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Office of Healthcare Inspections

VETERANS HEALTH ADMINISTRATION

Deficiencies in the Implementation and Leadership Oversight of Ketamine at the Eastern Oklahoma VA Health Care System in Muskogee

HEALTHCARE INSPECTION | REPORT #21-01836-66 | MARCH 9, 2023

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Executive Summary

The VA Office of Inspector General (OIG) conducted a healthcare inspection to assess allegations related to an anesthesiologist's self-referral of patients to the anesthesiologist's established private practice (private practice).[1]

The OIG also reviewed the facility's non-formulary medication request and approval processes, the evaluation process of patients with treatment-resistant depression for management with ketamine, leaders' response to staff concerns, completion of informed consent forms, the application of VA national protocol guidance for intravenous ketamine treatment, and the provision of stellate ganglion block procedures at the Eastern Oklahoma VA Health Care System (facility) in Muskogee.

Background

Ketamine is a general anesthetic used for medical and surgical procedures and pain control. Due to its hallucinogenic and dissociative effects, ketamine has significant potential for abuse. Recent studies have shown that ketamine can quickly and temporarily abate acute suicidal ideation and relieve depressive symptoms in patients with treatment-resistant depression.[2] Researchers have not established data on the safety and efficacy of ketamine use long-term for depression.[3] Furthermore, the optimal route of administration of ketamine for treatment of depression has not been established. Most studies have looked at the intravenous or intranasal (esketamine) administration of ketamine, but other routes include intramuscular, subcutaneous, sublingual, and topical administration.[4]

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[1] The underlined terms are hyperlinks to a glossary. To return from the glossary, press and hold the "alt" and "left arrow" keys together. The anesthesiologist reported two private practice sites: one in Tulsa, Oklahoma; and the second in Houston, Texas.

[2] Fernanda S. Correia-Melo, et al., "Comparative study of esketamine and racemic ketamine in treatment-resistant depression: Protocol for non-inferiority clinical trial," *Medicine 97*(38) (2018): 1-11. Gerard Sanacora et al., "A Consensus Statement on the Use of Ketamine in the Treatment of Mood Disorders, *Journal of the American Medical Association-Psychiatry* 74(4) (2017): 399-405. VA Pharmacy Benefits Management Services, Medical Advisory Panel, VISN Pharmacist Executives, and Office of Mental Health Somatic Treatment Field Advisory Committee, *Ketamine Infusion for Treatment Resistant Depression and Severe Suicidal Ideation National Protocol Guidance*, December 2017. The national protocol guidance was amended in October 2020 and April 2021. Unless otherwise specified, the guidance in the 2017 document was in effect at the time of the events discussed in this report and contains the same or similar language as the amended 2020 and 2021 documents.

[3] Samuel Wilkinson and Gerard Sanacora, "A new generation of antidepressants: an update on the pharmaceutical pipeline for novel and rapid-acting therapeutics in mood disorders based on glutamate/GABA neurotransmitter systems," *Drug Discovery Today* 24(2) (February 2019): 606-615.

[4] Colleen Loo, "Can we confidently use ketamine as a clinical treatment for depression?" *Lancet Psychiatry*, (2018):11-12.

In December 2017 and December 2019, respectively, VA issued national protocol guidance for both the use of intravenous ketamine (national ketamine guidance) and esketamine for treatment-resistant depression.[5] The Veterans Health Administration (VHA) national ketamine guidance provides general direction for patient selection, screening and referral, and administration of intravenous ketamine as well as allowing "facilities the flexibility to exercise modifications to the protocol as necessary to operationalize the use of ketamine for treating treatment-resistant depression or severe suicidal ideation." The guidance stated that "[e]ach facility will be responsible for developing and operationalizing a procedure to screen and refer potential candidates for treatment with ketamine."[6] Notably, the OIG did not find VHA policies or procedures guiding nor prohibiting sublingual ketamine prescribing.

The OIG learned, that in early 2020, the facility established a ketamine team composed of the anesthesiologist, a psychiatrist, and a psychiatric clinical pharmacy specialist (CPS); issued a Psychiatry Use of IV [Intravenous] Ketamine standard operating procedure (April 2020 SOP); and established an informal process for evaluating patients for ketamine treatment.[7] Each team member evaluated patients referred for ketamine treatment. The psychiatrist determined whether a patient had a diagnosis of treatment-resistant depression and had previously failed antidepressant medication trials; the anesthesiologist provided a medical evaluation and clearance for ketamine treatment; and the psychiatric CPS conducted a medication review of the electronic health record (EHR) and documented whether a patient had evidence of failed antidepressant medication trials. Meetings were held to discuss and provide clinical opinions about patients being considered for ketamine treatment. During the meetings, a determination was made whether a patient was approved for intravenous ketamine treatment, and the team's discussion and decision were documented in the EHR.

The April 2020 SOP required patients to have failed two trials of antidepressants to be considered for ketamine treatment.[8] The Pharmacy and Therapeutics Committee requested revisions to indicate that patients have four failed trials of antidepressants to align with national ketamine guidance, as well as the addition of EHR ketamine order, consult, and relevant progress

[5] VA, *Ketamine Infusion for Treatment Resistant Depression and Severe Suicidal Ideation National Protocol Guidance*, December 2017. VA Pharmacy Benefits Management Services, Medical Advisory Panel, VISN Pharmacist Executives, and Office of Mental Health and Suicide Prevention, *Intranasal Esketamine for Treatment Resistant Depression National Protocol Guidance*, December 2019.

[6] VA, *Ketamine Infusion for Treatment Resistant Depression and Severe Suicidal Ideation National Protocol Guidance*, December 2017.

[7] Facility Standard Operating Procedure (SOP) 116-071, *Psychiatric Use of IV [Intravenous] Ketamine, Muskogee, OK*, April 21, 2020.

[8] Facility SOP 116-071. VA, *Ketamine Infusion for Treatment Resistant Depression and Severe Suicidal Ideation National Protocol Guidance*, (2017).The national ketamine guidance includes either an antidepressant trial or psychotherapy as a failed treatment trial.

note templates. In May 2020, a revised SOP that included the revisions was approved by the Pharmacy and Therapeutics Committee.

Alleged Self-Referrals

The OIG reviewed documentation and interviewed facility staff to address an allegation that the anesthesiologist self-referred facility patients, who were not approved by the facility for intravenous ketamine, to the private practice. The OIG did not substantiate that the anesthesiologist self-referred facility patients to the private practice. The anesthesiologist told the OIG that two facility patients had independently contacted the private practice seeking ketamine treatment for pain.[9] One patient, Patient A, received ketamine treatment.[10]

Patient A had a history of depression and posttraumatic stress disorder (PTSD), as well as chronic severe pain related to a previous burn injury and amputation. The patient received ketamine treatment for pain and PTSD at, or authorized by, three VHA facilities prior to establishing care at the facility.

In summer 2020, the patient presented to the facility's Tulsa community-based outpatient clinic for care. A primary care provider entered consults to both the pain and the mental health clinics.[11] The pain clinic consult was discontinued because the schedulers were unable to reach Patient A. Patient A completed a telephone visit with a psychiatrist the following month. The psychiatrist continued the patient's medications and documentation did not reflect a discussion regarding ketamine.

In fall 2020 during a primary care appointment, the patient reported that ketamine therapy had helped in the past. Over a three-month period that began in late winter, during mental health, primary care and pain clinic appointments, the patient requested ketamine treatment. In early 2021, the patient expressed interest in restarting ketamine for *pain control* to a facility psychiatrist, who encouraged the patient to have a discussion with the primary care provider about a referral for ketamine treatment. Later that month, the primary care provider agreed to refer the patient to community care to receive ketamine for treatment of *depression*. A psychologist reviewed the community care consult documenting, "[w]e do provide this service in-house. If not appropriate for in-house services, likely will not refer to the community" and documented a plan to alert the ketamine team members and the patient's psychiatrist and ketamine team members.

In the spring of 2021, the patient's psychiatrist discussed the VA guidance for intravenous ketamine use with including not actively using any illicit substances and a willingness to try a

[9] The OIG reviewed subpoenaed records from the private practice for the two patients.

[10] The other patient did not receive intravenous ketamine and therefore, is not discussed within this report.

[11] In this report, the OIG considers the Pain Clinic, Chronic Pain Clinic, Pain Management Clinic, Pain Program, and Rehabilitation Pain Clinic synonymous terms and uses the term Pain Clinic.

new antidepressant in conjunction with ketamine.[12] The patient did not agree to meeting the guidance.

Text messages from Patient A's spouse to the anesthesiologist's private practice reflect that the following day, the anesthesiologist's staff informed Patient A's spouse of the cost of the ketamine treatment at the private practice. The OIG reviewed records from the anesthesiologist's private practice and found that nine days later, the patient signed an Agreement for Treatment with Ketamine.

Thirteen days after the psychiatrist discussed VA guidance with Patient A, the pain team met to discuss the patient's care and documented that the patient "recieved [*sic*] ketamine infusions for PTSD at a previous VA but does not meet clinical criteria for ketamine infusions here. Discussed that there is no option for the ketamine and that burns cause a significant hyperalgesia." The documented plan was to offer the patient a referral to the pain clinic coordinator or to the anesthesiologist to discuss medication options.

The anesthesiologist documented in Patient A's private practice medical record "I do not want to appear to profit off of my VA patients…[t]his is an ethical dilemma due to my VA employment" as the patient reported being "abandoned" by the VA. Four days later, the patient received intravenous ketamine for chronic pain at the private practice. The anesthesiologist documented "After much thoughts [*sic*], I decided to provide [Patient A] the infusion despite being a VA patient. I reiterated to [the patient] that [the patient] should pursue a VA option but I will manage [the patient's] care in the meantime due to [the patient's] extensive [*sic*] circumstances."

The OIG concluded that the anesthesiologist provided intravenous ketamine to one patient, Patient A, at the private practice to manage the patient's complex case but did not self-refer the patient to the private practice.[13] In response to reported staff concerns of the anesthesiologist's self-referring patients, and six months after the OIG notified the facility of the healthcare inspection, the facility conducted an Administrative Investigation Board in November 2021, and concluded there was no evidence to support that the anesthesiologist self-referred patients.[14]

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[12] VA, *Ketamine Infusion for Treatment Resistant Depression and Severe Suicidal Ideation National Protocol Guidance*, (2017).

[13] Although the OIG did not find documented evidence of self-referral in patients' EHRs, there were electronic messages between the anesthesiologist and a staff member regarding the anesthesiologist's intent to refer facility patients to the private practice. The anesthesiologist denied self-referring patients to the private practice and referred to the electronic messages as "antiphrasis where you just say opposite of what you mean." The anesthesiologist stated the intent of the communication was to end the conversation with the staff member because of having disagreements with the staff member in the past. The anesthesiologist's electronic messages with the staff member of intent to self-refer patients could give the appearance of a conflict of interest; specifically, using a public office for private gain under the Government ethics law. 5 CFR § 2635.801(c).

[14] VA Handbook 0700, *Administrative Investigation Boards and Factfindings,* August 17, 2021. An Administrative Investigation Board is "a type of administrative investigation…for collecting and analyzing evidence, ascertaining facts, and documenting complete and accurate information regarding matters of interest to VA."

Prescribing Sublingual Ketamine and Inconsistent Non-Formulary Medication Process

The OIG substantiated that the anesthesiologist prescribed sublingual ketamine to treat a patient with depression (Patient B). The OIG determined the anesthesiologist also prescribed sublingual ketamine for two additional patients to provide pain control. The OIG did not find VHA prohibited prescribing sublingual ketamine.

Patient B had a history of depression, PTSD, and mild traumatic brain injury. In early 2020, the patient saw the anesthesiologist who stated that the patient would likely benefit from intravenous ketamine therapy, however, because the intravenous ketamine protocols and policies were not established by the facility, the anesthesiologist planned to order sublingual ketamine. Approximately three weeks later, the patient's psychiatrist documented that the patient started taking ketamine.

In summer 2020, after the patient expressed interest in pursuing the intravenous treatment, the anesthesiologist ordered labs in anticipation of a tentative appointment. The next day, a ketamine team's psychiatric CPS documented, "[p]er chart review, Veteran does NOT [capitalization in original text] meet medication trial criteria to receive IV [intravenous] ketamine infusion from the VA."

During a visit with the anesthesiologist approximately two weeks later, the patient reported feeling that ketamine was a "lifeline." The anesthesiologist documented the plan to continue with ketamine.

In early 2021 after the anesthesiologist referred the patient to the ketamine team, a second ketamine team psychiatric CPS reviewed the patient's chart for appropriateness of intravenous ketamine treatment. The CPS determined that the patient did not meet four elements of the inclusion criteria including the lack of four adequate antidepressant medication trials.

In spring 2021 at a follow-up appointment with the patient's psychiatrist, the patient reported that ketamine was the only thing that helped with depression and did not cause side effects. In early summer 2021, the patient requested a new prescription for sublingual ketamine from the anesthesiologist.

The OIG concluded that the anesthesiologist prescribed sublingual ketamine to treat Patient B's depression and to two other patients for pain control.

VHA policy requires each facility have non-formulary medication request and appeal processes to ensure "[d]ecisions are evidence-based and timely" and requests for non-formulary agents are addressed and reviewed."[15] The chief of pharmacy clinical services told the OIG that the

[15] VHA Directive 1108.08(1). *VHA Formulary Management Process*, November 2, 2016, Amended August 29, 2019.

facility's process for obtaining approval of non-formulary medication prescriptions required a provider to place a non-formulary request consult and a pharmacist to approve or deny the request. If a non-formulary medication request was denied, the provider could submit an appeal.

While reviewing the provision of sublingual ketamine, the OIG determined that the anesthesiologist submitted non-formulary medication requests for two of three patients prescribed sublingual ketamine. Sublingual ketamine was a non-formulary medication; a medication not required to be available at all VA medical facilities.[16]

The OIG did not find evidence in the EHR that the anesthesiologist submitted a non-formulary request for the third patient (Patient B). When asked about the non-formulary request for the third patient, the anesthesiologist told the OIG, "I think I may have asked or I may have done a non-formulary request with the patient."

The facility's pharmacy staff approved one patient's non-formulary request for sublingual ketamine; however, the request for the other patient was denied due to the lack of "compelling evidence for the requested indication" and the inability to prepare the sublingual ketamine at the facility. The OIG determined that there were inconsistencies with pharmacy's approval of non-formulary medication requests for sublingual ketamine due to a lack of clarity regarding the processes. Reasons for the discrepancy between approval and denial were unclear to the OIG.

Facility Leaders' Inadequate Responses to Concerns

The OIG determined that facility leaders' failure to address reported safety concerns and resolve staff conflict contributed to ongoing frustration, lack of collaboration, and negative interactions among staff related to ketamine prescribing.

The OIG substantiated that the chief of behavior medicine and the psychiatry section chief did little to respond to a reported safety concern regarding the anesthesiologist's ketamine prescribing practices and found that the chief of surgery did not address a similar concern reported by the psychiatry section chief and associate chief of pharmacy clinical services.

