Root Cause Analysis of Adverse Events Involving Opioid Overdoses in the Veterans Health Administration

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Objective: The Veterans Health Administration (VHA) serves a population with compounding risk factors for opioid misuse, including chronic pain, substance use disorders, and mental health conditions. The objective of this study was to analyze opioid-related adverse events and root causes to inform mitigation strategies associated with opioid prescribing and administration.

Methods: The researchers conducted a retrospective analysis of root cause analysis reports of opioid overdose events between August 1, 2012, and September 30, 2019. These adverse events were investigated locally by multidisciplinary hospital teams and reported by VHA facility patient safety managers to the National Center for Patient Safety for further aggregation and analysis. Type of event, location, and root causes were categorized.

Q2
Q3   **Results:** Eighty-two adverse event reports were identified. Patients were primarily male with an average age of 61.4 years. Staff medication administration errors were the most common event type (57.3%), with most events resulting from process errors (65.9%) occurring in the health care setting (85.4%). Overall 36 events (43.9%) resulted in major or catastrophic harm. There were 172 root causes identified. The most common root causes were staff not following existing policy or lack of existing hospital policy on opioid management (18.0%); staff lacked training in areas such as managing the use or administration of opioids, correct use of opioid dispensing equipment, and recognition and proper response to an overdose (12.2%); and poor communication of opioid prescribing or administration during handoffs between clinical teams (11.6%). A lack of standardization in processes, training, and policies on opioid prescribing and screening, medication administration, equipment/pumps purchase and use, and contraband searches was a common theme throughout.

Conclusion: Errors in prescribing and administration of opioid medication can result in significant harm. A lack of standardized opioid administration practices and training, controlled substance policies, and interdisciplinary communication were frequent factors in adverse opioid events and should be a focus for future prevention.

The opioid overdose epidemic continues to diversify with the use of prescription opioids and illicit substances.[1–3] In 2017, 67.8% of the 70,237 drug overdose deaths in the United States involved opioids.[1] In 2019 the Centers for Disease Control and Prevention (CDC) and *Morbidity and Mortality Weekly Reports* (MMWR) reported that 15 states had an increase in opioid-related overdose deaths across various age groups, racial/ethnic groups, and county urbanization levels.[1,2,4,5]

The Veterans Health Administration (VHA) is greatly affected by the opioid epidemic, as it serves a population with compounding risk factors for opioid-related overdoses.[6–9] Veterans have significantly higher rates of chronic pain, post-traumatic stress disorder (PTSD), receipt of opioid prescriptions, substance use disorders, suicide, and other mental health conditions as compared to the US civilian population.[6,8,10] Approximately 20 veterans die by suicide every day, and many of these deaths involve prescription or illicit opioids.[11] Veterans are nearly seven times more likely to abuse opioids when comparing VHA to private insurance patients.[12] The prevalence of unintentional overdoses among veterans is nearly double compared to the US civilian population,[10] which may be attributable to veterans being more likely to receive an opioid prescription.[6,13]

The opioid epidemic has led to multiple VHA initiatives to address opioid-related adverse events within and outside VHA settings. Recent VHA efforts include an Opioid Safety Initiative (2013), Opioid Overdose Education and Naloxone Distribution (2013), a Stratification Tool for Opioid Risk Mitigation (2015), and updates to the VA/DOD [US Department of Veterans Affairs / US Department of Defense] Clinical Practice Guideline for Opioid Therapy for Chronic Pain (published 2003, amended 2017). For perspective, in fiscal year 2019, the VHA dispensed opioid medication to 426,648 veterans.

Adverse events involving medication error remain a significant cause of mortality and morbidity in the United States.[14–18] Numerous studies have examined rates of opioid overdose– or suicide-related events and risk factors among the veteran population, but to our knowledge none have reviewed root causes of opioid-related overdoses in VHA settings or associated with recent VHA care and treatment. The primary objective of this study was to analyze the types of reported opioid-related adverse events

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and root causes occurring among patients prescribed and administered opioids in VHA settings. Secondary objectives were to inform enhancements to VHA policy with intent to further mitigate harm associated with opioid prescribing and administration.

