DEVELOPMENT AND IMPLEMENTATION OF AN EVIDENCE-BASED BUPRENORPHINE-NALOXONE MEDICATION ASSISTED TREATMENT PROGRAM IN A PRIMARY CARE SETTING

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The Supervisory Committee certifies that this ***disquisition*** complies with North Dakota State University's regulations and meets the accepted standards for the degree of

DOCTOR OF NURSING PRACTICE

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ABSTRACT

Opioid abuse is one of the most significant drug-related public health threats in the United States (U.S. Drug Enforcement Agency, 2016). Approximately 115 Americans die every day from an opioid overdose in the United States (Center for Disease Control and Prevention, 2017). Coupled with counseling, medication assisted treatment (MAT) can successfully treat opioid use disorder and sustain recovery by providing a more individualized approach to therapy (Substance Abuse and Mental Health Services Administration, 2016).

The purpose of this project was to assist a primary care clinic (PCC) in Fargo, ND with the development, implementation, and evaluation of a buprenorphine-naloxone MAT option for opioid use disorder (OUD) patients in collaboration with a chemical dependency residential center (CDRC). This was accomplished through the development of evidence-based guidelines, consent for treatment forms, and a provider order-set, and educating nurses at the primary care clinic on the use of the Clinical Opiate Withdrawal Scale. Additionally, nurse practitioner confidence in utilizing medication-assisted treatment was evaluated two months post-project implementation using a 5-point Likert Scale, while nurse practitioners also identified strengths and weaknesses of the project via free hand data entry.

The analysis at the conclusion of this project included the overall results of the pre and posts implementation Likert Scale surveys and qualitative questionnaires. Nurse Practitioner confidence in treating OUD patients, knowledge of community resources for addiction resources, understanding the pathophysiology of opioid addiction, and willingness to provide medication assisted treatment improved post-implementation. Through analysis of the qualitative questionnaire, nurse practitioners indicated positive feelings about the program and the working relationship within the PCC and with the CDRC. Lack of experience working with OUD

patients was indicated in nurse practitioner responses as a weakness. Results generalized within the confines of the PCC may indicate more experience working with OUD patients could lead to increased nurse practitioner confidence in treating the patient population.

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DEDICATION

This dissertation is dedicated to my family. To my caring wife, Sarah, and my wonderful son, Lucas. Your love, patience, support, and encouragement have meant more to me than you could ever imagine. To my parents, Gail and Jay, your wisdom, guidance, and love have been pillars during my educational career.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF APPENDIX TABLES

CHAPTER ONE. INTRODUCTION

Background

A report by the U.S. Drug Enforcement Agency referred to opioids (including prescription drugs, heroin, and fentanyl) as the most significant drug-related threats to the United States (US) (2016). In 2017, an estimated 11.4 million people aged 12 years or older misused opioids in the past year (Bose, Hedden, Lipari, & Park-Lee, 2018). According to the Center for Disease Control and Prevention (CDC) National Center for Health Statistics (NCHS) (2017), the rate of drug overdose deaths involving natural and semisynthetic opioids (oxycodone and hydrocodone), heroin, and synthetic opioids other than methadone (fentanyl, fentanyl analogs, and tramadol) have all increased dramatically since 1999 (Hedegaard, Warner, & Miniño). In fact, the number of opioid overdose deaths in 2016 was five times higher than in 1999, with approximately 115 Americans dying every day from an opioid overdose in the U.S. (CDC, 2017). Of the 42,000-total opioid-related deaths in 2016, a staggering 40% of the overdose fatalities involved a prescription opioid (CDC, 2017).

According to U.S. State Prescribing Rates, in 2016, North Dakota (ND) had one of the lowest retail opioid prescriptions dispensing rates in the U.S. at 47.8 per 100 persons, while, in comparison, Alabama and Arkansas' dispensing rate was 121.0 and 114.6 respectively per 100 persons (CDC, 2017). Although ND also had one of the fewest opioid related death rates in the country, the state was not immune to the increasing trend of opioid associated fatalities. In 2016, 54 opioid-related overdose deaths occurred in ND, which accounted for 70% of all drug-related overdose deaths. This was an increase from 34 deaths the year prior and from the 11 opioid related deaths in 2013 (Kaiser Family Foundation, 2018).

Significance

Providers faced the difficult task of treating pain while also addressing the abuse associated with years of narcotic over prescribing. As prescription opioids sold to pharmacies, hospitals, and doctors' offices nearly quadrupled from 1999 to 2010, the number of overdose related deaths from prescription painkillers also quadrupled (CDC, 2017). Such factors created a public health epidemic, which required a multifaceted approach to treating addiction and preventing opioid related deaths.

According to the Substance Abuse and Mental Health Services Administration (SAMSHA), medication assisted treatment (MAT) incorporates the use of medications to treat patients with substance abuse disorders. Coupled with counseling, MAT can successfully treat opioid use disorder (OUD) as well as sustain recovery by providing a more individualized approach to therapy (SAMSHA, 2016). "Treatment has shown to improve patient survival, increase retention in treatment, decrease illicit opiate use and other criminal activity among people with substance use disorders, increase patients' ability to gain and maintain employment, and improve birth outcomes among women who have substance use disorders and are pregnant" (SAMSHA, 2015, para. 10).

At the state and national levels, significant gaps between treatment need and capacity existed. MAT had been underutilized despite evidence that MAT improves treatment retention, reduces opioid use, and reduces risk behaviors that could lead to comorbidities such as HIV and hepatitis (Jones, Campopiano, Baldwin, & McCance-Katz, 2015). Slow adoption of evidence-based treatment options for opioid dependence may have been attributed to misapprehensions regarding the substitution of one opioid for another. Additionally, discrimination against MAT patients, lack of training for primary care providers, and negative opinions toward MAT in

communities and among health care professionals may all act as barriers to the adoption of MAT programs (SAMSHA, 2015).

Offering MAT may improve adherence to addiction treatment. Conversely, the efficacy of behavioral counseling in treating opioid dependent patients was not universally accepted. Some studies have failed to demonstrate improvement in completion or retention rates when combining MAT for opioid dependence with counseling services (Fiellin et al., 2013; Ling et al., 2013; Weiss et al., 2011) while others have (Moore et al., 2016). However, a lack of psychosocial support had been found to be a barrier for providers prescribing buprenorphine (Andrilla, Coulthard, & Larson, 2017; Hutchinson, et al., 2014). To improve provider confidence in prescribing buprenorphine for treatment of OUD, a primary care clinic utilized the counseling services of a chemical dependency residential center.

Problem Statement

Opioid addiction is an epidemic affecting every state in the nation. Although North Dakota's overdose deaths have been lower than the national average, the statistics remain alarming (Kaiser Family Foundation, 2018). Methadone had historically been used to treat opioid addiction in the U.S. but can only be prescribed in treatment programs certified by SAMHSA. However, the availability of and access to treatment centers have not met the increasing need for MAT services created by the prescription drug dependence epidemic (Jenkins & Ravert, 2013). Opportunities within the primary care setting exist to manage OUD, specifically with MAT, which have positive benefits across numerous values. Such values included lowering mortality risk, transmission of HIV and hepatitis through sharing of needles, contracting STIs through unsafe sexual contact, and other risk-taking behaviors (SAMSHA, 2015). However, primary care MAT for OUD haven't been utilized due to a variety of barriers

such as provider confidence in their ability to treat OUD patients, organizational support, and need for psychosocial counseling of patients (Hutchinson, et al., 2014).

Project Description

Project Purpose

The project purpose was to assist a clinic in Fargo, ND with the development, implementation, and evaluation of a MAT option for patients with OUD. The primary care clinic (PCC) nurse practitioners (NPs) began treating OUD patients using a MAT program. The program also worked in partnership with a chemical dependency residential center (CDRC) in Fargo, ND, which provided addiction counseling. Guidelines, consent for treatment forms, provider order-set and screening, examination, and other health related considerations were created to facilitate the transition to providing MAT. Nurse practitioner confidence in treating the OUD patient population and NP's opinions of the program's effectiveness were evaluated after receiving a buprenorphine-naloxone (BUP/NX) prescription waiver and again two months after implementation of the project.

Project Objectives

The project objectives were as follows:

1. Evidence-based guidelines, consent for treatment forms, and a provider order-set necessary for MAT program implementation are completed prior to program implementation. The BUP/NX consent and agreement forms are in Appendix B, C, and D; provider order-set is in Appendix G.
2. Prior to implementation, nurses at the PCC are knowledgeable about and successfully using Clinical Opiate Withdrawal scale (COWS). An example of the COWS is in Appendix A.

3. PCC nurse practitioners will feel confident in treating OUD using BUP/NX MAT.
4. At two months post-implementation, providers are able to identify program strengths and weaknesses.

Chapter One briefly introduced the background and significance of opiate use in the United States and provided a brief description of the dissertation project and objectives. The ensuing chapter will review the literature on the medication buprenorphine, providing BUP/NX MAT through primary care, and describe the theoretical framework for the project.

CHAPTER TWO. LITERATURE REVIEW AND THEORETICAL FRAMEWORK

A literature review on opioid addiction treatment practices using buprenorphine in the primary care setting revealed several recent articles. Multiple databases were searched, including Academic Search Premier (EBSCO), CINAHL, PubMed, and Medline. Key words included buprenorphine, naloxone, primary care, barriers, medication assisted treatment, opioid, addiction, and outcomes. Inclusion criteria included primary care, medication assisted treatment with buprenorphine or buprenorphine-naloxone, and opioid use disorder. Articles that included other medication assisted treatment treatments such as methadone and naltrexone were also included but only when compared with buprenorphine or buprenorphine-naloxone. Articles about treatments using buprenorphine or buprenorphine-naloxone and subjects who did not have opiate addiction were excluded.

Literature Review

The American Society of Addiction Medicine (ASAM) defined addiction as "a primary, chronic disease of brain reward, motivation, memory, and related circuitry. Dysfunction in these circuits leads to characteristic biological, psychological, social, and spiritual manifestations. This is reflected in an individual pathologically pursuing reward and/or relief by substance use and other behaviors" (2011, para. 1). The Diagnostic and Statistical Manual of Mental Disorders, 5th edition (DSM-5) criteria for diagnosis of OUD described two or more symptoms must be experienced within a 12-month period to define OUD with severity being determined by the number of symptoms experienced (American Psychiatric Association, 2018). Symptoms of OUD include:

- Using larger amounts of opioids or over a longer period than intended.
- There is a persistent desire or unsuccessful efforts to cut down or control opioid use.

- A great deal of time is spent in activities necessary to obtain the opioid, use the opioid, or recover from its effects.
- Craving or a strong desire to use opioids.
- Failure to fulfill major role obligations at work, school, or home due to recurrent opioid use.
- Continued use despite recurrent or persistent social or interpersonal problems caused or exacerbated by opioid use.
- Giving up or reducing social, occupational, or recreational activities due to opioid use.
- Recurrent opioid use in physically hazardous situations.
- Continued opioid use despite physical or psychological problems caused or exacerbated by its use.
- Tolerance (marked increase in amount; marked decrease in effect).
- Withdrawal syndrome as manifested by cessation of opioids or use of opioids (or a closely related substance) to relieve/avoid withdrawal symptoms.

The Institute of Medicine's (IOM) report *The Future of Nursing: Leading Change, Advancing Health* recommended removal of barriers in order to allow advanced practice registered nurses to practice to the full extent of their education in order to meet the needs of a changing health system (2011). Furthermore, NPs offer an opportunity to address gaps in patient access to high quality, patient-centered, and affordable health care, particularly in rural areas. A study by Ortiz et al. (2018) considered how select patient outcomes in rural health clinics differed between eight southern states that had restricted, reduced, or expanded scope of practice. The quality of patient outcomes was not reduced when Advanced Practice Registered Nurse (APRN) roles were expanded (Ortiz et al., 2018). The expansion of APRN autonomy may help

to relieve burden of physicians in terms of providing diagnoses, prescriptions, treatments, consultations, and other services.

Such consideration may be applicable to the NP providing MAT for OUD patients. In fact, the U.S. Department of Health and Human Services (HHS) identified the current misuse, abuse, and mortality associated with opiate abuse as a national crisis and identified five priorities for which to focus their efforts. Such priorities included better addiction prevention, treatment and recovery services, overdose reversing drugs, data collection, pain management, and research (2017). To improve access, $485 million in grants was offered to each state for evidence-based prevention and treatment programs (HHS, 2017). Such grants were distributed through SAMHSA and supplemented by additional grants provided to state and local communities (HHS, 2017). Grant funding, along with recent changes to prescriptive privileges for NPs and physician assistants (PAs), allowed an opportunity for additional MAT services.

The Drug Addiction Treatment Act of 2000 (DATA 2000) enabled qualifying physicians to obtain a waiver to practice MAT for OUD in primary care practice with buprenorphine (SAMHSA, 2016). However, until 2016, NPs and PAs were prohibited from prescribing and treating OUD with buprenorphine. On July 22, 2016, the Comprehensive Addiction and Recovery Act (CARA) was signed into law. Section 303 of the CARA expanded prescribing privileges to NPs and PAs for five years until October 1, 2021 (SAMHSA, 2018). Nurse Practitioners and PAs may apply for a waiver to prescribe buprenorphine, a partial opioid agonist used to treat opioid addiction, following 24 hours of training. Topics covered in the training sessions included opioid maintenance and detoxification; clinical use of FDA-approved drugs for MAT, patient assessment and treatment planning, psychosocial services, staff roles, and diversion control (American Society of Addiction Medicine, 2018). Once a waiver had been

received, the NP or PA may prescribe buprenorphine for up to 30 patients immediately. After one year or practice, a provider may apply for a waiver to allow for treatment of up to 100 patients (American Society of Addiction Medicine, 2018).

