IMPROVING STANDARDIZATION IN CARE OF PATIENTS WITH CHRONIC PAIN: A FOCUS ON HARM REDUCTION

by

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DEDICATION

To my husband, Evan, whose unwavering support and belief in me made this possible.

AUTHOR NOTE

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ABSTRACT

Background: The opioid crisis remains a major public health issue in the US, with escalating opioid-related deaths annually. Long-term opioid therapy (LTOT) for chronic pain carries a high risk of adverse events, including opioid use disorder (OUD), overdose, and mortality. Standardizing harm-reduction practices, like risk assessment, naloxone access, and early OUD identification, can mitigate risks and enhance patient outcomes.

Local Problem: Primary care patients with chronic pain on LTOT need harm reduction to improve patient safety and quality of life.

Methods: A six-week plan-do-study-act cycle was employed. Descriptive statistics assessed intervention feasibility.

Intervention: The Opioid Risk Tool (ORT) evaluated individual risk for developing an OUD. Patients who screened positively (score ≥ 3) on the ORT received provider evaluation, using DSM-5 criteria, for OUD diagnosis. If diagnosed, patients received education about OUD and treatment options with buprenorphine. Naloxone prescriptions were offered by nurses to all patients with chronic pain.

Results: All 17 patients with chronic pain completed the ORT, with 9 (53%) identified as high-risk, and 2 (11.8%) diagnosed with OUD. No referrals were made for buprenorphine therapy. Additionally, 13 (76%) patients were offered naloxone prescriptions, and 100% of offered prescriptions were filled.

Conclusion: Implementing harm-reduction practices for patients on LTOT for chronic pain is feasible. Further projects will assess the long-term sustainability and impact on patient outcomes.

Keywords: chronic pain; long-term opioid therapy; opioid use disorder; naloxone; harm reduction; opioid risk tool; buprenorphine; opioid overdose.

CHAPTER ONE

REVIEW OF LITERATURE

The opioid epidemic was declared in 2017 and is an ongoing public health crisis in America. The use of opioids, either illicit or prescription, is at an all-time high and continues to climb each year. Opioid use carries serious risks, including overdose, developing a misuse disorder, and ultimately death (Dowell et al., 2016). Death related to prescription opioids has increased dramatically since 1999 and continues to trend upwards year over year (National Institute on Drug Abuse [NIDA], 2022). In 2017, 191 million opioid prescriptions were sent to retail pharmacies in the United States (US), representing a prescribing rate of 58.5 opioid prescriptions per 100 persons (CDC, 2018; Dowell et al., 2016). In 2020, among people aged 12 and older, 9.3 million people reportedly misused prescription opioids in the past year compared to 902,000 people who used heroin (Substance Abuse and Mental Health Services Association [SAMHSA], 2021a). An estimated 80% of heroin users reported non-medical use of prescription pain relievers prior to heroin initiation (Jones, 2013; Strand et al., 2022). These staggering statistics highlight the need for safer prescribing practices in primary care offices, including: risk screening and early identification of opioid use disorder (OUD), Naloxone prescriptions, and referral to medical treatment programs for opioid use disorder (Dowell et al., 2016).

Primary care providers (PCP) are the leading prescribers of opioids for acute and chronic pain, yet standardizations in screening for opioid use disorder (OUD) is lacking (Lasser et al., 2016). Patients who take prescription opioids for any amount of time can develop an opioid use disorder (OUD); however, the longer the duration of opioid therapy the higher the risk, with as many as 25% of patients receiving long-term opioid therapy (LTOT) developing OUD (Dowell

et al., 2016). To employ safe prescribing practices, primary care providers should routinely assess prescription drug monitoring programs (PDMP), prescribe the lowest effective dosage of opioid medications, provide naloxone education and prescriptions, and offer evidence-based treatment for OUD using buprenorphine (Dowell et al., 2016; Klimas et al., 2019). Improving the safety of pain management starts with primary prevention through PCPs and other healthcare personnel caring for patients receiving prescription opioids (Dowell et al., 2016; Lasser et al., 2016; Strand et al., 2022; Webster & Webster, 2005). In rural communities, primary care providers have higher prescribing rates of opioid medications, while prescribing rates for naloxone and buprenorphine are lower than the national average (Dowell et al., 2016; Stein et al., 2021; Zoorob et al., 2018).

In 2020, the Centers for Disease Control and Prevention reported 91,799 deaths related to drug overdose, and 75% of these deaths involved an opioid (CDC, 2020). Opioid use and drug overdoses continue to rise every year, threatening the well-being of our communities and future generations (Gomes et al., 2018; CDC, 2022). Early recognition of opioid misuse in primary care settings and standardized prescribing practices will foster safe clinical decision-making and improve patient outcomes (Dowell et al., 2016).

This literature review will describe the opioid crisis's impact on state and national populations. To improve patient outcomes and provide evidence-based care, the literature will focus on chronic pain, opioid use disorder, naloxone, and medications for opioid use disorder (MOUD) programs. Medical treatment for opioid use disorder will include buprenorphine, as it is approved for use in a primary care setting (SAMHSA, 2021b; SAMHSA, 2021c). The Opioid Risk Tool (ORT), which evaluates the risk of developing OUD, will be discussed at length, and

the benefits of use in clinical practice will be determined. The importance of prescribing naloxone to prevent overdose death will be discussed along with the significance of patient education to reduce stigma and increase awareness.

Opioid Use Disorder

Opioid Use Disorder is diagnosed using criteria explained by the Diagnostic and Statistical Manual of Mental Disorders, 5th Edition (DSM-5), published by the American Psychiatric Association (APA). The DSM-5 criteria describe a problematic pattern of opioid use that includes several characteristics that reflect compulsive or inappropriate behavior occurring in the previous 12 months (APA, 2013, p541-542). The burden of OUD is underrepresented, highlighting the importance of screening and education as a standardized care process (Gomes et al., 2018; SAMHSA, 2021c).

In 2020, among people aged 12 or older, 2.7 million had an opioid use disorder in the past year, compared to 2.1 million in 2017 (SAMHSA, 2021a; Strand et al., 2022). Patients with OUD can have problems with illicit opioids such as fentanyl and heroin, prescription medications such as oxycodone and hydrocodone, or both. Patients with underlying risk factors, such as: nonfunctional status due to pain, a personal history of substance abuse, a family history of substance abuse, psychological trauma or stress, chronic disease, and adverse childhood events, should be evaluated for the risk of developing OUD (Gomes et al., 2018; L. Webster, 2017; Webster & Webster, 2005). Opioid use disorder is a chronic lifelong disorder associated with an increased risk of overdose, relapse, and death (APA, 2013; CDC, 2016; Gomes et al., 2018; Klimas et al., 2019).

Gomes et al. (2018) evaluated the burden of opioid-related mortality in the US between 2001 and 2016. Mortality rates increased by 345%, from 9,469 to 42,245. As many as 1 in 65 deaths in the US was opioid-related in 2016 amongst all age groups. Adults aged 25-34 years represented the highest mortality, with one in five deaths being opioid-related (Gomes et al., 2018). The increased incidence of OUD and opioid-related mortality speaks to this growing public health burden in the United States. Treatment options for OUD are more accessible than in the past, but rely on early identification of OUD and referral to treatment programs (Klimas et al., 2019; Webster & Webster, 2005). An estimated 90% of patients diagnosed with an OUD do not obtain the recommended addiction treatment, increasing concern for overdose and opioid-related deaths (Bryant et al., 2021).

Chronic Pain

Chronic pain is any pain lasting longer than three months or past the expected time for tissue healing and is one of the most common reasons adult Americans seek medical care (Chou et al., 2015; Dowell et al., 2016). In 2016, the prevalence of chronic pain was estimated to be 20.4% (about 50 million) of US adults, with an additional 8% (about 20 million) of US adults having high-impact chronic pain (CDC, 2018). These population-based statistics demonstrate increased opioid use prevalence in individuals experiencing poverty, low education, and adults with Medicare or Medicaid (CDC, 2018). Socioeconomic status is a common factor in high-impact chronic pain prevalence and can be linked to the patient's ability to successfully navigate the health care system (CDC, 2018). In 2019, 22.1% of US adults with chronic pain used a prescription pain reliever in the last three months (Dahlhamer et al., 2018).

The CDC created an opioid prescribing guideline for chronic pain in 2016 to provide recommendations to PCPs prescribing opioids for chronic pain outside of active cancer treatment and palliative care. Pain is treated with various therapies depending on the type of pain. The primary objectives of managing chronic pain are to establish improved pain and function that depend on the individual's needs (Dowell et al., 2016). Non-opioid drugs, such as nonsteroidal anti-inflammatory drugs (NSAIDs), and nonpharmacologic therapies, such as physical therapy, are the preferred treatment for chronic pain (Dowell et al., 2016). However, because of the physical and mental demands of pain, opioid medications are often prescribed (Chou et al., 2015; van Rijswijk et al., 2019).

The CDC guideline, written by Dowell et al. (2016), recommends that if opioids are used for chronic pain, the lowest effective dose should be prescribed, with a recommendation of maintaining doses at ≤ 50 MME per day. Increasing opioid dosage to ≥ 90 MME per day should be avoided without careful justification and clinical assessment due to the increased risk for physical dependence and misuse (Dowell et al., 2016). The patient's risk for opioid use disorder and aberrant behaviors should be assessed before starting therapy and periodically during the continuation of therapy (Cheatle et al., 2019; Dowell et al., 2016; Webster & Webster, 2005). Additional CDC recommendations include: a review of the prescription drug monitoring programs (PDMP), urine drug testing, avoiding concurrent opioid and benzodiazepine prescriptions, naloxone prescriptions, and offering or arranging evidence-based treatment for OUD (Dowell et al., 2016).

Chronic Pain and OUD

The interaction between OUD and chronic pain is dynamic, and both carry a significant health burden (MacLean et al., 2019). Chronic pain patients are often maintained on long-term opioid therapy (LTOT), which is described as the use of prescription opioids for ≥ 90 days (Dowell et al., 2016). As many as one in four patients receiving LTOT can struggle with opioid addiction, and the prevalence of developing an OUD while on LTOT for chronic pain is 8.5%-41.3% (Dowell et al., 2016; MacLean et al., 2019).

Chronic pain often precedes OUD in patients receiving prescription opioids, and 24% to 68% of those diagnosed with OUD report moderate to severe chronic pain (MacLean et al., 2019). Higher doses of LTOT are associated with an increased risk of opioid misuse, overdose, and impaired endocrine and immune function (Chou et al., 2015; Dowell et al., 2016; Powell et al., 2021). While a higher risk of adverse events is seen in patients receiving long-term therapy or high doses of opioids for pain management, it is essential to understand that persistent pain and OUD share similar challenges. Living with an opioid use disorder or chronic pain can produce emotional stress, withdrawal symptoms and negatively impact functioning (MacLean et al., 2019; Powell et al., 2021). The diagnosis of one disorder may also precipitate the development or progression of the other due to basic neuroadaptations that occur in the corticolimbic circuitry in the brain (MacLean et al., 2019). The symbiotic relationship between these disorders emphasizes the importance of evaluating them together to optimize treatment outcomes.

Significance of the Problem in Montana

Substance abuse affects individuals and families across a lifespan and requires public health support to improve outcomes and prevent death. Thus, the Montana Substance Use

Disorder Task Force develops a strategic plan every two to three years to lessen the impact of substance abuse in Montana. The strategic plan aims to analyze the current substance abuse trends and identify available resources and strategies to address substance abuse disorder statewide (Montana Department of Public Health and Human Services [DPHHS], 2020).

An estimated 100 people die annually from a drug overdose in Montana, and more than 15,000 emergency department visits each year result from substance abuse (DPHHS, 2020). For every 100 Montana residents, 89 prescriptions for opioids are written, and as many as one in nine high school students has reported misuse of prescription drugs (DPHHS, 2020). In five years, from 2014-2019, 712 Montanans died from drug-related deaths, with 37.5% of those deaths being linked to opioids (MDHHS, 2021). While Montana has seen a decline in opioid-related deaths compared to the national trend, preliminary data suggests that in 2021 the United States saw the highest number of opioid-related deaths recorded in its history (CDC, 2022; DPHHS, 2021). The opioid crisis is an ongoing battle, but Montana remains proactive in identifying risks and preventing mortality associated with opioid misuse.

In recent years, Montana has made several improvements in standardizing opioid-related care. Overall, the average daily morphine milligram equivalents (MME) declined from 58.3 MME in 2014 to 40.3 MME in 2019 (MDHHS, 2021). Since 2016 there has been a significant effort to increase the number of providers who can prescribe buprenorphine for OUD, increasing buprenorphine prescriptions from 27 per 1,000 in 2014 to 81 per 1,000 in 2019 (DHHS, 2021). In 2019, the state legislature required all Montana licensees authorized to prescribe or dispense prescription drugs to register with the Montana Prescription Drug Registry (MPDR). In 2021, a law enacted by the state of Montana mandated the use of the MPDR before prescribing an opioid

or benzodiazepine to a patient, except in certain circumstances, including: hospice care, a total number of doses lasting less than seven days which cannot be refilled, an emergency, a technological failure, and chronic pain patients on long-term opioid therapy who have their MPDR reviewed every three months (Mandatory Use of Prescription Drug Registry, 2021).

In 2017, Montana Legislature passed the 2017 House Bill (HB) 333, the Help Save Lives from Overdose Act which increased access to opioid antagonists such as Naloxone (Help Save Lives from Overdose Act, 2017). This legislature and the Montana Department of Public Health and Human Services (DPHHS) issued a standing order to allow pharmacies to distribute naloxone to any individual in a position to assist a person at risk of experiencing an opioid-related drug overdose (Help Save Lives from Overdose Act, 2017). The expansion of naloxone prescribing is an effort that the state of Montana has taken to reduce opioid-overdose deaths and promote safe prescribing practices.

Economic Cost

According to Luo et al. (2021), the US economic cost of opioid use disorder (OUD) and opioid overdose deaths topped 1.02 trillion dollars in 2017. These costs included healthcare and hospitalization, opioid use disorder treatment, criminal justice, lost work productivity, and reduced quality of life (Luo et al., 2021). Costs vary from state to state and primarily depend on the reported number of diagnosed OUD cases and overdose deaths. The estimated annual cost of prescription opioid deaths in Montana is $1.4 million (Montana Department of Justice, 2017).

Methods

Search Strategies

The literature review was prepared using the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) statement guidelines (See Appendix A). A systematic search for clinical and scientific research included five databases -- CINAHL, Google Scholar, PubMed, Ovid, and PsychINFO. Articles written in English and published between January 2015 and August 2022 were searched to identify relevant studies. Search terms included: "opioid" AND "chronic pain," "chronic pain" AND "opioid use disorder," "opioid use disorder," "safe prescribing practices," "opioid risk tool," "Naloxone," "buprenorphine," and "primary care." References lists of the selected articles were reviewed to identify studies that may have been missed in the initial search. National and local organizations such as the CDC and DPHHS were also examined for current statistical data and established guidelines (see Appendix B).

Eligibility

Articles written in any medical setting were included, although preference was given to those in a primary care setting. Interventions were led by various medical professionals and were not excluded based on provider type. Articles that did not provide measured outcomes or included Methadone or Naltrexone as a primary treatment focus were excluded due to clinical site restrictions. The review included only articles available in English and full text.

Study Selection

A total of 89 articles were screened. Seventy-one articles were assessed for eligibility. A total of 17 were selected to be a part of the literature review. Articles were excluded if they were

abstract only, did not contain measured outcomes, or included naltrexone or methadone as primary variables.

Quality Assessment

This review includes quantitative studies with measured outcomes, systematic reviews, RCTs, nonrandomized intervention, cohort, and cross-sectional studies. Rapid critical appraisal of the chosen study articles was used to assess for quality. The Polit and Beck Evidence Hierarchy scale was used to determine the level of evidence of each article (2021). A study by Webster & Webster (2005) was included as it is the founding study for the Opioid Risk Tool. Due to a limited number of articles endorsing the ORT within the past five years, the scope was broadened to encompass literature beyond the typical five-year time frame. The included literature supports the current evidence-based interventions described in this review.

Review of Literature

Screening for Risk of OUD:
Opioid Risk Tool

The Opioid Risk Tool (ORT) was developed and validated in 2005 by Webster & Webster. Their preliminary study monitored aberrant drug-related behaviors (ADRB) over 12 months at a pain clinic. The ORT measured the likelihood of a patient misusing opioids in the future and placed a risk category of low, moderate, or high on the result (Webster & Webster, 2005). The ORT focuses on preexisting conditions or experiences that may increase the risk of developing opioid misuse in patients given a prescription for opioid medication. Webster and Webster (2005) demonstrated that 94.4% of patients with low-risk ORT scores had no ADRB, and 90.9% of those with a high-risk score on the ORT displayed ADRB. The development of the

ORT included Webster and Webster's clinical experiences and the evidence-based risk factors associated with abuse to support this ten-item self-administered questionnaire. They aimed to identify patients at risk for ADRB before or during the management of prescription opioids (Webster & Webster, 2005).

