Increasing Drug Screens and Prescription Drug Monitoring
Program Assessments for Patients Enrolled in Opioid Replacement Therapy
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Abstract

Opioid use disorder is an epidemic that has a devastating impact on public health, morbidity and mortality, and the escalating economic burden of healthcare (U.S. Department of Health & Human Services, 2013). The rates of prescriptive and non-prescriptive opioid misuse are on the rise (Compton, Boyle, & Wargo, 2015). One approach in managing opioid use disorder is opioid replacement therapy (ORT). In response to increasing rates of opioid use disorder, the Drug Addiction Treatment Act of 2000 permitted “qualifying physicians” to treat opioid use disorder in an office-based setting. The FDA approved medication buprenorphine, a partial opioid agonist, is used in the treatment of opioid use disorder in an office-based setting. Despite its efficacy, there is significant concern about the potential misuse and diversion of buprenorphine (Federation of State Medical Boards, 2013).

The purpose of the Quality Improvement project was to increase drug screens and prescription drug monitoring program assessments (PDMP) for patients enrolled in ORT. Drug screens and PDMP assessments are commonly used to mitigate the potential risk of misuse and diversion associated with ORT. Quarterly random drug screens and PDMP assessments were implemented for patients enrolled in ORT in an office-based setting in Dallas, Texas. In this setting there are three clinicians. Data collected included the number of drug screens and PDMP assessments. Retrospective data included 60 chart reviews for data before intervention, and 64 charts after intervention. The frequency of drug screenings and PDMP assessments were measured using a Monitoring Score. The six-month study period was April 1, 2015 to September 30, 2015. Charts met criteria for inclusion if the patient enrolled in ORT was in maintenance treatment, diagnosed with
opioid use disorder, and at least 18 years of age or older. Charts were excluded if the patient was enrolled in induction ORT, hospitalized during the study period, or under the age of 18 years old.

Clinicians demonstrated a significant increase in the number of drug screens and PDMP assessments post protocol implementation. Prior to implementing the protocol, 68% of patient charts showed a Monitoring Score of 0, indicating no record of drug screens or PDMP assessments. Post implementation, there were no charts reviewed that reflected a Monitoring Score of 0 reflecting a significant increase in drug screens and PDMP assessments. In fact 80% of the charts had a Monitoring Score of 3 or higher, with 4 being maximum assessment possible.

The Opioid Use Disorder Protocol served as a tool to engage clinicians in a comprehensive ORT treatment plan that promotes safe prescribing. The QI project suggests that implementing a guideline for the frequency of drug screenings and PDMP assessments is an effective way to reinforce clinician behavioral change in managing the potential risk of ORT. DNP scholarly projects using quality improvement initiatives are significant contributions to nursing practice and improving health outcomes. This protocol has made a positive impact on clinician practice; clinicians report that the protocol improved the quality of care provided at Live Oak Counseling.
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“Opioid use disorder, like all substance use disorders, is a chronic illness for which there is no cure” (Sharfstein & Olsen, 2014). According to the Center for Substance Abuse Treatment (2005), opioids have been widely used for pain management since the early 1800s. By the 1900s, opioids were linked to increased rates of death, hepatitis, criminal behavior, and 300,000 reported cases of addiction (CSAT, 2005). Approximately 15% of individuals treated with opioids for pain management also report addiction to prescriptive medications (Hojsted, Nielsen, Gulstrand, Frich, & Sjogren, 2010). The use of opioids over the years has evolved into concerns of safety, diversion, and a substantial concern for opioid use disorder. In 2012, 2 million Americans reported prescriptive opioid misuse use while an additional 467,000 reported an addiction to heroin (National Institute on Drug Abuse, 2014).

Although opioid use disorder was managed with opioids in the early 1800s, abstinence was the preferred approach to treatment (Sharfstein & Olsen, 2014). Due to the variations among treatment approaches and recommendations among organizations, the treatment of opioid use disorder has been a topic of great controversy (Sharfstein & Olsen, 2014). Many felt recovery was simply a choice to abstain from opioid use and not a medical illness (Sharfstein & Olsen, 2014). The controversy of treating opioid use disorder, as a medical illness is that medication management simply replaces one drug addiction for another. In 1919, the United States Supreme Court ruled that opioid use disorder was not a disease and those who suffered were not patients (CSAT, 2005). Opioid use disorder was not considered a medical condition at this time; it was considered a sign of weakness (Sharfstein & Olsen, 2014).
Opioid use disorder is an epidemic that has a devastating impact on public health, morbidity and mortality, and the escalating economic burden of healthcare (U.S. Department of Health & Human Services, 2013). Opioids attach to receptors found in the brain causing responses of reduction in pain, euphoria, sedation, and respiratory depression (Kosten & George, 2002). Chronic use of opioids can cause the development of abnormalities in the brain that increase risk of developing tolerance or addiction (Kosten & George, 2002). Continued use of opioids can contribute to memories of intense feelings of pleasure causing increased motivation for repeated use (Kosten & George, 2002). Repeated exposure also produces tolerance, requiring higher amounts of opioids to induce the same pleasurable effect. Changes in the brain that reduce the ability to use appropriate judgment and create a pattern of impaired control over opioid use are known as addiction (ASAM, 2015a).

