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Fort Bragg: Risk Mitigation in Chronic Opioid Therapy for Pain

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Abstract

Phase II Site: Womack Army Medical Center, Fort Bragg, NC

DNP Project Title: Fort Bragg: Risk Mitigation in Chronic Opioid Therapy for Pain in Primary Care

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Background: Millions of people suffer from chronic non-cancer pain (CNCP). Many of those patients receive chronic opioid therapy. In the military, the risk of chronic pain increases due to service-related injuries. To address the safety concerns related to opioid use, the VA/DoD published an evidence-based Clinical Practice Guideline (CPG) on the management of chronic pain and safe opioid prescribing practices. The use of risk mitigation strategies decreases the adverse outcomes related to chronic opioid use, including opioid misuse, abuse, respiratory depression, and death.

Purpose: To review the use of risk mitigation strategies for patients on chronic opioid therapy for pain in primary care at Fort Bragg and compare it to the 2017 VA/DoD Chronic Opioid Therapy for Pain CPG.

Project Design: A review of the literature focused on articles addressing clinical guidelines for CNCP, opioid therapy, and risk mitigation, including articles cited in the CPG. Articles were evaluated for rigor and recommendations for the risk mitigation strategies of UDT, co-prescription of naloxone, and co-prescription of benzodiazepines were compared. A retrospective chart review of patients currently on opioid therapy for CNCP assessed the use of UDT, naloxone, and benzodiazepine co-prescription. The results of the chart review were compared to both the CPG recommendations and the findings of the literature review.

Organizational Impact/Implications for Practice: Review of more recent literature supports the CPG recommendations. Results of chart review demonstrate that risk mitigation strategies were more consistently evident within the military treatment facility when compared to care received in the civilian network. Benzodiazepine co-prescription with opioids was low. Over 75 percent of patients received naloxone prescription consistent with guidelines. Use of UDT was inconsistent, which is partially attributable to vague guidelines. An incidental finding was that many active duty service members who were treated for chronic pain with opioids did not have a current physical profile.

Fort Bragg: Risk Mitigation in Chronic Opioid Therapy for Pain

The opioid epidemic, declared a public health emergency by the Department of Health and Human Services in 2017, continues to be a cause for concern and must be addressed to ensure the health and safety of the American people. Over 100 million Americans suffer from chronic non-cancer pain each year (Institute of Medicine, 2011), with an estimated 20 percent of these patients presenting to primary care each year to receive opioid therapy. The number of opioid prescriptions has increased 7.3 percent from 2007 to 2012, with the most significant increase in prescriptions originating in the areas of family practice, general practice, and internal medicine (Center for Disease Control and Prevention (CDC), 2016).

The primary benefit of using opioids for chronic pain is an improvement in the quality of life for patients. A survey of patients on long-term prescription pain medication performed by the Washington Post and Kaiser Family Foundation explored the perspectives of patients and their household members. More than half (57 percent) of the patients surveyed felt that long-term prescription painkillers improved their quality of life (DiJullo, Wu, & Brodie, 2016). Chronic opioid therapy (COT) does, however, pose several risks to patients. The harms of long-term opioid use are well documented and are a growing concern both in the general public and the Military Health System (MHS). Patients using opioids for chronic pain are at an increased risk for substance misuse, abuse, and death from an accidental overdose. With the steady increase of opioid prescriptions in the United States, there has also been an increase in deaths related to pharmaceutical opioids. Mortality from opioid overdose is often related to respiratory depression. Between 1997 and 2017, the CDC estimates that opioids were involved in approximately 400,000 deaths from overdose (CDC, 2019). Deaths from prescription opioids

have increased 2.8-fold from 2002 to 2015, accounting for over 22,000 deaths in 2015 alone (National Institute on Drug Abuse, 2018).

To address the safety concerns related to long-term opioid use for pain, the Department of Veterans Affairs (VA) and the Department of Defense (DoD) developed an evidence-based Clinical Practice Guideline (CPG) to advise providers on the management of chronic pain and safe opioid prescribing practices (VA and DoD, 2017). One of the expected outcomes of this CPG is minimizing preventable morbidity and mortality related to opioid use through a group of risk mitigation strategies. Included in these recommendations are the co-prescription of rescue naloxone, not prescribing opioids to patients who use benzodiazepines, and regular urine drug screening to screen for misuse and abuse (VA and DoD, 2017). Adoption of the CPG's risk mitigation strategies results in the appropriate management of chronic pain and decreases the adverse outcomes associated with the already existing national epidemic (Toblin, Quartana, Riviere, Walper, & Hoge, 2014).

Significance of the Problem

Impact on the Military Health System

The military is not immune to the opioid crisis; thousands of service members are on chronic opioid therapy. Military personnel are more prone to chronic pain than the civilian population, with rates approaching nearly 44 percent versus percent, respectively. The hazards of duty, combat exposure, extended work hours, and demanding physical activity place military personnel at a higher risk for chronic pain (Toblin et al., 2014). Additionally, service members are at increased risk of developing psychiatric trauma symptoms and comorbid chronic musculoskeletal pain conditions (McGreary, McGreary, Moreno, and Gatchel, 2016). As a result, opioid prescriptions for chronic pain management have increased dramatically in the

MHS and have subsequently been accompanied with increases in opioid overdose, abuse, addiction, and diversion (Chou, et al., 2015). This has significantly increased the financial burden on the MHS through management of the side effects of the medications and acute care due to overdose. Contributing factors to the current opioid epidemic are multifactorial and related to variation in care, provider unfamiliarity with available resources in managing chronic pain, and current knowledge gaps in pain management evidence-based practice (EBP) (Office of the Surgeon General et al., 2010). The VA/DoD CPG describes several risk mitigation strategies that strive to promote safe prescribing practices and increase patient safety. This project will focus on only three of the strategies: urine drug screening, co-prescription of naloxone, and avoidance of concurrent use of benzodiazepines and opioid therapy (VA and DoD, 2017). Due to the significant impacts that the mismanagement of opiate therapy could have on individual and military unit preparedness, the use of these strategies is necessary for maintaining the highest readiness and lethality of the fighting force.

Impact to Fort Bragg

Fort Bragg is the largest military base by population, supporting over 50,000 troops and over 90,000 others, including family members, Department of the Army Civilians, and contractors (Fort Bragg, 2019). Units on Fort Bragg include the XVIII Airborne Corps, the 82nd Airborne Division, US Army Special Operations Command, the Joint Special Operations Command, and is home to the Special Operations Qualification Course (Fort Bragg, 2018). Units conduct rigorous training activities to maintain readiness for instant high mobility world-wide deployed operations. Injuries from training and multiple deployments predispose service members to chronic pain. When treated with opioids, the management of chronic pain could significantly impact the operability of the soldier and his unit's mission by limiting the

deployability of these individuals. The United States Central Command (USCENTCOM) MOD 13 lists narcotics and narcotic combinations as deployment-limiting medications requiring a waiver (USCENTCOM, 2017). A duty limiting medical profile is also mandated for soldiers on opioids for the duration of the therapy per Executive Order (EXORD) 224-17 (Headquarters, Department of the Army, 2017).

Clinical Question

The purpose of this project was to review the use of risk mitigation strategies for patients on chronic opioid therapy for pain in primary care at Fort Bragg and compare it to the 2017 VA/DoD Chronic Opioid Therapy for Pain CPG. The clinical inquiry this project sought to answer is: in military beneficiaries aged 18-65, how did the management of patients receiving chronic opioid therapy in the Fort Bragg healthcare system compare to the 2017 VA/DoD Chronic Opioid Therapy for Pain Clinical Practice Guideline (CPG)?