Cheatle et al. (2019) developed a revised ORT to predict OUD in patients with chronic nonmalignant pain (CNMP). The original version of the ORT contained gender-specific scoring and a question about preadolescent sexual abuse, which was only weighted for females as this factor increased the prevalence of OUD by fivefold according to the original study findings (Cheatle et al., 2019; Webster & Webster, 2005). However, the original study's findings based the risk of developing OUD on the predisposition of psychiatric disorders in women with a history of preadolescent sexual abuse, not a direct correlation to OUD (Cheatle et al., 2019). Cheatle et al. (2019) removed the gender-weighted scoring and eliminated the question regarding preadolescent sexual abuse based on a comparison screening between the original and modified ORT. Removal of the preadolescent sexual abuse question was notably superior in predicting the development of OUD in patients receiving LTOT (Cheatle et al., 2019). The revised unweighted ORT (ORT-OUD) is the first screening tool to predict the risk of developing OUD in primary care patients with CNMP receiving long-term opioid therapy (Cheatle et al., 2019). This screening tool was adopted by the National Institute on Drug Abuse (NIDA) and is available on their website free of charge (see Appendix C).

Since the development of the ORT, few studies have been conducted to challenge its validity. Of the studies performed, variable results concerning the specificity and sensitivity of the ORT to detect ADRBs and further predict the risk of developing OUD in specific populations

have been noted (Clark et al., 2018; Khoury et al., 2022)**.** Clark et al. (2018) evaluated the use of the original ORT in an academic pain management center. The researchers found that the self-report ORT was not a valid test in their adult pain population largely due to changes in ADRB qualification overtime and a lack of willingness to self-report risk factors (2018). The question involving preadolescent sexual abuse was not found to have weight in predicting ADRBs or risk factors for developing OUD in this study (Clark et al., 2018).

In another study by Khoury et al. (2022), the ORT was used to establish a risk profile in patients undergoing shoulder surgery in an orthopedic practice. Khoury et al. report that orthopedic providers have a high incidence of opioid prescribing in the United States, with as many as 75% of prescriptions going unused, presenting the concern for overprescribing and misuse. The results of this study did not support the use of ORT as a pre-surgery screening to correlate to the risk of opioid misuse postoperatively (Khoury et al., 2022). A study by Strand et al. (2022) looked at implementing screening using the ORT in a community pharmacy. Findings supported the use of the ORT in risk stratification and primary prevention of OUD in patients prescribed opioid medications.

Research suggests the ORT sensitivity may lie in patients with chronic pain types, patients on LTOT, preexisting substance use, and underlying mental illness as opposed to patients with acute/episodic pain (Cheatle et al., 2019; Khoury et al., 2022; Webster & Webster, 2005). While the ORT is commonly used, there is a continued need for further research to determine its reliability in accurately predicting the risk of developing OUD (Dowell et al., 2016). The ORT is a non-diagnostic tool that can be used to identify some of the risk factors associated with developing OUD. The modified ORT has a higher sensitivity and specificity with

both positive and negative predictive values and should be used in the care of patients with CNMP receiving LTOT (Cheatle et al., 2019).

Medication-Based Treatment for Opioid Use Disorder (MOUD)

MOUD programs combine medications and behavioral resources, such as counseling, patient education, and case management, as an effective, evidence-based intervention for treating OUD (SAMHSA, 2021b). Approved medications for the treatment of opioid use disorder include buprenorphine, methadone, and naltrexone. Under the Comprehensive Addiction and Recovery Act of 2016 (CARA), practice guidelines for treating OUD with Buprenorphine were established nationally (Department of Health and Human Services [DHHS], 2021). According to these practice guidelines, any practitioner, including: physicians, physician's associates, nurse practitioners, certified nurse midwives, and clinical nurse specialists, can prescribe buprenorphine with a valid Drug Enforcement Administration (DEA) license after obtaining an x-waiver certification or filing a notice of intent (NOI) to treat patients with buprenorphine (DHHS, 2021).

Buprenorphine is a schedule III partial opioid agonist that effectively manages OUD's physical withdrawal symptoms and lowers the potential for opioid misuse (SAMHSA, 2021b). As a partial opioid agonist, the maximal effects of buprenorphine are less than half that of a full agonist, such as heroin, and reach a ceiling where a higher dose does not increase the negative effect (Zoorob et al., 2018). Buprenorphine has long been a favorable treatment for OUD due to its ceiling effects on minimizing respiratory depression and decreased risk for overdose compared to other treatments like methadone (DHHS, 2021; SAMHSA, 2021b; SAMHSA, 2021c; Powell et al., 2021). Buprenorphine can be combined with naloxone and administered as

a singular medication. Combined medications are preferred due to a lower likelihood of misuse (Zoorob et al., 2018). Methadone must be prescribed by a medical provider at a certified SAMHSA Opioid Treatment Program (OTP) site and is not available in a primary care setting (SAMHSA, 2021b). Evidence supports using buprenorphine for treating chronic pain in patients using LTOT, suggesting patients with OUD and chronic pain may reap the benefits of both pain relief and addiction therapy; however, further research is needed (Powell et al., 2021).

Healthcare providers are responsible for expanding access to evidence-based treatment for OUD. Treatment goals with MOUD are to sustain recovery, increase patient survival, and improve patients' quality of life (SAMHSA, 2021c). Widening the treatment net by integrating MOUD into primary care creates supportive programs that increase access, reduce stigma, and offer alternatives to those suffering from opioid misuse. Expanding access to office-based treatments in rural settings can reduce patient travel times, improve compliance rates, and respond to the community's needs for evidence-based treatment options (Brady et al., 2021; SAMHSA, 2021b).

Naloxone

Naloxone is an opioid receptor antagonist that binds to opioid receptors and blocks or reverses the effects of opioids (CDC, 2019). This medication is widely used by emergency personnel to temporarily reverse the respiratory depression that is often the cause of opioid-related death. In a community setting, when someone displays the signs of opioid overdose naloxone can be administered to restore normal breathing patterns long enough for medical help to arrive. Evidence shows that naloxone has few adverse side effects and is safe to be administered to any individual suspected of suffering from opioid poisoning (Wermeling, 2015).

Many opioid overdose deaths occur at home and having naloxone available during a time of need could mean saving a life (CDC, 2019).

To reduce harm and prevent opioid-related death Naloxone prescribing has been at the front of public health and legislative efforts. In the CDC Guideline for Prescribing Opioids for Chronic pain—2016, naloxone prescribing is recommended as a standard practice in patients receiving LTOT as an adjunct to harm reduction and overdose prevention (Dowell et al., 2016). Despite these recommendations, the national average of naloxone per high-dose opioid prescription is 1:70 (CDC, 2019). While the overall number of naloxone prescriptions remains low, there is a steady increase in the total number of prescriptions each year (CDC, 2019; Coffin et al., 2016; Stein et al., 2021).

Several studies have demonstrated the positive effects of co-prescribing naloxone and opioids in a primary care setting. Co-prescribing Naloxone for patients receiving LTOT is an acceptable and effective clinical action that can help to prevent opioid-related deaths (Behar et al., 2016; Coffin et al., 2016; Stein et al., 2021). Coffin et al. (2016) reports that Naloxone co-prescribing is associated with a reduction in opioid-related ED visits, providing an ancillary benefit of its use. Behar et al. (2016) demonstrated that at the time of the study, potential barriers to naloxone prescribing included a lack of access and standardized logistics for Naloxone distribution. However, the legislature has since expanded access to naloxone for laypersons in all 50 states eliminating this barrier (CDC, 2019). Behar et al. (2016) highlighted the importance of identifying staff to educate patients on the use of naloxone and the signs of opioid overdose. The impact of naloxone prescribing can be maximized through education, demonstration of use, and co-prescribing (Behar et al., 2016; Dowell et al., 2016).

Results

Literature review revealed that harm-reduction practices such as: early identification of risk using a standardized risk assessment tool, access to naloxone, and MOUD programs are essential to the safe prescribing of opioid medications and prevention of drug overdose (Cheatle et al., 2019; Dowell et al., 2016; Strand et al., 2022). Successful revision of the opioid risk tool (ORT) to exclude gender specificity has improved the sensitivity for predicting OUD risk (Cheatle et al., 2019). Adding screening as a part of the routine evaluation in patients receiving LTOT was not harmful to patients and provided benefit (Cheatle et al., 2019; Webster & Webster, 2005). Co-prescribing Naloxone is a safe and beneficial intervention to reduce opioid-related death (Behar et al., 2016; Coffin et al., 2016; Dowell et al., 2016; Stein et al., 2021). MOUD treatment programs in primary care using buprenorphine are an effective and evidence-based therapy for those suffering from OUD.

Implications for Practice

Prescription opioid medications have become the leading contributor to drug abuse in America, surpassing cocaine, and heroin (Clark et al., 2018). Primary care providers are uniquely positioned to provide comprehensive, coordinated care to a diverse population of patients. Thus, they are crucial to implementing standardized care of chronic pain patients and early identification of OUD. Management of a chronic disease, such as OUD, is better served in a setting that can give familiar support and promote long-term recovery, such as a primary care-based MOUD program. Endorsement from national guidelines improves the quality of care and sustainability of treatment outcomes by recommending evidence-based interventions.

Organizations like the CDC, DHHS, and SAMHSA have provided several evidence-based resources to assist clinicians with identifying and managing patients with OUD.

Opioid use disorder is a chronic and complex disease that requires a team approach to long-term care and management. Increasing access to these services by offering them in a primary care office-based setting can promote trust, provide continuity of care, and reduce opioid-related mortality (Brady et al., 2021; Dowell et al., 2016; Lasser et al., 2016; SAMHSA, 2021c). Interventions such as: implementing screening to identify the risk of OUD, co-prescribing naloxone for patients on LTOT, identifying and diagnosing OUD, and referring patients for MOUD using buprenorphine can foster more standardized and safe prescribing practices (Cheatle et al., 2019; Dowell et al., 2016).

CHAPTER TWO

PROJECT PROPOSAL

Introduction and Problem

According to the Substance Abuse and Mental Health Services Administration (SAMHSA) (2021), an estimated 9.5 million Americans aged 12 and older misused opioids in the past year. Specifically, 9.3 million people misused prescription opioid medications (SAMHSA, 2021c). In 2020, opioids were responsible for 68,630 deaths, accounting for 74.8% of all overdose deaths in the United States (Centers for Disease Control and Prevention [CDC], 2020). The impact of these deaths reaches far beyond the individual and creates a significant burden for the families, the communities, and the healthcare systems caring for them.

The National average of opioid prescriptions was 43.3 per 100 persons in 2020, with some counties having prescriptive rates that are much higher (CDC, 2020). In Montana, the prescribing rate is double the national average at 89 prescriptions per 100 persons, indicating aberrant prescribing practices (Montana Department of Health and Human Services [MDHHS], 2020). The high number of opioid prescriptions in America creates an opportunity for misuse and increased risk of overdose and potential death. The use of naloxone to prevent opioid overdose is a harm-reduction strategy that should be available to all high-risk patients (Dowell et al., 2016). The state of Montana recognizes this issue and has made naloxone available to anyone who would like to access it through the Montana legislation 2017 House Bill (HB)333, making it widely available from any pharmacy without a prescription (Help Save Lives from Overdose Act, 2017).

Identifying and treating patients with opioid use disorder (OUD) is a critical intervention to reduce opioid-related mortality. The prevalence of diagnosed opioid use disorder (OUD) was 1.6 million people in 2019; however, opioid prescription records suggest that the number of patients without a formal diagnosis of OUD is five times higher (SAMSHA, 2021c). Proper patient education and standardized opioid prescribing practices in the primary care setting are essential to reduce the harms associated with opioid misuse.

Problem Statement

The identified problem is a lack of standardized chronic pain management and harm reduction practices offered by primary-care providers to patients receiving opioid prescriptions for chronic pain. Evidence-based harm-reduction practices include screening for the risk of OUD, prescriptions for naloxone to prevent overdose death, and referral for evidence-based treatment if OUD is present. The inquiry questions for this project are: if we increase harm-reduction practices can we improve the quality of care and reduce high-risk behavior in chronic pain patients with opioid misuse? If we increase access to naloxone, do we have fewer opioid-related deaths? Do we improve quality outcomes and long-term recovery by treating OUD with buprenorphine?

These questions will drive the implementation of standardized harm-reduction practices into the yearly evaluation of adults with chronic pain who are receiving long-term opioid therapy (LTOT) seen in a single primary care site. Updating the chronic pain annual care plan to include annual ORT-OUD screening, naloxone prescription renewal, and referral for OUD treatment, if diagnosed, will contribute to patient and population harm reduction, and promote evidence-based care by standardizing treatment strategies.

Organization and Microsystems Assessment

The chosen project site is currently treating 219 patients with chronic pain on LTOT using the ICD-10 diagnosis codes of chronic pain syndrome (G89.4), other chronic pain (G89.29), and long-term (current) use of opiate analgesic (Z79.891). The clinic has established guidelines for patients receiving LTOT for chronic pain management and updates the patient's plan of care yearly. The project site has started a medical treatment program for OUD (MOUD) using buprenorphine, creating a primary care-based resource for a rural Montana community. Four patients are currently enrolled in the MOUD program and receiving weekly prescriptions for a buprenorphine/naloxone combination drug known as Suboxone. A clinic-based pharmacy located on-site assists patients with obtaining Suboxone prescriptions at the time of their appointment. However, the site lacks a standardized protocol that supports the screening and identification of OUD, a referral process to the MOUD program, and Naloxone prescriptions in patients receiving LTOT for chronic pain. The lack of evidence-based interventions places the patients and the community at risk for complications related to OUD and opioid-related death.

Site stakeholders recognize the need for standardized screening and harm-reduction practices in the population of patients experiencing chronic pain. The stakeholders have experienced patients with opioid overdose and high-risk behavior that can lead to opioid misuse. The project site wanted to address the lack of access to MOUD treatment and bring the management of OUD into the primary care office. The stakeholders are supportive of expanding awareness and education about the risks of opioid use to reduce the stigma associated with MOUD treatment and naloxone prescribing. The need for this project was determined through

discussion with the medical and clinic directors responsible for developing the MOUD program for the site.

Rational

The DNP project will use the quality improvement framework of the Plan-Do-Study-Act (PDSA) cycle. The planned interventions include three process development tasks: implementing the opioid risk tool (ORT) in patients with chronic pain on LTOT and further evaluating those with scores equal to or greater than three, offering naloxone to each patient on LTOT, and referrals to medical treatment for patients with OUD. According to evidence-based guidelines offered for staff review, the planned interventions were agreed upon during the planning phase. This project's assumption for success is based on the first PDSA cycle using a small three-person champion team to implement the intervention. Due to the iterative nature of the PDSA cycle, the planned interventions will be implemented, studied over six weeks for efficacy, and modified to meet the needs of the site specifically. Oversite of the interventions performed weekly by the DNP student allows for dynamic change of the process if necessary. The process of PDSA provides a perpetual assessment, through the study phase, to adopt change and spread the improvement process outwards to the entire site after project completion, as well as adapt project interventions based on data obtained during implementation. A consistent evaluation of the new staff process, starting on a small scale, will help determine the adaptations that can improve safer opioid use practices across the state.

This QI project's planning (P) phase includes a training and education session with the champion team and the site manager, as outlined in Table 1. The purpose of the session is to discuss the project's goals and explain the workflows surrounding screening, prescribing, and

referral. Planning will include printing the ORT-OUD tool, workflows, and patient education handouts. Specific integration of documentation into the EHR will be discussed at the project education session. A templated documentation statement or dot phrase to support the provider's documentation of the diagnosis of OUD will be developed with the champion PA and is available in Appendix D. The implementation or do (D) phase will include administering the ORT-OUD to all patients with chronic pain diagnosis codes, nursing staff offering naloxone prescriptions, assessing for OUD by the PA provider, and referring for MOUD treatment if OUD is diagnosed by the PA. These interventions will occur from January 13, 2023- February 23, 2023. All data will be collected weekly and adapted as necessary during that timeframe. This intervention's study (S) phase will include evaluating the collected data and feedback from the champion team. The final act (A) phase will be adopting or abandoning the studied interventions based on the best practice outcomes and staff satisfaction. A logic model that describes the project's short-term, intermediate, and long-term outcomes is available in Appendix D.

Table 1. Staff Education Outline.