METHODS

Study Design

This is a retrospective analysis of reported veteran opioid-related adverse events associated with treatment in the VHA for the period August 1, 2012, to September 30, 2019. In 1999 the VHA National Center for Patient Safety (NCPS) implemented the use of root cause analysis (RCA) investigation and established a national RCA database to review and identify contributing factors to close calls or adverse events. We searched the NCPS RCA database for opioid-related events occurring in inpatient and outpatient settings, both on and off VHA grounds. This project has been approved by the Institutional Review Board, White River Junction VA Medical Center (VAMC), White River Junction, Vermont, and does not include human subjects. All data were deidentified.

Description of Setting and Sampling Technique

All adverse events, including opioid-related events, are investigated at each VA medical facility by the facility Patient Safety Manager (PSM). When reviewing adverse events, PSMs score each event using a standard Safety Assessment Code (SAC) matrix. The SAC score rates the event based on the severity of the event (outcome from catastrophic to minor harm), and the probability of the event happening again (frequent to remote). High SAC score events must undergo an individual RCA, while remaining events are reported as an incident report through the VHA's patient safety event reporting system for later aggregated analysis.[19–21] All reports of patient safety events are reported to the NCPS for further aggregation, for analysis, and to be catalogued.

Adverse events are defined within the VHA as "untoward incidents, therapeutic misadventures, iatrogenic injuries, or other adverse occurrences directly associated with care or services provided within the jurisdiction of a medical facility, outpatient clinic, or other VHA facility."[21] (p. 2) Adverse events are considered to be preventable, and the RCA process identifies systemic changes that can help to prevent similar events from occurring in the future. RCA is a standardized method for reviewing and investigating the causes within a system that resulted in an adverse event.[19,21] RCA is a process used for investigating adverse events to understand the root causes (causal factors) of the events. Events are investigated locally by multidisciplinary hospital teams. The facility PSM is typically trained in RCA and safety protocols and leads the RCA team investigations. RCA reports are narrative reports that describe what happened leading up to and during an adverse event, why the event occurred (underlying causes for the event), and how to prevent future similar events from occurring within the system.[19,21] The RCA focuses on systems issues and vulnerabilities, and therefore the information within these reports includes little demographic data about individuals involved in the events. RCA teams outline the changes and actions that can be made at the unit or facility level to address the outline root causes of a given event to prevent them from reoccurring. The RCA process has been described in more detail elsewhere.[20]

Identifying Relevant RCA Reports

All adverse events related to opioids in the VHA were included regardless of administration or location (patient administered, professional administered, inpatient, outpatient, inside a health care setting, outside a health care setting). These cases are adverse events directly related to VHA care and processes. Therefore, veterans who acquire and overdose on opioids outside of the VHA system of care are not included in the scope of this study. The search was conducted using natural language processing software PolyAnalyst (Megaputer Intelligence, Inc., Bloomington, Indiana) to search for events that included the key terms "overdose," "accidental," and "opioid," yielding 230 results during this time frame. Only individual event RCAs were included. Safety reports with limited information and aggregated RCAs were excluded. RCAs were excluded if the event did not relate directly to opioid overdose (for example, related to another medication such as benzodiazepine, heparin, or insulin). After all exclusion criteria were applied, the resulting data set yielded 82 RCAs, including 3 RCAs that were initiated but halted before completion.