Focus Areas

This project has three focus areas. The first focus area is a review of the CPG recommendations that address risk mitigation in chronic opioid therapy for pain. The second is a review of the literature to determine if there is current evidence to update the recommendations regarding risk mitigation strategies. The third focus is a retrospective assessment of the current use of risk mitigation in patients on chronic opioid therapy managed in Womack Army Medical Center (WAMC). The first aim was a review of selected recommendations in the 2017 VA/DoD CPG that specifically address risk mitigation. For this project, the author selected three recommendations. Recommendation Three advises ongoing risk mitigation strategies and assessment for opioid use disorder. Recommendation Five cautions against the concurrent use of chronic benzodiazepines and opioids. Recommendation Seven advocates the use of risk

mitigation strategies on the initiation of long-term opioid therapy. This project assessed adherence to these recommendations by evaluating the use of the following risk mitigation strategies: avoidance of benzodiazepine co-prescription, naloxone co-prescription, and urine drug testing in patients on chronic opioid therapy.

Benzodiazepine co-prescription. Benzodiazepines are central nervous system (CNS) depressants often used in the treatment of insomnia and anxiety. They are helpful for short-term management due to their sedative effect. The combination of benzodiazepines and other CNS depressants, such as opioids, has been shown to increase the risk of overdose and death (Park, Saitz, Ganoczy, Ilgen, & Bohnert, 2015; VA and DoD, 2017). Due to the potentially fatal combination of these medications, they should not be prescribed together, and patients should be promptly tapered off of one or both. If the medications must be used together, lower doses of both should be used. The military population is more prone to developing psychiatric symptoms coupled with chronic pain syndromes that may lead providers to contemplate prescribing benzodiazepines, while on opioid therapy for pain (McGreary et al., 2016). Given the severity of co-prescribing opioids and benzodiazepines, adherence to Recommendation Five of the CPG is imperative as the risks often outweigh the benefits.

Naloxone co-prescription. Community-based distribution programs of naloxone, a short-acting opioid antagonist used to reverse an opioid overdose, has been associated with a decrease in opioid-related deaths (Behar, et al., 2017). To address potential harmful side effects of opioids and increased risk of overdose, the CDC recommends that primary care providers consider offering a naloxone prescription to patients at a higher risk for overdose (i.e., patients prescribed 50 MED or more per day, co-prescribed benzodiazepines, or history of substance use

disorder) (CDC, 2016). The Department of Defense (DoD) and Department of Veterans Affairs (VA) also recommend prescribing take-home naloxone rescue kit in their CPG (VA/DoD, 2017).

Urine Drug Testing. Urine drug testing (UDT) is a useful tool for monitoring adherence to opioid therapy and assessing for substance use disorder, use of illicit substances, and diversion. A study by Ives et al. (2006) found that chronic pain patients had misuse rates higher than 30 percent, validating the necessity of utilizing urine drug screening as a means of management. Also, with the increased risk of morbidity and mortality from opioid misuse, urine drug screening promotes trust in the provider-patient relationship, strives to improve patient safety, and verifies adherence to the current regimen (VA and DoD, 2017).

The second aim was a review of the available literature to ensure that new evidence supports the recommendations in the CPG. The third aim was a retrospective chart review to evaluate the current care provided to patients on chronic opioid therapy, assessing adherence to selected risk mitigation strategies recommended by the CPG as well as findings from the literature review.

Relevance to Military Nursing

Improving adherence with evidence-based practices for the management of chronic pain patients can be instrumental in halting the progression of the opioid epidemic, reducing adverse outcomes of opioid use, decreasing healthcare costs, and maintaining the readiness of our total force (Schoneboom et al., 2016). The short-term goals of this project are to determine the current state of care provided to patients receiving chronic opioid therapy at Womack Army Medical Center and its outlying clinics and compare it to the available literature as well as the recommendations outlined in the VA/DoD CPG. The long term goals of this project are to increase awareness of the CPG recommendations, improve concordance with evidence-based

risk mitigation strategies, and influence local practice and policy to reflect the findings of the literature review.

Military service members are at higher risk of developing chronic pain due to the high operational demands of deployments and training. Provider adherence to evidence-based risk mitigation strategies for chronic pain patients on chronic opioid therapy in the MHS is imperative to limit the spread of the opioid epidemic and safeguard patients against risks such as dependence and overdose. The anticipated global impact is an increase in awareness of the management of chronic opioid therapy patients, improved patient safety, and decreased costs for the Fort Bragg primary care clinics. Appropriate use of opioid risk mitigation strategies will facilitate the delivery of highly-reliable healthcare and protect the mission readiness of patients seen in the Fort Bragg primary care clinics.

Organizing Framework

This project seeks to improve the quality of health care through provider utilization of risk mitigation strategies as recommended by the VA/ DoD CPG for opioid therapy for chronic pain (VA/DoD, 2017). The Johns Hopkins Nursing Evidence-Based Practice (JHNEBP) Model is a problem-solving approach to clinical decision-making. The model uses a three-part process to guide evidence-based care implementation and improve the care of patients (Dang & Dearholt, 2017). The framework of this model aligns well with the goals of this project.

The first part of the JHNEBP model is to define the problem and develop a clinical question. This part of the project was completed with the development of a clinical question and discussions with key stakeholders. The second part includes a thorough review of the available evidence and the development of recommendations for implementation into practice. This part will be a two-step process consisting of a review of the literature and a review of information

gathered during a retrospective record review. The third part of the model is the translation of evidence into practice. This part of the project will focus on identifying next steps regarding practice and policy changes as well as the dissemination of results (Dang & Dearholt, 2017).

Project Design

General Approach

The Defense Health Agency (DHA) will assume full administrative control of the MHS by October of 2021. The DHA recognizes the VA/DoD and CDC guidelines as best practice concerning risk mitigation for patients on chronic opioid therapy for pain. The DHA's Procedural Instruction on pain management and opioid safety in the (MHS) instructs military treatment facilities to follow the VA/DoD guidelines to promote opioid safety for patients on chronic opioid therapy for pain (DHA, 2018). Because the VA/DoD clinical practice guidelines are based upon the best available evidence, they will serve as the primary body of evidence to support this project (VA/DoD, 2017). An additional literature review with a focus on risk mitigation in patients who are on chronic opioid therapy for pain, particularly urine drug testing, co-prescription of naloxone, and co-prescription of benzodiazepines. Finally, the records of 50 active duty service members and family members will be reviewed to evaluate compliance with the CPG recommendations.

Setting

This project was conducted at Womack Army Medical Center, Fort Bragg, North Carolina, and its outlying clinics. Data were collected through a retrospective review of records using the military's electronic medical record, the Armed Forces Health Longitudinal Technology Application (AHLTA). Stakeholders at the facility were informed of this project and endorsed their support.

Procedural Steps

This project was designed to assess the current state of care around the problem-based trigger of the national opioid crisis. The topic was vetted through the WAMC Phase II site directors and key stakeholders, who validated that the problem was consistent with the location where the project will be taking place. Additionally, they confirmed that this clinical issue is a priority for the organization.

A review of the VA/DoD 2017 CPG on Chronic Opioid Therapy for Pain was conducted. For this project, recommendations three, five, and seven were selected due to their focus on risk mitigation in long-term opioid use. Recommendation three advises providers to use ongoing risk mitigation strategies for patients receiving opioids for their chronic pain. Recommendation five urges against combining benzodiazepines and opiates. Finally, recommendation seven advocates the use of specific risk mitigation strategies in the care of patients on chronic opioid therapy, including the co-prescription of naloxone and periodic urine drug testing (VA/DoD, 2017).