Opioid use disorder is characterized by a pattern of opioid use causing significant distress. Diagnostic criteria occur along a continuum of severity ranging from mild to severe (American Psychiatric Association, 2013). A combination of at least two of the following criteria must be met in a 12 month period: (1) taking larger amounts of opioids than intended, (2) unsuccessful attempts to control opioid use, (3) requiring increased amounts of time to obtain opioids or recover from use, (4) desire or cravings of opioids, (5) inability to fulfill personal duties due to opioid use, (6) continued exposure despite effects (7) lack of involvement in previous valuable social or occupational activities due to opioid use (8) opioid use in hazardous situations (9) continued use despite awareness of problem, (10) tolerance, requiring larger amounts of opioids to achieve desired effect

There was a significant breakthrough in the treatment of opioid use disorder in the 1960s with the introduction of methadone (CSAT, 2004). Treatment with methadone for opioid use disorder includes medication management in conjunction with counseling and other social support groups, also known as opioid replacement therapy. Opioid replacement therapy is of great importance given the increase in opioid use disorder and relapse rates with abstinence. The treatment for opioid use disorder was now treated as a medical condition; a treatment approach beyond abstinence that includes medication management (CSAT, 2004). In 1974, the Narcotic Addiction Act limited opioid replacement therapy (ORT) with methadone within an Opioid Treatment Program (CSAT, 2004). Opioid Treatment Programs (OTP) is a highly structured and supervised treatment program that provides psychosocial, medication management, and other support services for the treatment of opioid use disorder. OTPs are federally certified clinics that are contained in a variety of settings including inpatient and intensive outpatient services. OTPs require frequent follow up, in most cases requiring patients to report daily for observed medication dosing and intensive therapy (ASAM, 2010). Research has shown the benefits of ORT in reducing illicit opioid use, reducing associated negative health effects, and enhancing overall physical and psychological recovery (CSAT, 2005). Despite the efficacy of ORT with methadone, there are many barriers to treatment in the OTP setting including limited access to healthcare professionals due to federal regulations. Due to increase in opioid use disorder, the

Another significant breakthrough happened in 2000 with the Drug Addiction Treatment Act. This law permitted "qualifying physicians" to treat opioid use disorder in an office-based setting with Scheduled III-V medications approved by the FDA (SAMHSA, 2014). Buprenorphine was approved for treatment in an office-based setting in 2002; methadone continues to have limitations for treatment in an OTP program (ASAM, 2013). Advance Practice Registered Nurses do not fall under the umbrella of "qualified physicians" and therefore are not able to prescribe medications for the treatment of opioid use disorder. Although APRNs are not "qualified physicians", they provide other parameters of care including education about risk and benefits, guidance during the treatment process, and implement strategies to mitigate potential risk of ORT. Physicians interested in providing ORT with buprenorphine in an office-based setting are required to obtain a Drug Addiction Treatment Act (DATA) 2000 waiver. In order to be granted a DATA 2000 waiver, physicians must meet qualifications such as addiction medication certification, at least eight hours of opioid addiction training, or participation as an investigator in a previous opioid medication trial (SAMHSA, 2014). DATA 2000 waivers limit the treatment of up to 100 patients for opioid use disorder at any one time (SAMHSA, 2014).

Buprenorphine, a partial agonist, is used for ORT in an office-based setting. There are two formulations of buprenorphine; it can be given alone or in combination with naloxone. Because of the ceiling effect, buprenorphine has less misuse potential than full agonist medications such as methadone. Naloxone is an opioid antagonist; it
displaces opioids from receptors thus counteracting the euphoric effects of opioids (Hahn, 2011). The safety profile for the combination buprenorphine is safer because the naloxone component serves as a deterrent for misuse by injection (Hahn, 2011). The risk of misuse for the mono-therapy compound is much higher than the risk associated with combination product (Colson, 2012). The mono-therapy compound can be crushed and injected to experience euphoria and other abusive effects of opioids. Because the naloxone has little sublingual but high intravenous bioavailability, the combination buprenorphine would cause withdrawal symptoms if attempts were made to misuse by taking intravenously (Colson, 2012). In numerous studies, buprenorphine has shown promising benefits of treatment in patients who suffer from opioid use disorder by contributing to adherence to treatment and relapse prevention (Magura et al., 2007).

Problem

Despite the efficacy of ORT in the treatment of opioid use disorder, there is still significant concern about the potential misuse and diversion of buprenorphine (Federation of State Medical Boards, 2013). Misuse, as defined in the Diagnostic and Statistical Manual of Mental Disorder, 5th Edition (DSM-5) (American Psychiatric Association, 2013), includes any use of a prescription medication other than how directed by the health care provider or used by a patient within good medical practice. Diversion is an act that redirects a prescriptive medication from its legitimate purpose of distribution. The challenges of treating patients who suffer from opioid use disorder require a multifaceted treatment plan including medication, support services, and necessary approaches to minimize misuse and diversion. Random drug test and prescription drug monitoring program utilization are two of the most common methods of
monitoring misuse and diversion. The same standards set for drug screening in an OTP do not apply in an office-based setting. In an OTP, federal regulations mandate drug screenings eight times per year, these guidelines are also recommended principles for use in an office-based setting (CSAT, 2005). Currently there are no federal or Texas state regulations mandating a minimum frequency of drug screens or PDMP utilization for ORT in an office-based setting.

Access to the PDMP is available to individual practitioners and pharmacist in each state. As of June 2014, legislative mandates had only been passed in 22 states requiring prescribers to utilize the PDMP (PDMP Center of Excellence, 2014) as a part of their professional practice. In Kentucky, prescribers are required to check the PDMP upon initial prescription and every three months for any Schedule II or Schedule III prescription containing hydrocodone (PDMP Center of Excellence, 2014). Currently, prescribers and pharmacist utilization of the PDMP is voluntary in the state of Texas.

