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Implementation and Evaluation of Whole Health Opioid Safety Shared Medical Appointments in

a Veteran Population: A Quality Improvement Study

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University of San Francisco

N789E DNP Project

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Acknowledgements

It is with sincere gratitude that I acknowledge my husband Frank for his unwavering kindness, patience, and support while I completed this late-in-life journey of obtaining my DNP. All glory goes to my Lord and Savior Jesus Christ who has provided me the drive, determination, and needed abilities to complete this challenging degree. My heartfelt thanks to Dr. Mary Lynne Knighten, my Chair, mentor, and friend, who helped me focus on the clinical significance that my project was making on the current and future lives of Veterans. A special thank you to Dr. Sara Horton-Deutch, who provided her expertise as my second reader. To my best friend Cheri, thank you for all the support, encouragement, and words of reassurance when I needed them. I would like to acknowledge my peers in Cohort 10, who proved to be a tremendous source of strength, friendship, and support throughout the entire program. Finally, I would like to recognize and thank the interdisciplinary staff and Veterans at the VA who I have had the privilege of working with throughout this program. My decision to return to the workforce after a 30-year Air Force career turned out to be a God-directed one, a true calling to give back to those who served, so that I can change the world from here!

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Abstract

Problem: The most recent data from the Centers for Disease Control and Prevention (CDC, 2018b) suggest that 130 Americans die from an opioid overdose each day, thus creating an unprecedented number of opioid-related deaths in the United States to date.

Context: Of particular interest to the author and this DNP project is that Veterans are twice as likely to die from an opioid overdose, compared to the average American, making this epidemic a priority for Veterans Health Administration (Wilkie, 2018).

Interventions: The author developed a 9-session Opioid Safety Shared Medical Appointment (SMA) program to reduce opioid reliance in Veterans using an 8-member interdisciplinary team. Comparisons were made of 90 participants who received training via Cohort I, comprised of 30 participants led by a patient-aligned care team (PACT) that met monthly over 9 months and included health coaching, to Cohort II, comprised of 30 participants led by a PACT team that met weekly over 9 weeks and excluded health coaching, to Cohort III (control), comprised of 30 participants who received training via routine, status quo, in-office education. The curriculum was based on a whole health model and introduced self-care modalities and opioid safety education. A comprehensive whole health toolkit was developed containing resource materials and educational handouts for Veterans to use throughout the course of the opioid SMA.

Outcome Measures: Outcome measures for evaluation of this evidence-based project include morphine equivalent daily dose (MEDD), pain scores, and use of complementary alternative modalities (CAMs).

Results: Data analysis revealed the only cohort with a statistically significant reduction in MEDD was Cohort I with health coaching ($p < 0.0064$). Cohort II (without health coaching) did not have a significant reduction in MEDD ($p < 0.64$), but did have a significant reduction in pain

scores ($p < 0.02$) and a significant increase of CAMs ($p > .01$). Cohort III (control group in-office education) did not have a significant reduction in MEDD ($p < 0.88$) or pain scores ($p < 0.26$) and had no significant increase in the use of CAMs ($p < 0.33$). However, findings of this work across all three cohorts included clinically significant improvements in MEDD, pain scores, and use of CAMs.

Conclusions: Using whole health SMAs may provide an effective, evidenced-based, cost-effective approach to managing chronic pain, decreasing MEDD and pain scores, and increasing CAM use among Veterans. While results support the clinical significance of this model, findings warrant additional investigation.

Key words: *opioids, Veteran, Veterans Administration, reliance, whole health, shared medical appointments*

Introduction

Problem Description

The setting for this quality improvement (QI) project was the primary care (PC) outpatient clinic in a large tertiary Veterans Administration (VA) healthcare facility located in the state of Alabama, providing care for approximately 65,000 Veterans each year, with approximately 85,000 outpatient visits. All patients seen at the VA are adults, with a mean age of 65.5 years.

Opioid prescribing for the treatment and relief of chronic pain has risen precipitously over the last several decades, escalating the death toll of Americans dying from an opioid overdose to approximately 130 per day (Centers for Disease Control and Prevention [CDC], 2018b). In 2017 alone, more than 70,000 Americans died due to drug overdoses, which included both illicit drugs and legally prescribed opioids (National Institute on Drug Abuse [NIDA], 2019). The United States opioid crisis has reached critical mass, with approximately 4% of U.S. adults consuming opioids for chronic pain relief (Clark & Schumacher, 2017). Chronic pain has been reported by 50% of Veterans using the VA healthcare system (Gellad, Good, & Shulkin, 2017).

To illustrate the magnitude of the problem on a local level, in 2017, Alabama providers wrote 107.2 opioid prescriptions for every 100 persons, the highest prescribing rate in the nation, and almost twice the average U.S. rate of 58.7 prescriptions (NIDA, 2019). The State of Alabama experienced an 11% increase in death rates from opioids from 2016 to 2017 (NIDA, 2019). The latest available data at the facility where the study was conducted reported 12% of Veterans are on prescribed chronic opioids (Slack, 2018). VA patients on long-term opioids are required to sign an informed consent form for long-term opioid use (U.S. Department of Veterans Affairs,

2020). Included in the consent is information on the risks of long-term opioid use and the requirement for the Veteran to provide monthly urine drug screens. In the event a Veteran's urine drug screen contains illegal substances, the prescriber is required to immediately address the safety concerns regarding mixing illegal opioids with prescribed opioids. This change of practice DNP project was selected because healthcare teams and individual clinicians have been seeking solutions to end the opioid crisis, with limited success.

Although the national focus has been placed on identifying the cause of the opioid epidemic, little success has been achieved at developing a comprehensive approach to reducing reliance on powerful and addictive pain medications. Looking at the magnitude of this crisis, in 2017, illicit and prescribed opioids were responsible for 47,600 overdose deaths in the United States, 67.8% of all overdose deaths (CDC, 2017). Opioids have now surpassed firearms as the leading cause of accidental deaths in the United States (Siegel, 2018). Furthermore, Dasgupta, Beletsky, and Ciccarone (2018) reported that the United States and Canada lead the world in the highest per capita opioid consumption, with 41% of overdoses occurring in urban counties, 26% occurring in the suburbs, 18% occurring in small metropolitan areas, and 15% occurring in rural areas. In 2017 alone, an estimated 17.4% of the U.S. population was prescribed one or more opioids, with the average person receiving 3.4 prescriptions (CDC, 2018a). This evidence highlights the urgent need for a solution to the unacceptable opioid crisis facing our nation.

Earlier methods to address the opioid crisis, such as forced reductions, have been found to produce counteractive and unsafe results, necessitating alternative approaches to decrease opioid reliance (Joseph, 2019). Much debate and blame have transpired regarding how our nation ended up in an opioid crisis. To date, sustainable approaches to effectively reduce opioid reliance remain elusive.

To move toward a safer and patient-centered approach to reduce opioid reliance and improve the patients' quality of care, an interdisciplinary team brought together two emerging and effective modes of care. The whole health model was used within the context of a shared medical appointment (SMA) with a group of Veterans derived from a single provider's panel of patients. An SMA is a medical appointment where patients are seen by clinical staff in a group setting that combines education and discussion regarding self-management of a chronic condition or disease (Omogbai & Milner, 2018). The SMAs were 90-minute appointments and included opioid safety education using whole health concepts.

Available Knowledge

PICOT Question

Melnik, Ford, and Overholt's (2017) intervention template was used to develop the following population, intervention, comparison, outcome, time (PICOT) question for this change of practice DNP project: (P) For Veterans reliant on opioids, (I) what is the effect of shared medical appointments, with a full patient-aligned care team using a whole-person health approach and health coaching on opioid usage, pain scores, and use of complementary alternative modalities, (C) compared to education via office visits (T) over 12 months?

Search Methodology

The literature review to support this project was conducted from February 2019 to March 2020. To ensure the strongest and most relevant evidence, 90 articles were reviewed using the Johns Hopkins Nursing Evidence-Based Practice Guidelines and scoring system (Dang & Dearholt, 2018). This tool appraised the strength and quality of evidence found in each study and helped determine the inclusion and exclusion criteria for addressing the author's evidence-based practice question. The inclusion criteria included full-text articles, published in English, from

2014 to 2019. The search yielded 15 studies, which included research, non-research, and supportive studies (one editorial) that provided statistics and evidence on the opioid crisis. The articles were chosen based on their relevance to the QI topic and the strength of their evidence. To gain the strongest evidence, multiple databases were searched and included the Cochrane Library, PubMed, Cumulative Index to Nursing and Allied Health Literature (CINAHL) databases and evidenced-based journals. The search used the following keywords: *opioids*, *reliance*, *whole health*, *group appointments*, and *Veterans*. Inclusion criteria included articles from 2005 to 2020 from peer-reviewed journals and published in the United States. Exclusion criteria included book chapters and articles outside the United States.

Summary of Evidence

After reviewing the abstracts, 73 articles were excluded that failed to align with the study's scope and relevance. The final literature selection criteria were determined after reviewing the strength, weaknesses, limitations, and quality of the evidence; 15 articles demonstrated the best possible evidence upon which this intervention was based. The search resulted in four Level II A/B, seven Level III A/B, one Level IV A/B, and three Level V, A studies. The search revealed a noticeable gap in the literature pertaining to the use of a whole health approach and SMAs to address the opioid crisis or to decrease opioid usage in the Veteran population. Therefore, most articles were qualitative and geared toward QI initiatives and statistical data regarding the opioid crisis. A summary of results from the appraised evidence is included in an evaluation table (see Appendix A). Three themes emerged from the summary of evidence in the review of articles and research studies: (a) impact of the opioid crisis, (b) use of SMAs in clinical settings, and (c) past approaches and modalities to address the opioid crisis.

Impact of the opioid crisis. From 1999 to 2014, nearly 400,000 Americans died from an opioid overdose, including prescription and illicit opioids (CDC, 2017). The estimated total economic burden of prescription opioid misuse in our nation has skyrocketed to \$78.5 billion annually, which includes the cost of healthcare, addiction treatment, lost productivity, and criminal justice involvement (CDC, 2017). The following review of the literature depicts the extent of the opioid crisis and genesis of the crisis.

Tyndale and Sellers (2018), nationally recognized experts, opined based on experiential evidence that prescription opioid sales in the United States nearly quadrupled from 1999 to 2014, without a significant change in the amount of pain reported by Americans. The United States is the leading nation for the highest rate of opioid prescribing. The rapid rise in opioid overdose death rates in the United States was driven by three separate waves of lethal drugs. The first wave of prescription opioid mortality started in the late 1990s, followed by a second wave of deaths from heroin starting in 2010, culminating in the current third wave of deaths due to synthetic opioids, which include illicit fentanyl and fentanyl analogs (Tyndale & Sellers, 2018). Tyndale and Sellers point to the urgent need for more leadership and funding to find an evidence-based solution to the opioid crisis.

In an integrative review conducted by Chen, Shiels, Thomas, Freedman, and Berrington (2018), a comparative analysis of data from 13 countries of premature mortality from drug overdoses was reviewed. Using the World Health Organization's mortality database to collect the yearly number of deaths due to drug overdoses, the search was limited to adults aged 20 to 64. Findings indicated the U.S. opioid overdose death rates were more than twice the number of those in any other country. Overdose death rates were highest for men in the 35- to 49-year age group and for women ages 50 to 64 years. Drug overdose deaths more than doubled in the 21st

century, with an estimated 63,632 deaths in 2016. This study's limitations included restrictions to those countries with the highest quality data, differences in coding practices, and the inability to compare the contributions of specific drugs to mortality death rates of each country (Chen et al., 2018).

To further illustrate the magnitude of the problem, New Jersey's Governor Christie led a commission to assist the President in developing recommendations to combat the opioid crisis, to include a national curriculum to educate prescribers on standards of care for administering opioids. Through subject matter expert interviews and testimonies, the governmental consensus panel determined that a multi-pronged approach is needed to address our nation's opioid crisis. Mental health services in our nation are lacking, as only 10.6% of youth and adults in the United States who need treatment for opioid addiction are receiving it (Christie et al., 2017). Recommendation strategies to reduce the opioid supply of illegal drugs into the United States include improved collaboration and information sharing between law enforcement agencies to target the supply chains (Christie et al., 2017). The illegal entry of opioids into our nation has contributed to the overall crisis and must be addressed. The commission's recommendations apply to both the Veteran and non-Veteran population who consume illegal opioids and supports the use of an interdisciplinary whole health approach to combat the opioid crisis.

To highlight the extent of the opioid crisis, Han et al. (2017) discussed findings from the National Survey on Drug Use and Health of non-institutionalized American adults ($n = 51,200$) who reported opioid use. The purpose of this labor-intensive, in-person, qualitative study, conducted by the Substance Abuse Mental Health Services Administration, was to measure prescription opioid use, misuse, use disorders and motivation for use. Survey results revealed that 37.8% of U.S adults used prescribed opioids, 4.7% misused opioids, and 0.8% had an opioid

use disorder. The purpose of this study was to link use disorders to economic and behavioral health issues, as misuse was most commonly reported in high-risk individuals, such as the uninsured, unemployed, low income, or those with a mental health history (Han et al., 2017). As discussed previously, Veterans are included in this at-risk population.

Edmond et al. (2018) conducted a cross-sectional survey ($n = 460$) over 12 months to examine rates and correlations of non-pharmacological modalities (NPMs) use in Veterans during recent Middle Eastern conflicts. This qualitative study's findings with meta-synthesis included 43.7% of male Veterans and 56.3 % of female Veterans who had received care in PC settings reported chronic pain. Most Veterans reported using a minimum of one NPM within the past 12 months of the survey. A major limitation of this study was the lack of measurement of the effect of the NPM on Veteran pain levels. This study's findings can be used to tailor pain management strategies using NPM of the patient's choice.

Nahin (2018) conducted a qualitative study of data extracted between 2010 and 2014 from the National Health Interview Survey (NHIS) Sample Core and the NHIS Adult Functioning and Disability Supplement. This labor-intensive survey ($n = 67,696$) compared pain levels in a population of Veterans ($n = 6,647$) and non-Veterans ($n = 61,049$). Survey participants with severe pain were identified by a validated pain severity system that was part of the NHIS Adult Functioning and Disability Supplement. Veterans are generally considered healthier than the average citizen upon entering active duty due to the rigorous physical and mental health screening requirements to join the service. While serving, active duty military are considered high risk for combat and non-combat related injuries and are frequently exposed to both environmental and mental stressors. Results revealed that more Veterans (65.6%) than non-Veterans (56.4%) reported pain in the three months before the time of the survey. The percentage

of severe pain was also higher in Veterans (9.1%) versus non-Veterans (6.3%), particularly those who had served in recent military conflicts. The study findings did not link specific causes for increased pain levels in Veterans compared to non-Veterans and did not offer a risk-mitigating strategy for the Department of Defense consideration. The study findings reflect the need for revised pain management strategies in the outpatient setting, especially for the Veteran population.

Although most of the information reviewed by the author regarding the impact of the opioid crisis was found in recommendations, qualitative studies, and QI studies, the data supported an immediate need to find a solution to the opioid crisis in the Veteran population.

*SMA*s in clinical settings. In a prospective study, Romanelli, Dolginsky, Byakina, Bronstein, and Wilson (2017) demonstrated the benefit of SMAs for addressing various chronic medical conditions, including chronic pain. Survey data from 130 patients who attended SMAs showed improvements in patients' confidence levels to manage their pain and their healthcare team's ability to assist them in managing their pain. Overall, satisfaction with attending the SMA was 81%. The authors discussed the positive impact SMAs have on improving patient satisfaction, increasing connectivity with the clinical care team, resiliency, and facilitating care coordination. This study reflects the value of SMAs in promoting opioid safety and awareness, along with shared decision-making with the patient's healthcare team. Romanelli et al. noted that the use of SMAs in PC clinic settings increases however, a standardized approach to implementing SMAs is needed and supports this change of practice DNP project.

Several studies evaluated the impact of SMAs on patients with diabetes. The strongest evidence to support practice changes in the use of SMAs was found in work done by Drake, Meade, Hull, Price, and Snyderman (2018). Their quasi-experimental study reviewed survey data

($n = 12$) from Type II diabetes mellitus patients who attended eight SMAs over seven months. The study reviewed the feasibility of incorporating personalized health planning into SMAs and collected qualitative data from focus groups, patients, and clinical staff. Clinical outcomes included reductions in hemoglobin A1C, low density lipoprotein, body mass index, blood pressure and an increase in achievement of health goals. The use of personalized health planning in SMAs in the clinical setting shows great promise in helping the patient and healthcare team identify health goals and plan a delivery of care that is patient-centered.

In a QI study by Omogbai and Milner (2018), SMAs were launched for a group of Veterans with diabetes. The VA reported the diabetic population to be at 24%, compared to the national average of 9%. This qualitative study involved male Veterans ($n = 30$), with a mean age of 64.7 years ($SD = 5.36$), who attended an SMA from October 15, 2015, to March 15, 2016. The following clinical data points were assessed: A1C, blood pressure, total cholesterol, HDL, LDL, triglycerides, body mass index, and VA hospitalizations. At the end of the SMA, a decrease was observed across the three data points of blood pressure, total cholesterol, and triglycerides, with only minimal changes in the mean HDL levels. This study supports the use of SMAs to impact clinical outcomes positively.

In a systematic review of 17 randomized control trials and nonrandomized cluster-controlled trials, Edelman et al. (2012) found significant improvements in patients' clinical outcomes after attending SMAs; outcomes included hemoglobin A1C (-0.55 percentage points {95% CI, -0.11 to -0.99}) and improved systolic blood pressure (-5.2 mmHg {95% CI, -3.0 to -7.4}); however, there was not an improvement in low density lipoprotein cholesterol (-6.6 mg/dl {95% CI, 2.8 to 16.1}). This study indicates that SMAs can be a useful approach to impact

clinical outcomes among patients with diabetes and supports their use for other clinical conditions.