A literature review was conducted to compare current evidence to the recommendations of the CPG. The Cumulative Index to Nursing and Allied Health Literature (CINAHL), PubMed, and Google Scholar were utilized to identify articles for inclusion. The database searches focused on the concepts of clinical guidelines, chronic pain, opioids, and risk mitigation, using the following keywords: clinical guidelines, practice guidelines, chronic pain, chronic non-cancer pain, non-cancer pain, opioids, narcotics, controlled substances, risk mitigation, and risk management. Searches were limited to scholarly and peer-reviewed journal articles published in English after January 1, 2013, for CINAHL and PubMed, and after January 1, 2016, for Google Scholar. As of September 7, 2018, this search yielded 170 articles. Included in the literature review were articles cited as references for CPG recommendations three, five, and seven. There

were 34 articles cited in the CPG, yielding a total of 204 items for review, of which 13 duplicates were removed.

The titles and abstracts of the 191 articles were evaluated for inclusion. Inclusion criteria were articles that described or discussed the use of risk mitigation strategies in the care of patients on opioid therapy for chronic non-cancer pain. Exclusion criteria were articles that addressed pediatric or geriatric populations, acute pain, cancer pain, substance use disorder, and acute treatment of opioid-related overdoses in the emergency room setting. This title and abstract review excluded 140 articles. Fifty-one articles met the inclusion criteria for full-text review. The full-text review excluded additional articles due to not meeting inclusion criteria or rigor. The final literature review included 17 articles, of which eight related to Urine Drug Testing (UDT), nine related to naloxone co-prescription, and nine articles pertaining to benzodiazepine co-prescription. The results are presented in a PRISMA diagram (see Appendix G).

Finally, a retrospective review was conducted of the outpatient medical records on 50 patients taken from a list of patients aged 18-64 prescribed a Morphine Equivalent Dosage (MED) of 50 or higher between April and September 2018, generated by the CarePoint system. Patients who were on chronic opioids for cancer pain were excluded. Active duty service members and their family members were prioritized for inclusion in the sample due to the impact on individual and unit readiness. The remaining patients were randomly selected using a random number generator. The record review process consisted of a review of the medication list, laboratory results, and appointment history. The medication list was reviewed for opioid prescriptions including dosage and type, benzodiazepine co-prescription, naloxone co-prescription, and the dispensing pharmacy. Next, a review of laboratory results assessed for the presence of UDT results and frequency of testing. Primary care appointments and specialty care

appointments that addressed chronic pain or opioid use was determined through a review of previous encounters and the Health Artifact and Image Management Solutions (HAIMS) portal. Additionally, the ICD-10 code or codes associated with opioid prescriptions was recorded.

HIPAA Concerns (IRB)

This project focused on evaluating providers' adherence to the VA/DoD CPG for Opioid Therapy for Chronic Pain risk mitigation strategies. To assess adherence, medical records of patients treated for chronic pain in the primary care clinics on Fort Bragg was needed. This project was not designed to develop or contribute to generalizable knowledge and is therefore not considered research according to the Department of Health and Human Services Protection of Human Subjects. However, some laws applied to the information subject to review, notably the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The data reviewed will not be displayed or utilized other than assessing provider adherence to CPG recommendations.

Project Results

This project reviewed the electronic medical records of 50 chronic opioid patients. The record population included seven active duty service members, 38 family members of active duty service members, and five family members of retirees. Among the charts reviewed, the most common opioids prescribed were oxycodone (22 percent), oxycodone/acetaminophen (Percocet) (20.9 percent), and hydrocodone (9.3 percent). Most patients (64 percent) had more than one opioid for pain prescribed for pain.

The most common ICD-10 code associated with opioid prescriptions was G89.4, chronic pain syndrome (30.43 percent). The second most common code associated with opioid prescription was M54.5, low back pain (10.14 percent). Only three patients did not have documentation of an ICD-10 code related to opioid prescriptions (4.34 percent), and only one

chart had an opioid prescription associated with the ICD-10 code Z76.0, encounter for the issue of repeat prescription (1.44 percent).

Benzodiazepine Co-Prescription

The VA/DoD 2017 CPG recommends against concurrent use of benzodiazepines and opioids due to the increased risk of overdose and death from respiratory depression (NIDA, 2018b). There is moderate quality evidence that the harms of concurrent use of benzodiazepines and opioids outweigh the potential benefits. The authors of the CPG recognize that there is variation in patient preference and the acceptance of risk, especially in patients already receiving both medications. However, it emphasizes the potential adverse outcomes for initiating or continuing chronic opioid therapy in patients using chronic benzodiazepines. Further, the authors of the CPG recommend that the use of benzodiazepines be considered a contraindication to long-term opioid therapy (VA/DoD, 2017).

Nine of the articles included in the literature review discussed the co-prescription of opioids and benzodiazepines. Both the VA/DoD CPG and the literature caution against the combination of these two medications due to the increased risk of CNS depression and death from respiratory depression (VA/DoD, 2017; Manchikanti et al., 2017; CDC, 2016; Kaye et al., 2017; Park et al., 2015; Barth et al., 2017; Reisfeld et al., 2013; Peglow & Binswanger, 2018). To mitigate the risks associated with long-term opioid use, the recommendation is that patients prescribed both opioids and benzodiazepines also receive rescue naloxone kits (Manchikanti et al., 2017; CDC, 2016). Also, if both medications are considered essential, lower doses of both medicines should be used (Reisfeld et al., 2013). A complete evidence table for benzodiazepine co-prescription is available in Appendix H.

The co-prescription of benzodiazepines was assessed during the review of patients' medication lists. Patients were considered to be receiving chronic benzodiazepines if they had prescriptions for 90 consecutive days or longer. In the retrospective chart review, six (6) of the patients prescribed chronic opioids were also prescribed benzodiazepines (12 percent). Of the six patients with prescriptions for both medications, four (4) also had a record of rescue naloxone prescription. However, none (0) of those naloxone prescriptions were current. Naloxone prescriptions dispensed within the past 12 months were considered current.

Naloxone Co-Prescription

It is widely accepted that take-home naloxone is as an effective risk mitigation strategy to prevent death from an opioid overdose. The VA/DoD cites multiple studies and systematic reviews that support the use of take-home rescue naloxone as a life-saving intervention in the event of an opioid-related overdose. Naloxone co-prescription is further supported by the American Medical Association (AMA), the Substance Abuse and Mental Health Services Administration (SAMHSA), and other medical societies. The VA/DoD CPG recommends that take-home naloxone be offered to patients on chronic opioid therapy with moderate to strong evidence (VA/DoD, 2017).

Nine of the articles included in the literature review discussed the co-prescription of take-home naloxone as a risk mitigation strategy in chronic opioid therapy. The available literature is congruent with the CPG recommendation to offer naloxone to patients. The prescription of take-home naloxone is associated with a decrease in the number of emergency room (ER) visits for opioid-related overdoses and reduced overdose mortality (CDC, 2016; Walley et al., 2013; McDonald & Strang, 2016; Coffin et al., 2016; Wheeler et al., 2015). Providers should offer naloxone to patients receiving high doses of opioids (50 MED or higher), prescriptions from

multiple providers, co-prescribed benzodiazepines, a history of substance use disorder, and patients in the process of discontinuing opioids (Manchikanti et al., 2017; CDC, 2016; Kaye et al., 2017; Peglow & Binswanger, 2018). A complete evidence table on naloxone co-prescription is available in Appendix I.

In the chart review, the co-prescription of rescue naloxone kits was assessed by reviewing patients' outpatient medication lists. The most recent dispense date was recorded for all patients who had a rescue naloxone kit prescription on the outpatient medication list. If there was no record of naloxone dispensed, the chart review tool was marked "not applicable." Of the medical records reviewed, 38 out of 50 patients had received naloxone (76 percent). Of the 20 patients who had opioids dispensed by WAMC pharmacies, 19 also had a co-prescription of naloxone (95 percent). 30 patients who had opioids dispensed by network pharmacies, only 19 had a co-prescription of naloxone (63 percent). Per local policy as well as North Carolina state law, all prescriptions expire 12 months after being dispensed and no longer considered current. Of the records reviewed, 18 of 50 patients (36 percent) had a current order of naloxone. 20 patients who had opioids dispensed by WAMC pharmacies, nine out of 20 (45 percent) had a current naloxone prescription. For patients who had opioids dispensed from network pharmacies, nine of 30 (30 percent) had a current naloxone prescription.