The second psychiatric CPS told the OIG of reporting a patient safety concern to the psychiatry section chief and associate chief of pharmacy clinical services regarding the anesthesiologist prescribing sublingual ketamine for treatment-resistant depression to Patient B who had not met

[16] VHA Directive 1108.08(1). VA established a National Formulary, which is a list that includes drugs and drug-related supplies that must be available for prescription at all VHA facilities. VHA policy requires that each facility must have a request and approval process for non-formulary medications and supplies. VHA policy also requires each facility have a non-formulary medication request and appeal process to ensure "[d]ecisions are evidence based and timely" and requests for non-formulary agents are addressed and reviewed.

VA criteria for intravenous ketamine.[17] The psychiatry section chief and the associate chief of pharmacy clinical services informed the OIG that they did not take direct action to evaluate the concern but referred their concerns to the chief of surgery who was the anesthesiologist's supervisor. The chief of surgery reported being unsure about what to do with the reported information and explained the concern was more in the purview of the chief of behavior medicine and the psychiatry section chief.

The OIG concluded that, at the time of the inspection, beyond having informal discussions, the chiefs of behavior medicine and surgery, associate chief of pharmacy clinical services, and psychiatry section chief did not formally respond to concerns regarding the anesthesiologist's ketamine prescribing practices. This missed opportunity to strategically review a patient safety concern and educate staff on the outcome of the review impeded professional collaboration.

In mid-June 2021 the Chief of Staff requested assistance from the Veterans Integrated Service Network (VISN) Chief Medical Officer to address the ongoing disagreement between Pharmacy and Psychiatry Services concerning the prescribing of intravenous ketamine for patients. The Chief of Staff felt that psychiatrists had clinical expertise to make decisions regarding ketamine treatment and psychiatric CPSs were "overstepping some authorities in terms of withholding or denying the use of ketamine in patients that were not responding to conventional medical management." The VISN Chief Medical Officer reported working with the VISN pharmacy lead to identify patients and develop a plan to conduct an evaluation of the issue.

After the OIG notified the facility of the healthcare inspection, the Facility Director learned about the disagreement between pharmacists and psychiatrists. Additionally, the Facility Director told the OIG of wanting to assure that staff members were operating within the scope of their licenses.[18] In February 2022, the Interim Facility Director reported working with the VISN CMO to have external providers conduct peer reviews.[19]

[17] The OIG found evidence in a patient's EHR that the psychiatrist was aware the patient was taking sublingual ketamine for treatment of depression and was benefitting from the medication. The OIG determined the patient's psychiatrist gave no indication that treatment with sublingual ketamine was unsafe. The associate chief of pharmacy clinical services was the acting chief of pharmacy clinical services from early June 2020 through mid-May 2021.

[18] The Facility Director discussed in this report left the facility and the Interim Facility Director began in late January 2022.

[19] VHA Directive 1190, *Peer Review for Quality Management*, November 21, 2018. The OIG reviewed peer review documentation and found evidence that the Interim Facility Director and the facility's Peer Review Committee acted in accordance with VHA policy.

Poorly Defined Process for Evaluation of Patients to Receive Ketamine Treatment

During the inspection, the OIG identified inconsistent or poorly defined processes related to evaluations of patients for ketamine treatment and completion of informed consents for patients receiving intravenous ketamine.

The OIG determined that the informal process that the facility had established for the ketamine team to review patients for intravenous ketamine treatment and determine whether intravenous ketamine would be approved was not maintained after the team's original psychiatrist transferred to another VA facility and a second psychiatric CPS joined the team. The changes in team members challenged a consistent approach to the evaluation process and the dynamic of the team.

The OIG reviewed the EHRs of 11 patients who were evaluated between spring 2020 and summer 2021 by the ketamine team for intravenous ketamine treatment and interviewed ketamine team members. Six of the 11 patients were approved for intravenous ketamine; 5 of the 6 patients received ketamine treatment.[20] The OIG did not find documented evidence in the EHR that the ketamine team discussed or decided on approval or denial for ketamine treatment for 4 of the 5 patients who were not approved for ketamine treatment.

Interviews revealed that within the ketamine team, some individuals felt compelled to address the needs of the individual patient, whereas others steadfastly pointed to the written guidance criteria that a patient needed to fail four treatment trials before approval of ketamine treatment. The OIG concluded that without discussion by the multidisciplinary team to evaluate patients for intravenous ketamine treatment, clinical decisions were not made based on the individual experience and needs of each patient.

A Patient Received Approval for Ketamine in the Community without Ketamine Team Review

The OIG determined that the facility's failure to establish or formally define a process to review patients for intravenous ketamine may have contributed to a nurse approving a community care consult for ketamine treatment for a patient without a decision by the ketamine team.[21] The nurse told the OIG of approving the consult after reviewing the patient's EHR, which indicated that the patient had taken several medications for major depression without benefit, met with the ketamine team, and was approved for ketamine treatment. However, the OIG did not find

[20] The OIG found documented evidence in the EHR that one of the approved patients was unable to receive ketamine treatments due to limitations with transportation.

[21] VHA, "Veteran Community Care Veterans Care Agreements (VCAs) Fact Sheet," July 8, 2020. Under a Veterans Care Agreement, VHA mental health providers may refer patients, who are appropriate for ketamine treatment, to the community when a facility does not provide the treatment.

documented evidence of the ketamine team's patient case review or approval for intravenous ketamine as indicated by the nurse, or ketamine team communication with the patient regarding the team's approval or denial for ketamine treatment.

Inaccurate Completion of Informed Consent Forms for Ketamine for Treatment-Resistant Depression

The OIG reviewed five patients' informed consents for intravenous ketamine for treatment-resistant depression and determined that neither the anesthesiologist nor a psychiatrist accurately documented the indication for ketamine use on the informed consent forms as required by VHA.[22]

The facility's April 2020 SOP requires verbal and written consent for intravenous ketamine. Additionally, VHA requires that during the informed consent process providers "[g]ive a clear and concise explanation of the patient's condition(s) or diagnosis(es) that relates to the recommended treatment or procedure" and the indications for the treatment or procedure.[23]

Instead of treatment-resistant depression or suicide ideation, the anesthesiologist or ketamine treatment psychiatrist indicated moderate to severe nerve pain in four patients' informed consents. Also, the anesthesiologist indicated opioid use disorder on one consent.

Application of National Ketamine Guidance

During the inspection, the OIG had concerns that the national guidance for four failed treatment trials in the current episode of depression is potentially burdensome to patients suffering with severe mood disorders.[24] The failed trials, augmentation treatment, psychotherapy, and often, additional antidepressant trials, may add up to more than a year of preliminary treatment, during which time, patients are at risk for adverse clinical outcomes and psychosocial consequences such as loss of employment or interpersonal relationships.[25]

The OIG interviewed VHA program office leaders and reviewed a synthesis of literature to determine the background of the national ketamine guidance and scientific recommendations on

[22] VHA Handbook 1004.01(5), *Informed Consent for Clinical Treatments and Procedures*, August 14, 2009, amended September 20, 2017, April 4, 2019, June 25, 2020, January 4, 2021 and September 17, 2021. Facility SOP 116-071.

[23] Facility SOP 116-071. VHA Handbook 1004.01(5). "In VHA, patients have the right to accept or refuse any medical treatment or procedure recommended to them."

[24] VA, *Ketamine Infusion for Treatment Resistant Depression and Severe Suicidal Ideation National Protocol Guidance*, (2017).

[25] Within the context of this report, the OIG considered an adverse clinical outcome to be death, a progression of the disease, worsening prognosis, suboptimal treatment, or a need for higher-level care.

the selection of patients for ketamine treatment.[26] The OIG found that the current scientific opinions on the selection of patients for ketamine treatment differs from the national ketamine guidance with respect to the acceptable number of prior treatment failures in a current episode of depression. Subsequently, patients who cannot endure preliminary treatments outlined in VHA guidance, may be denied the benefits of intravenous ketamine treatment and their providers deprived of avenues to obtain clinical results.

Deficiencies with Stellate Ganglion Block Care Coordination and Completing Informed Consent Forms

The OIG reviewed the provision of stellate ganglion block (SGB) treatment for 33 patients and substantiated that the anesthesiologist did not notify psychiatrists prior to offering SGB treatment to three patients.[27] VHA requires care coordination between providers to promote optimal health outcomes and utilize VHA resources effectively.[28]

VA allows facilities to offer SGB treatment to patients with PTSD who are under the care of a VA mental health provider and whose PTSD symptoms have not improved after receiving other treatment. An SGB is performed by using a small needle to inject a "local anesthetic into the front of the neck." The anesthetic blocks nerve impulses from the stellate ganglion to areas of the head, neck, arm, and chest and thereby reduces pain.[29] An anesthesiologist or medical provider with similar training would provide the SGB.[30] Clinical consults are a tool used for communication between a provider seeking advice or expertise from another provider regarding the management of a patient.[31]

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[26] VHA leaders included the National Program Director for Psychopharmacology and Somatic Treatments and National Pharmacy Benefits Management Clinical Pharmacy Program Manager.

[27] Johns Hopkins Medicine, "Stellate Ganglion Block," accessed January 20, 2022, https://www.hopkinsmedicine.org/pain/blaustein_pain_center/pain_procedures/stellate_ganglion_blocks.html. A procedure involves the insertion of a needle into the neck near the stellate ganglion which is "a group of nerves that supply the head, upper extremities, and organs of the chest. A stellate ganglion block may be performed to determine the cause of pain in these areas or to treat pain."

[28] VHA Directive 1110.04(1), *Integrated Case Management Standards of Practice*, September 6, 2019, amended May 18, 2020. The amended version contains the same or similar language regarding requirement for care coordination between providers to promote optimal health outcomes and utilize VHA resources effectively.

[29] Cedars Sinai, "Stellate Ganglion Blocks," accessed May 12, 2021, https://www.cedars-sinai.org/programs/pain-center/conditions-treatments/stellate-ganglion-blocks.html.

[30] VHA National Center for Healthcare Advancement and Partnerships, "Stellate ganglion block works for PTSD, can be an additional option for Vets, say three VA doctors," accessed on September 27, 2022, HAP Healthcare Advancement Initiative News - National Center for Healthcare Advancement and Partnerships.

[31] VHA Directive 1232(4), Consult Processes and Procedures, August 24, 2016 amended June 28, 2019, April 5, 2021, and December 14, 2021. The amended version contains the same or similar language regarding the definition of a clinical consult.

The OIG would expect communication between providers about coordination of patients' treatments. The use of structured processes for reviewing and tracking referrals, such as clinical consults, may improve care coordination.

The OIG also determined that the anesthesiologist did not accurately document the indication for SGB use on the patients' informed consent forms. The OIG reviewed informed consent documents for six patients who received SGB for PTSD and found that the anesthesiologist documented the reason for the procedure as pain, and not PTSD, for four patients. The anesthesiologist told the OIG of using a consent form for SGBs for pain procedures and having to manually input the indication for use as PTSD on the form, but did not explain why the incorrect reason was indicated.

The OIG made one recommendation to the VHA Under Secretary for Health regarding determining whether the acceptable number of previous treatment failures in a current episode of depression should be modified to align with current scientific recommendations. The OIG made four recommendations to the Eastern Oklahoma VA Health Care System Director related to evaluating and educating staff on non-formulary medication requests and appeals processes; ensuring informed consents for intravenous ketamine treatment and stellate ganglion blocks are documented in accordance with VHA policy; evaluating the facility's standard operating procedure for ketamine treatment; and taking action to ensure leaders continue to resolve disagreement between prescribers and pharmacists.

Comments

During VHA's review of an OIG draft report, it is usual practice for VHA to submit comments for consideration and discussion. For this report, VHA provided technical comments to the OIG during the draft phase. The OIG considered and reviewed the comments. Based on the review, some changes were made to the report for clarification, but no changes were made to OIG findings and recommendations.

The Under Secretary for Health and the Veterans Integrated Service Network and Facility Directors concurred with recommendations 1, 2, 3, and 4 and submitted acceptable action plans (see appendixes A and C). The OIG will follow up on the plans and recently implemented actions to ensure that they have been effective and sustained. The Under Secretary for Health concurred in principle with recommendation 5. Based on information provided, the OIG considers recommendation 5 closed.

VHA commented in their response to recommendation 5 that authors of an article, *Synthesizing the Evidence for Ketamine and Esketamine in Treatment-Resistant Depression: An International Expert Opinion on the Available Evidence and Implementation*, which is referenced in this

report, were biased.[32] The OIG notes that this expert opinion paper was published in a peer reviewed journal that has substantial impact in the field of psychiatry and is the flagship journal of the American Psychiatric Association. Seven of the 25 internationally recognized authors of this paper published research articles cited in the updated *VA/DoD Clinical Practice Guideline for the Management of Major Depressive Disorder*.[33]

The OIG takes issue with further comments from the Under Secretary for Health that there are no significant changes to the industry opinion regarding off-label usage of ketamine for treatment-resistant depression. The 2016 version of the *VA/DoD Clinical Practice Guideline for the Management of Major Depressive Disorder* stated "Given the limited information on ketamine's safety and duration of effect, we recommend against the use of ketamine to treat MDD [major depressive disorder] outside of a research setting."[34] In contrast, the updated clinical practice guideline, published in February 2022, states that "Evidence suggests both ketamine infusion and intranasal esketamine improve depressive symptoms in patients with MDD [major depressive disorder] who have not responded to at least two previous adequate trials of antidepressant medications."[35] This illustrates the significant change in industry opinion regarding the use of ketamine for treatment-resistant depression.

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[32] "Synthesizing the Evidence for Ketamine and Esketamine in Treatment-Resistant Depression: An International Expert Opinion on the Available Evidence and Implementation."

[33] *VA/DoD Clinical Practice Guideline for the Management of Major Depressive Disorder*, February 2022.

[34] VA/DoD Clinical Practice Guideline for the Management of Major Depressive Disorder, April 2016.

[35] VA/DoD Clinical Practice Guideline for the Management of Major Depressive Disorder, February 2022.

Contents

Abbreviations

COS	Chief of Staff
CPS	clinical pharmacy specialist
DoD	Department of Defense
EHR	electronic health record
FDA	Food and Drug Administration
OIG	Office of Inspector General
PTSD	posttraumatic stress disorder
SGB	stellate ganglion block
SOP	standard operating procedure
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network

Introduction

The VA Office of Inspector General (OIG) conducted a healthcare inspection to assess allegations related to an anesthesiologist's self-referral of patients to the anesthesiologist's established private practice (private practice).[1] The OIG also reviewed the evaluation of patients with treatment-resistant depression for management with ketamine, leaders' response to staff concerns, and the provision of stellate ganglion block (SGB) procedures at the Eastern Oklahoma VA Health Care System (facility) in Muskogee.

Background

The facility, part of Veterans Integrated Service Network (VISN) 19, is comprised of a 61-bed hospital located in Muskogee, Oklahoma, and is classified as level 2, medium complexity.[2] The facility provides acute inpatient care, as well as outpatient primary, surgical and specialty care, and operates behavior medicine clinics in Muskogee and Tulsa.

