Pain Management and Opioid Risk Mitigation in the Military

Jennifer Sharpe Potter, PhD, MPH*; Lt Col Vikhyat S. Bebarta, USAF MC†; Elise N. Marino, BA*; Rosemarie G. Ramos, PhD, MPH‡; Barbara J. Turner, MD*

ABSTRACT Opioid analgesics misuse is a significant military health concern recognized as a priority issue by military leadership. Opioids are among those most commonly prescribed medications in the military for pain management. The military has implemented opioid risk mitigation strategies, including the Sole Provider Program and the Controlled Drug Management Analysis and Reporting Tool, which are used to identify and monitor for risk and misuse. However, there are substantial opportunities to build on these existing systems to better ensure safer opioid prescribing and monitor for misuse. Opioid risk mitigation strategies implemented by the civilian sector include establishing clinical guidelines for opioid prescribing and prescription monitoring programs. These strategies may help to inform opioid risk mitigation in the military health system. Reducing the risk of opioid misuse and improving quality of care for our Warfighters is necessary. This must be done through evidence-based approaches with an investment in research to improve patient care and prevent opioid misuse as well as its sequelae.

INTRODUCTION

Prescription opioid analgesics are the most misused drug class in the United States and second only to marijuana among all illicit drugs of abuse. The negative consequences of opioid misuse include opioid-related emergency department visits, poisoning deaths, opioid-related addiction treatment, and suicide. The term "misuse" encompasses a broad spectrum of problematic utilization of opioid medications, ranging from simply taking an opioid more frequently than prescribed for pain relief to purposefully taking these drugs to attain a "high."

Opioid misuse afflicts both civilian and military communities. In 2010, senior military leadership recognized the need to mitigate opioid misuse as a military health priority and recommended a more cautious approach to prescribing opioids as well as more research on the surveillance, detection, and management of opioid misuse.7-9 These recommendations reflected concerns about an increase in opioid-related adverse events among active duty military personnel and those who have recently separated from the military. Growing evidence supports this concern. For example, of urine drug screen tests that were positive for prescription drugs in 2009, 21% were associated with illicit use.⁵ Because, there are few analgesic alternatives for the management of moderate to severe pain, it is important to develop to an opioid risk mitigation strategy that provides effective, appropriate pain management although reducing

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the risks for our active duty personnel, their dependents, and their beneficiaries.

To be successful, opioid risk mitigation must maintain access to opioids while addressing three priorities: (1) to ensure the safety of the patient for whom the drug is being prescribed (e.g., avoid improper or unnecessary prescribing), (2) to prevent use by persons for whom opioids were not prescribed (e.g., medication sharing, accidental poisoning), and (3) to prevent diversion (e.g., selling the drugs). Achieving these goals requires a delicate balance of risks and benefits. An aggressive policy limiting access to opioids could harm patients who can benefit and would not misuse this therapy. Physicians are understandably concerned that excessive regulatory oversight may deny access to opioids for their patients with legitimate medical indications. This concern might be expected to be heightened for a military physician treating a returning combat veteran. But it is important to balance the need to address pain with the risks associated with opioid misuse that interferes with military preparedness, including combat readiness and fitness for duty. Ultimately, misuse can deplete the ranks of deployable warriors.

The following discussion offers an overview of diverse strategies that are being developed and implemented in the civilian sector as well as the Military Health System (MHS) to reduce the risks associated with opioid prescribing. The experience with these strategies in both environments shows important opportunities as well as continuing challenges in stemming opioid misuse. On the basis of this overview, we offer recommendations for building an opioid misuse risk mitigation system for service members, dependents, and their beneficiaries.

Opioid Misuse in the Civilian Sector and the Military

Opioid analgesic (OA) prescribing has become ubiquitous. OAs prescribed in 2010 to treat every American aged 19 or older with 5 mg hydrocodone every 4 hours for 1 month. ¹⁰ In the civilian sector, accidental overdose from opioids has

^{*}The University of Texas Health Science Center at San Antonio, 7703

Floyd Curl Drive, San Antonio, TX 78229.

†Department of Emergency Medicine, San Antonio Military Medical Center, 3851 Roger Brooke Drive, Fort Sam Houston, TX 78234.

[‡]Wilford Hall Ambulatory Surgical Center, 2200 Bergquist Drive, Lackland *Air Force* Base, San Antonio, TX 78236.

