DEPARTMENT OF VETERANS AFFAIRS

OFFICE OF INSPECTOR GENERAL

Office of Healthcare Inspections

VETERANS HEALTH ADMINISTRATION

Alleged Inadequate Mental Health Treatment at the Dayton VA Medical Center Ohio

HEALTHCARE INSPECTION | **REPORT #17-03382-294** | **SEPTEMBER 20, 2018**

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Executive Summary

The VA Office of Inspector General (OIG) conducted a healthcare inspection of the Mental Health Residential Rehabilitation Treatment Program (MH RRTP) at the Dayton VA Medical Center (Facility), Ohio, to assess allegations made regarding the care of a resident (Resident X) who died approximately 36 hours after admission to the MH RRTP.

The confidential complainant alleged that Facility staff failed to

- Treat Resident X for mental health and addiction problems, therefore Resident X "committed suicide," and
- Assign Resident X a counselor but instead "prescribed more pills."

Additionally, the OIG team reviewed Facility leaders' actions following Resident X's death.

The OIG did not substantiate that Facility staff failed to treat Resident X's MH and addiction problems. The OIG team concluded that Facility staff provided appropriate overall management from Resident X's initial treatment request through the MH RRTP admission. However, the OIG team did find that Facility staff failed to complete one Clinical Institute Narcotic Assessment score as ordered on the day of the resident's death that would have corresponded with administration of medication for opioid withdrawal symptoms. The absence of the Clinical Institute Narcotic Assessment score limited understanding of the severity of Resident X's clinical symptoms at the time of the medication administration. However, the OIG team was unable to determine if the presence of this score would have altered the course of events that day.

The OIG was unable to substantiate or not substantiate that Resident X died by a suicidal act. Resident X denied intent or a plan for suicide when a Facility provider assessed Resident X at a walk-in triage MH appointment. Resident X also denied suicidal thoughts during the Facility MH RRTP admissions screening and upon admission. Facility staff completed required suicide risk assessments and determined that Resident X was not at high-risk for suicide.[1, 2] Further, the Coroner ruled the death as accidental. Although the evidence indicates that it was unlikely Resident X died by a suicidal act, the OIG cannot definitively determine Resident X's intentions.

The OIG did not substantiate that Facility MH RRTP staff failed to assign a counselor to Resident X. On the day of admission, staff assigned an interdisciplinary team (that included

[1] The Assessment and Management of Risk for Suicide Working Group, *VA/DoD Clinical Practice Guideline for Assessment and Management of Patients at Risk for Suicide*, Version 1.0 - June 2014; VHA Directive 1101.05(2), *Emergency Medicine*, September 9, 2016, amended March 7, 2017.

[2] VHA Handbook 1162.02, *Mental Health Residential Rehabilitation Treatment Program (MH RRTP)*, December 22, 2010.

counseling staff) to Resident X. However, counseling staff did not meet with Resident X on the day of the admission, and Resident X was not provided with a therapeutic activity schedule to attend therapy groups over the weekend. The OIG substantiated that a Facility MH RRTP Physician Assistant prescribed medications for Resident X's opioid withdrawal management consistent with the history and physical assessment.

The OIG team determined that Facility leaders completed required administrative reviews following Resident X's death. Facility managers implemented new screening and admission processes, established a resident privilege levels program,[3] and initiated a plan to increase Medication Assisted Treatment accessibility. To enable a veteran's informed consent in the process of rehabilitation and recovery, VHA requires that staff provide veterans with information regarding expectations, rules, and limitations of the program prior to admission. However, the OIG team determined that MH RRTP staff did not provide information regarding the MH RRTP privileging levels program to veterans prior to admission. The OIG team also identified concerns about whether the privileging levels program was congruent with MH RRTP goals of rehabilitation and recovery.

The OIG made three recommendations related to MH RRTP nursing staff completing clinical scales to assess and quantify the severity of opioid use withdrawal symptoms; providing timely therapeutic activity schedules; and reviewing the residents' privileging levels program.

Comments

The Veterans Integrated Service Network and Facility Directors concurred with the recommendations and provided an acceptable action plan. (See Appendixes B–C, pages 28–31 for the comments.) The OIG will follow up on the planned actions until they are completed.

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[3] The Facility's MH RRTP Veteran Level Procedure Program Standard Operating Procedure identified Levels 1–3 that outlined decreasing restrictions as the level increased. The standard operating procedure described privileges residents gained by their number of days in the MH RRTP and rules adherence. Privileges included permission to leave the MH RRTP building, eligibility for passes and visitors, and cell phone use and possession.

Contents

Abbreviations

7N	7 North Clinic
CDC	Centers for Disease Control and Prevention
CINA	Clinical Institute Narcotics Assessment
EHR	electronic health record
ESP	Emergency Stabilization Program
H&P	history and physical examination
IDT	interdisciplinary team
IMF	illicitly manufactured fentanyl
MAT	Medication Assisted Treatment
MH	mental health
MH RRTP	Mental Health Residential Rehabilitation Treatment Program
OIG	Office of Inspector General
OTP	Opioid Treatment Program
PA	physician assistant
RCA	root cause analysis
SOP	standard operating procedure
SUD	substance use disorder
SW	social worker
TJC	The Joint Commission
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network

Introduction

Purpose

The VA Office of Inspector General (OIG) conducted a healthcare inspection of the Mental Health Residential Rehabilitation Treatment Program (MH RRTP) at the Dayton VA Medical Center (Facility) to assess allegations made regarding the mental health (MH) care of a resident (Resident X) who died approximately 36 hours after admission to the MH RRTP.

Background

The Facility, located in Montgomery County, Ohio, is part of VA's Veterans Integrated Service Network (VISN) 10. The Facility is a complexity level 1c hospital[4] that provides MH services as well as acute, primary, specialty, and long-term care. The Facility's community based outpatient clinics are located in Lima, Middletown, and Springfield, Ohio, and Richmond, Indiana. The Facility has sharing agreements with Wright-Patterson Air Force Base and 11 non-VA hospitals.

In fiscal year 2017, the Facility served more than 40,000 patients and operated 390 beds, which included 200 community living center, 91 inpatient, and 99 MH RRTP beds. The Facility's MH RRTP provides structured supportive care 24 hours per day, seven days per week for up to 99 residents.[5]

The Facility is affiliated with the Wright State University Boonshoft School of Medicine, the School of Professional Psychology, and nursing programs such as the Wright State University, University of Cincinnati, Miami University, and Kettering College of Medical Arts.

Domiciliary Care Program

Established in the 1860s to provide a home for disabled volunteer soldiers of the Civil War, the Domiciliary Care Program is the VA's oldest health care program. In recent years, the Domiciliary Care Program evolved into a clinical rehabilitation and treatment program for veterans with a variety of psychosocial and psychiatric care needs including homelessness, post-traumatic stress disorder, and substance use disorder (SUD). In 2005, the Veterans Health

[4] The VHA Facility Complexity Model categorizes medical facilities by complexity level based on patient population, clinical services offered, educational and research missions, and administrative complexity. Complexity Levels include 1a, 1b, 1c, 2, or 3. Level 1a facilities are considered to be the most administratively complex. Level 3 facilities are the least complex. VHA Office of Productivity, Efficiency and Staffing, http://opes.vssc.med.va.gov/FacilityComplexityLevels/Pages/default.aspx. (The website was accessed on March 26, 2018.)

[5] Residents are veterans who live in the MH RRTP and participate in rehabilitation and treatment services.

Administration (VHA) integrated the Domiciliary Care Program with the MH RRTP and mandated that Domiciliary RRTPs adhere to MH RRTP policies and guidelines.[6] MH RRTPs utilize professional and peer support to provide therapeutic treatment to residents who are capable of self-care and do not require a higher bedside level of care.[7] Per VHA, MH RRTP treatment is patient centered to meet the individual needs of each resident. Residents identify and address goals of rehabilitation, recovery, health maintenance, improved quality of life, and community integration. VHA also specifies guidelines and requirements for MH RRTP staff levels including "core staffing requirements."[8]

MH RRTP Admission Process

Initial Screening

For admission to the MH RRTP, a VHA or non-VA provider may refer the veteran or a veteran may self-refer.[9] Regardless of referral source, a Facility screening team must review the referral information prior to admission. For admission to an MH RRTP, a veteran must: not meet criteria for inpatient psychiatric or medical admission; not present as a significant risk of harm to self or others; be capable of self-preservation and basic self-care; and present with identified treatment and rehabilitation needs, which can be met by the program.[10]

VHA requires that a team of clinicians, including licensed MH providers, reviews the veteran's medical information and determines if the admission is appropriate and a "best" fit for the MH RRTP.[11] The team must provide the veteran with information regarding expectations, rules, and limitations of the program "…in advance of admission to enable the Veteran to make an informed decision and to begin the process of a rehabilitation and recovery."[12] A physician or other qualified health care provider must screen the veteran to identify ongoing psychiatric and medical treatment needs and to ensure the medical appropriateness of admission.[13]

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[6] VHA Handbook 1162.02, *Mental Health Residential Rehabilitation Treatment Program (MH RRTP)*, December 22, 2010. This handbook was scheduled for recertification on or before the last working day of December 2015 and has not yet been renewed.