Treatment-Resistant Depression

While occasional periods of sadness are normal aspects of human experience, some people develop severe and persistent symptoms of depression that affect their ability to function in important areas of their lives and may be diagnosed with a depressive disorder. Symptoms of depression can include depressed mood; diminished interest in activities; disturbances in sleep, weight, and appetite; fatigue or loss of energy; feelings of worthlessness; diminished ability to think, concentrate, or make decisions; and sometimes suicidal thoughts or behaviors.[3] There are a range of interventions used to treat depression, including a variety of pharmacotherapy, somatic,

[1] The underlined terms are hyperlinks to a glossary. To return from the glossary, press and hold the "alt" and "left arrow" keys together. The anesthesiologist at issue is a full-time Veterans Health Administration employee who works in anesthesia, surgery, mental health, and the Pain Clinic, who told OIG of maintaining private practices. In this report, the OIG considers the Pain Clinic, Chronic Pain Clinic, Pain Management Clinic, Pain Program, and Rehabilitation Pain Clinic synonymous terms and uses the term Pain Clinic for consistency purposes. The anesthesiologist reported two private practice sites: one in Tulsa, Oklahoma, and the second in Houston, Texas.

[2] The facility has four community-based outpatient clinics located in, Idabel, McAlester, Tulsa, and Vinita, Oklahoma. VHA Office of Productivity, Efficiency and Staffing, "Facility Complexity Model Fact Sheet," January 28, 2021. The VHA Facility Complexity Model categorizes medical facilities by complexity level based on patient population, clinical services offered, and educational and research missions. Complexity levels include 1a, 1b, 1c, 2, or 3. Level 2 means the facility has a "medium volume, low risk patients, few complex clinical programs, and small or no research and teaching programs." All changes in the fact sheet are retroactive to October 1, 2020.

[3] Diagnostic and Statistical Manual of Mental Disorders, "Depressive Disorders," accessed April 18, 2022, https://dsm.psychiatryonline.org/doi/full/10.1176/appi.books.9780890425596.dsm04.

and psychotherapy approaches.[4] Patients are commonly considered to have treatment-resistant depression when they do not respond to treatment.[5]

Ketamine

In 1970, the U.S. Food & Drug Administration (FDA) approved ketamine for use as a general anesthetic for surgery and medical procedures and pain control.[6] Ketamine can cause dissociation and hallucinations, and has been used illicitly for recreational purposes. The U.S. Drug Enforcement Administration classifies ketamine as a controlled substance due to its potential for abuse and addictive properties. With a potential for abuse, individuals may develop physical and psychological dependence on the drug.[7]

Recent studies have shown that ketamine can quickly and temporarily abate acute suicidal ideation and relieve depressive symptoms in patients with treatment-resistant depression.[8] Researchers have not established data on the safety and efficacy of long-term ketamine use for depression.[9] Furthermore, the optimal route of administration of ketamine for treatment of depression has not been established. Most studies have looked at the intravenous administration of ketamine, but other routes include intramuscular, intranasal, subcutaneous, sublingual, and topical administration.[10]

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[4] VA and Department of Defense (DoD), *VA/DoD Clinical Practice Guideline for the Management of Major Depressive Disorder*, April 2016. Bradley N. Gaynes, et al., "Defining treatment-resistant depression," Depression and Anxiety, 2020; 37:134–145.

[5] Gaynes, "Defining treatment-resistant depression."

[6] U.S. Food & Drug Administration, "FDA approves new nasal spray medication for treatment-resistant depression; available only at a certified doctor's office or clinic," news release, March 5, 2019, https://www.fda.gov/news-events/press-announcements/fda-approves-new-nasal-spray-medication-treatment-resistant-depression-available-only-certified and "KETALAR (ketamine hydrochloride) injection," https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/016812s040lbl.pdf.

[7] "Ketamine," National Library of Medicine, National Center for Biotechnology Information, accessed August 27, 2021, https://pubchem.ncbi.nlm.nih.gov/compound/ketamine.

[8] Fernanda S. Correia-Melo, et al., "Comparative study of esketamine and racemic ketamine in treatment-resistant depression: Protocol for non-inferiority clinical trial," *Medicine 97*(38) (2018): 1-11. Gerard Sanacora et al., "A Consensus Statement on the Use of Ketamine in the Treatment of Mood Disorders, *Journal of the American Medical Association-Psychiatry* 74(4) (2017): 399-405. VA Pharmacy Benefits Management Services, Medical Advisory Panel, VISN Pharmacist Executives, and Office of Mental Health Somatic Treatment Field Advisory Committee, *Ketamine Infusion for Treatment Resistant Depression and Severe Suicidal Ideation National Protocol Guidance*, December 2017. The national protocol guidance was amended in October 2020 and April 2021. Unless otherwise specified, the guidance in the 2017 document contains the same or similar language as the amended 2020 and 2021 documents.

[9] Samuel Wilkinson and Gerard Sanacora, "A new generation of antidepressants: an update on the pharmaceutical pipeline for novel and rapid-acting therapeutics in mood disorders based on glutamate/GABA neurotransmitter systems," *Drug Discovery Today* 24(2) (February 2019): 606-615.

[10] Colleen Loo, "Can we confidently use ketamine as a clinical treatment for depression?" *Lancet Psychiatry*, (2018):11-12.

Although research has indicated that ketamine can produce antidepressant effects when administered for treatment-resistant depression, this indication is not FDA approved. Lack of FDA approval of a medication for a specific use does not mean the drug is not to be prescribed for treatment but may indicate insufficient data are available on the safety and efficacy of use of the drug to support the FDA's approval process. Providers may prescribe FDA approved drugs for non-FDA approved uses when medically indicated for a patient.[11]

In December 2017 and December 2019, respectively, VA issued national protocol guidance for use of intravenous ketamine (national ketamine guidance) and intranasal esketamine for treatment-resistant depression.[12] Esketamine is chemically related to ketamine but is a distinctly different drug with a separate formulation.[13] In patients with suicidal ideation and major depressive disorder, VA and Department of Defense (DoD) "suggest offering ketamine infusion [intravenous] as an adjunctive treatment for short-term reduction in suicidal ideation."[14]

The facility offers intravenous ketamine only for treatment-resistant major depressive disorder and severe suicidal ideation. Although VHA approved ketamine for the treatment of intractable neuropathic pain, a facility mental health leader reported to the OIG that the facility had not implemented ketamine for this indication.[15] As of August 2, 2021, the VHA Office of Mental Health and Suicide Prevention reported there were 21 facilities providing intravenous ketamine treatments for treatment-resistant depression.

Prior OIG Reports

An OIG report was published on August 24, 2021, related to deficiencies in care coordination for patients receiving ketamine for treatment-resistant depression in the community at the VA San Diego Healthcare System in California. The OIG made two recommendations to the Under Secretary for Health related to community care and the need for further research related to the use of ketamine and esketamine for treatment-resistant depression and four recommendations to

[11] U.S. Food & Drug Administration "Understanding Unapproved Use of Approved Drugs Off Label," accessed August 27, 2021, https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/understanding-unapproved-use-approved-drugs-label.

[12] VA, *Ketamine Infusion for Treatment Resistant Depression and Severe Suicidal Ideation National Protocol Guidance*, December 2017. VA Pharmacy Benefits Management Services, Medical Advisory Panel, VISN Pharmacist Executives, and Office of Mental Health and Suicide Prevention, *Intranasal Esketamine for Treatment Resistant Depression National Protocol Guidance*, December 2019.

[13] U.S. Food & Drug Administration, "FDA approves new nasal spray medication for treatment-resistant depression; available only at a certified doctor's office or clinic," news release, March 5, 2019.

[14] VA and DoD, *VA/DoD Clinical Practice Guideline for the Assessment and Management of Patients at Risk for Suicide*, Version 2.0, May 2019.

[15] Facility Standard Operating Procedure (SOP) 116-071, *Psychiatric Use of IV [Intravenous] Ketamine, Jack C. Montgomery VA Medical Center, Muskogee, OK*, April 21, 2020. VA Pharmacy Benefits Management Services, Medical Advisory Panel, VISN Pharmacist Executives, and the National Pain Management Strategic Coordinating Committee, *Ketamine Infusion for the Treatment of Intractable Neuropathic Pain*, June 2018.

the Facility Director related to community care processes. As of July 2022, one recommendation remained open.[16]

Allegations, Related Concerns, and Other Findings

On March 6, 2021, the OIG received allegations related to an anesthesiologist's practice. Specifically, the allegations and related concerns were

- the anesthesiologist self-referred patients to the anesthesiologist's established private practice for treatment with intravenous ketamine after the patients were not approved by the facility's ketamine team for intravenous ketamine;
- the chief of behavior medicine and the psychiatry section chief did not respond to a staff concern regarding the anesthesiologist's ketamine prescribing practices;
- the anesthesiologist prescribed sublingual ketamine for a patient with depression who was not approved for ketamine treatments at the facility; and
- the anesthesiologist offered patients SGBs as treatment for PTSD without notifying the patients' psychiatrists.

The OIG found contributing factors that adversely impacted the facility's ability to implement the use of ketamine for treatment-resistant depression were [17]

- the facility's poorly defined process for evaluating patients for ketamine treatment led to disagreement between ketamine team members;[18]
- facility leaders' inability to resolve disagreements within the ketamine team; and
- deficiencies in completion of informed consent and evaluation of a community care consult related to the use of intravenous ketamine.

Scope and Methodology

The OIG initiated the hotline inspection in April 2021. The OIG conducted virtual interviews in May and June of 2021. The OIG interviewed the complainant, the VHA National Program Director for Psychopharmacology & Somatic Treatments, and the VISN 19 Chief Medical Officer. Other interviewees included the Facility Director; Chief of Staff (COS); Deputy COS;

[16] VA OIG, *Deficiencies in Coordination of Care for Patients with Treatment-Resistant Depression at the VA San Diego Healthcare System in California*, Report No 20-03359-220, August 24, 2021. The Facility Director discussed in this report left the facility and the Interim Facility Director began in late January 2022.

[17] VA, *Ketamine Infusion for Treatment Resistant Depression and Severe Suicidal Ideation National Protocol Guidance*, December 2017.

[18] Facility staff told the OIG that the anesthesiologist, CPS, and original ketamine team psychiatrist formed a ketamine team to discuss and provide clinical opinions about the patients being considered for ketamine treatment, determine whether the patient is approved for intravenous ketamine treatment, and document the team's discussion and decision in the electronic health record.

Associate Director for Patient Care Services; chiefs of behavior medicine, pharmacy, and surgery; the psychiatry section chief; associate chief of pharmacy clinical services; chairperson, pharmacy and therapeutics committee; the anesthesiologist; staff psychiatrists; psychiatric clinical pharmacy specialists (CPS); a ketamine clinic nurse; a current and a former compliance officer; and an attorney from the VA Office of General Counsel.[19]

The OIG reviewed relevant VHA and facility policies and procedures and documents and the electronic health records (EHRs) of 65 patients whose care was associated with the related allegations and concerns identified by the OIG, complainant, or facility staff members. The OIG reviewed selected clinical research literature related to the use of ketamine for treatment-resistant depression and SGBs for posttraumatic stress disorder (PTSD). The OIG also reviewed email and electronic messaging correspondence from VHA staff members related to the issues under review.

The OIG subpoenaed records from two community pharmacies to assist in determining whether facility patients were seen by the anesthesiologist at the private practice. The OIG also subpoenaed the private practice for medical records for two patients.

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, Pub. L. 117-286 § 3(b) (to be codified at 5 U.S.C. § 401, *et seq*.). 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.

[19] In this report, the OIG discusses CPSs as defined by the qualification standards in VA Handbook 5005/55, *Staffing*, April 15, 2002. This handbook was amended June 7, 2012, and was in effect at the time of the events discussed.

Patient Case Summaries

Patient A

Patient A had a history of depression and PTSD, as well as chronic severe pain related to a burn injury and amputation. The patient was approved for and received ketamine treatment at or authorized by three VHA facilities prior to establishing care at the facility discussed in this report.

In summer 2020, the patient presented to the facility's Tulsa community-based outpatient clinic for care. At that visit, the patient's family member informed a primary care provider that the patient had been diagnosed with complex regional pain syndrome and approved for ketamine therapy treatment for pain and PTSD. The primary care provider entered consults to both the pain and the mental health clinics. The pain clinic consult was discontinued because the schedulers were unable to reach the patient. The Mental Health Clinic consult was completed via a telephone visit with a psychiatrist the following month. The psychiatrist continued the patient's current medications and documentation did not reflect a discussion regarding ketamine.

In early fall, 2020 the primary care provider had a telephone visit with the patient for chronic pain due to burn injuries and previous surgeries. The patient stated that ketamine therapy had helped in the past. The provider prescribed the patient medications for pain.

In early 2021, the patient expressed interest in restarting ketamine for *pain control* to a psychiatrist, who encouraged the patient to have a discussion with the primary care provider about a referral for ketamine treatment. Later that month, the primary care provider agreed to refer the patient to community care to receive ketamine for treatment of *depression*. A community care consult psychologist reviewer documented, "[w]e do provide this service in-house. If not appropriate for in-house services, likely will not refer to the community" and documented a plan to alert the patient's psychiatrist and ketamine team members. Less than two weeks after being placed, the community care consult psychologist reviewer discontinued the consult with the comment "this consult is requesting ketamine for pain management; [Behavior Medicine Service] does not use ketamine for this purpose."[20] The following day the patient's primary care provider entered a comment stating, "This consult is for treatment of depression. This is quite clearly explained in the consult request and in my most recent office notes. Please do not cancel this consult without directly speaking with this veteran, who has already received this treatment through [three] separate VA medical centers."

In spring 2021, the patient's psychiatrist spoke to the patient by phone and discussed the VA guidance for intravenous ketamine use and explained that the patient should not be actively using

[20] The OIG did not request clarification from the community care consult psychologist related to the reference to pain management as opposed to depression when the consult was discontinued.

any illicit substances and should be willing to try a new antidepressant in conjunction with ketamine.[21] The patient did not agree to meeting the guidance.

Thirteen days later, at the request of facility leaders, the pain team met to discuss the patient's care and documented that the patient "recieved [*sic*] ketamine infusions for PTSD at a previous VA but does not meet clinical criteria for ketamine infusions here. Discussed that there is no option for the ketamine and that burns cause a significant hyperalgesia. Discussed potential options for topical compounded medications however the VA doesn't cover this." The plan was to offer the patient a visit with the pain clinic coordinator or with the anesthesiologist to discuss medication options.

The next day the anesthesiologist documented in the patient's private practice medical record "I do not want to appear to profit off of my VA patients…[t]his is an ethical dilemma due to my VA employment" as the patient reported being "abandoned" by the VA.

Four days later, the patient received intravenous ketamine for chronic pain at the private practice.

Two days later, the pain clinic coordinator documented leaving a message for the patient.[22]

Patient B

Patient B had a history of depression, PTSD, and mild traumatic brain injury. In early 2020, the patient's psychiatry resident entered a consult requesting an evaluation for ketamine treatment for depression. The patient saw the anesthesiologist who agreed that the patient would likely benefit from intravenous ketamine therapy, however, because the intravenous ketamine protocols and policies were not established by the facility, the anesthesiologist planned to order sublingual ketamine.

Approximately one month later, the patient's psychiatrist documented that the patient started taking ketamine and recommended that the patient continue to work with the anesthesiologist regarding ketamine therapy.