Despite the adoption of DATA 2000 and expansion to allow APRNs and PAs to prescribe buprenorphine, primary care opioid addiction therapy has been severely underutilized. Too few providers have a waiver to prescribe the medications that would allow patients with OUD to receive MAT. A greater number of primary care providers, outside of addiction specialists, are needed to provide MAT treatment for OUD (Jenkin & Ravert, 2013).

A treatment program contributes to the health of the Fargo community by decreasing the risk of contracting diseases such as HIV, hepatitis, and STIs though intravenous drug use and poor choices. According to the SAMHSA (2017), "people with substance use disorders are at greater risk of contracting or transmitting an HIV infection because the misuse of drugs and/or alcohol can impair judgment and contribute to poor decision making" (para. 2).

Sharing needles, drug paraphernalia, or unprotected sex with infected individuals increases the likelihood of contracting diseases like HIV and hepatitis B and C. One study by Zibbell et al. (2018) found the annual incidence rate of acute hepatitis C infection increased more than 2-fold (from 0.3 to 0.7 cases/100,000) from 2004 to 2014 with a significant correlation to the use of opioid injection. Efforts to increase the number of MAT programs may prevent the spread of HIV, hepatitis, and other transmittable infections by improving treatment retention rates and decreasing risk-taking behaviors (SAMHSA, 2015).

What is Buprenorphine?

According to SAMHSA (2016), "unlike methadone treatment, which must be performed in a highly structured clinic, buprenorphine was the first medication to treat opioid dependency

that was permitted to be prescribed or dispensed in physician offices, significantly increasing treatment access" (para. 3). The reason may be due to the unique properties of the medication itself. Buprenorphine is a partial opioid agonist, which means that there is less risk of euphoria, physical dependence, and potential for abuse or misuse. Buprenorphine has a "ceiling effect" which means that the agonist effects of the medication increases linearly with higher doses until reaching a plateau. Once reached, no further doses of buprenorphine will increase the agonist effect, thus lowering the risk of abuse or side effects compared to full opioid agonists (heroin or oxycodone) or methadone (The National Alliance of Advocates for Buprenorphine Treatment (NAABT), n.d.).

Buprenorphine offers a relatively mild withdrawal profile; however, it has high affinity for, but low intrinsic activity at, μ receptors (NAABT, n.d.). The μ receptors are targeted receptors for endogenous, natural, and synthetic opioids in the brain (Lawrence et al, 2018). Such an effect means that the receptor that binds endogenous opioids, (endorphins), and natural or synthetic opioids, (morphine or methadone), are displaced by buprenorphine. Buprenorphine will essentially *knock off* other opioids to occupy the receptor and block other opioids from attaching to it (NAABT, n.d.). As such, the use of buprenorphine while acutely using other opioids may cause acute withdrawal symptoms. However, due to a slow dissociation rate from the μ receptor, buprenorphine allows prolonged suppression of opioid withdrawal and such properties allow for buprenorphine to be dosed on a less frequent basis once maintenance has been established (Center for Substance Abuse Treatment, 2004).

Although the abuse potential decreases, epidemiological studies and human laboratory studies indicate that buprenorphine can be abused (Center for Substance Abuse Treatment, 2004). The combination of buprenorphine with naloxone (BUP/NX) helped to minimize abuse

potential. Naloxone, an opioid antagonist, helps to discourage intravenous abuse of buprenorphine. The addition of naloxone precipitates withdrawal in physically dependent patients if misused intravenously, however, naloxone's bioavailability is low if taken as directed (NAABT, n.d.).

The Center for Substance Abuse Treatment (CSAT) Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction, published in 2004, remains a relevant guideline. Certain medications and comorbidities may preclude patients as acceptable treatment candidates or may require additional monitoring. Seizure disorders, patients receiving antiviral human immunodeficiency virus (HIV) treatment, hepatitis, significant untreated psychiatric comorbidities, and pregnancy require careful monitoring and/or consideration for alternative treatment (Center for Substance Abuse Treatment, 2004). Concurrent use of sedatives such as alcohol, benzodiazepines, and hallucinogenic drugs may also interfere with treatment adherence (Kampman & Jarvis, 2015).

Buprenorphine, in combination with antiepileptic medications (e.g., phenytoin, carbamazepine, and valproic acid) may alter the metabolism of both medications; increasing risk for seizure. As such, therapeutic levels of seizure medications should be monitored (Center for Substance Abuse Treatment, 2004). Similarly, HIV treatment with antiviral medications that inhibit, induce, or are metabolized by the cytochrome P450 3A4 enzyme system, may alter metabolism of both buprenorphine and the antiviral agent (Center for Substance Abuse Treatment, 2004). However, HIV infected patients have been successfully treated with buprenorphine. A study conducted by Carrieri et al. (2000) found no significant short-term effect of buprenorphine on HIV viral load in highly active antiretroviral therapy treated patients. In a

more recent study, Altice et al. (2011) concluded, "among those retained on buprenorphine-naloxone, HIV treatment outcomes did not worsen and were sustained" (p. 6).

Contraindications include patients with hypersensitivity to buprenorphine or its metabolites and patients with severe liver impairment. In pregnant patients with opioid addiction, methadone or buprenorphine as a monotherapy are acceptable treatment options. However, the use of combination BUP/NX lacked sufficient evidence for use in pregnant women (Kampman & Jarvis, 2015).

How is Buprenorphine Administered?

BUP/NX treatment occurs in three phases and includes the induction, stabilization, and maintenance phase. During the induction phase, the patient would ideally have abstained from using opioids for 12 to 24 hours as initiation of BUP/NX while having other opioids in their system may cause acute withdrawal (SAMHSA, 2016). Ideally, patients should be in moderate withdrawal when administering the first dose. The use of a standardized, objective measurement tool, such as the Clinical Opioid Withdrawal Scale (COWS) reduces bias from patient subjective exaggeration of withdrawal symptoms to avoid discomfort (Clinical Tools, Inc., 2018). See Appendix A for an example of the COWS.

The COWS is an instrument used to evaluate eleven items that include clinical signs and symptoms of opioid withdrawal and to make inferences about a patient's severity of opioid dependence (Wesson & Ling, 2003). It is considered a valid measurement tool for acute opioid withdrawal (Altintoprak et al., 2015; Tompkins et al., 2009). Benefits of the COWS tool include rapid administration (<2 minutes), use in the inpatient and outpatient setting, and utilization of both subjective and objective findings to reduce patients feigning responses (Wesson & Ling, 2003). As buprenorphine may precipitate acute withdrawal if opioids are occupying the mu

receptors of the brain, it is important that the patient experience mild to moderate withdrawal symptoms (score of > 5 with >10 preferable) prior to induction (mdcalc.com, n.d.).

According to Kampman and Jarvis (2015), the induction of BUP/NX should start with a dose of 2/0.5–4/1 mg sublingual film and may be increased in increments of 2/0.5-4/1 mg depending on severity of withdrawal symptoms to a maximum first day dose of 8/2-12/3 mg. Although at home induction of buprenorphine outside of the clinic setting is possible, it was not considered best practice for new providers to do so (Kampman & Jarvis, 2015). Instead, the initial induction should take place while being monitored within the clinic for 1-2 hours, noting any hypersensitivity, withdrawal, or other adverse reactions (Clinical Tools, Inc., 2018).

On day two of the induction process, the provider may need to increase or decrease the dose of BUP/NX based on the patient's day one reaction. Patient withdrawal symptoms may prompt the provider to add 4/1 mg to the day one dose, with the option of titrating the dose by an additional 2/0.5 – 4/1 mg, as necessary. However, the day two dose should not exceed 16/4 mg. Day 3 and up without relief of cravings or experiencing withdrawal symptoms should be given an initial dose of 18/4.5 – 20/5 mg sublingually and be increased similarly to day two with a maximum dose not exceeding 32/8 mg (Clinical Tools, Inc., 2018 and Center for Substance Abuse Treatment, 2004). However, other literature recommends not exceeding 24/6 mg due to a lack of efficacy related to the ceiling effect of the medication (Kampman & Jarvis, 2015).

"The stabilization phase begins after a patient discontinued or greatly reduced their misuse of the problem drug, no longer has cravings, and experiences few, if any, side effects" (SAMHSA, 2016, para. 18). During the stabilization phase, each patient continues the determined dose following induction. According to Kampman and Jarvis (2015), weekly or at least bi-weekly office visits that include urine drug screens and pill counts, promote patient

compliance. Dosing of BUP/NX may also be adjusted by 2/0.5–4/1 mg weekly, with most patients stabilizing on daily doses of 16/4–24/6 mg, while some patients may require up to 32/8 mg daily (Center for Substance Abuse Treatment, 2004).

The maintenance phase is the last stage of the treatment process and may continue indefinitely. However, medication discontinuation, on a predetermined date, is an option if mutually agreed upon by patient and provider. Slowly tapering drug therapy can minimize withdrawal symptoms (Center for Substance Abuse Treatment, 2004). The tapering process may take several months to complete. To support relapse prevention, patients may remain in counseling during and after the discontinuation process (Kampman & Jarvis, 2015). Unfortunately, relapse rates remain high. According to Ling et al. (2009), approximately 88% of patients have positive urine drug tests three months post-taper. Nevertheless, relapse and opioid use do not result in patient dismissal from the BUP/NX treatment program. Rather, patient relapse triggers reevaluation of the BUP/NX dose, the frequency of office visits, and the regularity of behavioral counseling (Clinical Tools, Inc., 2018). Opioid addiction, not unlike other chronic diseases, may relapse, and consequently, treatment modification must follow.

How does Buprenorphine-Naloxone Efficacy Compare to Other Treatments?

Comparisons of long-term BUP/NX treatment outcomes with more traditional treatment options, such as methadone, lack enough evidence supporting superiority of one treatment option. The success of medication-assisted treatment largely depends on the patient's individual risk factors. Therefore, patient risk factors and personal preferences are of utmost importance in treatment choice. Srivastava, Kahan, and Nader (2017), found that methadone and BUP/NX were both considerably more effective than abstinence-based treatment. Methadone treatment resulted in higher program retention rates, while BUP/NX had a lower risk of overdose. As

such, methadone was preferred for patients at a greater risk of dropouts and patients displaying severe withdrawal symptoms and cravings even after reaching optimal BUP/NX doses. However, patients at greater risk for methadone toxicity, polysubstance abuse, as well as the elderly and patients with a prolonged QT interval should begin treatment with BUP/NX (Srivastava, Kahan, & Nader, 2017).

Hser et al. (2016) also compared mortality rates attributable to MAT programs in the United States between 2006 and 2009. In the study, patients received either buprenorphine or methadone for 24 weeks; follow-up interviews occurred in periodic intervals up to an average of 4.5 years after treatment. Seven hundred ninety-five participants completed the study (~ 74% follow-up rate). Hser et al. (2016) found no significant differences in mortality between the two groups (23 deaths/630 buprenorphine patients versus 26/450 methadone patients). Few differences were found between methadone and buprenorphine treatments and, when compared to no treatment, both were associated with less opioid use at follow-up (2016).

A more recent longitudinal study by Hickman et al. (2018) compared all-cause mortality and opioid drug-related poisoning mortality between methadone with buprenorphine in the United Kingdom. Patients on buprenorphine had lower rates of all-cause mortality and opioid drug-related poisonings at each treatment period. However, the treatment duration (mean and median) was much shorter than that of methadone (173 and 40 versus 363 and 111, respectively) (2018). The study speculated the short duration of treatment with buprenorphine and the higher mortality risk after treatment cessation may indicate that neither buprenorphine nor methadone are particularly effective in limiting drug-related poisonings (Hickman et al., 2018). However, as noted previously, the maintenance phase of buprenorphine treatment is not limited and may

continue indefinitely or until a patient feels, they are ready to wean off the medication (Center for Substance Abuse Treatment, 2004).

Patient preference regarding MAT for OUD is important to consider. Patients who received BUP/NX reported a more positive treatment experience compared to patients treated with methadone (Hill et al., 2015). Respondents described a feeling of being *clear-headed*, improvement in general well-being and concentration, less social stigma, reduced craving, decreased side effects, and easier withdrawal from BUP/NX vs. methadone (Hill et al., 2015). Patients' also described treatment in primary care settings as a more convenient and therapeutic environment for sobriety and relapse prevention while experiencing more respect, trust, and empathy from providers (Jenkinson and Ravert, 2013).

What are the Barriers to Buprenorphine MAT?

Several barriers limit the number of patients able to receive MAT with BUP/NX. In a study by Hutchinson et al. (2014), 120 physicians working in Washington State, received training and earned a waiver to prescribe buprenorphine. Nearly all 78 physicians who responded to interviews (and had not previously been prescribing buprenorphine or were not in their residencies) had a positive attitude toward MAT. However, only 22 of the physicians actively prescribed buprenorphine, with 95% (21/22) of the physicians practicing in a family medicine setting. Some of the barriers described by the physicians included a lack of institutional support, lack of office partners who also prescribed buprenorphine, lack of mental or psychosocial support for patients, time constraints, and a general lack of confidence in their ability to manage this population of patients (Hutchison et al, 2014).

Similar provider barriers were common among other studies. Indeed, DeFlavio, Rolin, Nordstrom, and Kazal Jr. (2015) found that barriers for rural physicians in New Hampshire and

Vermont included a lack of knowledge, time, space, or interest; mistrust of people with addiction or buprenorphine as a treatment; burdensome regulations and a difficult patient population. However, the majority (70%) of respondents felt a responsibility to treat opioid addiction among patients seen in the primary care setting (2015).

The results of a national study of rural physicians identified many of the same provider barriers as described above (DeFlavio, Rolin, Nordstrom, and Kazal Jr., 2015 and Hutchison et al, 2014). Interestingly, physicians who had never prescribed, but held a buprenorphine waiver, identified prescribing barriers with greater frequency compared to physicians who actively prescribed buprenorphine. Such barriers included time constraints, lack of patient need, resistance from practice partners, lack of specialty backup for complex problems, lack of confidence in their ability to manage OUD patients, concerns about DEA intrusions on their practice, and attraction of drug users to their practice (Andrilla, Coulthard, and Larson, 2017).