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increased over four-fold nationally from 1999 to 2009. 11 Overall, opioids were involved in three quarters of the more than 22,000 drug-overdose deaths in 2010 in civilian settings. 12 In particular higher dose, long-term OA therapy has been associated with significantly increased risks of misuse and overdose. 13

A 2008 Department of Defense Survey of Health Related Behaviors among Active Duty Military Personnel⁷ has also found a substantial increase in opioid misuse, doubling from 2002 to 2005 and nearly tripling from 2005 to 2008. In 2008, 10.1% of service members acknowledged misusing opioids in the prior month, although 17.2% misused in the preceding 12 months. Rates of misuse among Army personnel were significantly greater than that for the Navy, Air Force, or Marine Corps. Among active duty Army personnel, 13.4% misused opioids in the past month and 21.5% in the past 12 months. In other words, more than 1 in 5 active duty service members reported opioid misuse in the past 12 months.⁷ It is notable that under-reporting misuse occurs even on anonymous surveys, so these numbers likely underestimate the magnitude of opioid misuse.

Historically, systematic monitoring of substance abuse has rarely discriminated between prescription opioids or other prescription medications with abuse liability. A recent comprehensive Institute of Medicine (IOM) report¹⁴ on substance use disorders noted major limitations on information about etiology and treatment of nonalcohol-related substance use disorders in the military because of the stigma and underreporting associated with these disorders. However, as the IOM committee noted, data sources exist that may be used in the future to better evaluate the extent of opioid misuse. For example, modifications were made to the 2008 Department of Defense Survey of Health Related Behaviors among Active Duty Military Personnel⁷ to characterize opioid use as a class separate from other prescribed substances. Further, the Military Personnel Drug Abuse Testing Program was updated in October 2012 to include urine drug screening for opioids. 15 This program now offers a valuable resource to monitor opioid misuse trends over time.

Pain and Opioid Prescribing in the Military

According to the 2011 U.S. Army Posture Statement, pain is the leading cause of both short- and long-term disability among military personnel. Over 25% of recruits have suffered at least 1 pain-related injury during Basic Combat Training. Indeed, pain was the primary reason for aeromedical evacuation out of theater for Operation Iraqi Freedom (OIF). The impact of pain on our service members can persist long after military service. In the Veterans Affairs medical system, nearly half of Operation Enduring Freedom (OEF)/OIF veterans have at least 1 pain diagnosis, and 29% of OEF/OIF veterans report widespread chronic pain.

Opioids are prescribed commonly in the military to manage chronic pain⁵ as in the civilian sector.²¹ Combat-related

injuries during the wars in Iraq and Afghanistan have led to substantial increases in prescribing of opioids for pain. ²² In 2009, military physicians wrote 3.8 million opioid prescriptions, which is four times the number of opioid prescriptions written in 2001. ²² In the Army, oxycodone and hydrocodone have become the second and third most commonly prescribed analgesics. ⁵ Overall, 14% of Army service members are prescribed an opioid. ⁵ Rising use of opioids likely represents a variety of factors including military-specific reasons such as injuries from two wars as well as general factors such as both military and civilian health care providers using opioids as a primary pain management strategy.

The majority of individuals who are being prescribed an opioid for acute or chronic pain will not misuse their medication. However, as noted previously, the risk of misuse increases with long-term opioid therapy for chronic pain. Effective strategies to reduce the risk of opioid misuse are needed to insure that this widespread use of opioids can be used more safely. The civilian sector has been struggling with rising use of opioids and well-documented problems with misuse. The civilian experience with developing strategies to address these challenges may be informative as the military develops its own initiatives to increase the safety and effectiveness of opioid prescribing.

Opioid Risk Mitigation Strategies in the Civilian Sector

Nationally, civilian expert panels have promulgated guidelines to reduce risks associated with opioid therapy such as periodic urine drug testing, regular office visits to review treatment, and avoiding early refills.^{23,24} However, the civilian community in general has been slow to adopt these recommendations. For example, in the study of 1,612 patients on long-term opioid therapy in several academic general internal medicine practices in Philadelphia, only 8.0% of these patients received 1 or more urine drug test, only half were seen at least once in a 6-month period while they were being prescribed opioids, and 23.4% were given early refills.² Patients at higher risk of misuse were more likely to receive an early opioid drug refill at this location. The use of these monitoring strategies also differed by race and ethnicity, with African-Americans being monitored more closely despite having an overall lower risk of misuse compared to Caucasians.²⁶ These deficiencies offer support for a more comprehensive, equitable management plan for patients in primary care settings who are receiving long-term opioids.