Data Processing and Analysis

We developed a codebook to capture the patient characteristics of the veterans involved in the events, location of the event, mortality/patient harm, event type, root causes, and actions for future prevention. The root causes and actions were coded based on the findings of the individual RCA teams. Two authors [B.N., C.S.] independently coded the first 10 RCAs. There was strong interrater agreement ($\kappa = 0.89$) on the 10 RCAs. The remaining 72 RCAs were split between the authors [B.N., C.S.] for coding, with consensus coding completed on complex cases. A descriptive analysis of RCA data was conducted summarizing the types of events, location, patient characteristics (when available), root causes, and prevalence of naloxone utilization. Event types were classified into three main categories: upstream events, process events, and downstream events. Upstream events precede medication administration and include pharmacy or provider transcription or labeling errors, bar code medication administration scanning error, and ordering error. Process events relate to medication handling

Table 1. Number of RCAs That Met Inclusion Criteria by Fiscal Year (N = 82)

Fiscal Year*	Number of RCAs
2013	18
2014	13
2015	10
2016	14
2017	9
2018	11
2019	7

RCA, root cause analysis.
* The Veterans Health Administration fiscal year runs from October 1 to September 30.

Table 2. Characteristics of Patients Experiencing a Reported Adverse Opioid Overdose Event (N = 82)

Demographic Characteristic	Frequency	%
Gender*		
Male	50	90.9
Female	5	9.1
Age in years†		
20–39	8	17.7
40–59	8	17.7
60–79	24	53.3
80–99	5	11.1
Location of adverse event		
Internal medicine unit/ICU	26	31.7
Off-site	12	14.6
Surgery department	9	11.0
Community living center	9	11.0
Mental health residential rehabilitation	6	7.3
Emergency department	6	7.3
Palliative/hospice care	6	7.3
Acute psychiatry unit	4	4.9
Hospital grounds	1	1.2
Outpatient mental health department	1	1.2
Residential pain rehabilitation	1	1.2
Sleep lab	1	1.2
Substance use diagnoses		
Opioid use disorder	11	45.8
Alcohol use disorder	6	25.0
Stimulant use disorder	2	8.3
Sedative use disorder	1	4.2
Cannabis use disorder	1	4.2
Substance use disorder, unspecified	3	12.5
Mental health diagnoses		
Mood disorders	10	35.7
Post-traumatic stress disorder	9	32.1
Neurocognitive disorders	5	17.9
Personality disorders	2	7.1
Attention deficit hyperactivity disorder	1	3.6
Schizophrenia	1	3.6
Reversal agent (naloxone)‡		
Administered	32	39.0
Not administered	18	22.0
Mortality rate§		
Nonfatal overdose	54	80.6
Fatal overdose	13	19.4

* Not reported for 27 patients.
† Not reported for 37 patients.
‡ Not reported for 32 patients.
§ Not reported for 15 patients.

at the provider-patient interface and include administration or dispensing of the wrong medication dosage, wrong medication timing, and dispensing the wrong type of medication. Downstream errors occur with transfer of the opioid medication to the patient and include patient medication error, substance abuse, suicide attempt, and suicide.

RESULTS

Demographics

A total of 82 RCA reports of opioid adverse drug events were identified for the study period, ranging from 7 to 18 RCAs per VA fiscal year, which runs from October to September (Table 1). Table 2 synthesizes all the patient demographic information provided within the reviewed RCAs. Of the 55 RCAs that reported gender, 50 (90.9%) were males and 5 (9.1%) were females. Of the 45 RCAs that reported age, the average age was 61.4 years, and 29 (64.4%) were aged older than 60 years. A preexisting mental health condition and/or substance use disorder was reported in 22 RCAs (26.8%) with the following breakdown: opioid use disorder (11), mood disorders (10), post-traumatic stress disorder (9), alcohol use disorder (6), stimulant use disorder (2), personality disorders (2), and 1 each for schizophrenia, attention deficit/hyperactivity disorder (ADHD), adjustment disorder, sedative use disorder, and cannabis use disorder. The majority of events occurred in a health care setting (70 events, 85.4%): 26 within internal medicine units and ICUs, 9 in surgery departments, 9 in community living centers, 6 in emergency departments, and the remainder in palliative/hospice care, residential mental health units, acute psychiatric units, sleep labs, outpatient mental health departments, residential pain rehabilitation, or on hospital grounds. Only 12 (14.6%) of the RCAs were associated with an event occurring outside of a health care associated with a VHA provider-prescribed opioid.