Morbidity and Mortality

The rates of prescriptive and non-prescriptive opioid misuse are on the rise, prescriptive opioids are now responsible for more deaths than all illicit drugs combined (Compton, Boyle, & Wargo, 2015). Mortality rates associated with opioid misuse have escalated significantly. In 2013, 24,000 American deaths were linked to opioid use (Hedegaard, Chen, & Warner, 2015). It is estimated that each case of prescription opioid misuse accounts for two deaths per hour, estimating 17,000 deaths annually (ASAM, 2015a). Hospital admissions and emergency department visits for opioid use disorders are escalating; the most common opioids reported at emergency department visits were oxycodone, hydrocodone, and methadone products (SAMHSA, 2010).
Prescriptive opioid use is considered a major factor in the escalating rates of heroin abuse, 4% of individuals that report prescriptive opioid misuse also report heroin use within five years of utilizing prescriptive medications for the first time (Muhuri, Gfroerer, & Davis, 2013).

Economic Burden

A 2005 study by White, Birnbaum, Mareva, Daher, Vallow, Schein, and Katz found the cost of healthcare for patients who misused opioids were 8 times the cost of those that did not. Annual healthcare cost were estimated at $16,000 for someone who misused opioids compared to $1,800 for someone with no misuse. The higher cost of healthcare is attributed to opioid poisoning, prescriptions, and opioid related healthcare costs. Drug diversion is emerging and contributing to the healthcare economic burden. Diversion comes in many forms; patients can attempt to get pain medication under false pretenses or even attempt to get prescriptions from multiple providers. The estimated costs of opioid diversion were reported above $72 billion, cost is attributed to emergency department visits, hospitalizations, and other medical expenses (Coalition Against Insurance Fraud, 2013).

The psychiatrist at Live Oak Counseling Center in Dallas, Texas has a DATA 2000 waiver to treat opioid use disorder with ORT in an office-based setting. Prior to implementing the quality improvement protocol, a set standard for the frequency of drug screens or PDMP assessments for patients enrolled in ORT did not exist. Clinicians noticed a pattern of request for early refills for some patients enrolled in ORT, while also receiving an influx of calls from pharmacists reporting other patients for "doctor shopping". An assessment of all three clinicians approach in mitigating the risk
associated with ORT displayed inconsistencies among the use of drug screens and PDMP assessments. In addition to the inconsistent routines among clinicians, the continuity of care is another barrier to mitigating associated risk because patients often receive care from different clinicians at Live Oak Counseling. Consulting with the same clinician for follow up can be valuable to the patient and clinician. The patient may feel more comfortable addressing cravings and the possibilities of relapse once they've developed a therapeutic relationship with a clinician. Having a single clinician to manage ORT care can assist the clinician in clinical decision-making and increases insight when patients are requesting early refills or consistently displaying signs of misuse. Drug screens and PDMP data provide valuable information for clinicians to assess misuse and diversion of prescriptive medications. Although current recommendations from national organizations recommendations support implementing drug screens and PDMP assessment, the optimal frequency of testing is unclear. Unfortunately, clinicians often view random drug screens in intensive or initial phases of addiction treatment and not as an approach that can minimize future relapse and help the clinician to make informed decisions (ASAM, 2013).

A quality improvement approach was chosen for the Doctorate of Nursing Practice scholarly project. The quality improvement protocol was implemented in a psychiatric office-based setting over a six-month period. There is one psychiatrist, one psychiatric mental health nurse practitioner, and one physician assistant on staff. Although the PMHNP and PA are not DATA 2000 certified, they are involved in managing patients enrolled in ORT under the certified psychiatrist. There were two aims of the study: (1) establish a standardized approach to utilizing drug screens and PDMP
assessments and (2) initiate a clinician change in behavior to increase safety precautions and decrease potential risk associated with ORT in an office-based setting. The protocol consisted of quarterly random drug screens and PDMP assessments. A chart review was completed at baseline and post protocol implementation for patients enrolled in ORT. All qualified charts were reviewed for the number of drug screens and PDMP assessments. This quality improvement project does not satisfy the definition of "research" under 45 CFR 46.102(d), and therefore this study is not subject to the HHS regulations for the protection of human subjects in research (45 CFR part 46) (UTA Human Subjects Review Committee, April 17, 2015).