In mid-spring 2020, the anesthesiologist documented that the facility now provided intravenous ketamine for treatment of drug-resistant depression and requested that the patient's psychiatrist consider referring the patient for ketamine treatment. The ketamine team's original psychiatrist documented that it would not be possible to screen and approve the patient in time for a ketamine

[21] VA, *Ketamine Infusion for Treatment Resistant Depression and Severe Suicidal Ideation National Protocol Guidance*, (2017).

[22] The OIG did not find additional documentation from the Pain Clinic in the patient's EHR; however, as of September 2022, the patient continued to receive treatment at the facility.

infusion six days later and, after speaking with the anesthesiologist, determined that the anesthesiologist would refill the sublingual ketamine.[23]

In summer 2020, the anesthesiologist documented that the sublingual ketamine had worked well for the patient and had contacted the patient by phone to let the patient know that intravenous ketamine was available. When the patient expressed interest in pursuing the intravenous treatment, the anesthesiologist ordered labs in anticipation of a tentative appointment. The next day, the ketamine team psychiatric CPS documented, "[p]er chart review, Veteran does NOT [capitalization in original text] meet medication trial criteria to receive IV [intravenous] ketamine infusion from the VA."[24]

Two weeks later, the patient met with a newly assigned psychiatrist and expressed a desire to continue sublingual ketamine. During a visit with the anesthesiologist two days later, the patient reported feeling that ketamine was a "lifeline." The anesthesiologist documented the plan to continue with ketamine.

In early 2021, the patient met with a different, newly assigned psychiatrist. In addition, the patient met with the anesthesiologist to discuss intravenous ketamine treatment and the anesthesiologist provided a referral for the patient to the ketamine team.

Twelve days later, a second ketamine team psychiatric CPS reviewed the patient's chart for appropriateness of intravenous ketamine treatment. The CPS determined that the patient did not meet four elements of the inclusion criteria including the lack of four adequate antidepressant medication trials.

In spring 2021, at a follow-up appointment with the patient's psychiatrist, the patient reported that ketamine was the only thing that helped with depression and did not cause side effects. In =early summer 2021, the patient requested a new prescription for sublingual ketamine from the anesthesiologist.

Patient C

Patient C was diagnosed with a major depressive disorder. During spring and summer 2020 telehealth clinic appointments, the ketamine team's original psychiatrist documented that the patient met initial screening criteria for intravenous ketamine treatment, that this was discussed with the patient, and that the plan was to schedule an evaluation for treatment. In early fall 2020, in response to a call from the patient, the ketamine team's interim psychiatrist documented that the patient needed to be referred for ketamine treatment evaluation, and that "it does not appear

[23] Staff told the OIG that the original psychiatrist led the ketamine team before leaving the facility for employment at another VHA facility and was replaced by an interim psychiatrist, and, subsequently, the ketamine team's new psychiatrist.

[24] In this report, the OIG will discuss only CPSs as defined by VA Handbook 5005/55, *Staffing*, April 15, 2002. This handbook was amended June 7, 2012, and in effect at the time of the events discussed in this report.

that [the patient] has had sufficient [antidepressant medication] trials" to meet the inclusion criteria for ketamine treatment but could be assessed by the patient's new mental health provider.

In mid-Fall 2020, during an appointment with a newly assigned mental health provider (provider) at the Tulsa community-based outpatient clinic, the patient expressed interest in ketamine treatment for depression. The provider noted in the plan "Vet declines any medications at this time, will place ketamine consult." The provider documented that the ketamine team's interim psychiatrist and the anesthesiologist would be informed of the patient's interest in ketamine treatment. The ketamine team's interim psychiatrist responded that the patient could be scheduled for a screening psychiatric evaluation and that the ketamine team's second psychiatric CPS would review the patient's antidepressant medication trial history.

Three days later, the ketamine team second psychiatric CPS reviewed the patient's relevant medication history and documented "would not consider patient to have met adequate medication trials." The CPS also documented that the patient would need to be discussed with the ketamine team to determine approval or disapproval. One week later the CPS documented having met with the patient for additional medication review and indicated that the patient had adverse reactions from two additional antidepressants. The CPS informed the patient about the facility's assessment for consideration of intravenous ketamine and described the ketamine treatment processes at the facility.

The following week, the ketamine team's interim psychiatrist evaluated the patient for intravenous ketamine and documented that the patient had a long history of depression and that the number of failed antidepressants to date was "not enough" to qualify for ketamine treatment. In the same EHR note, the psychiatrist indicated "[t]here are no clear contraindications for ketamine, [the patient's] history of medication trials is sparse but [the patient] is not interested in trying other antidepressants…and would seek ketamine outside the VA if necessary."

Early 2021, the patient attended a second appointment at the Tulsa community-based outpatient clinic with the provider who documented that the patient indicated not hearing from the ketamine clinic. Two days later, the provider placed a community care consult for ketamine treatment for major depressive disorder and specified the patient's inability to travel to the facility due to geographical inaccessibility as justification for the community care consult. The provider's consult request stated that the patient was approved for ketamine treatment by the ketamine team and that the patient could not find transportation for this treatment.[25] The following month, the consult was canceled due to needing additional authorization. In mid- spring 2021, the mental health provider resubmitted the consult. The following day, community care staff approved the

[25] Although a provider documented the patient met with and was approved by the ketamine team, the OIG did not find any evidence in the EHR that the patient was approved by the ketamine team for intravenous ketamine treatment.

consult and documented initiating contact with a community provider to coordinate scheduling intravenous ketamine treatments for the patient.

The patient reported receiving an initial intravenous ketamine treatment at a community clinic the same month the consult was resubmitted and that the experience was more profound than anticipated and that "some changes" were evident. At a follow-up appointment with the mental health provider in early summer 2021, the patient reported having completed the sixth and final ketamine treatment. In mid-summer 2021, the mental health provider entered a new community care consult for continuation of ketamine infusions at the non-VA clinic. The request for additional treatments with the community care provider was approved on the same day.

Inspection Results

Section I: Allegations and Related Concerns

1. Alleged Self-Referrals

The OIG did not substantiate that the anesthesiologist self-referred facility patients who were not approved by the facility for intravenous ketamine to the private practice.

VA employees are subject to federal regulations that address ethical practices including potential conflicts of interest. Self-referring, or the appearance of self-referring, VA patients to a VA physician's private practice is a potential conflict of interest.[26]

The OIG reviewed documentation that included electronic messages from the anesthesiologist to a staff member about intending to self-refer patients, whom the facility had not approved for intravenous ketamine, to the private practice. Another staff member reported the anesthesiologist shared that patients were referred to the private practice for ketamine "because the VA ha[d] refused to give them care, and so [the anesthesiologist] fe[lt] ethically responsible to provide them ketamine and, therefore, t[ook] them into [the] practice." The staff members, however, were unable to provide specific patient names to the OIG.

The anesthesiologist told the OIG that two veteran patients had contacted the private practice seeking treatment.[27] Following the interview, the anesthesiologist provided an email to the OIG stating that Patient A had contacted the private practice in early spring 2021, to request intravenous ketamine and "[m]y staff attempted to get [the patient's] care into the VA. [The patient] was turned down but when they [private practice anesthesiologist staff] read the problems [the patient] was having, they sent [the patient] to my clinic." Text messages from Patient A's spouse to the anesthesiologist's private practice reflect that the following day, the anesthesiologist's staff informed Patient A's spouse of the cost of the ketamine treatment, which included consultation, evaluation, and infusion. The private practice staff requested and received Patient A's insurance information and received a copy of the patient's Medicare coverage. The OIG subpoenaed records from the anesthesiologist's private practice, and found that nine days later, Patient A had signed an Agreement for Treatment with Ketamine.

Four days later, the anesthesiologist documented in Patient A's private practice medical record "I do not want to appear to profit off of my VA patients…[t]his is an ethical dilemma due to my VA employment" as the patient reported being "abandoned" by the VA. Four days later, the patient received intravenous ketamine for chronic pain at the anesthesiologist's private practice.

[26] 5 C.F.R. § 2635.801.

[27] The OIG reviewed subpoenaed records from the private practice for the two patients. One patient did not receive ketamine and therefore, is not discussed within this report.

The anesthesiologist documented, "[a]fter much thoughts [*sic*], I decided to provide [Patient A] the infusion despite being a VA patient. I reiterated to [Patient A] that [the patient] should pursue a VA option but I will manage [the patient's] care in the meantime due to [the patient's] extensive [*sic*] circumstances." The patient's private practice record contained a paid receipt from the anesthesiologist's private practice. In response to questioning about billing, the anesthesiologist told the OIG of having wanted to provide the ketamine infusion for free, but that the patient had Medicare.[28]

The anesthesiologist reported to the OIG of being present at the May 2021 pain team meeting to discuss and determine Patient A's candidacy for intravenous ketamine treatment. However, until the patient was seen at the private practice, the anesthesiologist did not recall that Patient A was the patient discussed and had been denied ketamine treatment by the pain committee. The anesthesiologist documented in a private practice progress note:

> During the conversation, it became apparent that [Patient A] may be a VA patient. [The patient's] history is similar to a patient I recently discussed in a pain committee but I can't confirm if [the patient] is the same person.

The anesthesiologist documented ultimately realizing that Patient A was the same patient who had been discussed at the May 2021 meeting. After verifying Patient A's identity, the anesthesiologist documented initially telling Patient A of being unable to treat the patient in the private practice and referred to the situation as a "big dilemma" acknowledging not wanting to "appear to profit off of my VA patients, but at the same time" being "ethically moved" by the patient's symptoms and current situation. The anesthesiologist further documented having told the patient that, "I will think about whether I want to deny [the patient's] treatment due to my VA employment."

The OIG learned that in a June 2021 meeting with the facility COS and psychiatrists, the VISN Chief Medical Officer was made aware that two facility patients were seen at the private practice. The VISN Chief Medical Officer understood that the anesthesiologist did not solicit patients and was unclear about authority to review the anesthesiologist's private practice.

The Facility Director reported to the OIG of being made aware around June 2021 of the private practice but was not aware if the anesthesiologist self-referred patients. The following month, the Facility Director received documentation of the anesthesiologist's electronic messages with a staff member, reflecting the anesthesiologist's potential intent to self-refer patients to the private practice. Additionally, the Facility Director reported the allegation to the facility Compliance and Business Integrity Officer, and the facility conducted an investigation.

[28] "Lower costs with assignment," accessed July 14, 2022, https://www.medicare.gov/your-medicare-costs/part-a-costs/lower-costs-with-assignment. Providers participating in Medicare agree to charge "the Medicare deductible and coinsurance amount" for covered services.

The facility conducted an Administrative Investigation Board in late November 2021, six months after the OIG notified the facility of the healthcare inspection, regarding an allegation of the anesthesiologist's self-referring patients to the private practice.[29] The Administrative Investigation Board concluded there was no evidence to support that the anesthesiologist self-referred patients. The facility's administrative review did not have any findings related to potential conflicts of interest.

The OIG concluded that the anesthesiologist provided intravenous ketamine to one patient, Patient A, at the private practice to manage the patient's complex case but did not self-refer the patient to the private practice.[30]

2. Facility Leaders' Inadequate Responses to Concerns

The OIG substantiated that the chief of behavior medicine and the psychiatry section chief did little to respond to a reported concern regarding the anesthesiologist's sublingual ketamine prescribing practices. In addition, the OIG found that the chief of surgery did not address a similar concern reported by the psychiatry section chief and associate chief of pharmacy clinical services.

VHA is committed to becoming a High Reliability Organization in which safety and reliability is reflected in the decisions and actions of leaders, who facilitate an assessment of practices and clear and timely communication.[31] According to The Joint Commission, committed leaders will promote quality and safety discussions and initiate actions to create a safe hospital culture.[32]

During interviews, the second psychiatric CPS told the OIG of reporting a patient safety concern to the psychiatry section chief and associate chief of pharmacy clinical services regarding the

[29] VA Handbook 0700, *Administrative Investigation Boards and Factfindings,* August 17, 2021. An Administrative Investigation Board is "a type of administrative investigation…for collecting and analyzing evidence, ascertaining facts, and documenting complete and accurate information regarding matters of interest to VA." The Facility Director requested other findings based on evidence from the Administrative Investigation Board including the anesthesiologist's compliance with pain assessment and management and medication prescribing requirements.

[30] Although the OIG did not find documented evidence of self-referral in patients' EHRs, there were electronic messages between the anesthesiologist and a staff member regarding the anesthesiologist's intent to refer facility patients to the private practice. The anesthesiologist denied self-referring patients to the private practice and referred to the messages as "antiphrasis where you just say opposite of what you mean." The anesthesiologist stated the intent of the communication was to end the conversation with the staff member because of having disagreements with the staff member in the past. The OIG concluded that the anesthesiologist's electronic messages with the staff member of intent to self-refer patients could give the appearance of a conflict of interest, specifically, using a public office for private gain under the Government ethics law. 5 CFR § 2635.801(c).

[31] "What is a High Reliability Organization?" U.S. Department of Veterans Affairs, February 2020, accessed August 6, 2021.

[32] The Joint Commission LD.03.01.01. "Leaders create and maintain a culture of safety and quality throughout the hospital."

anesthesiologist prescribing sublingual ketamine for treatment-resistant depression to Patient B who had not met VA criteria for intravenous ketamine.[33]

The psychiatry section chief and the associate chief of pharmacy clinical services informed the OIG that they did not take direct action to evaluate the concern, but referred the concern related to the anesthesiologist's prescribing sublingual ketamine to the chief of surgery who was the anesthesiologist's supervisor.

The chief of surgery recalled that the chief of behavior medicine and the psychiatry section chief reported a concern about the anesthesiologist's ketamine prescribing but was not made aware of any violation of practice by the anesthesiologist. The chief of surgery reported being unsure about what to do with the reported information and explained the concern was more in the purview of the chief of behavior medicine and the psychiatry section chief. The only discussion the chief of surgery recalled having with the associate chief of pharmacy clinical services was to request education on the use of ketamine. The chief of surgery also reported having a discussion in late May 2021 with the anesthesiologist, however, that discussion was specifically related to treating veterans in the private practice.[34]

The OIG concluded that, at the time of the inspection, beyond having informal discussions, the chiefs of behavior medicine and surgery, associate chief of pharmacy clinical services, and the psychiatry section chief did not formally respond to concerns regarding the anesthesiologist's ketamine prescribing practices. This missed opportunity to strategically review a reported safety concern and to educate staff on the outcome of the review further compromised staff trust and impeded professional collaboration. The OIG learned that after the OIG notified the facility about the healthcare inspection, the Interim Facility Director initiated peer reviews to evaluate the prescribing practices and evidence of self-referral. The OIG reviewed peer review documentation and found evidence that the Interim Facility Director and the facility's Peer Review Committee acted in accordance with VHA policy.[35]

3. Prescribing Sublingual Ketamine and Inconsistent Non-Formulary Medication Process

The OIG substantiated that the anesthesiologist prescribed sublingual ketamine to treat a patient with depression (Patient B) and found the anesthesiologist also prescribed sublingual ketamine

[33] The OIG found evidence in the EHR that the patient's psychiatrist was aware that the patient was taking sublingual ketamine for treatment of depression and was benefitting from the medication. The OIG determined there was no indication from the patient's psychiatrist that treatment with sublingual ketamine was unsafe. The associate chief of pharmacy clinical services was the acting chief of pharmacy clinical services from early June 2020 through mid-May 2021.