Types of Adverse Events

Figure 1 summarizes the RCA reports by type of event and level of severity assigned by the facility PSM. Of the 82 adverse events, 13 (15.9%) were characterized as upstream events, 54 (65.9%) were process-related events, and 15 (18.3%) were downstream events. Overall, 36 (43.9%) of the events—9 upstream events, 16 process events, and 11 downstream events— resulted in major or catastrophic harm. Staff medication administration errors were identified as the most common events reported (n = 47, 57.3%) and associated with administration of the wrong medication, incorrect dosage for individual patient, or poorly timed administration. Of the 67 RCA reports that included a description of the outcome, 13 (19.4%) revealed fatal overdoses, and 54 (80.6%) were reported as nonfatal over-
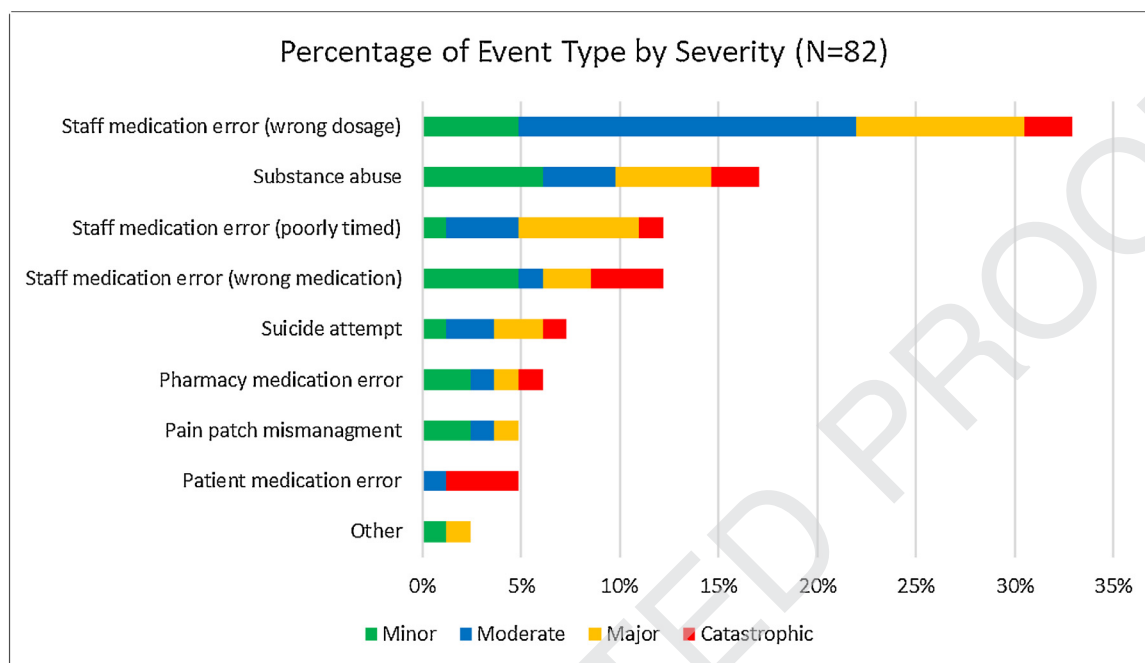
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Figure 1: The graph shows the percentage of adverse event type by level of severity.

doses. A total of 15 (18.3%) RCA reports did not include a description of the outcome (Table 1). Administration of naloxone, an opioid reversal agent, was reported in 32 (39.0%) overdoses, while it was recorded as not given in 18 (22.0%) and undeterminable in 32 (39.0%) RCA reports.