Washington state has been a leader in developing standards for managing chronic pain with opioids. The Washington state Medicaid Program issued an interagency guideline recommending that prescribing of opioids should be restricted, especially at high doses over 120 morphine equivalent units per day.²⁷ The guideline recommends that pain should first be managed using alternative physical, behavioral, and non-opioid drug interventions (e.g., physical therapy, cognitive

behavioral therapy, nonsteroidal anti-inflammatory drugs, antidepressants, and antiepileptics). Before initiating opioid therapy, providers are encouraged to assess the risks of opioid analgesics using standard screening tools, e.g., the Opioid Risk Tool, ²⁸ as well as potential benefits of OA treatment. Patients' management plans should differ according to guidelines that reflect the risk–benefit assessment. ²⁷

Another example of risk reduction guidelines were developed by experts working for a Washington state-based Health Maintenance Organization.²⁹ These guidelines recommend that a single physician should be designated to manage opioid therapy when both the patient and physician concur that opioid therapy should be continued for long term (>90 days). An important aspect of these guidelines is an individualized care plan, specific to an individual's clinical presentation, which includes clear expectations about patient behaviors including adhering to visits, storing the medication in a safe place, and taking the OA as directed. As part of this plan, providers and patients must agree on specific clinical goals to support continuing opioid therapy. Patients benefit from being well-informed about the potential risks of longterm opioid use, ranging from mild side effects to more remote possibilities including abuse liability. In addition, patients are asked to provide informed consent for treatment, which is then documented in the electronic medical record. In the first year after these guidelines were instituted, there was a significant increase in care plans by physicians, with almost 85% of patients receiving a care plan.²⁹ The experience in Washington State supports closer monitoring of prescribing practices and use of risk mitigation strategies. Similarly, close oversight of prescribing patterns and use of risk mitigation approaches offers important opportunities for the military.

Quality of Care Metrics

In the civilian sector,²⁵ population-based data from administrative databases and electronic medical records are increasingly used to evaluate the quality and safety of prescribing practices with the ultimate objective of reducing adverse events. Qualities of care metrics for medication prescribing include reductions in high opioid dosing, excessive acetaminophen doses in combination with opioids, and concurrent benzodiazepine prescribing. Quality of care indicators in regard to patterns of care for pain management include promoting single physician or site prescribing, avoiding emergency department visits, and use of nonpharmacological pain management modalities (e.g., physical therapy, acupuncture, and chiropractic care for low back pain). Again, these are all metrics that can be used in the military sector.

Prescription Monitoring Programs

Another opioid risk mitigation strategy used in the civilian community is the Prescription Monitoring Program (PMP), a state-administered reporting system that is currently operational in 41 states.³⁰ These programs obtain data about opioid

prescriptions from all pharmacies to examine prescribing trends and to characterize potentially risky behaviors including multiple prescribers and/or unusually high amounts or frequencies of prescriptions. PMPs use prescribing data to develop "algorithms" or measures to identify activity suggesting opioid misuse. Examples of these algorithms include five or more prescribers (i.e., doctor shopping), three or more pharmacies, or three or more early refills (i.e., before expected time of refill) within a year.³⁰ PMPs have a number of applications: (1) to monitor individual patients for patient care and safe opioid use; (2) to serve as a public health surveillance tool for detecting illicit behaviors (e.g., "doctor shopping", inappropriate prescribing, questionable pharmacy practices, and prescription forgery and fraud); (3) to allow tracking of medical and nonmedical use of opioids to inform policy (e.g., prescribing, opioid access, health disparities); and (4) to provide a foundation for standardized reporting and queries for prescribers to share with their patients.

Several studies have documented the effectiveness of PMPs based on reductions in prescription sales³¹ and doctor shopping.^{30,32} In a review of recent studies, Wang and Christo³³ concluded that emerging evidence supports the implementation of PMPs to reduce opioid misuse. To maximize the benefit of this program, they note that the program needs adopted nationwide and has to be linked to electronic medical records.

Military Opioid Risk Mitigation Strategies

The need for improved approaches to ensure safe opioid prescribing in the military has been highlighted recently by the Office of The Army Surgeon General Pain Management Task Force in a seminal report entitled Providing a Standardized DoD and Veterans Health Administration Vision and Approach to Pain Management to Optimize the Care for Warriors and their Families. This report emphasized the critical importance of a comprehensive pain management system to address the acknowledged gap in military pain management strategies.

Sole Provider Program

One example of opioid risk monitoring in the military is the Warriors in Transition High-Risk Medication Review and the Sole Provider Program. The Sole Provider Program identifies individuals determined by health care providers or military commanders as being at increased risk for opioid misuse. Once enrolled in the program, one prescribing provider monitors opioid use and assesses for potential high-risk behaviors such as unscheduled or premature medication requests. However, there are disadvantages to the existing Sole Provider Program. It currently has limited implementation, primarily in the Warrior Transition Battalions. The program also lacks a systematic approach to identifying individuals at increased risk. The current approach of

subjectively determining risk of misuse can result in misidentification and has not undergone a rigorous evaluation of its effectiveness in mitigating misuse.