A study by Marino, Campbell, and Nunes (2016) also found that lack of knowledge, time constraints, access to ancillary support (mental health services), lack of other prescribers, lack of space, and lack of reimbursement were commonly cited barriers. Not only did the physicians consider treating addicted patients time consuming, the unique aspects of the care required proved difficult to incorporate in the primary care setting (2016).

Finally, according to Jones, Campopiano, Baldwin, and McCance-Katz (2015), "Consistently identified barriers included willingness to prescribe, low provider confidence in addressing addiction, limited access to addiction experts, lack of institutional or office support, lack of behavioral health services, and reimbursement concerns" (p. e55). Development of a clinic-based BUP/NX MAT program at the PCC may benefit from understanding common prescribing barriers.

Theoretical Framework: Social Ecological Model

The development of a BUP/NX MAT program in the primary care setting required a multifocal, multidisciplinary approach. The Social Ecological Model (SEM) is a theory-based framework for understanding the multilayered and collaborative effects of personal and environmental influences that determine behaviors (Glanz, 2016). The principles of the theory suggested that creating an environment conducive to change is important to making it easier to adopt healthy behaviors (Glanz, 2016). According to the United Nations Children's Fund (UNICEF), the SEM provided guidance for developing successful programs through social environments, identifying behavioral and organizational influences, and mediating health promotion within organizations. Included in the model were five levels of influence: individual, interpersonal, organizational, community, and policy, with effective approaches to public health prevention and maintenance incorporating all levels (2015).

1. **Individual**: Regards the patient, their knowledge, attitudes, behavior, gender, age, religious identity, racial/ethnic identity, sexual orientation, economic status, values, goals, expectations, literacy, stigmas, and other factors may all occupy the individual level. Providers' feelings and beliefs about treating OUD with MAT for OUD is an important consideration.
2. **Interpersonal**: At the interpersonal level, friends, family, and health care providers help overcome individual-level barriers by affecting social and cultural norms. The stigma of addiction and addiction treatment, may "contribute to social isolation, reduce help-seeking behaviors, and undermine long-term recovery" (Jones, Campopiano, Baldwin, & McCance-Katz, 2015, p. e58).

3. **Organizational**: Facilitates individual behavior change with organizational systems and policies, which can affect how well services are provided. Organizational support is essential for the success of the program because lack of institutional support was a frequently cited barrier to prescribing BUP/NX (Andrilla, Coulthard, & Larson, 2017; Hutchinson, et al., 2014; Jones, Campopiano, Baldwin, & McCance-Katz, 2015; Marino, Campbell, & Nunes, 2016).
4. **Community**: The community level involved cooperation and support between community institutions by providing and sharing communication, services, and resources. The community level included members of the community who share the concerns about a given public health topic. The level included law enforcement, healthcare institutions, city and state government, community groups and organizations such as the CDRC. To make an impact on the opioid epidemic, a multidisciplinary team with community support was necessary. An additional resource could include the Minnesota and ND prescription-monitoring program.
5. **Policy**: The policy level involves local, state, national, and global laws and policies, including those concerning the allocation of resources and services. For example, interpreting and implementing existing policy such as the expansion of prescriptive privileges to nurse practitioners and physician assistants through the DATA 2000 and CARA.

The use of the SEM presented the unique ability to address the multi-layered nature of opioid addition and to provide an individualized, yet structured approach to treatment. Instead of focusing solely on individual-level factors, the interplay between the different ecological levels may enhance treatment outcomes.

CHAPTER THREE. PROJECT SIGNIFICANCE, DESIGN, AND IMPLEMENTATION

Significance

The Fargo-Moorhead community lacked primary care opioid use disorder BUP/NX treatment options; however, there were a few private practice facilities and one methadone-dispensing clinic. Members from a primary care clinic (PCC) and chemical dependency residential center (CDRC) joined forces to provide a comprehensive treatment program for OUD.

Education was an integral component to the success of the program. A frequently cited barrier to prescribing buprenorphine was a lack of knowledge or ability to manage OUD or addicted patients (Hutchinson, et al., 2014). Several studies also indicated a lack of providers willing to prescribe MAT and organizational support were common barriers (Andrilla, Coulthard, & Larson, 2017; Hutchinson, et al., 2014; Jones, Campopiano, Baldwin, & McCance-Katz, 2015; Marino, Campbell, & Nunes, 2016). Nurse practitioners could obtain a waiver to prescribe buprenorphine for up to 30 patients (in year one) through SAMHSA after 24 hours of training (8 hours of which is specific to safe medication prescribing) (American Society of Addiction Medicine, 2018). Formal training was necessary to prepare NPs for the challenges of working with an opioid addicted patient population and unique treatment program.

Lack of mental health or specialty services was a frequently mentioned concern of providers (Andrilla, Coulthard, & Larson, 2017; Hutchinson, et al., 2014; Jones, Campopiano, Baldwin, & McCance-Katz, 2015; Marino, Campbell, & Nunes, 2016). Some studies indicated neutral benefit of behavioral therapy with buprenorphine retention rates (Fiellin et al, 2013; Ling et al., 2013; Weiss et al, 2011). However, provider comfort in utilizing mental health/addiction services to work with their patients' psychosocial concerns may aid in provider comfort to

continue prescribing BUP/NX. An interprofessional relationship with a behavior and licensed addiction service provider may benefit a primary care clinic when serving the OUD patient population.

An agreement was reached between the PCC and CDRC to develop a MAT program for OUD. After brainstorming with both facilities, the current project resulted. The following section will briefly describe the services of both the PCC and the CDRC. The creation of a BUP/NX MAT program will be subsequently discussed along with ways to manage potential barriers.

Primary Care Clinic and Chemical Dependency Residential Center

The PCC is a family-oriented health care clinic serving the Fargo-Moorhead area. The clinic provides a wide variety of services including medical, dental, pharmaceutical, nutrition, vision, physical therapy, laboratory, X-ray, homeless health, and behavioral health services. All patients are accepted regardless of ability to pay or insurance status; allowing a greater number of underserved patients eligible to receive MAT for opioid addiction.

The PCC offers patients federally qualified discount opportunities to assist patients in accessing affordable healthcare. The Access Plan is a sliding scale fee program that provides discounts on medical, dental, and prescription services based on household size and gross income. Patients are eligible if their income does not exceed 200% of the Federal Poverty Guidelines and patient financial eligibility is reviewed annually. An Access Plan application is completed each year and a PCC representative determines the patient/family eligibility status ([redacted] Access Plan, 2017).

The CDRC offers residential and nonresidential chemical dependency evaluation and treatment as well as mental health services in the Fargo-Moorhead area. The services offered by

CDRC are diverse and include, but are not limited to, mental health diagnostic assessments, individual and group therapy, DUI educational seminars, narcotics anonymous (NA) groups, relapse prevention groups, and more. CDRC does not offer MAT for opioid addiction, however, management agreed to collaborate with the PCC to provide the service to CDRC residents.

Congruence of the Project to the Organization's Strategic Goals

The PCC's mission was to provide affordable, comprehensive care for individuals, and to improve the health of the community. An organizational priority became enhancing access to opioid addiction treatment in the Fargo community and surrounding metropolitan area. The BUP/NX treatment program spoke to the mission and philosophy of the organization. The combination of services of PCC and the CDRC allowed each facility to contribute expertise in medical care and mental health services to provide comprehensive care for patients with OUD.

Project Design

The program incorporated the Plan, Do, Study, Act (PDSA) framework. PDSA is a quality improvement tool for implementing changes on a small scale, analyzing the results, and then acting on what was learned (HHS, 2013). *Plan* involved the project design, *Do* involved the project implementation, *Study* involved the project evaluation, and *Act* included recommendations for future study. The framework worked well with the mission of the PCC and objectives set forth which aimed to improve access to opioid addiction treatment.

The project was a new concept in the treatment of OUD in the Fargo-Moorhead community. Traditional methods to treat OUD, such as methadone clinics, as well as private treatment programs were available. However, no outpatient clinic in the city had developed a primary care model utilizing BUP/NX for outpatient OUD treatment. A program of this degree required a great deal of planning and several steps were necessary prior to project initiation.

Between March 2018 and May 2018, discussion of an evidence-based BUP/NX program was discussed between members of the PCC. Determination of needs was established and networking with additional community organizations including the CDRC began May 2018 through September 2018. The initial literature review of BUP/NX use in primary care was completed between June 2018 and October 2018. Networking with CDRC representatives and PCC representatives to discuss necessary forms and other project needs occurred September 2018. Providers at the PCC completed the mandatory 24-hour training to receive a buprenorphine prescription waiver through the Department of Vermont Health Access in Vermont between June 2018 and September 2018. IRB approval and project official start date occurred November 14, 2018.

Five PCC nurse practitioners received 24-hours of training to apply for a DATA waiver to treat up to 30 patients the first year and a new Drug Enforcement Agency (DEA) number. Development of treatment guidelines specific to PCC, consent forms, and a provider order-set were created. Nurses were trained in the use of the COWS scoring tool while recruitment of BUP/NX participants fell on the CDRC to refer eligible patients.

Patients received addiction counseling and case management services at the CDRC while NPs at the PCC provided medication assistance to promote retention of patients and to prevent relapse. The CDRC referred patients to the PCC who desired treatment with BUP/NX and met the ASAM criteria for OUD. A licensed addiction counselor provided the diagnosis to OUD prior to the patient's referral to the PCC. Appointment scheduling and coordination of transportation were the responsibility of CDRC employees. PCC NPs each assumed medical responsibility for no more than five new BUP/NX patients during the pilot program.

Upon diagnosis of OUD, the CDRC referred patients to the PCC who desired treatment with BUP/NX MAT and did not have severe concurrent addiction to alcohol, methamphetamine, or benzodiazepines, severe mental health disorders that would impair their ability to take BUP/NX, or patients under 18 years of age. Appointment scheduling and coordination of transportation was the responsibility of CDRC employees. Commonly, transportation was provided through the City of Fargo Metro Area Transit bus system, which was unable to bring the patients directly to the clinic but was able to bring them within a couple blocks of the clinic. Addiction specialists at the CDRC provided their recommendation for referral to the PCC; scheduling coordinators at the PCC scheduled patients to establish care with a primary care provider trained in prescribing MAT with BUP/NX. Nurses roomed the patients and provided the treatment agreement form as well as the consent for treatment with BUP/NX. Next, the NP assessed the patient, reviewed the consent forms, and explained the process of induction. A COWS baseline score was gathered. If additional laboratory tests were indicated, the NP placed the order by utilizing the new patient evaluation order-set in Centricity (the electronic medical record utilized at the PCC). Inductions took place in the clinic. PCC NPs each assumed medical responsibility for no more than five new BUP/NX patients during the pilot program.

The objective was to deliver high quality, focused care to a larger number of patients participating in the MAT program. Limiting treatment time to one day per week was considered too large of an obstacle during the induction phase, which requires frequent visits and close monitoring for adverse reactions and effective dosing (Clinical Tools, Inc., 2018). Through discussions with the project team, the practical solution, at least during induction, was to incorporate MAT into everyday practice.

Consent for treatment, provider order-set, and treatment guidelines streamlined the evaluation and treatment process. Treatment guidelines consisted of, but were not limited to, qualifications for treatment, utilizing the COWS for opioid withdrawal scoring, initial BUP/NX dosing, and prescribing of BUP/NX once the induction phase had ended. Guidelines were derived from the Center for Substance Abuse Treatment clinical guidelines for the use of buprenorphine in the treatment of opioid addiction (2004) and Vermont buprenorphine clinical practice guidelines (2015). Exclusions for treatment included severe addiction to additional substances such as methamphetamine, alcohol, or benzodiazepines, severe mental health disorders or cognitive impairment, or patients under 18 years of age. An example of the buprenorphine/naloxone consent and agreement form is in Appendix B. Provider order-set included orders for referrals to the CDRC for continuation for counseling, urine drug screen collected either at the PCC or CDRC, comprehensive metabolic panel, hepatitis C Ab with reflex to hepatitis C PCR, hepatitis B surface antigen, hepatitis B surface antibody, HIV 1 Ag HIV ½ Ab with reflex to confirmation, hepatic panel, and urine HCG. Provider order-set was imported into the Centricity electronic medical record system. The project start date was November 14, 2018.

Financial reimbursement for services rendered, dispensing of buprenorphine through the PCC pharmacy, and assistance in enrolling patients in an Action Plan were determined prior to seeing patients but were not the responsibility of the project. Other details including number of patients treated by each provider, observation space, and roles of supporting staff such as registration personnel and nurses were defined by their respective organizations.

Financial reimbursement was complicated and may be multifactorial. The cost of BUP/NX medication was covered by the 340B Drug Pricing Program, which offers discounted

prices on medications as part of a Medicaid rebate program (340bhealth.org, 2018). The patient cost of BUP/NX was no greater than the clinic's purchase price. Patients who were on the Action Plan or who had insurance but still fell below the poverty level could use the 340B discount program. However, the financial implications were complex and beyond the scope of the project.

Stakeholders

Stakeholders in the project included representatives from the CDRC such as counselors, case managers, the clinical director, and the CEO. Shareholders from the PCC included the medical director, nurse practitioners, nurses, appointment schedulers, pharmacists, and financial enrollment staff.

Project Implementation

The implementation of the project constituted the "Do" phase of the PDSA. Official project start date followed approval by the Institutional Review Board (IRB) of North Dakota State University (NDSU) on November 14, 2018. Five NPs completed the required 24-hours of training to receive a buprenorphine prescriptive waiver prior to the project start date. Additional training in utilizing the COWS was completed by nurses at the PCC during a brief, 10-minute in-service discussion on February 4, 2019. The presentation took place during the nurses' monthly meeting and consisted of a brief overview of COWS scoring, the purpose of the scale, and other subjective and objective aspects to consider while assessing opiate withdrawal. An example of the COWS was distributed to the attendants in order to follow along with a PowerPoint presentation. Presentation of the COWS tool is found in Appendix H.