[7] VHA Handbook 1162.02.

[8] VHA Handbook 1162.02.

[9] Facility MH RRTP Standard Operating Procedure (SOP), *Screening/Access/Admissions SOP*, March 12, 2015. This SOP was in effect during the time of OIG review; it was rescinded and replaced by MH RRTP SOP, *Screening/Access/Admissions SOP*, March 12, 2017.

[10] VHA Handbook 1162.02.

[11] The team is referred to as a "screening team." Similarly, Facility staff use the term "screening board;" VHA Handbook 1162.02.

[12] VHA Handbook 1162.02.

[13] VHA Handbook 1162.02.

VHA requires that facilities admit veterans "in the most expeditious manner possible," and prioritize the veterans by the order in which screened, absent other clinical considerations that would require expedited admission.[14] Once a veteran is approved for admission, the Admissions Coordinator provides the veteran a tentative admission date, dependent on bed availability. If a bed is not available, the veteran is placed on a wait list. The Facility MH RRTP Medical Director or Chief may approve expedited admission for situations such as homeless female veterans or a patient being released from an acute inpatient bed.[15] MH RRTP staff must offer outpatient treatment and contact the veteran weekly when a veteran is on an admission's waiting list more than two weeks.[16]

Admission Assessments

After admission, new residents and an interdisciplinary team (IDT) complete a comprehensive intake assessment, develop a treatment plan, and determine the length of stay.[17, 18] Per VHA, within seven days of a resident's admission, a medical provider must complete a history and physical examination (H&P), including a review of health history, psychiatric status and needs, and status of drug and/or alcohol abuse.[19] VHA also requires MH RRTP nursing staff to perform an assessment within 24 hours of admission, including vital functions, medication management assessment, and evaluation of high-risk behaviors and psychiatric/medical conditions.[20] The Facility MH RRTP Documentation standard operating procedures (SOP) requires a medical provider's completion of an H&P and a nurse's assessment within one business day of admission.[21]

Consistent with VHA requirements, Facility MH RRTP clinicians must complete a comprehensive biopsychosocial assessment including current emotional and behavioral functioning, health history, living situation, social and developmental history, military history and trauma screening, and financial and legal issues within "5 working days" of admission.[22, 23]

[14] VHA Handbook 1162.02.
[15] Facility MH RRTP SOP.
[16] Facility MH RRTP SOP, *Screening/Access/Admissions SOP*.
[17] The Facility refers to the IDT to as the Treatment Team.
[18] VHA Handbook 1162.02.
[19] VHA Handbook 1162.02.
[20] VHA Handbook 1162.02.
[21] Facility MH RRTP SOP, *MH RRTP Documentation SOP*, November 17, 2015.
[22] VHA Handbook 1162.02.
[23] Facility MH RRTP SOP.

Therapeutic Activities

VHA requires that MH RRTP treatment program activities are available for a minimum of four hours a day for seven days a week.[24] The Facility MH RRTP Admission Checklist specifies that a social worker (SW) provides new residents with their therapeutic activity schedules during the admissions process.

Opioid Overdose and Risk for Veterans

In October 2015, the Centers for Disease Control and Prevention (CDC) issued a Health Advisory[25] highlighting the increase of unintentional fentanyl related overdose fatalities. In a November 2016 report, the Drug Enforcement Administration[26] referred to prescription drugs, heroin, and fentanyl as the most significant drug-related threats to the nation. Veterans who receive VHA care, "have almost twice the risk for accidental overdose compared to the general… population."[27] Further, individuals in substance abuse treatment programs, residential programs, and correctional facilities are at high-risk for overdose.

The CDC reported that inadvertent fatal overdoses in Ohio increased 98 percent from 2010 to 2015. In Montgomery County, Ohio, unintentional overdose deaths increased 40 percent from 2015 to 2016, making the county "…one of the epicenters of the opioid epidemic in the state."[28]

Fentanyl

Fentanyl is a synthetic opioid pain medication that is more potent than morphine. Fentanyl is used in medical settings for anesthesia and is prescribed to treat patients with severe or chronic pain.[29] Illicitly manufactured fentanyl (IMF) delivers heroin-like effects, including reduced feelings of pain, increased euphoria, and relaxation. The drug is often mixed with heroin and/or

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[24] VHA Handbook 1162.02.

[25] "The Centers for Disease Control and Prevention collaborates to create the expertise, information, and tools that people and communities need to protect their health through health promotion, prevention of disease, injury and disability, and preparedness for new health threats." https://www.usa.gov/federal-agencies/centers-for-disease-control-and-prevention. (The website was accessed on March 2, 2018.)

[26] The Drug Enforcement Administration enforces the United States' controlled substances laws and regulations. https://www.dea.gov/about/mission.shtml. (The website was accessed on March 11, 2018.)

[27] Oliva, EM, Christopher, MLD, Wells, D, et al., Opioid overdose education and naloxone distribution: Development of the Veterans Health Administration's national program, March–April 2017, *Journal of the American Pharmacists Association*. 57:S168-S179.

[28] Daniulaityte R, Juhascik MP, Strayer KE, et al., Overdose Deaths Related to Fentanyl and Its Analogs – Ohio, January-February 2017, *Morbidity and Mortality Weekly Report*. 66:904-908, September 1, 2017.

[29] Fentanyl is a drug that when sold illegally is known by names that include China White, Apache, Tango and Cash, TNT, Jackpot, Murder 8, Goodfella, and Dance Fever. https://www.drugabuse.gov/nidamed-medical-health-professionals. (The website was accessed on March 2, 2018.)

cocaine to increase the potency, with and without the user's knowledge.[30] IMF comes as a powder, on blotter paper, or as tablets that mimic other less potent drugs and can be swallowed, inhaled, injected, or absorbed through mucous membranes. IMF's high potency and rapid onset are likely to increase the user's risk for addiction, withdrawal symptoms, and overdose; especially if the user is unaware that the substance consumed contained fentanyl. High dosages of fentanyl can also result in respiratory depression and death. (For additional information on the role of fentanyl in the opioid crisis, see Appendix A.)

VHA Treatment for Opioid Use Disorders

VHA facilities offer a continuum of care for opioid use disorder that includes standard outpatient services, intensive outpatient programs, opioid withdrawal management, opioid substitution therapies[31] (also known as opioid replacement therapies), MH RRTP, and acute hospital services.[32] Although not all VHA medical facilities directly provide the entire continuum of services to eligible veterans, all services must be accessible to veterans by referral to other VHA facilities, coordination with other VISNs, sharing agreements, contracts, or non-VA care.[33]

Facility Opioid Withdrawal Management

The Facility provides inpatient and outpatient opioid withdrawal management, also referred to as detoxification (or "detox").[34] Veterans who present with acute withdrawal symptoms may be admitted to the emergency department (ED) for observation, the locked psychiatry unit, or acute

[30] Heroin is an illegal, highly addictive drug processed from morphine. https://www.drugabuse.gov/publications/research-reports/heroin/what-heroin. (The website was accessed on March 2, 2018.)

[31] Opioid substitution therapies are drug therapies used to treat opioid dependence and include methadone, heroin, buprenorphine, and naltrexone. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4171401/. (The website was accessed on March 5, 2018.)

[32] VHA Handbook 1160.04, *VHA Programs for Veterans with Substance Use Disorders (SUD),* March 7, 2012. This handbook was scheduled for recertification on or before the last working day of March 2017 and has not yet been renewed.

[33] VHA Handbook 1160.01, *Uniform Mental Health Services in VA Medical Centers and Clinics*, September 11, 2008, amended November 16, 2015. This Handbook was scheduled for recertification on or before the last working day of September 2013. The amendment in 2015 did not reset the certification date; it has not yet been renewed.

[34] Substance Abuse Mental Health Services Administration, *Detoxification and Substance Abuse Treatment*, October 2015. https://store.samhsa.gov/shin/content//SMA15-4131/SMA15-4131.pdf. (The website was accessed on June 25, 2018.)

medicine. If a veteran is medically and psychiatrically stable, Facility staff may refer the veteran to outpatient treatment.[35]

The Facility offered medications for outpatient opioid withdrawal management in three different locations: outpatient SUD treatment clinic, 7 North Clinic (7N),[36] and the Opioid Treatment Program (OTP).[37] Providers may refer to the outpatient programs by submitting an electronic health record (EHR) consult request, requesting a clinic appointment, or instructing the veteran to present to the MH RRTP and SUD treatment walk-in clinics to be seen the same day. Additionally, the Facility utilizes the Veterans Choice Program for non-VA referrals to opioid withdrawal management.[38, 39]

MH RRTP Opioid Withdrawal Management

MH RRTP residents who are not at risk of withdrawal can also receive opioid withdrawal management.[40] MH RRTP admission may be appropriate for veterans who need outpatient detoxification, meet the criteria for MH RRTP including medical stability, and are able to participate in treatment activities.[41] However, MH RRTPs are not the appropriate level of care for veterans with moderate to severe withdrawal risk.[42]

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[35] VHA Handbook 1160.06, *Inpatient Medical Health Services*, September 16, 2013; VHA Directive 1036, *Standards for Observation in VA Medical Facilities*, February 6, 2014, amended August 25, 2017; VHA Handbook 1160.04.

