⁵ Further, the MSA did not consult with the MHNP as expected when unable to schedule the patient's appointment as requested by the MHNP.

Failure to Discuss Medication Risks

The United States Food and Drug Administration requires that certain medications with "serious warnings, particularly those that may lead to death or serious injury" include a <u>boxed warning</u> also known as a black box warning.¹⁶ The boxed warning alerts healthcare professionals of risks to consider when prescribing the medication to a patient.¹⁷

Mirtazapine includes a boxed warning for "increased risk of suicidal thoughts or actions" in young adult patients, "especially within the first few months of treatment."¹⁸ The boxed warning advises to "closely monitor all antidepressant-treated patients for clinical worsening and emergence of suicidal thoughts and behaviors."¹⁹

At the time of the patient's care, VHA required that, "all treatments and procedures require the prior, voluntary informed consent of the patient" including "the expected benefits and known risks associated with the recommended treatment or procedure."²⁰

The OIG found that the MHNP documented providing the patient with medication information; however, did not discuss mirtazapine's boxed warning of increased risk of suicidal ideation or behavior for young adults. On day 46, the MHNP diagnosed the patient with unspecified traumaand stressor-related disorder and prescribed hydroxyzine and mirtazapine. The MHNP documented discussing medication effects, "including risks vs [versus] benefits, SEs [side effects]" with the patient, and advised the patient to take mirtazapine at night to prevent daytime drowsiness. The MHNP noted that "patient education sheets will be provided with dispensed medications." On day 53, pharmacy staff mailed the mirtazapine to the patient, and it was delivered on day 56.

¹⁵ VHA, "National Return To Clinic (RTC) Order Standard Operating Procedure (SOP)," last updated September 7, 2022.

¹⁶ 21 C.F.R.§ 201.57.

¹⁷ "What Does it Mean If My Medication Has a 'Black Box Warning'?," Cleveland Clinic, accessed July 13, 2023, https://health.clevelandclinic.org/what-does-it-mean-if-my-medication-has-a-black-box-warning/.

¹⁸ At the time the MHNP prescribed mirtazapine to the patient, the patient was considered a young adult. The US Food and Drug Administration describes a "young adult" as a patient 24 years old or younger. US Food and Drug Administration, "REMERON® (mirtazapine) tablets, for oral use."

¹⁹ US Food and Drug Administration, "REMERON® (mirtazapine) tablets, for oral use."

²⁰ VHA Handbook 1004.01(5), *Informed Consent for Clinical Treatments and Procedures*, August 14, 2009, amended September 17, 2021, was rescinded and replaced by VHA Directive 1004.01(3), *Informed Consent for Clinical Treatments and Procedures*, December 12, 2023, amended May 1, 2024. The policies contain similar language related to informed consent discussion.

The interim chief of pharmacy and chief of psychiatry told the OIG that providers should advise patients about medication boxed warnings as part of the risks and benefits discussion when a medication is prescribed. The interim chief of pharmacy also reported when mirtazapine is mailed to a patient, it is typical practice to include an information sheet that notes the increased risk of suicidal thoughts and behaviors for young adults.²¹

The patient's family member told the OIG that the patient received the prescriptions by mail and took the medication for approximately one month and reported that the MHNP did not "go over" the medication with the patient. In an interview with the OIG, when asked about the medication risks discussed with the patient, the MHNP reported not discussing the risk of suicidal ideation related to mirtazapine and that pharmacy staff would mail the patient the information with the medication.

The OIG would have expected the MHNP to provide information about the mirtazapine boxed warning directly to the patient given the applicability of the warning for the patient. The MHNP's failure to provide the patient education regarding mirtazapine's boxed warning likely resulted in the patient's insufficient awareness of the need to self-monitor for suicidal thoughts and seek supportive resources as needed.

Inadequate Assessment of Suicide Risk

The OIG found that the MHNP did not complete the required suicide risk screening during the patient's initial mental health evaluation on day 46.²²

VHA policy and facility procedures require the Columbia Suicide Severity Rating Scale (C-SSRS) to be completed during outpatient mental health intake evaluations.²³ The C-SSRS is an evidence-supported tool consisting of questions that assess a patient's suicide risk.

During the patient's initial mental health evaluation on day 46, the MHNP completed a "Brief Suicide Risk Assessment" with the patient that included five questions evaluating the patient's feelings of hopelessness; suicidal ideation, plan, and attempts since the patient's last

²¹ "The Consolidated Mail Outpatient Pharmacy (CMOP) software processes and automatically transmits prescription data from a Veterans Affairs Medical Center (VAMC) to a CMOP host facility, where prescriptions are mailed from an integrated and highly automated outpatient prescription dispensing system." VA, *Consolidated Mail Outpatient Pharmacy (CMOP) Version 2.0 Technical Manual*, April 1997, Revised September 2021.

²² Assistant Under Secretary for Health for Clinical Services/Chief Medical Officer, "Eliminating Veteran Suicide: Suicide Risk Screening and Evaluation Requirements and Implementation (Risk ID Strategy)," memorandum to VISN Director (10N1-23) et al., November 13, 2020; Facility, "Suicide Risk Screening and Evaluation" (standard operating procedure), March 28, 2022.

²³ Assistant Under Secretary for Health for Clinical Services/Chief Medical Officer, "Eliminating Veteran Suicide: Suicide Risk Screening and Evaluation Requirements and Implementation (Risk ID Strategy)," memorandum; Facility, "Suicide Risk Screening and Evaluation."

appointment; and psychosocial stressors.²⁴ The appointment that the patient considered as the last appointment is unclear, given that the patient attended a primary care appointment on day 14, approximately a month prior, and also spoke with a social worker four days prior for a case management phone screening. The patient denied feeling hopeless and thoughts of suicide and reported problems related to "Significant Other Stressors/Ending of relationship with significant other." The MHNP selected "No further assessment/intervention for suicide needed at this time" regarding the patient's responses. The MHNP did not complete the C-SSRS, which would have prompted questions about the patient's wishes for death; suicidal thoughts, plan, intention to carry out the plan in the prior month; as well as the patient's lifetime history of suicidal and suicidal preparatory behaviors.

In an interview with the OIG, the MHNP reported the understanding that routine completion of the C-SSRS with patients was not required, including during new patient clinic appointments, and was only completing it if prompted by a reminder in a patient's EHR. The MHNP reported completing the Brief Suicide Risk Assessment template for assigned patients. The suicide prevention coordinator told the OIG that the MHNP likely did not complete the C-SSRS because when the VHA requirement was first implemented in 2018, mental health leaders decided not to include the C-SSRS in the outpatient mental health intake template and staff were relying on their ability to remember to complete the Screening.²⁵ The chief of psychiatry told the OIG that providers receive an alert to complete the C-SSRS during follow-up mental health appointments and was unsure if the alert occurs during intake appointments, reporting that nurses may complete the screen. As of March 2024, in response to an internal review, facility leaders implemented changes that included the C-SSRS in outpatient mental health intake templates.

The OIG determined that the MHNP did not complete the C-SSRS as required at the patient's outpatient mental health intake appointment because of lack of knowledge about the VHA and facility requirement and facility use of an intake template that did not include the C-SSRS. The MHNP's failure to complete the required C-SSRS may have contributed to an inadequate assessment of the patient's suicide risk.²⁶

²⁴ A psychosocial stressor is "a life situation that creates an unusual or intense level of stress that may contribute to the development or aggravation of mental disorder, illness, or maladaptive behavior" such as divorce or prolonged illness. American Psychological Association, *Dictionary of Psychology*, "psychosocial stressor," accessed June 5, 2024, <u>https://dictionary.apa.org/psychosocial-stressor</u>.

²⁵ An administrative officer reported to the OIG that the leader who had been in the associate chief of staff, mental health position in 2018 was no longer employed by the VA at the time of this inspection. The suicide prevention coordinator described serving as the facility's suicide prevention program manager.

²⁶ Assistant Under Secretary for Health for Clinical Services/Chief Medical Officer, "Eliminating Veteran Suicide: Suicide Risk Screening and Evaluation Requirements and Implementation (Risk ID Strategy)," memorandum; Facility, "Suicide Risk Screening and Evaluation."

Failure to Monitor the Patient's Medication Response

The Joint Commission instructs prescribers to monitor a patient's "response to the first dose of a new medication" for negative side effects.²⁷ During the mental health evaluation with the patient on day 46, the MHNP ordered an initial 60-day supply of mirtazapine with one refill and placed a return to clinic (RTC) order for a follow-up appointment with a CID of approximately two months later, on day 102. On day 63, more than two weeks after the patient's evaluation, the MHNP placed another RTC order and that same day an MSA scheduled the patient's appointment for day 162, approximately two months after the requested date.