[34] The chief of surgery reported having received assurance from the anesthesiologist that the anesthesiologist was aware that treating facility patients in the private practice was inappropriate if the patients received care at the VA.

[35] VHA Directive 1190, *Peer Review for Quality Management*, November 21, 2018.

for two patients to provide pain control; however, the OIG did not find VHA policies or procedures guiding nor prohibiting sublingual ketamine prescribing.[36] During the inspection, the OIG identified inconsistencies with pharmacy approval of non-formulary medication requests for sublingual ketamine.

Sublingual Ketamine Prescribing

The OIG reviewed the anesthesiologist's sublingual ketamine prescribing to address an allegation that the anesthesiologist provided sublingual ketamine for a patient with depression who was not approved for intravenous ketamine treatments at the facility. The OIG found the anesthesiologist prescribed sublingual ketamine for three patients.[37] Although sublingual ketamine use was not encouraged by the VHA Office of Mental Health and Suicide Prevention, the OIG did not find VHA policies or procedures prohibiting sublingual ketamine prescribing.[38] A facility leader and a National Clinical Pharmacy Program Manager told the OIG that VHA policy did not prohibit VHA providers from prescribing sublingual ketamine.[39]

A psychiatry resident referred Patient B to the anesthesiologist, who determined the patient would benefit from intravenous ketamine treatment for depression and documented a plan to order sublingual ketamine in the interim. One of the patient's psychiatrists told the OIG of having limited experience with sublingual ketamine and agreed with the anesthesiologist prescribing the ketamine to treat Patient B's depression. In February 2020, the anesthesiologist documented a plan to prescribe sublingual ketamine because intravenous ketamine treatment protocols were not established at the facility. In April 2020, the facility created the Psychiatry Use of IV [Intravenous] Ketamine standard operating procedure (April 2020 SOP). The anesthesiologist continued to prescribe sublingual ketamine through early summer 2021, which was after the facility established the April 2020 SOP, and after the ketamine team psychiatric CPSs documented that the patient did not meet criteria for intravenous ketamine in mid-year2020 and early 2021.[40]

The anesthesiologist prescribed sublingual ketamine for treatment of chronic pain for two additional patients. One of the patients was not referred for intravenous ketamine and the other

[36] Sublingual ketamine was dispensed by a community pharmacy.

[37] The anesthesiologist's privileges allowed for ketamine administration and pain management treatment.

[38] During an interview, the VHA National Program Director for Psychopharmacology & Somatic Treatments reported that the Office of Mental Health and Suicide Prevention supports and encourages ketamine infusion only. The Director reported having an understanding that evidence was not available to support other routes of administration.

[39] VHA Handbook 1108.11(1), *Clinical Pharmacy Services*, July 1, 2015, amended June 29, 2017. The National Clinical Pharmacy Practice Office develops practice models, initiatives, and projects, and provides "guidance on issues related to clinical pharmacy practice."

[40] Facility SOP 116-071.

was evaluated and denied due to not meeting inclusion criteria for intravenous ketamine treatment for pain control.[41]

The OIG concluded that the anesthesiologist prescribing sublingual ketamine to patients for either pain control or depression is not prohibited by VHA.

Inconsistent Sublingual Ketamine Non-Formulary Medication Approval Process

The OIG identified inconsistencies with the pharmacists' approval of non-formulary medication requests for sublingual ketamine. VA established a National Formulary, which is a list that includes drugs and drug related supplies that must be available for prescription at all VHA facilities. VHA policy requires each facility have non-formulary medication request and appeal processes to ensure "[d]ecisions are evidence-based and timely" and requests for non-formulary agents are addressed and reviewed.[42]

The chief of pharmacy clinical services told the OIG that the facility's process for obtaining approval of non-formulary medication prescriptions required a provider to place a non-formulary request consult and a pharmacist to approve or deny the request. If a non-formulary medication request was denied, the provider could submit an appeal. The chief of behavioral medicine, or the chairperson, pharmacy and therapeutics committee as applicable, conducted the non-formulary appeal process for review and approval of mental health medications. The chairperson, pharmacy and therapeutics committee stated that the specific non-formulary medication requests are generally not discussed in the meetings. The chairperson reported that when a pharmacist declined a non-formulary request, a pharmacy manager would include a specialist, who had expertise with the medication, to assist in deciding the outcome of a non-formulary appeal.

The OIG spoke with the VHA National Program Director for Psychopharmacology & Somatic Treatments who reported that routes other than intravenous ketamine are considered "experimental" and are not part of the VHA standard mental health treatment. However, VHA facilities can choose to offer treatments, such as other routes of ketamine, that are not part of standard health treatments based on facility approval. Often a facility pharmacy and therapeutics committee would be involved in a facility's decision to provide medications considered outside of a standard health treatment.

[41] VA, "*Ketamine Infusion for Treatment Resistant Depression and Severe Suicidal Ideation National Protocol Guidance,*" December 2017. The national ketamine guidance provides general direction on ensuring access to ketamine treatment. Patient selection criteria in the guidance indicates that a patient needed to fail four treatment trials. A CPS documented in the patient's EHR that the patient would not meet inclusion criteria for pain due to not having adequate trials of tricyclic antidepressants (a group of antidepressants that affect brain chemicals).

[42] VHA Directive 1108.08(1). *VHA Formulary Management Process*, November 2, 2016, Amended August 29, 2019.

The OIG reviewed the EHRs of the three patients for whom the anesthesiologist prescribed sublingual ketamine between February 2020 and June 2021 and found that the anesthesiologist submitted non-formulary medication requests for sublingual ketamine to control pain for two of the three patients. The OIG did not find evidence in the EHR that the anesthesiologist submitted a non-formulary request for the third patient (Patient B). When asked about the non-formulary request for the third patient, the anesthesiologist told the OIG, "I think I may have asked or I may have done" a non-formulary request with the patient.

The facility's pharmacy staff approved one patient's non-formulary sublingual ketamine request; however, the request for the other patient was denied due to the lack of "compelling evidence for the requested indication" and the inability to prepare sublingual ketamine at the facility. Reasons for the discrepancy between approval and denial were unclear to the OIG. The anesthesiologist told the OIG of not continuing to submit non-formulary medication requests after a facility pharmacy staff's denial.

The psychiatry section chief told the OIG that the CPSs have the authority to deny non-formulary medication requests including ketamine "end of story." The psychiatry section chief reported establishing meetings with pharmacy to review the process for non-formulary request denials.

The OIG determined that there were inconsistencies with pharmacy's approval of non-formulary medication requests for sublingual ketamine due to a lack of clarity regarding the processes. While pharmacy and psychiatry established meetings to review the process of non-formulary requests for ketamine and antipsychotics, further evaluation of the non-formulary medication approval and appeal process is warranted.

4. SGB Treatment Deficiencies

The OIG substantiated that the anesthesiologist did not notify psychiatrists prior to offering SGB treatment to three patients. During the review, the OIG also found that the anesthesiologist did not accurately document the indication for SGB use on the patients' consent forms.

SGBs are used to treat numerous medical problems including complex regional pain syndrome, cancer pain, peripheral vascular disease, and PTSD.[43] An SGB is performed by using a small needle to inject a "local anesthetic into the front of the neck." The anesthetic blocks nerve impulses from the stellate ganglion to areas of the head, neck, arm, and chest and thereby reduces pain.[44] VA allows facilities to offer SGBs to patients with PTSD who are under the care

[43] Osman Hakan Gunduz and Ozge Kenis-Coskun, "Ganglion blocks as a treatment of pain: current perspectives," *Journal of Pain Research*, 2017, accessed May 11, 2022, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5734237/pdf/jpr-10-2815.pdf.

[44] Cedars Sinai, "Stellate Ganglion Blocks," accessed May 12, 2021, https://www.cedars-sinai.org/programs/pain-center/conditions-treatments/stellate-ganglion-blocks.html.

of a VA mental health provider and whose PTSD symptoms have not improved after receiving other treatment. An anesthesiologist or medical provider with similar training would provide the SGB.[45]

Communication between the Anesthesiologist and Psychiatrists

The OIG substantiated that the anesthesiologist did not notify psychiatrists prior to offering SGB treatment to three patients. VHA requires care coordination between providers to promote optimal health outcomes and utilize VHA resources effectively.[46] Clinical consults are a tool used as communication between a provider seeking advice or expertise from another provider regarding the care and management of a patient.[47]

During interviews with the OIG, the psychiatry section chief acknowledged that referrals for SGBs come from the treating psychiatrist when all other types of treatment have failed. The anesthesiologist confirmed providing SGBs for patients with PTSD who were referred by their psychiatrists.

The OIG reviewed 33 patients who received or were offered SGB treatment by the anesthesiologist. A psychiatrist, who referred 70 percent (23 of 33) of the patients to the anesthesiologist for SGBs, told the OIG of sending electronic messages to the anesthesiologist after obtaining verbal consents from the patients. The psychiatrist was not aware of risk factors with the SGBs and felt comfortable not being part of the process once the anesthesiologist was involved.

For three of the 33 patients, the anesthesiologist did not notify psychiatrists prior to offering SGB treatments. The psychiatric CPSs notified psychiatrists about two patients who received SGB procedures. The first patient's (Patient B) psychiatrist documented acknowledgment of the SGB after the procedure was completed and of subsequent SGBs.

For the second patient, the anesthesiologist reported having a discussion with the patient's psychiatrist after the psychiatric CPS contacted the psychiatrist about patients' SGB treatments. The OIG found documented evidence in the EHR that the patient's psychiatrist documented deferring to the anesthesiologist's decision to provide SGBs. During an interview with the OIG, the anesthesiologist could not recall having contacted a psychiatrist before scheduling the third

[45] VHA National Center for Healthcare Advancement and Partnerships, "Stellate ganglion block works for PTSD, can be an additional option for Vets, Say three VA doctors," accessed on September 27, 2022, HAP Healthcare Advancement Initiative News - National Center for Healthcare Advancement and Partnerships.

[46] VHA Directive 1110.04(1), *Integrated Case Management Standards of Practice*, September 6, 2019, amended May 18, 2020. The amended version contains the same or similar language regarding requirement for care coordination between providers to promote optimal health outcomes and utilize VHA resources effectively.

[47] VHA Directive 1232(4), *Consult Processes and Procedures,* August 24, 2016, amended June 28, 2019, April 5, 2021, and December 14, 2021. The amended version contains the same or similar language regarding the definition of a clinical consult.

patient's SGB procedure. The anesthesiologist withheld the procedure after the patient's psychiatrist requested to explore other treatment options.

The OIG would expect communication between the providers about coordination of the patients' SGB treatments. The use of structured processes for reviewing and tracking referrals, such as clinical consults, may improve communication between providers and care coordination.[48]

Incorrect Indication Documented for SGB Procedures

The OIG determined that the anesthesiologist did not accurately document the indication for SGB use in patients' informed consent forms. VHA requires that during the informed consent process, providers must document that the indications for the treatment or procedure have been discussed with the patient.[49]

The OIG reviewed informed consent documents for six patients who received SGB for PTSD. The OIG found that the anesthesiologist documented the reason for the procedure as pain and not PTSD for four patients. For three of the four patients, PTSD was noted in the comments section of the consent form. The anesthesiologist told the OIG the facility has a consent form designed for pain procedures, which must be manually changed when used for SGB procedures to treat PTSD.

The OIG concluded that the anesthesiologist did not accurately document the indication for the SGBs on informed consent forms in accordance with VHA requirements.

Section II: Contributing Factors that Adversely Impacted the Facility's Ability to Implement Ketamine Treatment

During the inspection, the OIG found that the facility's poorly defined process for evaluating patients for ketamine treatment and facility leaders' inability to resolve a disagreement among the ketamine team adversely impacted the implementation of ketamine treatment. Additionally, the OIG identified deficiencies in implementing procedures related to the use of intravenous ketamine.

[48] VHA Directive 1232(2), *Consult Processes and Procedures*, August 24, 2016, amended June 28, 2019. A clinical consult is a request from the provider seeking assistance from another provider regarding services, evaluation, or treatment that may benefit the patient.

[49] VHA Handbook 1004.01(5), *Informed Consent for Clinical Treatments and Procedures*, August 14, 2009, amended September 20, 2017, April 4, 2019, June 25, 2020, January 4, 2021, and September 17, 2021. The amended versions contain the same or similar language regarding requirements for providers to give clear and concise explanations of the patient's condition or diagnosis.

Ketamine and Esketamine for Treatment-Resistant Depression at VHA

In July 2019, VHA Deputy Under Secretary for Health for Operations and Management issued a memorandum to the VISN 19 Network Director that invited the facility to offer esketamine treatment. Facility leaders elected to pursue the opportunity to provide ketamine treatment for treatment-resistant depression, at the facility.[50] The psychiatry section chief told the OIG the decision was to institute intravenous ketamine treatment instead of intranasal esketamine. The OIG learned that the psychiatry section chief worked with the anesthesiologist, who had previous experience with ketamine treatment in private practice.

National ketamine guidance provides general direction for patient selection, screening, and referral, administration of intravenous ketamine, and allows "facilities the flexibility to exercise modifications to the protocol as necessary to operationalize the use of ketamine for treating treatment-resistant depression or severe suicidal ideation." The guidance stated that "[e]ach facility will be responsible for developing and operationalizing a procedure to screen and refer potential candidates for treatment with ketamine."[51]

Facility Initiation of Ketamine Treatment

During an OIG interview, a psychiatric CPS reported that in early 2020, the facility established a ketamine team, the April 2020 SOP, and an informal process for evaluation of patients for ketamine treatment.[52] The April 2020 SOP required that patients must have two failed trials of antidepressants to be considered for ketamine treatment.[53]

During the Pharmacy and Therapeutics Committee's April 2020 meeting, members reviewed the April 2020 SOP and requested revisions to indicate that patients have four failed trials of antidepressants to align with national ketamine guidance, as well as the addition of EHR ketamine order, consult, and relevant progress note templates.[54] In May 2020, an SOP that included the revisions was approved by the Pharmacy and Therapeutics Committee.

[50] Deputy Under Secretary for Health for Operations and Management memo, "Invitation to Participate as Early Adopters for Intranasal Esketamine for Treatment Resistant Depression," July 29, 2019.

[51] VA, *Ketamine Infusion for Treatment Resistant Depression and Severe Suicidal Ideation National Protocol Guidance*, (2017).

[52] Facility SOP 116-071.

[53] Facility SOP 116-071.

[54] VA, *Ketamine Infusion for Treatment Resistant Depression and Severe Suicidal Ideation National Protocol Guidance*, (2017).The national ketamine guidance includes either an antidepressant trial or psychotherapy as a failed treatment trial.

1. Poorly Defined Process for Evaluation of Patients to Receive Ketamine Treatment

The OIG determined that the facility's ketamine team, composed of the anesthesiologist, the original psychiatrist, and the psychiatric CPS established an informal process for the ketamine team to review patients for intravenous ketamine treatment. However, the informal process was not maintained after the team's original psychiatrist transferred to another VA facility and a second psychiatric CPS joined the team. The changes in team membership affected the consistency of the evaluation process as well as the team dynamic.