In a pre-post cohort, QI study at two VA facilities with PC clinics, Cain et al. (2017) sought to improve hypertensive VA patients' ($n = 21$) access and quality of care through their participation in pharmacist-led SMAs. The aim was to decrease blood pressure and improve medication adherence for those Veterans attending a pharmacist-led SMA. The study's findings showed that the Veterans who attended a pharmacist-led SMA had significant reductions in systolic blood pressure; however, the medication adherence did not change significantly from baseline. This study suggests a strong linkage between education in group settings over individual office appointment education. SMAs could easily be replicated for various other health conditions in other healthcare settings.

Wadsworth et al. (2019) conducted a systematic review without meta-analysis of 1,359 papers, qualitative studies, and quantitative studies, comparing outcomes from patients who attended SMAs versus those who had received in-office visits. Overall results indicated positive patient-provider qualitative advantages over in-office visits to include improved communication time with their provider. Wadsworth et al. noted that patients reported being more satisfied with their care after attending SMAs versus the care they received during in-office visits in multiple qualitative studies. Patients perceived providers were less hurried during SMAs than in regular office visits. The authors pointed out that the use of SMAs is increasing in popularity in primary care settings, yet a gold standard for conducting an SMA does not yet exist, which supports the need for further study.

Each of the above studies using SMAs positively impacted the participants' health outcomes and supports the use of SMAs in decreasing opioid reliance in the Veteran population.

Past approaches and alternative modalities. Nationally, numerous approaches to combating the opioid crisis have been explored. Complementary and alternative modalities (CAMs) exist to assist individuals reliant on opioids to find alternatives to taking opioids for pain relief. CAMs, such as mindfulness, acupuncture, tai chi, and meditation, help provide patient-centered treatments and present palatable alternatives for the patient reliant on chronic pain medications.

In a qualitative factor analysis observational study, Betthausen et al. (2014) reviewed interviews and surveys from Veterans ($n = 97$) at a VA facility to assess their acceptability of CAM, conventional medicine, mind-body integration, and belief in CAM. Previous Veteran-focused studies found that 23% to 50% of Veterans utilize some form of CAM, and those not currently using CAM would be open to using a CAM, if it was made available to them. Findings from this study included the Veterans' acceptability for using CAMs as an effective means to maintain health. Veterans who reported current CAM use endorsed the following modalities: spirituality/prayer (39%), meditation/yoga/relaxation/imagery (21%), herbal/botanical supplements (19%), and dietary (19%). The most frequently used CAM was massage, at 61%. This study underlines the importance of assessing Veterans' willingness to explore CAM options as alternatives to pain medications.

In a systematic scoping review with meta-analysis, Rani, Johnston, Bormann, Hull, and Taylor (2014) reviewed the literature from 1976 to 2014 to determine the Veterans and active duty personnel's mind-body practices to determine gaps in the literature regarding CAM usage in this population. The most observed practices were meditation ($n = 25$), relaxation exercises with imagery ($n = 20$), physical therapy and spinal manipulation ($n = 16$), and acupuncture ($n = 11$). Recommendations were made for further research on the most frequently used CAMs to improve

Veterans and active duty personnel's health. These findings support the effectiveness of CAMs for Veterans and active duty personnel in developing whole health treatment plans in the PC setting.

Frank et al (2017), in a systematic review with randomized control trials with meta-analysis, synthesized the effectiveness of methods to decrease long-term opioid therapy (LTOT) for chronic pain in U.S. adults. The patient outcomes assessed were the severity of pain, quality of life, function, withdrawal symptoms, substance abuse, and adverse events. Findings included that pain levels and quality of life functions may improve both during and after opioid reduction. Data synthesis was completed of 67 studies, including 11 randomized control trials and 56 observational studies. Opioid tapering was reported as challenging for both the clinician and the patient, with routine discontinuation ranging between 8% to 35%. In one survey of patients on LTOT, approximately 50% of patients verbalized a desire to cut down or discontinue their opioid use; however, 80% were still being prescribed high-dose opioids one year later. In patients who had a non-fatal opioid overdose, 91% remained on opioids after the overdose. Little evidence exists to help clinicians safely guide patients through the process of tapering off LTOT, especially in the PC setting, where the majority of LTOT is prescribed. Care provided by multidisciplinary teams, along with close follow-up, was noted as positive attributes of programs evaluated in this study. This systematic review underscores the importance of physicians discussing the risks and benefits of tapering LTOT and referring patients to multidisciplinary pain teams for additional support while decreasing their usage of opioids.

In synthesizing the evidence from literature review, no single approach emerged related to using a whole health approach to decrease opioid reliance. However, the positive patient outcomes that occurred with past diabetes mellitus and hypertension SMAs support the need for

immediate practice change for implementation in the PC setting to reduce opioid usage. The literature review clearly depicted the medical, financial, and psychological impact of opioid reliance and supported finding a risk mitigating approach. Additionally, the evidence demonstrates that SMAs are superior over in-office education. The author found it remarkable that literature review yielded zero evidence of past practices for using SMAs to reduce opioid reliance. Although literature review added significant value to the body of evidence regarding the opioid crisis and causative factors, further study is needed to fill the gap between identification of the problem of opioid reliance and the solution for a practical, cost-effective, and sustainable approach for managing chronic pain.

Rationale

Two theoretical frameworks heavily influenced the development and interpretation of this project, including Pender's (2011) health promotion model (HPM) and the VA's proactive health and well-being model (Gaudet & Kligler, 2018).

Pender's Health Promotion Model

A commonly used behavioral change model, Pender's (2011) HPM uses social cognitive theory and its factors (perceived strengths, barriers, self-efficacy) to influence engagement in health promoting behaviors, such as reducing reliance on opioids. The model assumes that individual differences (i.e., demographics, personality), interpersonal influences, and behavioral and environmental factors interact with each other to influence the cognitive, motivational processes requisite for behavior change. Five core concepts, including person, environment, nursing, health, and illness, comprise the model and provide rich sources of interventional content and strategies, including specific, measurable, achievable, realistic, and timely (SMART) goal setting. The use of SMART goals proved to be an integral component of this DNP project.

The concept of self-efficacy—a person’s belief in his/her capacity to execute behaviors needed to produce specific performance attainments (Bandura, 2013)—also heavily influenced this project, secondary to its temporal implications for behavioral change. For example, developing self-efficacy requires reinforcement (i.e., behavioral feedback) for approximated behavior over time (Bandura, 2013). Over iterations of positive behavioral feedback (i.e., positive or negative reinforcement) for applying new information/knowledge, self-efficacy grows as behavior improves, and behavior improves as self-efficacy increases. This behavioral process resulted in the team’s decision to change the frequency of SMAs from monthly to weekly.

The HPM model was chosen for this DNP project as each of the principles, including self-efficacy, aligned with the SMA opioid safety program’s whole health concepts. Additionally, the concepts guided each phase of this QI study by focusing on how they are interrelated to achieve optimal health by selecting healthy behaviors. Pender’s (2011) HPM had applicability in the development, implementation, and aim of this QI study.

Veterans Administration’s Proactive Health and Well-Being Whole Model

Also with origins in health promotion theory, the second theoretical framework used in this QI project was the VA’s Proactive and Well-Being Model (see Appendix B), which outlines the eight dimensions of health and served as the underpinning for this QI project (Simmons, Drake, Gaudet, & Snyderman, 2016). This model moves beyond the traditional disease model, which centers on “What’s the matter?” to a broader question of “What matters most?” (Gaudet & Kligler, 2019). These alternative conversations with Veterans with chronic pain help healthcare staff gain a broader view of how pain interferes with patients’ goals. At this juncture, the healthcare team can truly begin to partner with the Veterans in helping them connect how their present behaviors may be working against them in achieving their whole health goals.

Gaudet and Kligler (2019) discussed the 15-year history of integrating a new paradigm of whole health in the VA. The VA's Office of Patient-Centered Care and Cultural Transformation (OPCC & CT) researched and evaluated this transformation from the usual endpoints of reduced indications of disease to the measurement and collection of well-being outcomes. According to Gaudet and Kligler, to achieve this major change, the VA system has adopted a whole health strategy, which includes addressing practices of the Veteran, their family, and the community, along with social determinants. The authors stressed the importance of assessing specific outcome data to determine when a true transformation has occurred related to the Veterans' health and well-being. Through motivational interviewing and shared goal setting, the healthcare team can assist the Veteran set SMART goals directed at facilitating movement toward the Veteran's unique mission, aspiration, and purpose (Gaudet & Kligler, 2019).

In this study, health coaching and facilitation of shared SMART goals, within the SMA confines, assisted Veterans in addressing a broader array of health and life issues and potentially improving their quality of life and reliance on opioids. The whole health model was chosen for this DNP project based on its direct applicability in the SMA curriculum development and implementation.

Specific Aim

This change of practice DNP project was completed in September 2020. This QI study's specific purpose was to assess the impact of SMAs on morphine equivalent daily dose (MEDD), pain scores, and use of CAMs for managing pain. SMAs were used to introduce concepts of self-care, opioid safety education, and goal setting.

AIM Statement

The overarching aim of this project included: By September 2020, 30 Veterans at the VA project site who participated in a 9-month whole health opioid safety SMA led by patient-aligned care team (PACT) staff to include a health coaching component, will have a 10% or greater decrease in the MEDD, decreased pain scores, and a 10% increase in the use of CAMs for pain management. This will be compared to 30 patients who participated in a 9-week whole health opioid safety SMA led by PACT staff without health coaching, compared to 30 Veterans who received standard, in-office education. An outline for the course curriculum delineates the differences between the composition of the three cohorts (see Appendix C).

Methods

Context

A whole health SMA opioid safety program was developed to assist Veterans decrease their MEDD and pain scores and increase their use of CAMs. This QI study was launched at a tertiary outpatient VA healthcare facility in the southern United States to answer our nation's call to assist Veterans decrease their opioid reliance. A 9-week opioid safety program was implemented, comprised of 90-minute weekly appointments, known as SMAs, using a whole health framework. SMAs are also referred to as group appointments, which combine a medical appointment with education and discussion regarding self-management of a chronic condition or disease (Omogbai & Milner, 2018). The SMA was designed as a single, 90-minute appointment. Each SMA began with obtaining verbal consent from each Veteran.

Stakeholders. A stakeholder analysis was conducted to prioritize the top four stakeholders involved in implementing this DNP project: Veterans on chronic opioids at a large urban VA, PC teams at the VA, external PC teams, and the project site's executive leadership team (ELT). The author believes the most likely element at the project site that influenced and supported this DNP project was stakeholder awareness of the urgent need to find a solution to ending the opioid crisis among Veterans. Each stakeholder group was aware and open to the need for change from the status quo opioid safety education delivery mode. Specific considerations for each group are described below.

Veterans. For Veterans on chronic opioids at the project site, the major perspectives included the Veterans' anticipation and excitement of finding an approach to choose how to reduce their reliance on opioids, while still managing their pain. The Veterans' perspectives were key to program implementation, as without their voluntary participation, belief in the program,

and ability to make behavior changes, the program would have failed. An added advantage of the innovation was the pre-established connectivity between the Veteran and their PC team who conducted the SMAs. The Veterans' agreement to participate in this voluntary program was a testament to their vested interest in making behavior changes, such as reducing their opioid reliance and reflecting the shared decision-making power between themselves and their PC team. The group of stakeholders' strategic approach included partnering with their PC team to determine alternative modalities to control their pain.

Internal Primary Care Teams. The major perspectives of PC teams at the project site included excitement about the possibility of implementing the same approach as their co-workers in finding an alternative approach to decreasing their Veterans' reliance on opioids, while still managing their pain. To connect with this group of stakeholders, patient-care outcomes and program successes of prior SMAs conducted by PC teams they work with were shared to build enthusiasm and to gain potential participation in the program. To further connect with this group of stakeholders, they were provided the opportunity to attend a 3-day opioid safety mini-residency provided by the implementation team to gain insight into running their SMA, which included in-depth instructions, lessons learned, and resources to begin their program. The type of power for this group of stakeholders was one of shared power, in that the program empowered them to meet a need they had to assist their Veterans decrease opioid reliance. The project site's PC teams' strategic approach was to partner with PC teams they knew had an innovative approach that produced promising outcomes in opioid reduction using whole health concepts.

External primary care teams. The external PC team stakeholders' major perspectives included their interest and curiosity regarding what the VA had implemented that could assist their patients to decrease their reliance on opioids, while still managing their pain. The

participation of external PC teams in the program was instrumental in program spread and has the potential to answer our nation's call to end the opioid crisis. Connections were made with this group of stakeholders, to include poster presentations, public presentations, journal articles, and publications, including the American Hospital Association's Opioid Stewardship Implementation Guide. Additionally, this group of stakeholders was provided the opportunity to attend a 3-day opioid safety mini-residency provided by the implementation team to gain insight into how to run their SMA, including in-depth instructions, lessons learned, and resources to begin their program. Like the project site's PC teams, external PC stakeholders held shared power, in that the program offered to meet a need they had to assist their Veterans decrease opioid reliance. The strategic approach of external PC teams was to partner with the implementation team to learn about the innovative approach that produced promising outcomes in opioid reductions using whole health concepts.

Executive leadership team. The major perspectives of the project site's ELT stakeholders included their willingness to provide their support in terms of resources and encouragement for making this innovation successful. Their ongoing support from day one was key to program implementation to align time and resources for both conducting SMAs and mini-residencies. To connect with this group of stakeholders and garner ongoing program support, frequent briefings were given to share program outcomes and successes. The implementation team recently participated in a video highlighting the team's work with reducing opioid reliance in the Veteran population, as an example of work being accomplished to become a high reliability organization. The project site's ELT held positional power over the implementation team. The group of stakeholders' strategic approach was to provide ongoing support of the

needed resources of time, space, and personnel to continue this successful, innovative program in helping Veterans and other Americans reduce their opioid reliance.

After prioritizing the project's stakeholders, a power analysis (Grace, 2017) versus interest review was completed to categorize each group based on their power and interest over this project. The Veterans and ELT stakeholders were categorized as high power, high interest, indicating they needed to be managed closely, with the greatest efforts to satisfy them. The project site's PC teams and external PC teams were categorized as low power, high interest, indicating they needed to be kept informed and communicated with often to ensure no major issues were experienced.

Future plans to influence the VA culture and external healthcare systems to make it open and receptive include promoting the ease of program implementation, sharing our team's expertise and resources by invitation to participate in a mini-residency, and sharing the outcomes and successes of prior SMAs.

Interventions

The author held primary responsibility for all portions of this DNP change of practice project, which took place between February 2019 and December 2020. The author worked closely with an interdisciplinary team at the project site, to include the PC physician and pharmacist who managed the participants MEDD throughout the project.

Shared medical appointments. The first intervention chosen by the author for this project was to evaluate outcomes from Veterans who attended opioid safety SMAs, consisting of nine sessions led by two different PACTs, compared to outcomes from Veterans receiving the status quo, in-office education only. This evidence-based intervention was chosen to determine the clinical efficacy and impact of delivering opioid safety education via SMAs over traditional in-

office education. Healthcare staff involved in this project came from different backgrounds, held different beliefs, and were racially diverse.

The original SMAs were led by Cohort I, comprised of a complete PACT, including a physician, registered nurse (RN), licensed practical nurse (LPN), and medical service assistant (MSA). The facilitator coordinated the SMAs, secured the meeting location, facilitated the data collection tools, and determined topics for the each SMAs' education portion. Additional interdisciplinary staff (dietician, social worker, psychologist, pharmacist) were consulted and used as subject matter experts throughout the SMA course. Cohort I met monthly over a 9-month period and included health coaching as part of their curriculum to assist the Veterans formulate SMART whole health goals. Cohort II was led by a complete PACT who met weekly over a 9-week period and did not include health coaching. Both Cohort I and Cohort II followed a curriculum based on the whole health model and included opioid safety education during each session. Intermittent education was also provided to Cohort I and Cohort II in specific areas related to self-care by interdisciplinary staff. Didactic teaching sessions, utilizing multimedia and short training videos, were used by Cohort I and Cohort II to promote discussion and self-reflection. Educational materials were provided to both cohorts by the VA's OPCC & CT, including the Wheel of Health and eight dimensions of self-care. Integrative healing modalities were introduced during the SMAs, such as mindfulness, tai chi, yoga, and physical therapy. Cohort III was comprised of 30 Veterans receiving in-office, status quo opioid safety education over nine months by the provider, without a full PACT, health coaching, or educational materials, or the use of a whole health curriculum.

Toolkit. The second intervention included developing a whole health comprehensive toolkit containing resource materials and educational handouts for Veterans to use throughout the

opioid safety SMA. The author chose the toolkit based on the need to consolidate handouts and educational materials to guide Veterans through each SMA session and provide a standardized approach for other PACTs to use. A copy of the toolkit index is included as Appendix D. The toolkit was comprised of materials supplied by the VA's OPCC & CT, along with educational materials prepared by subject matter experts for in-class instruction. For example, the content included agendas for each class, ground rules, and listings of additional resources for participants to access, such as video links for tai chi and yoga demonstrations. The toolkit was posted on the project site's SharePoint and made accessible for other teams to conduct SMAs.

Gap Analysis

The desired state of finding a safe and effective approach to decreasing opioid usage in the Veteran population is clearly supported in the literature. The VA's current approach for decreasing Veterans' chronic use of opioids includes adherence to a four-pronged strategy that includes education, pain management, addiction and treatment, and risk mitigation (Gellad et al., 2017). However, a review of the literature identified a noticeable gap between the VA's strategy to address the opioid crisis affecting the Veteran population and a patient-centered whole health (holistic) approach to reducing usage, while managing pain (see Appendix E). To address the gap, specific interventions were put into place, including developing and implementing a nine-session whole health curriculum of SMAs on opioid safety in PC clinics at the author's site. Each session included a component on opioid safety and focused on one of eight dimensions of whole health.

The sessions for Cohort I were conducted over nine months and included a health coaching component. The author served as the facilitator for Cohort I and coordinated various whole health educational topics presented by interdisciplinary subject matter experts. The

sessions for Cohort II were conducted over nine weeks, but did not include a health coaching component. A facilitator coordinated various whole health educational topics presented by interdisciplinary subject matter experts. The control group, Cohort III, did not include health coaching, did not use a facilitator, and did not use interdisciplinary subject matter experts to provide whole health education.