BUP/NX MAT guidelines, consent for treatment, and a provider order-set were utilized on November 14, 2018 to navigate the evaluation and treatment process. An example of the

BUP/NX consent and agreement form is in Appendix B. The consent for treatment forms and provider order-set were distributed on August 22, 2019 to the medical director and NPs who had completed the required BUP/NX training. Additionally, the clinical service manager and a nurse at the PCC received the documents who had completed independent research by touring the CDRC and methadone clinic in Fargo, ND. They edited the consent forms and order-set to better reflect the needs of the PCC, which were approved on September 24, 2019 by the PCC stakeholders. Due to the timeline needs of the PCC, the forms were completed prior to the project start date. However, the initial confidence survey was distributed on November 16, 2018 to NPs at three clinic locations in Fargo, ND and West Fargo, ND. Post-implementation confidence surveys were distributed on January 28, 2019 during a MAT provider meeting at the PCC. Additionally, qualitative, open-ended questionnaires were dispersed at the same time as the post-implementation confidence surveys.

Institutional Review Board Approval

No patient contact was required to fulfill the objectives of the project. The project did not involve interviewing patients and no patients are identified in the evaluation. Additionally, at no time were provider's personal information collected or accessed. This practice improvement project was considered exempt by the NDSU IRB in accordance with federal regulations on November 14, 2018. The exemption letter is in Appendix I.

CHAPTER FOUR. EVALUATION

The "Study" component of the PDSA comprised the evaluation of the project. The plan for project evaluation utilized initial and post-implementation surveys to evaluate NP confidence in providing MAT as well as a qualitative questionnaire to evaluate strengths and weaknesses of the program. Likert scale survey scores averaged, and questionnaire responses coalesced by the author.

Objective 1 Evaluation

Objective 1: Evidence-based guidelines, consent for treatment forms, and a provider order-set necessary for MAT program implementation are completed prior to program implementation. Guidelines, consent forms, and provider order-set developed using recommendations from the Department of Vermont Health Access Managed Care Entity's *Vermont Buprenorphine Clinical Practice Guidelines*, Center for Substance Abuse Treatment *Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction Treatment Improvement Protocol (TIP) Series 40*, and American Society of Addiction Medicine *National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use*. Objective 1 evaluation consisted of review and approval of the treatment guidelines, consent forms, and provider order-set by representatives of the PCC prior to implementation.

The consent for treatment forms and provider order-set were distributed on August 22, 2019 to the medical director, NPs, clinical service manager, and a nurse at the PCC. The clinic service manager and a nurse revised the forms to fit the needs of the PCC. The PCC stakeholders approved the two consent for treatment forms and the provider order-set on

September 24, 2019. Paper copies of the consent forms were kept at the PCC. Once the patient signed the document, the consent forms were placed in a patient's medical file.

Objective 2 Evaluation

Objective 2: Prior to implementation, nurses at the PCC are knowledgeable about and successfully using COWS. Use of the COWS tool presented to nurses at the PCC during their monthly meeting. Evaluation of objective 2 consisted of immediate verbal feedback collected following the presentation in an open forum construct.

Objective 3 Evaluation

Objective 3: PCC nurse practitioners will feel confident in treating OUD using BUP/NX MAT. Evaluation of NP confidence consisted of provider confidence surveys administered at the start of project implementation and two months post-implementation. A 5-point Likert scale reflecting the response categories of strongly agree, agree, undecided, disagree, strongly disagree was used. The survey consisted of 15 statements created to evaluate the various determinants that affect provider confidence in MAT. Statements also evaluated common barriers associated with providing MAT for OUD. The provider confidence surveys were distributed along with a plain manila envelope. The NPs returned the surveys to the manila envelope and the co-investigator collected the envelopes. The NPs were asked not to sign their names to protect anonymity. An example of the survey is in Appendix C. The statements within the survey were original and did not come from a previously utilized survey.

Surveys and questionnaires were stored at the PCC after completion and picked up within 24-hours by the investigator in their sealed manila envelopes. Once collected and the data reviewed, the unused forms were again sealed in a manila envelope and placed in a locked area

for secure storage within the investigators home. No other person had access to the completed forms aside from the investigator.

Objective 4 Evaluation

Objective 4: At 2 months post-implementation, providers are able to identify program strengths and weaknesses. Evaluation of objective 4 was via a questionnaire and confidence survey. As previously, NPs received the questionnaire and survey in individual manila envelopes and the coinvestigator collected the envelopes with the completed documents. There were no identifying marks on the envelope or the completed forms for respondent anonymity. The questionnaire consisted of nine open-ended questions designed to elucidate the perceived strengths and weaknesses of the project. An example of the questionnaire is in Appendix F. Like the confidence survey, the questionnaire did not originate from a previously utilized questionnaire.

CHAPTER FIVE. RESULTS

Demographics

The sample size consisted of five NPs who completed the initial survey and four NPs that completed the two-month post-implementation survey. All five NPs were female. Professional experience as a NP ranged between 3 and 11 years. No additional demographic information was collected.

Objective 1 Results: Project Forms and Provider Order-Set

Objective 1: BUP/NX guidelines, consent for treatment form, treatment agreement form, and provider order-set were finalized prior to program implementation. The PCC administration, NPs, clinical service manager, and nurses reviewed the forms August 22, 2018. The clinical service manager and PCC nurse amended the documents September 24, 2018 to better reflect the needs of the clinic. The NPs used the guidelines, consent form and treatment agreement form, and the provider order-set during the MAT project starting November 16, 2018. An example of the consent form and treatment agreement is in Appendix B, Appendix C, and Appendix D. The provider order-set is in Appendix H.

Objective 2 Results: COWS Tool Presentation

Objective 2: Prior to implementation, nurses at the PCC are knowledgeable about and successfully using COWS. The objective was not met. The PCC nurses were not using the COWS tool prior to project implementation on November 14, 2018. The COWS presentation occurred on February 4, 2019 at the PCC in Fargo at 12:00 pm. The presentation lasted approximately 10 minutes. Fourteen nurses attended the presentation. The nurses provided verbal feedback via an open forum, question-answer type format following the presentation. Prior to the presentation, three nurses were familiar with the COWS, while the remaining eleven

were introduced to the content for the first time at the presentation. The nurses expressed an interest in using COWS, however, they were concerned about using COWS in the clinical setting without additional training.

Objective 3 Results: Provider Confidence Surveys

Nurse practitioner confidence was measured pre and post project implementation by a 5-point Likert scale survey. The Likert scale responses consisted of strongly agree (5), agree (4), undecided (3), disagree (2), and strongly disagree (1). Results averaged and are in Table 1. Baseline confidence survey N=5. Post-implementation confidence survey N=4. One statement was not answered in the post-implementation confidence survey. The response rate was 100% at baseline and 80% post-implementation.

Table 1

Provider Confidence Survey

Statements	Baseline N=5	Post N=4	Diff
1. I view opioid addiction as a chronic disease.	4.2	4.3	0.1
2. I can identify resources in the community to aid in addiction therapy.	4.0	4.5	0.5
3. I can identify specialty services for complex comorbidities.	4.0	4.3	0.3
4. I feel knowledgeable regarding the pathophysiology of opioid abuse.	3.8	4.5	0.7
5. I am willing to provide medication assisted treatment (MAT) for opioid use disorder (OUD).	4.6	4.8	0.2
6. I am confident in my ability to identify opioid abuse among my patients.	3.8	4.3	0.5
7. I am confident in my ability to manage patients with MAT for opioid abuse.	3.4	3.8	0.4
8. The organization that I work for helps support my efforts to treat OUD.	4.8	4.8	0.0
9. I can identify fellow providers who provide MAT with buprenorphine/naloxone for OUD.	4.2	4.8	0.6
10. I feel that there is resistance from my associates or place of work to continue/start MAT for opioid addiction.	1.2	1.8	0.6
11. I am hesitant to prescribe buprenorphine/naloxone due to prescription misuse or diversion.	2.8	2.5	-0.3
12. I am hesitant to prescribe buprenorphine/naloxone due to concerns about cost reimbursement.	1.6	1.5	-0.1
13. I believe that I have enough time during office visits to address my patient's addiction treatment.	2.4	2.8	0.4
14. I am comfortable talking about opioid abuse/addiction with my patients.	4.4	4.5	0.1
15. I would feel more confident in providing MAT for OUD if my patient is also receiving addiction counseling.	4.8	4.8	0.0

The statements on the provider surveys may be organized into four themes, which include confidence or lack of confidence, knowledge, willingness, and perception.

Theme 1: Confidence

Statements 6, 7, 14, and 15 are measurements of provider confidence while statements 11 and 12 relate to the provider hesitance or lack of confidence. Nurse practitioners indicated feeling considerably more confident identifying opioid abuse and in managing patients treated with MAT two months post-implementation. Nurse practitioner confidence in discussing abuse and addiction with patients slightly increased. The purpose of statements 11 and 12 was to inquire about provider hesitancy in prescribing MAT due to fear of patient misuse, diversion, or because of reimbursement concerns. Statement 11 and 12 responses decreased two months post-implementation, which would suggest an increase in provider confidence.

Theme 2: Knowledge

Statements 2, 3, 4, and 9 pertain to knowledge about opioid addiction and community resources. At two months post-implementation, NPs felt more knowledgeable about community addiction resources, other MAT providers, as well as specialty care for patients with comorbid illnesses. The largest increase in mean scores was in NP perceived knowledge about the pathophysiology of opioid addiction. The baseline mean of 3.8 falls in to the *undecided* to agree range, while the post-implementation mean of 4.5 was in the *agree* to *strongly agree* range.

Theme 3: Willingness

Statement 5 related to NPs willingness to provide MAT to OUD patients. Nurse Practitioners were just slightly more willing to provide MAT to OUD patients when surveyed post implementation. Baseline and post implementation scores were both in the *strongly agree* range (4.6, 4.8 respectively).

Theme 4: Perception

The four statements pertaining to provider perception were 1, 8, 10, and 13. Nurse Practitioners' perceived slightly less resistance from their associates about the MAT program. Furthermore, NPs *strongly agreed* that the PCC supported the MAT program, and the perception of organizational support did not change over the two months. The NPs perception of having enough time with the patient increased from baseline. Finally, the NPs believed that opioid addiction is a chronic disease, and there was only a minute increase in that belief.

Objective 4 Results: Qualitative Provider Questionnaire

The questionnaire was administered with the NP confidence surveys at the January 28, 2019 provider meeting, two months after program implementation. The qualitative questionnaire consisted of nine open-ended, short answer questions. Four NPs completed the questionnaire (response rate of 80%). Responses were randomized to decrease the possibility of identifying the respondent. Responses are in Table 2.

Table 2

Provider Interview Questions and Responses

Qualitative Interview Question	Provider Responses
What do you perceive as the strengths of the program?	Access to medical care by accepting patients without health insurance. Utilizing the Action Plan sliding scale fee to assist with patient's ability to pay. Treatment that allows more normalized routine such as work, family, and other responsibilities. Patient comfort receiving treatment in an office setting. Support from providers, clinic staff and addiction counselors at the CDRC.
What are the weaknesses of the program?	Lack of addiction counselor within the PCC. Inexperience with treating OUD patients. Lack of rapid, inhouse drug testing and nursing staff to support expanded MAT program. Only taking referrals from one facility (CDRC).
What are your opinions about the referral process and relationship with CDRC employees?	Knowledgeable and good communication. Good working relationship. Having a counselor on site may limit miscommunications.
What have been the biggest barriers for providers and the clinic in first three months of the program?	Proper dosing Assessing appropriateness for outpatient treatment Getting patient set up for outpatient treatment Informing the community about MAT service Not enough experience due to low patient volume
Do feel the evaluation process is comprehensive and meets the needs of providers, the clinic, and the patients? Explain your answer.	CDRC does initial evaluation prior to referral which can lead to some miscommunication and discrepancies. Both providers and patients seem satisfied with the evaluation and treatment process. CDRC provides some formal education.
What is your current patient load and what do you believe is an acceptable patient load going forward?	Between 0-5 patients Acceptable patient loads vary, but providers managing a greater number of OUD patients list a higher number of acceptable patients. Some providers are not able to give a definitive number, while others feel between 5 and 20 is acceptable.
What factors have promoted patient retention in the program?	Availability and access to other services Supportive environment Commitment to recovery and following contract/guidelines.
Have you found the program forms or evaluation tools lack clarity? If so, how?	Forms are acceptable and do not lack clarity. However, forms are long, and patients may not read them carefully or understanding them, especially if they are going through withdrawal.
What recommendations for improvement would you like to see made to the program?	In-house counselor Case manager to follow-up with patient compliance Better understanding of which patients are outpatient appropriate and which need more complex care. More general in-house support services.

CHAPTER SIX. DISCUSSION AND RECOMMENDATIONS

Interpretation

The purpose of the project included development of an evidence-based BUP/NX MAT program and evaluation of NP confidence in providing MAT for OUD patients. The NPs responses on the two questionnaires were generally positive two months after project implementation. Overall, the NPs felt more confident, knowledgeable, and supported by clinic administration and staff in treating patients with an opioid addiction. Additionally, NPs were as willing to participate in MAT at two months post-implementation as they were at baseline.

Objective One: Project Forms and Provider Order-Set

The first objective was met. An evidence-based treatment guideline, provider order-set and patient consent for treatment form were developed and subsequently reviewed on August 22, 2018 and approved on September 24, 2018. The clinical service manager and nursing staff customized the forms for PCC, with only minor revisions of the original forms. Forms were available for use at the PCC/CDRC MAT for the OUD program on November 16, 2018. See Appendixes for approved documents.