Urine Drug Testing

The VA/DoD CPG recommends the use of random urine drug testing (UDT) as an additional method of assessing patients for adherence to the prescribed opioid regimen as well as a screening method for substance misuse. Because of the false positive and false negative rates associated with general urine drug screenings, availability of accurate and timely confirmatory testing is critical. The VA/DoD guidelines recommend gas chromatography-mass spectrometry

(GC-MS) or liquid chromatography-mass spectrometry (LC-MS) as the confirmatory testing method because they are highly sensitive and specific for opioid metabolites. The CPG recommends obtaining UDT results before initiating or continuing long-term opioid therapy and periodically after that at the provider's discretion (VA/DoD, 2017).

Eight (8) of the articles included in the literature review discussed the use of UDT as a risk mitigation strategy in chronic opioid therapy for pain. The literature supports the use of UDT for monitoring patients on chronic opioid therapy. Urine drug testing is useful for monitoring adherence to patient-provider pain contracts as well as screening for substance use disorder or the use of illicit substances (Manchikanti et al., 2017; CDC, 2016; Kaye et al., 2017; Starrels et al., 2010; Barth et al., 2017; Cone et al., 2014). The use of GC-MS or LC-MS is recommended for testing, with GC-MS being the gold standard for definitive testing (VA/DoD, 2017; Argoff et al., 2018). The frequency of UDT should be based on the patient's history, information from the Prescription Drug Monitoring Program (PDMP), and their risk for substance misuse or abuse based on a validated risk stratification tool (Manchikanti et al., 2017; Argoff et al., 2018; CDC, 2016; Starrels et al., 2010; Peglow & Binswanger, 2018; Cone et al., 2014). A complete evidence table on naloxone co-prescription is available in Appendix J.

In the retrospective chart review, a review of patients' laboratory results assessed for the presence of UDT results. The dates of test results were recorded to determine how many patients had a record of UDT results as well as how many times UDT was ordered annually. Additionally, the HAIMS database was reviewed, and dates of UDT results found in network providers' notes were recorded. During the chart review period, 22 patients (44 percent) had at least one UDT result recorded. Of those 22 patients, nine had one UDT result within the preceding 12 months, seven had two UDT results, and six had three or more UDT results in their

records. Twenty-eight patients (56 percent) had no UDT results available for review in their electronic health record.

Military Medical Readiness

Seven (7) active duty service members met the criteria for inclusion in the chart review. Five of the seven service members (71 percent) received their chronic pain management and chronic opioid prescriptions from off-post providers. None (0) of the service members had a co-prescription of benzodiazepines. While five of the seven service members had a record of rescue naloxone prescription, only two of the prescriptions were current and dispensed within the preceding 12 months. Three of the seven service members (43 percent) had a record of UDT in the past 12 months. Two of the seven service members with chronic opioid prescriptions (29 percent) had a current profile in the MEDPROS system as mandated by EXORD 224-17.

Analysis of the Results

The literature review found that current literature is mostly congruent with the 2017 VA/DoD CPG on chronic opioid therapy for pain. The articles in the literature review expanded on the risk mitigation strategies of naloxone co-prescription and urine drug testing. Articles recommended certain patient groups should be considered for naloxone co-prescription and listed potential criteria to be used to determine the frequency of urine drug testing. Overall, the recommendations for the risk mitigation strategies of avoidance of benzodiazepine co-prescription, naloxone co-prescription, and urine drug testing in patients on chronic opioid therapy are supported, and the use of these strategies is evidence-based practice.

Some trends stood out during the analysis of the chart review results. The most significant trend is that for patients who receive opioid prescriptions from WAMC generally had more consistent risk mitigation utilized in their plan of care. This finding was especially true of

naloxone co-prescription. The majority of patients receiving opioids from WAMC pharmacies had an initial prescription for take-home naloxone. However, it is noted that rates of naloxone dispensing were lower when looking at current prescriptions, defined as being dispensed within the past 12 months.

One other trend that raised concern was military readiness. Most of the active duty service members received chronic opioid therapy from off-post providers. Similar to the dependent population, the majority of patients had naloxone co-prescribed. However, only two service members had a current naloxone prescription. Additionally, only two service members had active profiles in the MEDPROS system for their opioid prescriptions. This finding represents a significant concern for individual and unit readiness.

Organizational Impact

The intended impact of this project was to improve military readiness at the individual and unit level, decrease overall healthcare costs, and improve healthcare outcomes. The routine use of risk mitigation strategies in patients on long-term opioids is associated with reduced a risk of overdose and opioid-related morbidity and mortality. A decrease in morbidity and mortality translates to improved patient outcomes as well as a reduction of costs to the WAMC organization.

The results of this project were presented to the leadership of Womack Army Medical Center with recommendations for improvement. Suggestions were to perform a needs assessment of primary care providers and develop annual face-to-face training for providers on chronic pain and opioid therapy; this training would augment the already existing DHA computer-based safe opioid prescriber training. Additional recommendations were made to update the naloxone policy to renew prescriptions without having to dispense a new kit. The Chief of Pharmacy was present

for the presentation and validated the findings of this project. He also recognized that while WAMC has been successful in initially prescribing and dispensing take-home naloxone rescue kits to patients, there has been difficulty in tracking patients whose kits have not expired and do not require a new kit to be dispensed but have a prescription that has expired. Another recommendation was to add a policy regarding urine drug testing for chronic opioid patients that included criteria that could be used by the primary care provider to determine a patient's risk for substance misuse (i.e., history of substance abuse, coexisting mental health diagnosis and severity of symptoms, MED).

The final recommendations made to the command were regarding military readiness. The first recommendation was to recapture active duty service members and active duty family members who are on chronic opioid therapy back into the WAMC system. The findings of the chart review demonstrate that WAMC provides more consistent risk mitigation practices to patients compared to the civilian network. Due to the direct impact the care of these beneficiaries has on individual and unit readiness, it is imperative to ensure these patients are recaptured into the WAMC network. The second recommendation was to redistribute EXORD 224-17 on the profiling of active duty service members using opioids, with a performance improvement (PI) project to track and improve compliance with the EXORD. These profiles not only protect the service members but also inform commanders of the status of their soldiers and the readiness of their units to deploy.

Implications for Practice & Policy

This project confirmed that the current literature is mostly in concordance with the recommendations of the VA/DoD CPG regarding risk mitigation strategies in chronic opioid therapy for pain. There is some room for additions to the CPG recommendations regarding

naloxone co-prescription and the frequency of UDT in patients on chronic opioid therapy. Currently, the MHS uses the Risk Index for Overdose or Serious Opioid-induced Respiratory Depression (RISORD) as the primary criteria to offer and dispense take-home naloxone kits to chronic opioid patients (DHA, 2018). Womack AMC's Pharmacy Department has a standing order allowing pharmacists to use the RISORD to assess the patient on chronic opioids for risk of overdose, dispense naloxone, and provide education on overdose recognition and naloxone administration (WAMC, 2017).

A significant finding of the retrospective chart review is that patients who receive chronic opioids from WAMC pharmacies are more likely to have a take-home rescue naloxone kit. There is a need to determine how to document when a patient is offered naloxone and refuses, and when a prescription needs to be renewed without a new kit being dispensed. However, the standing order for pharmacists to assess patients for risk of overdose and opioid-induced respiratory depression and dispense naloxone is a best practice. The policy used by Womack AMC pharmacies should be implemented throughout the MHS to ensure beneficiaries are receiving this life-saving, evidence-based intervention to mitigate the risks of chronic opioid therapy.