Outline of Staff Education Session/Training
I. Importance of implementing OUD screening in patients with chronic pain
a. Current statistics
b. Overview of literature
i. CDC Prescribing Opioids for Chronic Pain Guideline
II. ORT-OUD
a. How it works and what it tells us
b. Screening results and how to interpret them
c. Workflow
d. How to transfer the results into the EHR
III. Naloxone
a. Workflow & Nursing responsibilities
b. Tips for talking with patients about it
c. Standing order and pharmacy involvement
IV. OUD
a. Diagnosis codes
b. Dot phrase
c. DSM Criteria
V. MOUD
a. Referral process
b. Dot phrase
VI. Patient Education
a. Naloxone handout
b. Naloxone education for the waiting room
c. MOUD handout

Specific Aims

Through process development and stakeholder training, this project aims to increase the healthcare team's awareness of the risks associated with prescription opioid medications and to reduce overdose deaths in patients with chronic pain receiving LTOT. Creating a standardized process for screening and harm-reduction the clinic staff can provide thoughtful and comprehensive care that improve patient outcomes. The project goals are to increase screening for the risk of developing OUD using the ORT-OUD, increase the number of Naloxone

prescriptions offered to patients with chronic pain diagnosis, identify patients at high risk (score of ≥3 on the ORT-OUD) for developing OUD using the DSM-5 criteria, and increase referrals for patients diagnosed with OUD to the clinic-based MOUD program, see Appendix D. The list of SMART goals/outcomes can be viewed in Table 3. The short-term outcomes are to achieve 25% of the above-mentioned goals within the first three weeks of project implementation. The mid-term goals at project completion are to provide screening, naloxone prescriptions, and evaluation using the DSM-5 criteria for OUD in 100% of eligible patients with chronic pain diagnosis. The goal for referral to the MOUD program is 50% of patients by project completion. The goal for referral is set lower than the others because literature indicates that patient acceptance for MOUD treatment may require additional education and support before entrance into the program (SAHMSA, 2021c, Zoorob et al., 2018). Although beyond the six-week project timeline, the ultimate goal of the project is to improve patient's quality of life and promote long-term OUD recovery. Addressing the opioid crisis in America begins in the primary care office by implementing evidence-based harm reduction strategies to prevent overdose and death related to opioid misuse.

Context

The Doctor of Nursing Practice (DNP) quality improvement (QI) project site is a rural community health clinic in Southwestern Montana that provides primary, preventative, and behavioral health to patients of all ages. The clinic employs four medical providers and support staff: registered nurses (RNs), medical assistants (MAs), pharmacists, pharmacy technicians, licensed counselors, social workers, and administrative personnel. However, to provide consistency in data collection a small stakeholder group will be used. The project interventions

will include one physician assistant (PA), a registered nurse (RN), and a medical assistant (MA), as well as support from the site manager.

The intended project population is adult patients with chronic pain prescribed chronic opioids who present for a scheduled chronic pain management follow-up during the six-week project implementation. The patients at the chosen site possess several unique characteristics, making them at higher risk for developing chronic pain, including: predominant Medicare/Medicaid insurance coverage, low-income households, and jobs or responsibilities requiring manual labor known to increase their risk for injury (CDC, 2018; Dowell et al., 2016). This community health center aims to provide access to care, regardless of the patient's ability to pay. The chosen site currently uses safe prescribing practices, such as performing a PDMP review on a 3-month basis and prescribing the lowest possible opioid dose; However, stakeholders support the expansion and standardization of additional harm-reduction strategies. The in-house pharmacy has access to naloxone, at no cost, which can be dispensed through a standing order issued by the state of Montana. The clinic also developed a primary care MOUD program providing access to Suboxone prescriptions available from the on-site pharmacy. The planned interventions will be implemented in a three-person team that includes an MA, a PA, and an RN. This team has strong team dynamics and is devoted to raising awareness and promoting change in their patients on LTOT for chronic pain through harm-reduction practices. The following interventions will involve a lead role for each team member and foster a collaborative approach to change.

Interventions and Implementation

With approval by Montana State University's Internal Review Board, the proposed interventions will begin on January 13, 2023. The clinical site does not have an IRB or requirement for study approval, but a letter of site support was obtained during planning phase. A patient visit summary, completed by the three-person pilot team, will be used to collect data for this project and can be viewed in Table 2. This summary will be provided to staff for each patient to document the raw data collected. It will briefly describe the project and contain checkboxes for each data collection step. No patient identifiers will be recorded in the summary. The summaries will be collected and analyzed weekly.

Budget

The clinical site is in the process of developing a medication for opioid use disorder program (MOUD) that allows their patients to have access to evidence-based treatment with buprenorphine. Diagnosis for OUD will be determined by the champion PA provider using the Diagnostic and Statistical Manual Fifth Edition (DSM-5) criteria for OUD, available in Table 3. If the patient meets the DSM-5 criteria for diagnosis, a specified ICD-10 code will be documented during that visit. The ICD-10 codes will include opioid use disorder (F11.90) or opioid use with opioid-induced disorder (F11.99). A dot phrase will be developed in the clinic EHR to document the diagnosis of OUD, which criteria were met for diagnosis, and if a referral was made for buprenorphine therapy. A staff message will then be sent by the provider to the MOUD coordinator, who sets up an intake appointment. A patient education handout detailing OUD and treatment options, see Appendix E, will be provided/offered to the patient at that time. The provider or the RN can review the education handout with the patient and answer any

questions they may have. The newly developed process is noted in Figure 3. The goal of this process will be to refer 50% of patients diagnosed with OUD to the MOUD program.

Figure 1. Patient Visit Summary.

STUDY WEEK _____

Harm-Reduction Practices for Chronic Pain Patients

The purpose of this quality improvement project is to identify risk factors for developing Opioid Use Disorder (OUD), increase naloxone prescriptions, and refer patients for treatment as a part of harm-reduction.

MA Responsibilities and documentation:

Evaluate patient for chronic pain using the ORT-OUD.

- Once the screening is completed just like SBIRT, PHQ-9 etc.
  - The result will be entered into the EHR.
  - Place the paper copy of the ORT into the QI folder located in the pod.
  - Verbally communicate the ORT score to the provider.
- Was ORT screening completed?
  - ☐ Yes ☐ No
- Was the score ≥3?
  - ☐ Yes ☐ No

RN Responsibilities and documentation

Does the patient have a prescription for naloxone?

- Yes:
  - Ensure it is updated in the chart and not expired.
- No:
  - Offer one and provide the education handout.
- Interested:
  - Enter the order into the EHR
  - Provide additional education and demonstration using the intranasal simulator
  - Provide them with naloxone in clinic from lab stock or the pharmacy
  - Reassess use at next follow-up

- Was a naloxone prescription offered?
  - ☐ Yes ☐ No
- Did they receive a prescription in the clinic?
  - ☐ Yes ☐ No

Provider Responsibilities and documentation

If a patient score is ≥3 (high-risk) on the ORT they should be evaluated for OUD using the DSM-V criteria at that visit.

- If OUD is diagnosed provide the education handout on MOUD

- Was the DSM criteria used?
  - ☐ Yes ☐ No
- Was OUD diagnosed?
  - ☐ Yes ☐ No
- Was a referral for MOUD made?
  - ☐ Yes ☐ No

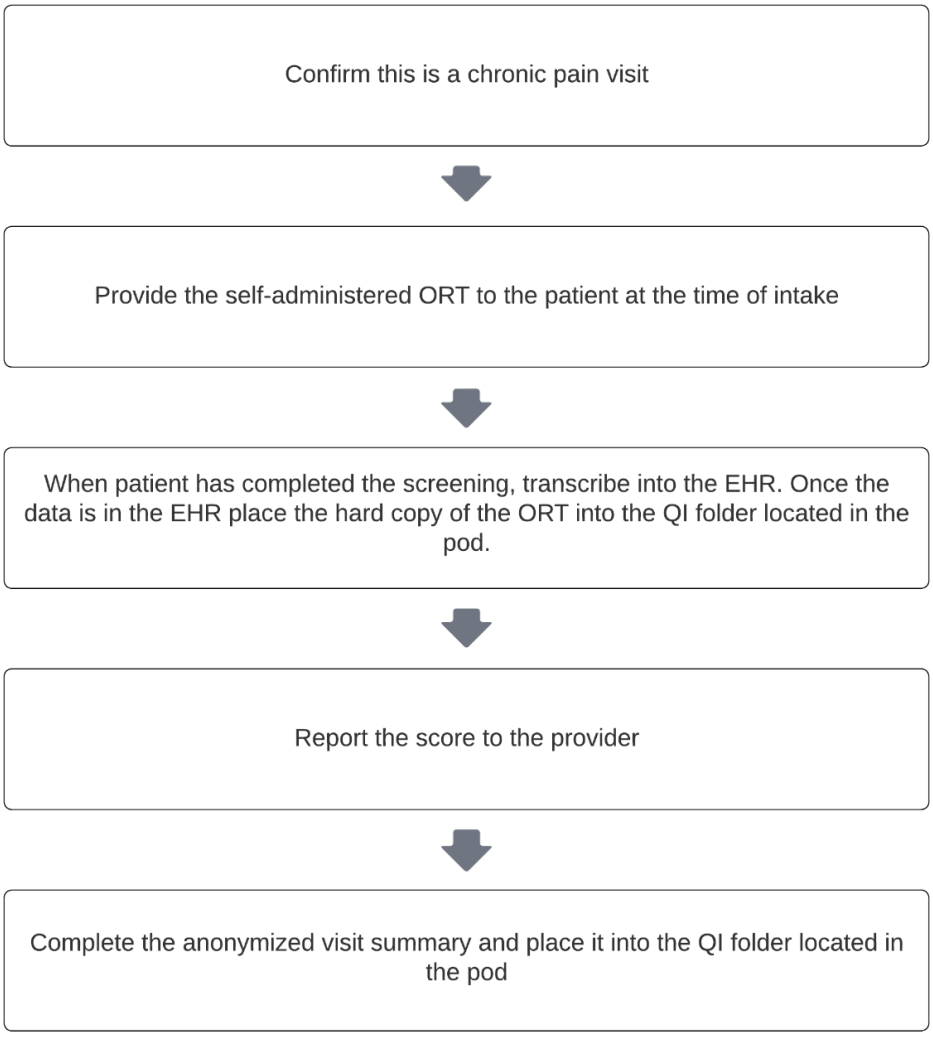
Chronic Pain Management

The proposed practice change will standardize the annual assessment and management of patients receiving LTOT for chronic pain. The first intervention will integrate the modified opioid risk tool (ORT-OUD) into all yearly chronic pain management visits. The ORT-OUD is a nine-item self-administered tool that assesses the risk of developing an opioid use disorder (Cheatle et al., 2019; Webster & Webster, 2005). This tool creates a risk profile based on a patient's history of substance abuse, their family history of substance abuse, and the diagnosis of certain underlying psychological conditions, see Appendix A. The National Institute on Drug Abuse (NIDA) supports using this tool in chronic pain patients, but they do not specify the frequency at which it should be performed (United States Department of Health and Human Services, 2022). The clinical site has no current process for risk screening for OUD; thus, this project will initiate screening for the risk of OUD on an annual basis.

For this project, all adult patients with ICD-10 codes for chronic pain seen between January 13, 2023, and February 23, 2023 are identified by the pilot team during a morning huddle, for any scheduled visit and will be given the ORT-OUD by the MA at the beginning of the visit. A printed workflow diagram will explain the screening steps for the ORT-OUD integration and can be viewed in Figure 1. The MA will transcribe the results into the electronic health record (EHR) and then provide the PA with a hard copy of the screening. A score of ≤ 2 indicates a low risk of developing OUD, and the evaluation for risk will be at the provider's discretion. If the patient has a score of ≥ 3, then the provider will use the DSM-5 criteria to evaluate the presence of OUD during that visit. The PA or RN will provide the patient with an education handout explaining the OUD risk and treatment options, see Appendix E. The number

of ORT-OUD screenings administered during the specified time frame will be evaluated, with a goal of 100% of patients completing the screening tool. The long-term goals of this intervention are to administer the ORT-OUD yearly in all patients with chronic pain receiving LTOT and to increase the number of identified patients with underlying OUD, thus referring to the MOUD program.

Figure 2. MA ORT-OUD Screening Workflow.



The cost of this practice change will include the paper and ink required to print hard copies of the ORT-OUD during the project's evaluation period. Although integrating all screening directly into the EHR would ease provider completion, this adaptation would take additional time and budgeting, thus is a long-term goal beyond the project timeframe. Potential barriers to this intervention will be a patient refusing to complete the screening, a patient answering dishonestly, the MA forgetting to give the tool to the patient, the champion MA being absent, and the provider or staff failing to document the use of the screening tool. A champion team shares rapport and consistent practice, and a workflow will be printed to address the identified barriers. The champion team will receive weekly feedback from the DNP project-lead to allow rapid action changes and enhance process compliance.

The second intervention includes the champion PA offering naloxone for all patients with chronic pain seen during the above-noted timeframe. According to the CDC Guidelines for Prescribing Opioids for Chronic Pain—2016, the patients at the highest risk for opioid overdose are those with a personal history of overdose, a substance use disorder, opioid dosage ≥50 MME/day, and those with concurrent benzodiazepine use (Dowell et al., 2016). All patients with chronic pain on LTOT will be offered a Naloxone prescription; however, those who meet the above criterion are at the highest risk of adverse events and overdose. If the patient desires a prescription, the RN or PA will provide a Naloxone handout to the patient, see Appendix F. The RNs will then offer training demonstrations to each patient using a hands-on intranasal simulator. The RN educates patients, and anyone accompanying them during the visit on the signs of opioid overdose. An order for naloxone is entered into the EHR by the RN per an existing standing order, and the prescription is dispensed to the patient in the clinic by the RN. The champion RN

will document the number of prescriptions entered into the EHR on the anonymized patient visit summary. Patients screened using the ORT-OUD from January 13, 2023-February 23, 2023, will be offered a prescription for naloxone, with a goal of 100%.

Naloxone prescriptions are available at no cost through the clinic-based pharmacy. Funding is provided by the Montana Department of Health and Human Services (MDHHS) under the Help Save Lives from Overdose Act (2017). The clinic-based pharmacy can dispense four doses of Naloxone Nasal Spray 4 mg to each patient using a standing order issued by the MDHHS on January 1, 2022. The clinic pharmacy staff document these prescriptions and report them to the State of Montana for tracking purposes.

Potential barriers in this second intervention include patient refusal, lack of awareness of how naloxone can save lives, the stigma associated with having a prescription for naloxone, and naloxone prescriptions sent to an outside pharmacy. The champion RN will address these barriers through in-person education and training. Information about naloxone will also be displayed on a television in the patient waiting room, see Appendix G. Developing a written workflow, Figure 3, for naloxone will keep all prescriptions in-house and improve the monitoring of harm-reduction practices. If the patient chooses not to obtain a naloxone prescription from the clinic, there are options for obtaining naloxone from an outside pharmacy at little or no cost. Patient education will include information on how to obtain naloxone from outside pharmacies without a prescription and the signs of opioid overdose.

Figure 3. Nursing Workflow for Naloxone Prescriptions in Patients with Chronic Pain.