[36] 7N is a clinic under the Facility's Mental Health Service that offers opioid withdrawal management.

[37] VHA Handbook 1160.04.

[38] Congress established Choice under the Veterans Access, Choice, and Accountability Act of 2014, which allowed eligible veterans to receive care from providers in their communities, rather than at a VHA facility. Veterans are eligible to receive care through Choice if; for example, they live more than 40 miles from a VHA facility or would wait greater than 30 days to receive services through VA. Veterans Access, Choice and Accountability Act of 2014, (Pub.L.113-146), Section 101(s) (1). https://www.gpo.gov/fdsys/pkg/PLAW-113publ146/pdf/PLAW-113publ146.pdf. (The website was accessed on March 7, 2018.)

[39] Department of Veterans Affairs, "Veterans Choice Programs." updated June 19, 2018. https://www.va.gov/COMMUNITYCARE/programs/veterans/VCP/index.asp. (The website was accessed on March 7, 2018.)

[40] The Management of Substance Use Disorders Work Group, *VA/DoD Clinical Practice Guideline for The Management of Substance Use Disorders*, Version 3.0 – December 2015; VHA Handbook 1162.02; VHA Handbook 1160.04.

[41] VHA Handbook 1162.02; VHA Handbook 1160.04.

[42] VHA Handbook 1162.02; VHA Handbook 1160.04.

Medication Assisted Treatment

The Substance Abuse and Mental Health Services Administration[43] describes Medication Assisted Treatment (MAT) as "…the use of FDA-approved medications, in combination with counseling and behavioral therapies, to provide a "whole-patient" approach to the treatment of substance use disorders."[44] Providers must apply for a waiver and have the ability to write for Schedule III, IV, and V[45] medications such as buprenorphine (Subutex®) and buprenorphine/naloxone (Suboxone®).[46] These medications assist with reducing opioid withdrawal symptoms, cravings, and risk of overdose. Additionally, the American Society of Addiction Medicine[47] established MAT guidelines.[48]

Opioid Withdrawal Scales

VA suggests that clinicians use validated clinical scales to assess and quantify the severity of withdrawal symptoms for patients with opioid use disorder. Commonly used scales include Clinical Institute Narcotics Assessment (CINA), Objective Opioid Withdrawal Scale, Subjective Opioid Withdrawal Scale, and Clinical Opioid Withdrawal Scale.[49, 50, 51] The Facility MH RRTP nursing staff utilized the CINA when ordered by a provider, a scale that measures signs and

[43] SAMHSA, part of the US Department of Health and Human Services, is a federal agency whose "mission is to reduce the impact of substance abuse and mental illness on America's communities." http://www.samhsa.gov/about-us. (The website was accessed on March 8, 2018.)

[44] Medication Assisted Treatment is the combination of medication and behavioral therapies to treat substance use disorders. https://www.samhsa.gov/medication-assisted-treatment. (The website was accessed on March 7, 2018.)

[45] The Drug Enforcement Administration categorizes substances into five categories based upon the Controlled Substances Act. https://www.dea.gov/druginfo/ds.shtml. (The website was accessed on March 11, 2018.)

[46] SAMHSA, *Legislation, Regulations, and Guidelines.* https://www.samhsa.gov/programs-campaigns/medication-assisted-treatment/legislation-regulations-guidelines. (The website was accessed on March 8, 2018.)

[47] ASAM is a professional medical society "dedicated to increasing access and improving the quality of addiction treatment." https://www.asam.org/about-us. (The website was accessed on March 9, 2018.)

[48] ASAM, *National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use*, https://www.asam.org/docs/default-source/practice-support/guidelines-and-consensus-docs/asam-national-practice-guideline-supplement.pdf?sfvrsn=24. (The website was accessed on March 9, 2018.)

[49] ASAM, *National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use*, https://www.asam.org/docs/default-source/practice-support/guidelines-and-consensus-docs/asam-national-practice-guideline-supplement.pdf?sfvrsn=24. (The website was accessed on March 9, 2018.)

[50] The Management of Substance Use Disorders Work Group, *VA/DoD Clinical Practice Guideline for The Management of Substance Use Disorders*, Version 3.0 – December 2015.

[51] SAMHSA, *Medications for Opioid Use Disorder for Healthcare and Addiction Professionals, Policymakers, Patients, and Families,* https://store.samhsa.gov/shin/content//SMA18-5063FULLDOC/SMA18-5063FULLDOC.pdf (The website was accessed on March 9, 2018.)

symptoms observed during withdrawal. The CINA is scored on a 0 to 31 scale with the higher the score, the more severe the withdrawal symptoms.[52]

Opioid Withdrawal Symptoms and Medications

Symptoms occur when opioid use is discontinued, particularly after extensive use. Symptoms appear within 12 hours of last use for short-acting opioids (such as heroin) and within 30 hours of use for long-acting opioids (such as methadone). Opioid withdrawal symptoms include muscle aches; tearing; runny nose; dilated pupils; goose bumps; agitation; anxiety; insomnia; sweating; yawning; abdominal cramping; vomiting; diarrhea; and nausea.[53, 54] To relieve opioid withdrawal symptoms, providers may prescribe clonidine[55] along with adjunctive medications such as ondansetron (Zofran®) for nausea, loperamide for diarrhea, and a nonsteroidal anti-inflammatory drug (such as ibuprofen) for pain.[56]

ED

VHA EDs provide resuscitative therapy and stabilization for acutely ill patients 24 hours a day, 7 days a week.[57] Once the patient is stabilized, ED providers are responsible for the patient's transition of care as part of the discharge process. ED providers are "…not to write any orders that extend control and responsibility for the patient beyond the treatment given in the ED…," such as initiation of MAT. However, ED providers are required to arrange a follow-up MH appointment prior to a patient's discharge (if applicable).[58]

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[52] SAMSHSA, *SAMHSA Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction*. https://www.ncbi.nlm.nih.gov/books/NBK64245/pdf/Bookshelf_NBK64245.pdf. (The website was accessed on May 16, 2018.)

[53] ASAM, *National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use*, https://www.asam.org/docs/default-source/practice-support/guidelines-and-consensus-docs/asam-national-practice-guideline-supplement.pdf?sfvrsn=24. (The website was accessed on March 9, 2018.)

[54] SAMHSA, *Medications for Opioid Use Disorder for Healthcare and Addiction Professionals, Policymakers, Patients, and Families,* https://store.samhsa.gov/shin/content//SMA18-5063FULLDOC/SMA18-5063FULLDOC.pdf. (The website was accessed on March 9, 2018.)

[55] VA/DoD Clinical Practice Guideline for the Management Of Substance Use Disorders, (2013), p. 61. Clonidine is a medication that may be considered "as a second line agent for symptom relief during inpatient medically supervised opioid withdrawal."

[56] SAMHSA, *Medications for Opioid Use Disorder for Healthcare and Addiction Professionals, Policymakers, Patients, and Families,* (The website was accessed on March 9, 2018.)

[57] VHA Directive 1101.05(2), *Emergency Medicine*, September 9, 2016, amended March 7, 2017.

[58] VHA Directive 1101.05(2).

Veteran Suicide Rates

A VA review of 55 million veteran records over the period of 1979–2014 concluded that the number of veteran deaths by suicide averaged 20 per day.[59] In 2014, the annual rate of suicide among U.S. civilian adults was 15.2 per 100,000, while the rate of suicide among veterans was 35.3 per 100,000.[60]

VHA Suicide Risk Assessment and Reporting

VHA Office of Patient Care Services, Mental Health Services developed a suicide risk assessment and suicide prevention program that includes standardized screening questions followed by in-depth evaluation with assessment of patients' suicide risk when screenings are positive.[61, 62] VHA established the High-Risk for Suicide Patient Record Flag to alert providers of patients at high-risk for suicide. Based on a patient's standardized risk assessment, a VHA provider determines the clinical indication for an EHR alert or flag.[63]

MH RRTP Suicide Assessment

VHA and Facility policies require that a provider completes suicide risk assessments prior to and at the time of a veteran's MH RRTP admission.[64]

Sentinel Events

The Joint Commission (TJC) defines a sentinel event as a patient safety event that "results in…death, permanent harm, [or] severe temporary harm and intervention required to sustain life."[65] VHA requires that sentinel events have an "…immediate investigation and response"

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[59] U.S. Department of Veterans Affairs Office of Suicide Prevention, *Suicide Among Veterans and Other Americans, 2001-2014,* August 3, 2016 (updated August 2017).

[60] Facts about Veteran Suicide, July 2016, VA Suicide Prevention Program, http://www.va.gov/opa/publications/factsheets/Suicide_Prevention_FactSheet_New_VA_Stats_070616_1400.pdf. (The website was accessed on March 10, 2018.)

[61] The Assessment and Management of Risk for Suicide Working Group, VA/DoD Clinical Practice Guideline for Assessment and Management of Patients at Risk for Suicide, Version 1.0 - June 2013.