The patient's family member told the OIG that the MHNP did not follow up after prescribing medication for the patient. In an interview with the OIG, the MHNP reported typically following up with patients newly prescribed mirtazapine in six to eight weeks to allow time for the medication to take effect. The MHNP also told the OIG about providing the patient with instructions to call the MHNP, suicide crisis hotline, or present to a walk-in clinic if experiencing suicidal ideation or a worsening of mental health symptoms. However, the OIG did not find evidence in the patient's EHR that these crisis resources were provided to the patient.

In an interview with the OIG, the chief of psychiatry reported that "two months [follow up] sounds appropriate because we are low, low, low on providers here." The interim chief of pharmacy told the OIG that mental health providers with limited availability may request that a pharmacist follow up with the patient to evaluate medication effects and adjust medication dosage as needed.

Given that the mirtazapine was newly prescribed to the patient and included a boxed warning for close monitoring, the OIG would have expected the MHNP to plan follow-up contact with the patient sooner to assess the patient's response to the medication. The MHNP reported being unaware of the patient's follow-up appointment being scheduled beyond the requested date and cited scheduling availability as the reason for the delay.

The OIG determined that the MHNP's failure to closely monitor the patient after initiating mirtazapine prevented a timely evaluation of worsening symptoms or emerging adverse medication effects including suicidal thoughts and behaviors. The lack of close monitoring could also result in a failure to assess medication effectiveness for mental health symptoms and provide necessary adjustments to the treatment.

²⁷ "The Joint Commission E-dition," The Joint Commission, accessed July 13, 2023, <u>https://e-dition.jcrinc.com/MainContent.aspx</u>.

Scheduling Delays

VHA MSAs should contact patients to schedule a follow-up appointment within two business days after a provider places the RTC order.²⁸ VHA requires that staff document all scheduling contact attempts in a patient's EHR.²⁹

On day 46, the MHNP placed the patient's RTC order and submitted another RTC order on day 63. In an interview with the OIG, the MHNP reported placing the second RTC order after becoming aware from the patient's EHR that the follow-up appointment was not scheduled. On day 63, a MSA scheduled the patient for day 162. The access operations manager told the OIG that the delay in scheduling the follow-up appointment with the patient may have been due to MSA staffing shortages and competing scheduling priorities. Facility leaders provided the OIG with data that reflected approximately 42 percent of MSA positions were not filled between days 46 and 63. See table 1.

VHA requires that scheduling staff, including MSAs, schedule RTC orders in accordance with the CID.³⁰ An Office of Integrated Veteran Care management analyst reported that when an MSA is unable to schedule an appointment by the CID, the MSA "may be required to review" the patient's community care eligibility.

In an interview, when asked why the patient's follow-up appointment was not scheduled until day 162 despite the MHNP's request to see the patient by day 102, the MSA reported to the OIG that the patient's appointment was scheduled based on the MHNP's next availability. The MSA also said that community care would have been considered if the MHNP would have requested the patient be seen outside the VA. The access operations manager told the OIG that the patient's follow-up mental health appointment being scheduled approximately two months after the CID was "not unusual" due to limited provider staffing. The MSA supervisor reported to the OIG the expectation that MSAs inform providers if the next available appointment date for RTC orders exceeds the CID. The access operations manager also reported that when follow-up appointments cannot be scheduled by the CID, MSAs should discuss the delay with the requesting provider to determine whether to offer a community care referral to the patient. In an interview with the OIG, the MSA confirmed not notifying the MHNP regarding the patient's appointment date exceeding the CID but could not recall why that notification did not occur.

The associate chief of staff, mental health and the chief of psychiatry reported that MHNP and psychiatrist vacancies and difficulties recruiting for open positions contributed to scheduling delays. However, facility leaders provided the OIG with data that indicated all MHNP positions

²⁸ VHA, "National Return To Clinic (RTC) Order Standard Operating Procedure (SOP)."

²⁹ VHA "Minimum Scheduling Effort for Outpatient Appointments Standard Operating Procedure (SOP)," updated October 26, 2021.

³⁰ VHA Directive 1230.

(9 of 9) were filled and 67 percent of psychiatrist positions (4 of 6) were filled from the day the MHNP placed the initial RTC order for the patient to the day the MSA scheduled the patient's follow-up appointment. The OIG concluded that the 2 of 15 MHNP and psychiatrists vacant positions seems unlikely to account for the delay for this patient's follow-up appointment. See table 1.

Table 1. Outpatient Mental Health Staffing from the RTC Order Request to theScheduling of the Patient's Follow-up Appointment (Days 46–63)

Position	Number of Filled Positions (%)	Number of Vacancies (%)
MHNPs	9 (100%)	0 (0%)
Psychiatrists	4 (67%)	2 (33%)
MSAs	3.5 (58%)	2.5 (42%)

Source: OIG analysis of data provided by facility leaders.

Note: Sometime between days 61 and 91, one additional MSA position was filled; therefore, MSA filled and vacant position totals are approximate.

The OIG concluded that MSA staffing vacancies may have contributed to staff's failure to initiate timely scheduling efforts, and ultimately not scheduling the patient's follow-up appointment until approximately four months after the patient's initial visit with the MHNP. The delay in the provision of mental healthcare follow-up prevented assessment and potential treatments that may have mitigated the patient's suicide risk.

2. Deficiencies in Staff's Suicide Risk Assessment, Lethal Means Safety Counseling, Consultation, and Follow-up for the Patient

The OIG substantiated that during a PTSD evaluation, a social worker failed to sufficiently assess suicide risk, conduct <u>lethal means safety counseling</u> with the patient, and consult with the patient's prescriber. The OIG also found that staff failed to arrange follow-up PTSD treatment for the patient and that a supervisory social worker provided inadequate oversight of the social worker.

Suicide Risk Assessment and Lethal Means Safety Counseling

VHA instructs providers to review mental health screening tools completed by patients outside of a visit and "take the appropriate clinical actions."³¹ When a patient reports thoughts of being "better off dead or hurting [themselves]" on a depression rating scale, VHA requires that staff

³¹ "Guideline for the Collection, Monitoring and Use of Asynchronous Veteran Self-Reported Health Data," VHA, accessed June 15, 2023, <u>https://dvagov.sharepoint.com/sites/VACOMentalHealth/SitePages/Async_Comms-Data.aspx</u>. (This site is not publicly accessible.) Patients "may use mobile apps or online platforms" to complete mental health screens that are sent to their providers.

conduct "appropriate clinical assessment and follow up."³² VHA advises providers to complete a comprehensive suicide risk evaluation that includes "suicidal ideation, plan, intent, suicidal or self-harm behaviors, risk factors and protective factors" and document the patient's suicide risk level and plan for reducing risk.³³ If a patient reports access to firearms, VHA instructs clinicians to consider "options for improving safe storage," including offering gun locks, involving a family member or friend, and exploring "temporary off-site storage of the firearm."³⁴

Inadequate Suicide Risk Assessment and Lethal Means Safety Counseling

During the PTSD evaluation on day 98, the patient reported "passive suicidal thoughts without any plan or intent approximately 2 to 3 weeks ago" and denied current suicidal ideation. The patient denied a history of suicide attempt, reported access to a firearm, and that the "firearm and ammo are stored in two separate locations." The patient completed PTSD and depression rating scales that the social worker sent the patient through text and electronic mail. Approximately two hours after the PTSD evaluation, the social worker received the patient's depression rating scale results.³⁵ The depression rating scale indicated "moderately severe symptoms," which included the patient had thoughts of being "better off dead" and self-harm several days during the prior two weeks.

In an interview with the OIG, the social worker acknowledged not following up with the patient in response to the patient's depression rating scale results. The social worker described not being concerned about the patient's suicide risk based on a discussion with the patient regarding protective factors, including "future plans and goals and [the patient's] support systems." The social worker also reported the impression that the patient's suicide risk was "minimal" based on the patient's report of no prior suicide attempts or plan and because the extent of the patient's suicidal ideation was "vague death wishes." The social worker reported not considering completing a comprehensive suicide risk evaluation, which would have evaluated and

³⁴ "Safety Plan Reminder Dialogue Template: Instruction Guide," VHA Office of Mental Health and Suicide Prevention, accessed February 7, 2024, <u>dvagov.sharepoint.com/sites/VACOMentalHealth/Safety Planning</u> <u>SBR/Forms/AllItems.aspx?id=%2Fsites%2FVACOMentalHealth%2FSafety Planning SBR%2FSafety</u> <u>Planning%2FClinician Instructions and Quick Guides%2FSafety Plan Note Template User</u> <u>Guide%2Epdf&parent=%2Fsites%2FVACOMentalHealth%2FSafety Planning SBR%2FSafety</u> Planning%2FClinician Instructions and Quick Guides. (This site is not publicly accessible.)