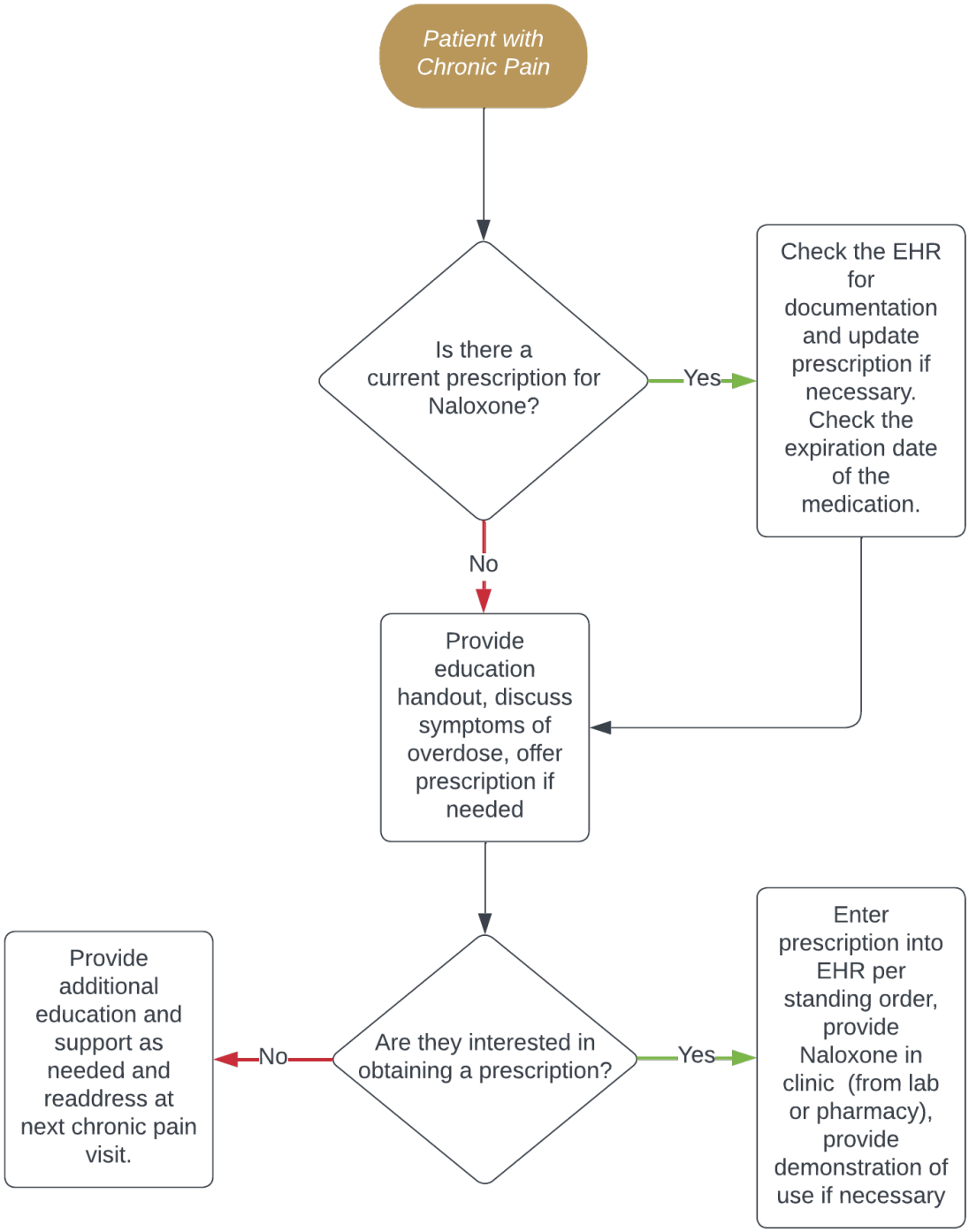


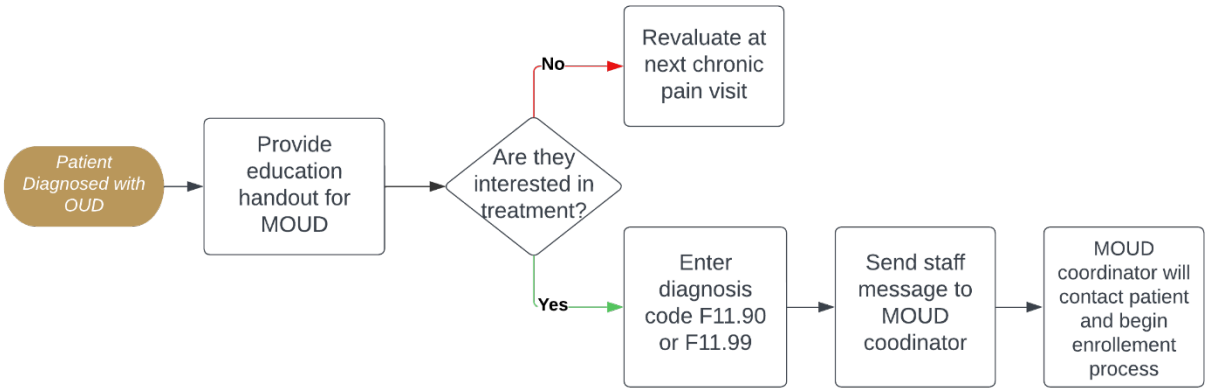
Table 2. DSM-5 Diagnostic Criteria of OUD.

Patients must meet 2 of the following 11 criteria to receive a diagnosis of OUD.
1. Opioids are often taken in larger amounts or longer period than intended
2. Unsuccessful efforts to control opioid use
3. Large segment of time allocated to obtaining, using, or recovering from opioids
4. Strong desire to use opioids
5. Use of opioids is deterring one from daily activities such as work, school, or home
6. Continued opioid use despite its use causing an inability to fulfill responsibilities
7. Reduction or elimination of social occupational or recreation activities due to opioid use
8. Ongoing opioid use although physically hazardous
9. Ongoing opioid use despite having knowledge of such hazards
10. Experiencing tolerance to opioids
11. Experiencing withdrawal from opioids

Note: American Psychiatric Association. (2013). Opioid-Related Disorders. *Diagnostic and statistical manual of mental disorders* (5th ed.).

Patients diagnosed with OUD will have met at least two of the eleven criteria described by the DSM-5, as noted in table 2. These criteria are defined by problematic opioid use and distress in the 12 months prior to evaluation. Patients who score ≥3 on the ORT-OUD will be evaluated by the PA using the DSM-5 criteria to formalize the diagnosis. The goal of this project will be to evaluate 100% of patients with chronic pain on LTOT who screen high (≥3) on the ORT-OUD using the DSM-5. Because the DSM-5 is the only tool for diagnosing OUD, this process will be included for consistency and proper diagnosis.

Figure 4. Provider MOUD Referral Workflow for Patients with Chronic Pain.



The benefit of this QI project is the nominal cost associated with change. Implementation of the discussed interventions can be integrated without significant budget adjustments. Patients will be screened at routine chronic pain visits, and no additional clinic visit is needed. The current workflow of a patient visit allows 10 minutes of education time with the RN at the end of the visit and will not significantly impede current practice. The associated costs will include printing patient educational materials, copies of the ORT-OUD, and the patient visit summary. Naloxone is available at no cost to the clinic or the patients. A final budget has yet to be determined as site stakeholders are still deciding on the educational material to be printed. The DNP students' volunteer contribution to the site also reflects cost savings. Suppose the average nurse's salary in Montana is $30/hour and a total of 270 hours were worked over the course of this project, the total savings for the clinic is $8100.

Evaluation

Table 3. List of SMART Goals.

SMART Goal #1: 100% of patients with chronic pain on LTOT seen between January 13 – February 23, 2023, will have filled out the self-administered ORT-OUD screening tool at their chronic pain visit.

- Stakeholder agreement and implementation of the ORT-OUD risk tool
- The CDC Prescribing Opioids for Chronic Pain Guideline—2016 will be used to guide the importance of screening and harm reduction practices.
- 100 ORT-OUD screeners will be printed from the NIDA website and provided to the site to be kept in the project folder in the pod. The team will identify the patients with chronic pain, based on ICD-10 codes (G89.4, G89.29, Z79.891), who need to be screened daily at the morning huddle. The MA is responsible for initiating the screening process.
- The project lead will develop a patient visit summary to document project outcomes. See Table 2
- The project lead will hold an education/demonstration session for the champion team to streamline the process. See Table 1
- The clinic director will need to approve the date and time for the staff education to occur before the implementation date of January 13, 2023.
- The process of transcribing the screening tool results into the EHR will need to be demonstrated to the champion team and will be completed at the education/training session by the RN.
- The ORT-OUD will be added to the annual pain contract.

Data to be collected	***Method of Collection and who is responsible***	***Planned data analysis***
Number of ORT-OUD screenings administered	The MA will provide a paper risk tool to the patient at the beginning of their visit. The MA will then take the tool and manually enter it into the EHR. The paper copy will remain anonymous and be placed in a secure folder collected by the project lead weekly.	Descriptive statistics of the rate of change will be documented as a percentage. The number of screenings will be presented as a run chart that is evaluated weekly, allowing for adjustments in workflow if necessary.

Table 3. List of SMART Goals continued.

The total number of chronic pain visits as determined by ICD code at time of scheduling	Each week the EHR will be reviewed by the project lead, and the total number of patients will be documented.	This data will be presented as a run chart.
SMART Goal #2: 100% of patients with chronic pain on LTOT seen between January 13-February 23, 2023, will be offered a prescription for naloxone.		
• Based on input from the team of stakeholders, the project lead will develop a workflow for naloxone prescribing, See Figure 2 • The DPHHS grant will allow naloxone to be obtained on-site at no cost to the patient via a standing order. • Educational materials will be sourced from the CDC and SAMHSA websites and provided to staff for distribution to patients, see Appendix F • Education sheets will be uploaded and sent to the clinic director to be placed on the waiting room television. o This will be done to create awareness, inspire curiosity, and reduce the stigma • Naloxone prescriptions will be added to the annual chronic pain agreement by the clinic director. o Site stakeholders continue to discuss the exact phrasing; thus, it is not yet included • The project lead will develop a patient visit summary to document project outcomes, see Table 2		
Data to be collected	***Method of Collection and who is responsible***	***Planned data analysis***
The total number of Naloxone prescriptions offered.	The provider or RN will enter a prescription into the EHR. The RN will indicate if naloxone was offered/prescribed on the anonymized visit summary.	Descriptive statistics with the rate of change will be displayed as a percentage, and a run chart will provide visual trends over time. The trend will be evaluated weekly to allow for adjustments in the workflow as necessary.
The total number chronic pain visits as determined by ICD code at time of scheduling	Each week the EHR will be reviewed by the project lead, and the total number of patients will be documented.	This data will be presented as a run chart.

Table 3. List of SMART Goals continued.

SMART Goal #3: 100% of patients with chronic pain who screen ≥3 (high-risk) on the ORT-OUD between January 13-February 23, 2023, will be evaluated by the provider using the DSM-5 criteria for diagnosing OUD.

• The project lead will hold an education/demonstration session before implementation for the champion team to streamline the process.
• The DSM-5 criteria will be printed and provided to the PA as a handout for ease of access while evaluating the patient.
• A dot phrase for the EHR will be developed to document the diagnostic process.
  o Site stakeholders continue to discuss the exact phrasing; thus, it is not yet included.
• The use of specific ICD-10 codes (F11.90 and F11.9) will be used if the patient meets the criteria of an OUD.
• Educational materials will be sourced from the CDC and SAMHSA websites and provided to staff for patient education, see Appendix E.
  o Site stakeholders continue to discuss the exact documents; thus, they are not yet included.
• The project lead will develop a patient visit summary, see Table 2, to document project outcomes.

Data to be collected	***Method of Collection and who is responsible***	***Planned data analysis***
Total number of patients whom the provider evaluated using the DSM-5 criteria	The provider will document this in the EHR and on the anonymized visit summary.	Descriptive statistics with the rate of change will be displayed as a percentage, and a run chart will provide visual trends over time. The trend will be evaluated weekly to allow for adjustments in the workflow as necessary
The total number of patients who screened high risk (≥3) on the ORT	The MA will provide the paper screening tool to the provider with the calculated results. If the result is ≥3, the provider will use the DSM-5 criteria as part of their visit assessment.	This data will be presented as a run chart.

Table 3. List of SMART Goals continued.

SMART Goal #4: 50% of patients with chronic pain on LTOT seen between January 13-February 23, 2023, who are diagnosed with an OUD will be referred to the clinic-based MOUD program.

- Based on input from the team of stakeholders, the project lead will develop a workflow for referral to the MOUD program, see Figure 3
- The use of specific ICD-10 codes will be used if the patient is diagnosed with OUD (F11.90 and F11.9).
- A dot phrase for the EHR will be developed to document the diagnostic process.
    - Site stakeholders continue to discuss the exact phrasing; thus, it is not yet included.
- Educational materials will be sourced from the CDC and SAMHSA websites, see Appendix E and provided to staff for patient education.
    - Site stakeholders continue to discuss the exact documents; thus, they are not yet included.
- The project lead will develop a patient visit summary, see Table 2, to document project outcomes.

Data to be collected	***Method of Collection and who is responsible***	***Planned data analysis***
The total number of patients who are referred for MOUD.	The provider will document this in the EHR. The RN will send a staff message to the MOUD coordinator indicating the need for patient referral. The RN will report on the patient visit summary.	Descriptive statistics with the rate of change will be displayed as a percentage, and a run chart will provide visual trends over time. The trend will be evaluated weekly to allow for adjustments in the workflow as necessary
The total number of patients who met the DSM-5criteria for diagnosis of OUD.	The provider will document the diagnosis in the EHR using ICD-10 codes F11.90 and F11.99. They will also report the diagnosis on the patient visit summary.	This data will be presented as a run chart.

CHAPTER THREE

QI MANUSCRIPT

Introduction

The opioid crisis remains a significant public health challenge in the United States (US), with increasing opioid-related deaths each year. In a primary care setting, early detection of use disorders and implementation of harm reduction is essential to providing safe and complete care. Harm reduction is a comprehensive prevention strategy focusing on the continuity of care and improving patient and family outcomes.

Patients receiving long-term opioid therapy (LTOT) for chronic pain are at risk for adverse events related to opioid use, including opioid use disorder (OUD), overdose, or death. With 9.3 million Americans reporting prescription opioid misuse in 2021, the demand for close follow-up and harm reduction is evident (Substance Abuse and Mental Health Services Association [SAMHSA], 2021c). The Centers for Disease Control and Prevention (CDC) released updated guidelines for prescribing opioids for chronic pain in late 2022. This guideline offers flexible recommendations for safe prescribing practices with the understanding that pain is a complex phenomenon influenced by multiple factors (Dowell et al., 2022). This guideline highlights the importance of risk screening, early OUD diagnosis, and harm reduction practices like naloxone and buprenorphine.

The primary care setting is the optimal location to implement harm and risk reduction. Because the primary care provider (PCP) manages LTOT for patients with chronic pain, they must promote safe prescribing practices and mitigate adverse events. Harm reduction practices

found effective include screening for the risk of developing OUD using the Opioid Risk Tool (ORT), naloxone prescriptions for patients on LTOT, early diagnosis of OUD using the Diagnostic and Statistical Manual of Mental Disorders Fifth Edition (DSM-5), and medications for OUD (MOUD), like buprenorphine (Dowell et al., 2022).

Background

Chronic Pain and Long-Term Opioid Therapy

Chronic pain is any pain lasting longer than three months or past the expected time for tissue healing and is one of the most common reasons adult Americans seek medical care (Chou et al., 2015; Dowell et al., 2022). In 2019, the prevalence of chronic pain was approximately one in five US adults, and one in 14 experienced "high-impact" chronic pain, defined as having pain on most days in the previous three months which limits life or work activities (Dowell et al., 2022). Chronic pain can be related to underlying medical disease, medical treatments, inflammation, or an unknown cause (Dowell et al., 2022). Many therapeutic options exist for managing chronic pain, and treatment aims to improve pain and function while minimizing patient risks.

A patient experiencing chronic pain can have an increased risk of poor functioning, anxiety, depression, financial ramifications, isolation, and suicidality, thus negatively impacting quality of life (Cohen et al., 2021). Illness or stressors can also increase a patient's risk of uncontrolled chronic pain (Cohen et al., 2021). Understanding the dynamics of this relationship should guide the approach to chronic pain management and promote individualized patient care plans. Assessing high-risk behavior patterns as a routine part of chronic pain management can aid in the early identification of problematic opioid use. Long-term opioid therapy (LTOT) has

long been essential to chronic pain management, but carries significant potential risks (Dowell et al., 2022). LTOT, defined as prescription opioid use longer than 90 days, comes with an increased risk for accidental overdose and the development of an OUD, thus should be managed with close healthcare follow-up and continued discussion of treatment goals (Dowell et al., 2022).

Opioid Use Disorder (OUD)

The DSM-5 defines OUD as a problematic pattern of opioid use that includes several characteristics that reflect compulsive or inappropriate behavior occurring in the previous 12 months (APA, 2013, p541-542). OUD exists on a continuum of mild to severe (see Table 1). Any patient prescribed opioid medications are at a potentially increased risk of developing an OUD. The use of safe prescribing practices, patient education about OUD, and early identification through screening tools are crucial to create awareness of the diagnosis and initiate provider and patient discussions about treatment.

In 2020, 2.7 million Americans aged 12 and older were known to have an OUD (SAMHSA, 2021a.). Chronic pain often precedes OUD in patients receiving prescription opioids, and 24% to 68% of those diagnosed with OUD report moderate to severe chronic pain (MacLean et al., 2019). In patients with chronic pain on LTOT, the prevalence of OUD has been found between 23.9%-26.5%, with a slightly lower prevalence of 21.5% in clinics utilizing standardized risk reduction practices (Boscarino et al., 2020; Von Korff et al., 2017). Although this percent reduction seems negligible, when scaled to the population effected by OUD, this means improving the quality of life of tens of thousands of Americans.

OUD is a lifelong chronic disease associated with an increased risk of overdose, relapse, and death (APA, 2013; CDC, 2016; Gomes et al., 2018; Klimas et al., 2019). However, like other chronic diseases such as diabetes or cardiovascular disease, it is treatable and requires continual care and sometimes lifelong treatment to sustain recovery (SAMHSA, 2021b).

Table 4. DSM-5 Criteria for Diagnosing OUD.