Most chronic pain and chronic opioid patients can and should be managed by primary care providers. The treatment and management of chronic pain are similar to other chronic diseases and conditions, requiring a multimodal approach that includes lifestyle changes, complementary therapies, and medications, with appropriate consultations to pain specialists and clinical pharmacists. With further education and exposure to patients with the condition of chronic pain, particularly those using long-term opioids, primary care providers will become proficient in managing this low-volume but high-risk population.

Future Directions for Research and Practice

As recommended to Womack AMC's leadership team, the development of a policy for determining the frequency of urine drug testing in chronic opioid therapy patients is essential to ensuring the delivery of evidence-based care. The policy should include the development of a risk stratification system to determine a minimum frequency for testing (i.e., annually, every six months). The literature recommends either specified criteria or the use of a validated tool. A possible future direction for research is the development and validation of a risk stratification tool or the validation of criteria to stratify a patient's risk for substance misuse or abuse. Another EBP project could identify an already established risk stratification tool for use at WAMC. Also recommended to WAMC leaders was a needs assessment of primary care providers to assess their comfort level regarding the management of patients with chronic pain and chronic opioid therapy. Then using this needs assessment, the development or use of an education program through PI or EBP to address the education needs identified. Since opiate misuse is a national concern, a similar needs assessment of providers throughout the MHS can determine what further education needs exist in the primary care provider population on a national scale.

There were two gaps noted during the literature review. The first is regarding take-home naloxone programs. Almost all of the articles discussed or cited community-based studies and programs. There is less evidence regarding take-home naloxone programs based in the primary care setting. Future research could assess the effectiveness of primary care-based take-home naloxone programs.

Similarly, while the literature supports all of the risk mitigation strategies, the effectiveness of those strategies, particularly urine drug testing and avoidance of benzodiazepines, in preventing opioid misuse and abuse has not been studied. Further, there is a

gap in the literature regarding the direct effect that primary care-based risk mitigation strategies have on opioid-related morbidity and mortality. This gap represents an opportunity for future research as well.

Limitations

There were two significant limitations to this project. The first was the limited information available during the retrospective chart review. Many of the patients included in the chart review are seen off-post for their chronic pain care; only 13 of the 50 patients (26 percent) received prescriptions for chronic opioids from WAMC providers. There is a known time lag between when a civilian network providers notes are acquired by outpatient records and when they are uploaded into HAIMS. A large number of those patients had either few or no notes from civilian providers in their records, making it difficult to assess the frequency of urine drug testing. The second limitation was the limited scope of the retrospective chart review regarding benzodiazepine co-prescription. This project was limited to determining the presence of benzodiazepine prescriptions in patients who were on chronic opioid therapy for pain. A more in-depth review of the patients prescribed both opioids and benzodiazepines is needed to determine whether appropriate patient education and risk mitigation was included as a part of their care plan.

Conclusion

The primary benefit of chronic opioid therapy for pain is the improvement in the quality of life for patients suffering from chronic pain. While chronic opioid therapy may improve the quality of life for patients, it poses several risks. The harms of long-term opioid use are well documented and are a growing concern. Patients using opioids for chronic pain are at an increased risk for substance misuse, abuse, and death from an accidental overdose. In the

military, soldiers are more prone to chronic pain than the civilian population due to the hazards associated with duty, training, and combat exposure. Chronic opioid therapy is a significant concern to readiness due to the associated risks, and risk mitigation strategies are crucial in the care of MHS beneficiaries.

This project assessed the use of risk mitigation strategies in patients on chronic opioid therapy, specifically the avoidance of benzodiazepine co-prescription, urine drug testing, and the co-prescription of take-home naloxone. The results of the project demonstrate that care provided by the MTF was more congruent with the literature and the CPG, and patients had more consistent risk mitigation strategies utilized in their care. Patients receiving chronic opioid prescriptions from WAMC are more likely to have had naloxone co-prescribed (95 percent versus 63 percent) and more likely to have UDT results in their chart (65 percent versus 30 percent) than patients receiving opioid prescriptions in the civilian network. It was also noted that active duty personnel are inconsistently profiled in the MEDPROS system, representing a lack of compliance with Army policy. These findings represent a significant gap in care and communication with commanders that could potentially place soldiers at risk and threaten units' mission readiness. For these reasons, active duty service members must be recaptured into the WAMC network.

This project has the potential to springboard future policy and practice changes as well as further research in the area of chronic pain and long-term opioid therapy management in the primary care setting. The findings have identified several potential PI projects, including the improvement of compliance with EXORD 224-17 and a needs assessment of primary care providers that would drive the development of provider education. Further research and PI

initiatives will enhance the care MHS beneficiaries receive and will result in a stronger and more lethal force.

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Appendix A

CITI Certificate

COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

COMPLETION REPORT - PART 1 OF 2
COURSEWORK REQUIREMENTS*

* NOTE: Scores on this Requirements Report reflect quiz completions at the time all requirements for the course were met. See list below for details. See separate Transcript Report for more recent quiz scores, including those on optional (supplemental) course elements.

- **Name:** Lisa Bowers (ID: 5747057)
- **Email:** lisa.bowers@usuhs.edu
- **Institution Affiliation:** Office of the Under Secretary of Defense (Personnel and Readiness) (ID: 603)
- **Phone:** 732-986-2721

- **Curriculum Group:** OUSD P&R Human Research
- **Course Learner Group:** Biomedical Investigators and Research Study Team
- **Stage:** Stage 1 - Biomedical Investigators

- **Report ID:** 20637534
- **Completion Date:** 31-Aug-2016
- **Expiration Date:** 31-Aug-2019
- **Minimum Passing:** 80
- **Reported Score*:** 83

REQUIRED AND ELECTIVE MODULES ONLY	DATE COMPLETED	SCORE
Avoiding Group Harms - U.S. Research Perspectives (ID: 14080)	29-Aug-2016	3/3 (100%)
Recognizing and Reporting Unanticipated Problems Involving Risks to Subjects or Others in Biomedical Research (ID: 14777)	31-Aug-2016	3/5 (60%)
Populations in Research Requiring Additional Considerations and/or Protections (ID: 16680)	31-Aug-2016	4/5 (80%)
Module for Non-DoD Personnel Conducting Research Involving Human Subjects Supported by the DoD (ID: 16769)	31-Aug-2016	No Quiz
History and Ethics of Human Subjects Research (ID: 498)	31-Aug-2016	7/7 (100%)
Basic Institutional Review Board (IRB) Regulations and Review Process (ID: 2)	31-Aug-2016	5/5 (100%)
Informed Consent (ID: 3)	31-Aug-2016	5/5 (100%)
Social and Behavioral Research (SBR) for Biomedical Researchers (ID: 4)	31-Aug-2016	4/4 (100%)
Records-Based Research (ID: 5)	31-Aug-2016	2/3 (67%)
Genetic Research in Human Populations (ID: 6)	31-Aug-2016	3/5 (60%)
Vulnerable Subjects - Research Involving Children (ID: 9)	31-Aug-2016	3/3 (100%)
Vulnerable Subjects - Research Involving Pregnant Women, Human Fetuses, and Neonates (ID: 10)	31-Aug-2016	2/3 (67%)
FDA-Regulated Research (ID: 12)	31-Aug-2016	4/5 (80%)
Conflicts of Interest in Research Involving Human Subjects (ID: 488)	31-Aug-2016	3/5 (60%)
Office of the Under Secretary of Defense (Personnel and Readiness) (ID: 912)	31-Aug-2016	No Quiz
Stem Cell Research Oversight (Part II) (ID: 14584)	31-Aug-2016	4/5 (80%)

For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution identified above or have been a paid independent Learner.