Gantt Chart

The DNP project took place from January 2019 to December 2020. A Gantt chart is provided to illustrate the project's milestones (see Appendix F). The author's original Gantt chart, developed in the first semester of the DNP program for this QI project, changed after receiving internal feedback. The original project's topic was aimed toward the development of a staff toolkit for future teams to use for launching their own SMAs. After consultation with the DNP's chairperson, the author changed the QI project course to include comparing clinical outcomes from three groups of Veterans. The Gantt chart depicted activities from the start of the project through completion, to include required coursework needed for graduation. Milestones included planning, implementation, evaluation, and closeout phases of the project.

Assessment and problem identification. The assessment and problem identification phase was initiated in February 2019 and included developing the PICOT question and Aim Statement. The evidence-based literature review regarding the impact of the opioid crisis, SMAs in clinical settings, and past approaches and modalities was completed in October 2019. It formed the basis of this change of practice DNP project.

Planning. The planning phase took place from June 2019 through October 2020 and included retrospective record reviews of 90 participants in three cohorts in this study.

Additionally, a toolkit for Veteran use during opioid safety SMAs was finalized during this phase of the project.

Implementation. The implementation phase took place from November 2019 through July 2020. It included analyzing extracted data, interpreting findings, and formulating assumptions from data collected from 90 medical records of participants involved in this project. During this phase, a SharePoint site was created comprised of educational materials and slide presentations that could be used to conduct opioid safety SMAs locally and at other VA facilities.

Evaluation. The project evaluation began in August 2020 with data analysis and synthesis of project findings and submission of the final DNP project concludes December 2020 with the final DNP project presentation.

Work Breakdown Structure

This project involved evaluating the effectiveness of whole health opioid safety SMAs for Veterans reliant on opioids at the project site. A top-down approach of the work breakdown structure (WBS) was used to execute the objectives of this change of practice DNP project by graphically displaying the increments of work into individual steps to ensure all tasks aligned with the proposed timeline and priorities in the project (see Appendix G). The approach selected to conduct the WBS was based on the nursing process, including assessment and problem identification, planning, implementation, and evaluation. The author identified the tasks early since formulating the four phases of the WBS were continued through to the full implementation of the project. The WBS fit well into the VA culture and served as an effective means to track and trend progress from start to completion.

In preparation for constructing the WBS, a meeting was conducted with the on-site mentor to determine the project's scope, implementation, and associated costs. The WBS was key to the successful completion, launch of interdisciplinary use, and enterprise-wide dissemination of SMAs for a whole health approach for Veterans to choose sustainable and effective non-medication alternatives for chronic pain. The potential for sustainable lifestyle changes for Veterans reliant on opioids for pain management is extremely important and relevant to our nation, individuals, and communities during this crisis.

Strength, Weaknesses, Opportunities, and Threats (SWOT) Analysis

The interventions in this project were analyzed using a SWOT analysis (see Appendix H).

Strengths. This program's identified critical strength was the baseline outcome data collected by the original SMA team, which revealed promising results. The SMA built comraderie, a sense of community, and accountability and empowered Veterans to decide how to manage their pain based on their preferences and goals. An additional strength of this program included the program's whole health foundation, where the Veteran oversaw all healthcare decisions made about him or her, placing them in charge of all healthcare decisions affecting them.

Weaknesses. The program's identified weakness was its ability to be spread throughout other VA facilities, due to primarily the PACT providers' resistance to change from the traditional method of delivering opioid safety training during routine in-office appointments. Additional weaknesses included not all Veterans reliant on chronic opioids in the SMAs due to work or family constraints and those uncomfortable in group settings.

Opportunities. Opportunities were identified, such as inviting PACTs who had not yet integrated opioid reduction strategies to observe SMA sessions while progressing to understand the potentially improved outcomes from running group appointments. Another opportunity of this project was in the potential cost savings, as multiple patients could be seen during one SMA. The opportunity exists for future grant funding to assist with the spread of the opioid safety program enterprise-wide. An additional opportunity is for the success of this QI project to be spread to other VA facilities nationwide.

Threats. Identified threats included PACTs deciding to deviate from the specified training curriculum to educate their patients on opioid safety. Additionally, there was reluctance from PACT staff to explore what really mattered in their lives with their patients. Other threats included that Veteran participation in SMAs was voluntary, which may have negatively affected attendance. Finally, Veterans may be resistant, fearful, physiologically dependent, or not ready to make whole health changes. Like so many initiatives and programs, a major barrier for spreading this program was the Coronavirus pandemic that ravished our nation. As of March 2020, the all-hands-on-deck philosophy was applied to all healthcare personnel in combating the historical virus. Due to infection control practices and social distancing requirements, all face-to-face appointments and group meetings were cancelled until further notice. Mitigation plans have included working with Veterans to find alternative approaches that would be acceptable and effective for managing their pain. As a transformational leader, during this pause, the author has remained passionate and connected with every PACT team and all stakeholders to maintain this important project's work. The use of systems thinking helped to overcome uncontrollable barriers by finding new methods to understand and revise the nature of things, to include how to intervene to improve population health (Peters, 2014).

Project Budget

Although hard to quantify, the major return on investment from this DNP project was assisting Veterans in decreasing their opioid reliance. The budget (see Appendix I) for this project included the following staff salaries needed to conduct a 90-minute SMA: \$154 for the PC physician, \$45 for the RN, \$31 for the LPN, \$27 for the MSA, and \$85 for the pharmacist, totaling \$342 in personnel costs. The full opioid safety SMA program was comprised of nine sessions, with personnel costs totaling \$3,078.

The total budget to complete this project for the first year, comprised of 12 SMAs, was \$9,653, with a projected 2% cost of living increase for the subsequent two years. A one-time, upfront training requirement to attend the mini-residency to prepare the staff to conduct an SMA was required at the cost of \$5,496, which included \$53 for printing educational materials and plastic binders training materials collected throughout the SMAs.

Although no additional revenue was directly placed back into the budget, in the end, these healthy behavior changes could eventually impact Veterans' lives and result in less drain on the VA healthcare system. Data specific to associated healthcare expenditures related to opioid reductions were not found in the review of literature. Veterans potential benefits in life-long, healthy behavior changes, including decreasing their opioid reliance, may far outweigh the minimal costs associated with conducting a 9-week SMA on opioid safety.

Responsibility/Communication Plan

The communication plan included keeping all stakeholders aware of the project's progression from initiation through completion (see Appendix J). To achieve this plan, weekly meetings with the University of San Francisco (USF) advisor, Dr. Mary Lynne Knighten, via phone, email, zoom, or text messages, were conducted. Monthly meetings occurred with the

ELT, director of PC clinics, and fellow team members. Additional weekly meetings were conducted with the field advisor at the project site. Monthly meetings were conducted with the lead pharmacist and University of Alabama faculty member, who served as an on-site mentor to the author through the completion of the project.

Cost-Benefit Analysis

The author's business plan for implementing an opioid safety SMA program was a cost-benefit venture, in that opioid safety education was provided for up to 20 Veterans in a group setting over 90 minutes at a cost to the organization of \$342 per SMA, versus the present option, where 20 Veterans received opioid safety education via routine office visits at \$250 per visit, for a cost of \$5,000. A cumulative annual cost avoidance of \$62,424 (for 20 Veterans) will be realized within three years of program implementation (see Appendix K). The financial analysis reflected variations in the way we provide opioid safety education to our Veterans and provided an opportunity to improve future care delivery throughout the VA enterprise.

A cost-benefit analysis for achieving this goal yielded a strong return on investment, with a projected cumulative 3-year cost-benefit of \$51,970.06. Along with the potential 3-year cost-benefit, the intangible benefits of implementing an opioid safety SMA program included providing education in a humane, patient-centered, compassionate manner. The DNP project aligned with the Birmingham VA Medical Center's mission to honor Veterans by providing exceptional healthcare that improves their health and well-being. Additionally, the author's financial analysis was directly aligned with DNP Essential II: Clinical Scholarship and Analytical Methods for Evidenced-Based Practice (American Association of Colleges of Nursing, 2006).

In addition to the number of lives lost each year to opioid overdoses, the opioid crisis has had a significant financial impact on our nation. Current estimates from the CDC reflect an estimated \$78.5 billion a year economic burden from the opioid crisis, which includes healthcare costs, productivity losses, treatment for addiction, and criminal justice involvement (NIDA, 2019). Results support the SMA whole health conceptual framework model utilizing an interdisciplinary staff as a cost-effective approach to reduce opioid reliance and improve opioid safety in a Veteran population.

Study of the Interventions

Continuous Quality Improvement (CQI). The author's chosen CQI approach used to assess the impact of the interventions in this project used the four stage, problem solving model of plan, do, study, act (PDSA; see Appendix L). The use of a PDSA model was chosen as it provided the author a scientific method to determine if the interventions led to achieving the projects aim (Institute for Healthcare Improvement, 2016).

This change of practice DNP project required a review of existing clinical practices for delivering opioid safety education at the project site. Evaluation of clinical data from retrospective record reviews was conducted to establish whether the outcomes were due to the interventions. Record reviews, also known as chart reviews, are a frequently used process to collect retrospective data to answer clinical questions (Sarkar & Seshadri, 2014). To ensure the accuracy and quality of the extracted data, the author personally completed all record reviews. The data collection instrument used was a *de novo* form without established validity or reliability and has been identified as a valuable lesson learned from this study.

Outcome Measures

Comparisons were made between the opioid safety outcome measures of those who received training via Cohort I, comprised of a PACT team that met monthly over nine months and included health coaching, to Cohort II, comprised of PACT staff that met weekly over nine weeks and excluded health coaching, to Cohort III (control), who received training via routine, status quo, in-office education only. The following outcome measures were selected to accurately represent the phenomenon under study, based on their impact on the safety of the Veteran population:

1. The MEDD 12 months post-program completion compared to the MEDD pre-SMA.
2. A reduction in the pain score 12 months post-program completion compared to the pre-SMA score.
3. An increase in CAM usage 12 months post-program completion compared to pre-SMA usage.
4. A comparison of outcomes and efficacy after 12-month completion of SMA related to eliminating health coaching from the standard of care used by Cohort II pre-SMA.

To ensure the data collection's completeness and accuracy, the instrument used for this QI project was a retrospective record review completed by the author. The author had planned to collect data from the PROMIS 29 form (see Appendix M) and a *de novo* Report Cards (see Appendix N) of SMA participants to assess their well-being and satisfaction; however, a random review revealed a systems issue in the form collection process. Therefore, all data were collected from retrospective reviews of computerized records of Veterans who participated in SMAs on opioid safety. All measures were recorded pre- and post-SMA and in-office visits. Descriptive statistics described trends in the data. The author obtained input from patients, staff, and leadership at the project site regarding their perspectives on this DNP project's chosen measures.

Before this change of practice DNP project, the author was unable to locate any evidence in the literature, or at the local level, of satisfaction or cost measures being evaluated related to decreasing opioid reliance using a whole health approach.

Analysis

The intended outcomes measures for this DNP project were as follows: a reduction in MEDD and pain scores and an increase in the use of CAMs for the management of pain. Results of pre- and post-SMA statistical and clinical findings are displayed in Table 1 in Section IV.

The quantitative data regarding MEDD and pain scores were obtained from retrospective record reviews. The qualitative data regarding the use of CAMs were obtained from retrospective record reviews. The author performed the retrospective record reviews. The data were collected using a *de novo* collection tool (see Appendix O). The author was assisted by an expert in statistics at the project site in extracting outcome data into an Excel spreadsheet, displayed as column charts. The data were stratified into three levels of variables, to include comparison groups of Veterans who have participated in the original team's opioid safety SMA over nine months with health coaching, to those who participated in another PACT's SMA over nine weeks without health coaching, to those Veterans who received in-office opioid safety education only. Time was recognized as a variable; in that Cohort I held their SMAs over nine months versus Cohort II, who held their SMAs over nine weeks. To determine the statistical significance, a *p* value of 0.05 was established. To determine clinical significance, a percentage change of outcome data was calculated pre- and post-SMA.

Ethical Considerations

On August 20, 2019, the USF DNP department determined that this project met the guidelines for an evidence-based change of practice project, as outlined in the DNP project checklist (statement of determination) and was approved as non-research (see Appendix P). Additionally, a statement of non-research determination was obtained from the VA (see Appendix Q). Prior to project implementation, the author completed a Human Subject Research course provided by the Collaborative Institutional Training Initiative. The VA facility leadership fully supported this project (see Appendix R). Issues with patient privacy concerns and the protection of participants' physical and psychological well-being were safeguarded in this project, as data were obtained via a retrospective record review using the computerized patient record system. This project complied with the Health Insurance Portability and Accountability Act, as names and identifiers were not collected, and all data were presented in aggregate form. No conflicts of interest were identified.

Jesuit Values

This QI project was directly congruent with the USF's Jesuit values for treating Veterans with respect and dignity while partnering with them in shared decision-making. In addition, it aligned with the Jesuit value of *Cura Personalis*, which means caring for the whole person with respect to their intellectual, spiritual, and physical health and autonomy (USF, 2019). Jesuit values and code of ethics values were clearly demonstrated in this project.

ANA Ethical Standards

Notably, Pender's HPM and the VA's whole health model, which served as the foundation for this project, aligned with the Jesuit value of caring for the whole person and the value of forming and educating agents of change. Furthermore, in alignment with the American

Nurses Association's (2015) Code of Ethics and Interpretive Statements, this project has added to the nursing profession by advancing scholarly inquiry in the area of health, safety, and well-being. Compassion and respect were shown for the participants involved in this study, both individually and collectively, throughout this project.

Results

The initial steps of the interventions included randomly assigning study participants into three cohorts. Modifications to the initial interventions were not needed and remained consistent throughout this change of practice DNP project. Data were collected before and after patient participation for each study group. A two-tailed, paired *t*-test was performed, with a *p*-value of ≤ 0.05 selected to indicate significance. As introduced earlier, clinical significance was calculated by percentage change pre- and post-SMA results.

Quantitative Findings

The project's sample size ($n = 90$) comprised Veterans on chronic opioids receiving care at the project site. As displayed in Table 1, data analysis revealed the only cohort with a statistically significant reduction in MEDD was Cohort I ($p < 0.0063$). Cohort II was the only one that made a statistically significant improvement in pain scores ($p < 0.0202$) and CAMs ($p = 0.0117$). However, in looking at the magnitude of change between the variables pre- and post-SMA, patients in all three cohorts made clinically significant improvements in reducing MEDD and pain scores and increased use of CAMs. These findings demonstrate proof of concept for the promise of SMAs in managing chronic pain in this population. Clinical improvements for each variable and cohort are reflected in percentages in Table 1.

Table 1

Change in Study Variables for Each Cohort

Variable	Cohort I (<i>n</i> = 30) 9-Month with Health Coaching	Cohort II (<i>n</i> = 30) 9-Week without Health Coaching	Control (<i>n</i> = 30) In-Office Only
MEDD	<u>Mean ± SD:</u> -21.8 ± 15	<u>Mean ± SD:</u> +0.75 ± 0.53	<u>Mean ± SD:</u> +0.57 ± 0.4
	<u>Clinical Change</u> 21% Reduction	<u>Clinical Change</u> 2.3% Reduction	<u>Clinical Change</u> 0.5% Reduction
	<u>p-value:</u> 0.0063	<u>p-value:</u> 0.6371	<u>p-value:</u> 0.8819
Pain Score	<u>Mean ± SD:</u> -0.4 ± 0.28	<u>Mean ± SD:</u> +1.13 ± 0.80	<u>Mean ± SD:</u> -0.6 ± 0.42
	<u>Clinical Change:</u> 29% Reduction	<u>Clinical Change:</u> 46% Reduction	<u>Clinical Change:</u> 27% Reduction
	<u>p-value:</u> 0.6085	<u>p-value:</u> 0.0202*	<u>p-value:</u> 0.2599
CAM	<u>Mean ± SD:</u> +0.10 ± 0.07	<u>Mean ± SD:</u> +0.2 ± 0.14	<u>Mean ± SD:</u> +0.1 ± 0.07
	<u>Clinical Change:</u> 23% Increase	<u>Clinical Change:</u> 20% Increase	<u>Clinical Change</u> 20% Increase
	<u>p-value:</u> 0.3746	<u>p-value:</u> 0.0117*	<u>p-value:</u> 0.3255

*P-value of ≤ 0.05 selected to indicate significance.

The first major clinical outcome of this change of practice DNP project was that each of the three cohorts made clinical improvements reducing MEDDs and pain scores and in increasing the use of CAMs.

Clinically Significant Findings

As compared to the above statistical findings, clinically significant findings of this study reflect the magnitude of change the intervention made on clinical practice and the quality of life for Veterans (Ranganathan, Pramesh, & Buyse, 2015). Of the 90 patients, 36 patients made reductions in their MEDD, 31 patients reported lower pain scores, and 19 patients added a CAM into their plan of care.

Clinical improvement in MEDD. Of the 30 patients in Cohort I, 13 patients reduced their MEDD, for a combined reduction of 21%, compared to Cohort II, where 10 patients reduced their MEDD, for a combined reduction of 2.3%, compared to Cohort III, where 13 patients reduced their MEDD, for combined reduction of 0.5%. The total MEDD percentage change post -SMA was 2,567.14 milliequivalents, compared to pre-SMA of 3,169.64 milliequivalents, for a combined 21% reduction. Cohort II MEDD post-SMA was 965 milliequivalents, compared to pre-SMA of 987.5 milliequivalents, for a combined reduction of 2.3%. Cohort III (control) MEDD post-SMA was 1457 milliequivalents, compared to pre-SMA of 141464, for a combined reduction of 0.5%.

Clinical improvement in pain scores. Of the 30 patients in Cohort I, nine patients reduced their pain scores, for a combined reduction of 29%, compared to Cohort II, where 14 patients reduced their pain scores, for a combined reduction of 46%, compared to Cohort III, where eight patients reduced their pain scores, for a combined reduction of 27%.