Review of literature

Opioids are reported as the greatest threat of diversion in the Medicaid system (CMS, 2012). Random drug screens and PDMP assessments substantially reduce misuse and diversion of opioids and other medications. In a 2012 study (Jain & Pattaanayak), patients enrolled in ORT with buprenorphine in an office-based setting were monitored for non-adherence and diversion by urine drug screens. Results concluded 30% of urine samples showed negative for buprenorphine; it can be assumed that these patients were diverting the buprenorphine. In addition, 50% of the drug screens displayed positive screenings for other non-prescribed medications. In a similar study conducted by Balhara and Jain (2012), 179 drug screenings were completed over a 12-month period for patients enrolled in ORT in an outpatient setting. Approximately 13% of screenings show continued use of opioids, heroine and morphine were two of the medications detected. Approximately 44% failed to detect buprenorphine in the urinalysis indicating noncompliance and potential diversion.
Patients treated in the office-based setting with ORT and at great risk for misuse and diversion. According to Moratti, Kashanour, Lomardelli, and Maisto (2010), 307 participants enrolled in ORT completed a questionnaire on the misuse of ORT medications. Approximately 23% of participant’s who received buprenorphine reported misusing buprenorphine intravenously during ORT. Given the potential risk, the need to implement policies to monitor adherence and mitigate risk is imperative. Surveillance with drug screens and PDMP assessments assist clinicians in making informed decisions. Drug testing is an essential tool in ORT to assess for the presence of illicit or prescriptive medications. Typical drug testing in ORT will test for the following: amphetamine, methamphetamine, barbiturates, benzodiazepines, cocaine, codeine, heroin, marijuana, methadone, opiates, and buprenorphine. The presences or absence of the above medications provide the clinician with objective measures in determining the patient’s progress in treatment. State run PDMP are designed to prevent abuse by offering real-time data on controlled substances filled by patients (Islam & McRae, 2014). By law, pharmacists are required to send records for Schedule II through V prescriptions to the Department of Public Safety (DPS) within seven days of prescription fill date (House Committee on Public Health, 2014). In 2012, this data became accessible to providers and pharmacist online. The PDMP provides clinicians with useful information in assessing potential risk of abuse and diversion of medications prescribed in ORT as well as controlled substances prescribed by other providers.

Implementing strategies to diminish the potential risk and improve outcomes is supported by numerous national organizations. The American Society of Addiction Medicine (2013) released a white paper reviewing the recommendations for drug testing
in the management of substance use disorders. They recommend drug testing no less than on a monthly basis with this population. ASAM notes the importance of random testing policies, even if infrequent, so that patients can understand that there is potential of testing at any time.

The Center for Substance Abuse Treatment published two Treatment Improvement Protocol (TIP) to provide clinicians with scientific based guidance in managing patients and making informed decisions about the use of products containing buprenorphine in the treatment of opioid use disorder. The TIP 40 (CSAT, 2004) provides guidelines for treating opioid use disorder with buprenorphine. TIP 40 (CSAT, 2004) recommendations include drug screenings on a monthly basis. Random drug testing is utilized to confirm the adherence to buprenorphine treatment, address relapse, and reinforce abstinence from other drug use.

Federal guidelines for best practices in the treatment of opioid use disorder in an OTP are contained in the TIP 43, a 387-page document. These federal guidelines are also recommended in other settings including office-based opioid treatment. According to the TIP protocol, a minimum of eight drug screens per year is recommended for patients in treatment for opioid use disorder. Random testing validates patients have remained drug free and promote safe health care.

A Risk Evaluation and Mitigation Strategy is an approach to assist health care providers in managing the potential risk associated with prescriptive medications. The FDA has implemented the Buprenorphine-containing Trans mucosal Products for Opioid Dependency Treatment (BTOD) Risk Evaluation and Mitigation Strategy Program (REMS). The BTODREMS assist clinicians in mitigating risk of overdose, misuse, and
diversion (BTODREMS, 2014). In addition, it informs patients, clinicians, and pharmacist of the risk associated with these products. The BTOD recommends urine drug screening as a measure of treatment goals in opioid replacement therapy. No frequency was defined by the BTODREMS.

Overdose and deaths from buprenorphine containing products are most often associated with concurrent use of opioids, benzodiazepines, and other prescriptive medications. The Federation of State Medical Boards (FSMB) has developed guidelines in regulating the use of buprenorphine products in an office-based setting; this resulted in the Model Policy (FSMB, 2013). This policy is designed to set consistent standards by encouraging state medical boards to adopt the guidelines. Recommendations include regular drug screens and state PDMP assessments to monitor patient’s compliance and abstinence from other drug use. No optimal frequency of drug testing or PDMP assessments was defined.

Project Framework

Treatment of opioid use disorder is complex; health care professionals provide a wide array of resources that are crucial to improving patient outcomes. Quality of care is based on evidence-based practices, which suggest the constant need to make changes and update existing guidelines. According to Weiner (2009), the precursor for the readiness to change is the member’s commitment to change and the confidence in the ability to do so. Although change is a vital component of progression, attempts to do so often fail due to unstructured approaches (Mitchell, 2013). One of the most utilized models for organizational change is Kotter and Cohen’s Model of Change (Melnyk & Fineout-Overholt, 2011). This model provides a series of steps to assist in managing change in
clinicians who treat patients with opioid use disorder. Prior to implementing the Opioid Use Disorder Protocol, management at Live Oak Counseling expressed concerns that could potentially impede the process. Due to these concerns, there was a lack of support from management, which created inconsistent practices from clinicians. One of the many concerns was patient refusal to complete drug screens due to financial reasons. In addition, management endorsed concerns about the lack of resources and support staff to assist in drug screens and lack of access to the PDMP system. Once management felt prepared to handle the potential barriers of change and an understanding of the process, support improved.

The first step of this model was to increase a sense of urgency (Melnyk & Fineout-Overholt, 2011). In creating a sense of urgency, it was imperative that all members of the team recognize the need for change. Prior to implementing the protocol, clinicians endorsed concerns that current practices did not meet recommendations from national organizations by failing to implement strategies to minimize risk associated with ORT. Particularly, failing to complete random drug screenings and PDMP assessments. Clinicians also endorse the awareness that continuing current practices could substantially increase the risk for non-adherence, misuse, and diversion of opioids.