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CITI Program
Email: support@citiprogram.org
Phone: 888-529-5929
Web: https://www.citiprogram.org

COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

COMPLETION REPORT - PART 2 OF 2
COURSEWORK TRANSCRIPT**

** NOTE: Scores on this Transcript Report reflect the most current quiz completions, including quizzes on optional (supplemental) elements of the course. See list below for details. See separate Requirements Report for the reported scores at the time all requirements for the course were met.

- **Name:** Lisa Bowers (ID: 5747057)
- **Email:** lisa.bowers@usuhs.edu
- **Institution Affiliation:** Office of the Under Secretary of Defense (Personnel and Readiness) (ID: 603)
- **Phone:** 732-986-2721

- **Curriculum Group:** OUSD P&R Human Research
- **Course Learner Group:** Biomedical Investigators and Research Study Team
- **Stage:** Stage 1 - Biomedical Investigators

- **Report ID:** 20637534
- **Report Date:** 31-Aug-2016
- **Current Score**:** 83

REQUIRED, ELECTIVE, AND SUPPLEMENTAL MODULES	MOST RECENT	SCORE
History and Ethics of Human Subjects Research (ID: 498)	31-Aug-2016	7/7 (100%)
Informed Consent (ID: 3)	31-Aug-2016	5/5 (100%)
Social and Behavioral Research (SBR) for Biomedical Researchers (ID: 4)	31-Aug-2016	4/4 (100%)
Records-Based Research (ID: 5)	31-Aug-2016	2/3 (67%)
Genetic Research in Human Populations (ID: 6)	31-Aug-2016	3/5 (60%)
Vulnerable Subjects - Research Involving Children (ID: 9)	31-Aug-2016	3/3 (100%)
Vulnerable Subjects - Research Involving Pregnant Women, Human Fetuses, and Neonates (ID: 10)	31-Aug-2016	2/3 (67%)
FDA-Regulated Research (ID: 12)	31-Aug-2016	4/5 (80%)
Office of the Under Secretary of Defense (Personnel and Readiness) (ID: 912)	31-Aug-2016	No Quiz
Conflicts of Interest in Research Involving Human Subjects (ID: 488)	31-Aug-2016	3/5 (60%)
Avoiding Group Harms - U.S. Research Perspectives (ID: 14080)	29-Aug-2016	3/3 (100%)
Basic Institutional Review Board (IRB) Regulations and Review Process (ID: 2)	31-Aug-2016	5/5 (100%)
Stem Cell Research Oversight (Part II) (ID: 14584)	31-Aug-2016	4/5 (80%)
Recognizing and Reporting Unanticipated Problems Involving Risks to Subjects or Others in Biomedical Research (ID: 14777)	31-Aug-2016	3/5 (60%)
Populations in Research Requiring Additional Considerations and/or Protections (ID: 16680)	31-Aug-2016	4/5 (80%)
Module for Non-DoD Personnel Conducting Research Involving Human Subjects Supported by the DoD (ID: 16769)	31-Aug-2016	No Quiz

For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution identified above or have been a paid independent Learner.

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Collaborative Institutional Training Initiative (CITI Program)
Email: support@citiprogram.org
Phone: 888-529-5929
Web: https://www.citiprogram.org

Appendix B

USU (VPR) Form 3202N

USU
Uniformed Services University

OFFICE OF RESEARCH
4301 JONES BRIDGE ROAD
BETHESDA, MAYLAND 20814
PHONE: (301) 295-3303; FAX: (301) 295-6771

NOTICE OF PROJECT APPROVAL

Change Number: Original

VPR Site Number:	GSN-61-10348
Principal Investigator:	del Rio, Nathan
Department:	Graduate School of Nursing
Project Type:	Student
Project Title:	Implementing a clinical practice guideline compliance report at Fort Bragg and Lacland AFB
Project Period:	1/18/2019 to 4/30/2019

Assurance and Progress Report Information:

Name	Sup	Approval Type	Status	Approved On	Forms Received
Progress Report	0			To be Submitted	N/A

Remarks:
This Notice of Project Approval has been reviewed and approved. Please remember that you must submit a final Progress Report (Form 3210) upon completion of this project.

Questions regarding this approval should be directed to the following person in the Office of Research:
Sharon McIver, (301) 295-9814.

[redacted] 11 Feb 2019

Yvonne T. Maddox, Ph.D. Date
Vice President for Research
Uniformed Services University of the Health Sciences

cc: del Rio, Nathan
File

Appendix C

MTF IRB Letter of Determination

DEPARTMENT OF THE ARMY
WOMACK ARMY MEDICAL CENTER
2817 REILLY ROAD
FORT BRAGG, NORTH CAROLINA 28310-7324

MCXC-DQS 17 October 2018

MEMORANDUM FOR MAJ Louis Magyar, AN, Assistant Professor, Uniformed Services University of the Health Sciences and Director, Doctor of Nursing Practice Phase II Program, Womack Army Medical Center (WAMC), 2817 Reilly Road, Fort Bragg, NC 28310-7301

SUBJECT: Determination for Project, "Improving Adherence to Clinical Practice Guidelines Risk Mitigation Strategies in Chronic Pain Management," WAMC Protocol Number 181002

1. The subject project was reviewed for applicability of human subjects protection regulations.

2. This project is an evidence based process improvement project to evaluate chronic pain management adherence to the clinical practice guideline and making evidence-based recommendations to WAMC key stakeholders. Although the evaluation is systematic it is not designed or intended to contribute to generalizable knowledge.

3. The undersigned has determined the protocol does not meet the definition of research as defined by 32 CFR 219.102(d): a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

4. This project will be conducted by MAJ Lisa Bowers for partial fulfillment of the requirements of the DNP degree program. MAJ Magyar will provide oversight of this activity.

5. The project may proceed as described with no further requirement for regulatory review and cannot be presented as research in any resulting presentation or publication. If you have not already done so, you will need to obtain appropriate permission from any impacted departments before implementing this project.

6. In the event that there is a change to the project that might change this determination, a modification to the project must be submitted for review.