[62] VHA Directive 1071, Mandatory Suicide Risk and Intervention Training for VHA Health Care Providers, June 27, 2014, rescinded and replaced by VHA Directive 1071, Mandatory Suicide Risk and Intervention Training for VHA Employees on December 22, 2017.

[63] VHA Directive 2008-036, *Use of Patient Record Flags to Identify Patients at High Risk for Suicide*, July 18, 2008. This directive expired July 31, 2013 and has not yet been renewed.

[64] The Assessment and Management of Risk for Suicide Working Group, *VA/DoD Clinical Practice Guideline for Assessment and Management of Patients at Risk for Suicide*, Version 1.0 – June 2013; VHA Handbook 1162.02; Facility MH RRTP SOP.

[65] The Joint Commission, Sentinel Event Policy and Procedures. https://www.jointcommission.org/sentinel_event_policy_and_procedures/. (The website was accessed on March 30, 2018.)

through a root cause analysis (RCA) process and/or other administrative actions designed to review the events and contributing factors such as an administrative investigation board.[66, 67] VHA does not require reporting sentinel events to TJC; VISN and facility policy govern the decision to report.[68] VISN 10 and the Facility do not require reporting to TJC.

Allegations

On April 11, 2017, the OIG Hotline Division received a telephone complaint. The complainant alleged that the Facility failed to treat Resident X's MH and addiction problems, and therefore Resident X committed suicide at the Facility in early 2017. VA Police notified the OIG Office of Investigations of Resident X's death. On May 4, 2017, the OIG Hotline Working Group requested that Facility leaders

1. Provide a review of the event and the care of Resident X from admission until the time of death, and.
2. Address if the Facility complied with its RRTP policies. If not, explain why not and corrective action taken or being taken.

On June 27, 2017, the OIG received the Facility Director's response and followed up with additional questions and requested the RCA report related to Resident X's death. As the OIG had additional questions after the extended time it took to receive the completed RCA, the OIG opened an inspection. The inspection focused on the allegations by the confidential complainant that Facility staff failed to

- Treat Resident X for MH and addiction problems, therefore Resident X "committed suicide," and
- Assign Resident X a counselor but instead "prescribed more pills."

Additionally, the OIG team reviewed Facility leaders' actions following Resident X's death.

[66] VHA defines the RCA process as "a process for identifying the basic or contributing causal factors that underlie variations in performance associated with adverse events…" VHA Handbook 1050.01, *VHA National Patient Safety Improvement Handbook*, March 4, 2011. This handbook was scheduled for recertification on or before the last working day of March 2016 and has not yet been renewed.

[67] VHA Handbook 1050.01.

[68] VHA Handbook 1050.01.

Scope and Methodology

The OIG team initiated the healthcare inspection on November 6, 2017, and conducted a site visit February 5–8, 2018.

For the time period July 2016 through April 2018, the OIG inspection team reviewed relevant VHA and Facility policies and procedures related to outpatient substance use treatment, MH RRTP substance abuse treatment, MH RRTP admissions, and non-VA drug treatment resources. The OIG team also reviewed medical literature including guidelines and recommendations from the CDC, National Institutes of Health, National Institute on Drug Abuse, the Substance Abuse and Mental Health Services Administration, and the American Society of Addiction Medicine.

The OIG team reviewed relevant issue briefs, meeting minutes, police report, email communications, and staff training records. The OIG team reviewed Resident X's healthcare assessment and treatment history for the seven months prior to Resident X's death. The OIG team reviewed Resident X's EHR, relevant closed-circuit television video recordings, and the Post-Mortem Examination report.

The OIG team interviewed Facility leaders, managers, and staff in MH, MH RRTP, OTP, ED, and the Quality Management Service who were knowledgeable about the issues under review. The OIG inspection team also interviewed the Deputy Coroner at the Montgomery County Coroner's Office.[69]

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 substantiate or not substantiate an allegation when the available evidence is insufficient to determine whether or not an alleged event or action took place.

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.

[69] The Montgomery County Coroner's Office reviewed Resident X's death.

Case Summary

Resident X was a veteran who had a history of opioid use disorder. In early 2017, Resident X died of a fentanyl overdose while admitted to the Facility's MH RRTP. (See Figure 1 for a timeline of events as described below.)

In winter 2016, Resident X presented to Facility MH triage without a scheduled appointment (Day 1) and requested substance use treatment. A psychologist evaluated Resident X that day.[70] Resident X told the psychologist of nearly daily heroin use over the previous five years with occasional two-week gaps. Resident X's last use of heroin, "or might have been fentanyl," was two weeks prior. Resident X was managing withdrawal symptoms by taking Subutex® (buprenorphine) obtained from a friend. Resident X admitted to thoughts of being a burden to everyone and that they would be better off without Resident X but denied suicidal intention or a plan of self-harm. Resident X mentioned prior treatment with prescription medication for depression and stated, "I refuse them. Too many side effect[s]." The psychologist recommended ED treatment for withdrawal symptoms and a referral to MH RRTP for an admission evaluation. Resident X did not think the symptoms warranted an ED visit and declined the MH RRTP referral. The psychologist advised Resident X of the MH RRTP evaluation walk-in option. Resident X agreed to go to the MH RRTP program "to see the place" and to confirm to come as a walk-in the next morning. Resident X was also offered outpatient treatment.

Resident X presented to the MH RRTP walk-in clinic on Day 29. An SW evaluated Resident X for an MH RRTP admission screening. Resident X denied thoughts of self-harm or past suicide attempts, and the SW's assessment was low-risk. Although accepted to the MH RRTP, Resident X was considering non-VA treatment. On Day 35, the SW documented in an EHR addendum note that Resident X decided to accept treatment at the Facility MH RRTP.

Seven days after accepting MH RRTP admission (Day 42), Resident X presented to the Facility ED requesting outpatient detoxification from opioids. An ED provider documented that Resident X was not withdrawing from opioids at that time and was discharged with no medications. The ED provider submitted a referral for Resident X to the substance use disorder outpatient drop in clinic. Resident X was advised to return to the ED for worsening or changing symptoms. The MH RRTP SW documented that Resident X presented that day as recommended by the ED provider; but, then declined to wait to be seen. Later that day, the SW spoke with Resident X by telephone and said Resident X would be called when an MH RRTP bed was available. On Day 44, MH RRTP staff called Resident X and offered an admission date for two days later (Day 46).

[70] Prior to this appointment, Resident X had a brief 2015 outpatient substance use treatment episode that ended after several missed appointments.

Resident X was admitted to the Facility MH RRTP on Day 46, which was a Friday, 11 days after agreeing to MH RRTP treatment. A physician assistant (PA) performed an H&P on Day 46 and noted that Resident X was pleasant and cooperative. Resident X reported insomnia and "pretty good" mood. Resident X denied thoughts of self-harm, past suicide attempts, or family history of suicide. The depression screen was negative. Resident X reported feeling optimistic about treatment and wanted to stop using heroin "to get clean so I can be a better person..." The PA documented that Resident X's last use of opioids was the day prior to admission. Resident X denied symptoms of withdrawal and admitted to a past heroin/fentanyl overdose the year prior at Resident X's father's home. Resident X also reported cocaine and cannabis use prior to admission, and a urine toxicology screen was positive for cannabis. Resident X reported a pending court date for possession of needles, an arrest that occurred after the MH RRTP admission screening.

The PA documented diagnoses of opioid use disorder, severe, with substance induced mood disorder; cocaine use disorder, severe; cannabis use disorder; and tobacco use disorder. Resident X declined to initiate MAT. The PA prescribed symptomatic opioid withdrawal medications including scheduled clonidine and as needed medications to treat stomach cramping, diarrhea, poor sleep, muscle spasms, anxiety, and nausea. The PA documented a plan for nursing staff to conduct CINA evaluations every four hours for 72 hours while Resident X was awake. The PA ordered the MH RRTP staff to refer Resident X to the ED if a CINA score was above 15. The PA also noted that a Naltrexone prescription would be considered after review of Resident X's liver and drug laboratory panel results and after Resident X was opioid free for seven days. An intranasal Narcan®[71] rescue kit was ordered, which Resident X reportedly picked up at the outpatient pharmacy.[72] An initial appointment with an MH RRTP psychiatrist was scheduled for the following Monday, the fourth day of the admission.

On Day 46, Resident X's first day of admission, a nurse documented that Resident X reported thoughts that if gone, the family would be better off and that Resident X denied suicide intention. Resident X denied ever formulating a suicide plan. Later that day, a nurse documented a CINA score of 5 with symptoms of a runny nose, sweating, and a tremor. Resident X received medications for anxiety, discomfort, muscle spasm, and poor sleep.

[71] Narcan is a medication used to emergently treat a known or suspected overdose with an opioid. https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/208411lbl.pdf (The website was accessed on April 19, 2018.)

[72] Oliva E, Christopher M, Wells D, Bounthavong M, Harvey M, Himstreet J, Emmendorfer T, Valentino M, Franchi M, Goodman F, Trafton J, Opioid Overdose Education and Naloxone Distribution: Development of the Veterans Health Administration's National Program. *Journal of the American Pharmacists Association,* Volume 57, Issue 2, Supplement, March–April 2017, Pages S168-S179.e4. http://dx.doi.org/10.1016/j.japh.2017.01.022. (The website was accessed on December 4, 2017.)