The second step was to build the guiding team (Melnyk & Fineout-Overholt, 2011). Prior to implementing the Opioid Use Disorder Protocol, PDMP assessments were not assessed consistently. Concerns were voiced that clinicians were underutilizing tools, such as the PDMP, to enhance closer monitoring and surveillance of this patient population. All clinicians set up accounts to access the PDMP system and we worked to navigate the system during office meetings. All three clinicians and staff members have
been involved in the process of identifying factors that could help or alter the successful implementation of the new guidelines.

The third step was to define a vision and strategy (Melnyk & Fineout-Overholt, 2011). Although there are no federal or state mandated guidelines on the optimal frequency of drug testing in an office-based setting, it is well known that patients who suffer from opioid use disorder are at significant risk for misuse and relapse. Clinicians are responsible for providing the best care possible to assist patients in achieving the ultimate goal of recovery. All clinicians in the practice collectively endorsed the awareness of the need to improve practices, and the benefit of implementing interventions to mitigate potential risk.

Communicating the vision was the fourth step of Kotter and Cohen’s Change model. Prior to implementing the protocol, there were five meetings with clinicians, administration, and support staff. All employees were accepting of the changes and recognize the need for change. Without support from all employees, change efforts may fail.

The fifth step was to empower and remove potential barriers. Live Oak Counseling Center had several barriers of implementation the protocol. We don’t have the necessary personnel to collect screenings, the restroom is located outside of the suite, and there is no onsite laboratory. Patients were notified at the time of their appointment that they were selected for a random screening. According to the protocol, patients had 24 hours from the time of notification to have the screening completed. Due to the short time span, clinicians decided to give patients the option to report to an outside laboratory such as Quest or Labor, or have an oral swab done at the time of their appointment. The
decision to use the swabs had multiple advantages; the maximum cost of to incurred and
uninsured was $99 compares to $700 if completed at Quest or Labor. Having the option
for onsite screening made the process simple for the patient and cheaper for the
uninsured.

"Short term wins help to demonstrate the viability of change and to build
momentum" (Pollack & Pollack, 2015). The sixth step was to create the short-term win.
After the first round of screening, all employees met to discuss the process. At this time,
recommendations for improvements were made and employees were praised for their
efforts and commitment to change. One of the recommendations for change included
being mindful of reporting drug screen results to the clinician as soon as results were
available. In the past, the standard was to place all screening results in a folder for
clinicians to review at their convenience.

The seventh step was ongoing persistence. After attaining PDMP and toxicology
results, clinicians had to make decisions about plan of care. Impromptu meetings with all
clinicians were held to discuss any unexpected screening results and plans for
interventions. Throughout the process, frequent communication regarding the success of
the screening and frequent reminders about the benefits of the protocol were provided on
a weekly basis.

Last, the eighth step was incorporating the change and making it stick. Live Oak
Counseling Center has already taken steps towards sustaining the guidelines implemented
by the DNP scholarly project. The month of January 2016 has already been set for the
next round of screening. During the month of January, all patients will be notified during
their appointment that they were selected for a random drug screen and PDMP
assessment. It was determined that future screening months will vary so that patients have a sense of randomness. In the future, PDMP assessments will be performed for each new patient, as well as continued quarterly drug screens and PDMP assessments.

**Project Objectives**

A protocol was implemented to assist clinicians in managing patients enrolled in ORT in an office-based setting. The objectives were to: 1) establish a standardized approach to utilizing drug screens and PDMP assessments and (2) increase clinician adherence in managing the potential risk associated with ORT in an office-based setting.

**Project Question**

In patients enrolled in opioid replacement therapy in an office-based setting, did use of an Opioid Use Disorder Protocol increase drug screenings and PDMP assessments?

**Methods and Procedures**

**Project Design**

A protocol was implemented to increase the frequency of drug screens and PDMP assessments to mitigate the potential risk associated with ORT in an office-based setting. The design of the protocol was to implement quarterly drug screening and PDMP assessments. Without establishing a predictable pattern, a month from each calendar quarter was selected for monitoring. The study period was April 1, 2015 – September 30, 2015. The month of May was selected for calendar quarter 2 (April 1, 2015- June 30, 2015) and the month of September for calendar quarter 3 (July 1, 2015- September 30, 2015).
Patients enrolled in ORT are required to present for follow up on a monthly basis. In April 2015, clinicians informed patients enrolled in ORT of the new office contract at their monthly appointment. The contract was reviewed and patients were asked to sign the contract (Appendix A). The contract outlined the requirement of monthly follow up, requirements for therapy or social support services, random drug screens, and PDMP assessments. Patients were also informed of the consequences of not signing the contract, unexpected drug test results and PDMP assessments, and the reason for monitoring patients enrolled in ORT. At May and September follow up appointments, clinicians notified each patient's enrolled in ORT that they had been selected for random drug screening and PDMP assessment. PDMP assessments were completed at the time of the appointment. Patients were notified of the 24-hour time limit to complete drug screens, and then given an option of a urine drug screen at an offsite laboratory or an oral swab in the office at the time of their appointment. At the end of the study period, a retrospective chart review was performed to determine if there was an increase in the frequency of utilizing drug screens and PDMP assessments in each quarter.

Baseline data was determined by performing a retrospective chart review for all qualified patients enrolled in ORT. Baseline data included the number of drug screens and PDMP assessments completed during the same time period in 2014 (April 1, 2014-September 30, 2014). The results comparing frequency of drug screens and PDMP assessments for baseline data (group A) and post implementation (group B) were compared for clinical and statistical significance. Areas of interest were the demographics of the patients included in the study and the unexpected findings before and after the intervention. Age, gender, race, drug of choice, employment status, marital
status, and the number of months in ORT were also collected and analyzed for patients included in the study.