The OIG interviewed ketamine team members and found that the team was formed to discuss and provide clinical opinions about patients being considered for ketamine treatment, determine whether intravenous ketamine treatment would be approved, and document the team's discussion and decision in the EHR. The OIG learned that in early 2020, the facility created the "Psychiatry Use of IV [Intravenous] Ketamine" standard operating procedure (April 2020 SOP), and an informal process for evaluation of patients for ketamine treatment.[55] Each team member evaluated patients referred for ketamine treatment. The psychiatrist determined whether a patient had a diagnosis of treatment-resistant depression and had previously failed antidepressant medication trials, and the anesthesiologist provided a medical evaluation and clearance for the patient. The psychiatric CPS conducted a medication review of the EHR and documented whether the patient had evidence of failed antidepressant medication trials.

Collaboration among the ketamine team members occurred through in-person meetings, phone conversations, EHR documentation, and electronic messaging. In August 2020, the ketamine team's original psychiatrist established weekly team meetings with agendas to discuss patient referrals, but indicated there were no meeting minutes recorded. A charter for the ketamine team was not established; however, the OIG did not find the facility had a requirement for a team charter.

During interviews, ketamine team members told the OIG that in September 2020, the original psychiatrist on the ketamine team transferred to another VA facility. An interim psychiatrist was involved with the team for approximately three months; the current ketamine team psychiatrist joined around October 2020. Additionally, a second psychiatric CPS joined the ketamine team in July 2020 and became the ketamine team's primary psychiatric CPS.

During an interview, the anesthesiologist reported being "very engaged in the process of discussing possible patients" when the treatment was first established. However, over time the anesthesiologist had less collaboration with ketamine team members, attended team meetings less frequently, and allowed the ketamine team psychiatrists and psychiatric CPSs to make the decisions for approving patients for ketamine treatment. The anesthesiologist reported that the

[55] Facility SOP 116-071.

psychiatric CPSs "independently decide whether the patient qualifies" for treatment. Additionally, the anesthesiologist had hoped that ketamine treatment would flourish but stated that "we had all these patients who were denied services because they [pharmacy] were saying they [patients] needed to fail four [antidepressant treatment trials]."

The current ketamine team psychiatrist reported that ketamine "is a life-saving, life changing drug" but expressed frustration about ketamine treatment at the facility due to the psychiatric CPSs having more control than psychiatrists to decide whether a patient receives ketamine treatments. During an interview with the OIG, the psychiatry section chief reported that CPSs had rigidly interpreted the national ketamine guidance and should have taken into consideration the referring psychiatrist's determination of a patient's clinical indication for ketamine treatment.

The ketamine team's second psychiatric CPS stated that patients have to meet an extensive list of criteria to be able to get ketamine including having suicidal ideation that needs immediate treatment or having a current diagnosis of major depressive disorder with four failed antidepressant medication trials. In addition, the CPS indicated that when a patient did not meet criteria for ketamine treatment, the ketamine team would meet and jointly decide whether to approve the patient for ketamine treatment, and document the team's decision in the EHR.

The OIG reviewed the EHRs of the 11 patients who were evaluated between April 2020 and June 2021 by two ketamine team psychiatric CPSs for intravenous ketamine treatment.[56] Six of the 11 patients were approved for intravenous ketamine and 5 of the 6 patients who were approved received ketamine treatment.[57]

The ketamine team psychiatric CPS completed four evaluations between April and August 2020 and determined that none of the 4 patients met the failed antidepressant medication trials criteria. The CPS documented in the patients' EHRs that after discussion with the ketamine team's original psychiatrist, 3 patients were approved for ketamine treatment. The CPS documented that the fourth patient was not approved.

The second ketamine team psychiatric CPS conducted eight evaluations between September 2020 and June 2021. The CPS indicated, based on available treatments, 3 patients met criteria and were approved for ketamine treatment. The CPS also indicated that 4 patients did not meet criteria because they did not have four failed antidepressant medication trials. However, the OIG did not find documented evidence in the EHR that the ketamine team discussed or decided on approval or denial for ketamine treatment for the 4 patients. None of the 4 patients received intravenous ketamine treatment at the facility. Additionally, the OIG found that the interim ketamine team psychiatrist documented that the ketamine team reviewed 1 patient and

[56] One patient was evaluated twice.

[57] The OIG found documented evidence in the EHR that one of the approved patients was unable to receive ketamine treatments due to limitations with transportation.

determined the patient would not be a candidate for ketamine treatment based on the patient's diagnosis.

Although psychiatric CPSs determined that 8 patients did not meet the failed antidepressant medication trials criteria, 3 of the 8 patients received ketamine treatment after discussion between the original ketamine team psychiatrist and the psychiatric CPS. Ketamine team members did not meet to discuss 4 patients who were denied ketamine treatment. Without discussion by the multidisciplinary team, the patients were not afforded the benefit of a diversified and nuanced assessment for treatment with intravenous ketamine.

The OIG concluded that the informal process the facility had implemented for reviewing patients for intravenous ketamine treatment was not maintained after changes occurred in ketamine team membership, which affected the approach to the evaluation process and the dynamic of the team. In addition, facility leaders did not define expectations for team members to discuss patients evaluated for ketamine or to document the team's decision regarding ketamine treatment. This resulted in disagreement among ketamine team members, specifically around the ketamine national guidance criteria that a patient needed to fail four treatment trials before approval of intravenous ketamine for treatment-resistant depression.

Application of National Ketamine Guidance of Inclusion Criteria

The OIG interviewed VHA program office leaders and reviewed a synthesis of literature to determine the background of the national ketamine guidance and scientific recommendations on the selection of patients for ketamine treatment.[58]

The VHA National Program Director for Psychopharmacology & Somatic Treatments reported that the determination to include four previous treatment trial failures as a criterion for ketamine national guidance was developed by the VA Pharmacy Benefits Management Services, and the VHA Office of Mental Health and Suicide Prevention in 2017. The VHA National Program Director for Psychopharmacology & Somatic Treatments stated there are "local opportunities to make exceptions where appropriate clinically and we allow local facilities to make those determinations." The National Pharmacy Benefits Management Clinical Pharmacy Program Manager told the OIG that the decision to include four previous treatment trial failures for ketamine national guidance was made in 2019, when esketamine was being considered by the committee. Two failed trials was thought to be too low of a bar with concerns to safety and efficacy of esketamine and eight failed trials was more typical in that patient population.

As summarized in the article, *Synthesizing the Evidence for Ketamine and Esketamine in Treatment-Resistant Depression: An International Expert Opinion on the Available Evidence*

[58] Roger S. McIntyre et al., "Synthesizing the Evidence for Ketamine and Esketamine in Treatment-Resistant Depression: An International Expert Opinion on the Available Evidence and Implementation," Am J Psychiatry 2021; 178:383–399.

and Implementation, "studies in adults with [treatment-resistant depression] have defined [treatment-resistant depression] as insufficient response to at least two antidepressants" during an episode. The publication points out "[a]n important observation with respect to ketamine's efficacy in adults with [treatment-resistant depression] is the possibility of attenuated [decreased] efficacy in individuals with greater degrees of treatment resistance in some, but not all, studies."[59] In other words, guidance for patients to fail a greater number of antidepressant trials potentially requires them to delay treatment to a point in their illness when they could be less likely to respond to ketamine. The authors concluded that studies suggest that "ketamine and esketamine may be considered in patients who have had at least two prior treatment failures."[60]

The OIG had concerns that the national guidance for four failed treatment trials in the current episode of depression is potentially burdensome to patients suffering with severe mood disorders.[61] The standard length for an adequate trial of antidepressant is six to eight weeks. Augmentation treatment typically adds another three to four weeks or more and, in many cases, there would be additional trials of antidepressants in which the patients do not tolerate a dose considered adequate for treating depression and would, therefore, not be counted toward meeting the guidance. Psychotherapy could add five to 20 weeks for each trial. The failed trials, augmentation treatment, psychotherapy and often, additional antidepressant trials may add up to more than a year of preliminary treatment, during which time, patients are at risk for adverse clinical outcomes and psychosocial consequences such as loss of employment or interpersonal relationships.[62]

The OIG found that the ketamine team psychiatric CPSs applied the inclusion and exclusion criteria from the national ketamine guidance without affording the flexibility allowed by the guidance to consider treatment in the context of individual patient needs. Within the ketamine team, some individuals felt compelled to address the needs of the individual patient, whereas others steadfastly pointed to the written guidance provided by national leaders. Subsequently, patients who cannot endure the preliminary treatments, such as to meet the failed trials criteria, may be denied the benefits of intravenous ketamine treatment and their providers deprived of avenues to obtain clinical results. Furthermore, the current scientific opinions on the selection of patients for ketamine treatment differ significantly from national ketamine guidance with respect to the acceptable number of prior treatment failures in a current episode of depression.

[59] "Synthesizing the Evidence for Ketamine and Esketamine in Treatment-Resistant Depression: An International Expert Opinion on the Available Evidence and Implementation."

[60] "Synthesizing the Evidence for Ketamine and Esketamine in Treatment-Resistant Depression: An International Expert Opinion on the Available Evidence and Implementation."

[61] VA, *Ketamine Infusion for Treatment Resistant Depression and Severe Suicidal Ideation National Protocol Guidance*, 2017.

[62] Within the context of this report, the OIG considered an adverse clinical outcome to be death, a progression of disease, worsening prognosis, suboptimal treatment, or a need for higher-level care.

2. Facility Leaders Did Not Effectively Resolve Ketamine Team Disagreement

The OIG determined that, although facility leaders were aware of disagreement among the ketamine team members, they did not resolve the conflict. Leaders have a responsibility to promote positive working relationships among staff and address conflicts openly as they arise. Failure to address disharmony can lead to poor quality of care.

During an interview, the OIG learned the COS requested assistance from the VISN Chief Medical Officer in mid-June 2021 to address the ongoing disagreement between Pharmacy and Psychiatry Services concerning the prescribing of intravenous ketamine. The COS felt that psychiatrists had clinical expertise to make decisions regarding ketamine treatment and psychiatric CPSs were "overstepping some authorities in terms of withholding or denying the use of ketamine in patients that were not responding to conventional medical management." The VISN Chief Medical Officer told the OIG that the psychiatrists discussed wanting "to have complete control over ketamine administration." The VISN Chief Medical Officer indicated that collaboration between pharmacy and psychiatrists to appropriately select patients was needed to make sure the parameters for ketamine administration were met. The VISN Chief Medical Officer reported working with the VISN pharmacy lead to identify patients and develop a plan to conduct an evaluation of the issue.

During interviews, the OIG learned that one week after meeting with the VISN Chief Medical Officer to request assistance to address pharmacy and psychiatry service concerns, the COS met with the chiefs of pharmacy and behavior medicine, and the psychiatry section chief "to resolve the situation." Following this meeting, the associate chief of pharmacy clinical services met with the chief of behavior medicine, psychiatry section chief, and psychiatrists to explain pharmacy staff's responsibility was to ensure criteria for use of restricted formulary medications including ketamine criteria were followed. In addition, the associate chief of pharmacy clinical services requested assistance from a national pharmacy program office to improve the integration of CPSs into Behavior Medicine Service.

After the OIG notified the facility of the healthcare inspection, the Facility Director learned about the disagreement between pharmacists and psychiatrists. Additionally, the Facility Director told the OIG of wanting to assure that staff members were operating within the scopes of their licenses. In February 2022, the Interim Facility Director indicated working with the VISN Chief Medical Officer to have external providers conduct peer reviews.

The OIG determined that, although facility leaders were aware of disagreement among ketamine team members, they did not effectively resolve the conflict. These unresolved differences contributed to an ongoing lack of collaboration and frustration between prescribers and pharmacists.

3. Deficiencies in Processes Related to Ketamine Use

The OIG identified deficiencies in processes related to completion of informed consents for patients receiving intravenous ketamine for treatment-resistant depression or suicidal ideation, and evaluation of a community care consult for a patient who received intravenous ketamine treatment.

Inaccurate Completion of Informed Consent

The OIG determined that neither the anesthesiologist nor a psychiatrist accurately documented the indication for ketamine use on the informed consent forms as required by VHA.[63]

The April 2020 SOP requires verbal and written consent for intravenous ketamine. VHA requires that during the informed consent process, providers "[g]ive a clear and concise explanation of the patient's condition(s) or diagnosis(es) that relates to the recommended treatment or procedure" and the indications for the treatment or procedure.[64]

The OIG reviewed five patients' informed consents for intravenous ketamine for treatment-resistant depression. On four of the informed consents, the anesthesiologist or ketamine treatment psychiatrist indicated the patient had moderate to severe nerve pain. On the other consent, the anesthesiologist indicated opioid use disorder as the reason for the intravenous ketamine instead of treatment-resistant depression or suicidal ideation. In the comment section of three of the patients' consent forms, the anesthesiologist noted drug-resistant depression, treatment-resistant depression, or chronic depression. When asked about documenting pain instead of treatment-resistant depression as the indication for use, the anesthesiologist told the OIG that the facility has a consent form designed for pain procedures that must be manually changed when used for ketamine treatment.

The OIG concluded that the anesthesiologist or a ketamine team psychiatrist did not accurately document the indication for ketamine treatment on the informed consents for five patients. The inaccurate intravenous ketamine indications on the informed consents is consistent with the SGB informed consent issue described in section 1.

[63] VHA Handbook 1004.01(5), Informed Consent for Clinical Treatments and Procedures, August 14, 2009, amended September 20, 2017, April 4, 2019, June 25, 2020, January 4, 2021 and September 17, 2021. Facility SOP 116-071.

[64] Facility SOP 116-071. VHA Handbook 1004.01(5). "In VHA, patients have the right to accept or refuse any medical treatment or procedure recommended to them."

A patient received approval for intravenous Ketamine in the community without Ketamine team review

The OIG determined that the facility's failure to establish or formally define a process to review patients for intravenous ketamine may have contributed to a nurse approving a community care consult for ketamine treatment for a patient without a decision by the ketamine team.[65]

Under a Veterans Care Agreement, VHA mental health providers may refer patients, who are appropriate for ketamine treatment, to the community when a facility does not provide the treatment.[66]

The OIG found that in the fall of 2020, two ketamine team members evaluated Patient C for intravenous ketamine for treatment-resistant depression; however, neither member documented an approval or denial of the treatment. The psychiatric CPS documented that the case would need to be discussed with the ketamine team to determine whether to approve intravenous ketamine treatment for the patient.

In early 2021, a mental health provider submitted a community care consult for Patient C to receive ketamine treatment. During an interview, the mental health provider told the OIG that the patient's previous psychiatrist documented in the EHR that the patient had met criteria for ketamine treatment. The mental health provider was "uncertain of any official approval" for the patient to receive ketamine treatment. In spring 2021, a registered nurse approved the patient's community care consult for ketamine treatment. The registered nurse told the OIG of approving the consult after reviewing the patient's EHR, which indicated that the patient had taken several medications for major depression without benefit, met with the ketamine team, and was approved for ketamine treatment. However, the OIG did not find documented evidence of the ketamine team's patient case review or approval for intravenous ketamine as indicated by the facility community care registered nurse, or communication from the ketamine team with the patient regarding the team's approval or denial for ketamine treatment.

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[65] VHA, "Veteran Community Care Veterans Care Agreements (VCAs) Fact Sheet," July 8, 2020. Under a Veterans Care Agreement, VHA mental health providers may refer patients, who are appropriate for ketamine treatment, to the community when a facility does not provide the treatment.