Clinical Improvement in Use of CAMs. Of the 30 patients in Cohort I, seven patients increased their use of CAMs, for a combined increase of 23%, compared to Cohort II, where six patients increased use of CAMs, for a combined increase of 20%, compared to Cohort III, where six patients increased use of CAMs, for a combined increase of 20%.

The second outcome from this change of practice DNP project was developing a Veteran toolkit for use during future SMAs. The toolkit was developed based on requests from PACTs for a consolidated packet of training materials to conduct opioid safety SMAs. The toolkit will benefit VA providers and clinicians who assist countless Veterans participating in the whole health opioid safety SMAs, both locally and nationally. The guide directly aligns with the Veteran Toolkit and will provide a consistent, standardized curriculum to deliver opioid safety education.

Missing data in this change of practice DNP project include participant demographic data of age, gender, and race, which have been identified as weaknesses of this study.

Discussion

Summary

The overarching aim of this DNP project was: By September 2020, 30 Veterans at the VA project site who participated in a 9-month whole health opioid safety SMA led by PACT staff to include a health coaching component would have a 10% or greater decrease in the MEDD and decreased pain scores and a 10% increase in the use of CAMs for pain management, compared to 30 patients who participated in a 9-week whole health opioid safety SMA led by PACT staff without health coaching, compared to 30 Veterans who received in-office opioid safety education. The outcome data from record reviews pre- and post-SMA provided evidence that the DNP project aim was successfully achieved with two of the three proposed outcomes within one year of implementation of the program. Based on the outcome data from Cohort I, the author believes the use of health coaching over nine months conducted in a group setting made the greatest contribution to project's success.

The chosen theoretical frameworks selected for use in this change of practice DNP project provided a firm foundation for building the whole health curriculum, focusing on the concept of self-efficacy for Veterans decreasing their opioid reliance.

This QI project's findings reflect that clinical improvements can be achieved when patients receive opioid safety education, are offered alternatives to manage their pain, receive health coaching, and set their own SMART goals. A second major outcome was the development of a Veteran toolkit for use during future SMAs. Although not originally intended, a third major outcome creating an Implementation Guide for PACT teams to use for launching opioid safety SMAs in other clinics and facilities. A copy of the Implementation Guide's index is included in Appendix S.

A valuable lesson learned from this project includes the importance of developing a comprehensive, validated data collection tool prior to conducting record reviews. Such a tool would have saved the author valuable time and would have added to the credibility of this project.

Several assumptions can be made from the results of this DNP project. Cohort I achieved a 21% decrease in MEDD. In part, results may reflect unique contributions of coaching and interventions of prolonged duration of nine months, compared to nine weeks in Cohort II and III. Self-efficacy, or the belief in one's capacity to produce change, plays a critical role in behavior change and requires behavioral feedback over time (Bandura, 2013). Therefore, Cohort I's reported a significant reduction in MEDD outcomes may have been due to its members having the opportunity to collect behavioral feedback and foster self-efficacy. Provider effects, or systematic effects of provider, on outcomes beyond treatment modalities, may also have contributed to observed outcomes (Lutz & Barklam, 2015).

An additional assumption is that Cohort I's primary goal in implementing SMAs was to reduce opioid usage, In contrast, Cohort II and III may have emphasized on the use of CAMs to manage their pain. In analyzing Cohort I's outcomes, an incidental finding was detected in participants achieving a statistically significant decrease in their MEDD, without achieving a statistically significant increase in their pain scores, indicating even though their opioid dose was decreased, the participants' pain did not statistically increase. This may be attributable to a lagged response and may result in future reported pain scores. Additionally, the possibility of a placebo effect occurring of Veterans believing they were going to improve; therefore, they did (The Placebo Effect, May 2019).

Assumptions can be made that patients may have difficulty distinguishing changes in their pain perception due to the chronicity of pain. A condition known as opioid-induced hyperalgesia has been found to create a paradoxical response in certain patients on chronic opioids; whereby, the treatment of pain causes the patient to become more sensitive to painful stimuli (Lee, Silverman, Hansen, Patel, & Manchikanti, 2011). Additionally, opioid tolerance, defined by Colvin, Bull, and Hales (2019) as the increased need for analgesia, is a condition that affects certain patients on chronic opioids, which may explain the lower change in pain scores in Cohort I and III.

Cohort II's and Cohort III's reduction in MEDD may be due to increased monitoring of provider's adherence to CDC and VA opioid prescribing guidelines, to include tapering methods to reduce patient's chronic opioid usage (Dowell, Haegerich, & Chou, 2016; U.S. Department of Veterans Affairs, 2017).

Cohort I achieved a 29% reduction in pain scores, compared to Cohort II (46%) and Cohort III (27%). Cohort II's and Cohort III's reductions in pain scores may be due to higher MEDD trends and increased emphasis on using CAMs to manage their pain. The reductions in reported pain scores in all three cohorts may be attributable to the team's focus on increasing the use of CAMs to control pain. Additional psychological factors of the participants, such as depression, anxiety, or level of coping skills, have been shown to influence variability in reporting pain levels (Schneider et al., 2012).

Clinical improvements were observed in pain score and complimentary medicine of Cohort II and Cohort III participants; however, these findings must be interpreted with caution due to the higher MEDD trend of both groups. Cohort I achieved a 23% improvement in use of CAMs, compared to Cohort II and Cohort III, who achieved a 20% increase in CAMs. Cohort I's

higher percentage may be due emphasis placed on using CAMs over medication for pain relief. To determine if access was a variable in patients increasing their use of CAMs, the author met with the administrative officer in charge of scheduling CAM appointments and determined equal accessibility to appointments at each cohort location. Additionally, increased usage of CAMs in Cohort II and Cohort III may have increased promotion by the PACT team. Cohort III's (control) method of providing opioid safety training using the status quo mode of delivering in-office sessions without a whole health set curriculum or health coaching may have contributed to their lower percent of MEDD reductions. An assumption can be made that Cohort III's in-office education was geared toward the provider's goal of decreasing MEDD, with little input from their patients on how to proceed with their pain management and whole health goals. An additional assumption can be made that the 20% increase in the use of CAMs in Cohort III was attributable to the provider's efforts and external pressures to address their patients' pain without increasing their MEDD.

Upon completion of the program, a new possibility for change occurred. Several participants expressed their desire to attend ongoing sessions to maintain their momentum and achieve progress in meeting their SMART goals. In response, and as part of the team's sustainability plan, monthly maintenance SMAs have been held for participants to continue their whole health journey. To familiarize SMA participants and staff with using virtual training platforms during the pandemic, education was provided by the implementation team and telehealth staff. Reference sheets with instructions were sent to each participant prior to the SMA start date. To date, ten virtual opioid safety SMAs have been successfully conducted, with an average of six Veterans per session.

Dissemination Plan

As a result of the team earning Gold Fellow Status from the VA Diffusion of Excellence Shark Tank competition, future dissemination plans of this best practice are to spread the approach and to sustain the process improvement, to include offering ongoing opioid safety mini-residency training to VA facilities, both locally and nationally. The team's latest spread includes training three PACTs using VA Video Connects virtual platform for a VA facility in the Northeast United States.

Unanticipated Outcomes.

Although not originally intended, based on requests from interested PACT teams, a major outcome of the project was creating an Implementation Guide (see Appendix S) for PACT teams to use for launching opioid safety SMAs in other clinics and facilities. The guide will provide a consistent, standardized curriculum that will support the patient toolkit.

An outcome from this DNP change of practice project provided the opportunity and capacity to sustain support for Veteran's behavior change was based on the request from participants to attend "alumni" SMAs after they completed of the nine-session program. As of October 2020, three groups of graduates have continued their whole health journey by attending monthly SMAs.

An additional opportunity arose during this project for the author to contribute to the publication of the American Hospitals Association (AHA) Opioid Stewardship Guide. Once fully launched, the guide, will be distributed to all U.S. hospitals to share best practices regarding opioid safety and care delivery nationally. The author's contribution to the guide included sharing the use of SMAs to help reduce opioid reliance in the Veteran population using a whole health approach.

As a result of earning Gold Level Status from the VA Diffusion of Excellence Shark Tank competition, disseminating this best practice has been spread to three PACTs at the Boston VA. Future plans include combining data from the Boston VA with that from the author's project site to compare and contrast data from a national perspective, to include possible publication.

As the COVID-19 pandemic moves forward, so does the opioid epidemic, as recent data indicate an 11.4% increase in opioid deaths occurring in January 2020, compared to the same period in 2019 (Advisory Board, 2020). The current Covid-19 related public health measures, such as shelter-in-place orders, have caused patients battling with sobriety and addiction to lose their support networks, resulting in feelings of isolation (Silva & Kelly, 2020). Although necessary, such public health measures to turn the pandemic's tide have been linked to poor mental health outcomes due to repercussions from fear, job loss, and need for social distancing. (Panchal et al., 2020).

To combat feelings of isolation and anxiety over not being able to connect to their healthcare team, the whole health opioid safety SMA team at the project site has started a series of weekly, virtual sessions via the VA's Video Connect platform. To date, the staff have held 12 SMAs using this virtual platform and have found Veterans receptive and excited about connecting and seeing their healthcare team on their computer screen. Sessions have included opioid safety measures, healthy eating, weight gain, body movement, and health coaching, where discussions have centered on the Veterans current goals, barriers to achieving goals, and potential options for their healthcare. Feedback to this point has been positive, with the same number of Veterans returning each week to the sessions. Several Veterans mentioned that they had not left their house for months and find these weekly sessions something they look forward to. A recent SMA discussion focused on sleep hygiene presented by a staff psychologist. Conducting virtual

whole health SMAs to reduce opioid reliance is expanding access to care for Veterans who would not routinely travel to the VA during this pandemic to receive supportive care. By continuing virtual SMAs during the pandemic, the team hopes to build trust with their patients and provide a sense of connectivity during these uncertain times. The team strongly believes this connectivity has empowered the Veterans to become in charge of their healthcare decisions during these uncertain times.

As a DNP-prepared leader, the author's future plans to influence the VA culture and external healthcare systems to adopt this approach include promoting the ease of program implementation and sharing the team's expertise and resources via mini-residency training. Additionally, the author will continue to present program successes on VA community of practice calls, reaching approximately 500 PC team members nationwide.

This change of practice DNP project has direct implications for advanced nursing practice, as it provides an opportunity for nurses to promote whole health opioid safety SMA programs, which have the potential to change lives, decrease the risk of opioid addiction, and influence future practice guidelines for addressing our nation's opioid crisis.

Interpretation

It can be inferred from the results of this DNP project that a one-size-fits-all approach does not exist for resolving the opioid crisis. However, the evidence from this project supports using whole health opioid safety SMAs can have a positive clinical effect on decreasing MEDDs and pain scores and increasing the usage of CAMs for pain management, despite variations in the approach. Positive results from this project were similar to outcomes from teams who used SMAs to impact other health conditions, such as diabetes and hypertension (Cain et al., 2017; Drake et al., 2018; Edelman et al., 2012; Omogbai & Milner, 2018). Results of this study

indicate that the clinical improvements made by patients in this study and the benefits of conducting opioid safety SMAs far outweigh the costs.

The results of this change of practice DNP project have direct implications for replication at other VA healthcare facilities, requiring involvement from both senior nursing executives and staff development professionals. Future implications for PACTs and staff development personnel include the ability to access the Veteran Toolkit and Implementation Guide to conduct future SMAs in their facilities.

Valuable outcomes for this project included Veterans who participated in SMAs with health coaching demonstrated a statistically significant decrease in their MEDD usage, compared to Veterans who attended SMAs without health coaching and those who received opioid safety education delivered in the traditional status quo mode of in-office education. However, at this time, the author does not have follow-up data and, so cannot speak to the intervention's sustainability. Results from Cohort III indicate maintaining the status quo in delivering opioid safety education did not make a statistically significant difference in impacting MEDDs, pain scores, or use of CAMs to manage pain; however, clinical improvements in each measure were achieved. Findings support the HPM and whole health conceptual frameworks used in this DNP project. The proposed financial estimates for conducting this project were forecasted accurately and resulted in substantial cost savings for the project site.

Limitations

The study's limitations should be acknowledged, including the retrospective data collection, differences in patient and team composition demographics, and institutional variance in implementation (9-month versus 9-week) SMAs. Additional limitations include that SMAs were conducted in a single VA facility and involved only Veterans in group settings, affecting the study outcomes. The small sample size of reviewed records ($n = 90$) may not have been adequate for detecting a statistically significant difference between the three groups of Veterans. The small number of studies and the study design may have limited the number of conclusions that could be drawn concerning the evidence-based practice question and aim. Also, Veterans may have been unable to participate in SMAs due to travel restrictions, travel costs, discomfort in groups, or mobility issues. Attendance, sex, race, and age demographics for the study participants were not collected and are identified weaknesses of this project. Reported pain scores were subjective and easily influenced by numerous objectives, such as time of day and state of mind. An identified weakness was the inability to collect qualitative findings for well-being and satisfaction via valid and reliable instruments (PROMIS 29 and *de novo* Report Cards) due to the lack of a standardized approach for collecting the forms. This system issue has been corrected for teams moving forward.

Identified barriers to the successful implementation of this program included lack of engagement by Veterans and staff in conducting and attending the weekly sessions. The program required time commitment and willingness to arrange schedules to participate. Additional barriers included difficulty in securing meeting space and obtaining protected clinic time to conduct the SMAs. Finally, an identified barrier for this change of practice DNP project was the

potential for leadership support to dwindle due to competing priorities, such as staff realignment during the Covid-19 pandemic.

Strategies to mitigate the noted limitations included the author presenting at various PACT staff meetings and morning huddles, sharing outcome data, and offering educational and logistical support for implementing SMAs. Additional future efforts could include leadership support in offering lunch-and-learn sessions to provide information on the severity of the opioid crisis impacting the Veteran population. Signage to provide awareness of the opioid crisis was placed around the project site, including elevator wraps (see Appendix T) and flyers promoting the importance of whole health modalities (see Appendix U). The COVID-19 pandemic has stretched the implementation team to find innovative modalities to conduct SMAs via telehealth platforms in lieu of face-to-face group sessions. The project site did not have locally distinctive characteristics that impacted the implementation of this DNP project. Although some selection is bias inherent, the findings of this study suggest benefit from conducting SMAs that incorporate health coaching over a longer period. Future studies are warranted to support these findings. Meaningful and logical next steps that could extend and compliment this study include forming larger cohorts, conducting and collecting SMA data from other VA facilities, and collecting more extensive data.

Conclusions

Results of this evidenced-based change of practice DNP project indicate the use of opioid safety SMAs using a whole health approach is a simplistic, cost-effective, and innovative approach to addressing a complex problem, the opioid crisis. The most significant result of this project was establishing an evidence-based, cost-effective approach that can be implemented in VA and non-VA facilities, which has shown to lead to sustained clinical improvements in MEDD, pain scores, and use of CAMs for managing pain. Each of the three cohorts in this project demonstrated clinical improvements, regardless of the approach used. This innovative program's primary goal was to fill the existing gap between the status quo of delivering opioid safety education by implementing SMAs using a whole health approach for managing pain and saving the priceless lives of thousands of American Veterans. Achieving this goal demonstrated a decrease in opioid usage and pain scores and an increase in the use of CAMs for managing pain in a Veteran population.

Spread of this practice has the potential to improve the lives of Veterans with chronic pain and chronic opioid reliance. Key findings from this project support using the SMA whole health conceptual framework utilizing an interdisciplinary staff as a mode to reduce opioid reliance, decrease opioid usage, and improve opioid safety in a Veteran population. The HPM, paired with the whole health model, provided the framework for this project for Veterans to identify interventions based on their perceived strengths, self-efficacy, and potential benefits from making lifestyle changes through creating SMART goals. Further investigation is needed to investigate this topic of interest.

The intangible benefits of implementing a whole health opioid safety SMA program include providing education in a humane, patient-centered, compassionate manner. The author

believes that it is no coincidence that this change of practice DNP project is being completed in September, during the observance of National Recovery Month. The purpose of this designation is to educate Americans that with help, those with a substance abuse disorder can live a rewarding and healthy life and reinforces that behavioral health is essential to overall wellness (National Association for Alcoholism and Drug Abuse Counselors, n.d.). The opportunity to answer our nation's call to defeat the opioid crisis will require a steady hand, strong leadership support, and a multi-pronged approach using interdisciplinary healthcare staff. The knowledge obtained through the USF's DNP-EL program will position the author perfectly to begin to change the world from here.

Other Information

Funding

This DNP project did not receive funding from any organization influencing the design, implementation, interpretation, or reporting of this work.

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Appendix A

Evidence Table

Purpose of Article or Review	Design / Method Conceptual Framework	Sample / Setting	Major Variables Studied (and their Definitions)	Measurement of Major Variables	Data Analysis	Study Findings	Level of Evidence (Critical Appraisal Score) / Worth to Practice / Strengths and Weaknesses / Feasibility / Conclusion(s) / Recommendation(s) /
Betthausen, L. M., Brenner, L. A., Forster, J. E., Hostetter, T. A., Scheider, A. L., & Hernandez, T. D. (2014). A factor analysis and exploration of attitudes and beliefs toward complementary and conventional medicine in veterans. <i>Medical Care</i> , 52(12), S50- S56. doi:10.1097/MLR.0000000000000219							
Purpose: Study aimed at exploring Veterans attitudes and beliefs regarding complementary alternative modalities (CAMs) and conventional medicine.	Design: Qualitative Factor Analysis, Observational Study Methods: Patients completed survey, interviews, and self-reported measures during a single visit Conceptual Framework: None Noted	Sample: 97 Veterans Setting: VA Primary Care visits	Independent Variable: Veteran Interviews Dependent Variable: Beliefs regarding CAM usage	Measurement of Independent Variable: Self-reported via interview Measurement of Dependent Variable: Extracted survey Results	Data Analysis: Three investigators conducted a principal factor analysis with a varimax of 27 items from survey.	Findings: Acceptability of CAMs was associated with a history of PTSD, mild traumatic TBI. Veterans supported use of wide range complementary modalities to manage pain.	Rating: Level III, A/B (High/Good Quality) Worth to Practice: Veterans believed that complementary modalities involving the mind and body should be incorporated into their care. Finding may assist providers in understanding Veterans willingness to use CAMs. Feasibility: CAMs cost-effective for pain management Strengths: Veterans endorsed a wide range of CAM alternatives to manage pain. Weaknesses: Small sample size, no conceptual framework noted. Conclusions: Veterans who participated in this study were receptive to the use of complementary modalities. Recommendations: Will incorporate findings into project to support importance of CAM usage as alternative for opioid usage to manage pain.