Controlled Drug Management Analysis and Reporting Tool

Currently, the DoD Pharmacoeconomic Center maintains the Controlled Drug Management Analysis and Reporting Tool (CD-MART) that offers a potentially valuable resource for providers at a military treatment facility. Top-MART allows a provider to create location-specific pharmacy dispensing reports based on number of prescriptions, pharmacies, providers, and total quantity of tablets/capsules. It is also possible to produce a report for a specific timeframe. For example, providers can obtain a list of all of their patients who have received controlled substance prescriptions within a specific period in one city or military base clinic.

Despite its potential, CD-MART has limitations. Currently, reports are generated only at the request of individual health care providers and not used systematically across the MHS. The system also provides little structured guidance or documentation concerning what constitutes risk even though it has been defined in other settings as described later. Furthermore, CD-MART has not been subjected to a systematic evaluation.

There are many opportunities to enhance CD-MART's value as a risk mitigation strategy. For example, validated screens for behaviors such as the Opioid Risk Tool²⁴ that have been associated with a high likelihood of misuse or abuse could be systematically applied. Then, management tools could be developed to promote closer monitoring and increased support of persons at increased risk of misuse. CD-MART could also produce standardized population and individual user-level reports to inform prescribing guidelines and the optimal utilization of PMP data. For instance, CD-MART data could augment the Sole Provider Program by providing data on individuals at high risk of misuse. In support of these opportunities, a recent IOM report on substance abuse in the military specifically cited CD-MART as an untapped resource to prevent substance abuse and dependence in military personnel.¹⁴

Shared Opportunities for Opioid Risk Mitigation in the Civilian and Military Sectors

Recent innovations in the structure of primary care practices in both the civilian sector and the MHS offer significant opportunities to incorporate clinical guidelines and quality of care metrics to reduce the risks of opioid misuse. The patient-centered medical home (PCMH) offers an integrative, comprehensive model of primary care i.e., especially valuable for managing clinically complex patients, such as those with chronic pain and other comorbidities. The PCMH takes advantage of the complementary skills of diverse health professionals who provide evidence-based care. Accessible, comprehensive care delivered by a PCMH has been shown

to improve clinical outcomes, ³⁶ reduce dependence on urgent care services, ³⁷ improve patient and provider satisfaction, and reduce costs of care. ³⁸

The PCMH takes advantage of an electronic medical record and offers case management for complex cases. For example, patients on long-term opioids could be tracked and offered support as needed to schedule and adhere to ancillary multidisciplinary care (e.g., physical therapy) and to insure that opioid prescriptions are not received in excess amounts or too soon. Some PCMH models even include onsite cognitive-behavioral counseling to help patients with mental health comorbidities. Overall, the PCMH uses the talents of providers from multiple disciplines to complement and augment the efforts of the physician.

In 2010, the TRICARE Management Activity (TMA) introduced the PCMH within selected clinics in Military Treatment Facilities. Within the first year, 655,000 of 9.5 million beneficiaries had enrolled in a PCMH program. At the current rate of growth, the TMA expects that as many as 3 million beneficiaries will enroll over the next few years. In September 2011, Wilford Hall Ambulatory Surgical Center became one of the initial four Air Force Military Treatment Facilities to incorporate the PCMH model throughout all of their specialty clinics. This initiative has great promise to provide the structure and expertise needed to improve the quality and safety of care for patients with chronic pain and who require longer-term opioid therapy.

Develop a Comprehensive Prescription Monitoring Program

The military has clear advantages over the fragmented health care system of the civilian sector because its CD-MART can be expanded to establish a national military PMP. Such a program would have distinct advantages over current state-based PMPs. For example, the military health care data system permits linkage between pharmacy data and electronic medical record data, including diagnosis, treatment, and clinical outcomes. These combined data sources offer a valuable resource to develop accurate approaches to predict misuse.

CONCLUSION

Although the full extent of opioid misuse and its relationship to opioid-prescribing practices in the military has not been well examined, it is clear that opportunities to improve outcomes abound. Rather than taking a piecemeal approach, a multipronged evidence-based approach can take advantage of strategies from both the civilian and the military sectors to develop effective systems to care for chronic pain, manage opioid prescribing, and reduce opioid misuse. In support of this, we described several examples of risk mitigation strategies, military, and civilian.

The military also has a unique opportunity to serve as a leader in innovative approaches to safer opioid prescribing and more effective pain management. The MHS is a universal health care system offering comprehensive, coordinated

care with a history of using systematic approaches to address health problems in its active duty members and their families.

Currently, the military medical system is at a tipping point in regards to opioid prescribing and OA misuse. Opioid risk mitigation strategies provide a foundation for identifying effective solutions to the dual objectives of treating pain effectively and protecting access to opioids for those in pain while improving patient safety and reducing adverse effects.

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