Population and Sampling Plan

The project was conducted in a mental health office-based setting in Dallas, Texas. Inclusion criteria for chart review consisted of patients 18 years or older with a diagnosis of opioid use disorder as defined by the American Psychiatric Association in the Diagnostic and Statistical Manual of Mental Disorder, fifth edition (2013). Patients were enrolled in maintenance treatment for ORT. Maintenance is the phase of treatment in which ORT medications reach steady state, and the patient no longer acts upon the need for relief with opioids or other addictive medications (ASAM, 2015b). Patients were excluded from chart review if they were under the age of 18 years old, undergoing induction treatment, or hospitalized at anytime during the study period. Induction is the phase of treatment in which ORT medication dosages still require adjustments and more frequent monitoring (ASAM, 2015b). There were 60 patients eligible for retrospective chart review at baseline, and 64 patients were eligible post intervention.

Measurement Methods

The Opioid Use Disorder Protocol was implemented on April 1, 2015. All office personnel, support staff, and clinicians were aware of the purpose and significance of the protocol. Prior to initiation, clinicians and staff members were informed of their role during office meetings. The primary goal of the study was to increase clinician use of drug screens and PDMP assessments to manage the potential risk associated with ORT in an office-based setting.
Each patient chart was reviewed at baseline and post protocol. Each chart was scored on a scale of 0 to 4 by using the Monitoring Score. The Monitoring Score was based on the number of documented drug screens and PDMP assessments completed during the study period. Each drug screen or PDMP assessment was measured as 1 point. If a clinician documented a May drug screen (Q2DS), May PDMP assessment (Q2PDMP), September drug screen (Q3DS), and September PDMP assessment (Q3PDMP), the chart was given a 4 point monitoring score. If the clinician documented a Q2DS and Q2PDMP only, the chart was given a monitoring score of 2.

The Opioid Use Disorder Flow Sheet (Appendix B) was developed for clinician’s documentation during the study duration. The flow sheet was placed in each qualified patients chart. During the selected quarterly months of the study, the role of the clinician was to inform the patient that they were selected for a random drug screen and PDMP assessment. Using the flow sheet, the clinician was to document the date of patient notification of drug screen and PDMP assessment, the actual date of drug screen, date PDMP assessment completed, and whether the drug screen or PDMP assessment produced unexpected findings.

The office manager served as the research assistant. The research assistant collected demographic data on patients included in the study with the Demographic Data Tool (Appendix C). Demographic data included age, gender, race, drug of choice, employment status, marital status, and the number of months in ORT treatment. The research assistant also collected baseline data during the retrospective chart review using the Baseline Data Collection Tool (Appendix D). Baseline data included the number of
drug screens and PDMP assessments completed from April 1, 2014 - June 3, 2014 (quarter 2) and July 1, 2014- September 30, 2014 (quarter 3).

**Data Collection**

According to the University of Texas at Arlington’s Institutional Review Board (UTA Human Subjects Review Committee, April 17, 2015), this quality improvement project did not satisfy the definition of “research” under 45 CFR 46.102(d), and therefore was not subject to the HHS regulations for the protection of human subjects in research (45 CFR part 46). The owner of Live Oak Counseling Center provided a letter of support of the DNP scholarly project to be implemented within the practice (Appendix E).

The research assistant completed all data collection. The data collection process (Appendix F) consisted of (1) assigning patient codes for confidentiality purposes, (2) collection of demographic data using the Demographic Data Tool, (4) collection of baseline data using the Baseline Data Tool, (5) placing the Opioid Use Disorder Flow Sheet in each qualified patient chart, (6) clinicians documented on the Opioid Use Disorder Protocol Flow Sheet during the study period, (5) at the end of the study period, a duplicate copy of each protocol was made and labeled with the patient codes (6) the de-identified Demographic Data Tool, Baseline Data Tool, and duplicate copy of the Opioid Use Disorder Flow Sheet were then given to the DNP student for analysis. The research assistant retained the list of patient names and matching patient codes.

**Data Analysis**

The data from the Demographic Data Tool, Baseline Data Tool, and Opioid Use Disorder Flow Sheet was entered into an excel program and analyzed in SPSS for analysis. Descriptive data statistics were utilized to analyze the data from the DNP
Scholarly Project. The frequency of drug screens and PDMP assessments at baseline (Group A) and post protocol implementation (Group B) were compared to determine clinical and statistical significance using the Mann Whitney U test.

The results comparing the frequency in drug screens and PDMP assessments between group A and group B were clinically and statistically significant. Statistical significance indicating the increased frequency and PDMP assessments was unlikely due to chance, and due to the implementation of the Opioid Use Disorder Protocol.

Project Limitations

There are several limitations in the study. The first limitation is the short 6-month study time period. Longer study duration could measure change over an extended period of time, providing data about the sustainability of the protocol within this setting. Another limitation of the study was the small sample size. A small sample size can produce a negative impact on the ability of the study to detect a true effect. The results increase risk of type I and type II errors versus a study with a larger sample size. In spite of the small sample size, the study produced clinical and statistical significance in adherence to the protocol.