Purpose of Article or Review	Design / Method Conceptual Framework	Sample / Setting	Major Variables Studied (and their Definitions)	Measurement of Major Variables	Data Analysis	Study Findings	Level of Evidence (Critical Appraisal Score) / Worth to Practice / Strengths and Weaknesses / Feasibility / Conclusion(s) / Recommendation(s) /
Cain, E. K., Gordon, A. N., Mooney, K. D., Aikens, G. B., Robinson, M. H., & Howard, M. E. (2017). Impact of shared medical appointment on hypertension clinical outcomes and medication adherence in a Veteran’s affairs health care system. <i>Journal of Pharmacy Technology</i> , 33(5), 177-182. doi:10.1177/8755122517714578							
<p>Purpose: This purpose of this QI study was to determine if pharmacist- led SMAs could improve access and quality of care by impacting specific measures in Veterans with hypertension</p>	<p>Design: Quality Improvement Study Methods: Participants were on a minimum of two hypertension medications, had a systolic blood pressure (SBP) of >140 mm Hg or diastolic blood pressure (DBP) of > 90</p>	<p>Sample: 21 Veterans Setting: Veterans who received care at two VA Primary Care clinics Conceptual Framework: None</p>	<p>Independent Variable: SMAs Dependent Variable: Positive effect on clinical reductions in hypertensive Veterans</p>	<p>Measurement of Independent Variable: Veterans who attended minimum of 2-Pharmacist-led SMAs Measurement of Dependent Variable: SBP reduction of 76.2% of participants</p>	<p>Analysis: Baseline comparison data was collected by two pharmacists and four Primary Care physicians who compared post-SMA intervention using McNemar’s exact test for matched pairs, differences in mean scores were evaluated using a paired, 2-tailed <i>t</i> test</p>	<p>Findings: Proportion of Veterans with controlled BP increased compared to baseline readings from 14.3% to 42.9%; SBP decreased for 76.2% of pts. DBP decreased for 52.4% of pts.</p>	<p>Rating: Level III, A/B (High/Good Quality) Worth to Practice: SMAs growing in popularity in PC settings Feasibility: SMAs cost-effective approach for impacting clinical results (HPN) Strengths: Utilized interdisciplinary team to conduct SMAs, Strong QI study, easily reproducible in like settings Weaknesses: Study points out that a Gold Standard for conducting SMAs is lacking Conclusions: Veteran diagnoses, suggests strong linkage between strength of education in group settings over individual office appointment education. Recommendations: Study findings will be incorporated into DNP project to support the use of SMAs to impact clinical outcomes using an interdisciplinary approach</p>

Purpose of Article or Review	Design / Method Conceptual Framework	Sample / Setting	Major Variables Studied (and their Definitions)	Measurement of Major Variables	Data Analysis	Study Findings	Level of Evidence (Critical Appraisal Score) / Worth to Practice / Strengths and Weaknesses / Feasibility / Conclusion(s) / Recommendation(s) /
<p>Chen Y., Shiels, M. S., Thomas, D., Freedman, N. D., & Berrington, A. (2018). Premature mortality from drug overdoses: A comparative analysis of 13 organization for economic co-operation and development member countries with high-quality death certificate data, 2001 to 2015. <i>Annals of Internal Medicine</i>. Advance online publication. doi:10.7326/M18-2415</p>							
<p>Purpose: To compare trends in premature death rates due to drug overdoses in 13 countries including the U.S.</p>	<p>Design: Integrative Review</p> <p>Conceptual Framework: None Noted</p> <p>Methods: Researchers used the World Health Organization Mortality Database to extract the annual number of deaths by a drug overdose</p>	<p>Sample: Data from 13 countries was extracted for the study</p> <p>Setting: Not indicated</p>	<p>Independent Variable: Premature death rates due to drug overdoses</p> <p>Dependent Variable: Data from 13 countries</p>	<p>Measurement of Independent Variable: Data from 13 countries analyzed</p> <p>Measurement of Dependent Variable: Data extraction</p>	<p>Analysis: Data was extracted by four authors of the study between 2001 and 2015 and included year, country, age, and gender using Stata software</p>	<p>Findings: U.S. mortality rate due to opioid overdoses was twice that of other countries involved in this study. These findings can be directly linked to the three waves of the U.S. opioid crisis</p>	<p>Rating: Level V, A (High Quality)</p> <p>Worth to Practice: Study findings support the need for an immediate solution to address the opioid crisis</p> <p>Feasibility: Study supports use in project depicting severity of opioid crisis</p> <p>Strengths: Used large, international sample from 13 countries</p> <p>Weaknesses: Study failed to compare impact of specific drugs effecting death rates by country</p> <p>Conclusions: The alarming statistics point to the urgent need to find a solution for resolving the opioid crisis</p> <p>Recommendations: Statistics provided in this study will be used to support project and provide an impetus for a solution to positively impact the alarming death rates due to drug overdoses in the U.S.</p>

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Christie, C., Baker, C., Cooper, R., Kennedy, P. J., Madras, B., & Bondi, P. (2017). <i>The president's commission on combating drug addiction and the opioid crisis</i> . Retrieved from: https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-1-2017.pdf							
<p>Purpose: To develop recommendations to combat the opioid crisis to include a national curriculum to educate prescribers on the standards of care for administering opioids</p>	<p>Design: Consensus Panel/Position Statement by Government Agency</p> <p>Methods: Gov. Christie led a Commission to assist the President of the U.S.</p> <p>Conceptual Framework: None</p>	<p>Sample: N/A</p> <p>Setting: Washington, DC</p>	<p>Independent Variable: Opioid Crisis</p> <p>Dependent Variable: Recommendations from panel experts</p>	<p>Measurement of Independent Variable: National statistics</p> <p>Measurement of Dependent Variable: Recommendations to be shared nationally</p>	<p>Analysis: Report presented verbally to the President of the U.S.</p>	<p>Findings: Mental Health services are lacking in the U.S. as only 10.6% of both youth and adults who need treatment for opioid addiction, receive it.</p>	<p>Rating: Level IV, A/B (High/Good) Quality</p> <p>Worth to Practice: The numerous recommendations to include increased media coverage via an opioid awareness campaign, data sharing, mental health services, state-based drug monitoring programs may inform clinicians and national leaders of the severity of the opioid crisis</p> <p>Feasibility: Actions and recommendations from the expert panel support need for immediate action in resolving opioid crisis and supports project</p> <p>Strengths: Panel comprised of subject matter experts</p> <p>Weaknesses: None noted</p> <p>Conclusions: A multi-pronged approach is needed to address the opioid crisis facing the U.S.</p> <p>Recommendations: Data and recommendations from this expert panel will be integrated into this project</p>

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Drake, C., Meade, C., Hull, S. K., Price, A., Snyderman, R. (2018). Integration of personalized health planning and shared medical appointments for patients with type 2 diabetes mellitus. <i>Southern Medical Journal</i> , 111(11), 674-682. doi:10.14423/smj.0000000000000892							
Purpose: Study reviews the feasibility of incorporating personalized health planning (PHP) into SMAs for patients with diabetes mellitus (DM).	Design: Quasi-experimental study Methods: Pts randomized to the PHP SMA (intervention) standard SMA (control). Conceptual Framework: None Noted	Sample: 12 patients attended SMAs Setting: The Duke Family Medicine Center	Independent Variable: SMA for DM patients Dependent Variable: Usefulness of PHP into SMAs	Measurement of Independent Variable: Evaluation of feasibility and implementation Measurement of Dependent Variable: Data extraction	Analysis: Two coders used Consolidated Framework for Implementation Research (CFIR) to organize data	Findings: Clinical outcomes included reductions in hemoglobin A1c, low density lipoproteins, BMI, and blood pressure. Achievement of health goals also obtainable through use of PHP during SMAs.	Rating: Level II, A/B (High/Good) Quality Worth to Practice: Use of the PHP's in SMAs can assist clinical teams in impacting DM related outcomes Feasibility: Cost-effective approach to achieve clinical outcomes supports whole health approach conceptual framework of project Strengths: Results of incorporating PHP into SMA would be a simple process to replicate Weaknesses: Small sample size Recommendations: Findings will be used in project to support use of PHPs in SMAs project to impact clinical

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Edelman, D., McDuffie, J. R., Oddone, E., Gierisch, J. M., Nagi, A., & Williams, J. W., Jr. (2012). <i>Shared medical appointments for chronic medical conditions: A systematic review.</i> (VAESP Project 09-010). Washington, DC: Department of Veterans Affairs							
<p>Purpose: To assess the effective-ness of SMAs on staff, patient, and economic outcomes to determine if the impact differed between clinical conditions, or specific interventions used</p>	<p>Design: Systematic Review of RCTs. Non-randomized cluster-controlled trials, controlled before-and-after studies, interrupted time-series designs</p> <p>Methods: Observational</p> <p>Conceptual Framework: None Noted</p>	<p>Sample: 19 RCTs and Observational Studies</p> <p>Setting: VA Primary Care clinics</p>	<p>Independent Variable: SMAs</p> <p>Dependent Variable: Veteran, staff, and economic outcomes</p>	<p>Measurement of Independent Variable: Record reviews</p> <p>Measurement of Dependent Variable: Data extraction</p>	<p>Analysis: Electronic analysis of results along with manual search of citations</p>	<p>Findings: SMAs may be most effective for medical conditions that have a high-risk of complications, such as diabetes mellitus where medication management and titration are important</p>	<p>Rating: Level II A/B (High/Good) Quality</p> <p>Worth to Practice: SMAs can positively affect clinical outcomes such as DM</p> <p>Feasibility: SMAs are effective in positively impacting clinical and economic outcomes, satisfaction of participants and staff</p> <p>Strengths: Large sample size of RCTs</p> <p>Weaknesses: None noted</p> <p>Conclusions: Reviews showed that using SMAs in small, closed groups, providing breakouts for medication management improved outcomes for Type 2 diabetes to include reductions in HBG A1C, systolic blood pressure</p> <p>Recommendations: Study findings will be incorporated into project to support the use of SMAs to impact clinical outcomes</p>

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Edmond, S. N., Becker, W. C., Driscoll, M. A., Decker, S. E., Higgins, D. M., Mattocks, K. M., & Haskell, S. G. (2018). Use of non-pharmacological pain treatment modalities among veterans with chronic pain: results from a cross-sectional survey. <i>Journal of General Internal Medicine</i> , 33(1), 54-60. doi:10.1007/s11606-018-4322-0							
<p>Purpose: To evaluate rates and correlates NPMs use in Veterans during recent conflicts</p>	<p>Design: Qualitative with Meta- Synthesis</p> <p>Methods: Data collected through record reviews and interviews</p> <p>Conceptual Framework: None Noted</p>	<p>Sample: Survey results from 460 Veterans with chronic pain defined as lasting > 3 months</p> <p>Setting: VA Primary Care clinics</p>	<p>Independent Variable: Surveys</p> <p>Dependent Variable: Effectiveness of alternative NPMs to manage clinical outcomes</p>	<p>Measurement of Independent Variable: Record reviews</p> <p>Measurement of Dependent Variable: Self-reported survey results</p>	<p>Analysis: Using regression analysis, calculated descriptive statistics to examine bivariate and multi-variable associations</p>	<p>Findings: Over 12-month period, approximately 43.7% of male Veterans and 56.3% of female Veterans in the study reported using a minimum of one NPM within the past 12 months</p>	<p>Rating: Level II A/B (High/Good Quality)</p> <p>Worth to Practice: NPMs can be alternative to opioid usage</p> <p>Feasibility: NPMs are a cost-effective, safe alternative for managing clinical outcomes</p> <p>Strengths: Moderate sample size, including adequate sample of female Veterans</p> <p>Weaknesses: Limited by cross-sectional design</p> <p>Conclusions: Further studies are needed to determine which NPM's are most effective in of care for various groups of Veterans, specific to disease condition, and treatment preferences.</p> <p>Recommendations: Findings support project in use of NPMs as alternative to using opioids for managing pain</p>

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Frank, J. W., Lovejoy, T. I., Becker, W. C., Morasco, B. J., Koenig, J., Hoffecker, L., ... Krebs, E. E. (2017). Patient outcomes in dose reduction or discontinuation of long-term opioid therapy. <i>Annals of Internal Medicine</i> , 167(3), 181. doi:10.7326/m17-0598							
<p>Purpose: Review completed to synthesize the effective-ness of methods to decrease long term opioid therapy (LTOT)</p>	<p>Design: Systematic Review with RCTs with Meta-Analysis</p> <p>Methods: Data collected through data extraction</p> <p>Conceptual Framework: None Noted</p>	<p>Sample: Two investigators reviewed abstracts of 67 studies (11 RCTs and 56 observational studies)</p> <p>Setting: None Noted</p>	<p>Independent Variable: Record Reviews</p> <p>Dependent Variable: Alternative methods to decrease LTOT</p>	<p>Measurement of Independent Variable: 67 studies</p> <p>Measurement of Dependent Variable: Data extraction</p>	<p>Analysis: Two reviewers extracted data to assess quality of data using the U.S. Preventive Services Task Force quality rating criteria</p>	<p>Findings: Review of eight interventions categories, including inter-disciplinary pain programs, buprenorphine assisted dose reductions, and behavioral interventions, were found Many studies reported dose reductions, but rates of opioid discontinuation varied widely</p>	<p>Rating: Level II A/B (High/Good) Quality</p> <p>Worth to Practice: Value in providers discussing benefits of tapering LTOT and referring to interdisciplinary pain teams</p> <p>Feasibility: Cost-effective means to find alternatives for managing pain</p> <p>Strengths: Study quality was good for three studies, fair for 13 studies</p> <p>Weaknesses: Heterogeneous interventions and outcome measures</p> <p>Conclusions: Evidence suggests that numerous interventions may reduce LTOY. Pain, function and the quality of life may improve when opioid doses are reduced</p> <p>Recommendations: Findings will be included in the project as evidence to support the use of various interventions as effective alternatives for LTOT</p>

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Han, B., Compton, W. M., Blanco, C., Crane, E., Lee, J., & Jones C. M. (2017). Prescriptive opioid use, misuse, and use disorders in U.S. adults. <i>Annals of Internal Medicine</i> , 167(5), 1-24. doi:10.7326/P17-9042							
<p>Purpose: Determine the rate of prescription opioid misuse, use, use disorders, and motivation for use by U.S. adults. for use was examined</p>	<p>Design: Qualitative</p> <p>Methods: Surveys</p> <p>Conceptual Framework: None</p>	<p>Sample: 51,200 adults</p> <p>Setting: 2015 Survey on Drug Use and Health (NSDUH) conducted in pts. homes</p>	<p>Independent Variable: Surveys</p> <p>Dependent Variable: National rates of opioid use, misuse, and motivation for use</p>	<p>Measurement of Independent Variable: In-person interviews</p> <p>Measurement of Dependent Variable: Data extraction</p>	<p>Analysis: SUDAAN software (RT) International (24) to account for the complex sample weights and design of the survey</p>	<p>Findings: Weighted NSDUH results estimated 91.8 million (37.8%) of U.S adults used prescription opioids, 11.5 million (4.7%) misused opioids, and 1.9 million (0.8%) had an opioid use disorder. 12.5% of adults that were prescribed opioids reported misusing them, of these, 16.7% reported having an</p>	<p>Rating: Level III A/B (High/Good) Quality</p> <p>Worth to Practice: Prescribers can gain increased understanding of opioid use, misuse, and reasons for usage</p> <p>Feasibility: Study findings support urgency to find a solution for the opioid crisis and supports project</p> <p>Strengths: Large sample size</p> <p>Weaknesses: NSDUH excluded homeless person not living in a shelter, institutionalized residents, or active-duty military personnel</p> <p>Conclusions: 2015 survey data revealed more than one-third of U.S adults reported using opioids. Reduction from pain was the key motivator for using opioids. The results indicate the need for expanding access to evidenced-based pain management programs and to provide ongoing education on the use of these addictive and powerful medications</p> <p>Recommendations: Results will be integrated into the project as evidence to support of the severity</p>

Purpose of Article or Review	Design / Method Conceptual Framework	Sample / Setting	Major Variables Studied (and their Definitions)	Measurement of Major Variables	Data Analysis	Study Findings	Level of Evidence (Critical Appraisal Score) / Worth to Practice / Strengths and Weaknesses / Feasibility / Conclusion(s) / Recommendation(s) /
						<p>opioid use disorder. The most common finding for motivation to use opioids was for relief of physical pain (63.4%)</p>	<p>of the opioid crisis and the urgency to find a solution</p>