Patients must meet 2 of the following 11 criteria to receive a diagnosis of OUD.
1. Opioids are often taken in larger amounts or longer periods than intended
2. Unsuccessful efforts to control opioid use
3. Large segment of time allocated to obtaining, using, or recovering from opioids
4. Strong desire to use opioids
5. Use of opioids is deterring one from daily activities such as work, school, or home
6. Continued opioid use despite its use causing an inability to fulfill responsibilities
7. Reduction or elimination of social occupational or recreation activities due to opioid use
8. Ongoing opioid use although physically hazardous
9. Ongoing opioid use despite having knowledge of such hazards
10. Experiencing tolerance to opioids
11. Experiencing withdrawal from opioids

Mild: Presence of 2-3 symptoms
Moderate: Presence of 4-5 symptoms
Severe: Presence of 6 or more symptoms
Note: American Psychiatric Association. (2013). Opioid-Related Disorders. *Diagnostic and statistical manual of mental disorders* (5th ed.).

Opioid Risk Tool

The opioid risk tool (ORT) was originally developed and validated in 2005 by Webster and Webster as a 10-item, gender-weighted screening tool. The ORT measured the likelihood of a patient misusing opioids in the future and placed a risk category of low, moderate, or high on

the result (Webster & Webster, 2005). The ORT focuses on preexisting conditions or experiences that may increase the risk of developing opioid misuse in patients prescribed opioid medication.

In 2019, the ORT was modified to eliminate gender as a contributing score modifier and became a 9-item, unweighted, self-administered screening tool known as the ORT-OUD. Cheatle et al. (2019) had successful findings supporting the superiority of non-specific gender screening and a higher clinical predictive value. The ORT-OUD is indicated any time opioids are prescribed and can be used at the initiation of opioid therapy or intermittently during treatment. Because it is based on aberrant drug-related behaviors, it is reasonable to predict that changes to ORT scoring can change at any time and should be used at different intervals in patient care, such as initiation of therapy, change in dosing, and annual follow-up (Cheatle et al., 2019, Dowell et al., 2022; Webster & Webster 2005). The ORT-OUD can accurately predict the risk of developing an OUD in patients with chronic pain receiving LTOT (Cheatle et al., 2019).

The ORT-OUD is divided into three risk categories: family history of substance abuse, personal history of substance abuse, and psychological disease. A single point is given for each positive item with a maximum score of nine, see Appendix C. A score of ≤2 indicates a low risk of developing an OUD. A score of ≥3 indicates a high risk of developing an OUD. The revised unweighted ORT (ORT-OUD) is the first screening tool to predict the risk of developing OUD in primary care patients with chronic nonmalignant pain receiving long-term opioid therapy (Cheatle et al., 2019). This screening tool was adopted by the National Institute on Drug Abuse (NIDA) and is available on their website free of charge (see Appendix C). It is important to remember that this screening tool is non-diagnostic and only provides insight into risk

stratification based on aberrant drug-related behaviors. Further healthcare provider evaluation of high-risk patients using the DSM-5 criteria is required to diagnose OUD.

Medications for Opioid Use Disorder (MOUD)

MOUD programs combine medications and behavioral resources, such as counseling, patient education, and case management, as effective, evidence-based interventions for treating OUD (SAMHSA, 2021b). Buprenorphine is a partial opioid agonist used to treat OUD that can be prescribed in a primary care setting by any licensed provider. Buprenorphine is used to normalize brain chemistry, block the euphoric effects of opioids, and relieve physiological cravings without the harmful effects of opioid use, such as respiratory depression or physical dependence (SAMHSA, 2023). Suboxone is a pharmaceutical combination of buprenorphine and naloxone used as a primary MOUD treatment option. It is combined to reduce misuse of buprenorphine and prevent opioid overdose if combined with additional opioids.

Access to MOUD in primary care is an essential component of harm reduction. Without treating OUD quickly and efficiently, there is less chance for successful recovery. The goal of MOUD is full recovery from OUD, with or without the continuation of medication therapy (SAMHSA, 2023). However, maintenance therapy minimizes cravings and withdrawal symptoms, allowing individuals to make the necessary lifestyle changes more safely (SAMHSA, 2021b).

Naloxone

Naloxone is an opioid receptor antagonist that binds to opioid receptors and blocks or reverses the effects of opioids (CDC, 2019). Emergency personnel widely use this medication to temporarily reverse the respiratory depression that often precedes opioid-related death.

Naloxone's quick ability to restore a regular breathing pattern gives people experiencing an opioid overdose a second chance to seek help and begin their path to recovery. Naloxone can be administered by family members, friends, and bystanders, increasing the likelihood of survival in someone experiencing an opioid overdose.

Naloxone is available in many forms, such as injectables, nasal sprays, and auto-injector devices. In community settings, naloxone nasal spray is the most widely accepted and used route of administration. Administration of naloxone is safe and has little to no effect if a person is not under the influence of opioids but will precipitate withdrawal in an opioid-dependent patient (Dowell et al., 2022). Studies have shown that co-prescribing naloxone and long-term opioid therapy have increased benefits and reduced mortality, economic cost, and emergency room visits (Behar et al., 2016; Coffin et al., 2016; Dowell et al., 2022). In support of the benefits of naloxone and efforts to expand access, the Food and Drug Administration (FDA) recently approved over-the-counter naloxone which is said to be available in the fall of 2023.

Project Aims

The identified problem is a lack of standardized chronic pain management harm reduction practices offered by primary-care providers to patients receiving LTOT for chronic pain management. Evidence-based harm reduction practices include: screening for the risk of developing an OUD using the ORT-OUD, offering prescriptions for naloxone to prevent overdose death, using DSM-5 criteria for providers to diagnose OUD, and initiating referral for evidence-based treatment for OUD with buprenorphine. The project aims to increase risk screening and access to naloxone in 100% of patients on LTOT. In patients identified as high-risk based on an ORT-OUD score of ≥3, the goal is to have providers use the DSM-5 criteria to

assess for OUD in 100% of high-risk patients. In those diagnosed with an OUD, the goal is to refer 50% to the primary care based MOUD program for treatment with buprenorphine.

Methodology

This quality improvement (QI) project used the Plan-Do-Study-Act (PDSA) model. The process of PDSA provided an opportunity for perpetual assessment throughout the project, intending to adopt change and eventually spread the QI process outwards through the larger practice site. A voluntary pilot team was selected during the planning phase of PDSA cycle to carry out the project interventions. Long-term objectives of the project include additional PDSA cycles to expand the interventions to all care teams at the project site. The development of a data collection tool allows documentation of all interventions on a combined document, see Figure 1. Success rates were determined based on goals set during the planning phase. Outcomes were analyzed using Microsoft Excel to produce descriptive statistics. A post-project staff debriefing provided qualitative feedback that supports adoption of the project interventions. The project participants maintained the confidentiality of patient information and properly de-identified the data collected on the patient visit summary.

Figure 5. Patient Visit Data Tool.

STUDY WEEK _____

Harm-Reduction Practices for Chronic Pain Patients

The purpose of this quality improvement project is to identify risk factors for developing Opioid Use Disorder (OUD), increase naloxone prescriptions, and refer patients for treatment as a part of harm-reduction.

MA Responsibilities and documentation:

Evaluate patient for chronic pain using the ORT-OUD.

- Once the screening is completed just like SBIRT, PHQ-9 etc.
  - The result will be entered into the EHR.
  - Place the paper copy of the ORT into the QI folder located in the pod.
  - Verbally communicate the ORT score to the provider.
- Was ORT screening completed?
  - ☐ Yes ☐ No
- Was the score ≥3?
  - ☐ Yes ☐ No

RN Responsibilities and documentation

Does the patient have a prescription for naloxone?

- Yes:
  - Ensure it is updated in the chart and not expired.
- No:
  - Offer one and provide the education handout.
- Interested:
  - Enter the order into the EHR
  - Provide additional education and demonstration using the intranasal simulator
  - Provide them with naloxone in clinic from lab stock or the pharmacy
  - Reassess use at next follow-up

- Was a naloxone prescription offered?
  - ☐ Yes ☐ No
- Did they receive a prescription in the clinic?
  - ☐ Yes ☐ No

Provider Responsibilities and documentation

If a patient score is ≥3 (high-risk) on the ORT they should be evaluated for OUD using the DSM-V criteria at that visit.

- If OUD is diagnosed provide the education handout on MOUD

- Was the DSM criteria used?
  - ☐ Yes ☐ No
- Was OUD diagnosed?
  - ☐ Yes ☐ No
- Was a referral for MOUD made?
  - ☐ Yes ☐ No

Participants and Setting

This project was identified as a QI project, and exemption was obtained from the Institutional Review Board for the Protection of Human Subjects Office of Research Compliance

at Montana State University. The setting for this project was an outpatient community health clinic in rural Montana. The clinic staff consists of two physicians, one PA, two nurse practitioners (NPs), four RNs, four MAs, and a clinic director specializing in family medicine/primary care. The project team sees 13-17 patients daily, with an average of 1-2 chronic pain patients included in the daily total. The team identified patients presenting for a chronic pain follow-up appointment each day at the morning huddle. These visits were then flagged to receive the harm-reduction interventions, which were initiated by the MA upon patient arrival.

Procedure

The pilot team is one of six provider teams at the clinic site and was chosen to initiate project integration. The pilot team, consisting of a sizable patient panel experiencing chronic pain, willingly participated in the intervention. The stakeholders at the site acknowledge the importance of having consistent harm-reduction procedures for patients with chronic pain, as they have witnessed risky behavior leading to an overdose. The project sought to improve the medical treatment provided to patients with chronic pain receiving LTOT. As a result, patients consented to ORT and DSM-5 screening upon agreeing to receive care, while participation in MOUD and accepting naloxone prescriptions remained voluntary. Workflows were tailored to meet the clinic's requirements and PDSA cycles were employed to attain the project's objectives: 100% ORT and DSM-5 screening, 100% offered naloxone prescriptions, and 50% referral to MOUD for patients with chronic pain. During project planning, education was provided to inform all participating clinicians of the QI project. A debriefing session was held after the education session to answer all questions prior to project implementation.

The clinic was provided with a secure folder that contained printed copies of the ORT-OUD screening tool; patient education materials on naloxone, OUD, and MOUD; a laminated copy of the DSM-5 criteria for OUD to be used by the PA; printed workflows for each intervention (see figures 2 and 3); and patient visit summaries used for data collection (see figure 1). At the request of the stakeholder team, education handouts that provided statistics about the opioid epidemic were printed and hung in patient rooms and placed on the informational television in the patient lobby. The original project proposal included developing dot phrases for documentation in the electronic health record. At the request of the PA, who believed developing dot phrases would be more appropriate after data collection and analysis, dot phrase development was discontinued during the project implementation.

The project assessed patients with chronic pain for the risk of developing an OUD using the ORT-OUD administered by the project MA. If the patient scored ≥3 on the ORT-OUD, the project PA used the DSM-5 criteria to evaluate for an opioid use disorder. If an OUD was diagnosed, the QI team provided education about OUD and treatment options. If the patient showed interest in MOUD using buprenorphine, the goal was to refer them for MOUD therapy. Additionally, all patients with chronic pain on LTOT who presented to the clinic during the project duration were offered a prescription for naloxone and given naloxone education by the project RN.

The project ran every Tuesday, Thursday, and Friday for six weeks, as this was the project teams regular workdays. Data were collected weekly, and verbal query from the stakeholders was used to determine a need for additional adaptations of the PDSA cycle. At the end of six weeks, a second staff debriefing session was held to discuss the project's overall

success and define any limitations for future implementation and project sustainability. The overall financial impact was minimal with the only accrued costs being the printed ORT tools, educational tools, and data collection documents. There was no disruption to the current patient workflow and no additional staff resources were needed to support the success of the project.

Figure 6. MA Workflow for ORT-OUD Screening.

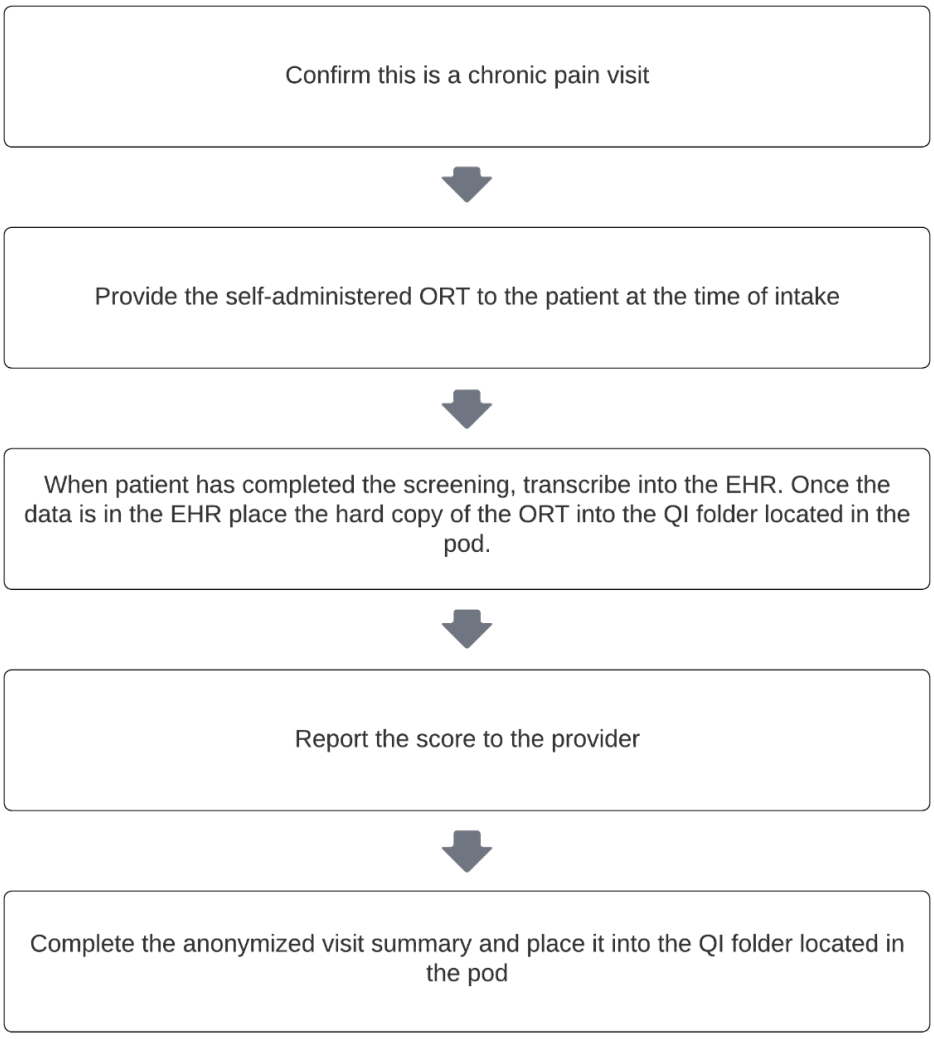
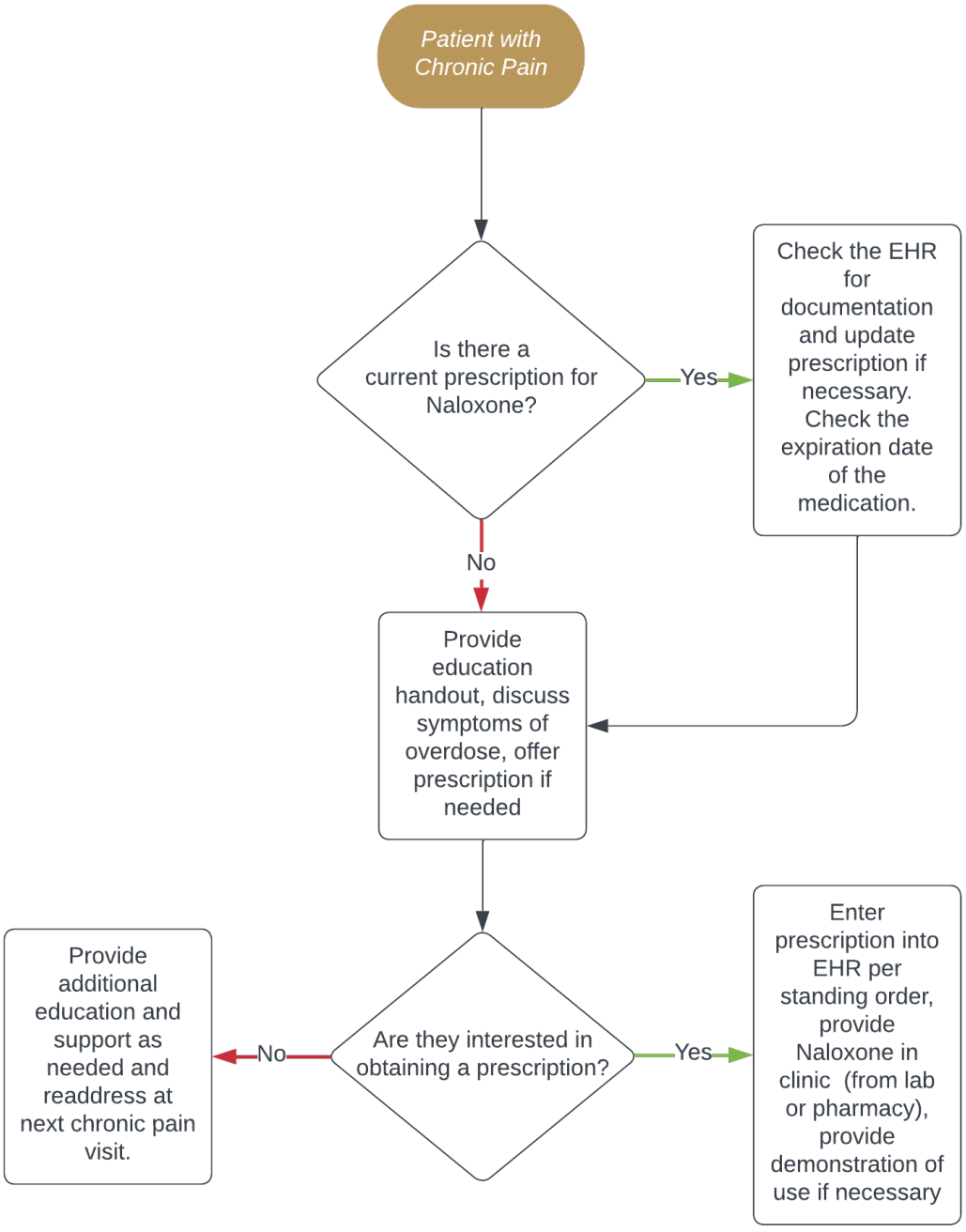


Figure 7. Naloxone Prescriptions in Patients with Chronic Pain Nursing Workflow.