³² VA Suicide Risk Identification Strategy, "Frequently Asked Questions (FAQ)," updated January 5, 2023, and April 4, 2024; Deputy Under Secretary for Health for Operations and Management, "Suicide Risk Screening and Assessment Requirements," memorandum to the Veterans Integrated Service Network (VISN) Directors, VISN Chief Medical Officers, VISN Mental Health Leads, May 23, 2018.

³³ VA Suicide Risk Identification Strategy, "Frequently Asked Questions (FAQ)"; Deputy Under Secretary for Health for Operations and Management, "Suicide Risk Screening and Assessment Requirements," memorandum.

³⁵ The social worker reported typically sending mental health rating scales to patients through text and electronic mail within the two days prior to a scheduled appointment. The social worker did not recall when the depression and PTSD rating scales were sent to the patient.

documented the patient's risk and protective factors and suicide risk level, based on the assumption that the patient would have had a negative C-SSRS result.³⁶

The social worker told the OIG about not considering completing a safety plan or conducting further lethal means safety counseling with the patient due to a lack of knowledge about VHA safety plans and options, such as gunlocks, at the time.³⁷ However, the OIG found that approximately one month prior to the patient's PTSD evaluation, the social worker completed required suicide prevention and lethal means safety trainings, which reviewed safety planning and recommended discussion of firearm removal from a patient's home and safe storage.³⁸

In an interview with the OIG, the supervisory social worker reported being responsible for PTSD clinic operations at the facility and described an expectation for a social worker to discuss lethal means safety counseling for patients with access to a firearm, including giving the firearm to someone and offering a gun lock. The supervisory social worker reported providing the social worker with additional safety planning training after the patient's death.

Given the patient's report of depression symptoms and firearm possession and responses on the depression rating scale indicating thoughts of death and self-harm, the OIG would have expected the social worker to pursue further evaluation, seek supervision, or consult with the patient's prescriber, as later discussed. The OIG would have also expected the social worker to discuss additional lethal means safety measures with the patient to enhance firearms safety. The social worker's failure to thoroughly evaluate the patient's suicide risk and conduct adequate lethal means safety counseling may have contributed to the social worker's underestimation of the patient's suicide risk and the patient's immediate access to the means to engage in suicidal behavior. Further, the social worker did not document the patient's risk and protective factors and suicide risk level. Failure to document a patient's risk and protective factors and suicide risk level in the EHR may result in lack of communication of important clinical information to other providers involved in the patient's care.

³⁶ VA Suicide Risk Identification Strategy, "Frequently Asked Questions (FAQ)."

³⁷ The facility leader reported to the OIG that the social worker's employment at the facility began in early fall 2022.

³⁸ Safe storage of firearms includes keeping ammunition out of the home, removing parts of the firearms such as the firing pin, and locking the weapon and giving someone else the key. VHA Directive 1071(1), *Mandatory Suicide Risk and Intervention Training*, May 11, 2022, amended June 21, 2022. Assistant Under Secretary for Health for Operations, "Lethal Means Safety (LMS) Education and Counseling," memorandum to VISN Directors, Medical Center Directors, Readjustment Counseling Services District Directors, and Readjustment Counseling Services Deputy District Directors, November 2, 2020.

Consultation with Prescriber

Patients experiencing suicidal thoughts with firearm access in the home are at increased risk for suicide.³⁹ Approximately seven weeks after the MHNP diagnosed the patient with unspecified trauma- and stressor-related disorder and prescribed mirtazapine, the patient reported moderate-severe symptoms of depression, including suicidal thoughts and possession of a firearm, to the social worker.

In an OIG interview, the social worker reported not having contact with the MHNP about the patient's care and thought it was not necessary at the time, based on the patient's presentation. The social worker told the OIG that PTSD clinic staff typically do not consult with prescribers unless a patient declines PTSD treatment or needs a medication refill, and that the PTSD evaluation results are shared through the patient's EHR. The social worker reported notifying a prescriber through a patient's EHR of a patient's new or worsening symptoms only when the patient is determined to be at high risk for suicide. The social worker reported that when a patient is at immediate risk for suicide, the patient is escorted to the outpatient mental health clinic for an emergency evaluation conducted by an available prescriber.

The MHNP reported to the OIG the expectation of being notified by the social worker through the patient's EHR about the patient's report of suicidal ideation. The supervisory social worker told the OIG that PTSD clinic staff did not notify a patient's assigned prescriber of new or worsening symptoms, such as suicidal ideation, and that there were no PTSD clinic policies or procedures in place to require alerting the prescriber. The suicide prevention coordinator described the expectation that the social worker contact the suicide prevention team if a patient screens positive on the comprehensive suicide risk evaluation, reports suicidal ideation with plan or intent, or if there is concern about a patient's suicide risk.

The OIG determined that the social worker did not perceive the patient to be at risk and therefore did not consider notifying the MHNP about the patient's report of firearm availability and the onset of suicidal ideation since the MHNP's most recent evaluation. The lack of notification to the MHNP about the patient's worsening depression symptoms hindered the MHNP's monitoring of the patient's medication response and contributed to a failure to address the patient's suicide risk factors.

³⁹ "Firearm Access is a Risk Factor for Suicide," Harvard T.H. Chan School of Public Health, accessed June 6, 2024, <u>https://www.hsph.harvard.edu/means-matter/means-matter/risk/</u>.

Follow-up Care

VHA requires providers to submit an RTC order prior to the end of a patient's visit that includes a CID when requesting a follow-up appointment for a patient.⁴⁰ When the patient is referred to another provider for mental health treatment and a "same day, direct, <u>warm handoff</u>" does not occur with that provider, VHA requires providers to enter a clinical consult request with the CID.⁴¹ Facility leaders are responsible for monitoring that staff provide "timely review and response" to consult requests.⁴²

During the day of the patient's PTSD evaluation, the social worker documented a plan for the patient to return to the PTSD clinic for individual therapy and sent the supervisory social worker an instant message to contact the patient to schedule a follow-up appointment. The social worker did not document a CID or submit an RTC order or consult request.

In an interview with the OIG, the social worker discussed typically informing patients that a staff member would contact the patient for a follow-up appointment and that the usual wait time for an appointment was within two months. The social worker told the OIG about not entering an RTC order for the patient because the patient was referred to the supervisory social worker for a specific PTSD evidence-based psychotherapy that the supervisory social worker provided. The supervisory social worker reported to the OIG that a PTSD clinic provider communicates a follow-up request to another provider for patient referrals within the PTSD clinic. The supervisory social worker acknowledged that there was not a tracking process in place to ensure that follow-up appointments for PTSD treatment were scheduled.

The supervisory social worker also reported calling the evidence-based psychotherapy coordinator by phone to refer the patient for PTSD follow-up treatment due to the supervisory social worker's lack of availability, and not documenting this contact.⁴³ The supervisory social worker reported learning of the patient's death prior to the follow-up coordination occurring. The evidence-based psychotherapy coordinator reported not receiving any contact regarding treatment coordination for the patient and estimated receiving patient referrals from the PTSD clinic staff on an approximately monthly basis due to limited PTSD clinic staff availability.

⁴⁰ VHA Directive 1230.

⁴¹ Assistant Under Secretary for Health for Clinical Services/Chief Medical Officer (CMO), "Standard Operating Procedures for Outpatient Mental Health Consults," memorandum to the VISN Director, VISN CMOs, VISN Chief Mental Health Officers, October 7, 2021; VHA Directive 1232(4).

⁴² VHA Directive 1232(4).

⁴³ The supervisory social worker approximated that the phone call to the evidence-based psychotherapy coordinator occurred the same day as the patient's PTSD evaluation. Evidence-based psychotherapies are research-supported "specific psychotherapeutic treatments" that have shown effectiveness in improving patients' mental health conditions and are typically provided by licensed mental health providers such as psychologists and social workers who have received specialized training in the evidence-based psychotherapy. VHA Directive 1160.05, *Evidence-Based Psychotherapies and Psychosocial Interventions for Mental and Behavioral Health Conditions*, June 2, 2021.

The OIG concluded that the lack of formal consult and documentation processes likely contributed to staff's failure to ensure a PTSD follow-up appointment for the patient. As a result, staff did not contact the patient after the PTSD evaluation to confirm a follow-up plan. The lack of a follow-up plan may have led to uncertainty for the patient about the accessibility of treatment to address PTSD-related concerns.