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<p>Nahin, R. L. (2017). Severe pain in veterans: The effect of age and sex, and comparisons with the general population. Journal of Pain, 18(3), 247-254 doi:10.1016/j.pain.2016.10.021</p>							
<p>Purpose: To provide national prevalence estimates of U.S. Veterans who reported severe pain levels and compares pain levels of non-Veterans of similar sex and age</p>	<p>Design: Qualitative Methods: Data collection from National Health Interview Survey (NHIS) Conceptual Framework: None</p>	<p>Sample: Data was extracted from the 2010 - 2014 NHIS of 67,696 adults who completed the Adult Functioning Survey Setting: VA Primary Care clinics</p>	<p>Independent Variable: Defined as a Veteran by either currently serving in the U.S. military or having had served. Dependent Variable: Self-reported assessment of pain over the past three months</p>	<p>Measurement of Independent Variable: Participants were identified as having severe pain via the imbedded coding system in the Adult Functioning and Disability Supplement Measurement of Dependent Variable: The Washington Group on Disability Statistics developed and validated questions through pilot surveys and cognitive testing</p>	<p>Analysis: X2 test used to assess the global associations between categorical variables and prevalence of pain. Contingency tables were used to assess the relationship between ordinal pain and all other categories.</p>	<p>Findings: 65.5% of military Veterans reported pain in the previous three months, with 9.1% reporting severe pain, as compared to pain reported from non-Veterans of 56.4%, and severe pain at 6.4%.</p>	<p>Rating: Level III A/B (High/Good) Quality Worth to Practice: Study points to the need for increased attention needed toward recognition and treatment of greater severe pain in the Veteran population Feasibility: Provides awareness of severity of pain in Veteran pop. Strengths: Large sample size, first study to compare severity of pain between U.S. military Veterans and non-Veterans Weaknesses: Cross-sectional data unable to prospectively Determine clinical outcomes, NHIS unable to retrieve information regarding pain treatment Conclusions: Prevalence of pain in Veterans compared to non-Veterans is alarmingly higher and must be addressed using evidenced-based modalities. The study recommends revised pain management strategies be offered to the Veteran population Recommendations: Study findings can be integrated into the project to support solution for managing severe pain in the Veteran population</p>

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Omogbai, T., & Milner, K. A. (2018). Implementation and evaluation of shared medical appointments in patients with diabetes: A quality improvement study. <i>Journal of Nursing Administration, 48</i> (3), 154-159. doi:10.1097/NNA.0000000000000590							
<p>Purpose: To implement and evaluate the clinical outcomes and satisfaction of Veterans with diabetes mellitus who attended SMAs</p>	<p>Design: Quality Improvement</p> <p>Methods: Record Reviews</p> <p>Conceptual Framework: The Chronic Care Model (CCM) provided the framework for this QI study. The CCM is designed to manage chronic diseases more efficiently and effectively</p>	<p>Sample: 30 male Veterans with DM who attended SMAs</p> <p>Setting: VA Primary Care clinics</p>	<p>Independent Variable: SMAs</p> <p>Dependent Variable: Clinical outcomes and satisfaction related to attending DM-SMAs</p>	<p>Measurement of Independent Variable: Record Reviews</p> <p>Measurement of Dependent Variable: Clinical outcome data and satisfaction survey results</p>	<p>Analysis: Data analyzed using SPSS version 23, descriptive statistics used to describe baseline and clinical outcomes data. Paired <i>t</i> tests used to compare baseline, three months, and three to six months of data</p>	<p>Record reviews of Veterans who participated in the DM SMA include significant reductions in A1c, triglycerides, total cholesterol, and systolic blood pressure when measured six months after the intervention. Veterans satisfaction scores increased significantly from 22.3 (SD, 2.59) to 35.4 (SD, 0.77)</p>	<p>Rating: Level V, A (High Quality)</p> <p>Worth to Practice: SMAs can positively impact specific clinical outcomes</p> <p>Feasibility: Cost-effective means to assess impact of SMAs on clinical outcomes</p> <p>Strengths: Study guided by strong conceptual framework</p> <p>Weaknesses: Certain Veterans voiced reluctance to discussing health status during SMA; small sample size</p> <p>Conclusions: Results of this QI study indicates that SMAs can be an effective modality to influence clinical outcomes and satisfaction in Veteran patients with DM. Recommendations include spreading the use of SMAs VA-wide for all Veterans with DM</p> <p>Recommendations: Results will be integrated into project as evidence to support use of SMAs to impact clinical outcomes and improve participant satisfaction</p>

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Rani, E. A., Johnston, J. M., Bormann, J. E., Hull, A., & Taylor, S. L. (2014). A systematic scoping review of complementary and alternative medicine mind and body practices to improve health of veterans and military personnel. <i>Medical Care</i> , 52(12), 1-15. doi:10.1097/MLR.0000000000000228							
Purpose: Review of mind-body practices by Veterans and active duty personnel to determine gaps in the literature and to provide recommendations for future research recommendations	Design: Systematic Scoping Review with Meta-Analysis Methods: One reviewer search five databases Conceptual Framework: None noted	Sample: 89 interventions of active duty military personnel practicing mind-body interventions Setting: None stated	Independent Variable: 2011 National VA survey Dependent Variable: Use of mind-body practices in a Veteran population	Measurement of Independent Variable: Data extraction Measurement of Dependent Variable: Article reviews for inclusion on mind-body interventions used in Veteran population	Analysis: PRISMA checklist was used to determine inclusion criteria	Findings: Interventions between 1976-2014 to assess 65 health and wellbeing outcomes; most practices were meditation (n=25), relaxation exercises with imagery (n=20), PT and spinal manipulation (n=16), and acupuncture (n=11)	Rating: Level III A/B (High/Good Quality) Worth to Practice: Beneficial in the primary care setting when planning approaches for future development of robust Veteran pain management plans of care Feasibility: Veterans open to mind-body interventions for managing pain Strengths: First systematic scoping review that reviewed all mind-body interventions specific to Veterans Weaknesses: Only articles published in English were included due to limited translation abilities; search strategy may have failed to identify all appropriate articles for inclusion in review Conclusions: Most prevalent mind-body practices used by Veterans and military personnel were meditation and acupuncture. Further research is indicated for use of Yoga in the Veteran population Recommendations: Review of predominant mind-body interventions will be integrated into project to support use of mind-body modalities to manage Veterans pain

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Romanelli, R. J., Dolginsky, M., Byakina, Y., Bronstein, D., & Wilson, S. (2017). A shared medical appointment on the benefits and risks of opioids is associated with improved patient confidence in managing chronic pain. <i>Journal of Patient Experience</i> , 4(3), 144-151. doi:10.1177/2374373517706837							
<p>Purpose: To evaluate the confidence levels of Veterans who attended an opioid shared medical appointment (SMA) on the treatment of chronic pain</p>	<p>Design: Prospective Study</p> <p>Methods: Participants handed an anonymous survey pre-post SMA</p> <p>Conceptual Framework: None noted</p>	<p>Sample: 130</p> <p>Setting: Ambulatory clinic within a health care system</p>	<p>Independent Variable: SMAs</p> <p>Dependent Variable: Confidence levels for managing pain</p>	<p>Measurement of Independent Variable: Survey responses</p> <p>Measurement of Dependent Variable: Data extraction</p>	<p>Analysis: Logistical regression models were used to explore differences in responses by baseline characteristics Descriptive statistics used to calculate responses</p>	<p>Findings: Chronic pain who attended SMAs on risks and benefits with opioid usage reported improvements in confidence in managing their pain, along with their healthcare team’s ability to manage pain</p>	<p>Rating: Level III A/B (High/Good) Quality</p> <p>Worth to Practice: SMAs can be an effective approach for improving patient confidence in managing pain</p> <p>Feasibility: Increased confidence to manage pain supports self-efficacy and whole health conceptual framework of probject</p> <p>Strengths: Easy to replicate, cost-effective, evidence-based</p> <p>Weaknesses: Study reviewed short term outcomes only, without a control group</p> <p>Conclusions: Patients demonstrated increased confidence in their ability and their healthcare team’s ability to manage pain increased through the use of SMAs.</p> <p>Recommendations: Results will be integrated into project to support importance of understanding Veterans confidence levels-self-efficacy in managing pain</p>

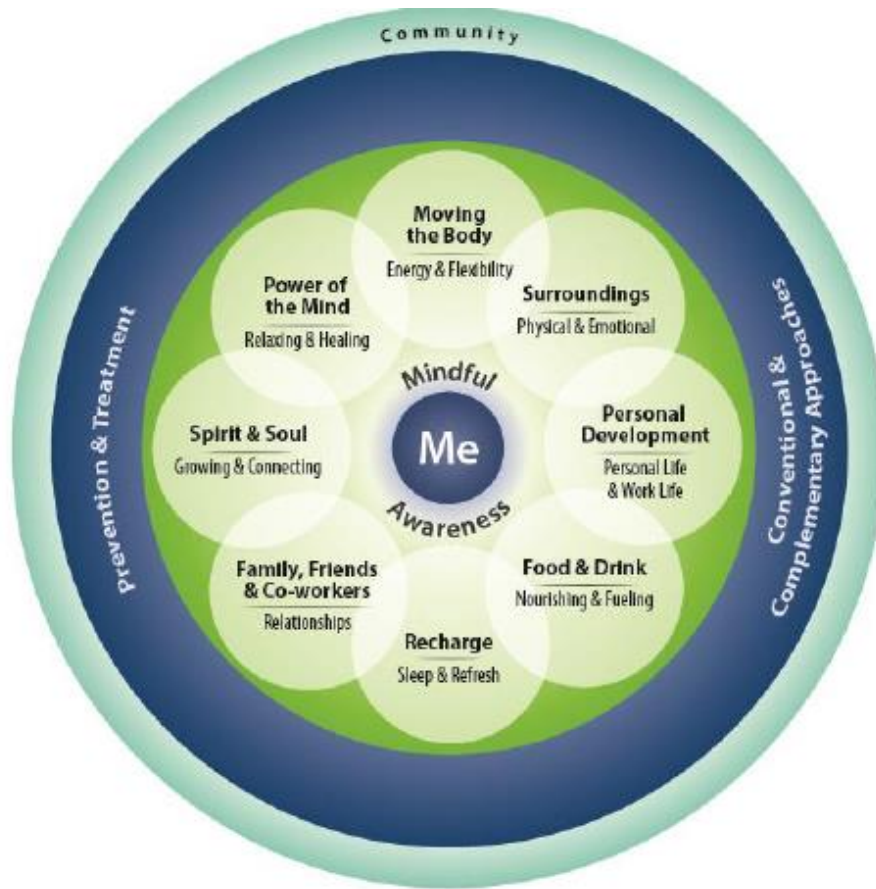
Purpose of Article or Review	Design / Method Conceptual Framework	Sample / Setting	Major Variables Studied (and their Definitions)	Measurement of Major Variables	Data Analysis	Study Findings	Level of Evidence (Critical Appraisal Score) / Worth to Practice / Strengths and Weaknesses / Feasibility / Conclusion(s) / Recommendation(s) /
Tyndale, R. F., & Sellers, E. M. (2018). Opioids: The painful public health reality. <i>Clinical Pharmacology and Therapeutics</i> , 103(6), 924-935. doi:10.1002/cpt.1074							
<p>Purpose: To discuss the profound consequences of the opioid crisis, pharmacologic aspects, public health policy and initiatives, research and treatment advances in both the U.S and other countries</p>	<p>Design: Opinion of nationally recognized expert(s) based on experiential evidence</p> <p>Methods: N/A</p> <p>Conceptual Framework: N/A</p>	<p>Sample: N/A</p> <p>Setting: N/A</p>	<p>Independent Variable: N/A</p> <p>Dependent Variable: N/A</p>	<p>Measurement of Independent Variable: N/A</p> <p>Measurement of Dependent Variable: N/A</p>	<p>Analysis: N/A</p>	<p>Findings: Data provided regarding prescription opioid sales in U.S. quadrupled from 1999 to 2014, without a significant change in the amount of pain reported by Americans. The U.S. is the leading nation for opioid prescribing. This rise in opioid-related overdose deaths can be attributed to three separate waves of lethal drugs: first wave of</p>	<p>Rating: Level V A (Good Quality)</p> <p>Worth to Practice: Expert opinions regarding the urgent need for more funding to find an evidenced-based solution to the opioid crisis. A whole health opioid safety SMA can be part of the solution</p> <p>Feasibility: N/A</p> <p>Strengths: Provides history of opioid crisis in the U.S. and current severity</p> <p>Weaknesses: Expert opinions limited to two authors; systematic reviews of rigorous studies needed to make change</p> <p>Conclusions: Public health crisis of opioid addiction and death rates will require additional scientific leadership and funding to make needed changes, to include a national summit to create research agenda</p> <p>Recommendations: Much of the data needed to make change will require research from federal and agencies and foundations</p>

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						<p>opioid mortality deaths began in the late 1990s followed by a second wave of deaths from heroin starting in 2010. The third wave has been occurring due to synthetic opioids</p>	

Purpose of Article or Review	Design / Method Conceptual Framework	Sample / Setting	Major Variables Studied (and their Definitions)	Measurement of Major Variables	Data Analysis	Study Findings	Level of Evidence (Critical Appraisal Score) / Worth to Practice / Strengths and Weaknesses / Feasibility / Conclusion(s) / Recommendation(s) /
Wadsworth, K. H., Archibald, T. G., Payne, A. E., Cleary, A. K., Haney, B. L., & Hoverman, A. S. (2019). Shared medical appointments and patient-centered experience: A mixed methods systematic review. <i>BMC Family Practice</i> , 20(1), 97. doi:10.1186/s12875-019-0972-1							
<p>Purpose: The use of SMAs in primary care settings are increasing; however, a standardized implementation approach is lacking</p>	<p>Design: Systematic review without meta-analysis Methods: Systematic review of qualitative, quantitative, mixed method studies without meta-analysis. Categorization of the extracted data informed a thematic synthesis Conceptual Framework: None Noted</p>	<p>Sample: 13 quantitative controlled trial, 11 qualitative papers, two mixed methods studies Setting: Two researchers extracted data in library setting</p>	<p>Independent Variable: SMAs Dependent Variable: Standardized approach to conduct SMAs</p>	<p>Measurement of Independent Variable: Review of previous studies Measurement of Dependent Variable: Data Extraction</p>	<p>Analysis: To evaluate qualitative studies, team used Trustworthiness of Qualitative Inquiry and ENTREQ PRISMA frameworks</p>	<p>Findings: Positive impact from SMAs included improved patient satisfaction, increase in feeling connected with clinical team, resiliency, and improved care coordination Review of past SMAs demonstrate lack of a Gold Standard for conducting them</p>	<p>Rating: Level III A/B (High/Good) Quality Worth to Practice: Primary Care setting is most appropriate setting to conduct SMAs; improved resilience and enhanced coping skills are important outcomes of SMAs Feasibility: SMAs are cost-effective delivery modality to improve clinical outcomes Strengths: Current review updates the evidence to support the use of SMAs and enhance patient-experience Weaknesses: Small number of studies limited by inclusion criteria, single-center facilities may limit generalizability Conclusions: Standardized training and implementation of SMA's is needed to ensure the most impactful outcomes. Recommendations: Results will be integrated into project to support importance of developing a standardized approach for a SMA curriculum on opioid safety</p>

Appendix B

VA Proactive Health and Well-Being Model



Note: The Circle of Health is a visual picture of the Whole Health approach to care. This helps you explore connections between important aspects of your life and your health and well-being. (Simmons, Drake, Gaudet, & Snyderman, 2016).

Appendix C

Team Composition Table

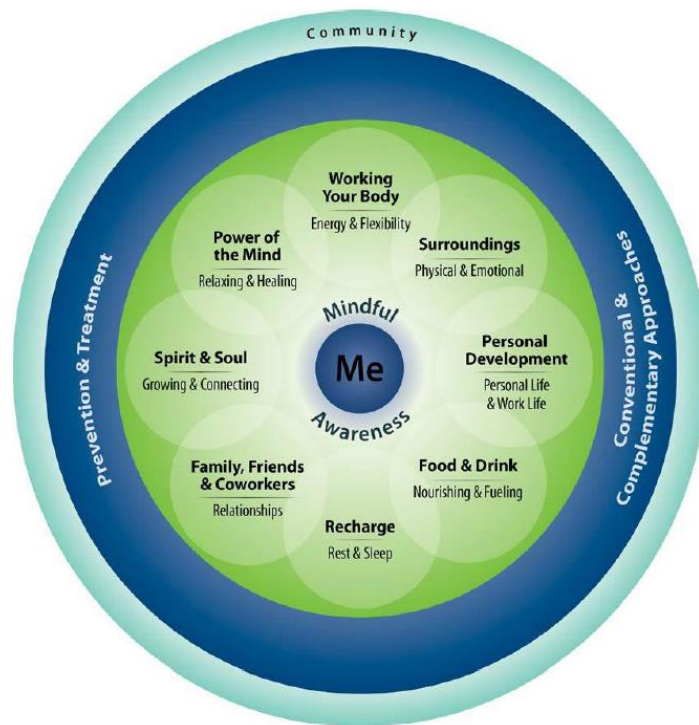
	Team I	Team II	Team III
Who was involved?	Full PACT Staff	Full PACT Staff	Provider only
Setting	Shared Medical Appointment	Shared Medical Appointment	Office Visit
Health Coaching Utilized?	Yes	No	No
Education Delivery	Handouts, Audiovisual, Classroom Instruction with Coaching	Handouts, Audiovisual, Classroom Instruction	Verbal
Time Frame	90 minutes every week for 9 Weeks to include health coaching (60 min.) starting Week 3	90 minutes every week for 9 Weeks	30 mins-1 Hour
Curriculum	<p>Structured around the Whole Health Wheel Session 1: Introduction to Whole health & Opioid Safety</p> <p>Session 2: Working the Body Opioid Safety: Overdose Prevention (Naloxone)</p> <p>Session 3: Surroundings Opioid Safety: Taking Opioids Responsibly Coaching Session</p> <p>Session 4: Personal Development Opioid Safety: Side Effects & Risk Coaching Session</p> <p>Session 5: Food & Drink Opioid Safety: Pain Care Plan Coaching Session</p> <p>Session 6: Recharge & Sleep Opioid Safety: Withdrawal, Dependence, Disorder Coaching Session</p> <p>Session 7: Relationships Opioid Safety: Alternatives Coaching Session</p> <p>Session 8: Spirit & Soul Opioid Safety: Opioid Tapering Coaching Session</p> <p>Session 9: Power of the Mind Relaxing & Healing Opioid Safety: Storage & Disposal Coaching Session</p> <p>Session 10: Full Circle Review</p>	<p>Structured around the Whole Health Wheel Session 1: Introduction to Whole health & Opioid Safety</p> <p>Session 2: Working the Body Opioid Safety: Overdose Prevention (Naloxone)</p> <p>Session 3: Surroundings Opioid Safety: Taking Opioids Responsibly</p> <p>Session 4: Personal Development Opioid Safety: Side Effects & Risk</p> <p>Session 5: Food & Drink Opioid Safety: Pain Care Plan</p> <p>Session 6: Recharge & Sleep Opioid Safety: Withdrawal, Dependence, Disorder</p> <p>Session 7: Relationships Opioid Safety: Alternatives</p> <p>Session 8: Spirit & Soul Opioid Safety: Opioid Tapering</p> <p>Session 9: Power of the Mind Relaxing & Healing Opioid Safety: Storage & Disposal</p> <p>Session 10: Full Circle Review</p>	Not Structured