Root Causes

There were 172 root causes identified (Figure 2). Policy and procedures, including lack of, incongruent, or not following an opioid management policy or procedure, was the most common root cause of adverse events involving opioid overdoses among VHA patients ($n = 31$, 18.0%). Examples of incongruent policy and procedures are as follows: standard of practice differs from hospital policy on two-factor patient identification, drugs restricted for IV push, or procedure variation between nursing rounds. A need for staff training in opioid management, medication-related equipment, and recognition or treatment of opioid overdoses accounted for 12.2% ($n = 21$) of the identified root causes. Some notable root causes reported were poor communication of medication administration and orders between shifts and disciplines ($n = 20$); problems with the physical environment within the hospital ($n = 9$); problems with medical equipment ($n = 8$); ineffective standard of practice for prescribing opioids, dose conversion, and tapering of opioids ($n = 8$); attachment of multiple medications to IV drip or pump ($n = 7$); and illegible or absent medication labels ($n = 7$). Medical equipment–related root causes pertained to computerized medication dispenser or IV pump malfunctions, predetermined amounts of medication via software, incorrect medication inside dispenser, or illegible or missing label produced by equipment. No root causes were reported for

3 RCAs that were initiated but halted before completion. Root cause analyses are typically halted if an adverse event is being investigated for an intentional or criminal act.

DISCUSSION

To the best of our knowledge, this is the first study that reviews opioid overdose adverse events using a national RCA database. The closest study identified was a 2015 study on in-emergency department opioid-related adverse events within two academic hospitals.[22] The use of this NCPS database enabled us to examine the types of adverse event reported in the system and the root causes attributed to said events, as well as review case examples for recommended actions. **Q6**

We found RCA that reports that identified root causes of staff medication errors emphasized a lack of opioid management training, a lack of standardized policies and procedures, nonintuitive medication equipment, and poor communication between staff regarding medication administration. Similarly, Beaudoin et al. found that 73% of patients administered naloxone had experienced an opioid-related adverse event due to a medication error.[22] The root causes we identified are consistent with previous studies on opioid prescribing.[22,24,25] When addressing these root causes it is critical to go beyond education and policy change and make clinical changes at the bedside—for example, standardizing medication administration equipment throughout the facility so that staff do not need to operate multiple types of pumps and using a checklist to standardize handoff communication. **Q7**
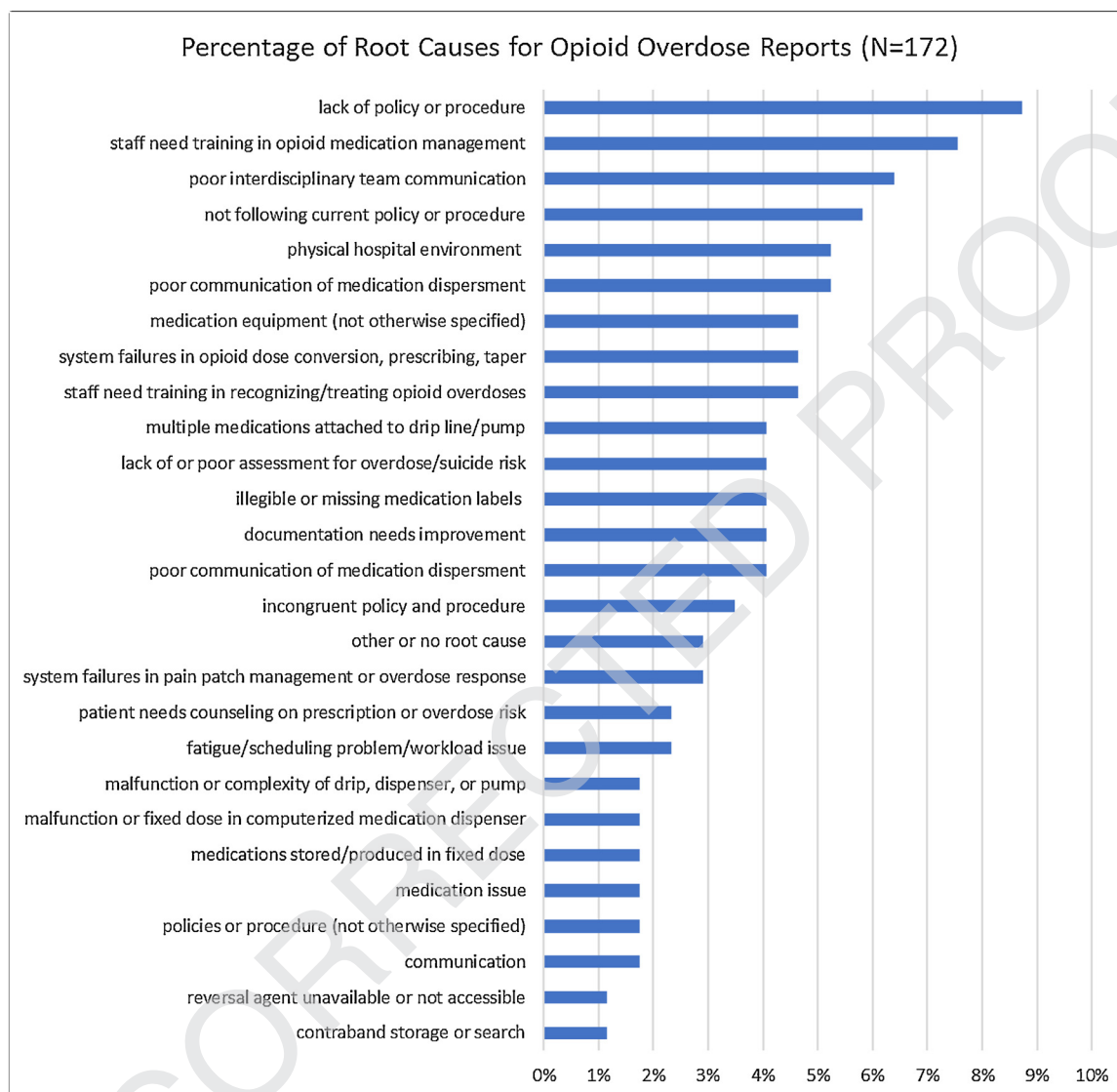
Figure 2: Shown here is the percentage of root causes for RCA reports of opioid overdose in the Veterans Health Administration. RCA, root cause analysis.