Supervisory Oversight of the Social Worker

VHA recognizes that "optimal diagnosis and treatment of PTSD requires specialized knowledge and skill," and "staff should have the capacity to address the severity, chronicity, complexity, and comorbidities associated with PTSD."⁴⁴ To this end, PTSD clinic providers are expected to have "expertise in PTSD and PTSD EBPs [evidence-based psychotherapies]."⁴⁵

A facility leader reported to the OIG that the social worker was hired approximately six weeks prior to conducting the patient's PTSD evaluation. In an interview with the OIG, the social worker described conducting psychiatric evaluations at a non-VA emergency department in the past. However, the OIG identified deficiencies in the assessment of the patient including a failure to address the patient's moderately severe depression symptoms and recent onset of suicidal thoughts. The social worker also reported lacking experience providing PTSD treatment upon starting at the facility. The social worker told the OIG that a typical practice was to instant message the supervisory social worker when clinical consultation was needed, and also reported that the supervisory social worker's availability was limited due to clinical demands. The social worker denied that anyone else was available for consultation.

The supervisory social worker told the OIG that the social worker was initially hired for a different clinic and reported awareness of the social worker's lack of qualification for a PTSD clinic provider. The supervisory social worker reported that oversight of the social worker occurred through informal check-ins and reported providing consultation to the social worker on an as-needed basis. The supervisory social worker reported not observing the social worker's therapy sessions or reviewing the social worker's EHR documentation and did not document consultation with the social worker. The supervisory social worker explained that formal supervision did not occur because the social worker was a licensed independent provider.⁴⁶

⁴⁴ VHA Directive 1160.03(1), *Programs for Veterans with Posttraumatic Stress Disorder (PTSD)*, November 16, 2017, amended April 24, 2019, was rescinded and replaced by VHA Directive 1160.03, *Programs for Veterans with Posttraumatic Stress Disorder (PTSD)*, October 16, 2023. The policies contain the same or similar language regarding PTSD staff expertise.

⁴⁵ VHA Directive 1160.03(1).

⁴⁶ A licensed independent provider is an individual "permitted by law" and the VHA to "provide patient care services independently, i.e. [that is], without supervision or direction, within the scope of the individual's license and in accordance with individually granted clinical privileges." VHA Directive 1110.02, *Social Work Professional Practice*, July 26, 2019.

In mid-summer 2023, the OIG notified facility leaders of concerns related to inadequate supervision of the social worker given the social worker's lack of providing PTSD treatment. The chief, quality management reported to the OIG that the supervision of the social worker "does require some improvement" and reported that the supervisory social worker planned to implement quarterly audits of the social worker's EHR documentation. The chief, quality management also reported that a "competency checklist will be developed for current and future staff members" in the PTSD clinic.

Given the supervisory social worker's awareness of the social worker's minimal experience working with PTSD patients, the OIG would have expected the supervisory social worker to ensure adequate oversight of the social worker's specialized PTSD care provision. The supervisory social worker's lack of oversight may have contributed to a failure to identify the social worker's inadequate suicide risk assessment and lethal means safety counseling for the patient and consequently, an underestimated and unmitigated suicide risk.

3. Failure to Submit TBI Consult

The OIG substantiated that facility staff did not submit a consult for a TBI evaluation following the patient's positive TBI screen, as required by VHA.⁴⁷

VHA requires that "post-9/11" veterans are screened for TBI to ensure provision of "appropriate treatments and services" upon entry into VA health care.⁴⁸ Veterans with positive screens must be offered further evaluation by a provider with TBI expertise.⁴⁹ According to facility guidance, following a positive TBI screen and consent from the patient, a TBI consult should be entered to request further evaluation of the patient.⁵⁰

Staff involved in the patient's care and the facility TBI coordinator provided conflicting information to the OIG about who is responsible for submitting a TBI consult following a patient's positive TBI screen. During the patient's appointment on day 7, the licensed practical nurse documented that the patient agreed to a TBI consult for evaluation after screening positive for TBI. The licensed practical nurse added the primary care nurse practitioner as an additional signer to the EHR documentation that included the patient's positive TBI screen. The licensed practical nurse reported to the OIG the understanding that the primary care nurse practitioner was responsible for entering the TBI consult.

⁴⁷ VHA Directive 1184, Screening and Evaluation of Post-9/11 Veterans for Deployment-Related Traumatic Brain Injury, January 3, 2022.

⁴⁸ VHA Directive 1184.

⁴⁹ VHA Directive 1184.

⁵⁰ Facility Traumatic Brain Injury (TBI) Care Coordination Agreement.

In an interview with the OIG, the primary care nurse practitioner reported not entering TBI consults for patients with a positive TBI screen because of the understanding that the clinic social worker or a nurse conducted follow-up. A registered nurse reported to the OIG being uncertain about who was responsible for entering a TBI consult. The registered nurse explained the understanding that because the primary care nurse practitioner placed a mental health consult, mental health staff would address the positive TBI screen.

The TBI coordinator told the OIG that the licensed practical nurse or primary care nurse practitioner should have entered the TBI consult following the positive screen. The TBI coordinator reported monitoring a report for patients who had not received an evaluation following a positive TBI screen on an approximately quarterly basis. For patients who had not received the evaluation, the TBI coordinator reported contacting the provider who conducted the positive TBI screen to request that a TBI consult be submitted and said that the contact to the provider may not be documented. The TBI coordinator reported not taking any action to address the lack of a TBI evaluation for the patient because when the report was reviewed, the patient was deceased.

In an interview, the associate chief of staff, specialty care reported to the OIG the expectation that the nurse who conducts a TBI screen would notify the provider of a patient's positive result. The associate chief of staff, specialty care said that a provider's review and signature were required to submit a TBI consult. The associate chief of staff, specialty care explained that the primary care nurse practitioner may have prioritized addressing the patient's mental health needs rather than the positive TBI screen result given the patient's positive PTSD and depression screens.

The OIG concluded that the primary care nurse practitioner failed to ensure that a consult was submitted due to a lack of knowledge about providers' responsibilities following a positive TBI screen. Failure to facilitate a TBI evaluation for the patient may have hindered the patient's access to TBI treatment.

4. Facility Leaders' Insufficient Administrative Actions Following the Patient's Death

The OIG found that

- facility staff did not inform facility leaders regarding closure of an incomplete root cause analysis action item,
- the Peer Review Committee (PRC) failed to address two system issues identified during the peer review process and document formal discussions as required,
- the suicide prevention coordinator failed to complete the BHAP Family Interview Tool-Contact (FIT-C) form after notification of the patient's death, as required,

- VHA leaders did not provide written guidance related to criteria or process for suicide prevention program staff to determine when not to contact family, and
- facility leaders did not conduct an institutional disclosure based on an erroneous understanding of requirements.⁵¹

Root Cause Analysis

The root cause analysis process utilizes a focused review with an interdisciplinary team approach to identify system issues that contribute to healthcare-related adverse events and define corrective actions to prevent future incidents.⁵² According to VHA, after a root cause analysis is conducted, "the organization must then implement an action plan to fortify its systems against vulnerabilities with the potential to impact patients."⁵³ Actions and outcomes identified during a root cause analysis must be monitored for completion and sustainment, ideally through a reporting system, such as a patient safety committee meeting.⁵⁴

The Facility Director initiated a root cause analysis eight days after facility staff received notification of the patient's death. The Facility Director concurred with the root cause analysis team's four identified action items and associated outcome measures. In April 2024, approximately a year and a half later, the patient safety manager informed the OIG that two outcome measures remained open.

The patient safety manager told the OIG that root cause analysis action updates occurred monthly in an executive leadership committee meeting and quarterly during a Quality and Patient Safety Committee meeting.⁵⁵ In October 2023, facility mental health leaders reported to the patient safety manager that it was not feasible to complete one of the identified action items due to a staffing shortage and the patient safety manager suggested closing the action item and the acting associate chief of staff, mental health agreed.⁵⁶ In April 2024, the patient safety manager told the OIG that the action item closure was not communicated to facility leaders and

⁵¹ VHA Directive 1190, *Peer Review for Quality Management*, November 21, 2018; VHA, *Suicide Prevention Program Guide*, November 2020, updated December 2022. The guides contain similar language related to the Behavioral Health Autopsy Program; Deputy Under Secretary for Health for Operations and Management, "Behavioral Autopsy Program Implementation," memorandum to Network Directors (10N1-23), December 11, 2012. A behavioral health autopsy is a "standardized medical record review" utilizing a national template and submitted via an approved suicide prevention SharePoint portal.

⁵² VHA Handbook 1050.01, *National Patient Safety Improvement*, March 4, 2011, was rescinded and replaced by VHA Directive 1050.01, *VHA Quality and Patient Safety Programs*, March 24, 2023, amended March 5, 2024. The policies contain similar language related to action items.