Appendix D

Toolkit Index

Whole Health Opioid Safety Patient Workbook

A Guide to Proactive Living and Well-Being
Birmingham VA Medical Center



U.S. Department of Veterans Affairs
Veterans Health Administration
Birmingham VA Medical Center

Whole Health Opioid Safety Course Overview

Session 1: Introduction to Whole Health & Opioid Safety

- a. Orientation to Course & Introductions
- b. Introduction to Pain & Opioids
- c. Retraining Your Brain: YouTube Video
- d. Introduction to Whole Health and the Wheel
- e. Self-Report Card
- f. Request cards

Session 2: Working the Body-Energy & Flexibility

- a. Opioid Safety: Overdose Prevention (Naloxone)
- b. Emotions and Pain
- c. What's mindfulness
- d. Wheel of Health: Working Your Body
- e. Arthurs Video (Power of Will, transformative healing through Power Yoga)
- f. Mindfulness Exercise
- g. Request cards

Session 3: Surroundings

- a. Opioid Safety: Taking Opioids Responsibly
- b. Wheel of Health: Surroundings
- c. Introduction to the Personal Health Inventory
- d. Mission, Aspiration, and Purpose
- e. Introduction to SMART goals
- f. Health Coaching
- g. Request cards

Session 4: Personal Development Growing & Changing

- a. Opioid safety: Side Effects & Risk

- b. Wheel of Health: Personal Development
- c. Complementary Health Exercise
- d. Health Coaching
- e. Request Cards

Session 5: Food & Drink-Nourishing & Fueling

- a. Opioid Safety: Pain Care Plan
- b. Wheel of Health: Food and Drink
- c. Complementary Health Exercise
- d. Health Coaching
- e. Request Cards

Session 6: Recharge, Sleep, & Refresh

- a. Opioid Safety: Opioid Withdrawal, Dependence, Disorder
- b. Wheel of Health: Recharge
- c. Complementary Health Exercise
- d. Health Coaching
- e. Request Cards

Session 7: Relationships-Friends, Family, Co-workers

- a. Opioid Safety: Alternatives to Opiates
- b. Wheel of Health: Family, Friends, Co-Workers
- c. Complementary Health Exercise
- d. Health Coaching
- e. Request Cards

Session 8: Spirit & Soul

- a. Opioid Safety: Opioid Tapering & Suboxone Treatment
- b. Wheel of Health: Spirit and Soul
- c. Complementary Health Exercise
- d. Health Coaching
- e. Request Cards

Appendix E

Gap Analysis

Desired State Attributes

- Finding a safe, effective and sustaining approach to decreasing opioid usage in the Veteran population

Current State Attributes

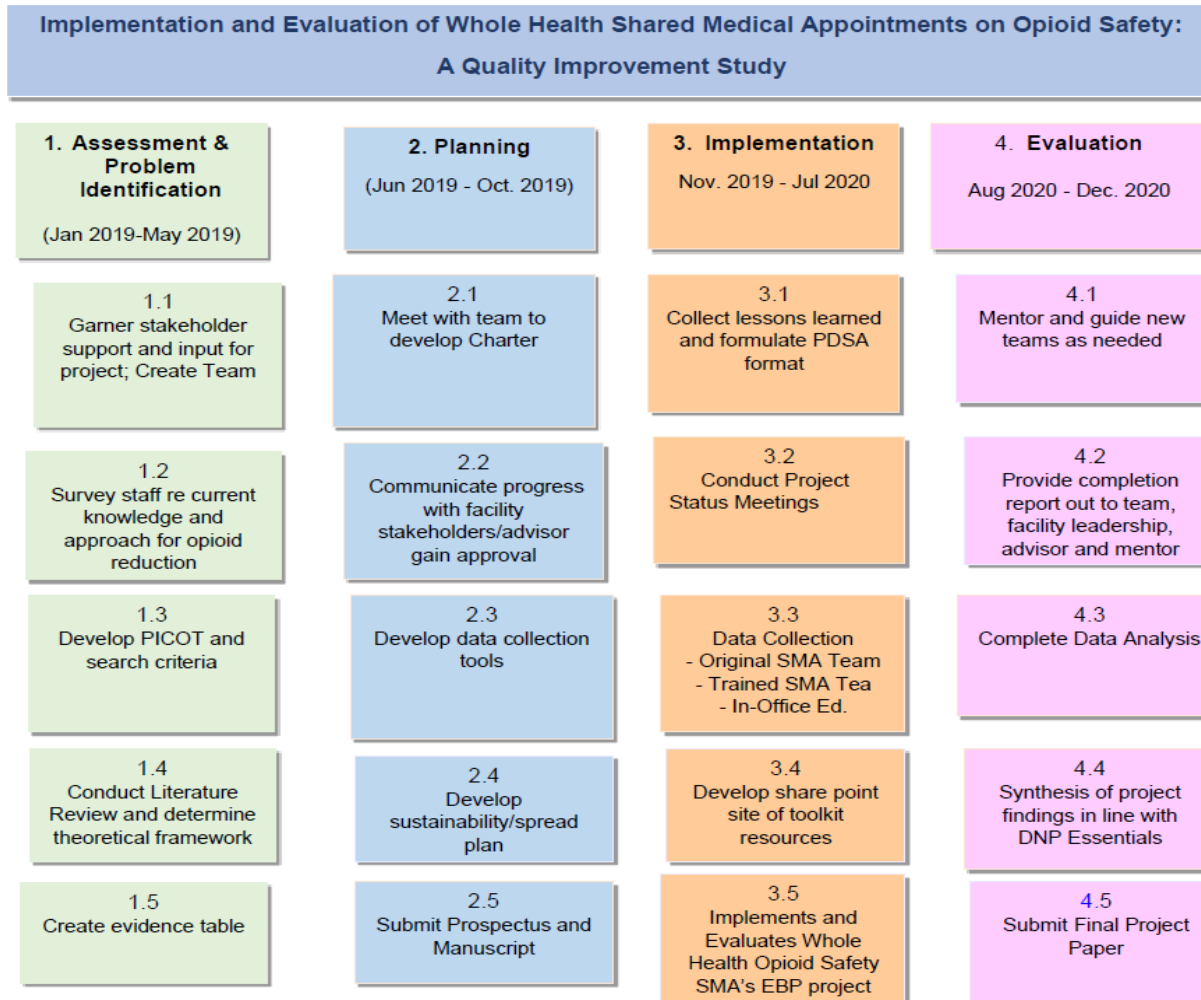
- VA's Four-Pronged Strategy
- Education
- Pain Management
- Addiction treatment
- Risk Mitigation

Defined Gap

- Lack of a Whole Health Approach that is patient-centered and sustainable in decreasing opioid usage while managing pain

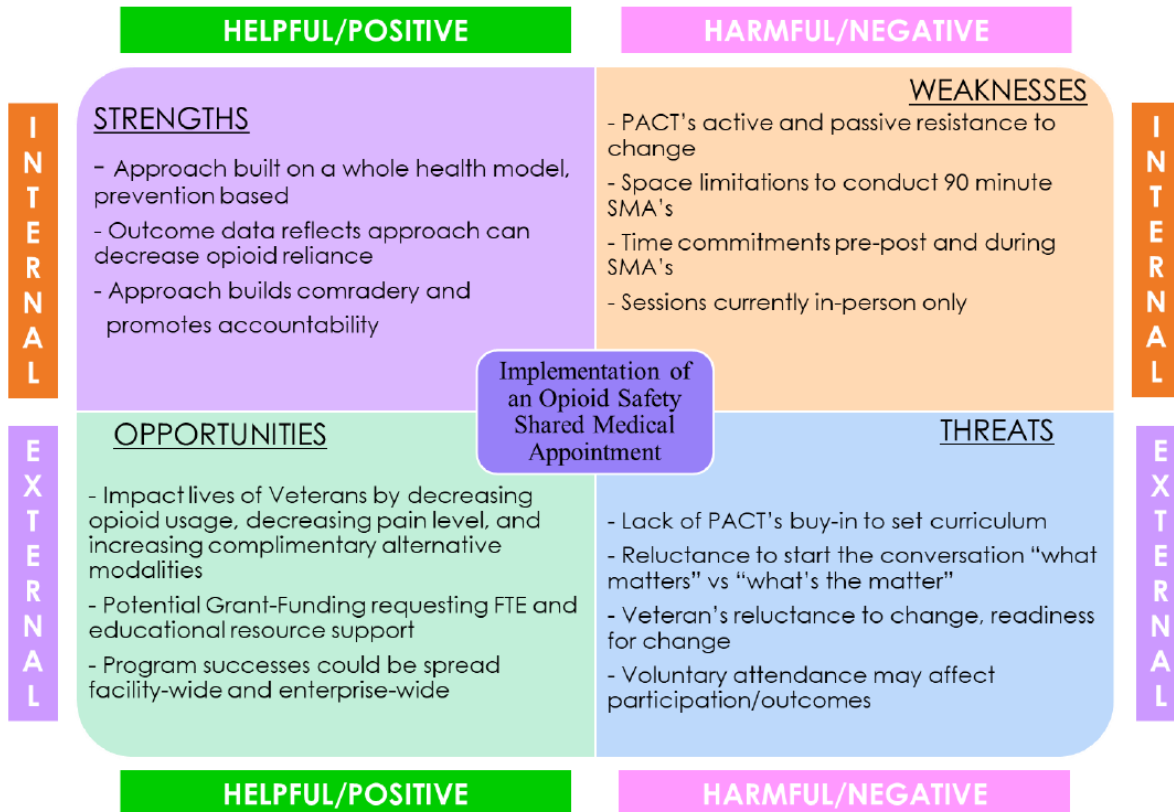
Appendix G

Work Breakdown Structure



Appendix H

SWOT Analysis



Appendix I

Project Budget: Costs Associated with 90-Minute, Nine Session SMA

Retroactive Chart Review By RN 90 pts = 30 min	\$3,375.00
Printing Paper (2)	\$8.00
Plastic Binders (15)	\$45.00
Primary Care Physician	\$3,510.00
RN	\$1,350.00
LPN	\$864.00
MSA	\$792.00
PharmD	\$2,196.00
Dietician	\$1,242.00
Revenue	\$0.00
TOTAL COST:	\$13,382.00

Appendix J

Responsibility / Communication Matrix

Communication	Frequency	Goal	Route
Academic Advisors			
Dr. Knighten	Weekly	Review project status, discuss barriers and updates, share progress	Email, zoom, phone calls
Co-Chair/Second Reader	As needed	To received feedback from draft prospectus	Email, zoom if necessary
Project Sponsors			
Executive Leadership Team (to include the Director, Chief of Staff, Chief Nurse Executive)	Monthly	Review project status, request support as needed	Face-to-face, Emails
Dr. J. Moates (Team Co-Leader)	Twice a week	Review Project from clinical perspective strategize about barriers and facilitators, provide updates	Email and conference calls
Dr. Huie (Director, Primary Care)	Monthly	Review Project from a Primary Care perspective, strategize about barriers and facilitators, provide updates	Email and conference calls
Site (Birmingham VA Medical Center)			
Dr. R. Moore (Mentor)	Bi-Monthly	Discuss data collection methodology and analysis plan	Face-to-face
Dr. B. Roop (PharmD)	Monthly	Review project status	Face-to-face
Project Site Nurse Educator			
J. Falkner	Twice a week	Discuss development and launching of patient educational Toolkit	Phone conference and face-to-face

Appendix K**Cost-Benefit Analysis**

Opioid Safety SMA Program	Year 1	Year 2	Year 3
SALARY COST			
Medical Doctor (MD)	\$ 1,848.00	\$ 1,884.96	\$ 1,922.66
Pharmacist (PharmD)	\$ 1,020.00	\$ 1,040.40	\$ 1,061.21
Registered Nurse (RN)	\$ 540.00	\$ 550.80	\$ 561.82
Licensed Practical Nurse (LPN)	\$ 372.00	\$ 379.44	\$ 387.03
Medical Service Assistant (MSA)	\$ 324.00	\$ 330.48	\$ 337.09
Other Cost			
Training	\$ 5,496.00	\$ 6,008.82	\$ 6,129.00
Supplies	\$ 53.00	\$ 54.06	\$ 55.14
Cumulative Cost	\$ 9,653.00	\$ 10,248.96	\$ 10,453.94
Benefit/Cost Avoidance			
Cost avoidance from primary care office visit	\$ 60,000.00	\$ 61,200.00	\$ 62,224.00
Cumulative Cost/Benefit	\$ 50,347.00	\$ 50,951.04	\$ 51,970.06

Assumptions

2% Cost of living adjustment annually

2% Annual Increase in Training/Supply Costs

Equal number of patients in SMA and Office groups

Appendix L

CQI Method

PLAN DO STUDY ACT (PDSA) FORM

Cycle #: N/A

Start Date: 1/2/20

Project Lead: S. Cox

Objective of this Cycle: Implement a Change

Project Title: Implementation and Evaluation of Whole Health Opioid Safety Shared Medical Appointments (SMA's)

Aim Statement (WHAT YOU ARE TRYING TO ACCOMPLISH):

- Specific- targeted population: Veterans on chronic opioids
- Measurable- what to measure and clearly stated goal: Veterans who completed SMA's lead by original training team (#1) with coaching component will realize a 10% decrease in opioid usage, pain scores and a 10% increase in use of complimentary alternative modalities (CAM's) over veterans trained by the original team (#2) who did not use coaching component, and those who received in-office education with no coaching component.
- Achievable- brief plan to accomplish it: Retrospective record review from 30 charts from each above group
- Relevant- why is it important to do now: According to the CDC (2018) in 2017 alone, more than 70,000 Americans died due to drug overdoses, which included both illicit drugs and opioids legally prescribed. According to VA Secretary Shulkin (2018) veterans are twice as likely to die from an opioid overdose as the average American due to underlying risk factors.
- Time Specific- anticipated length of cycle: The anticipated length of this PDSA cycle is from January 2, 2020 through May 2, 2020.

PLAN



Test/Implementation Plan (THINK ABOUT WHAT CHANGES YOU CAN MAKE THAT WILL RESULT IN IMPROVEMENT):

What change will be tested or implemented? Include how change will be conducted, who will run it, where it will be run and when it will be run unless already noted in Aim Statement above. (If needed, include specifics on tasks, responsibilities and due dates.)

The implemented changes include the review and comparison of outcomes from 90 outpatient medical records from three groups of veterans on chronic opioids.

Findings will be evaluated, and recommendations will be made for future training and implementation for opioid safety SMA's. Additionally, a veteran toolkit will be further developed and made accessible via a VA SharePoint accessible to other VA facilities upon request. The above changes will be implemented by Sherry Cox, R.N. in the Primary Care Clinic and provider offices at a large VA hospital in Alabama.

Prediction: Data Collection Plan (THINK ABOUT HOW YOU WILL KNOW THE CHANGE IS AN IMPROVEMENT): What data/measures will be collected? The outcome variables will be compared to evaluate the effect of SMA's with a coaching component, on variables of pain levels, opioid usage and addition of CAM's. The change will be considered an improvement if veterans have a 10% reduction in pain scores and opioid usage and a 10% increase in their use of CAM's. The process change will include the evaluation of the effect of health coaching.

Who will collect the data? Sherry L. Cox, R.N.

When will the collection of data take place? Jan. 2, 2020 – May 2, 2020

How will the data (measures or observations) be collected and displayed? The data will be collected on an excel spreadsheet using statistical analysis displayed graphically.

What decisions will be made based on data? Does access to the patient toolkit on the VA SharePoint increase standardized training formats for future SMA's? Does it inform future training evaluation of the original format versus an adaptable approach for training without the use of health coaching?

DO



Activities/Observations:

Record activities/observations that were done in addition to those listed in plan (above):

STUDY



Questions: Copy and paste Prediction from Plan above and evaluate learning. Complete analysis of the data. Insert graphic analysis whenever possible.

Prediction:

Learning (Comparison of questions, predictions, and analysis of data):

Summary (Look at your data. Did the change lead to improvement? Why or why not?):

ACT



Describe next PDSA Cycle: Based on the learning in “Study,” what is your next test?

Appendix M

Patient Report Outcomes Measurement Instrument



Patient: 521_____ - _____

Initial

Birmingham Whole Health Patient-driven Assessment Tool

Patient Reported Outcomes Measurement Instrument System- 29, Bokhour et. al. 3/24/15

We would like to ask you some questions about your health in general. Please respond to each question or statement by marking one box in each row.

Physical Function	Without any difficulty ₁	With a little difficulty ₂	With some difficulty ₃	With much difficulty ₄	Unable to do ₅
1. Are you able to do chores such as vacuuming or yard work?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Are you able to go up and down stairs at a normal pace?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Are you able to go for a walk of at least 15 minutes?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Are you able to run errands and shop?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Anxiety <i>In the past 7 days...</i>	Never ₁	Rarely ₂	Sometimes ₃	Often ₄	Always ₅
5. I felt fearful	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. I found it hard to focus on anything other than my anxiety	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. My worries overwhelmed me	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. I felt uneasy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Depression <i>In the past 7 days...</i>	Never ₁	Rarely ₂	Sometimes ₃	Often ₄	Always ₅
9. I felt worthless	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. I felt helpless	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. I felt depressed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. I felt hopeless	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Fatigue <i>During the past 7 days...</i>	Not at all ₁	A little bit ₂	Somewhat ₃	Quite a bit ₄	Very much ₅
13. I feel fatigued	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. I have trouble starting things because I am tired	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15. How run-down did you feel on average?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16. How fatigued did you feel on	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



Birmingham Whole Health Patient-driven Assessment Tool

Patient Reported Outcomes Measurement Instrument System- 29, Bokhour et. al. 3/24/15

average?