Incidents of patient substance abuse resulting in accidental overdoses were the second most common event type identified by RCA reports. For example, some patients presented to an emergency department or medicine unit and were administered or provided an opioid prescription without prior drug screening or chart review and later overdosed. Another notable example pertained to inpatient units not conducting thorough contraband searches or storage on patient admission or on patient return from a pass. One RCA team recommended the development of an electronic record flag for those at higher risk of opioid overdose. In addition, limiting passes or other opportunities for patients to leave units during their stay will help reduce access to illicit substances, ensuring that naloxone is readily available in all departments and staff are aware of designated locations. Again, a standardized contraband check, guided by a checklist that must be conducted with all patients coming onto the unit, can help to ensure that more hazardous materials are kept off the unit.

The third most common event type was suicide attempts involving VHA–administered or prescribed opioids. For all patients coming onto a medical or behavioral health unit it is critical to conduct a thorough search for hazardous items. This is often accomplished by having the patient change into pajamas, conducting an evaluation of their skin condition, and thoroughly searching their clothing and belongings, guided by a checklist for standardization. In addition, it is important for staff to be trained to recognize and assess symptoms of depression and suicidal ideation and have a specific plan for monitoring the patient and involving mental health staff when patients are displaying these symptoms. Develop clear guidelines to ensure that patients do not have access to their medications if they are at risk for suicide and that visitors are not allowed to bring medications to the pa-

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tient. Beyond developing policy, it is also critical to observe staff to see that they are carrying out the new guidelines.