On Day 47, a nurse documented a CINA score of 1 in the morning, positive for restlessness. The nurse also noted that Resident X had elevated blood pressure and complaints of anxiety rated as "6 to 7" out of 10. At 9:45 a.m., anxiety medication was provided to Resident X. Between 1 p.m. and 2 p.m., Resident X received medications for muscle spasm, pain, and nausea. There was no CINA score documented that coincided with this medication administration. At 4:33 p.m., a nurse documented the next and final CINA score of 2, positive for tremor and nasal congestion. Soon after, staff documented that Resident X was feeling better and signed out for a walk to "clear [his/her] head."

While Resident X was out, Resident X's father came to the MH RRTP to bring blankets. A nurse documented efforts to locate Resident X, which included a search of the building, a call to VA police describing Resident X, and a call to Resident X's phone (with no answer). Closed circuit television video showed Resident X walking into the ED entrance at 5:07 p.m.

At approximately 8:00 p.m., a visitor found Resident X in a locked stall in a restroom outside of the ED. The police report and EHR documentation indicated that there was blood and vomit in Resident X's mouth, nose, and on the clothes, and there was a plastic bag with capsules in a pocket in addition to capsules scattered in the toilet bowl. Facility staff initiated cardiopulmonary resuscitation[73] and continued resuscitation efforts during Resident X's transport to the ED. ED staff discontinued resuscitation efforts at 8:28 p.m. and pronounced Resident X dead. The Coroner's autopsy report listed cause of death as acrylfentanyl[74] intoxication and the manner of death as accidental.

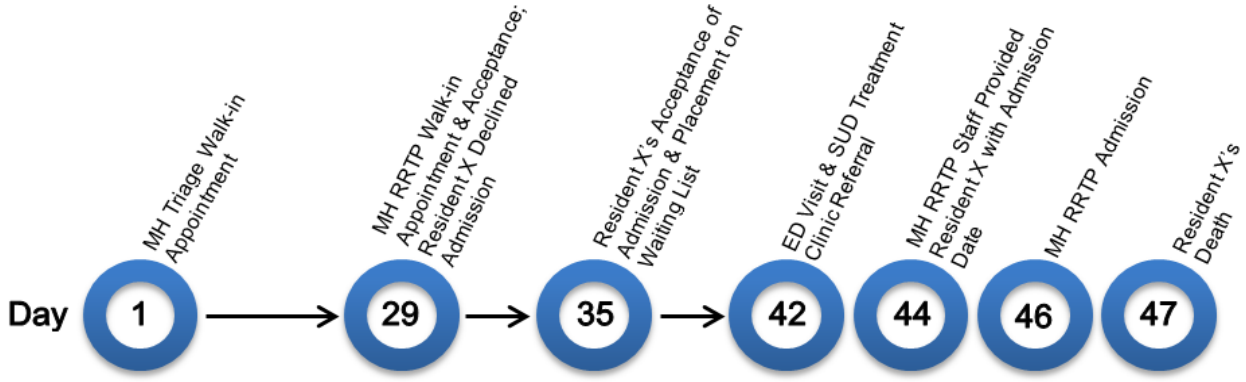

Figure 1. Timeline of Events.
(Source: VA OIG EHR analysis)

[73] Cardiopulmonary resuscitation (CPR) is a procedure "designed to restore normal breathing after cardiac arrest that includes the clearance of air passages to the lungs, mouth-to-mouth method of artificial respiration, and heart massage by the exertion of the pressure on the chest." Merriam-Webster, https://www.merriam-webster.com/dictionary/cardiopulmonary%20resuscitation. (The website was accessed on June 27, 2018.)

[74] Acrylfentanyl is a synthetic opioid. It is an analog of the prescription synthetic opioid Fentanyl. Acrylfentanyl: Another new psychoactive drug with fatal consequences. Guerrieri D, Rapp E, Roman M, Thelander G, Kronstrand R. Forensic Sci Int. August 2017; 277:e21-e29. doi: 10.1016/j.forsciint.2017.05.010. Epub May 22, 2017.

Inspection Results

Issue 1: Facility Staff Allegedly Failed to Treat Resident X for MH and Addiction Problems, Therefore Resident X "Committed Suicide"

The OIG did not substantiate that Facility staff failed to treat Resident X's MH and addiction problems. The OIG team concluded that Facility staff provided appropriate overall management from Resident X's initial treatment request through the MH RRTP admission. However, the OIG team did find that Facility staff failed to complete one CINA score on the day of the resident's death that would have corresponded with administration of medication for opioid withdrawal symptoms. The absence of the CINA score limited understanding of the severity of Resident X's clinical symptoms at the time of the medication administration. However, the OIG team was unable to determine if the presence of this score would have altered the course of events that day. A subsequent CINA score was low, and staff documented that Resident X reported feeling better prior to leaving the MH RRTP.

The OIG team was unable to substantiate or not substantiate that Resident X died by suicidal act. Resident X denied intent or a plan for suicide when a Facility provider assessed Resident X at a walk-in triage MH appointment. Resident X also denied suicidal thoughts during the Facility MH RRTP admissions screening and upon admission. Facility staff completed required suicide risk assessments and determined that Resident X was not at high-risk for suicide.[75, 76] Further, the Coroner ruled the death as accidental. Although the evidence indicates that it was unlikely Resident X died by a suicidal act, the OIG cannot definitively determine Resident X's intentions.

Resident X's MH Treatment

Resident X presented for a walk-in MH triage appointment on Day 1, reported near daily drug use, and requested substance abuse treatment. The MH provider offered SUD outpatient treatment and an MH RRTP referral, as well as an offer to have Resident X present as a walk-in to the ED for withdrawal treatment. Resident X declined all treatment options offered by the MH provider, choosing to self-refer at a future time for admission to the MH RRTP.

Between Day 1 and Day 29, Resident X did not have documented contact with the Facility. On Day 29, Resident X presented for a walk-in appointment at the MH RRTP. MH RRTP staff completed eligibility and admissions screening, and the screening team accepted Resident X for admission. Resident X was informed of admission; however, Resident X was still considering

[75] The Assessment and Management of Risk for Suicide Working Group, *VA/DoD Clinical Practice Guideline for Assessment and Management of Patients at Risk for Suicide*, Version 1.0 - June 2014; VHA Directive 1101.05(2).
[76] VHA Handbook 1162.02.

non-VA treatment. Six days later (Day 35), Resident X accepted an MH RRTP admission, but due to lack of bed availability, MH RRTP staff placed Resident X on a waiting list for admission. On the morning of Day 42, Resident X arrived at the Facility's ED requesting outpatient opioid detoxification and treatment. The ED provider determined opioid withdrawal symptoms were not present, entered an outpatient SUD treatment clinic referral, and discharged Resident X from the ED. Outpatient SUD treatment clinic staff unsuccessfully telephoned Resident X on Day 42 and Day 43, and staff mailed a letter to Resident X on Day 43.

On the afternoon of Day 42, Resident X appeared in the MH RRTP as a walk-in but declined to wait.[77] MH RRTP staff called Resident X later that day and stated that a bed was not yet available. On Day 44, MH RRTP staff informed Resident X of an admission date. MH RRTP staff admitted Resident X on Day 46.

MH RRTP Admission

On Day 46, the first day of MH RRTP admission, a nurse completed the admission assessment consistent with VHA and Facility policy.[78] An MH RRTP PA completed the H&P and assessed Resident X's recent use of opioids and previous overdose.[79] The PA ordered that nursing staff complete CINA evaluations every four hours during Resident X's waking time for the first 72 hours of admission. The PA directed nursing staff to refer Resident X to the ED if a CINA score was above 15.

On Day 47, nursing staff documented Resident X's morning CINA (score of 1), positive for restlessness. At that time, Resident X also presented with elevated anxiety and increased blood pressure and pulse. At 1:00 p.m., Resident X received as needed medication for opioid withdrawal; however, nursing staff failed to complete the required afternoon CINA.[80] Without the afternoon CINA, the severity of Resident X's symptoms at the time of medication administration was unknown. A nurse completed the evening CINA (score of 2) prior to Resident X signing out to go for a walk at 4:35 p.m.

After Resident X signed out, Resident X's father arrived at the MH RRTP. Resident X had not signed back in to the MH RRTP and could not be located. MH RRTP nursing staff alerted Facility police and initiated a search for Resident X. Nursing staff's attempt to call Resident X's cell phone at approximately 8:00 p.m. was unsuccessful. At 8:05 p.m., a visitor found Resident X unresponsive in a bathroom located near the ED. The visitor notified medical personnel, and ED

[77] A Facility staff member informed the OIG team that appointment logs/sign-in sheets were not retained, and therefore the OIG team was unable to determine how long Resident X waited.

[78] VHA Handbook 1162.02.

[79] VHA Handbook 1160.04.