⁵³ VHA National Center for Patient Safety, *Guide to Performing a Root Cause Analysis*, February 5, 2021, updated in March 2024. The guides contain similar language related to root cause analysis.

⁵⁴ VHA National Center for Patient Safety, *Guide to Performing a Root Cause Analysis,* February 5, 2021.

⁵⁵ Executive leaders attend the Quality and Patient Safety Committee meeting.

⁵⁶ At the time, the associate chief of staff, mental health was temporarily detailed to another position.

that mental health leaders were responsible to provide that information to the leadership team. The chief, quality management confirmed to the OIG that "this information was not directly communicated to Executive Leadership when this decision was made."

Given the Facility Director's concurrence with the root cause analysis review and the patient safety manager's routine reporting to facility leaders, the OIG would have expected facility leaders to be notified regarding the closure of the incomplete action item. The lack of communication regarding the closure of an incomplete action item diminished facility leaders' awareness of barriers to address system vulnerabilities and improve quality of care.

Peer Review Committee

Peer reviews for quality management are "intended to promote confidential and non-punitive assessments" of clinical care to determine whether there are process improvement opportunities.⁵⁷ VHA PRCs are responsible to hold "formal discussions" regarding a peer review and ensure formal meeting minutes reflect the discussions.⁵⁸

In mid-summer 2023, the OIG notified facility leaders of an unresolved system issue identified in a peer review. Approximately one week later, the chief, quality management reported to the OIG that the PRC confirmed the unresolved system issue had not been addressed and would be discussed in the next PRC meeting.

The risk manager told the OIG that the PRC typically discusses identified system issues; however, acknowledged that the PRC did not review and document a resolution for the system issue identified during the review of the patient's care. The OIG concluded that the risk manager's reason as to why the system issue was not reviewed was not a sufficient explanation. The Chief of Staff was unsure why the system issue was not reviewed and acknowledged that a resolution should have been documented in the meeting minutes.

The chief, quality management noted being responsible "going forward" for reviewing PRC meeting minute documentation before it is sent for approval by the Facility Director and Chief of Staff. In mid-fall 2023, the PRC meeting minutes included that the PRC recommended closure of the system issue.

In response to an OIG inquiry about a second system issue, the chief, quality management reported that the second system issue was addressed by the root cause analysis but "could not locate confirmation of any follow up with the PRC." In review of the root cause analysis, the OIG confirmed that the system issue was addressed. The Chief of Staff acknowledged that the PRC did not follow up on the system issue. The OIG concluded that the lack of PRC documentation to reflect discussions and tracking of actions to resolution may contribute to gaps

⁵⁷ VHA Directive 1190.

⁵⁸ VHA Directive 1190.

in communication and follow-up, and consequently a failure to mitigate identified patient safety risks.

BHAP

Since 2012, VHA has required gathering information following all reported patient deaths by suicide to identify contributory factors and to understand the circumstances affecting the patient's life prior to death.⁵⁹ VHA requires that a suicide prevention coordinator complete a behavioral health autopsy that includes an EHR review.⁶⁰ Additionally, the suicide prevention coordinator is expected to contact the next of kin to inform them about the BHAP family interview process and offer the opportunity to participate.⁶¹ The suicide prevention coordinator is required to document the family member's interest in participating in an interview on a FIT-C form.⁶² The FIT-C form includes an option for the suicide prevention coordinator to "indicate the best reason why contact was not possible." The EHR review and FIT-C form are required to be completed within 30 days of awareness of a patient's death by suicide.⁶³

The chief, quality management reported to the OIG that the suicide prevention coordinator conducted the BHAP EHR review approximately two weeks after learning of the patient's death by suicide. However, the OIG found that the suicide prevention coordinator did not complete the FIT-C form, as required.⁶⁴ In an interview with the OIG, the suicide prevention coordinator reported not contacting the patient's family because facility staff who had contact with the patient's family reported that outreach would upset the family. The suicide prevention coordinator coordinator reported considering outreach but did not pursue contact since it was beyond the 30-day requirement to complete the FIT-C form and that staff reported that the family was "still like really upset." The suicide prevention coordinator did not complete the FIT-C form because a family member was not contacted. When asked if the suicide prevention coordinator reported that the supervisor at the time was in an interim role and would not have been familiar with the situation.

The OIG found that VHA leaders did not provide written guidance related to criteria or process for suicide prevention program staff to determine when not to contact family. In an interview

⁵⁹ VHA, *Suicide Prevention Program Guide*, November 2020; Deputy Under Secretary for Health for Operations and Management, "Behavioral Autopsy Program Implementation," memorandum.

⁶⁰ VHA, Suicide Prevention Program Guide, November 2020; VHA Directive 1160.07, Suicide Prevention Program, May 24, 2021.

⁶¹ VHA, *Suicide Prevention Program Guide*, November 2020. For purposes of this report, the OIG refers to the next of kin as family member.

⁶² VHA, Suicide Prevention Program Guide, November 2020.

⁶³ VHA, Suicide Prevention Program Guide, November 2020; VHA Directive 1160.07.

⁶⁴ VHA, Suicide Prevention Program Guide, November 2020; VHA Directive 1160.07.

with the OIG, the VHA Director of the Center of Excellence for Suicide Prevention and Program Coordinator of Field Operations reported that suicide prevention program staff may decide to not contact a patient's family based on concerns about the family's reaction. However, the suicide prevention program staff member would be required to document the rationale for not contacting the family member in the FIT-C form. The VHA Director of the Center of Excellence for Suicide Prevention confirmed an absence of VHA written guidance and told the OIG that "specific circumstances that might 'qualify' as a reason to not call family members" have been discussed on calls and presentations with suicide prevention teams but the discussions were not documented.

The VHA Director of the Center of Excellence for Suicide Prevention told the OIG that given the variability of suicide prevention staffing among VHA medical centers, the national program office leaders afforded suicide prevention coordinators the discretion to determine independently whether to outreach family members. However, the OIG suggests that consultation with staff knowledgeable about the goals of BHAP, such as mental health service supervisors or leaders, should be considered in the process of decisions about outreach to family members. Such consultation would enhance the likelihood that decisions about family outreach are based on sound clinical judgment in the best interest of the family and not potentially compromised by limited information and perspective.

Grief reactions to suicide commonly include strong emotions such as guilt, blame, and anger.⁶⁵ VHA instructs <u>suicide postvention</u> staff to encourage self-care and coping, provide resources, and offer follow-up to manage grief over time.⁶⁶ VHA identifies the validation and normalization of "all reactions" as one component of postvention psychoeducation.⁶⁷ Based on these understandings, the OIG would have expected the suicide prevention coordinator to develop a plan for outreach to the family to complete the FIT-C form and offer postvention support. The suicide prevention coordinator's decision to not contact the family may have hindered the family member's access to resources to support grief management.

The absence of written VHA guidance regarding when not to contact family members likely contributed to the suicide prevention coordinator's failure to seek consultation regarding the

⁶⁵ National Action Alliance for Suicide Prevention, *Responding to Grief, Trauma, and Distress After a Suicide: U.S. National Guidelines*, April 2015.

⁶⁶ "Recommendations for Postvention – Meeting with Family/Loved Ones," VA, Uniting for Suicide Postvention, accessed April 17, 2024,

https://dvagov.sharepoint.com/:w:/r/sites/ECH/srsa/_layouts/15/Doc.aspx?sourcedoc=%7BB1C5F3D9-B22C-4069-ACB9-

B57A1D6CA216%7D&file=Recommendations_for_Postvention_Meeting_with_Family%2CLoved%20Ones_v.9.1 5.22.docx&action=default&mobileredirect=true&isSPOFile=1&clickparams=eyJBcHBOYW1lljoiVGVhbXMtRG Vza3RvcCIsIkFwcFZlcnNpb24iOiI0OS8yNDA0MTEyMjMxNSIsIkhhc0ZlZGVyYXRlZFVzZXIiOmZhbHNlfQ% 3D%3D. (This site is not publicly accessible).

⁶⁷ "Recommendations for Postvention – Meeting with Family/Loved Ones," VA, Uniting for Suicide Postvention.

decision and document the rationale in the FIT-C form. The suicide prevention coordinator's failure to seek consultation resulted in incomplete consideration of the family member's potential need for resources to support grief management and the offer for the family member to participate in the family interview process.