Pharmacy medication errors were also a commonly reported event. Of note, physical environment layout, computerized medication dispensers, high workload, and poor scheduling were identified as contributing root causes in other pharmacy errors that resulted in opioid overdoses. Prohibiting disruptions to medication order processing, dispensing, and labeling of prescriptions, such as assigning a staff member to answer calls while pharmacists tend to one patient prescription at a time, is recommended . Also recommended is implementation of a safety feature in the electronic medication order screen to validate dose and strength of the selected opioid along with notification to the ordering provider when a change is made to a medication order. Again, these are stronger actions because they force staff to change their behaviors at the front lines, rather than simply providing education.

Although none of the adverse events associated with transdermal fentanyl patches resulted in a fatal overdose, mismanagement or misuse of pain patches can lead to a catastrophic injury or death given the potency of fentanyl.[26,27] The adverse events consisted of two patients attempting to ingest a patch, a staff administration of two patches (medication error), and a patch not being removed on discharge when provided a prescription for oral opioids. Schifano et al., in a European study, found 23 cases of transdermal patch ingestion.[26] Implementing a standardized protocol for transdermal patch management, along with simulation-based staff training, may prevent the occurrence of an adverse event.

Our final type of event was accidental patient medication errors. This event was rarely reported in the VHA within the RCA database. We found that the primary root causes for patient medication error were illegible prescription bottle labels, conflicting instructions between bottle label and discharge plan, and unclear staff communication regarding the opioid prescription instructions and risks. These findings suggest that inpatient departments should implement pharmacy verification of outpatient medication orders prior to ordering providers' medication reconciliation and discharge instruction printout for patients. In addition, having a nurse review said discharge instructions and medication list with the patient prior to discharge is recommended. An RCA team recommended creating an easy-to-follow instruction handout.

Recommendations

Based on our findings, we offer the following recommendations for improvement of patient safety within the VHA. We were able to determine that many of these actions or similar actions were implemented at multiple VHA facilities. In addition, these recommendations were identified as feasible to implement at other health care facilities.

- Report all close calls or adverse events involving opioids to further identify trends and develop comprehensive preventive actions.[22]
- Develop and implement standardized policies and procedures for opioid management, including strategies for staff education on pain patch management, opioid tapering protocols, overdose risk assessment, opioid prescribing resources, medical equipment operation, contraband searches and storage, and compliance with protocols.[8,22]
- Provide simulation-based training for improvement of opioid overdose recognition and treatment, with emphasis on where to access naloxone in each individual VHA department and affiliate facility.
- Develop and implementat standardized procedures for patient-directed education on outpatient opioid prescriptions and offer naloxone prescriptions as an additional preventative measure.
- Reinforce VA/DOD guideline recommendations regarding development and implementation of standardized urine drug screening prior to and during opioid use with all patients considered for opioid therapy, accompanied by patient monitoring via follow-up appointments for at least three months upon opioid prescription receipt or discontinuation. This reduces risk of suicide attempts and overdose.[28–30]   Q9

Limitations

This study has several limitations. First, our NCPS RCA data are self-reported by staff to our patient safety program and so it is likely that we have missed some serious adverse events and close calls related to opioids. Second, opioid overdoses are potentially underreported to the patient safety system, particularly if the overdose occurred off-site or was attributed solely to patient error. Moreover, RCA reports are not reflective of the rate of opioid overdoses within the veteran population but is a retrospective study on types of adverse events and root causes to address and potentially prevent opioid-related overdoses within the VHA system., We did not include Joint Patient Safety Reporting (JPSR) system reports, safety reports, or aggregate reviews, which limited our ability to control for or describe demographics. Last, the predominantly male sample and organizational structure of the VHA may not be readily generalize to other health care systems.

CONCLUSION

VHA dispensing of opioid medication was associated with overdose events, fatality, and major and catastrophic harm. RCA review of these events identified attention to policy for medication administration and the ready availability of reversal agents as important lessons learned.   Q10

Q11

UNCITED REFERENCE

[23].

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