[80] At the time of Resident X's admission, Facility MH RRTP nurse staffing levels met VHA requirements.

staff initiated lifesaving resuscitation measures; however, they were unsuccessful. The ED provider pronounced Resident X deceased at 8:28 p.m. At approximately 10:20 p.m., nursing staff documented their earlier efforts to search for Resident X after the father's arrival, notification that Resident X was in the ED, and that Resident X reported feeling better prior to leaving the MH RRTP earlier in the day. Nursing staff told the OIG team that Resident X did not exhibit indications of distress or illness prior to leaving the building.

Suicide

The OIG team found that MH RRTP staff completed suicide risk assessments of Resident X consistent with VHA guidelines and policies.[81] In outpatient MH, Resident X denied any suicidal ideation, intention, or plan of self-harm, and did not report any depressive symptoms or increased anxiety. As such, throughout the care at the Facility, Resident X did not meet the requirements for a High-Risk for Suicide Patient Record Flag.[82]

A suicide risk assessment is required prior to and upon MH RRTP admission.[83] MH RRTP staff identified Resident X as having low-risk in the admission screening. The admitting provider's assessment documented that Resident X denied suicide intention or plans of self-harm. The OIG team found that Resident X received both requisite suicide risk assessments, and MH RRTP staff deemed Resident X as low-risk for suicide.

Coroner's Report

The Coroner told the OIG team that cause of death is identified through physical autopsy findings and medical history. To determine the manner of death, such as accident or suicide, the Coroner considers the autopsy findings and the circumstances leading up to the death.[84] The Coroner's report identified Resident X's cause of death as acrylfentanyl intoxication and the manner of the death as accidental.

[81] The Assessment and Management of Risk for Suicide Working Group, *VA/DoD Clinical Practice Guideline for Assessment and Management of Patients at Risk for Suicide*, Version 1.0 - June 2014; VHA Directive 1101.05(2).

[82] VHA Directive 2008-036.

[83] VHA Handbook 1162.02.

[84] Per the Montgomery County Coroner's office, "An autopsy is a systematic examination by a qualified physician of the body of a deceased person for the purpose of determining the cause of death and recovering, from the body, evidence of the cause of death. A record is made of the findings of the autopsy including microscopic and toxicologic laboratory tests." http://www.mcohio.org/government/elected_officials/coroner/faq_s.php. (The website was accessed on April 18, 2018.)

Issue 2: Facility Staff Allegedly Did Not Assign Resident X a Counselor but Instead "Prescribed More Pills"

The OIG team did not substantiate that the Facility MH RRTP staff failed to assign a counselor to Resident X. On the day of admission, staff assigned an IDT (that included counseling staff) to Resident X. However, counseling staff did not meet with Resident X on the day of the admission, and Resident X was not provided with a therapeutic activity schedule to attend groups over the weekend. The OIG team substantiated that the MH RRTP PA prescribed medications for Resident X's opioid withdrawal management consistent with the H&P assessment.

Therapeutic Activities

VHA policy requires that MH RRTPs provide therapeutic activities for residents.[85] MH RRTP managers told the OIG team that residents did not attend therapeutic activities on admission day because they must attend orientation sessions and medical assessments. Although the Facility MH RRTP offered therapeutic activities daily, staff did not provide Resident X with a schedule upon admission. According to the Facility MH RRTP SOP, an SW was required to meet with Resident X and provide a therapeutic activity schedule.[86] An SW did not meet with Resident X to provide a schedule. A Facility manager told the OIG team that, since January 2018, an SW provides therapeutic activity schedules to residents on the day of admission.

VHA requires that MH RRTP staff provide residents with a minimum of four hours per day of treatment or therapeutic activities, seven days per week. Further, VHA requires "Evening and weekend activities must have a direct relationship to assisting the Veterans in meeting treatment and rehabilitation goals."[87] However, the OIG team was unable to conclude that, if given the therapeutic activity schedule, Resident X would have presented to groups or that participation in groups on the second day of admission would have altered Resident X's outcome and prevented the death.

Prescribed Medications

The admitting provider ordered clonidine for opioid withdrawal management and additional medications that nursing staff could administer as requested by Resident X to address opioid withdrawal symptoms. Specifically, the admitting provider ordered the following medications as needed to address Resident X's symptoms: hydroxyzine pamoate (anxiety), dicyclomine (stomach cramping), loperamide (diarrhea), trazadone (sleep), methocarbamol (muscle spasms), ibuprofen and acetaminophen (pain), and ondansetron (nausea).

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[85] VHA Handbook 1162.02.

[86] Facility MH RRTP SOP; *Screening/Access/Admissions SOP*.

[87] VHA Handbook 1162.02.

On the second day of admission, Resident X received hydroxyzine pamoate (anxiety) in the morning with a respective CINA score of 1. Around 1:00 p.m., a nurse provided Resident X with a scheduled dose of clonidine (opioid withdrawal) and as needed medications, ibuprofen (pain relief), methocarbamol (muscle spasms), and ondansetron (nausea). Due to staff's failure to obtain a CINA score at the 1:00 p.m. administration of medications, there was no documented assessment of Resident X's withdrawal symptoms or symptom severity at that time.

Issue 3: Facility Actions Following Resident X's Death

The OIG team determined that Facility leaders completed required administrative reviews following Resident X's death. Facility managers implemented new screening and admission processes, established a resident privilege levels program, and initiated a plan to increase MAT accessibility.

Facility Actions

Following Resident X's death, Facility leaders initiated administrative actions consistent with VHA and Facility policies. The OIG team learned that in May 2017, Congressman Michael Turner submitted an inquiry to the Facility on behalf of Resident X's family. In June 2017, the Facility Director responded to Congressman Turner. The OIG team reviewed the Facility's response and found it to be accurate and thorough.

External Consultations

In January 2017, the MH Chief requested that consultants from Case Western Reserve University conduct a fidelity review[88] to examine the Facility MH RRTP dual diagnosis[89] treatment." The Case Western Reserve University consultants issued an August 2017 report that provided recommendations on ways to enhance the MH RRTP through structure, milieu, clinical processes, continuity of care, staffing, and training.

Further, at the request of Facility leaders, the VHA National MH Program Director, Substance Use Disorders reviewed the MAT program and identified opportunities for improvement in August 2017. These opportunities included changing programming, expediting induction of MAT, developing a detoxification clinic, and increasing Facility integration within the community.

[88] A fidelity review by the Center for Evidence-Based Practices at Case Western Reserve University "…provides a formal mechanism for external evaluation of service implementation. A fidelity review is not an audit or accreditation process. It is a quality-improvement process." https://www.centerforebp.case.edu/services/evaluationandresearch. (The website was accessed on March 29, 2018.)

[89] Dual diagnosis is a term describing a co-occurring substance use disorder and MH diagnosis. https://www.nami.org/Learn-More/Mental-Health-Conditions/related-conditions/dual-diagnosis. (The website was accessed on April 18, 2018.)

Facility's Screening and Admission Process Changes

Prior to March 2017, the MH RRTP staff screened veterans for admission on Tuesdays and Thursdays and then admitted residents Monday–Friday. In March 2017, MH RRTP managers increased screening days to Monday–Friday and then in June 2017, they discontinued Friday admissions. The MH Chief stated that this decision was made in response to the reduced weekend staffing resources. An MH RRTP staff member also told the OIG team that they do consider a Friday admission in special circumstances, such as a veteran's discharge from an acute inpatient bed. No significant changes were made in the Facility's updated MH RRTP Master Handbook and the recertified MH RRTP assessment and screening policy, which were both in effect in early 2017.[90]

Residents' Privilege Levels

MH RRTP managers implemented a privilege level system following Resident X's death. Facility and VISN managers told the OIG team that a residents' privilege system had been in effect historically and that for several years they had considered reestablishing a similar program. The managers acknowledged that Resident X's death led to implementation of this program in an effort to enhance resident safety.

Beginning October 2017, Facility MH RRTP staff assigned residents a privilege level and a corresponding color-coded lanyard at admission. The Facility's MH RRTP Veteran Level Procedure Program SOP identified Levels 1–3 that outlined decreasing restrictions as the level increased. The SOP described privileges residents gained by their number of days in the MH RRTP and rules adherence.[91] Privileges included permission to leave the MH RRTP building, eligibility for passes and visitors, and cell phone use and possession.[92] The IDT responds to a resident's violation(s). Contingent upon the violation, a resident receives a verbal warning for a first violation; a level reduction and a behavioral contract/homework assignment for a second violation; and determination of discharge from the MH RRTP for a third violation.[93]

According to the SOP, the level system is "…an incentive for Veterans in following guidelines of behavior." The SOP also states, "The Level System supports our commitment to provide a safe environment for recovery by providing consistent expectations for observable behaviors

[90] Facility MH RRTP SOP, *Screening/Access/Admissions* SOP.

[91] Facility MH RRTP SOP 116.02-02, *MH RRTP Veteran Level Procedure Program (SOP),* October 18, 2017. Upon admission, all residents are Level 1 (most restrictions and yellow lanyard) for 10 to 15 days. Residents graduate to Level 2 (green lanyard) for 15–60 days, and after 60 days move into Level 3 (least restrictions and green lanyard with special identification).

[92] Facility MH RRTP SOP 116.02-02.