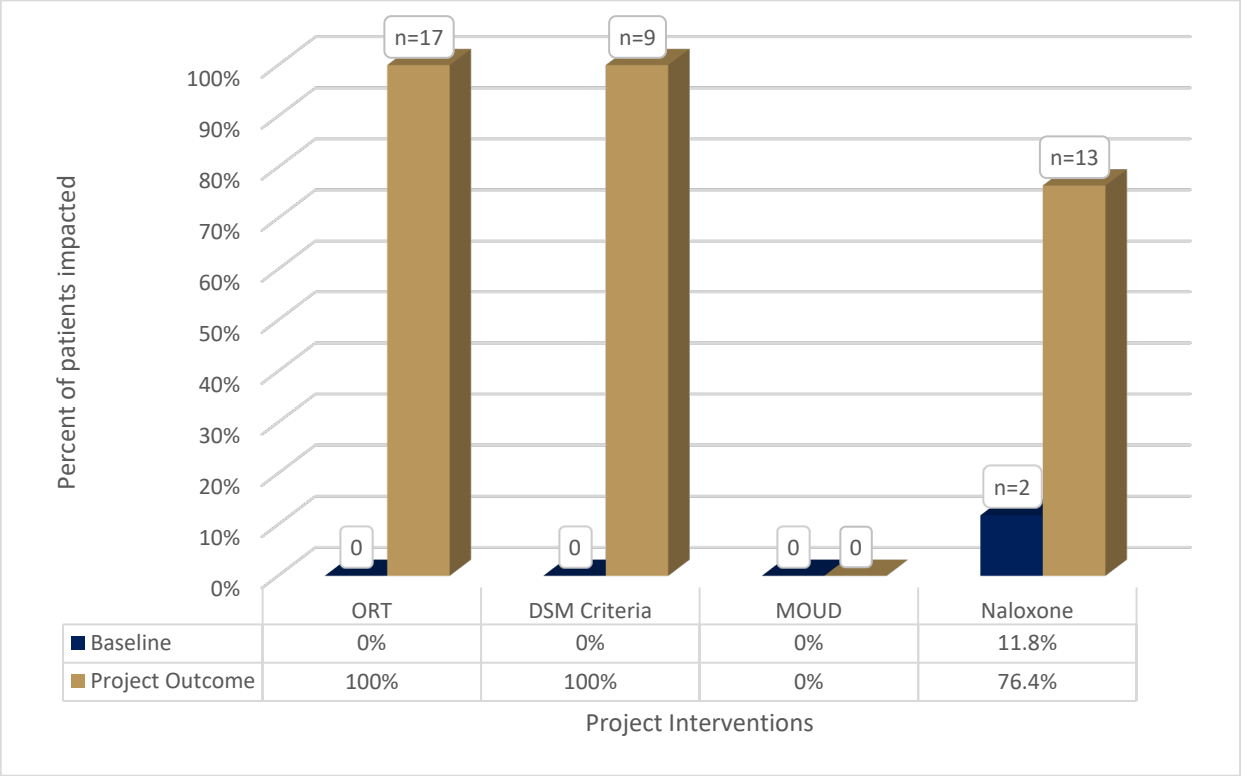
Results

During the six weeks between January 13, 2023, and February 23, 2023, the quality improvement project team attended to 199 patients. Among these, 17 patients (8.5%) had appointments for chronic pain follow-up. The age distribution of these 17 patients included 23.5% (n=4) aged between 18-45 years, while the rest were aged above 45 years.

All 17 patients completed the ORT-OUD throughout the study period, consistently achieving the project goal each week. Of these, 52.9% (n=9) had ORT-OUD scores of ≥3, indicating a high risk of developing OUD, with an average score of 3.35 (SD=2.18). The most prominent positive responses were linked to a family history of alcohol and a personal history of depression. The PA evaluated all high-risk patients (n=9) using the DSM-5 criteria to diagnose an OUD. Among patients with an ORT-OUD score of ≥3, two patients (22.2%) were diagnosed by the PA with an opioid use disorder, corresponding to 11.8% of the total sampled population (n=17) with active OUD.

No patients were referred to MOUD during the project timeframe. Naloxone prescriptions were offered by the RN to 13 patients (76.4%) over the six weeks. In project weeks 1, 4, 5, and 6, 100% of patients were offered naloxone, whereas weeks 2 and 3 had varying percentages. Among the offered naloxone prescriptions, all were filled at the time of the appointment from the nurse's stock. Of these prescriptions, 84.6% (n=11) were new, and 15.4% (n=2) were refilled.

Figure 8. Comparing project intervention baselines to outcomes.



Discussion

The overall results of this QI project displayed in Figure 4, were positive despite its short duration and small population sample. Four interventions were executed at chronic pain follow-up appointments with minimal interruption to the workflow. The project goals for the administration of the ORT and evaluation for OUD using DSM-5 criteria were met at 100%. Patient referral for MOUD using Suboxone was not achieved despite the diagnosis of OUD in two patients. The ORT-OUD was administered for every chronic pain visit leading to the identification of a significant number (52.9%; n=9) of patients with a high risk for developing an OUD. The updated CDC Clinical Practice Guideline for Prescribing Opioids for Pain acknowledges variability in risk screening tools such as the ORT. It encourages clinicians not to

overestimate the ability of risk-stratification tools to rule out the potential for OUD development with LTOT. Keep in mind that the ORT-OUD is a screen for aberrant drug-related behaviors and not a diagnostic tool, but it is helpful for the provider to know when to further evaluate utilizing the DSM-5 criteria.

The pilot PA reliably used the DSM-5 criteria to correctly identify and diagnose OUD in at-risk patients. The PA involved in the project felt that integrating the DSM-5 criteria into a systematic follow-up process increased familiarity with the requirements making the diagnosis of OUD more predictable and efficient. While the project did not observe any patients referred to the MOUD program, two patients (11.8%; n=2) were identified as candidates. The diagnosis of OUD has many complicated components involving patients' personal lives, care plans, and provider discretion. Treating underlying OUD in patients with chronic pain is complex, and the goal of care should include maximizing the benefits of pain reduction while minimizing the risk of adverse events (Dowell et al., 2022). Transitioning care to focus on treating OUD when patients have underlying chronic pain is not immediate and may take time to develop a care plan and set new goals. Providing evidence-based recommendations and patient education will result in informed, shared-decision making to support desired treatment outcomes (SAMHSA, 2021b).

The clinic had multiple changes in staffing and leadership during the project, and the MOUD program is being managed by the providers on an individual basis. The clinic is working to reestablish a streamlined approach for patients referred for MOUD using Suboxone. Integration of risk screening and diagnosis of OUD may yield more referrals to MOUD with a larger sample size and increased implementation duration.

The RN successfully performed harm-reduction education and distributed naloxone prescriptions, increasing the number of active prescriptions from 11.8% (n=2) to 76.4% (n=13). Overall, the intervention was able to increase the number of patients with naloxone prescriptions by 550%. This conversion ratio is promising and demonstrates that patients are receptive to understanding the possible harm associated with opioid therapy. Furthermore, 100% of offered naloxone prescriptions were filled onsite by the clinic RN, highlighting the importance of increased education and access to reduce stigma and advance harm-reduction efforts. Naloxone prescriptions were provided to most patients seen during the project timeframe missing only four patients (23.5%), due to a change in staffing that occurred during weeks two and three of the project. The pilot RN for the project felt empowered to provide education about naloxone and felt the patients were grateful for the information and resources provided to enhance their safety.

During the post-intervention debriefing session, the pilot RN reported that due to the ease of the process, other RNs across the clinic had begun integrating naloxone education and prescriptions into their chronic pain visits. While this was not a goal during the project timeframe, expanding harm reduction to all clinic providers is a long-term objective. The utility of naloxone co-prescription has been well documented in the chronic pain population and is a feasible intervention to reduce possible overdose and death in patients on LTOT (Dowell et al., 2022).

Limitations

The use of harm-reduction practices in patients with chronic pain has been successfully implemented into ongoing patient monitoring. However, further standardization is needed to clearly define the interval at which this new process occurs, preventing repeat screening. During

the project timeframe, all patients who presented for chronic pain follow-up received the harm reduction interventions. The future goals of this QI project include the integration of these interventions into the annual chronic pain management plan, thus encouraging the evaluation for risk and promotion of harm reduction annually. Change in staffing during the process resulted in a lack of naloxone prescriptions offered by the covering RN, resulting in 23.5% of patients not receiving naloxone. Missed opportunities to provide naloxone could be addressed through widespread education to all RNs and standardizing the process into the annual care plan.

No patients were referred to the MOUD program during the project timeframe, but as mentioned above, there can be a lag from the time of diagnosis to the transition to MOUD. The availability of this resource in a primary care setting provides the ability for continual follow-up and repeat discussion about care goals. Despite these limitations, the project dramatically increased the incidence of harm-reduction practices among patients with chronic pain.

Nurse Practitioner Implications

Nurse practitioners in primary care are uniquely positioned to foster a non-judgmental and patient-centered approach to managing patients with chronic pain. Establishing a rapport and educating about the risks of prescription opioid use can reduce stigma and promote self-awareness. Using ORT screening for early recognition and implementation of harm-reduction practices provides the opportunity to identify risks and recommend evidence-based interventions. Balancing the risks and benefits of LTOT for chronic pain requires frequent follow-up and management by a prescribing provider. Taking the time to consider safe prescribing practices and to assess individual patient risk associated with prescription opioid use is essential in providing safe and comprehensive care.

Conclusions

The use of harm-reduction practices in patients with chronic pain can be integrated into follow-up appointments without changing the dynamic of the visit. The ORT-OUD for risk screening in patients with chronic pain on LTOT effectively identifies high-risk behaviors associated with OUD. Proper diagnosis of OUD provides an opportunity for individualized treatment that focuses on minimizing risk and maximizing the benefits of pain management. Providing naloxone to patients with chronic pain spreads awareness of the potential dangers of opioid medications and offers a resource that can reduce morbidity and mortality.

The outcomes of this QI project are sustainable in managing patients with chronic pain and could be diversified to action in patients receiving opioid therapy for acute or subacute pain according to the updated CDC Clinical Practice Guideline for Prescribing Opioids for Pain (Dowell et al., 2022). The focus again is reducing the potential harms associated with opioid medications and providing a standardized process to evaluate patient risk. Expansion of these practices increases the number of patients identified as high risk for OUD, creates familiarity with diagnostic criteria for OUD, and promotes the distribution and education of life-saving naloxone.

CHAPTER FOUR

DNP ESSENTIALS REFLECTION

At the start of my DNP journey, I had a wealth of clinical experience as a nurse but no advanced nursing education. Having worked in several healthcare settings, I felt my time as a registered nurse was ending, and I was ready to start the next chapter of my career. I want to be a leader in healthcare, an advocate for patients and healthcare professionals, and an innovator of best practices. The DNP program has fostered this ability through clinical experience and quality improvement. The knowledge gained during this program has acted as a guide for professional development, allowing me to adopt systems thinking approach to care, expanding not only my scope of practice but the ability to drive change.

The DNP Essentials aim to establish uniformity in advanced nursing practice, fostering a more cohesive and efficient healthcare system. As a DNP-prepared nurse, I can assume leadership roles and swiftly apply knowledge to enhance care delivery and communication between patients and healthcare professionals. I have gained significant expertise in navigating complex organizational structures and addressing financial challenges, although this remains a weakness. Using a system thinking framework to cast a wide net of understanding about institutional decision-making allows me to provide comprehensive and informed care. While all the DNP Essentials have shaped my education, a few exemplify my future role as a family nurse practitioner.

DNP Essential VIII, Advanced Nursing Practice, most accurately describes my role as a family nurse practitioner. Throughout the DNP program, my specialization in advanced nursing

practice has grown through clinical experience and coursework. The nuances of performing a comprehensive physical exam were learned in NRSG 601 but were put into practice during my clinical rotations: Advanced Clinical II Primary Care for Midlife Families (NRSG 622), Advanced Clinical I-FI (NRSG 621), Advanced Clinical III: Primary Care for Aging Families (NRSG 623), and Advanced Clinical IV (NP, Family/Individual) Primary Care Clinical Preceptorship (NRSG 624). Each day in a clinical setting, I am refining my skills to enhance and tailor my approach to physical examination in a response to a variety of intricate patient interactions. Exposure to various clinical settings has expanded my knowledge of different populations and will inform my practice decisions. As a nurse, I have always cared for the adult population, and pediatrics is not my comfort zone. However, working with children during Advanced Clinical II Primary Care for Midlife Families (NRSG 622) and Advanced Clinical I-FI (NRSG 621) gave me the confidence and awareness to care for the pediatric population.

Nursing 675, DNP Scholarly Project not only supported my development and understanding of Essential III, Clinical Scholarship and Analytical Methods for Evidence-Based Practice, but also contributed to my ability to guide excellence in nursing practice and improve patient outcomes. Creating a QI project centered around patients with chronic pain in a rural community provided insight into population health, legal and ethical issues surrounding opioid misuse, and economic challenges in the healthcare system. Developing and evaluating a care delivery approach in a community health center guided my work with a sensitive and diverse population of patients and providers, exemplifying DNP Essentials III and VIII (AACN, 2006). Throughout my clinical and QI project interactions with my stakeholder team, I further exemplified Essential VIII by developing and sustaining relationships with patients and my

peers. I genuinely believe that being able to meet a person where they are and creating a plan of care or interaction from that point is where we can optimize care and form partnerships. Awareness of these differences is crucial to improving patient outcomes in advanced practice.

Evidence-based practice is the foundation for learning, adapting, discovering best practices, and influencing patient care. Throughout the DNP Essentials, there is a pattern that highlights the importance of analyzing literature and using evidence-based medicine to implement best practices. This process is detailed through Essential III, Clinical Scholarship and Analytical Methods for Evidence-Based Practice and exemplified in the following paragraphs.

Evidence Based Practice I (NRSG 604) contributed to my proficient understanding of critical appraisal of evidence and how to translate new knowledge into clinical practice by completing a PICO project on hyperlipidemia. Evidence Based Practice II (NRSG 605) continued to build on the concepts learned in NRSG 604 allowed me to complete another group PICO project on major depressive disorder and mindfulness and meditation. Nursing 675 allowed us to apply these skills and create a publishable manuscript based on our quality improvement (QI) efforts. QI is a systematic approach to addressing care gaps and using evidence to support process change (AACN, 2006). Completing a QI project is one of the great successes of my career, and I am grateful for the education that motivated this accomplishment. Successful completion of a QI project allowed me to disseminate my findings to my project site and my MSU faculty and peers in hopes of improving healthcare outcomes.

During my QI project, I used best practices to identify the risk of developing opioid use disorder. Opioid use disorder was both a clinical and a personal interest for me. As nurse practitioners in primary care, managing patients with chronic pain may be one of our biggest

challenges. It is not only the physical body that is impacted, but also the mind. Researching and evaluating evidence, understanding science-based theories about chronic pain, communicating with patients and peers, and collecting and analyzing data gave me the knowledge and experience I needed to complete my project. This rigorous process included facets from all the DNP Essentials. Determining how quality evidence should be incorporated into clinical practice and when it should inspire change will be a skill I will carry throughout my career.