The PCC NPs felt that the forms were very thorough, but time-consuming. To maximize NP/patient face-to-face time, the staff discussed having the patient complete the consent forms prior to seeing the NP. Staff also expressed concern about the patients' understanding of the consent form while experiencing opioid withdrawal symptoms in the induction phase of treatment. Forms should be reviewed and updated annually and as the need arises. The date of each revision should be added to the form. Perhaps, the forms, guidelines, and provider order set could be shared as a blueprint for the implementation of a BUP/NX MAT program at other clinics.

Objective Two: COWS Tool Presentation

Objective 2 was not met; the nursing education on the COWS assessment tool (Appendix A) did not occur prior to project implementation in November, rather, the educational presentation was on February 4, 2019. Because the nurses had not received the training, the tool was not used consistently during the first several months of the program. Due to the short allotment of time scheduled for COWS education (10 minutes), an in-depth discussion on each assessment category of the tool was not possible. Nurses provided feedback in an open forum question-answer format post-presentation. The feedback from nurses was generally positive. Ideally, more time should have been allocated for the education. I would recommend a minimum of 30 minutes to allow time for nurses to practice, or role-play with the COWS tool. PCC nurses are familiar with a variety of assessment tools. It would not be difficult to envision nurses using the COWS during OUD patient inductions. Nurses expressed interest in utilizing the COWS but also expressed concern about using COWS without additional training. Additional in-service training would be beneficial for the PCC nurses to familiarize themselves with the COWS. The provider qualitative questionnaire (objective 4) reaffirmed the need for knowledgeable staff to support the MAT program. Nurses' use of the COWS to assess for opioid withdrawal symptoms may improve quality of care by providing an evidence based standardized assessment of the patient.

Objective Three: Provider Confidence Surveys

Objective three was created to evaluate NP confidence at project initiation and two months post-implementation. The survey tool can be found in Appendix D. Five NPs completed the initial survey while four NPs completed the two-month post-implementation survey. One NP left one statement unanswered in the post-implementation survey.

Theme 1: Confidence

Statements 6, 7, 14, and 15 are measurements of NP confidence while statements 11 and 12 relate to the NP hesitance or lack of confidence. Nurse Practitioner confidence improved or remained the same at the two-month mark. Statements 11 and 12 inquired about provider hesitancy in prescribing MAT due to fear of patient misuse, diversion, or because of reimbursement concerns.

Statement 11 and 12 responses decreased two months post-implementation. Responses may suggest an increase in NP confidence managing OUD patients. The decreased risk of overdose with BUP/NX and coordination with the CDRC for drug testing, close follow-up, and counseling may have been positive influences in provider responses. Cost reimbursement does not appear to be a frequent concern, which may be due to the medication coverage through the 340B Drug Pricing Program and patient enrollment in the PCC Action Plan.

Statement 6 and 14 responses may have been due to conversing with patients regarding addiction experiences, NP prescriptive waiver training, application in practice, and use of the COWS tool. Nurse Practitioner confidence in managing patients with MAT for OUD (Statement 7) improved post-implementation but was still categorized as undecided. Some NPs lack of opportunity to manage OUD patients with MAT during the project may have influenced the responses.

Statement 15 responses did not change as NPs strongly agree that they would feel more comfortable treating OUD if patients were also receiving addiction counseling. Nurse Practitioners may have felt encouraged by the support of another organization to address the mental health aspect of addiction and be more willing to become MAT prescribers.

Theme 2: Knowledge

Statements 2, 3, 4, and 9 pertain to knowledge about opioid addiction and community resources. At two months post-implementation, NPs felt more knowledgeable about community addiction resources, other MAT providers, as well as specialty care for patients with comorbid illnesses.

The largest increase in mean scores was in NP perceived knowledge about the pathophysiology of opioid addiction (Statement 4). The baseline mean of 3.8 falls in to the *undecided* to *agree* range, while the post-implementation mean of 4.5 was in the *agree* to *strongly agree* range. Education and training to acquire a buprenorphine prescriptive waiver, along with application of training in practice, may have influenced NP responses.

Nurse Practitioners more strongly agreed post-implementation that they could identify community resources to aid in addiction therapy (Statement 2). The response may have been due to working with the CDRC. Nurse Practitioners may consider their partnership with the CDRC, which provides addiction counseling, as one of the new community resources. Responses to Statement 3 also improved two months post-implementation, which may have been due to NPs attributing specialty services with addiction counseling, familiarity with the referral process, and managing OUD patients. Additionally, NPs more strongly agreed they could identify fellow providers who prescribed BUP/NX to treat OUD (Statement 9). Each NP in the project had completed the required 24-hour training to receive a buprenorphine prescriptive waiver. Providers also attended mandatory meetings help by the PCC each month, during which time the topic of BUP/NX MAT was discussed. Due to proximity and familiarity, providers may not have found it difficult to identify additional MAT prescribers.

Theme 3: Willingness

Statement 5 related to NPs willingness to provide MAT to OUD patients. Nurse Practitioners were just slightly more willing to provide MAT to OUD patients when surveyed post implementation. Baseline and post implementation scores were both in the *strongly agree* range (4.6, 4.8 respectively).

Theme 4: Perception

The four statements pertaining to patient perception were 1, 8, 10, and 13. Nurse Practitioners perceived slightly less resistance from their associates about the MAT program. Furthermore, NPs *strongly agreed* that the PCC supported the MAT program and the perception of organizational support did not change over the two months. The NPs' perception of having enough time with the patient increased from baseline. Finally, the NPs believed that opioid addiction is a chronic disease, and there was only a minute increase in that belief.

Statement 1 showed no major deviation from baseline. Nurse Practitioners agreed that opioid addiction is a chronic disease at baseline and post implementation. Nurse Practitioners may have agreed with the statement due to a different understanding of managing addiction. Instead of considering opioid addiction a transient disease, NPs may have considered a need for chronic disease management.

Statement 8 showed no change from baseline. Nurse Practitioners strongly agreed their organization supported their effort to treat OUD. Organizational support was an important factor for NPs to feel that their work was valued and validated. Lack of organization support was a frequently cited barrier to prescribing MAT for OUD (Jones, Campopiano, Baldwin, & McCance-Katz, 2015). Multiple stakeholders with diverse responsibilities were affiliated with the project, indicating strong organizational support.

Nurse Practitioners indicated that they experienced more resistance from associates or place of work to continue/start MAT for opioid addiction (Statement 10). However, the post-implementation response remained in the *strongly disagree* to *disagree* category on the Likert Scale. The result may have been influenced by one fewer NP responding to the statement, but NPs seem to have perceived support from their associates to continue/start MAT.

Lastly, an improvement was seen in the NPs' perception of having enough time to address addiction treatment needs (Statement 13). However, the mean response was still in the *disagree* range. Appointment times varied from 20 to 40-minutes. The treatment consent forms were lengthy and took the patient a large portion of the office visit to complete. A shorter office visit meant the NP had less time for a thorough review of the patient's medical, surgical, and social history, including past and present illicit drug use. Often, the time for the NP to discuss treatment, provide education, and plan follow-up was insufficient.

Impression

Responses to the statements indicate an improved confidence in finding community resources for addiction, pathophysiology of opioid abuse, identifying opioid abuse among patients, and identifying additional MAT providers. Each listed area was an often-cited barrier to providing MAT, which may have indicated NPs' confidence in utilizing MAT for OUD improved following project implementation.

Objective Four: Qualitative Provider Questionnaire

The purpose of the questionnaire was to gather NP feedback about the BUP/NX MAT program. Nurse Practitioner responses were reported in random order and displayed in Table 2.

The NPs consider providing a service to patients in the community a program strength as the PCC treats patients regardless of their insurance or ability to pay. Less disruption of patients'

lives during treatment and the support and collaboration with other providers were also considered a strength. Lastly, support from providers, clinic staff, and the CDRC, which was considered a strength of the program, was notable since organizational support and additional prescribing providers are factors influencing willingness to prescribe MAT (Andrilla, Coulthard, & Larson, 2017).

When asked, "What are the weaknesses of the program?" the responses centered on the need for additional services at the clinic and the barriers for program growth when affiliated with just one facility (CDRC). The specific weaknesses listed included the lack of onsite counselors, delays in drug test results, and NP inexperience. The PCC and CDRC do not share the same electronic medical record (EMR) system, which impeded retrieving rapid results from drug testing. The testing policy stated that if a positive test result happened, the sample must be sent to another facility for confirmation because false positive results could occur. The PCC and CDRC may agree to utilize the same EMR or the CDRC may fax lab results to the PCC prior to patient visits. The PCC and CDRC both offer options for urine drug testing, so communication between providers at the PCC and staff at the CDRC may provide the necessary collaboration to establish the most efficient method of testing.

Two NPs managed the maximum allotment of OUD patients, while other NPs may not have managed a patient in the first 2 months of the program. Additionally, there were patients that left the program. Nurse Practitioners disagreed about an acceptable patient load. The NPs who treated the maximum number of OUD patients felt they could treat a larger number of patients, while the NPs who treated few or no OUD patients suggested the desire for a lower patient load. Such findings may have indicated more experience working with OUD patients could lead to more NP comfort in treating the patient population. Adjusting the exclusion

criteria for MAT to include patients with comorbid addictions, such as methamphetamine, may increase the number of available OUD patients.

Nurse Practitioners also expressed a need for in-house counselors and case-managers with whom to collaborate. The availability of addiction counselors within the PCC may assist with communication and ease of consult when treating complicated OUD patients. However, such a request was outside the scope of this project, as it would require the PCC to expand payroll and create a position for hire.

Although some NPs felt communication gaps between the CDRC and PCC existed, NPs also felt supported by fellow clinicians, staff members, and CDRC staff. Since lack of institutional support was an often-cited barrier to prescribing MAT for OUD, such a sentiment was a positive finding (Hutchison et al, 2014). The length and the understandability of the consent for treatment forms were concerning (Question 8). During the initial evaluation, staff felt patients did not read or understand the consent forms in its entirety due to the length and withdrawal experience.

Limitations

Generalizability of the data from the surveys outside of the PCC was limited due to the small provider sample size. However, the survey results may be generalized to the NPs within the confines of the PCC. The limited number of participants completing the survey might also make NPs cautious when answering the qualitative questions for concern of being recognized.

Under the buprenorphine prescriptive waiver, the NP can see up to 30 patients the first year and then apply for a waiver to treat up to 100 patients the ensuing year (American Society of Addiction Medicine, 2018). During the pilot program, no NP managed more than five OUD patients at a given time. As such, the opportunity for induction and follow-up care was limited.

Team members agreed that each NP could treat a maximum of five OUD at a given time during the program. Some NPs did not obtain the maximum patient volume. Lack of opportunity to treat OUD patients may have negatively affected NP confidence in their ability to provide MAT to this patient population.

Further limitations of the pilot program involved the length of time between project start date and evaluation of NP confidence and distribution of questionnaires. An interval of six months would allow an opportunity for NPs to manage a greater number of OUD patients. Surveys collected at longer intervals would also track progression of responses. With a larger sample of providers, researchers could have looked for a correlation between the effect of provider experience and provider confidence prescribing MAT. Lastly, inclusion of patients to gauge their impression of the project may have assisted in identifying strengths and weaknesses from a different perspective. However, the purpose of the project was to assist in the creation of a pilot program to use MAT for OUD in the primary care setting and not specifically improving confidence or identifying NPs' opinions of the project. To this end, the project was successful.

Recommendations

Recommendations for future studies constitute the "Act" section of the PDSA. Based on the data collected, including confidence surveys and interview questions, the project met the intended objectives. My recommendations are to:

- Encourage NPs at the PCC to continue treating OUD patients with BUP/NX.
- Encourage fellow providers, who did not take part in the pilot program, to consider the training to obtain a buprenorphine prescription waiver.

- Allow primary care providers, such as NPs, to make the diagnosis of OUD based on the DSM-V criteria instead of professionals at the CDRC solely making the diagnosis.
- Include the registered nursing staff in conducting COWS scoring. Although the provider may collect a baseline assessment of opiate withdrawal, nurses can use the tool for subsequent evaluations during the induction period to maximize efficiency.
- Discuss organizational roles. Understanding roles would be important for other clinics who may be considering adopting a similar model. The PCC and CDRC mutually benefitted from the alliance. Each of the organizations lacked at least one element of care that the other could offer. The patients benefited by the organizations' comprehensive and holistic treatment approach.
- Maximize visit appointment time by having patients read the consent for treatment forms prior to their visit with the primary care provider.
- Assess patient materials for health literacy level and readability with tools like the CDC clear communication index, Flesch Reading Ease test, and the Flesch-Kincaid Grade Level Test. All forms that are written at higher than a sixth-grade level should be revised to the lower literacy level.
- Increase appointment times for new OUD patient referrals to 40 and 60 minutes to accommodate discussion of the consent form, education regarding the medication and program, and to collect a thorough past medical, surgical, and social history.
- Allow more time to thoroughly describe the COWS tool as well as give examples of its use through case studies. Have nurses perform a return demonstration or observe nurses COWS use with a patient.

- Expand the length of time between project start date and evaluation of NP confidence and qualitative interview to six months with the confidence surveys collected at baseline, three months and six months. An interval of six months would allow NPs an opportunity to manage a greater number of OUD patients. In future projects, consider tracking quality measures, attrition and completion rates as a measure of patient and provider outcomes.
- Expand treatment to patients with multiple addictions as the referrals from the CDRC were limited to approximately 10 patients divided between five NPs.
- Determine the optimal patient load for the PCC providers going forward, one that may allow additional chances to provide MAT to OUD patients.
- Consider forming an alliance with more addiction treatment organizations to increase patient volume and allow NPs more opportunity to treat OUD patients.
- Form a lobby of providers and staff from the PCC and CDRC. The purpose of the lobby would be to advocate for improving access to MAT for OUD at the city government and state government levels.
- Schedule project follow-up meetings for all stakeholders every six months and as needed. The PCC and CDRC team should share the responsibility in determining the future direction of the program.

Dissemination

Dissemination of project and results may assist in improving NP practice and encourage expansion of current primary care provider roles. The plan for dissemination includes a poster presentation at NDSU Memorial Union on April 9, 2019 and submission for publication.