The third limitation is that the DNP student/researcher was one of the clinicians being monitored in the study. Knowledge of the study may have led to a change in behavior of the DNP student to adhere to the protocol. A possible control for this bias would be to analyze frequency of drug screen and PDMP assessments for each clinician by comparing pre intervention and post intervention data.

Clinicians at Live Oak Counseling complained of the amount of time needed to assess the PDMP and perform the oral swab. Due to time limitations of a 15-minute
follow up appointment, it was difficult to perform the oral swab and PDMP assessment in addition to assessing for treatment concerns and educating about the possible side effects and symptoms associated with ORT. Clinicians also complained of the excessive paper usage when printing out a copy of the PDMP to add to the chart for future reference.

**Results/Findings**

Of the 71 patients enrolled in ORT at Live Oak Counseling, 60 charts met inclusion criteria for Group A, baseline retrospective chart review. Group A consisted of patients enrolled in maintenance ORT from 4/1/2014 - 9/30/2014, without hospitalization, who were 18 years of age or older. There were 64 charts that met inclusion criteria for Group B, post intervention chart review. Group B consisted of patients enrolled in maintenance ORT from 4/1/2015 - 9/30/2015, without hospitalization, and 18 years of age or older.

The Monitoring Score was assessed for each group (Appendix G). The Monitoring Score range was from 0-4, with 4 being the highest level of patient monitoring and 0 being the worst. Group A reflected a Monitoring Score of 0 in 65% of chart reviews, indicating there were no drug screens or PDMP assessments for 39 of the 60 chart reviews between April 1, 2014 – September 30, 2014. Of the 60 charts reviewed, a Monitoring Score of 1 was reflected in eight, 2 in ten of the chart reviews, 3 in two of the chart reviews, and only one chart reflected a Monitoring Score of 4 for Group A. Of the 64 chart reviews in Group B, there were no cases of Monitoring Scores of 0 or 1. The Monitoring Score was a 2 in 13 of the chart reviews, 3 in 12 of the chart reviews, and a Monitoring Score of 4 in 39 (61%) of the 64 charts. According to the Mann Whitney U test, there is a 99.9 % confidence that the test was statistically
significant. There is a difference in the Monitoring Scores (drug screens and PDMP assessments) pre and post intervention; therefore the null hypothesis is rejected.

Other areas of interest include unexpected drug screens and PDMP findings. Expected drug screens showed evidence of buprenorphine, naloxone, and other medications known by the prescriber. Unexpected drug screens showed evidence of taking substances unknown by the clinician, negative for buprenorphine and naloxone, or any substance prohibited in ORT treatment such as opioids or other substances. If a participant had an unexpected drug screen due to undetected buprenorphine or naloxone levels, the clinician assumed the patient was diverting the ORT medication.

Post protocol implementation (Group B); there were 5 unexpected drug screens and 7 unexpected PDMP assessments in Q2. There were 3 unexpected drug screens and 5 unexpected PDMP assessments in Q3 (Table 1). Each patient was questioned regarding the unexpected drug screen or PDMP assessment. Patients were counseled about the health risk of taking other medications while in ORT, informed that they would be monitored more frequently, reminded of their ORT contract agreement, and warned that their ORT treatment agreement would be terminated if they failed to comply with the ORT contract. There were two patients with evidence of cocaine and heroin use. One patient was referred to an intensive outpatient program; the other was referred to a higher level of care and terminated from care at Live Oak Counseling. The patient was terminated because he had previously been given a warning regarding unexpected drug screen findings.
Another area of interest is the demographic data for patients enrolled in ORT.

Demographic data for Group A and Group B were analyzed to determine if significant differences exist between the two (Appendix H). Group A consisted of $n = 34$ (57%) males and $n = 26$ (43%) female compared to Group B which had $n = 38$ males (59%) and $n = 26$ (41%) females. Ethnicity of Group A was $n = 54$ (83%) White/Caucasian, $n = 3$ (5%) African American, $n = 2$ (3%) Asian, and $n = 5$ (9%) Hispanic. Group B ethnicity consisted of was $n = 54$ (85%) White/Caucasian, $n = 2$ (3%) African American, $n = 2$ (3%) Asian, and $n = 6$ (9%) Hispanic. The average age for both Group A and B was 43 years of age. Drug of choice for Group A consisted of hydrocodone for $n = 39$ (65%), oxycodone for $n = 9$ (15%), and heroin $n = 12$ (20%). Group B consisted of hydrocodone for $n = 43$ (67%), oxycodone for $n = 9$ (15%), and heroin for $n = 11$ (17%). Marital status for Group A reflected $n = 22$ (37%) married and $n = 38$ (63%) unmarried while Group B reflected $n = 22$ (34%) married and $n = 42$ (66%) unmarried. Employment status for Group A was $n = 55$ (925) employed, $n = 3$ (5%) unemployed, and $n = 2$ (3%) retired compared to group B $n = 60$ (94%) employed, $n = 3$ (5%) unemployed, and $n = 1$
(1%) retired. Months enrolled in ORT treatment averaged 50 for Group A and 46 for Group B.

Discussion

Although national, state, and community public health agencies have assisted in great strides to provide access to care; overall quality of care to mitigate risk requires further development. Treatment for opioid use disorder in an office-based setting should have detailed policies and procedures to govern the implementation of minimal frequency of drug screening and PDMP utilization. Implementing these policies will contribute to the safety and benefits of ORT. This study serves as guide for quality improvement to enhance current guidelines for close monitoring of patients who are high risk for misuse or diversion.