Essential II, Organizational and Systems Leadership for Quality Improvement and Systems Thinking, has been briefly discussed in the above paragraphs. However, my greatest weakness at the beginning of my DNP program was understanding the intricacies of health policy and economics. Gaining knowledge of how to practice initiatives are impacted by cost-effectiveness and budgeting is an area that I would consider myself developing. Balancing productivity with quality of care is essential to successful patient outcomes and the system's financial stability. As advanced practice providers, we must provide the best care possible while utilizing fiscally reliable resources for the patient and the institution. I have a grwhile still improving healthcare outcomes.

The most helpful display of synthesis of these concepts was writing my financial proposal in Finance and Budget Health Care Systems (NRSG 613). This assignment was constructed to significantly impact patient care with a reasonable financial budget that would return profits to a rural clinic over time. Our goal should always be to create sustainability within a system while improving patient outcomes. During my NRSG 675 QI project, I implemented four cost-effective harm reduction interventions that seamlessly integrated into the clinic's existing workflows. I utilized the free Opioid Risk Tool to screen patients for the risk of

developing opioid use disorder. Additionally, I promoted education and distribution of naloxone to patients with chronic pain at no cost, made possible by the Montana Department of Health and Human Services through the Help Saves Lives from Overdose Act. I have significantly improved my understanding of healthcare spending, cost-effectiveness, and reimbursement, but I look forward to gaining more experience in practice.

Another critical component of systems thinking is managing policy and ensuring personal accountability that will improve care delivery. Our ethics and policy course taught us to think broadly and acknowledge the challenges and diversity in our healthcare system. I examined the Affordable Care Act (ACA) and pre-existing conditions in my health policy issue analysis during Ethics, Law, and Policy for Advocacy in Healthcare (NRSG 612). At the time, legislature was challenging the coverage of pre-existing conditions under the ACA. In writing this policy analysis, I advocated to uphold the coverage of pre-existing conditions to promote social justice, equity, and ethical policies in healthcare. Understanding the concepts of law, ethics, and policy gave me a deep perspective on how the impact of a system can affect individual outcomes.

Essential V, Health Care Policy for Advocacy in Health Care, is a concept that is currently at the forefront of NP practice. As we battle state by state for full practice authority and strike down legislature nationwide trying to revoke or change our practice, we must have political activism and leadership to engage in action. We must be conscious of healthcare disparities, access to care, financial ramifications, and social justice as we provide care and influence process change. Clinical experiences introduced me to diverse patient populations with different economic backgrounds, highlighting the challenges in accessing equitable, high-quality healthcare. These experiences offered valuable firsthand insight into the factors that drive policy

change (AACN, 2006). While I have not been able to incorporate activism into my practice as a student, as DNP prepared NP, I plan to become an active member in nursing communities such as Montana Nurse Association and American Academy of Nurse Practitioners, who focus on advocacy and justice in all healthcare fields.

Starting this program during the Covid-19 pandemic was an unparalleled experience. The stress of the unknown, the exhaustion, and the scientific discovery were pivotal at a time when my career was doing the same thing. There were many lessons to be learned, not just from a healthcare perspective, but about disparity, prevention, and public health. Essential VII, Clinical Prevention and Population Health for Improving the Nation's Health, comes into play. As nurses, we have been trained to advocate for wellness and focus on health promotion. This is not a new concept. However, advancing my career in the face of a global pandemic presented a unique opportunity to integrate health promotion into my future practice naturally. Preventing the disease progression of Covid-19 through patient education, health promotion, and vaccination is a familiar concept in primary care. Being able to synthesize the latest and greatest evidence, as it becomes available, and addressing gaps in care due to the pandemic is a healthcare provider's reality. We must continue using the knowledge that emphasizes disease prevention and promotes wellness for individuals and communities.

The DNP Essentials are the guide for my responsibilities and duties as a doctoral-prepared nurse practitioner, but they are also the values that represent the type of provider I want to be. I want to specialize in primary care and focus my efforts on disease prevention and management, recognizing individual patients' needs, and facilitating informed decision-making. My coursework has taken me on a journey, some courses provided me with a wealth of

knowledge, and others reinforced the foundations of my nursing education. I will say that at the end of this journey, it all has its place and carries weight in every patient interaction.

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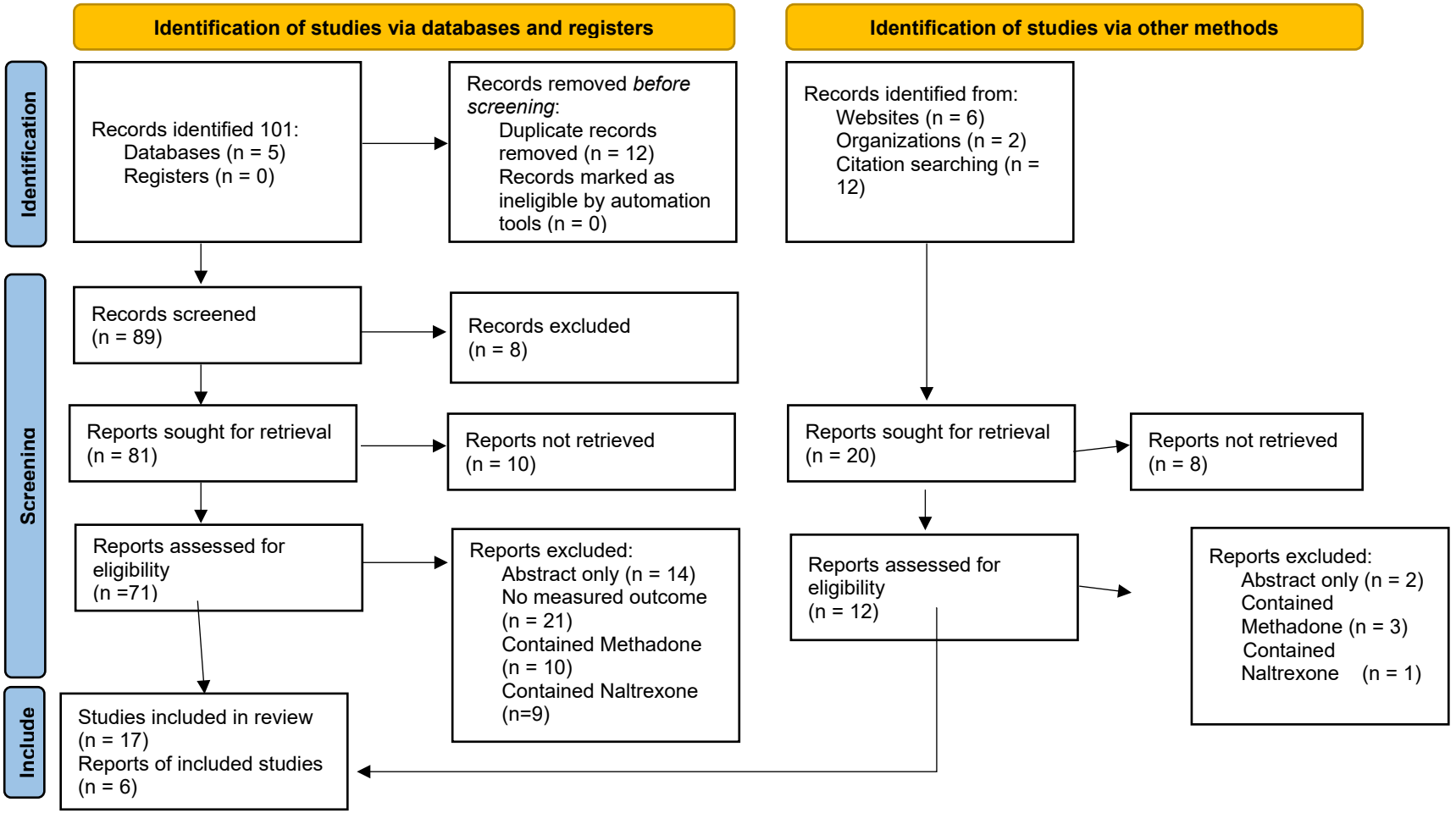
APPENDICES

APPENDIX A

PRISMA

Figure 9. PRISMA.



APPENDIX B

EVIDENCE TABLE

Table 5. Evidence Table.

Citation: (i.e., author(s), date of publication, & title)	Conceptual Framework/Purpose	Design/ Method	Sample/ Setting	Major Variables Studied and Their Definitions	Measurement of Major Variables	Data Analysis	Study Findings	Strength of the Evidence
Behar, et al. (2016).	Understand where naloxone prescriptions were most often prescribed and to what patients.	Cross-sectional survey	6 safety-net primary care clinics in San Francisco	Provider characteristics Naloxone prescribing	Anonymous survey using Qualtrics survey software	Fischer's exact, Kruskal-Wallis	Providers with more patients receiving opioid analgesics reported more naloxone prescriptions H=37.7, P=<0.001	LOE: IV Survey respondents were more inclined toward naloxone prescribing.
Brady, et al. (2021).	Assessing the impact of expanding access to buprenorphine through federally qualified health centers in Arizona	Cohort	All populated Arizona census blocks.	Population groupings, treatment locations	Mean drive times	Kruskal-Wallis H test, post-hoc Mann-Whitney U, P=<0.05	Outpatient office-based treatment decrease drive times by over 50%.	LOE:IV
Bryant, et al. (2021).	Examining the relationship between OUD and its related biomarkers	Systematic Review	Studies from PubMed, PsychINFO, and Cochrane databases for studies including OUD, opioid-related disorders, and potential biomarkers.	Patients with OUD or opioid-related disorders; physical biomarkers			Results suggest that patient with OUD have potential biomarkers that can be targeted to provide optimal treatment.	LOE: I Strengths: systematic review of literature Limitations: varied definitions of OUD, opioid-misuse, and varied measurement of biomarkers.

Table 5. Evidence Table continued.

Cheatle, et al. (2019).	Evaluate a unique cohort of patients with chronic nonmalignant pain	Cross-sectional naturalistic study	Large cohort of patients with chronic nonmalignant pain that were recruited from	Patient with Chronic nonmalignant pain on LTOT; opioid risk tool N=397 with OUD N=781 without OUD	10-item and 9-item ORT	ROC, AUC statistics, standard error, p-values	Increase predictability in the ORT-OUD that eliminates the preadolescent sexual abuse question.	LOE: IV Limitations: only Caucasians were used to increase the probability of discovering a genetic marker. These results cannot be generalized to non-Caucasian populations.
Clark, et al. (2018).	Analyze the validity of the ORT in a large, diverse population	Cross-sectional descriptive study	Academic tertiary pain management center	Chronic pain patients; ORT scores	Patient demographics, ORT scores, ADRB, pain intensity scores, opioid type and dose, smoking status, employment, marital status	Kruskal-Wallis analysis, Wilcoxon rank-sum, Pearson chi-square; p=<0.05	Recommend further study on the risk factors and risk factor categorization before adoption of the ORT for clinician aid or into EHR systems.	LOE: IV Limitations: potential work-up bias, lack of standardization in the EMR,

Table 5. Evidence Table continued.

Coffin, et al. (2016).	Assess the feasibility of and impact of prescribing naloxone to chronic pain patients.	2-year nonrandomized intervention study	6 safety net primary care centers in San Francisco	1,985 adults receiving LTOT for chronic pain. Naloxone prescriptions ED visits	Naloxone prescriptions, prescribed opioid dose, ED visits	P=0.005, 95% CI	Providing naloxone in a primary care setting is safe and may provide ancillary benefits such as reduced ED visits (P <0.001) 95% CI =0.22-0.64	LOE: III Limitations are that the results may not be generalizable beyond safety net settings.
Dowell, et al. (2016).	Create a standardized guide for safe opioid prescribing.	CDC guideline for prescribing opioids to chronic pain patients	N/A	N/A	N/A	N/A	N/A	LOE: I
Gomes, et al. (2018).	Addressing a leading public health problem in America	Serial cross-sectional design	Investigating deaths from opioid-related causes in the US from January 1, 2001-December 31, 2016.	Opioid related deaths; Death certificates	total number of deaths; percentage of deaths; associated person-years of life lost by age group	Cochran-Armitage test; p=0.05	The percentage of all deaths attributable to opioids increased from 292% (from 0.4% to 1.5%) resulting in 1.68 million person-years of life lost in 2016 alone. The highest burden was adults aged 24-35, with 20% of deaths involving opioids.	LOE: IV Limitations: Death investigations being managed at a state level and variability of death investigation may underestimate the number of opioid-related deaths due to misclassification.

Table 5. Evidence Table continued.

Khoury, et al. (2022).	Evaluation of safe practices in an orthopedic clinic	Retrospective review	81 patients who underwent shoulder surgery and completed 3 pre-operative risk and pain assessments in a single hospital system from 2018-2020.	ORT-O, SOAPP-R, PROMIS 3a	ORT-O score, SOAPP-R score, PROMIS 3a score	ROC curve, t-test; 95% CI	The ORT-O and PROMIS 3 a were not good predictors of post-operative opioid dependence, the SOAPP-R performed slightly better.	LOE: IV Limitations: various types of shoulder surgery and some are more painful than others. Strengths: preoperative, intraoperative, and post operative
Klimas, et al. (2019).	Safe prescribing practices and risk identification	Systematic Review	Original studies from MEDLINE and Embase investigating risks of prescription opioid addiction.	Likelihood ratios (LRs) for risk factors and screening tools	OUD-LR (17-22) Other substance disorder LR (4.2-17)	PRISMA, STARD, QUADAS	Absence of a mood disorder (LR 0.05) was associated with a lower risk of opioid addiction.	LOE: V
Lasser, et al. (2016).	Chronic care model of care	Cluster RCT	53-PCPs from the Boston area community-health centers and one urban safety-net-hospital-based primary care practice	Primary care providers; adherence to chronic opioid therapy guidelines	Nurse care management, use of patient registry, academic detailing, electronic tools	P=0.05	Pilot study demonstrated feasibility and acceptability, high frequency of aberrant behaviors, 28-day prescriptions were encouraged	LOE: II Strengths: randomization

Table 5. Evidence Table continued.

MacLean, et al. (2020).	To evaluate measurements and associations between pain severity and opioid cravings in individuals with chronic pain on LTOT and/or OUD	Systematic Review of RCTs and observational studies	A systematic search of PubMed, EMBASE, and PsychINFO were searched in 2018	Chronic pain, opioid use disorder	opioid cravings; pain severity	Cochrane Review Criteria; Newcastle-Ottawa Scale	Overall quality of evidence is moderate.	LOE:I Strengths: two reviewer process for screening
Powell, et al. (2021).	Synthesize evidence on rotation of buprenorphine from full opioid receptor agonist in chronic pain patients receiving LTOT	Systematic Review	A systematic search of PubMed, CINAHL, EMBASE, and PsychINFO from inception to November 3, 2020.	Buprenorphine, Pain intensity	N/A	PRISMA, GRADE system	Buprenorphine was associated with reduced chronic pain intensity in individuals on LTOT. Future studies are necessary.	LOE: I
Stein, et al. (2021).	Examine naloxone co-prescribing in the general population and how it varies by individual community characteristics.	Retrospective cross-sectional study	Individuals in all 50 states who filled opioid prescriptions in a retail pharmacy.	Co-prescribed naloxone	Percentage of long-term opioid therapy, number of prescriptions of opioid and naloxone	Logistical regression of pharmacy claims.	Co-prescription can help reduce overdose death. Co-prescribing rates remain low overall.	LOE: IV

Table 5. Evidence Table continued.

Strand, et al. (2022).	Report the utility of the ORT to identify patients at elevated risk for opioid misuse and deliver medication-safety related services to them.	Cohort study	Utilizing the ONE program in community pharmacies to screen all patients prescribed an opioid.	ORT; prescription for opioids	ORT scores (low, moderate, and high)	Chi-squared test, correlation analysis, Chronbach's alpha, p=0.05	The ORT effectively identified 8.2 and 3.9 % of patients at moderate and high risk of OUD.	LOE: IV
van Rijswijk, et al. (2019).	Evaluate the risks of developing iatrogenic OUD in chronic pain patients with psychiatric comorbidity	Systematic review	Literature search using PubMed, with key subjects "chronic pain," "psychiatry," and "opioid use disorder"	Psychiatric comorbidity, opioid use disorder	Diagnosis of depression, anxiety, OUD	PRISMA	Chronic pain patients with comorbid psychiatric disorders need a multidisciplinary approach and monitoring of opioid use.	LOE: IV
Webster, L. R., & Webster, R. M. (2005).	To provide clinicians with a brief screening tool to predict accurately which individuals may develop ADRB when prescribing opioids for chronic pain.	Cohort Study	185 consecutive new patients treated in a pain clinic, monitored for a period of 12-months.	ADRB; ORT	Scores on the ORT (low, moderate, high), presence of ADRB	C statistic calculation	Females- C=0.85, Males c=0.82 Known risk factors determine probabilities of displaying ADRB. Higher probability= more aberrant behaviors.	LOE: IV Limitations: lack of randomization, potential for bias, no blinding, small sample size

Table 5. Evidence Table continued.