[66] "Community Care Referrals for Esketamine (Spravato®) and IV [Intravenous] Ketamine" Office of Mental Health and Suicide Prevention Guidance, June 7, 2021. VHA Office of Community Care, Veteran Community Care General Information Fact Sheet," September 9,2019. VHA, "VA MISSION Act and New Veterans Community Care Program Fact Sheet," June 15, 2018. In 2018,Congress passed the Maintaining Internal Systems and Strengthening Integrated Outside Networks (MISSION) Act that defines circumstances that VHA may purchase care from a non-VHA provider (community care provider) when the facility is unable to deliver the necessary care and services, when care cannot be provided timely, or when care cannot be provided due to geographic inaccessibility. VHA, "Veteran Community Care Veterans Care Agreements (VCAs) Fact Sheet," July 8, 2020. Under the MISSION Act VHA may enter into Veteran Care Agreements with community providers for care for Veterans when they are not part of the VA's contracted care agreement. Veteran Care Agreements are intended to be used in limited circumstances where contracted services are not provided or sufficient.

During an interview, the OIG inquired about referring patients to community care for ketamine treatment when a facility does not provide the treatment. The VHA National Program Director for Psychopharmacology & Somatic Treatments reported having provided education for mental health providers, that patients who are evaluated and determined to be appropriate for ketamine treatment, are referred to the community for treatment. The psychiatry section chief indicated that prior to being authorized for intravenous ketamine treatment in the community, patients needed to be evaluated by the ketamine team and meet the facility's criteria for treatment-resistant depression.

The OIG concluded that not establishing or formally defining a process for reviewing patients referred for ketamine treatment may have contributed to approval of Patient C's community care ketamine treatment without a decision by the ketamine team.

Conclusion

The OIG did not substantiate that the anesthesiologist self-referred facility patients who were not approved by the facility for intravenous ketamine to the private practice. The OIG concluded that the anesthesiologist provided intravenous ketamine to one patient, Patient A, at the private practice to manage the patient's complex case but did not self-refer the patient to the private practice. The facility conducted an Administrative Investigation Board regarding an allegation of the anesthesiologist's self-referring veteran patients to the private practice. The Administrative Investigation Board concluded there was no evidence to support that the anesthesiologist self-referred patients.

The OIG substantiated that at the time of the inspection, beyond having informal discussions among themselves, the chiefs of behavior medicine and surgery, associate chief of pharmacy clinical services, and psychiatry section chief did little to respond to the reported concerns about the anesthesiologist's ketamine prescribing practices. The OIG learned that after the OIG notified the facility about the healthcare inspection, the Interim Facility Director initiated peer reviews to evaluate the appropriateness of prescribing practices and evidence of self-referral.

The anesthesiologist prescribed sublingual ketamine for three patients; however, the OIG did not find that prescribing sublingual ketamine was prohibited. The OIG determined that there were inconsistencies with the pharmacists' approval of non-formulary medication requests for sublingual ketamine due to a lack of clarity regarding processes. Reasons for the discrepancy between approval and denial were unclear to the OIG. While pharmacy and psychiatry had established meetings to review the process of non-formulary requests for ketamine and antipsychotics, further evaluation of the non-formulary medication approval and appeal process is warranted.

The OIG substantiated that the anesthesiologist did not notify psychiatrists prior to offering SGB treatment to three patients. Psychiatrists were ultimately informed about scheduled SGB

procedures; however, the OIG would expect communication between providers about coordination of patients' SGB treatments. The use of structured processes for reviewing and tracking referrals such as clinical consults may improve communication and care coordination. Additionally, the anesthesiologist did not accurately document the indication for SGB use on the patients' informed consent forms.

The OIG identified that the facility's poorly defined process for evaluating patients for ketamine treatment and the facility leaders' inability to resolve disagreements within the ketamine team adversely impacted the facilities ability to implement ketamine treatment.

The OIG concluded that in April 2020, the facility had implemented an informal process for reviewing patients for intravenous ketamine treatment. The informal process was not maintained after the team's original psychiatrist transferred to another VA facility and a second psychiatric CPS joined the team. The changes in team members challenged a consistent approach to the evaluation process and the dynamic of the team.

The OIG determined that ketamine team members did not meet to discuss four patients who were denied ketamine treatment. Without discussion by the multidisciplinary team, clinical decisions were not made based on the individual experience and needs of each patient for treatment with intravenous ketamine. This resulted in disagreement among ketamine team members specifically around the national guidance criteria that a patient needed to fail four treatment trials before approval of intravenous ketamine for treatment-resistant depression.

During the inspection, the OIG had concerns that the national guidance for four failed treatment trials in the current episode of depression is potentially burdensome to patients suffering with severe mood disorders. The OIG found that current scientific opinions on the selection of patients for ketamine treatment differ from national ketamine guidance with respect to the acceptable number of previous treatment failures in a current episode of depression.

Although facility leaders were aware of disagreements among ketamine team members, they did not resolve the conflict. These unresolved differences contributed to an ongoing lack of collaboration and frustration between prescribers and pharmacists.

The OIG determined that neither the anesthesiologist nor the ketamine team psychiatrist accurately completed informed consents for patients receiving intravenous ketamine for treatment-resistant depression.

The OIG concluded that not establishing or formally defining a process for reviewing patients referred for ketamine treatment may have contributed to approval of Patient C's community care ketamine treatment without a decision by the ketamine team.

Recommendations 1–5

1. The Eastern Oklahoma VA Health Care System Director evaluates the Eastern Oklahoma VA Health Care System's non-formulary medication request and appeal processes for ketamine and antipsychotic medication, implements necessary changes, and educates prescribing providers and pharmacists on the processes.

2. The Eastern Oklahoma VA Health Care System Director ensures that the Eastern Oklahoma VA Health Care System staff document informed consents for stellate ganglion blocks and intravenous ketamine treatment in accordance with Veterans Health Administration policy.

3. The Eastern Oklahoma VA Health Care System Director evaluates the standard operating procedure, *Psychiatric Use of IV Ketamine*, Eastern Oklahoma VA Healthcare System, and specifically delineates the mechanisms for referral and evaluation of patients, to include documentation of criteria for patients to receive ketamine treatment and ensures staff are educated and compliant with the procedure.

4. The Eastern Oklahoma VA Health Care System Director takes action to ensure Eastern Oklahoma VA Health Care System leaders continue to resolve disagreements between prescribers and pharmacists and foster the development of positive working relations among Anesthesiology, Pharmacy, and Psychiatry Services.

5. The Under Secretary for Health evaluates the *VA Ketamine Infusion for Treatment-Resistant Depression and Severe Suicidal Ideation National Protocol Guidance* to determine whether the acceptable number of previous treatment failures in a current episode of depression should be modified to align with current scientific recommendations.

Appendix A: Office of the Under Secretary for Health Memorandum

Department of Veterans Affairs Memorandum

Date: January 19, 2023

From: Under Secretary for Health (10)

Subj: OIG Draft Report, Deficiencies in the Implementation and Leadership Oversight of Ketamine at the Eastern Oklahoma Health Care System in Muskogee. (MCI# 2021-01836-HI-1174) (VIEWS 9078373)

To: Assistant Inspector General for Healthcare Inspections (54)
Director, Office of Healthcare Inspections (54 HL09)

1.Thank you for the opportunity to review and comment on the draft report about off-label ketamine use in a few patients with treatment resistant depression at the Eastern Oklahoma VA Health Care System (HCS) in Muskogee. The medical facility Director's memo addresses recommendations 1 through 4. VHA's response to recommendation 5 is attached.

2.VHA appreciates how difficult it is to treat depression especially when it is complicated by chronic pain, loss, isolation, or other health conditions. Every day, we work with each person to find a treatment or combination of treatments that will relieve suffering and improve wellness. Each person responds differently to drug, non-drug, and combination treatments. For these reasons, VHA released guidance which allows latitude for health care providers to tailor treatments for individual patients rather than establishing rigid policy.

3.VHA concurs in principle with OIG's recommendation 5 because there has not been significant change to the industry opinion regarding off-label usage of ketamine for treatment resistant depression since our last review of the available body of evidence and update of VHA's ketamine guidance. We regularly perform a comprehensive review of scientific recommendations and specific Veterans experiences with off-label usage of ketamine. The guidance was most recently updated in July 2022. The opinion paper OIG cited in its draft report was published in 2021. Subsequently, two editorials were published[12] about this opinion paper questioning the validity of the conclusions as well as the methodology of the work. Further evaluation of the authors of the opinion paper indicates there could be potential, significant conflicts of interest including patent holders and licensing agreements with payment for use of ketamine or esketamine for the treatment of depression. It could increase the risk of harm to

[1] Am J Psychiatry 2021; 178:12; 1129; doi: 10.1176/appi.ajp.2021.21060555.
[2] Am J Psychiatry 2021; 178:12; 1129; doi: 10.1176/appi.ajp.2021.21060576.

patients if VHA altered its guidance for off-label treatment with ketamine, a medication that can be dangerous, based on opinions from authors with potential financial conflicts of interest.

4.VHA expressed our concerns regarding this recommendation and the citation during a call with the OIG team and provided them with written comments. Comments regarding the contents of this memorandum may be directed to the [Government Accounting Office] GAO/OIG Accountability Liaison Office at VHA10BGOALACTION@va.gov.

(Original signed by:)

Shereef Elnahal. M.D., MBA.

Attachment

Under Secretary for Health Response

VETERANS HEALTH ADMINISTRATION (VHA)

Action Plan

OIG Draft Report: Deficiencies in the Implementation and Leadership Oversight of Ketamine at the Eastern Oklahoma VA Health Care System in Muskogee

Recommendation 5. The Under Secretary for Health evaluates the VA Ketamine Infusion for Treatment-Resistant Depression and Severe Suicidal Ideation National Protocol Guidance to determine whether the acceptable number of previous treatment failures in a current episode of depression should be modified to align with current scientific recommendations.

VHA Comments: Concur in Principle.

VHA's current guidance for off-label usage of ketamine for treatment resistant depression is in line with peer reviewed scientific recommendations balanced with the needs and unique characteristics of the VHA patient population with treatment resistant depression and suicidal ideations. A re-evaluation of the guidance is unnecessary at this time based on the available body of evidence.

VHA, as part of its management of formulary management guidance, regularly conducts comprehensive reviews of scientific recommendations and evidence from Veterans' experiences. VHA reviewed and updated the Ketamine guidance in October 2020, April 2021, February 2022, and most recently, in July 2022, which was after the time of the OIG visit to the Muskogee facility. There has not been significant change to the industry opinion regarding off-label usage of ketamine for treatment resistant depression since our last publication. VHA's guidance is also consistent with that of other larger insurers, such as Blue Cross Blue Shield of Massachusetts (094 Esketamine Nasal Spray (SpravatoTM) and Intravenous Ketamine for Mental Health Conditions Prior Authorization Request Form (bluecrossma.org)).

VHA appreciates OIG's independent review of the literature on this topic, however, the opinion paper from 2021 that OIG cited in its draft report is not typically the type of reference relied on for conclusive, evidence-based decisions[3]. Two editorials[4],[5], published subsequently, question the methodology of the work and the validity of the

[3] "Synthesizing the Evidence for Ketamine and Esketamine in Treatment-Resistant Depression: An International Expert Opinion on the Available Evidence and Implementation,"

[4] Am J Psychiatry 2021; 178:12; 1129; doi: 10.1176/appi.ajp.2021.21060555.

[5] Am J Psychiatry 2021; 178:12; 1129; doi: 10.1176/appi.ajp.2021.21060576.

conclusions reached in this opinion paper. VHA, when available, utilizes large, well conducted, randomized, double-blind, placebo-controlled, clinical trials, Food and Drug Administration summary reviews, Institute of Clinical and Economical Reviews (ICER), and U.S. package inserts melded with its understanding of the unique needs of Veterans to draft monographs, clinical recommendations, and criteria of use (CFU) documents. In review of the opinion paper cited above, it is clear, that the authors of the opinion paper may be biased by potential, significant conflicts of interest including patent holders and licensing agreements with payment for use of ketamine or esketamine for the treatment of depression which further confounds the conclusions.

The National Protocol Guidance for Ketamine Infusion for Treatment Resistant Depression and Severe Suicidal Ideation, recently updated in July 2022, is based on sound scientific principles including close review of the number of previous treatment failures in a current episode of depression**.** The July update, which occurred after the OIG facility visit, supports the completion of this recommendation.

Status: Closed Completion Date: July 2022

OIG Comments

VHA provided sufficient supporting documentation, and the OIG considers this recommendation closed.

VHA commented that authors of the referenced article *Synthesizing the Evidence for Ketamine and Esketamine in Treatment-Resistant Depression: An International Expert Opinion on the Available Evidence and Implementation*, were biased.[6] The OIG notes that this expert opinion paper was published in a peer reviewed journal that has substantial impact in the field of psychiatry and is the flagship journal of the American Psychiatric Association. It is also noteworthy that VHA relied on published research articles from seven of the 25 internationally recognized authors of this paper as evidenced by citations in the updated *VA/DoD Clinical Practice Guideline for the Management of Major Depressive Disorder*.[7]

While the OIG accepts that VHA reviewed their current national *Ketamine Infusion for Treatment Resistant Depression and Severe Suicidal Ideation National Protocol Guidance,* July 2022, the support provided to justify maintaining four treatment failures in that guidance does not align with current evidence-based practice or VHA's own clinical practice guidelines.[8] Because of this, the July 2022 national protocol guidance adds confusion to the management of

[6] "Synthesizing the Evidence for Ketamine and Esketamine in Treatment-Resistant Depression: An International Expert Opinion on the Available Evidence and Implementation."

[7] *VA/DoD Clinical Practice Guideline for the Management of Major Depressive Disorder*, February 2022.

[8] *Ketamine Infusion for Treatment Resistant Depression and Severe Suicidal Ideation National Protocol Guidance*, July 2022. *VA/DoD Clinical Practice Guideline for the Management of Major Depressive Disorder*, February 2022.

veterans with treatment-resistant depression and sets a stage on which issues such as those that are the subject of this report may re-occur.

The OIG takes issue with the Under Secretary for Health's comments that there are no significant changes to the industry opinion regarding off-label usage of ketamine for treatment-resistant depression. The July 2022 updated national Ketamine protocol guidance, cites the same 2014-2017 references used in previous versions, and so relies on an outdated literature base.[9] In contrast, the *VA/DoD Clinical Practice Guideline for the Management of Major Depressive Disorder* Version 4.0 published February 2022, relies on more current references. Furthermore, *VA/DoD Clinical Practice Guideline for the Management of Major Depressive Disorder* states that, "Evidence suggests both ketamine infusion and intranasal esketamine improve depressive symptoms in patients with MDD [major depressive disorder] who have not responded to at least two previous adequate trials of antidepressant medications."[10] Aside from supporting the two trials criterion, this is a substantial change from the 2016 version of the *VA/DoD Clinical Practice Guideline for the Management of Major Depressive Disorder* that stated "Given the limited information on ketamine's safety and duration of effect, we recommend against the use of ketamine to treat MDD [major depressive disorder] outside of a research setting."[11] This illustrates the significant change in industry opinion that has occurred in the interval, even within VHA.