[93] Facility MH RRTP SOP 116.02-02.

across the MH RRTP."[94] The MH Chief discussed with the VISN MH Lead the implementation of the SOP to balance resident safety needs with treatment needs. Facility staff told the OIG team that the MH Chief reviewed and approved the use of the SOP.

In advance of admission, the MH RRTP staff provided veterans with a Master Handbook that included program expectations, rules, and limitations. Additionally, MH RRTP staff provided a Rules, Regulations, and Informed Consent document that veterans sign at admission to reflect informed consent and agreement to adhere to the program rules. The OIG team found that information regarding the privileging levels program was not included in these documents, as required by VHA.[95] The OIG team also identified concerns about whether the privileging levels program was congruent with MH RRTP policy and goals that include individualized treatment planning and instilling personal responsibility to achieve optimal levels of independence upon discharge.[96]

Residents' Increased Access to MAT

Prior to early 2017, the Facility offered MAT through the outpatient SUD treatment clinic, 7N, and the OTP. However, a Facility provider told the OIG team that patients' access, especially for Suboxone®, was limited because of the limited availability of authorized prescribers.[97] Additionally, 7N provided care for a maximum of 30 patients. After early 2017, the Facility implemented initiatives to increase timely MAT access for residents.

Prior to early 2017, MH RRTP medical providers offered MAT to residents as part of the admission H&P. A Facility staff member told the OIG team that the next month, a Facility OTP prescriber, with authority to prescribe Suboxone®, began to provide care for MH RRTP residents, as requested by MH RRTP providers. An MH RRTP psychiatrist told the OIG team that by summer 2017, two MH RRTP psychiatrists received authority to prescribe Suboxone®. For fiscal year 2018, the MH Chief offered psychiatrists pay incentives to pursue Suboxone® prescription authority.

In February 2018, the Facility opened an Emergency Stabilization Program (ESP) to provide expedited access to Suboxone® MAT.[98] The MH RRTP Chief told the OIG team that the ESP

[94] Facility MH RRTP SOP 116.02-02.

[95] VHA Handbook 1162.02

[96] VHA Handbook 1162.02

[97] A prescriber is a medical professional who is licensed to write an order for medication. https://dictionary.cambridge.org/us/dictionary/english/prescriber. (The website was accessed on April 20, 2018.)

[98] Facility SOP, *Dayton VA Medication Assisted Therapy Walk-In Clinic Policy*, not dated; Facility SOP, *Substance Use Disorder Treatment Program, Substance Use Disorder (SUD) Treatment Program Suboxone®/ Buprenorphine Treatment*, January 1, 2018.

would also offer MAT to veterans prior to MH RRTP admission, as clinically indicated.[99] As of April 2018, MH RRTP staff referred three veterans to ESP prior to MH RRTP admission. Additionally, in September 2016, phase one of construction began on a building to house 7N, OTP, outpatient SUD treatment clinic, and ESP. The MH Chief informed the OIG team that the building is scheduled for completion in fiscal year 2019.

Facility ED

A Facility ED staff member told the OIG team that MH coverage was available at all times, which was consistent with VHA guidelines.[100] The Facility MH Consultation and Liaison team evaluates ED patients requesting MH treatment. This service operates Monday–Friday, 8:00 a.m.–12:00 a.m. After 12:00 a.m. and on weekends, there is an on-call psychiatrist available.

As of February 2018, the Facility hired four PAs who were co-located in the ED and scheduled for weekdays from 7:00 a.m. to 5:00 a.m. with 24-hour coverage on weekends. In April 2018, two PAs had completed training and were prescribing Suboxone®, and the other two PAs completed training with anticipated prescription certification obtained within three months.

Non-VA Collaboration

The MH Chief described ongoing collaboration between the Facility and the Greater Dayton Area Hospital Association[101] to establish a crisis center that includes a 16-bed opioid detoxification unit. This non-VA resource would provide expedited MAT access to veterans with an anticipated opening in 2019. As an example of additional non-VA collaboration, a Facility MH RRTP manager also reported quarterly participation on the board of the Alcohol, Drug Addiction and MH Services of Montgomery County.[102]

Facility Staff Training

Following Resident X's death, Facility managers enhanced the nurses' new employee orientation to include training on identification of opioid withdrawal including the use of CINA. Additionally, a MAT prescriber provided a presentation to the SW Department and reportedly

[99] Facility SOP, *MAT SOP*, not dated.

[100] VHA Handbook 1160.01; VHA Directive 1101.05(2).

[101] The Greater Dayton Area Hospital Association provides resources to 29 hospitals/health care facilities in the greater Dayton area, with a focus on quality health care. http://gdaha.org/about/. (The website was accessed on April 18, 2018.)

[102] The Alcohol, Drug Addiction and MH Services of Montgomery County "has the legal responsibility and authority for the provision of mental health and addiction treatment services and contracts with provider agencies to deliver services that assist consumers and clients." http://www.mcadamhs.org/about_us/index.php. (The website was accessed on April 18, 2018.)

included MAT information in other presentations to Facility staff. In November 2017, 20 MH RRTP staff received MAT training as part of a day-long staff meeting.

Conclusion

The OIG did not substantiate that Facility staff failed to treat Resident X's MH and addiction problems. The OIG team concluded that Facility staff provided appropriate overall management from Resident X's initial treatment request through the MH RRTP admission. However, the OIG team did find that Facility staff failed to complete one CINA score as ordered on the day of the resident's death that would have corresponded with administration of medication for opioid withdrawal symptoms. The absence of the CINA score limited understanding of the severity of Resident X's clinical symptoms at the time of the medication administration. However, the OIG team was unable to determine if the presence of this score would have altered the course of events that day. The OIG was unable to substantiate or not substantiate that Resident X died by suicidal act. Resident X denied intent or a plan for suicide when a Facility provider performed an assessment at a walk-in triage MH appointment. Resident X also denied suicidal thoughts during the Facility MH RRTP admissions screening and upon admission. Facility staff completed required suicide risk assessments and determined that Resident X was not at high-risk for suicide.[103, 104] Further, the Coroner ruled the death as accidental. Although the evidence indicates that it was unlikely Resident X died by a suicidal act, the OIG cannot definitively determine Resident X's intentions.

The OIG did not substantiate that Facility MH RRTP staff failed to assign a counselor to Resident X. On the day of the admission, staff assigned an IDT (that included counseling staff) to Resident X. However, counseling staff did not meet with Resident X on the day of the admission, and Resident X was not provided with a therapeutic activity schedule to attend groups over the weekend.

The OIG team substantiated that a Facility MH RRTP PA prescribed medications for Resident X's opioid withdrawal management consistent with the H&P assessment. The OIG team determined that Facility leaders completed required administrative reviews following Resident X's death. Facility managers implemented new screening and admission processes, established a resident privilege levels program, and initiated a plan to increase MAT accessibility. To enable a veteran's informed decision in the process of rehabilitation and recovery, VHA requires that staff provide veterans with information regarding expectations, rules, and limitations of the program prior to admission. However, the OIG team found that MH RRTP staff did not provide documented information regarding the MH RRTP privileging levels program to veterans prior to admission.

[103] The Assessment and Management of Risk for Suicide Working Group, *VA/DoD Clinical Practice Guideline for Assessment and Management of Patients at Risk for Suicide*, Version 1.0 - June 2014; VHA Directive 1101.05(2).
[104] VHA Handbook 1162.02.

The OIG team also identified concerns about whether the privileging levels program was congruent with MH RRTP goals of rehabilitation and recovery.

Recommendations 1–3

1. The Dayton VA Medical Center Director ensures that the Mental Health Residential Rehabilitation Treatment Program nursing staff complete validated clinical scales to assess and quantify the severity of withdrawal symptoms for patients with opioid use disorder, as ordered.

2. The Dayton VA Medical Center Director ensures that the Mental Health Residential Rehabilitation Treatment Program provides timely therapeutic activity schedules to residents, including weekend treatment activities.

3. The Dayton VA Medical Center Director consults with the Veterans Health Administration Mental Health Residential Rehabilitation Treatment Program Office to evaluate whether the resident privileging levels program was congruent with the goals of the Mental Health Residential Rehabilitation Treatment Program, and take action as necessary.

Appendix A: The Role of Fentanyl in the Opioid Crisis

In 2016, the CDC reported that overdose deaths involving fentanyl and fentanyl analogs[105] were contributing to the opioid epidemic.[106] In March 2017, the CDC informed Congress that "Drug overdose deaths in the United States have nearly tripled in the last 15 years." In previous years, the increase in overdoses was attributed to prescription opioids; however, the recent increase in fatal overdoses was attributed to the use of heroin and synthetic opioids, specifically IMF.[107] The Ohio Department of Health reports that fentanyl-related overdoses increased from 75 to 1,155 from 2012 to 2015.[108]

Fentanyl Analogs

Fentanyl analogs, such as acetylfentanyl, butyrylfentanyl, acrylfentanyl, furanylfentanyl, and β-hydroxythiofentanyl, are appearing within the illicit drug market, resulting in deadly consequences with lower amounts of ingestion. Acrylfentanyl use is especially potent and overdose risk extremely high as it is 100 times more powerful than morphine.[109] Acrylfentanyl is classified as a Schedule I substance[110] by the Drug Enforcement Administration under the

[105] Analogues are chemical compounds that are structurally similar to another but differ slightly in atomic composition. https://www.merriam-webster.com/dictionary/analogue. (The website was accessed on March 2, 2018.)