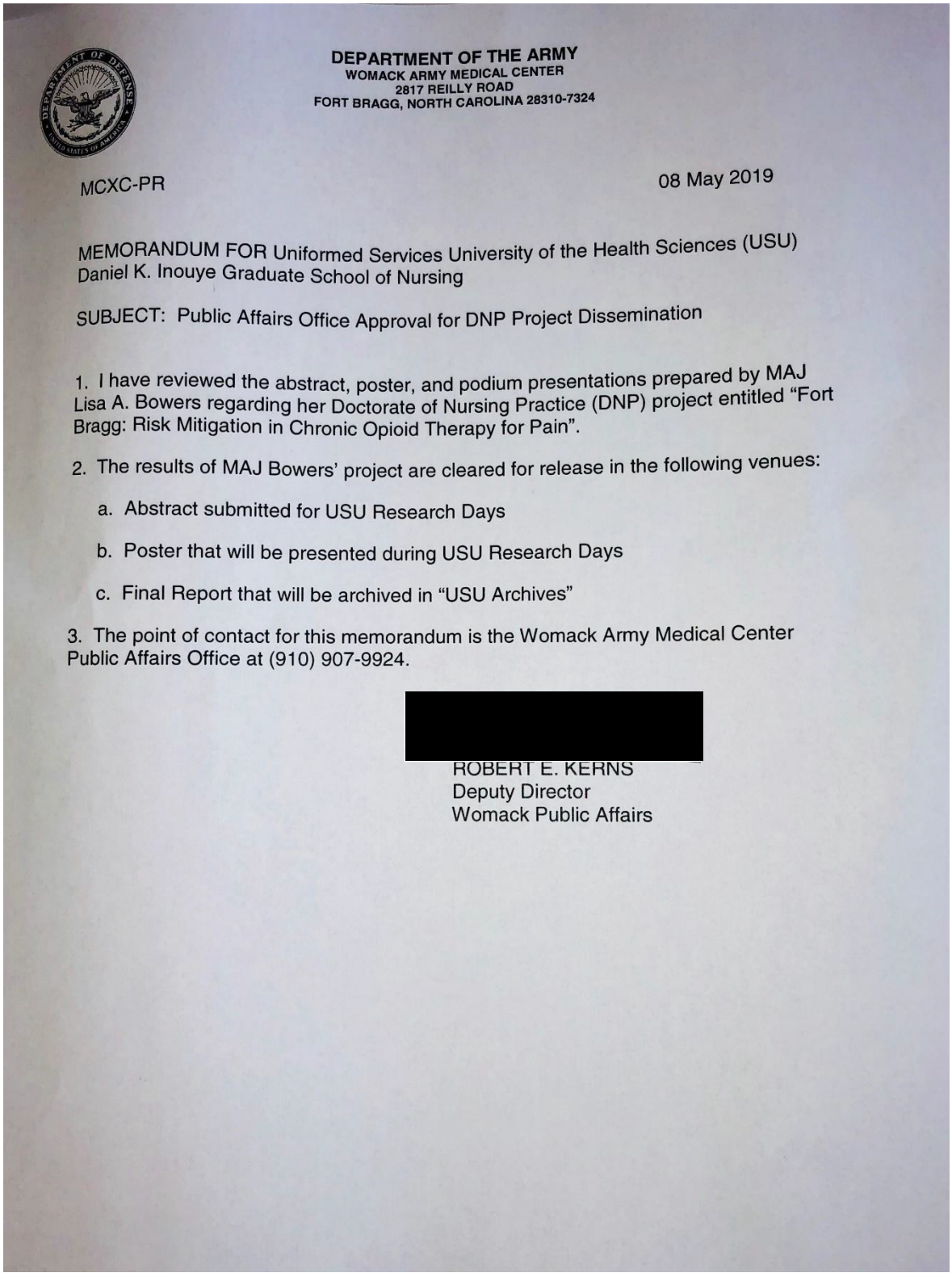
7. Point of contact for this action is the undersigned at 910-907-6307.

[redacted]

CARYN L DUCHESNEAU, CIP
Director, Human Research
Protection Program

Appendix D

PAO Clearance



DEPARTMENT OF THE ARMY
WOMACK ARMY MEDICAL CENTER
2817 REILLY ROAD
FORT BRAGG, NORTH CAROLINA 28310-7324

MCXC-PR

08 May 2019

MEMORANDUM FOR Uniformed Services University of the Health Sciences (USU) Daniel K. Inouye Graduate School of Nursing

SUBJECT: Public Affairs Office Approval for DNP Project Dissemination

1. I have reviewed the abstract, poster, and podium presentations prepared by MAJ Lisa A. Bowers regarding her Doctorate of Nursing Practice (DNP) project entitled "Fort Bragg: Risk Mitigation in Chronic Opioid Therapy for Pain".

2. The results of MAJ Bowers' project are cleared for release in the following venues:

   a. Abstract submitted for USU Research Days

   b. Poster that will be presented during USU Research Days

   c. Final Report that will be archived in "USU Archives"

3. The point of contact for this memorandum is the Womack Army Medical Center Public Affairs Office at (910) 907-9924.

[redacted]
ROBERT E. KERNS
Deputy Director
Womack Public Affairs

Appendix E

Chart Review Tool (Blank)

Record ID	Age	Sex	Ben Cat	Grade	MEDD Rx OCT	MEDD Rx SEP	MEDD Rx AUG	MEDD Rx JUL	MEDD Rx JUN	MEDD Rx MAY	Opioids Prescribed	ICD-10(s) Associated

Pharmacy	Last COT appt location	Last Primary Care Appt	Primary Care Clinic	Naloxone?	Naloxone Dispense Date	Benzodiazepine?	UDT date(s)?	AD Only: Profile?

Appendix F

DNP Project Completion Verification Form

Appendix G: Daniel K. Inouye Graduate School of Nursing
DNP Project Completion Verification Form

DOCTOR OF NURSING PRACTICE PROJECT
Completion Verification Form

The DNP Project titled: Fort Bragg: Risk Mitigation in Chronic Opioid Therapy for Pain was completed at Fort Bragg, North Carolina, by the following student(s):

(type student name)	*(signature)*	*(date)*
Lisa A. Bowers, MAJ, AN	[redacted]	18 April 2019

The DNP Practice Project Team verifies that the following components of the DNP project, accomplished by the above students, is of sufficient rigor and demonstrates doctoral level scholarship to meet the requirements for USUHS GSN graduation:

- Presentation of DNP project to the leadership/stakeholders at the Phase II Site,
- Abstract/Impact Statement (*Appendix F*), and
- DNP Project written report.

Verified by:

(type name)	*(signature)*	*(date)*	
Dr Heather Johnson	[redacted]	_____	Senior Mentor
MAJ Louis Magyar	[redacted]	19 April 2019	Team Mentor & Phase II Site Director

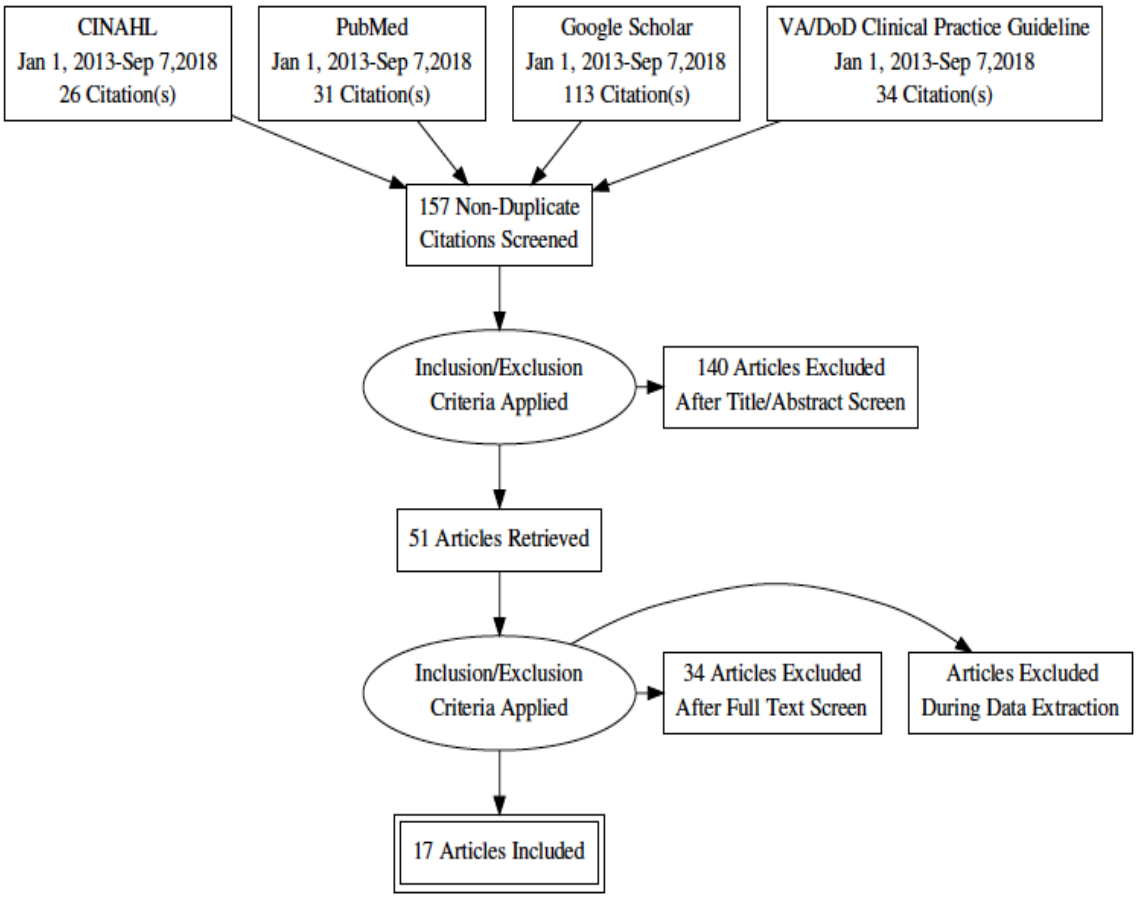
For RNA Students only *- add the following additional signature for final verification of project completion:*