Institutional Disclosure Considerations

An institutional disclosure is a formal process for facility leaders and clinicians to inform a patient or patient's personal representative when an adverse event occurred that resulted in the patient's injury or death, including specific information about the patient or representative's rights and recourse.⁶⁸ An institutional disclosure must be completed regardless of when the adverse event is discovered.⁶⁹ VHA requires an institutional disclosure of adverse events that cause death or disability, regardless of whether they resulted from an error.⁷⁰

In an interview with the OIG, the Chief of Staff did not recall any discussions to consider conducting an institutional disclosure for the patient. The chief, quality management and the risk manager told the OIG that an institutional disclosure to the patient's family was not completed because the patient's death did not occur at the facility. Although a patient's death by suicide while receiving care at a facility warrants a completion of an institutional disclosure, it is not limited to this circumstance.⁷¹ The chief, quality management reported the internal review outcomes did not warrant an institutional disclosure. The OIG concluded that facility leaders may have had an erroneous understanding of institutional disclosure requirements. The March 2024 OIG request for VHA to enhance clarification of institutional disclosure expectations addresses the concern of facility leaders' misunderstanding of requirements.⁷²

As discussed above, the OIG identified deficiencies in the patient's care including insufficient management of mental health treatment needs and administrative processes for the patient. Given facility leaders' failure to adequately consider conducting an institutional disclosure and the OIG-identified care deficiencies, facility leaders should consider an institutional disclosure.

⁶⁸ VHA Directive 1004.08, *Disclosure of Adverse Events to Patients*, October 31, 2018. VHA defines an adverse event as "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."

⁶⁹ VHA Directive 1004.08.

⁷⁰ VHA Directive 1004.08.

⁷¹ VHA Directive 1004.08; The Joint Commission, *Sentinel Event Policy and Procedures*, accessed May 1, 2024, <u>https://www.jointcommission.org/resources/sentinel-event/sentinel-event-policy-and-procedures/</u>.

⁷² VA OIG, *Institutional Disclosure Policy Requirements Should Be Clarified*, Management Advisory Memorandum No. 23-02386-91, March 13, 2024.

Conclusion

The OIG substantiated that the MHNP inadequately managed the patient's medication by failing to provide the patient information about the increased risk of suicidal thoughts and behaviors for young adults prescribed mirtazapine. The MHNP's failure to obtain the patient's informed consent regarding the boxed warning likely resulted in the patient's insufficient awareness of the need to self-monitor for suicidal thoughts and seek supportive resources as needed. The MHNP did not complete the C-SSRS as required with the patient because of a lack of knowledge about VHA and facility requirements and facility use of an intake template that did not include the C-SSRS. The MHNP's failure to complete the C-SSRS may have contributed to an inadequate assessment of the patient's suicide risk.

The MHNP did not adequately address the need for close monitoring after initiating mirtazapine, as specified in the boxed warning. The MHNP's failure to closely monitor the patient after initiating mirtazapine prevented a timely evaluation of worsening symptoms or emerging adverse medication effects, including suicidal thoughts and behaviors. The lack of close monitoring could also result in a failure to assess medication effectiveness for mental health symptoms and provide necessary adjustments to the treatment.

MSA staff did not initiate scheduling of the patient's follow-up appointment within two business days and scheduled the patient almost two months later than the MHNP's requested RTC date for the patient and approximately four months after the patient's initial visit. The delay in mental healthcare follow-up prevented assessment and potential treatments that may have mitigated the patient's suicide risk.

The OIG substantiated that during the PTSD evaluation, the social worker failed to sufficiently assess the patient's suicide risk, conduct lethal means safety counseling with the patient, and consult with the patient's prescriber. The social worker's failure to thoroughly evaluate the patient's suicide risk and conduct adequate lethal means safety counseling may have contributed to the social worker's underestimation of the patient's suicide risk and the patient's immediate access to the means to engage in suicidal behavior. The social worker's lack of notification to the MHNP about the patient's worsening depression symptoms hindered the MHNP's monitoring of the patient's suicide risk and medication effects and contributed to a failure to address the patient's suicide risk.

The lack of formal consult and documentation processes likely contributed to staff's failure to ensure a PTSD follow-up appointment for the patient. The lack of a follow-up plan may have led to uncertainty for the patient about the accessibility of treatment to address PTSD-related concerns. A supervisory social worker provided inadequate oversight of the social worker who was hired approximately six weeks prior to conducting the patient's PTSD evaluation. The supervisory social worker's lack of oversight may have contributed to a failure to identify the

social worker's inadequate suicide risk assessment and lethal means safety counseling for the patient and consequently, an underestimated and unmitigated suicide risk.

The OIG substantiated that facility staff did not submit a consult for TBI evaluation following the patient's positive TBI screen, as required. The primary care nurse practitioner failed to ensure that a consult was submitted due to a lack of knowledge about providers' responsibilities. Failure to facilitate a TBI evaluation for the patient may have hindered the patient's access to TBI treatment.

Facility staff did not notify facility leaders about closure of an incomplete root cause analysis action item. The lack of communication regarding the closure of an incomplete action item diminished facility leaders' awareness of barriers to address system vulnerabilities and improve quality of care. The PRC failed to address two system issues identified during the peer review process and document formal discussions, as required. The lack of PRC documentation to reflect discussions and tracking of actions to resolution may contribute to gaps in communication and follow-up, and consequently a failure to mitigate identified patient safety risks.

The suicide prevention coordinator failed to complete the required BHAP FIT-C form after notification of the patient's death. The absence of written VHA guidance regarding when not to contact family members likely contributed to the suicide prevention coordinator's failure to seek consultation regarding the decision and document the rationale in the FIT-C form. The suicide prevention coordinator's failure to seek consultation resulted in incomplete consideration of the family member's potential need for resources to support grief management and the offer for the family member to participate in the family interview process.

Facility leaders did not conduct an institutional disclosure based on an erroneous understanding of requirements. Given facility leaders' failure to adequately consider conducting an institutional disclosure and the OIG-identified care deficiencies, facility leaders should consider an institutional disclosure.

Recommendations 1–14

1. The VA Tuscaloosa Healthcare System Director conducts a full review of care provided to the patient by clinical staff, consults with Human Resources and General Counsel Offices, and takes action as needed.

2. The VA Tuscaloosa Healthcare System Director strengthens processes to ensure that providers provide patient education about applicable boxed warnings when prescribing psychiatric medication, and monitors compliance.

3. The VA Tuscaloosa Healthcare System Director ensures mental health staff conduct suicide risk screenings and assessments as required by the Veterans Health Administration, and monitors compliance.

4. The VA Tuscaloosa Healthcare System Director evaluates outpatient mental health clinic scheduling procedures; identifies barriers to timely appointment scheduling, including staffing levels; and takes action as warranted.

5. The VA Tuscaloosa Healthcare System Director strengthens processes to ensure adequate lethal means assessment and lethal means safety counseling with patients.

6. The VA Tuscaloosa Healthcare System Director reviews posttraumatic stress disorder clinic processes to consult with a patient's prescriber following worsening of a patient's mental health symptoms.

7. The VA Tuscaloosa Healthcare System Director ensures posttraumatic stress disorder clinic consult and documentation procedures align with Veterans Health Administration requirements.

8. The VA Tuscaloosa Healthcare System Director conducts a review of the supervisory oversight of the social worker and other clinicians in the posttraumatic stress disorder clinic to ensure the identification and follow-up of clinical concerns for patients with complex mental health needs.

9. The VA Tuscaloosa Healthcare System Director strengthens processes to ensure adherence to Veterans Health Administration and facility traumatic brain injury screening and consult requirements, and monitors compliance.

10. The VA Tuscaloosa Healthcare System Director evaluates the root cause analysis processes regarding reporting of incomplete action items in accordance with Veterans Health Administration requirements, takes action as needed, and monitors compliance.

11. The VA Tuscaloosa Healthcare System Director evaluates the Peer Review Committee processes on addressing identified system issues in accordance with Veterans Health Administration requirements, takes action as needed, and monitors compliance.

12. The Under Secretary for Health considers establishing written guidance regarding the Behavioral Health Autopsy Program family interview process, including suicide prevention program staff's consultation, to ensure that the decision to not outreach a family member is based on the best interest of the family.

13. The VA Tuscaloosa Healthcare System Director ensures compliance with the Behavioral Health Autopsy Program including completion of the Family Interview Tool-Contact Form.

14. The VA Tuscaloosa Healthcare System Director evaluates the care provided to the patient, determines if an institutional disclosure is warranted, and takes action as indicated.

Appendix A: Office of the Under Secretary for Health Memorandum

Department of Veterans Affairs Memorandum

Date: August 2, 2024

From: Under Secretary for Health (10)

- Subj: Office of Inspector General (OIG) Draft Report, Mismanaged Mental Health Care for a Patient Who Died by Suicide and Review of Administrative Actions at the VA Tuscaloosa Healthcare System in Alabama
- To: Assistant Inspector General for Healthcare Inspections (54)

1. Thank you for the opportunity to review and comment on OIG's draft report regarding mental health care for a patient who died at the VA Tuscaloosa Healthcare System. The Veterans Health Administration concurs with recommendation 12 and provides an action plan in the attachment.