[106] The Centers for Disease Control and Prevention issued a Press Release commenting on the rise of illicit opioid use and its subsequent increase in overdose deaths. https://www.cdc.gov/media/releases/2016/p1216-continuing-opioid-epidemic.html. (The website was accessed on March 5, 2018.)

[107] United States Congressional House Committee on Energy and Commerce Subcommittee on Oversight and Investigations. *The Next Wave of the Opioid Crisis. March 21, 2017.* 115th Congress (statement of Dr. Debra Houry, Director of the National Center for Injury Prevention and Control at the CDC). https://www.hhs.gov/about/agencies/asl/testimony/2017-03/fentanyl-next-wave-opioid-crisis.html?language=es. (The website was accessed on March 5, 2018.)

[108] 2015 Ohio Drug Overdose Data: General Findings, Ohio Department of Health, http://www.odh.ohio.gov/-/media/ODH/ASSETS/Files/health/injury-prevention/2015-Overdose-Data/2015-Ohio-Drug-Overdose-Data-Report-FINAL.pdf. (The website was accessed on June 25, 2018.)

[109] Schueler, H. (2017). Emerging Synthetic Fentanyl Analogs. *Academic Forensic Pathology*, Volume 7-Issue 1, pp.36–40. http://journals.sagepub.com/doi/full/10.23907/2017.004. (The website was accessed on March 11, 2018.)

[110] The Drug Enforcement Administration categorizes substances into five categories in accordance with the Controlled Substances Act. https://www.dea.gov/druginfo/ds.shtml. (The website was accessed on March 11, 2018.)

Controlled Substances Act[111] due to its no known approved application and high likelihood for abuse.[112]

Fentanyl Analogs in Ohio

Wright State University and the Montgomery County Coroner's Office/Miami Valley Regional Crime Laboratory collaboratively reviewed unintended overdose fatalities involving IMF analogs in 24 Ohio counties during early 2017. The authors asserted that IMF analogs were a public health concern and that the medical coroners' offices were not conducting IMF analog testing routinely. The authors concluded that there was a need to include IMFs in routine toxicology testing.[113]

Fentanyl Alert for Montgomery County, Ohio

On February 1, 2017, the Community Overdose Action Team issued an alert regarding the increased use of IMF and its analogs.[114] This advisory specifically highlighted the potency of acrylfentanyl. The alert also reported that naloxone may be ineffective and multiple doses might be required in the event of an overdose due to fentanyl analogs use.

[111] The Controlled Substances Act is the federal law under which substances are categorized into one of five schedules based upon the legal medical use of the drug and the drug's potential for abuse and safety risk. https://www.dea.gov/druginfo/csa.shtml. (The website was accessed on March 11, 2018.)

[112] Department of Justice, Drug Enforcement Administrations. *Schedules of Controlled Substances: Temporary Placement of Acryl Fentanyl Into Schedule I. Temporary Scheduling Order.* Federal Register /Vol. 82, No. 134 / Friday, July 14, 2017. https://www.ncbi.nlm.nih.gov/pubmed/28715161. (The website was accessed on March 26, 2018.)

[113] Daniulaityte R, Juhascik MP, Strayer KE, et al., Overdose Deaths Related to Fentanyl and Its Analogs–Ohio, January–February 2017, *Morbidity and Mortality Weekly Report*. 66:904-908, September 1, 2017.

[114] Established in the Fall of 2016, the Community Overdose Action Team's purpose is to address the opioid drug epidemic and reduce the number of fatal drug overdoses in Montgomery County, Ohio. The team, led by the Montgomery County Alcohol, Drug Addiction and Mental Health Services, and Public Health-Dayton and Montgomery County, also includes over 60 non-VA leaders who are representatives from public and private organizations. http://www.phdmc.org/coat. (The website was accessed on March 12, 2018.)

Appendix B: VISN Director Comments

Department of Veterans Affairs Memorandum

Date: August 22, 2018

From: Director, VA Healthcare System Serving Ohio, Indiana and Michigan (10N10)

Subj: Healthcare Inspection—Alleged Inadequate Mental Health Treatment at the Dayton VA Medical Center, Ohio

To: Director, Baltimore Office of Healthcare Inspections (54BA)
Director, Management Review Service (VHA 10E1D MRS Action)

1. Thank you for the opportunity to review the draft report of the Office of Inspector General—Alleged Inadequate Mental Health Treatment at the Dayton VA Medical Center, conducted February 5–8, 2018.
2. I have reviewed the document and concur with the recommendations. Relevant action plans have been established as detailed in the attached report.

(Original signed by:)
Jane Johnson, Quality Management Officer/Chief Nurse Advisor, VISN 10
for
Robert P. McDivitt, FACHE

Appendix C: Facility Director Comments

Department of Veterans Affairs Memorandum

Date: August 21, 2018

From: Director, Dayton VA Medical Center (552/00)

Subj: Healthcare Inspection--Alleged Inadequate Mental Health Treatment at the Dayton VA Medical Center, Ohio

To: Director, VA Healthcare System Serving Ohio, Indiana and Michigan (10N10)

1. Thank you for the opportunity to review the draft report of the Office of Inspector General–Alleged Inadequate Mental Health Treatment at the Dayton VA Medical Center, conducted February 5–8, 2018.
2. I have reviewed the document and concur with the recommendations. Relevant action plans have been established as detailed in the attached report.

(Original signed by:)
Jill K. Dietrich, JD, MBA, FACHE
Dayton VA Medical Center Director

Comments to OIG's Report

Recommendation 1

The Dayton VA Medical Center Director ensures that the Mental Health Residential Rehabilitation Treatment Program nursing staff complete validated clinical scales to assess and quantify the severity of withdrawal symptoms for patients with opioid use disorder, as ordered.

Concur.

Target date for completion: January 10, 2019

Director Comments

The Mental Health Residential Rehabilitation Treatment Program (MHRRTP) staff complete clinical scales to assess and quantify the severity of withdrawal symptoms for Veterans admitted with opioid use disorder. Based on evidenced based research, and recommendations from Mental Health providers, the facility elected to implement the Clinical Opiate Withdrawal Scale (COWS) assessment tool. The MHRRTP Registered Nurses (RNs) received comprehensive simulation lab training in the accurate, timely completion, and documentation of the COWS assessment. The COWS assessment is ordered by a Licensed Independent Practitioner (LIP) and was implemented in the MHRRTP on July 9, 2018.

An COWS assessment audit process was implemented in July 2018 with 100% compliance. Ten (10) charts of Veterans admitted to the MHRRTP each month will be randomly audited for validation that the COWS assessments were completed as ordered. These audits will be reported to the Mental Health Quality Council and the Quality, Safety, and Value Committee quarterly. The audits will be completed for two (2) quarters with a goal of 90% compliance to achieve monitor closure.

Recommendation 2

The Dayton VA Medical Center Director ensures that the Mental Health Residential Rehabilitation Treatment Program provides timely therapeutic activity schedules to residents, including weekend treatment activities.

Concur.

Target date for completion: February 10, 2019

Director Comments

MHRRTP provides therapeutic activity schedules to residents, including weekend treatment activities. To ensure an optimal and timely resident orientation, a new process was implemented in May 2018. The Social Worker meets with the resident on the day of admission to review the

orientation schedule, therapeutic activities, and provides the resident with a warm welcome and an opportunity to ask questions.

A random audit was implemented in August 2018. Ten (10) charts of Veterans admitted to the MHRRTP each month will be audited to validate the Social Worker and resident meet on the day of admission, and that the resident received the therapeutic activity schedule, including weekend treatment activities. These audits will be reported to the Mental Health Quality Council and the Quality, Safety, and Value Board quarterly. The audits will be completed for two (2) quarters with a goal of 90% compliance to achieve monitor closure.

Recommendation 3

The Dayton VA Medical Center Director consults with the Veterans Health Administration Mental Health Residential Rehabilitation Treatment Program Office to evaluate whether the resident privileging levels program was congruent with the goals of the Mental Health Residential Rehabilitation Treatment Program, and take action as necessary.

Concur.

Target date for completion: September 30, 2018

Director Comments

On Friday, August 17, 2018, Dayton VA Medical Center (VAMC) and V10 Mental Health Leadership conducted a conference call with VHA's National Director, MHRRTP to evaluate whether Dayton VAMC's resident privileging level Standard Operating Procedure (SOP) is congruent with national MHRRTP goals. The MHRRTP National Director verbalized understanding of Dayton's resident privileging process and in written follow-up communication stated, "There is no national MHRRTP policy that would prohibit the use of a "Limits" SOP as currently written." As encouraged by the VHA's National Director, MHRRTP, Dayton will review all pertinent policies to assure Veteran interventions and family support system engagements are individualized, while continually maintaining a safe environment. Also, Dayton will submit an ethics consult for review of the resident privileging levels to ensure there are no ethical conflicts.

OIG Contact and Staff Acknowledgments

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