_____	_____	_____
RNA Project Director *(type name)*	*(Signature)*	*(Date)*

Form Version: 26 Aug 2017

Appendix G

PRISMA Diagram



Appendix H

Evidence Table: Benzodiazepine Co-prescription

Author	Year	Article/ Study Type	Sample	Findings/Recommendations	Evidence Level	Quality
Manchikanti et al.	2017	CPG	19 articles	Patients receiving combinations of opioids and benzodiazepines should receive naloxone	I	A
CDC	2016	CPG	n/a	Avoid co-prescription. epidemiologic studies suggest that concurrent use of benzodiazepines and opioids may put patients at greater risk for potentially fatal overdose due to exacerbation of opioid-induced respiratory depression.	I	A
Kaye et al.	2017	Comprehensive Review	not stated	long-term benzodiazepine use indicates a higher abuse potential. Clinicians are strongly advised to avoid co-prescription	I	A
Park et al.	2015	Case cohort study	n=2400 veterans who died from a drug overdose while receiving opioids	30% of opioid-related deaths involved benzodiazepines. In US veterans, 49% or deaths from overdose while taking opioids died during a period of concurrent benzo prescription. Temazepam and alprazolam associated with increased toxicity compared with others. Temazepam associated with decreased risk compared to clonazepam.	IV	A
Turner & Liang	2015	retrospective cohort review	n=1,385 patients with diagnosis of overdose	odds ratio for overdose rose with daily opioid dose, highest in patients with depression and high opioid dose (>/= 100 MED). Risk of overdose rose increased with duration of benzodiazepine therapy	IV	A
Barth et al.	2017	Guideline Review	not stated	Guideline Review: most guidelines concordant that benzodiazepine co-prescription should be avoided, but not enough training for residents and providers	V	B
Reisfield et al.	2013	Commentary	not stated	20-50% of patients prescribed chronic opioids also receive benzodiazepines. The combination of benzodiazepines and opioids is potentially lethal. Near-absolute contraindications include active misuse, abuse, and addition. If both are essential (rare), doses of each should be lower	VII	B
Peglow & Binswanger	2018	Guideline Review	not stated	Combination of opioids and benzodiazepines places patients at a higher risk for overdose	I	B
Hawkins et al	2017	Anonymous Survey	n=55 primary care and n=31 mental health prescribers	over 80% of prescribers in both groups have concerns about concurrent use of benzodiazepines and opioids. Despite an agreement with CPGs prescribers report barriers to discontinuation: difficulty tapering, lack of time, patient stability on both medications without adverse effects	IV	A

Appendix I

Evidence Table: Naloxone Co-prescription

Author	Year	Article/ Study Type	Sample	Findings/Recommendations	Evidence Level	Quality
Manchikanti et al.	2017	CPG	n/a	Evidence suggests that opioid users can and will use naloxone to reverse opioid overdoses when properly trained. Patients receiving high dose opioids, prescriptions from multiple providers, or combinations of opioids and benzodiazepines should receive naloxone	I	A
CDC	2016	CPG	n/a	Naloxone should be offered if dosage reaches/exceeds 50 MED/day and patients taking benzodiazepines. No studies available on effectiveness for overdose prevention in chronic pain patients, but evidence of effectiveness in preventing death from overdose in community programs	I	A
Kaye et al.	2017	Comprehensive Review	not stated	Consider prescribing naloxone for patients with risk factors for opioid overdose (SUD, dosages more than 50 MED/day, concurrent benzo use	I	A
Walley et al.	2013	Interrupted Time Series Analysis	19 communities	2912 potential bystanders were trained, 327 reported rescues (primarily heroin overdoses). Communities with higher rated of trained bystanders had significantly reduced rate ratios compared with communities with no implementation. Differences in rates of acute care hospital utilization were not significant	IV	A
McDonald & Strang	2016	Systematic Review	22 studies	Take- home naloxone programs are found to reduce overdose mortality among participants and in the community with a low rate of adverse events	I	A
McAuley et al.	2015	Systematic Review/Meta-Analysis	25 studies	around 9% of naloxone kits distributed are likely to be used for peer administration within the first three months of supply for every 100 PWUD trained	I	A
Coffin et al.	2016	Non-randomized intervention	6 clinics, 1925 patients	Patients who received a naloxone prescription had 47% fewer opioid-related ED visits per month in the 6 months after naloxone Rx, and 63% fewer visits after 1 year compared with patients who did not receive naloxone.	III	A
Peglow & Binswanger	2018	Guideline Review	not stated	Optimal patient groups for naloxone have not yet been determined, consider in patients started on chronic opioid therapy and patients in the process of discontinuing (cited VA/DoD, CDC, Canadian guidelines)	VII	B
Wheeler et al.	2015	CDC Report	not stated	Providing naloxone kits to laypersons reduces overdose deaths, is safe, and is cost-effective. From 1996-2014, report of 26,463 overdose reversals based on survey of 136 organizations distributing naloxone.	VI	B

Appendix J

Evidence Table: Urine Drug Testing

Author	Year	Article/ Study Type	Sample	Findings/Recommendations	Evidence Level	Quality
Manchikanti et al.	2017	CPG	19 articles	UDT is useful for monitoring adherence. Should be used to establish a baseline measure of risk and monitor compliance. Use before initiating opioid therapy for chronic pain and at least annually. Follow up at the discretion of the clinician based on risk factor analysis/risk stratification: low, medium, high	I	A
Argoff et al.	2018	Comprehensive Review	6 recent CPGs, 41 references, expert panel	1. Use GC-MS, LC-MS, or LC-MS/MS. GC-MS is the gold standard of definitive testing, but LC-MS/MS is favored d/t less drug interference and smaller urine volume. 2. Frequency should be based on patient history, PDMP, and use of a validated tool for risk stratification (low, medium, high). 3. Frequency based on risk: all patients-annually, low-every 6 months to every 2 years, medium-1 to 3 x/year, high-2-4 x/year	I	A
CDC	2016	CPG	n/a	UDT provides information about drug use not reported by patients. Routine use of UDT may destigmatize their use. Use before starting opioids and periodically during use. No consensus on frequency, but more often for patients at a higher risk for SUD.	I	A
Kaye et al.	2017	Comprehensive Review	not stated	Useful for determining adherence, screening for illicit drug use, and identifying potential diversion. There is a need to enhance treatment after aberrant UDT results. No recommendation on frequency	I	A
Starrels et al.	2010	Systematic Review	11 studies	UDT is a valuable tool to detect the use of illicit/non-prescribed drugs. Adoption in primary care has been limited. Weak evidence, but there are theoretical benefits. UDT used at enrollment, annually, or both, more frequently at provider's discretion.	I	A
Barth et al.	2017	Guideline Review	not stated	Most guidelines concordant that UDT is useful, but not enough training for residents and providers	V	B
Peglow & Binswanger	2018	Guideline Review	not stated	Use UDT at the initiation of opioids and periodically throughout treatment.	I	B
Cone et al.	2014	Expert Opinion	not stated	UDT represents the most objective method for adherence monitoring. ASIPP guidelines: every 1-2 years for low risk, every 6-12 months for medium risk, every 3-6 months for high risk	VII	B