Sleep Disturbance <i>In the past 7 days...</i>	Very poor ₁	Poor ₂	Fair ₃	Good ₄	Very good ₅
17. My sleep quality was...	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Sleep Disturbance <i>In the past 7 days...</i>	Not at all ₁	A little bit ₂	Somewhat ₃	Quite a bit ₄	Very much ₅
18. My sleep was refreshing	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
19. I had a problem with my sleep	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
20. I had difficulty falling asleep	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Satisfaction with Social Role <i>In the past 7 days...</i>	Not at all ₁	A little bit ₂	Somewhat ₃	Quite a bit ₄	Very much ₅
21. I am satisfied with how much work I can do (include work at home)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
22. I am satisfied with my ability to work (include work at home)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
23. I am satisfied with my ability to do regular personal and household responsibilities	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
24. I am satisfied with my ability to perform my daily routines	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Pain Interference <i>In the past 7 days...</i>	Not at all ₁	A little bit ₂	Somewhat ₃	Quite a bit ₄	Very much ₅
25. How much did pain interfere with your day to day activities?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
26. How much did pain interfere with work around the home?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
27. How much did pain interfere with your ability to participate in social activities?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
28. How much did pain interfere with your household chores?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Pain Intensity <i>In the past 7 days...</i>
29. How would you rate your pain on average?
<input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/> 6 <input type="checkbox"/> 7 <input type="checkbox"/> 8 <input type="checkbox"/> 9 <input type="checkbox"/> 10



Birmingham Whole Health Patient-driven Assessment Tool
The CollaborATE Measure, Bokhour et. al. 3/24/15

No pain

*Worst imaginable
pain*

Thinking about your office visits with your VA primary care medical team over the past six months...

1. How much effort was made to help you understand your health issues?

0 1 2 3 4 5 6 7 8 9 10

No Effort **Every effort**

2. How much effort was made to listen to the things that matter most to you about your health issues?

0 1 2 3 4 5 6 7 8 9 10

No Effort **Every effort**

3. How much effort was made to include what matters most to you in choosing what to do next?

0 1 2 3 4 5 6 7 8 9 10

No effort **Every effort**

Appendix N

My Health Report Card

Team:		Last 4:	Date:
Please answer each question by placing a number (0 to 5) in the shaded			
Education		0-1 Disagree 2-3 Agree 4-5 Strongly Agree	
1	With my Team's help, I might be able to reduce my usage of opioid pain medicine.		
2	I am managing my pain better by taking fewer pain pills every month		
3	I have tolerance to my pain meds since they do not work like they once did		
4	My pain medicines sometimes work opposite of what they were intended		
			Total
Safety		Yes-No	
5	I have taken more pain pills than prescribed in a day and placed myself at risk for accidental overdose		
6	I keep a Naloxone overdose emergency kit handy and know how to use it		
			Total
My Health Plan		0-1 Disagree 2-3 Agree 4-5 Strongly Agree	
7	There is more to my health than simply my physical health		
8	I am responsible for my Health		
9	I have begun integrating Complementary & Alternative techniques to help manage my pain		
10	I am committed to reducing pill usage as one of my Health goals		
11	I trust my medical team to help me achieve my Health Goals		
12	I am more physically active since I began a Whole Health Program		
			Total

Appendix O

Data Collection Tool

Patient Code: _____

Cohort:	Prior to SMA	End of SMA
MEDD		
Pain score		
Addition of Complimentary Alternative Modality Tai Chi ___ Yoga ___ PT ___ Meditation ___ Acupuncture ___ Other (specify) _____		

Prior: Most recent data point before first SMA

End: Most recent data point after last SMA

Appendix P

USF Statement of Determination



DNP Statement of Non-Research Determination Form

Student Name: Sherry L. Cox

Title of Project: Implementation and Evaluation of Whole Health Opioid Safety Shared Medical Appointment: A Quality Improvement Study

Brief Description of Project:

Over the past two years, a patient aligned care team (PACT) at a large urban VA medical center in Alabama efforts have centered around finding an approach to assist Veterans decrease their reliance on opioids using a whole health approach. During this time, the interdisciplinary team has held a series of shared medical appointments (SMAs) to assist Veterans in creating their best life through the establishment of specific, measurable, action-based, realistic, time-bound (SMART) goals and self-reflection. Many of the Veterans in our SMA's have chosen to focus their SMART goal on reducing their opioid reliance. To date, the original successes of the three SMA groups conducted by the original training cadre include a 72% reduction in opioid usage. The team's outcomes have created a demand to spread their approach throughout the VA system. The team began teaching their approach to other PACTs and to date, have trained 13 teams throughout Alabama, Georgia and Wisconsin. To date, no prior comparisons between the three groups of patients have been conducted. The project will compare the outcomes from three groups of patients: patients who were trained via the original SMA conducted by the training cadre, to patients who attended a team taught by the original team, to those patients receiving in-office opioid safety education.

A) Aim Statement: By September 2020, the use of Opioid Safety SMA's using a whole health approach will decrease Veteran's opioid usage and pain scores and increase their use of complimentary alternative modalities for managing pain, while improving their satisfaction with pain management.

B) Description of Intervention: Opioid safety program consisting of nine weekly sessions based on a whole health curriculum using health coaching and establishment of SMART goals.

C) How will this intervention change practice? The use of a whole health patient-centered approach in assisting Veterans to reduce their opioid reliance has the potential to change lives, decrease risk of opioid overdose and influence practice guidelines for addressing our nations opioid crisis.

D) Outcome measurements: Comparisons will be made between the opioid safety



outcome measures of reduction in opioid usage, reduction in pain scores and the use of complimentary alternative modalities to three groups: those who received training via the original team, those who received training via a team trained by the original team, to those receiving opioid safety education via routine in-office visits. This quality improvement project will be conducted via a retrospective record review using a random sample of 30 records from each of the above groups.

To qualify as an Evidence-based Change in Practice Project, rather than a Research Project, the criteria outlined in federal guidelines will be used:
<http://answers.hhs.gov/ohrp/categories/1569>

This project meets the guidelines for an Evidence-based Change in Practice Project as outlined in the Project Checklist (attached). Student may proceed with implementation.

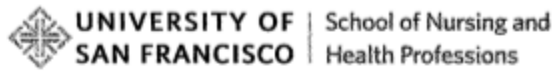
This project involves research with human subjects and must be submitted for IRB approval before project activity can commence.

Comments:

EVIDENCE-BASED CHANGE OF PRACTICE PROJECT CHECKLIST *

Instructions: Answer YES or NO to each of the following statements:

Project Title: Implementation and Evaluation of Whole Health Opioid Safety Shared Medical Appointment: A Quality Improvement Study	YES	NO
The aim of the project is to improve the process or delivery of care with established/ accepted standards, or to implement evidence-based change. There is no intention of using the data for research purposes.	x	
The specific aim is to improve performance on a specific service or program and is a part of usual care. ALL participants will receive standard of care.	x	
The project is NOT designed to follow a research design, e.g., hypothesis testing or group comparison, randomization, control groups, prospective comparison groups, cross-sectional, case control). The project does NOT follow a protocol that overrides clinical decision-making.	x	
The project involves implementation of established and tested quality standards and/or systematic monitoring, assessment or evaluation of the organization to ensure that existing quality standards are being met. The project does NOT develop paradigms or untested methods or new untested standards.	x	
The project involves implementation of care practices and interventions that are consensus-based or evidence-based. The project does NOT seek to test an intervention that is beyond current science and experience.	x	
The project is conducted by staff where the project will take place and involves staff who are working at an agency that has an agreement with USF SONHP.	x	



The project has NO funding from federal agencies or research-focused organizations and is not receiving funding for implementation research.	x	
The agency or clinical practice unit agrees that this is a project that will be implemented to improve the process or delivery of care, i.e., not a personal research project that is dependent upon the voluntary participation of colleagues, students and/ or patients.	x	
If there is an intent to, or possibility of publishing your work, you and supervising faculty and the agency oversight committee are comfortable with the following statement in your methods section: <i>"This project was undertaken as an Evidence-based change of practice project at X hospital or agency and as such was not formally supervised by the Institutional Review Board."</i>	x	

ANSWER KEY: If the answer to **ALL** of these items is yes, the project can be considered an Evidence-based activity that does **NOT** meet the definition of research. **IRB review is not required. Keep a copy of this checklist in your files.** If the answer to **ANY** of these questions is **NO**, you must submit for IRB approval.

*Adapted with permission of Elizabeth L. Hohmann, MD, Director and Chair, Partners Human Research Committee, Partners Health System, Boston, MA.

STUDENT NAME (Please print):

Sherry L. Cox

Signature of Student: *Sherry L. Cox* DATE Sept. 17, 2019

SUPERVISING FACULTY MEMBER (CHAIR) NAME (Please print):

Mary Lynne Knighten, DNP, RN, NEA-BC

Signature of Supervising Faculty Member (Chair): *Mary Lynne Knighten* DATE 09/21/2019

Appendix Q

Signed Statement of Non-Research Determination Form

Student Name: Sherry L. Cox

Department of Veterans Affairs	Birmingham VA Medical Center (BVAMC) Research vs. Non-Research Operations Evaluation
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Instructions: In accordance with [VHA Program Guide 1200.21](#), "VHA Operations Activities That May Constitute Research," BVAMC employees may conduct certain operations activities which may or may not constitute research. Whenever the research versus non-research status of an operations activity may be in question, a determination of the status must be made.

Please submit this form to the BVAMC IRB Administrator by sending a PDF copy with electronic signature to latanya.higginbottom@va.gov. Please reference the [VHA Operations Activities that May Constitute Research](#) decision tree for an overview of how a decision between research and non-research activities is determined.

Project Title:	Impact of Whole Health Opioid Safety Shared Medical Appointments on Opioid Safety in a Veteran Population
Project Lead:	Sherry L. Cox, Dr. Joseph Moates
Email/Phone:	sherry.cox2@va.gov
Department/Service:	Primary Care

CONDITIONS TO BE CONSIDERED FOR DETERMINATION OF RESEARCH VS. NON-RESEARCH OPERATIONS	TRUE	FALSE*
*NOTE: For answers that are marked "false," you must provide an explanation on page 3.		
1) The project is designed and/or implemented for internal VA purposes in support of the VA mission(s).	<input checked="" type="checkbox"/>	<input type="checkbox"/>
2) The findings are designed to be used by and within VA (or by entities responsible for overseeing VA).	<input checked="" type="checkbox"/>	<input type="checkbox"/>
3) The project is not designed for the purpose of contributing to generalizable knowledge.	<input checked="" type="checkbox"/>	<input type="checkbox"/>
4) The project is not designed to produce information that expands the knowledge base of a scientific discipline (or another scholarly field).	<input checked="" type="checkbox"/>	<input type="checkbox"/>
5) The project is not funded or otherwise supported as research by the Office of Research and Development (ORD) or any other sponsor.	<input checked="" type="checkbox"/>	<input type="checkbox"/>
6) The project does not involve administration, dispensing and/or use of any drugs, devices and/or biologics.	<input checked="" type="checkbox"/>	<input type="checkbox"/>
7) The project does not involve design characteristics typically reflective of research, e.g.: <ul style="list-style-type: none"> • Double-blind interventions • Use of placebo controls • Prospective patient-level randomization to clinical interventions not tailored to individual benefit 	<input checked="" type="checkbox"/>	<input type="checkbox"/>
8) The proposal includes provisions to ensure that the safety, rights, and welfare of patients and staff are appropriately protected as applicable.	<input checked="" type="checkbox"/>	<input type="checkbox"/>
9) The project is not intended to meet the requirements set forth by a master's program (or other university level degree program) that requires "research" be conducted.	<input checked="" type="checkbox"/>	<input type="checkbox"/>
10) The activity will not be supplemented or modified before, during, or after implementation in order to produce information to expand the knowledge base of a scientific discipline or scholarly field of study or otherwise contribute to generalizable knowledge.	<input checked="" type="checkbox"/>	<input type="checkbox"/>



PROJECT DESCRIPTION

Reason for Project Locally initiated Mandated by _____

In the following fields, please provide enough information about the proposed project that a reviewer understands why and how the work will be performed. Please define all acronyms. Failure to address the following will delay determination of your project.

1. Objectives(s): *What is the purpose of the project? What are the issues/questions being addressed and why?*

The objective of this project is to assess the benefits of a whole health SMA on opioid safety and opioid risk mitigation. The goal of this project is to investigate the utility of a whole health SMA on opioid safety and opioid risk mitigation. Opioid prescribing for the treatment and relief of chronic pain has risen precipitously over the last several decades escalating the death toll of American's dying from an opioid overdose to ~ 130 per day. The widespread use and unsafe prescribing practices seen today has likely contributed to what we now perceive as the opioid crisis. Much debate and blame has transpired regarding how our nation ended up in an opioid crisis. Although the news coverage is growing concerning this epidemic, little forward movement is occurring toward finding an approach to decrease opioid reliance that's effective and sustainable. Our project will evaluate the benefits of a whole health SMA on opioid safety and opioid risk mitigation. The variables for this study include assessing opioid usage, pain scores, and use of complimentary alternative modalities to those who attended shared medical appointments to those who received in-office opioid safety education.

2. Methodology: *How will the work be conducted and where? Who will be involved? Please be detailed in how the work will be conducted including data collection and analysis.*

This is a retrospective review of computerized patient medical records comprised of patients who participated in a whole health shared medical appointment (SMA) focused on opioid safety and risk mitigation and those receiving in-office patient education on opioid safety. A retrospective chart review will be conducted by the lead investigator at the Birmingham VA reviewing computerized patient medical records of 60 patients who participated in a whole health SMA on opioid safety and risk mitigation and collecting data on a specific data collection form (enclosed). An additional record review will be conducted by the lead investigator from 30 records of patients who received opioid safety education via in-office education. The following data will be collected: name, last four of SSN, demographics, weight, height, opioid prescribed, length of therapy, morphine equivalent daily dose (MEDD), risk index for overdose or serious opioid induced respiratory depression (RIOSORD) score, pain score, naloxone distribution, and addition of non-opioid pharmacotherapy or non-pharmacotherapy modalities for the treatment of pain. All measures will be recorded as prior to SMA, end of SMA or current. No patient interaction will occur at any point during the study. No patient interaction, in person or telephonically, will occur. Data will be collected based on the information presented in the data collection form and stored as a spreadsheet on the VA research drive.

3. Impact/Significance: *What will be done with the resulting information?*

Based off the results of the chart review, we will determine measurable differences between groups. Preliminary data indicate validity of the quality intervention of a whole health SMA. The intervention will be further tested through partnering with additional teams. The lessons learned from this quality improvement project will be shared with other VA facilities for potential diffusion of innovations.

Signature of Responsible Project Lead: SHERRY COX 902091 Digitally signed by SHERRY COX 902091
Date: 2019.07.31 15:36:32 -05'00' Date: 7/31/2019

Print Name of Responsible Project Lead: Sherry L. Cox



Provide an explanation below for responses marked "false" on page 1.
Please number your responses to indicate the question (#1-10) you are addressing.

Appendix R

Letter of Support



DEPARTMENT OF VETERANS AFFAIRS
Medical Center
700 South 19th Street
Birmingham, AL 35233

August 27, 2019

Dear Sir, Ma'am,

This is a letter of support for Sherry L. Cox to implement her DNP Comprehensive Project at the Birmingham VA Medical Center (BVAMC). Sherry L. Cox will use the name of our institution in her DNP Comprehensive Project Paper and in future presentations and publications in accordance and consistent with VA policies.

Sincerely,

A handwritten signature in cursive script that reads "Rebecca Huie".

Rebecca Huie, DNP, RN, ACNP, VHA-CM
Director, Primary Care

Appendix S

Implementation Guide Index

**VA SHARED MEDICAL APPOINTMENTS
FOR VETERANS ON CHRONIC OPIOIDS**
Implementation Guide



**Maximizing Patient and Provider Expertise to
Strengthen Care Management**

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 - [B. Benefits for Veterans](#).....
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[9. VA SHARED MEDICAL APPOINTMENTS FOR VETERANS ON CHRONIC OPIOIDS Frequently Asked Questions \(FAQs\)](#)

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[PATIENT:](#)

[10. References](#)

[11. Supplemental Materials, Tools, and Web-Based Resources](#)

[ENROLLMENT LETTER](#)

[ALUMNI LETTER](#)

[WORK EXCUSE](#)

[WHOLE HEALTH OPIOID SAFETY SMA CLINIC GRID, DOCUMENTATION, & CODING GUIDELINES:](#)

[WHOLE HEALTH OPIOID SAFETY SHARED MEDICAL APPOINTMENT SCHEDULE](#)

[MY HEALTH REPORT CARD](#).....

[PROMIS-29 Questionnaire](#)

Appendix T

Signage



Appendix U Program Flyer



A WHOLE HEALTH APPROACH FOR REDUCING OPIOID RELIANCE

What is Whole Health?

Whole Health is an approach centered around **what matters to you, not what is the matter with you**. It uses group sessions to introduce self-care techniques like mindfulness and yoga. These techniques help you take charge of your health and well-being and live life to the fullest.

How Will This Help Me?

The Whole Health System Model includes key elements that focus on:

- Me:** It begins with you, the “Me” at the center. Your story is unique and your whole health begins with what matters to you
- Self Care:** You have the power to impact your well-being. Whole Health provides the support you need to make the changes you want
- Professional Care:** Your health care team is here to help
- Community:** Friends, family, and others who support you on your journey



Me +
 Self Care +
 Professional Care +
 Community =
 Whole Health

ct
WANT TO KNOW MORE?