Targeted journals for publication include peer-reviewed journals in advanced nursing practice, substance abuse and treatment, interprofessional practice or practice management.

Implications for Future Research

The desired outcome of the project was to assist in creating a BUP/NX MAT program that is not only high quality and evidence based, but also one that meets the needs of the providers, patients, and community. The project is unique in that the two organizations (PCC and CDRC) collaborated to serve the needs of the community as well as each organization. Future research may focus on patient outcomes, patient satisfaction, and provider satisfaction of collaborative programs compared to independent programs. The opioid epidemic is a priority of many national, state, and local agencies (U.S. Drug Enforcement Agency, 2016). With the limited patient access to addiction programs, primary care may be an ideal option for BUP/NX MAT. Applying a theoretical framework such as the SEM may also help address the multilayered influences that determine behavior and create an environment conducive to change through collaboration with additional community organizations. Finally, the pilot program implemented at the PCC provided a blueprint for other clinics to develop a similar primary care model to address opioid dependence.

Application to the Nurse Practitioner Role

Nurse Practitioners are well-educated health care providers who manage acute and chronic illnesses. As more opioid addicted patients seek treatment, the NP must be knowledgeable and prepared to meet the challenge. Through Section 303 of the CARA, NPs may receive training and utilize their knowledge and skill to manage OUD in the primary care setting (SAMHSA, 2018). The results of the confidence survey may help to ease concerns of

NPs about prescribing BUP/NX for OUD. The blueprint from this pilot project may also be beneficial to other clinics considering starting a MAT for OUD program.

Primary care opioid addiction therapy has been underutilized while more traditional MAT, such as methadone, has several barriers influencing compliance and satisfaction with the therapy (Jenkin & Ravert, 2013; Hill et al., 2015). The primary care setting offers an opportunity to manage OUD as a chronic illness using BUP/NX MAT. Several barriers limit the number of primary care providers being willing to prescribe MAT for OUD (Andrilla, Coulthard, & Larson, 2017). However, obtaining the training needed to become knowledgeable and confident providers would allow NPs the opportunity to fill the gaps in the management of OUD.

Nurse Practitioners may further help to reduce the stigmatization of OUD by being supportive and not passing judgement during patient interactions (Cadet & Tucker, 2019). Treatment programs rooted in primary care settings may offer a convenient and therapeutic environment for patient sobriety and relapse prevention while experiencing more respect, trust, and empathy from providers (Jenkinson and Ravert 2013). Taking a patient-centered approach to care, including shared decision making between providers and patients, may help patient retention, prevent relapses, and overcome barriers to seeking MAT for OUD (Cadet & Tucker, 2019).

Conclusion

Opioid addiction is an epidemic affecting every state in the nation (Kaiser Family Foundation, 2018). MAT, combined with counseling, can successfully treat OUD, help sustain recovery, and decrease risk behaviors by providing individualized approach to opioid addiction therapy (SAMHSA, 2016). However, significant gaps between treatment need and capacity exist at the state and national level (Jones, Campopiano, Baldwin, & McCance-Katz, 2015). Offering

MAT through the primary care setting may increase the availability of treatment options for OUD patients. Additionally, NPs offer an opportunity to address gaps in patient access to high quality, patient-centered, and affordable health care (IOM, 2011) including MAT for OUD through Section 303 of the CARA (SAMHSA, 2018). Utilization of an interdisciplinary model to address the multilayered and collaborative effects of personal and environmental influences of OUD may help to provide an individualized and structured approach to treatment.

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APPENDIX A. CLINICAL OPIATE WITHDRAWAL SCALE (COWS)

For buprenorphine/naloxone induction: Enter scores at time zero, 1-2 hours after first dose, and at additional times buprenorphine/naloxone is given over the induction period.	**DATE/TIME**	**DATE/TIME**	**DATE/TIME**
Resting Pulse Rate: (record beats per minute) *Measured after patient is sitting/lying for one minute.* **0** = 80 or below; **1 =** 81-100 ; **2** =101-120; **4** => 120			
Sweating: *Over past ½ hour not accounted for by room temperature or patient activity.* **0** no report of chills or flushing **1** one report of chills or flushing; **2** flushed or observable moistness on face **3** beads of sweat on brow or face **4** sweat streaming off face			
Restlessness: *Observation during assessment.* **0** able to sit still; **1** reports difficulty sitting still, but is able to do so; **3** frequent shifting or extraneous movements of legs/arms; **5** unable to sit still for more than a few seconds			
Pupil Size: ***Observation during assessment.*** **0** pupils pinned or normal size for room light; **1** pupils possibly larger than normal for room light; **2** pupils moderately dilated; **5** pupils so dilated that only rim of the iris is visible			
Bone or Joint aches*: If patient was having pains previously, only the additional component attributed to opiate withdrawal is scored.* **0** not present; **1** mild diffuse discomfort; **2** patient reports severe diffuse aching of joints/muscles **4** patient is rubbing joints or muscles and is unable to sit still because of discomfort			
Runny nose or tearing: *Not accounted for by cold symptoms or allergies.* **0** not present; **1** nasal stuffiness or unusually moist eyes; **2** nose running or tearing; **4** nose constantly running or tears streaming down cheeks			
GI Upset: *Over last ½ hour.* **0** no GI symptoms; **1** stomach cramps; **2** nausea or loose stools; **3** vomiting or diarrhea; **5** multiple episodes of diarrhea or vomiting			
Tremor: *Observation of outstretched hands.* **0** no tremor; **1** tremor can be felt, but not observed; **2** slight tremor observable; **4** gross tremor or muscle twitching			
Yawning: *Observation during assessment.* **0** no yawning **1;** yawning once or twice during assessment; **2** yawning three or more times during assessment; **4** yawning several times/minute			
Anxiety or Irritability: **0** none; **1** patient reports increasing irritability or anxiousness; **2** patient obviously irritable, anxious; **4** patient so irritable or anxious that participation in the assessment is difficult			
Gooseflesh skin: **0** skin is smooth; **3** piloerection of skin can be felt or hairs standing up on arms; **5** prominent piloerection			
Total Score			
Observer's Initials			
Blood Pressure/Pulse			
Dose of Suboxone® Given			

SCORE: **Mild: 5-12; Moderate: 13-24; Moderately Severe: 25-36; Severe Withdrawal: More than 36.**

Adapted from *DEPARTMENT OF VERMONT HEALTH ACCESS MANAGED CARE ENTITY VERMONT BUPRENORPHINE PRACTICE GUIDELINES* Revised 08/2015
http://dvha.vermont.gov/for-providers/buprenorphine-practice-guidelines-revised-final-10-15.pdf

APPENDIX B. CONSENT FOR TREATMENT WITH BUPRENORPHINE/NALOXONE

COMBINATION THERAPY MEDICATION

Buprenorphine and naloxone are medications approved by the Food and Drug Administration (FDA) for treatment of people with opioid dependence. Qualified providers can treat patients for opiate dependence. Buprenorphine can be used for detoxification or for maintenance therapy. Maintenance therapy can be used as long as medically necessary. Buprenorphine/Naloxone is one treatment option for opiate addiction and other options such as methadone, naltrexone, and counseling may be used if Buprenorphine/Naloxone is ineffective. Counseling is the only other form of treatment that may be used in combination with Buprenorphine/Naloxone. Buprenorphine/Naloxone should not be used with other medications specifically indicated for opiate addiction.

Buprenorphine itself is an opioid, although it affects the brain differently than other opiates. It is not as strong an opioid as heroin or morphine. Buprenorphine, when used as a medication-assisted treatment for opiate addiction (M.A.T.), suppresses withdrawal symptoms, cravings for opiates, does not cause euphoria (the feeling of being "high") in opiate dependent patients, and blocks the effects of other opiates for at least 24 hours-48 hours. Buprenorphine treatment can still result in physical dependence of the opiate type.

If you are dependent on opiates, you should be in active, moderate withdrawal when you take the first dose of buprenorphine. The more withdrawal you are able to be in for the induction process, the better we will be able to determine a good dose of medication for you to be on. If you are not in withdrawal, buprenorphine may cause significant opioid withdrawal since it blocks the effects that other opiates have in your body. For that reason, you should take the first dose in the office and remain in the office for observation.

Buprenorphine/Naloxone films/tablets must be held under the tongue until it is dissolved completely. Do **NOT** swallow the film/tablet. The medication is not absorbed well in the stomach. If the medication is swallowed, you will not receive the full benefit of the medication and it may not resolve your withdrawal symptoms. Allow the medication to dissolve fully under your tongue. This may take up to 10 minutes. The medication is then absorbed over the next 30 to 120 minutes from the tissue under the tongue.

Some patients find that it takes several days to get used to the transition from the opioid they had been using to buprenorphine. During that time, any use of other opioids may cause an increase in symptoms. After you become stabilized on buprenorphine, it is expected that other opioids will have less effect. Attempts to override the buprenorphine by taking more opioids could result in an opioid overdose. You should not take any other medication without discussing it with your medical provider first.

Combining buprenorphine with alcohol and/or certain medications may be hazardous. The combination of buprenorphine with alcohol and/or benzodiazepines (such as Valium, Librium, Ativan, Xanax, Klonopin, etc.) has resulted in deaths. If a benzodiazepine is prescribed,

It must be taken only as prescribed and with approval from your Buprenorphine/Naloxone prescriber and any specialist providers.

Buprenorphine/Naloxone is extremely dangerous for infants and children. They can stop breathing and die quickly after taking in tiny amounts of this medication. This is why it is very important to keep medication locked/secured at all times and out of the reach of children at all times. **911 should be called immediately if there is any chance an infant/child may have ingested buprenorphine/naloxone.**

I have read and reviewed this information with my medical provider and I understand how Buprenorphine/Naloxone treatment is utilized to treat an opioid use disorder. I understand the risks and benefits of this treatment. I have an opportunity to discuss my questions with my provider and I consent to proceeding with Medicated Assisted Treatment.

_____
Patient Signature

_____
Patient's Printed Name

_____
Date

APPENDIX C. BUPRENORPHINE/NALOXONE TREATMENT CONTRACT

As a participant in buprenorphine/naloxone treatment for opioid use disorder, I agree to the following by reviewing and initialing each statement and signing this treatment contract:

- I agree to keep all my scheduled appointments or change the appointment in advance, except in case of emergency. _____
- I agree that my prescriptions for Buprenorphine/Naloxone will **only** be given to me at my office visits. A missed visit will result in my not being able to get my medication/prescription until the next scheduled visit. _____
- I agree to use a single pharmacy for ***all of my prescription medications***_____ My chosen pharmacy is._____. I will not transfer my prescription to other pharmacies or fill at multiple pharmacies. _____. If I choose to switch pharmacies, I may do so one time and will notify [redacted] nursing staff._____
- I agree to obtain my prescriptions for Buprenorphine/Naloxone only from my provider _____ at [redacted]. I will notify any other health care provider and dentist that I am on buprenorphine/naloxone therapy and will not seek additional controlled substances from other providers. _____
- I agree to report an accurate health history and symptoms to the health care team involved in my care. I will also inform my provider prior to any dental surgery or other surgical procedures. _____
- I understand/agree that if I have a mental health disorder in addition to my opioid use disorder, it is important that I am following my treatment plan with my behavioral health provider and that [redacted] has access to those records. It is also important that my behavioral health provider has access to my [redacted] records. _____
- I agree to take my Buprenorphine/Naloxone as prescribed, not to skip doses, and not to adjust the dose unless discussed with my provider first. _____
- I agree **NOT to sell, share, or give any of my medication to another person.** Also, I agree not to buy or sell used film wrappers. _____
- I agree not to deal, buy, or use any drugs at [redacted] in its parking lots or property. Additionally, I agree to not engage in any illegal activity at [redacted] _____
- I agree to provide up to date contact information and have a reliable phone number where I can be reached. My phone will be charged at all times. I will have minutes on my phone. I will always have my phone in my possession. I will have a voicemail box set up on my phone and make sure there is available space for nursing to leave a voicemail. I will return nursing's phone call within 24 hours. _____
    - My primary phone numbers are. _____ and _____
- I agree that if I am going to be unreachable for any reason, I must discuss this with [redacted] nursing staff beforehand and explain the situation._____
- I agree that if I am planning an out of town trip, I agree to provide 2 weeks (14 day) notice to [redacted] nursing staff to discuss any potential treatment adjustments. _____
- I agree that the medication I receive is my responsibility and I agree to keep it safe and secure and locked up. I agree that lost/ stolen prescriptions and medication will not be

replaced regardless of why it was lost/ stolen. **Also,** Lost/stolen prescriptions must be reported to the police and a police report must be provided at the next visit. I understand that if my medications are lost/stolen, my provider is not expected to provide "make-up" doses. _____