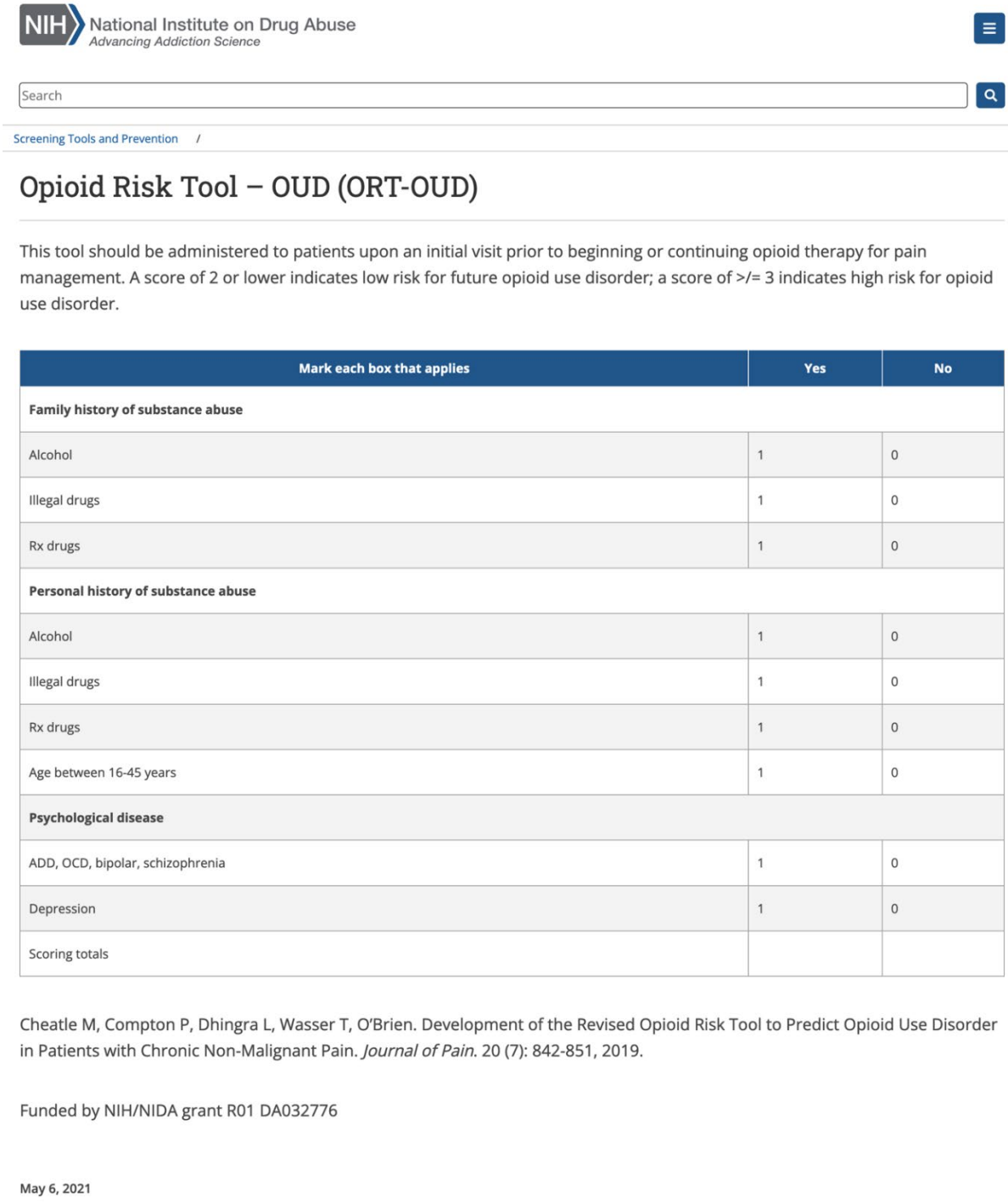
Webster, L. R. (2017).	Encouraging a greater understanding and better assessment of risk for suicide, addiction, misuse in patients taking opioids.	Narrative Review	Patients who use opioids; opioid use disorder	General population of patients who use opioids for chronic pain.	N/A	N/A	Tools are available for clinical decision-making. biological, social, and psychiatric risk factors exist for opioid-related harm.	Level VII Strengths: expert opinion and support from literature Weakness: Review without quantitative or qualitative data

ADRB-aberrant drug related behaviors
LTOT-long-term opioid therapy
ORT-Opioid Risk Tool
OUD-opioid use disorder
OTP-opioid treatment program
ROC-receiver operating characteristic

APPENDIX C

OPIOID RISK TOOL

Figure 10, Opioid Risk Tool.



NIH National Institute on Drug Abuse
Advancing Addiction Science

Search

Screening Tools and Prevention /

Opioid Risk Tool – OUD (ORT-OUD)

This tool should be administered to patients upon an initial visit prior to beginning or continuing opioid therapy for pain management. A score of 2 or lower indicates low risk for future opioid use disorder; a score of >/= 3 indicates high risk for opioid use disorder.

Mark each box that applies	Yes	No
Family history of substance abuse		
Alcohol	1	0
Illegal drugs	1	0
Rx drugs	1	0
Personal history of substance abuse		
Alcohol	1	0
Illegal drugs	1	0
Rx drugs	1	0
Age between 16-45 years	1	0
Psychological disease		
ADD, OCD, bipolar, schizophrenia	1	0
Depression	1	0
Scoring totals		

Cheatle M, Compton P, Dhingra L, Wasser T, O'Brien. Development of the Revised Opioid Risk Tool to Predict Opioid Use Disorder in Patients with Chronic Non-Malignant Pain. *Journal of Pain*. 20 (7): 842-851, 2019.

Funded by NIH/NIDA grant R01 DA032776

May 6, 2021

APPENDIX D

LOGIC MODEL

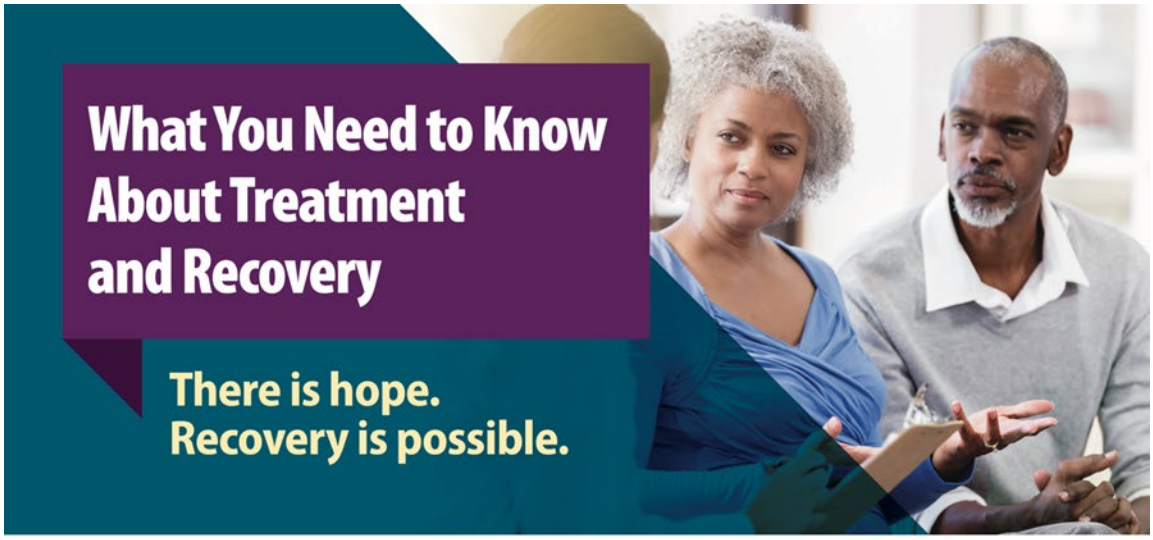
Table 6. Logic Model.

Standardizing a workflow for chronic pain management: Risk screening, naloxone, and opioid use disorder. **Goal: Improving screening in chronic pain patients to identify underlying OUD and providing resources for treatment.**					
INPUTS	**ACTIVITIES**	**OUTPUTS**	**OUTCOMES**		
What we invest	**What we do**	**What we get**	**short-term results**	**intermediate results**	**long-term results**
• Adequate staffing to conduct the screening • Printed screening tools • Printed patient education handout/pamphlet • Printed clinical pathway to MOUD • Printed clinical pathway for chronic pain management. • Naloxone prescriptions from the pharmacy. • Administrative and provider support for screening and referrals. • Referral resources in the community.	Risk Screening: • Integrate risk screening for opioid use disorder (OUD). • Train staff on the use of ORT as an effective screening tool. Naloxone: • Provide an evidence-based handout for naloxone • Create a nursing workflow for naloxone prescribing • Standardize prescriptions for naloxone in chronic pain patients who are high-risk for opioid overdose. OUD • Improve diagnostics • Create a referral process to the MOUD program.	Risk Screening: • Identification of at-risk patients • Staff trained on the use and benefits of the opioid risk tool Naloxone • Standardized naloxone prescribing. • Staff trained to provide education on naloxone OUD • An increase in the identification of patients with OUD • Increased access to MOUD • Standardized referral process for MOUD	In the first 3-weeks of project implementation: Risk Screening: • 25% of patients will be screened using the ORT Naloxone • 25% of patients will be offered naloxone OUD • 25% of patients that screen ≥3 on the ORT will be evaluated using. The DSM-5 criteria • 25% of patients who are diagnosed with OUD will be referred for MOUD	By March 2023 at the project completion: Risk Screening: • 100% of chronic pain patients will have completed screening with the opioid risk tool Naloxone • 100% of patients will be offered naloxone OUD • 100% of patients identified as high-risk on the ORT will be evaluated using the DSM-5 criteria for OUD. • 50% of patients who screen positive for OUD will be given a referral to the MOUD program by the champion provider.	By the end of 2023: Risk Screening: • The opioid risk tool will be used by all four providers in the primary care clinic. Naloxone • 100% of patients on long-term opioid therapy will obtain naloxone. OUD • In one year, the number of patients enrolled in the MOUD program will increase by 100%.

APPENDIX E

OUD PATIENT EDUCATION

Figure 11. OUD Patient Education.



Addiction Is A Disease

Opioids are highly addictive, and they change how the brain works. Anyone can become addicted, even when opioids are prescribed by a doctor and taken as directed. In fact, millions of people in the United States suffer from opioid addiction.

Signs of Opioid Addiction

A major warning sign of addiction is if a person keeps using opioids even though taking them has caused problems—like trouble keeping a job, relationship turmoil, or run-ins with law enforcement. Other signs can include:[1]

Opioid Use Disorder

Sometimes referred to as "**opioid addiction,**" opioid use disorder is a chronic and relapsing disease that affects the body and brain. It can cause difficulties with tasks at work, school, or home, and can affect someone's ability to maintain healthy relationships. It can even lead to overdose and death.

- **Trying to stop or cut down on drug use, but not being able to.**
- **Taking one drug to get over the effects of another.**
- **Stealing drugs or money to pay for drugs.**
- **Using drugs because of being angry or upset with other people.**
- **Being scared at the thought of running out of drugs.**
- **Overdosing on drugs.**

[1] findtreatment.gov/content /understanding-addiction/addiction-can-affect-anyone

To learn more about opioid misuse, go to **cdc.gov/RxAwareness.**

CDC

24629_CDC_Rx_Awareness_Fact_Sheet_2_v09.indd 1 8/4/20 3:54 PM

Recovery Is Possible

Recovery does not happen overnight. Asking for help from family, friends, co-workers, and others can make a big difference. Tell them your reasons for quitting and ask them to check in with you about how things are going. If you know or suspect someone is struggling, ask if you can help.

Treatment Can Help

Treatment can help people get their lives back before it is too late. No single treatment method is right for everyone, but research shows that combining behavioral therapy with medication is the most effective approach for overcoming opioid addiction.

Addiction is a disease that for many involves long-term follow-up and repeated care to be effective and prevent relapse. **When people make a recovery plan that includes medication for opioid use disorder, their chances of success increase.** Medications can help normalize brain chemistry, relieve cravings, and in some cases prevent withdrawal symptoms.

Medication-Assisted Treatment Options

Talk with your doctor to find out what types of medication are available in your area and what options are best for you. Be sure to ask about the risk of relapse and overdose.

Methadone

- Available as daily liquid
- Can only be used in a certified opioid treatment program setting

Buprenorphine

- Available as dissolving tablet, cheek film, or 6-month implant under the skin
- Can be prescribed by a doctor for use outside of a clinic

Naltrexone

- Can be prescribed by any healthcare provider who can legally prescribe medication
- Only used for people who have not used opioids for at least 7–10 days

Find Treatment Services

Use these resources to find services that fit your needs:

Mental Health and Addiction Insurance Help: **hhs.gov/programs/topic-sites/mental-health-parity/mental-health-and-addiction-insurance-help/index.html**

Health Center Locator: **findahealthcenter.hrsa.gov**

Behavioral Health Treatment Services Locator: **findtreatment.samhsa.gov**

Opioid Treatment Program Directory by State: **dpt2.samhsa.gov/treatment/directory.aspx**

Additional resources to access help:

- **Medication-Assisted Treatment (MAT)**
- **Decisions in Recovery: Treatment for Opioid Use Disorder**
- **Facing Addiction in America | The Surgeon General's Report on Alcohol, Drugs, and Health**

APPENDIX F

NALOXONE PATIENT EDUCATION

Figure 12. Naloxone Patient Education.

Fact Sheet: Family and Caregivers

How and When to Use Naloxone for an Opioid Overdose

Naloxone saves lives because it can very quickly restore normal breathing to a person whose breathing has slowed or stopped as a result of overdosing on opioid medications, heroin, or other drugs (e.g., cocaine, methamphetamine) that are mixed or laced with the opioid fentanyl.[1]

What are the signs of an opioid overdose?

During an overdose, a person's breathing can be dangerously slowed or stopped, causing brain damage or death. It's important to recognize the signs and act fast, even before emergency workers arrive. Signs of an overdose may include:[2]

- Small, constricted "pinpoint pupils"
- Falling asleep or loss of consciousness
- Limp body
- Slow, shallow breathing
- Choking or gurgling sounds

Naloxone (Narcan®) temporarily reverses the effects of overdose from drugs made from opium or opioids, including:[3]

- heroin
- morphine
- oxycodone (OxyContin®)
- methadone
- fentanyl
- hydrocodone (Vicodin®)
- codeine
- hydromorphone
- buprenorphine

If you give naloxone to a person who has not taken an opioid medicine, it will not hurt them.[5] To learn about training on how to give naloxone, visit getnaloxonenow.org.

Centers for Disease Control and Prevention
National Center for Injury Prevention and Control

LEARN MORE: cdc.gov/opioids/naloxone

Fact Sheet: Family and Caregivers

Side effects of naloxone

Naloxone can (but does not always) cause withdrawal symptoms, unpleasant physical reactions, when an individual stops using a substance that they depend on. Withdrawal symptoms may be uncomfortable but are not life-threatening.[3]

Withdrawal symptoms may include:

- Fever
- Nausea
- Feeling restless or irritable
- Fast heart rate
- Sweating
- Vomiting
- Shaking

What to do if you think someone has overdosed on opioids[2]

Naloxone can (but does not always) cause withdrawal symptoms, unpleasant physical reactions, when an individual stops using a substance that they depend on. Withdrawal symptoms may be uncomfortable but are not life-threatening.[3]

1. Call 911 immediately.
2. Give naloxone as quickly as possible, if available. Do not wait for emergency workers to arrive before giving naloxone.
3. Try to keep the person awake and breathing.
4. Lay the person on their side to prevent choking.
5. Stay with the person until emergency workers arrive.
6. Naloxone is a temporary treatment. More than one dose might be needed under some circumstances, especially if an overdose event involves illicitly manufactured fentanyl and fentanyl-related substances.[4,5]

Remember, naloxone is a safe medicine. By carrying naloxone, you can save a life.[6] After naloxone is used or if it is expired, make sure to let your provider or pharmacist know so you can get more.

For more information and resources on naloxone, visit cdc.gov/opioids/naloxone, and for drug overdose prevention, visit cdc.gov/drugoverdose.

[1] https://www.drugabuse.gov/publications/drugfacts/naloxone
[2] https://www.cdc.gov/drugoverdose/pdf/patients/Preventing-an-Opioid-Overdose-Tip-Card-a.pdf
[3] https://www.drugabuse.gov/publications/drugfacts/naloxone
[4] https://emergency.cdc.gov/han/2020/han00438.asp
[5] https://www.fda.gov/drugs/drug-safety-and-availability/fda-recommends-health-care-professionals-discuss-naloxone-all-patients-when-prescribing-opioid-pain
[6] https://www.hhs.gov/surgeongeneral/priorities/opioids-and-addiction/naloxone-advisory/index.html

APPENDIX G

NALOXONE EDUCATION – WAITING ROOM

Figure 13. Naloxone Education – Waiting Room.