[9] *Ketamine Infusion for Treatment Resistant Depression and Severe Suicidal Ideation National Protocol Guidance*, July 2022.

[10] VA/DoD Clinical Practice Guideline for the Management of Major Depressive Disorder, February 2022.

[11] VA/DoD Clinical Practice Guideline for the Management of Major Depressive Disorder, April 2016.

Appendix B: VISN Director Memorandum

Department of Veterans Affairs Memorandum

Date: November 9, 2022

From: VA Rocky Mountain Network (10N19)

Subj: Healthcare Inspection— Deficiencies in the Implementation and Leadership Oversight of Ketamine at the Eastern Oklahoma Health Care System in Muskogee.

To: Office of the Under Secretary for Health (10)
Director, Office of Healthcare Inspections (54HL09)
Director, GAO/OIG Accountability Liaison Office (VHA 10BGOAL Action)

1. I have reviewed the findings, recommendations, and action plan of the Eastern Oklahoma VA Health Care System in Muskogee. I am in agreeance with the above.

(*Original signed by:*)

Ralph T Gigliotti, FACHE
Director, VA Rocky Mountain Network (10N19)

Appendix C: Facility Director Memorandum

Department of Veterans Affairs Memorandum

Date: November 1, 2022

From: Interim Director, Eastern Oklahoma VA Health Care System (623)

Subj: Healthcare Inspection—Deficiencies in the Implementation and Leadership Oversight of Ketamine at the Eastern Oklahoma Health Care System in Muskogee.

To: Director, VA Rocky Mountain Network (10N19)

1. I have read and concur with findings and recommendations 1 through 4 in the OIG Report entitled, *Deficiencies in the Implementation and Leadership Oversight of Ketamine at the Eastern Oklahoma Health Care System in Muskogee.*
2. My responses to report recommendations 1 through 4 can be found in the attached document.
3. If there are any questions regarding the responses to the recommendations or any additional information is required, please contact the Chief of Quality, Safety and Value.

(*Original signed by*:)

Kimberly Denning, DNP, RN
Interim Health System Director
Eastern Oklahoma VA Healthcare System

Facility Director Response

Recommendation 1

The Eastern Oklahoma VA Health Care System Director evaluates the Eastern Oklahoma VA Health Care System's non-formulary medication request and appeal processes for ketamine and antipsychotic medication, implements necessary changes, and educates prescribing providers and pharmacists on the processes.

Concur.

Target date for completion: April 30, 2023

Director Comments

On July 28, 2022, Pharmacy and Therapeutics Committee re-designed their review process for non-formulary medication request and appeal processes for ketamine and antipsychotic medications for completion of non-formulary medication requests. Education was provided to Pharmacists and providers. Monthly reports will be generated, reviewed, and reported to the Quality, Safety, and Value Committee starting in January 2023 for two consecutive quarters until at minimum, a 90% completion rate per quarter for the audits is achieved. Provider and pharmacist re-education on the process for both non-formulary requests and the appeals process was completed November 23, 2022.

Recommendation 2

The Eastern Oklahoma VA Health Care System Director ensures that the Eastern Oklahoma VA Health Care System Staff documents informed consents for stellate ganglion blocks and intravenous ketamine treatment in accordance with Veterans Health Administration policy.

Concur.

Target date for completion: April 30, 2023

Director Comments

Eastern Oklahoma VA Healthcare System obtains and documents informed consents per Veterans Health Administration policy for stellate ganglion blocks and intravenous ketamine treatment. Behavioral Health will perform consent audits for stellate ganglion blocks and intravenous ketamine treatment of either 30 records, or 100% if less than 30 procedures are performed. Behavioral Health will report to Quality Safety and Value Committee quarterly, starting January 2023 until at minimum, 90% success rate is achieved for two consecutive quarters.

Recommendation 3

The Eastern Oklahoma VA Health Care System Director evaluates the standard operating procedure, *Psychiatric Use of IV Ketamine*, Eastern Oklahoma VA Healthcare System, and specifically delineates the mechanisms for referral and evaluation of patients, to include documentation of criteria for patients to receive ketamine treatment and ensures staff are educated and compliant with the procedure.

Concur.

Target date for completion: April 30. 2023

Director Comments

Behavioral Medicine Service Psychiatry Section did a review of [Medical Center Policy] MCP 11-126, Psychiatric Use of IV Ketamine, to evaluate for the mechanisms for referral and evaluation of patients.

Behavioral Medicine Service Psychiatry Section Chief will review monthly, either 30 records, or 100% if less than 30 ketamine treatment patients are seen, to ensure compliance with ketamine policy and procedures and to ensure patients meet the criteria for treatment. This will be reported to Quality, Safety and Value Committee quarterly until at minimum, 90% success rate is achieved for two consecutive quarters.

Recommendation 4

The Eastern Oklahoma VA Health Care System Director takes action to ensure Eastern Oklahoma VA Health Care System leaders continue to resolve disagreement between prescribers and pharmacists and foster the development of positive working relations among Anesthesiology, Pharmacy, and Psychiatry Services.

Concur.

Target date for completion: March 31, 2023

Director Comments

On July 28, 2021, the Pharmacy and Therapeutics Committee approved a formal process for resolving non-formulary appeals. Eastern Oklahoma VA Healthcare System MCP 623-119190-037, is currently being updated and Section IV.b.11, Formulary Appeals, specifically describes step-by-step processes for escalation to the Chief of Staff for resolution. The appeals committee is interdisciplinary, including but not limited to physicians and pharmacists.

Pharmacy will audit for conflicts that need to be escalated to the Chief of Staff by reviewing either 30 records, or 100% if less than 30 appeals are performed and begin reporting results January 2023 to Quality, Safety and Value Committee until at minimum, 90% success rate for

the audits is achieved for two consecutive quarters. Chief of Quality, Safety, and Value will escalate report to Medical Executive Committee.

Glossary

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

anesthesiologist. "[A] physician specializing in anesthesiology," which is "a branch of medical science dealing with… anesthetics."[12]

anesthetic. "[A] drug that causes a person to lose feeling and to feel no pain in part or all of the body."[13]

augmentation. The act of making greater or more intense.[14]

clinical pharmacy specialist. A pharmacist who provides direct patient care, autonomously and as medication experts, "to assist primary care and specialty care teams in meeting the medication therapy needs of their patients."[15]

community care. VHA purchased care from a non-VHA provider (community care provider) when the facility is unable to provide the necessary care and services, when a patient cannot safely travel due to medical reasons, when care cannot be provided timely, or when care cannot be provided due to geographic inaccessibility.[16]

complex regional pain syndrome. "[A] condition of chronic, severe, often burning pain usually of part or all of one or more extremities that typically occurs following an injury, that is often accompanied by swelling, skin discoloration, allodynia, abnormal sweating, and impaired motor function in the affected area, and that is of unknown pathogenesis."[17]

controlled substance. "[A] drug that requires permission from a doctor to use."[18]

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[12] *Merriam-Webster.com Dictionary*, "anesthesiologist," accessed August 31, 2021, https://www.merriam-webster.com/dictionary/anesthesiologist. *Merriam-Webster.com Dictionary*, "anesthesiology," accessed April 27, 2022, https://www.merriam-webster.com/dictionary/anesthesiology.

[13] *Merriam-Webster.com Dictionary*, "anesthetic," accessed September 1, 2021, https://www.merriam-webster.com/dictionary/anesthetic.

[14] *Merriam-Webster.com Dictionary*, "augment," accessed May 1, 2022, https://www.merriam-webster.com/dictionary/augment.

[15] VHA Handbook 1108.11(1).

[16] "Veteran Community Care Veterans Care Agreements (VCAs) Fact Sheet." "Veteran Community Care General Information Fact Sheet."

[17] *Merriam-Webster.com Dictionary*, "complex regional pain syndrome," accessed August 17, 2021, https://www.merriam-webster.com/dictionary/complex%20regional%20pain%20syndrome.

[18] *Merriam-Webster.com Dictionary*, "controlled substance," accessed September 1, 2021, https://www.merriam-webster.com/dictionary/controlled%20substance.

depression. "[A] mood disorder that is marked by varying degrees of sadness, despair, and loneliness and that is typically accompanied by inactivity, guilt, loss of concentration, social withdrawal, sleep disturbances, and sometimes suicidal tendencies."[19]

dissociation. Characterized by feelings of detachment from reality, including the physical environment and self.[20]

esketamine. An intranasal medication used "for the treatment of treatment-resistant major depressive disorder."[21]

hallucinations. Experiencing sensory perceptions in response to a neurological disturbance or drugs, such as seeing images, or hearing sounds that seem real but are not.[22]

hyperalgesia. The "increased sensitivity to pain."[23]

intramuscular. "[S]ituated in, occurring in, or administered by entering a muscle," such as administered by an injection into the muscle.[24]

intranasal. "[L]ying within or administered by way of the nasal structures."[25]

intravenous. "[S]ituated, performed, or occurring within or entering by way of a vein," such as administered by an infusion into the vein.[26]

ketamine. A Drug Enforcement Administration controlled substance that can promote relief of pain and cause loss of feeling (anesthetic properties).[27]

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[19] *Merriam-Webster.com Dictionary*, "depression," accessed August 17, 2021, https://www.merriam-webster.com/dictionary/depression.

[20] "How do Dissociative Drugs Work?," National Institutes of Health, accessed September 1, 2021, https://www.drugabuse.gov/publications/research-reports/hallucinogens-dissociative-drugs/what-are-effects-common-dissociative-drugs-brain-body.

[21] VA, "Intranasal Esketamine for Treatment Resistant Depression National Protocol Guidance."

[22] *Merriam-Webster.com Dictionary*, "hallucinations," accessed August 17, 2021, https://www.merriam-webster.com/dictionary/hallucinations.

[23] *Merriam-Webster.com Dictionary*, "hyperalgesia," accessed November 19, 2021, https://www.merriam-webster.com/medical/hyperalgesia.

[24] *Merriam-Webster.com Dictionary*, "intramuscular," accessed August 16, 2021, https://www.merriam-webster.com/dictionary/intramuscular.

[25] *Merriam-Webster.com Dictionary*, "intranasal," accessed August 17, 2021, https://www.merriam-webster.com/dictionary/intranasal.

[26] *Merriam-Webster.com Dictionary*, "intravenous," accessed August 17, 2021, https://www.merriam-webster.com/dictionary/intravenous#medicalDictionary.

[27] National Library of Medicine PubChem, "Ketamine," accessed August 27, 2021, https://pubchem.ncbi.nlm.nih.gov/compound/ketamine.*Merriam-Webster.com Dictionary*, "anesthetic," accessed September 1, 2021, https://www.merriam-webster.com/dictionary/anesthetic.

major depressive disorder. "[A] serious mood disorder involving one or more episodes of intense psychological depression or loss of interest or pleasure that lasts two or more weeks and is accompanied by irritability, fatigue, poor concentration, sleep disturbances, weight gain or loss, feelings of worthlessness or guilt, and sometimes suicidal tendencies."[28]

neuropathic. Related to "damage, disease, or dysfunction of one or more nerves."[29]

non-formulary. "Drugs or supplies that are defined as commercially available products, but are not included on the [VA National Formulary]."[30]

peripheral vascular disease. A disease that affects blood vessels outside of the heart.[31]

pharmacotherapy. "The treatment of disease and especially mental illness with drugs."[32]

posttraumatic stress disorder. "[A] psychological reaction occurring after experiencing a highly stressing event … that is usually characterized by depression, anxiety, flashbacks, recurrent nightmares, and avoidance of reminders of the event."[33]

psychiatrist. "[A] medical doctor who diagnoses and treats mental, emotional, and behavioral disorders."[34]

psychological. "[D]irected toward the will or toward the mind specifically in its conative function."[35]

psychopharmacology. "The study of the use of medications in treating mental disorders."[36]

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[28] *Merriam-Webster.com Dictionary*, "major depressive disorder," accessed September 2, 2021, https://www.merriam-webster.com/dictionary/major%20depressive%20disorder.

[29] *Merriam-Webster.com Dictionary*, "neuropathy," accessed July 8, 2022, https://www.merriam-webster.com/dictionary/neuropathic.

[30] VHA Directive 1108.08(1).

[31] *Merriam-Webster.com Dictionary*, "peripheral vascular disease," accessed September 1, 2021, https://www.merriam-webster.com/medical/peripheral%20vascular%20disease.

[32] *Merriam-Webster.com Dictionary*, "pharmacotherapy," accessed April 25, 2022, https://www.merriam-webster.com/dictionary/pharmacotherapy.

[33] *Merriam-Webster.com Dictionary*, "post-traumatic stress disorder," accessed August 17, 2021, Post-traumatic Stress Disorder | Definition of Post-traumatic Stress Disorder by Merriam-Webster.

[34] *Merriam-Webster.com Dictionary*, "psychiatrist," accessed September 2, 2021, https://www.merriam-webster.com/dictionary/psychiatrist.

[35] *Merriam-Webster.com Dictionary*, "psychological," accessed September 1, 2021, https://www.merriam-webster.com/dictionary/psychological.

[36] "What Is Psychopharmacology," American Society of Clinical Psychopharmacology, accessed September 2, 2021, https://ascpp.org/resources/information-for-patients/what-is-psychopharmacology/.

psychotherapy. Psychological interventions and approaches used to treat mental or emotional disorder.[37]

somatic. Brain stimulation treatments.[38]

stellate ganglion block. A procedure involves the insertion of a needle into the neck near the stellate ganglion which is "a group of nerves that supply the head, upper extremities, and organs of the chest. A stellate ganglion block may be performed to determine the cause of pain in these areas or to treat pain."[39]

subcutaneous. "[A]dministered under the skin."[40]

sublingual. "[A]dministered under the tongue."[41]

traumatic brain injury. "[A]n acquired brain injury caused by external force" such as by a bullet, or in an accident or fall.[42]

treatment-resistant depression. "Patients whose depressive disorder does not respond satisfactorily to adequate treatment."[43]

[37] VA/DoD Clinical Practice Guideline for the Management of Major Depressive Disorder. Version 3.0, April 2016, Merriam-Webster.com Dictionary, "psychotherapy," accessed March 27, 2022, https://www.merriam-webster.com/dictionary/psychotherapy.

[38] VA/DoD, 'Clinical Practice Guideline for the Management of Major Depressive Disorder. Version 3.0," 2016.

[39] Johns Hopkins Medicine, "Stellate Ganglion Block," accessed January 20, 2022, https://www.hopkinsmedicine.org/pain/blaustein_pain_center/pain_procedures/stellate_ganglion_blocks.html.

[40] *Merriam-Webster.com Dictionary*, "subcutaneous," accessed August 31, 2021, https://www.merriam-webster.com/dictionary/subcutaneous.

[41] *Merriam-Webster.com Dictionary*, "sublingual," accessed August 17, 2021, https://www.merriam-webster.com/dictionary/sublingual.

[42] *Merriam-Webster.com Dictionary*, "traumatic brain injury," accessed august 30, 2022, https://www.merriam-webster.com/dictionary/traumatic%20brain%20injury.

[43] Gaynes, "Defining treatment-resistant depression," 134.

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U.S. House of Representatives: Stephanie Bice, Josh Brecheen, Tom Cole, Kevin Hern, Frank Lucas

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