- I agree to avoid driving or operating heavy machinery/dangerous equipment until I am familiar with the effects of the buprenorphine/naloxone._____
- I agree not to obtain buprenorphine (Suboxone, Zubsolv,), other opioids (such as morphine, fentanyl, hydrocodone, oxycodone, or tramadol), benzodiazepines (for example, Lorazepam, Diazepam/Valium, Clonazepam/Klonopin, Alprazolam/Xanax, etc.), Gabapentin, or Lyrica from any other healthcare providers, pharmacies, or other sources without telling my [redacted] provider. _____
- I understand that mixing buprenorphine with other medications, especially benzodiazepines, can be dangerous and could lead to death. There is also a risk of overdose death from mixing buprenorphine (Suboxone) with alcohol or other types of sedatives, such as barbiturates. _____
- I agree to inform all of my professional providers about any of the following:
    - Use of medication in any other way that prescribed._____
    - Use of other opioids, alcohol, illicit benzodiazepines, or other illicit drugs._____
- I understand that Buprenorphine/Naloxone by itself may not be enough treatment for my addiction, and I agree to participate in counseling/support groups as discussed and agreed upon with my healthcare provider. I agree to follow all recommendations for counseling and psychiatric services and make all records from outside providers available to my [redacted] provider. _____
- I understand and agree that the [redacted] nursing staff or my [redacted] provider may request phone updates or records from my addicting counseling staff at any time regarding my progress and attendance of treatment/therapy sessions. Also, I understand that my treatment provider may request verbal updates and records from [redacted] at any time._____
- I agree to treat staff with respect and not to disturb other patients or threaten, verbally abuse, or in any manner accost staff members or patients while on or around clinic property. _____
- I will not use any nicotine-containing products in/around clinic property. _____
- I agree to provide random urine samples for drug testing and have my healthcare provider test my blood alcohol level whenever I am asked to do so. I understand that failure to provide a urine sample within 24 hours of when requested could result in involuntary tapering of Buprenorphine/Naloxone and discontinuation of treatment._____
- I agree to be 20 minutes early for my appointments. I understand that if I am late 10 minutes or more that I may be asked to reschedule my appointment and will not get my prescription that day. I agree that I will arrange my own reliable transportation in advance and make it to my appointments in a timely fashion. _____
- If I am female, I confirm that I am not pregnant. I agree to prevent pregnancy and use reliable birth control while using buprenorphine containing products. I agree to inform my provider if I become pregnant as other treatment options may be discussed. I understand that my provider has the ability to prescribe birth control if needed and that condoms are free to me at [redacted]. _____

- If I contract Hepatitis I will let my medical provider know as my liver function may need to be monitored more closely._____
- I agree to keep all unused doses of medication, medication film wrappers, and the original containers from the pharmacy and bring them to each appointment to be inspected and counted._____
- I understand that my provider may also require random film counts. If I am called to come in for a random film count, I will present to [redacted] within 24 hours of being called. I will present with all remaining films and wrappers from used films since last prescription was provided. _____
- I agree that my goal is to stop using addictive drugs, and that I will work to stop using all addictive and illegal drugs during my treatment with Buprenorphine/Naloxone. _____
- I understand that if I decrease my use of opioids (stop using heroin, pain pills) or substitute buprenorphine for these drugs, I have a higher risk of dying from an overdose if I relapse as my body is no longer used to the higher doses of opioids that I was previously using. _____
- I understand that if I relapse when I have been taking buprenorphine, at first I may not get high from the other opioids because buprenorphine blocks their effect. I understand that if I keep using larger and larger amounts to try to get high, I could stop breathing and die. _____
- **I understand that Buprenorphine/Naloxone is extremely dangerous for infants and children. They can stop breathing and die quickly after taking in tiny amounts of this medication.** I agree to keep my supply of this medication locked securely away from others, especially infants and children. I agree to call 9-1-1 immediately if anyone other than myself has been in contact with my medication and inform my medical provider._____
- I understand that relapse is sometimes part of the recovery process. I agree to discuss any concerns or relapses with my provider to discuss ways to prevent future occurrences. If I feel like I may relapse, I will contact my provider immediately _____
- I agree to not eat any foods or bakery items that contain poppy seeds, including "everything" bagels or use any mouthwash or cough syrup containing alcohol. I understand that this will not be accepted as an excuse for a positive drug screen._____
- I agree to sign and have an active release of information on file to [redacted] for all of my mental health records, hospitalizations/ER visits, addiction treatment providers/counselors, and any other medical services. I understand that revocation of any releases of information may result in dismissal from the buprenorphine/naloxone program._____
- I understand that, like all health care providers, [redacted] staff are mandated reporters of suspected abuse, neglect or exploitation of vulnerable groups of people including children and elderly adults. Healthcare providers and nurses are legally required to report any potential or suspected abuse/neglect of these populations._____
- I understand that provider will regularly check the pharmacy controlled substance online database on a regular basis and any controlled substances (such as benzodiazepines, opioids, stimulants, gabapentin, Lyrica, sleep medication) prescribed and filled without my provider's knowledge could result in dismissal from buprenorphine/naloxone treatment program_____

- I understand that I will be considered to have left the buprenorphine/naloxone treatment program against medical advice if I am not able to be contacted within 3 days of a missed appointment._____
- I understand that if I leave the program against medical advice and wish to re-engage, I will need to be re-evaluated by an addiction counselor to see if buprenorphine/naloxone is an appropriate treatment for me and my counselor will need to be in touch with my [redacted] buprenorphine prescribing provider as to his/her recommendations. If I am re-accepted to the program I will have to re-start at a higher level of care._____
- I have reviewed the [redacted] Medicated Assisted Treatment for Opioid Use Disorder and am agreeable to the plan of care. I understand that once I graduate from Stable Level Care, my provider and I may agree on a Maintenance Level of Care which can be individualized to me and my current progress with my disease. I understand that failure to maintain or progress at one level of care may require me to go back to a higher level of care._____
- I agree that if I accrue any bills at [redacted] I will work with the billing office to start a payment plan if I cannot afford my bill. I understand that if the balance of my bill reaches or exceeds $200 dollars without actively trying to make payments on my bill that I may not be able to go to my office visits and therefore will not get my prescription. _____
- I understand that failure to comply with this Treatment Contract, recommendations from my healthcare provider, or recommendations from my addiction counselor could carry implications to my current treatment plan such as (ranging from less severe to most severe);_____
    - Transfer to a higher level of care within [redacted] (for example, more frequent office visits, more frequent urine screenings, more frequent film counts, shorter prescriptions.)
    - Conferences with my care team regarding my progress and appropriateness for continuing medication assisted treatment.
    - Involuntary tapering of buprenorphine and dismissal from buprenorphine treatment program at [redacted]
    - In severe cases if the safety of well-being of our staff/patients is in question, I may be discharged from [redacted] and asked not to return for a specified amount of time.
- I understand that my buprenorphine/naloxone treatment may be discontinued, I may be involuntarily tapered off my buprenorphine medication, and I may be discharged from the buprenorphine/naloxone program if the terms of this agreement are violated. _____

Patient signature_____

Date_____

Provider name & signature_____

Date_____

APPENDIX D. BUPRENORPHINE/NALOXONE MEDICATION CALL BACK FOR FILM COUNTS AND REFILL INFORMATION

- Medication Film Counts and Call-backs are an important aspect of treatment and a tool to help assure Buprenorphine/Naloxone (Suboxone) is taken as directed and is not being diverted (sold, shared, horded, etc.). If you do not return for a medication call-back or do not bring your films in for a film count, we must assume that you are engaged in one or more of these behaviors._____

- You must save the container that you received your medication in, the film wrappers, and any films that you have not yet taken and they must be readily available to be counted and examined by nursing at any time_____

- It is your responsibility to have a working phone number for staff to be able to use. If you cannot be reached due to an outdated phone number, full voicemail, etc., then the call-back is considered unsuccessful. It is your responsibility to check your voicemail each day and delete old messages to ensure room for new messages. _____

- If you are called by nursing for a Call-Back and asked to come in for a film count, we expect that nursing is able to reach you by phone to notify you of the need to do this. There should be no more than 8 business hours lapse between the nursing calling you and you returning her call. Once the nurse has been in touch with you, you must present to the clinic with the unused portion of your medications still in the original wrappers, the empty wrappers, and whatever container you originally received the medication in._____

- Be aware that due to the risk of diversion of buprenorphine containing products, nursing staff will be examining and counting the films left in the prescription, counting the number of used film wrappers from previously used doses, and comparing lot numbers. _____

- In addition to call-backs, it is expected that at **each office visit** you bring in any unused films in addition to the film wrappers. _____

- It is your responsibility to have your medication and the film wrappers safely secured at all times (in a locked box preferably). Having your medication/film wrappers stolen or lost will not be considered a reasonable excuse in the event of the need for a call back. _____

Refills

Medication will NOT be refilled on weekends, holidays, or after regular business hours. Refills will only be given in the office visit. Monitoring and being responsible for your medication is your responsibility and an important part of your recovery.

Patient Signature: _____

Date: _____

APPENDIX D. PROVIDER SURVEY

Statement	Strongly Disagree	Disagree	Undecided	Agree	Strongly Agree
1. I view opioid addiction as a chronic disease.	1	2	3	4	5
2. I can identify resources in the community to aid in addiction therapy.	1	2	3	4	5
3. I can identify specialty services for complex comorbidities.	1	2	3	4	5
4. I feel knowledgeable regarding the pathophysiology of opioid abuse.	1	2	3	4	5
5. I am willing to provide medication assisted treatment (MAT) for opioid use disorder (OUD).	1	2	3	4	5
6. I am confident in my ability to identify opioid abuse among my patients.	1	2	3	4	5
7. I am confident in my ability to manage patients with MAT for opioid abuse.	1	2	3	4	5
8. The organization that I work for helps support my efforts to treat OUD.	1	2	3	4	5
9. I can identify fellow providers who provide MAT with buprenorphine/ naloxone for OUD.	1	2	3	4	5
10. I feel that there is resistance from my associates or place of work to continue/ start MAT for opioid addiction.	1	2	3	4	5
11. I am hesitant to prescribe buprenorphine/naloxone due to prescription misuse or diversion.	1	2	3	4	5
12. I am hesitant to prescribe buprenorphine /naloxone due to concerns about cost reimbursement.	1	2	3	4	5
13. I believe that I have enough time during office visits to address my patient's addiction treatment.	1	2	3	4	5
14. I am comfortable talking about opioid abuse/addiction with my patients.	1	2	3	4	5
15. I would feel more confident in providing MAT for OUD if my patient is also receiving addiction counseling.	1	2	3	4	5

APPENDIX F. PROVIDER INTERVIEW QUESTIONS:

In regard to the Buprenorphine-Naloxone Medication Assisted Treatment Program:

1. What do you perceive as the strengths of the program?

2. What are the weaknesses of the program?

3. What are your opinions about the referral process and relationship with CDRC employees?

4. What have been the biggest barriers for providers and the clinic in first three months of the program?

5. Do feel the evaluation process is comprehensive and meets the needs of providers, the clinic, and the patients? Explain your answer.

6. What is your current patient load and what do you believe is an acceptable patient load going forward?

7. What factors have promoted patient retention in the program?

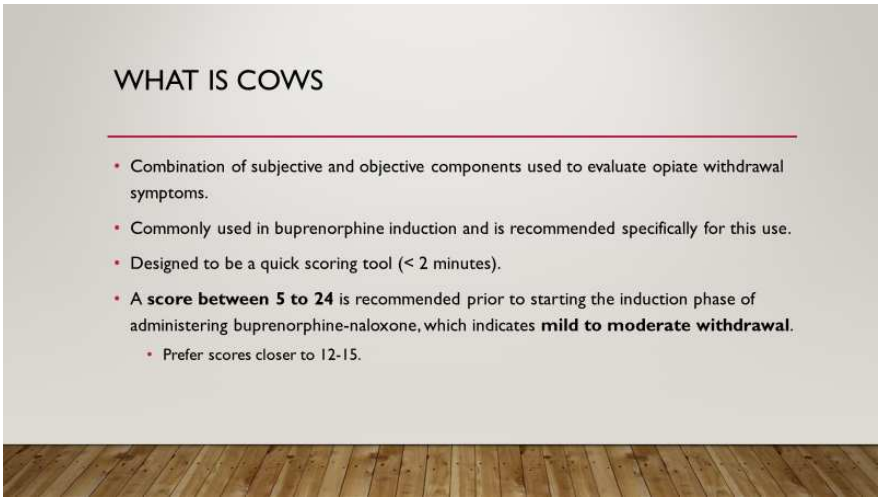
8. Have you found the program forms or evaluation tools lack clarity? If so, how?

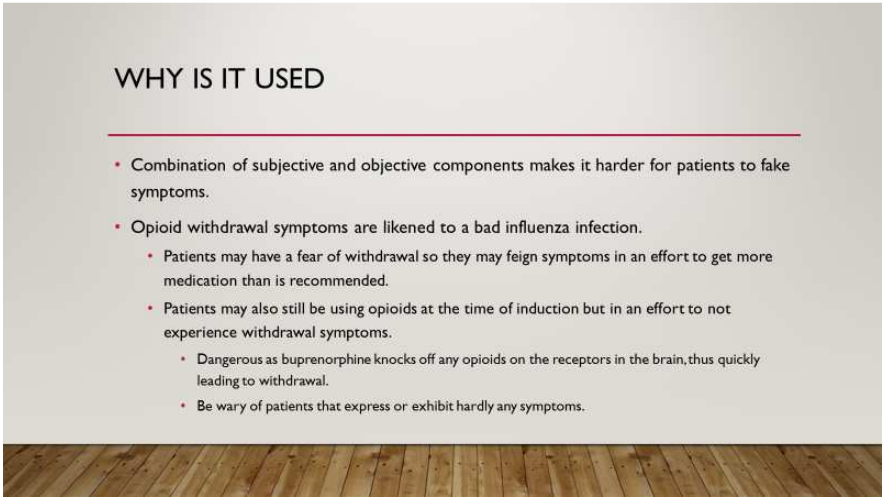
9. What recommendations for improvement would you like to see made to the program?

APPENDIX G. MEDICATION ASSISTED TREATMENT PROVIDER ORDER SET

- ☐ Referral to CDRC
- ☐ CDRC Collected and Observed UDS Standing Order
- ☐ CDRC Collected and Observed Urine Drug Screen
- ☐ Comprehensive Metabolic Panel
- ☐ Hepatitis C Ab with reflex to hepatitis C PCR
- ☐ Hepatitis B surface antigen
- ☐ Hepatitis B surface antibody
- ☐ HIV 1 Ag HIV ½ Ab with reflex to confirmation
- ☐ Hepatic panel
- ☐ Urine, HCG.