2. We are deeply saddened by the passing of this Veteran. We are committed to improving the delivery of mental health services across the system and preventing Veteran suicide.

3. Comments regarding the contents of this memorandum may be directed to the GAO OIG Accountability Liaison Office at vha10oicgoalaction@va.gov.

(Original signed by:) Shereef Elnahal, M.D., MBA

[OIG comment: The OIG received the above memorandum from VHA on August 13, 2024.]

Office of the Under Secretary for Health Response

VETERANS HEALTH ADMINISTRATION (VHA)

Action Plan

OIG Draft Report, Mismanaged Mental Health Care for a Patient Who Died by Suicide and Review of Administrative Actions at the

VA Tuscaloosa Healthcare System in Alabama

(OIG Project Number 2023-02393-HI-1375)

<u>Recommendation 12.</u> The Under Secretary for Health considers establishing written guidance regarding the Behavioral Health Autopsy Program family interview process, including suicide prevention program staff's consultation, to ensure that the decision to not outreach a family member is based on the best interest of the family.

VHA Comments: Concur

VHA agrees to consider clarifying guidance to assist facilities with implementation of the Behavioral Health Autopsy Program family interview process. To close this recommendation, VHA will provide evidence that supports consideration of updated guidance.

Status: In process

Target Completion Date: February 2025

Appendix B: VISN Director Memorandum

Department of Veterans Affairs Memorandum

- Date: August 13, 2024
- From: Director, VA Southeast Network (10N7)
- Subj: Office of Inspector General (OIG) Draft Report: Mismanaged Mental Health Care for a Patient Who Died by Suicide and Review of Administrative Actions at the VA Tuscaloosa Healthcare System in Alabama
- To: Office of the Under Secretary for Health (10) Director, Office of Healthcare Inspections (54MHP1) Executive Director, Office of Integrity and Compliance (10OIC)

1. I have completed a full review of the OIG Draft Report, Mismanaged Mental Health Care for a Patient Who Died by Suicide and Review of Administrative Actions at the VA Tuscaloosa Healthcare System in Alabama. We deeply regret the circumstances that impacted the quality of care delivered to one of our Veterans.

2. I concur with the recommendations and action plan submitted by the Tuscaloosa Healthcare System in Alabama.

3. I appreciate the opportunity for this review as part of a continuing process to improve the care of our Veterans.

4. If you have any questions or require further information, please contact the VISN 7 Quality Management Officer.

(Original signed by:)

David M. Walker, MD, MBA, FACHE Network Director

[OIG comment: The OIG received the above memorandum from VHA on August 13, 2024.]

Appendix C: Facility Director Memorandum

Department of Veterans Affairs Memorandum

Date: August 2, 2024

- From: Director, VA Tuscaloosa Healthcare System (679/00)
- Subj: Office of Inspector General (OIG) Draft Report: Mismanaged Mental Health Care for a Patient Who Died by Suicide and Review of Administrative Actions at the VA Tuscaloosa Healthcare System in Alabama

To: VISN 7 Network Director, VA Southeast Network (10N7)

1. Thank you for the opportunity to review and comment on the draft report "Mismanaged Mental Health Care for a Patient Who Died by Suicide and Review of Administrative Actions at the VA Tuscaloosa Healthcare System in Alabama."

2. I concur with the facility's response, recommendation, and submitted action plan. Tuscaloosa VA Medical Center is committed to providing high-quality Veteran-centered using evidence-based practices, collaboration, and innovation.

3. Comments regarding the contents of this memorandum may be directed to the Chief of Quality Management.

(Original signed by:) John F. Merkle, FACHE, VHA-CM Director, Tuscaloosa VAMC

[OIG comment: The OIG received the above memorandum from VHA on August 13, 2024.]

Facility Director Response

Recommendation 1

The VA Tuscaloosa Healthcare System Director conducts a full review of care provided to the patient by clinical staff, consults with Human Resources and General Counsel Offices, and takes action as needed.

_X _Concur

Nonconcur

Target date for completion: January 2025

Director Comments

The Tuscaloosa Healthcare System Director completed a full review of the care provided to the patient by clinical staff on May 30, 2024. The Director will meet with Human Resources and General Counsel before August 31, 2024, and will continue to take action until complete.

Recommendation 2

The VA Tuscaloosa Healthcare System Director strengthens processes to ensure that providers provide patient education about applicable boxed warnings when prescribing psychiatric medication, and monitors compliance.

_X _Concur

Nonconcur

Target date for completion: January 2025

Director Comments

The Tuscaloosa Healthcare System Director will strengthen the processes to ensure that providers provide patient education about applicable boxed warnings when prescribing psychiatric medication and monitor compliance. On July 3, 2024, Tuscaloosa VAMC's Pharmacy department developed a list of anti-depressants and corresponding boxed warnings. The list and boxed warning patient education will be provided to all prescribers.

Veterans prescribed a new psychiatric medication will receive initial boxed warning patient education from the ordering provider. Two weeks following the start of the new medication, Veterans will have a follow up appointment with a member of the care team (PharmD., MD, or APN), and within six weeks from start of medication will have an appointment with PharmD or ordering provider. Compliance will be monitored by the facility's local Pharmacy and Therapeutic Committee monthly.

Recommendation 3

The VA Tuscaloosa Healthcare System Director ensures mental health staff conduct suicide risk screenings and assessments as required by the Veterans Health Administration, and monitors compliance.

_X _Concur

Nonconcur

Target date for completion: January 2025

Director Comments

The Tuscaloosa Healthcare System added the Columbia Suicide Risk Screening (C-SSRS) to the Mental Health Outpatient nursing template on March 12, 2024. This was done to ensure mental health staff conduct suicide risk screenings and assessments as required by Veterans Health Administration and monitor compliance with C-SSRS.

The Medical Record Committee (MRC) will monitor compliance through medical record audits.

Recommendation 4

The VA Tuscaloosa Healthcare System Director evaluates outpatient mental health clinic scheduling procedures; identifies barriers to timely appointment scheduling, including staffing levels; and takes action as warranted.

_X _Concur

Nonconcur

Target date for completion: August 2024

Director Comments

The Tuscaloosa Healthcare System evaluated outpatient mental health clinic scheduling procedures to identify barriers to timely appointment scheduling. As a result of this review, Mental Health Outpatient Clinic clinical and non-clinical staff will meet daily using the Behavioral Health Interdisciplinary Program (BHIP) standardized template and providers will include in their Return-to-Clinic (RTC) order if extra scheduling efforts are needed. VA Tuscaloosa Healthcare System developed a contingency plan for a potential Medical Support Assistant (MSA) shortage. At the primary level, MSA floats are assigned to each area, and for the secondary level, MSA Leads and MSA Supervisors will provide coverage.

OIG Comments

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

Recommendation 5

The VA Tuscaloosa Healthcare System Director strengthens processes to ensure adequate lethal means assessment and lethal means safety counseling with patients.

_X_Concur

Nonconcur

Target date for completion: January 2025

Director Comments

The Tuscaloosa Healthcare System will complete a safety plan and comprehensive suicide risk evaluation (CSRE) with each positive suicide screen. The safety plan will include a full discussion on lethal mean safety, including a focus on firearm secure storage through providing gun locks, offering removal of weapons from the home, and/or giving weapons to a family member. The Quality and Patient Safety Committee will conduct monthly chart audits.

Recommendation 6

The VA Tuscaloosa Healthcare System Director reviews posttraumatic stress disorder clinic processes to consult with a patient's prescriber following worsening of a patient's mental health symptoms.

_X _Concur

Nonconcur

Target date for completion: January 2025

Director Comments

The Tuscaloosa Healthcare System will review the posttraumatic stress disorder clinic (PTSD) processes to consult with a patient's prescriber following the worsening of a patient's mental health symptoms. The PTSD clinic will develop a standard operating procedure (SOP) to include how clinic staff will provide the ordering provider and/or mental health provider with a warm handoff report by phone and identify the provider as a cosigner to clinic notes in Computerized Patient Record System (CPRS) of any Veteran exhibiting worsening symptoms. The Performance Improvement Committee for Mental Health will monitor development until completion.

Recommendation 7

The VA Tuscaloosa Healthcare System Director ensures posttraumatic stress disorder clinic consult and documentation procedures align with Veterans Health Administration requirements.

_X_Concur

Nonconcur

Target date for completion: January 2025

Director Comments

The Tuscaloosa Healthcare System reviewed the PTSD clinic consult and documentation procedures to ensure they align with Veterans Health Administration requirements. The Tuscaloosa Healthcare System will set up posttraumatic stress disorder clinics and develop a follow-up process for additional therapies.

Recommendation 8

The VA Tuscaloosa Healthcare System Director conducts a review of the supervisory oversight of the social worker and other clinicians in the posttraumatic stress disorder clinic to ensure the identification and follow up of clinical concerns for patients with complex mental health needs.

_X _Concur

Nonconcur

Target date for completion: January 2025

Director Comments

The Tuscaloosa Healthcare System will conduct a supervisory oversight of all clinicians in the PTSD clinic. To ensure the identification and follow-up of clinical concerns for patients, the social work supervisors across the facility will establish a process to review the new social workers' documentation for the first 90 days and provide feedback. Social work supervisors will audit and provide feedback for a random sample of social work documentation every 6 months thereafter.

The Medical Record Committee (MRC) will monitor compliance monthly through medical record audits.

Recommendation 9

The VA Tuscaloosa Healthcare System Director strengthens processes to ensure adherence to Veterans Health Administration and facility traumatic brain injury screening and consult requirements, and monitors compliance.

_X _Concur

_Nonconcur

Target date for completion: January 2025

Director Comments

The Tuscaloosa Healthcare System Director will strengthen processes to ensure adherence to Veterans Health Administration and facility traumatic brain injury (TBI) screening and consult requirements. The Chief of Social Work is working with the Health Informatics team to have a TBI consult generated for all positive TBI screens. The process will be monitored monthly by the Quality and Patient Safety Committee.

Recommendation 10

The VA Tuscaloosa Healthcare System Director evaluates the root cause analysis processes regarding reporting of incomplete action items in accordance with Veterans Health Administration requirements, takes action as needed, and monitors compliance.

_X _Concur

Nonconcur

Target date for completion: January 2025

Director Comments

The Tuscaloosa Healthcare System Director evaluated the root cause analysis (RCA) processes regarding reporting of incomplete action items in accordance with Veterans Health Administration requirements. As a result, to ensure follow-up actions are acted upon appropriately, the Chair of the Quality and Patient Safety Committee will present the Director with incomplete RCA action items and actions in the Executive Leadership Council, and action taken as warranted.

Recommendation 11

The VA Tuscaloosa Healthcare System Director evaluates the Peer Review Committee processes on addressing identified system issues in accordance with Veterans Health Administration requirements, takes action as needed, and monitors compliance.

_X _Concur

Nonconcur

Target date for completion: January 2025

Director Comments

The Tuscaloosa Healthcare System reviewed the peer review committee processes on addressing identified system issues in accordance with Veterans Health Administration requirements. The Peer Review Committee will document System issues and subsequent handoff to the responsible owner for completion will be documented in the peer review committee minutes.

Recommendation 13

The VA Tuscaloosa Healthcare System Director ensures compliance with the Behavioral Health Autopsy Program including completion of the Family Interview Tool-Contact Form.

_X __Concur

Nonconcur

Target date for completion: January 2025

Director Comments

The Tuscaloosa Healthcare System Director will ensure the Suicide Prevention Coordinator reports compliance with the Behavioral Health Autopsy Program including completion of the Family Interview Tool-Contact Form to the Quality and Patient Safety Committee monthly. The Tuscaloosa Healthcare System will explore additional strategies regarding the behavioral health autopsy program and provide updates to OIG as needed.

Recommendation 14

The VA Tuscaloosa Healthcare System Director evaluates the care provided to the patient, determines if an institutional disclosure is warranted, and takes action as indicated.

_X _Concur

Nonconcur

Target date for completion: August 2024

Director Comments

The Tuscaloosa Healthcare System Director determined an institutional disclosure is warranted. The institutional disclosure will be completed as outlined in VHA Directive 1004.08, Disclosure of Adverse Events to Patients, published October 31, 2018. The institutional disclosure was completed on Thursday, August 1, 2024.

Glossary

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

boxed warning. Used to "communicate potential rare but dangerous side effects," for "medications that carry serious safety risks," as required by the United States Food and Drug Administration.¹

cholesterol. A waxy substance found in the blood that is needed to build healthy cells, but elevated levels of cholesterol may increase the risk of heart disease.²

hydroxyzine. An antihistamine medication used to treat anxiety and induce sleep.³

lethal means. Objects such as medications, firearms, or sharp items that can be used in suicide attempts or other self-directed violence.⁴

lethal means safety counseling. A patient-centered counseling strategy to promote safety behaviors.⁵

mirtazapine. A medication used to treat depression.⁶

posttraumatic stress disorder. A mental health condition triggered by experiencing or witnessing a terrifying event and characterized by flashbacks, nightmares, severe anxiety, and uncontrollable thoughts about the event.⁷

⁷ Mayo Clinic, "Post-traumatic stress disorder (PTSD)," accessed January 31, 2024, <u>https://www.mayoclinic.org/diseases-conditions/post-traumatic-stress-disorder/symptoms-causes/syc-20355967</u>.

¹ 21 C.F.R.§ 201.57; Cleveland Clinic, "What Does it Mean If My Medication Has a 'Black Box Warning'?," accessed July 13, 2023, <u>https://health.clevelandclinic.org/what-does-it-mean-if-my-medication-has-a-black-box-warning/</u>.

² Mayo Clinic, "High cholesterol," accessed April 11, 2024, <u>https://www.mayoclinic.org/diseases-conditions/high-blood-cholesterol/symptoms-causes/syc-20350800</u>.

³ Mayo Clinic, "Hydroxyzine (Oral Route)," accessed January 31, 2024, <u>https://www.mayoclinic.org/drugs-supplements/hydroxyzine-oral-route/description/drg-20311434</u>.

⁴ VA Mental Illness Research, Education and Clinical Center, Center of Excellence, "Lethal Means Safety & Suicide Prevention," accessed April 8, 2024, <u>https://www.mirecc.va.gov/lethalmeanssafety/</u>.

⁵ Rocky Mountain Mental Illness Research, Education and Clinical Center (MIRECC) for Suicide Prevention, "What is Lethal Means Safety Counseling?," accessed July 29, 2024,

https://www.mirecc.va.gov/visn19/lethalmeanssafety/counseling/.

⁶ Mayo Clinic, "Mirtazapine (Oral Route)," accessed January 31, 2024, <u>https://www.mayoclinic.org/drugs-supplements/mirtazapine-oral-route/description/drg-20067334</u>.

suicidal preparatory behavior. Acts or preparation toward making a suicide attempt such as buying a gun or collecting pills.⁸

suicide postvention. An "organized, immediate and on-going support" provided to suicide loss survivors to promote healing that "reduces suicide risk for those impacted."⁹

traumatic brain injury. A condition that "usually results from a violent blow or jolt to the head or body," and can have a wide range of physical and psychological effects.¹⁰

unspecified trauma- and stressor-related disorder. A diagnosis used when a clinician "chooses not to specify the reason" a patient does not meet full criteria for a specific trauma-related disorder, including presentations where there is "insufficient information to make a more specific diagnosis."¹¹

warm handoff. A "transfer of care between two members of the health care team, where the handoff occurs in front of the patient."¹²

⁹ "Uniting for Suicide Postvention (USPV)," VA USPV SharePoint, <u>https://dvagov.sharepoint.com/sites/ECH/srsa/SitePages/Postvention%20Resources.aspx</u>. (This SharePoint site is

⁸ VISN 19 Mental Illness Research, Education and Clinical Center, Center of Excellence, "VISN 19 MIRECC SDV Decision Tree," accessed March 25, 2024,

https://www.mirecc.va.gov/visn19/education/sdvtree/sdv_tree.asp#:~:text=Preparatory%20Behavior%20Acts%20or %20%20preparation%20towards%20engaging%20in,%28e.g.%2C%20writing%20a%20suicide%20note%2C%20gi ving%20%20things%20away%29.

not publicly accessible.) ¹⁰ Mayo Clinic, "Traumatic brain injury," accessed January 31, 2024, <u>https://www.mayoclinic.org/diseases-</u> <u>conditions/traumatic-brain-injury/symptoms-causes/syc-20378557</u>.

¹¹ American Psychiatric Association, *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, Text Revision (DSM-5 TR)*, "Trauma- and Stressor-Related Disorders," accessed August 30, 2023, https://dsm.psychiatryonline.org/doi/full/10.1176/appi.books.9780890425787.x07_Trauma_and_Stressor_Related_Disorders.

¹² VHA Directive 1160.01, Uniform Mental Health Services in VHA Medical Points of Service, April 27, 2023.

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