APPENDIX H. POWERPOINT PRESENTATION





CONDUCTING THE TEST

- Screening doesn't have to take long
  - First task is measuring a pulse. During this time (1 minute), observe other aspects of the patient.
    - **Objective**: Yawning, goose bumps, tremors, fidgeting, running/stuffy nose, sweating, pupil size, etc.
    - Can then ask about **subjective symptoms**: GI upset, anxiety, restlessness, or feeling chilled/flushed.
    - Use this initial exam as baseline data. Conduct the test again 30 minutes after first dose and then 2 hours after the first dose. May require additional screenings.
    - Providers may conduct the initial screen, but nurses are a valuable component to maintaining patient flow. Therefore, conducting the COWS may be quite helpful during the induction phase.

OTHER CONSIDERATIONS

- Consider other factors that may influence the COWS scoring.
  - Examples:
    - Running/walking prior to appointment.
    - Accompanying cold or other acute illness.
    - Chronic pain (back, neck, shoulder, etc.).

REFERENCES

- Clinical Opiate Withdrawal Scale (COWS). (2011). The National Alliance of Advocates for Buprenorphine Treatment. Retrieved from https://www.naabt.org/documents/cows_induction_flow_sheet.pdf
- Clinical Opiate Withdrawal Scale. (2015). National Institute on Drug Abuse. Retrieved from https://www.drugabuse.gov/sites/default/files/files/ClinicalOpiateWithdrawalScale.pdf
- COWS Score for Opiate Withdrawal. (2018). MDCalc. Retrieved from https://www.mdcalc.com/cows-score-opiate-withdrawal

APPENDIX I. NDSU IRB APPROVAL

NDSU NORTH DAKOTA STATE UNIVERSITY

November 14, 2018

Dr. Tina Lundeen
Nursing

Re: IRB Determination of Exempt Human Subjects Research:
Protocol #PH19088, "Development and Implementation of an Evidence-Based Buprenorphine-Naloxone Medication Assisted Treatment Program in a Primary Care Setting"

Co-investigator(s) and research team: Jordan Coplin
Date of Exempt Determination: 11/14/2018 Expiration Date: 11/13/2021
Study site(s): Family HealthCare
Sponsor: n/a

The above referenced human subjects research project has been determined exempt (category #2b) in accordance with federal regulations (Code of Federal Regulations, Title 45, Part 46, Protection of Human Subjects). This determination is based on the protocol submission (received 11/7/2018) with updated information sheet (received 11/14/18).

Please also note the following:
• If you wish to continue the research after the expiration, submit a request for recertification several weeks prior to the expiration.
• The study must be conducted as described in the approved protocol. Changes to this protocol must be approved prior to initiating, unless the changes are necessary to eliminate an immediate hazard to subjects.
• Notify the IRB promptly of any adverse events, complaints, or unanticipated problems involving risks to subjects or others related to this project.
• Report any significant new findings that may affect the risks and benefits to the participants and the IRB.

Research records may be subject to a random or directed audit at any time to verify compliance with IRB standard operating procedures.

Thank you for your cooperation with NDSU IRB procedures. Best wishes for a successful study.
Sincerely,

Kristy Shirley, CIP, Research Compliance Administrator

For more information regarding IRB Office submissions and guidelines, please consult http://www.ndsu.edu/research/integrity_compliance/irb/. This Institution has an approved FederalWide Assurance with the Department of Health and Human Services: FWA00002439.

INSTITUTIONAL REVIEW BOARD
NDSU Dept 4000 | PO Box 6050 | Fargo ND 58108-6050 | 701.231.8995 | Fax 701.231.8098 | ndsu.edu/irb

Shipping address: Research 1, 1735 NDSU Research Park Drive, Fargo ND 58102

APPENDIX J. EXECUTIVE SUMMARY

Project Summary

The purpose of this project was to assist a primary care clinic (PCC) in Fargo, ND with the development, implementation, and evaluation of a buprenorphine-naloxone medication assisted treatment (MAT) option for opioid use disorder (OUD) patients in collaboration with a chemical dependency residential center (CDRC). Opioid abuse is one of the most significant drug-related public health threats in the United States (U.S. Drug Enforcement Agency, 2016). Approximately 115 Americans die every day from an opioid overdose in the United States (Center for Disease Control and Prevention, 2017). North Dakota had one of the fewest opioid related death rates in the country with 54 opioid-related overdose deaths in 2016. However, this was an increase from 34 deaths the year prior and from the 11 opioid related deaths in 2013 (Kaiser Family Foundation, 2018).

Coupled with counseling, MAT can successfully treat opioid use disorder and sustain recovery by providing a more individualized approach to therapy (Substance Abuse and Mental Health Services Administration (SAMHSA), 2016). Methadone had historically been used to treat opioid addiction in the U.S. but can only be prescribed in treatment programs certified by SAMHSA. The availability of and access to certified treatment centers have not met the increasing need for MAT services created by the prescription drug dependence epidemic (Jenkins & Ravert, 2013). Opportunities within the primary care setting exist to manage OUD with buprenorphine-naloxone.

Background

The project was a new concept in the treatment of OUD in the Fargo-Moorhead community. Traditional methods to treat OUD, such as methadone clinics, as well as private

treatment programs were available. However, no outpatient clinic in the Fargo, ND community had developed a primary care model utilizing BUP/NX for outpatient OUD treatment. Members from a PCC and CDRC joined forces to provide a comprehensive treatment program for OUD. The objective was to deliver high quality, focused care to a larger number of patients participating in the MAT program. Nurse practitioners could obtain a waiver to prescribe buprenorphine for up to 30 patients (in year one) through SAMHSA after 24 hours of training (8 hours of which is specific to safe medication prescribing) (American Society of Addiction Medicine, 2018). Patients received addiction counseling and case management services at the CDRC while NPs at the PCC provided medication assistance

Between March 2018 and May 2018, discussion of an evidence-based BUP/NX program was discussed between members of the PCC. Determination of needs was established by PCC providers and staff. Networking with additional community organizations including the CDRC began May 2018 through September 2018. The initial literature review of BUP/NX use in primary care was completed between June 2018 and October 2018. Networking with CDRC representatives and PCC representatives to discuss necessary forms and other project needs occurred September 2018. Providers at the PCC completed the mandatory 24-hour training to receive a buprenorphine prescription waiver through the Department of Vermont Health Access in Vermont between June 2018 and September 2018.

Stakeholders in the project included representatives from the CDRC such as counselors, case managers, the clinical director, and the CEO. Shareholders from the PCC included the medical director, nurse practitioners, nurses, appointment schedulers, pharmacists, and financial enrollment staff.

Process

Five NPs completed the required 24-hours of training to receive a buprenorphine prescriptive waiver prior to the project start date. Additional training in utilizing the COWS was completed by nurses at the PCC during a brief, 10-minute in-service discussion on February 4, 2019. BUP/NX MAT guidelines, consent for treatment, and a provider order-set were distributed on August 22, 2019 to the medical director and NPs who had completed the required BUP/NX training. The clinical service manager and a nurse at the PCC edited the consent forms and order-set to better reflect the needs of the PCC, which were approved on September 24, 2019 by the PCC stakeholders. Due to the timeline needs of the PCC, the forms were completed prior to the project start date. The initial provider confidence surveys were distributed on November 16, 2018 to NPs at three clinic locations in Fargo, ND and West Fargo, ND. Post-implementation confidence surveys were distributed on January 28, 2019 during a MAT provider meeting at the PCC. Additionally, qualitative, open-ended questionnaires were dispersed at the same time as the post-implementation confidence surveys.

Evaluation of NP confidence consisted of provider confidence surveys administered at the start of project implementation and two months post-implementation. A 5-point Likert scale reflecting the response categories of strongly agree, agree, undecided, disagree, strongly disagree was used. The survey consisted of 15 statements created to evaluate the various determinants that affect provider confidence in MAT. Statements also evaluated common barriers associated with providing MAT for OUD. The response rate was 100% at baseline and 80% post-implementation with one statement not responded to by one provider.

The questionnaire consisted of nine open-ended questions designed to elucidate the perceived strengths and weaknesses of the project. Four NPs completed the questionnaire

(response rate of 80%). Responses were randomized to decrease the possibility of identifying the respondent. The statements within the survey and questions within the questionnaire were original and did not come from a previously utilized survey.

Findings and Conclusions

The NPs used the guidelines, consent form and treatment agreement form, and the provider order-set during the MAT project starting November 16, 2018. Following the in-service presentation, the PCC nurses expressed an interest in using COWS, however, they were concerned about using the tool in the clinical setting without additional training. The analysis at the conclusion of this project also included the overall results of the pre and posts implementation Likert Scale surveys and qualitative questionnaires. The statements on the provider survey were organized into four themes, which include confidence or lack of confidence, knowledge, willingness, and perception. Responses to the statements indicate an improved confidence in finding community resources for addiction, understanding the pathophysiology of opioid abuse, identifying opioid abuse among patients, identifying additional MAT providers, and willingness to provide MAT. Each listed area was an often-cited barrier to providing MAT, which may have indicated NPs' confidence in utilizing MAT for OUD improved following project implementation. Results are as follows:

Table J1

Provider Confidence Survey

Statements	Baseline N=5	Post N=4	Diff
6. I view opioid addiction as a chronic disease.	4.2	4.3	0.1
7. I can identify resources in the community to aid in addiction therapy.	4.0	4.5	0.5
8. I can identify specialty services for complex comorbidities.	4.0	4.3	0.3
9. I feel knowledgeable regarding the pathophysiology of opioid abuse.	3.8	4.5	0.7
10. I am willing to provide medication assisted treatment (MAT) for opioid use disorder (OUD).	4.6	4.8	0.2
16. I am confident in my ability to identify opioid abuse among my patients.	3.8	4.3	0.5
17. I am confident in my ability to manage patients with MAT for opioid abuse.	3.4	3.8	0.4
18. The organization that I work for helps support my efforts to treat OUD.	4.8	4.8	0.0
19. I can identify fellow providers who provide MAT with buprenorphine/naloxone for OUD.	4.2	4.8	0.6
20. I feel that there is resistance from my associates or place of work to continue/start MAT for opioid addiction.	1.2	1.8	0.6
21. I am hesitant to prescribe buprenorphine/naloxone due to prescription misuse or diversion.	2.8	2.5	-0.3
22. I am hesitant to prescribe buprenorphine/naloxone due to concerns about cost reimbursement.	1.6	1.5	-0.1
23. I believe that I have enough time during office visits to address my patient's addiction treatment.	2.4	2.8	0.4
24. I am comfortable talking about opioid abuse/addiction with my patients.	4.4	4.5	0.1
25. I would feel more confident in providing MAT for OUD if my patient is also receiving addiction counseling.	4.8	4.8	0.0

Through analysis of the qualitative questionnaire, nurse practitioners indicated positive feelings about the program and the working relationship within the PCC and with the CDRC providing a service to underserved patients in the community, and less disruption of patients' lives during treatment. Lack of onsite counselors, delays in drug test results, and NP inexperience were indicated in nurse practitioner responses as a weakness. The patient consent forms were considered extensive with understandability a concern. Nurse Practitioners disagreed about an acceptable patient load. The NPs who treated a greater number of OUD patients felt they could treat a larger number of patients moving forward, while the NPs who treated few or no OUD patients suggested a lower patient load. Such findings may have indicated more

experience working with OUD patients could lead to more NP comfort in treating the patient population within the confines of the PCC.

Table J2

Provider Interview Questions and Responses

Qualitative Interview Question	Provider Responses
What do you perceive as the strengths of the program?	Access to medical care by accepting patients without health insurance. Utilizing the Action Plan sliding scale fee to assist with patient's ability to pay. Treatment that allows more normalized routine such as work, family, and other responsibilities. Patient comfort receiving treatment in an office setting. Support from providers, clinic staff and addiction counselors at the CDRC.
What are the weaknesses of the program?	Lack of addiction counselor within the PCC. Inexperience with treating OUD patients. Lack of rapid, inhouse drug testing and nursing staff to support expanded MAT program. Only taking referrals from one facility (CDRC).
What are your opinions about the referral process and relationship with CDRC employees?	Knowledgeable and good communication. Good working relationship. Having a counselor on site may limit miscommunications.
What have been the biggest barriers for providers and the clinic in first three months of the program?	Proper dosing Assessing appropriateness for outpatient treatment Getting patient set up for outpatient treatment Informing the community about MAT service Not enough experience due to low patient volume
Do feel the evaluation process is comprehensive and meets the needs of providers, the clinic, and the patients? Explain your answer.	CDRC does initial evaluation prior to referral which can lead to some miscommunication and discrepancies. Both providers and patients seem satisfied with the evaluation and treatment process. CDRC provides some formal education.
What is your current patient load and what do you believe is an acceptable patient load going forward?	Between 0-5 patients Acceptable patient loads vary, but providers managing a greater number of OUD patients list a higher number of acceptable patients. Some providers are not able to give a definitive number, while others feel between 5 and 20 is acceptable.
What factors have promoted patient retention in the program?	Availability and access to other services Supportive environment Commitment to recovery and following contract/guidelines.
Have you found the program forms or evaluation tools lack clarity? If so, how?	Forms are acceptable and do not lack clarity. However, forms are long, and patients may not read them carefully or understanding them, especially if they are going through withdrawal.
What recommendations for improvement would you like to see made to the program?	In-house counselor Case manager to follow-up with patient compliance Better understanding of which patients are outpatient appropriate and which need more complex care. More general in-house support services.

Recommendations for Further Action

Results generalized within the confines of the PCC may indicate more experience working with OUD patients could lead to increased nurse practitioner confidence in treating the patient population. Offering MAT through the primary care setting may increase the availability of treatment options for OUD patients while NPs may further address gaps in patient access to high quality, patient-centered, and affordable health care. Future research may focus on patient-specific outcomes, patient satisfaction, and provider satisfaction of collaborative programs compared to independent programs. Considerations in forming an alliance with more addiction treatment organizations may allow NPs more opportunity to treat OUD patients and increase patient volume. Formation of a lobby group comprised of providers and staff from the PCC and CDRC may advocate for improving access to MAT for OUD at the city government and state government levels. Finally, the blueprint from this pilot project may also be beneficial to other clinics considering starting a MAT for OUD program.