This quality improvement study was based on federally regulated guidelines for generally accepted practices in an ORT, specifically OTPs. OTPs must provide testing and analysis for potential drugs of abuse including drug screens at least eight times per year (CSAT, 2005). The implementation of the DNP project serves as an essential step in identifying the clinical need to develop more comprehensive approaches in mitigating risk and improves quality of care in this challenging patient population.

Conclusions

After the implementation of the Opioid Use Disorder Protocol, there was a significant increase in the frequency of drug screens and PDMP assessments for patients enrolled in ORT. When drug screens and PDMP assessments are completed in random intervals, patients are unable to detect potential screenings. Knowing the potential of
random testing may deter patients from misuse and diversion. These random approaches can increase compliance to treatment and help patients achieve long-term abstinence.

In the cases of unexpected drug testing or PDMP results, counseling, further assessment, and interventions including referral to higher level of care were implemented. Patients were educated about the risk of opioid misuse in ORT, alternative treatment options when necessary, and the consequences of future care at Live Oak Counseling on repeated offense. Suspension of treatment was not considered on a first offense of unexpected drug screening or PDMP assessment. Patients were informed that the response to a second unexpected result would result in referral to a higher level of care and termination of services at Live Oak Counseling.

**Implications**

**Practice Implications**

The treatment of opioid use disorder requires a multi-faceted approach. Further research, including an extension of this study should be considered to analyze patient adherence to treatment and relapse rates. The six-month study time frame limited the ability to analyze long-term changes. Future studies over an extended period of time should be studied to detect recovery rates, particularly for chronic illness such as opioid use disorder.

Clinicians at Live Oak Counseling have requested to continue minimum quarterly drug screens and PDMP assessments and have verbalized the benefits to the patient’s safety and outcomes of care. Clinicians have already made recommendations to improve the protocol to enhance sustainability. The project reminded the clinicians of the significance of monitoring and mitigating potential risk in this population.
Although “qualified physicians” do not include APRNs, APRNs play a vital role in the treatment of opioid use disorder. In 2010, the Institute of Medicine released a statement recognizing the barriers that access to care presents and promoted the ability of APRNs to practice to the full extent of their educational training and scope of practice (IOM, 2010). Extending prescriptive authority of buprenorphine products to APRNs is an essential tool in increasing access to care for patients who suffer from opioid use disorder. If prescriptive privileges are extended to APRNs, future studies are needed to compare patient outcomes for current “qualified physicians” and APRNs. The International Nurses Society on Addictions (IntNSA) supports the amendment of the DATA 2000 to include APRNs as qualified practitioners to prescribe buprenorphine products (Strobbe & Hobbins, 2012). Extending the waiver to APRNs increases access to treatment that has shown significant improvement in outcomes for patients who suffer from opioid use disorder. In order to implement changes to improve the epidemic of opioid use, senators have introduced The Recovery Enhancement for Addiction Treatment (TREAT) Act. ASAM has given full support to both SB1455 and HB 2536 to increase access to care for ORT by extending APRNs the eligibility of receiving the waiver and certification to treat opioid use disorder (Zussman-Dobbins, 2015).

Policy Implications

The misuse and diversion of medication in this patient population is of great concern, and reasonable monitoring strategies should be implemented to prevent such behavior. Although structure and rigor in an office-based setting is less than that in an OTP, rigor to mitigate the potential risk associated with ORT should be comparable to the care provided in OTPs. A change to a minimum acceptable frequency of drug testing
and PDMP assessment for the treatment of opioid use disorder in an office-based setting is necessary. Insurance companies, pharmacies, and, office-based settings can use many approaches to reduce the incidence of mitigating risk, including on a federal level. Regardless of the approach, a system of universal precautions is an essential component to improving the chance of recovery.

There is a tremendous amount of evidence supporting the value of PDMPs as one of the most valuable tools in mitigating risk of opioid misuse (Islam & McRae, 2014). Currently, there are mandates in 22 states to utilize the PDMP, however, Texas is not one of them (Islam & McRae, 2014). Legislative mandates for registration and utilization for PDMP utilization have been adopted in many states: however, Texas is not one (PDMP Center of Excellence, 2014). Prescribers in the state of Kentucky are required to access the PDMP upon initial prescription and every three months for any Schedule II or Schedule III prescription containing hydrocodone (PDMP Center of Excellence, 2014). State and federal polices should be implemented to address the potential risk associated with opioid use disorder. PDMP data is limited to controlled substances filled in state. Although helpful, drug misuse and diversion often cross state lines. Visibility and sharing data among states can decrease the potential associated with controlled substances.
References


Federation of State Medical Boards. (FSMB, 2013). Model policy on DATA 2000 and


Muhuri, P. K., Gfroerer, J. C., & Davies, M. C. (2013). Associations of nonmedical pain reliever use and initiation of heroin use in the United States CBHSQ [Center for Behavioral Health Statistics and Quality]


APPENDIX A: Opioid Use Disorder Treatment Contract

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<thead>
<tr>
<th>Initial</th>
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<td><strong>Appointments</strong></td>
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<td><strong>Monitor Use</strong></td>
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<td><strong>Termination of Contract</strong></td>
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Patient Signature
Witness Signature

Date:
Date:
APPENDIX B: Opioid Use Disorder Flow Sheet

Patient Code Number: __________

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<th>Clinician Initials</th>
<th>Date of Drug Screen Notification</th>
<th>Date PDMP Checked</th>
<th>Date of Actual Urine Screening</th>
<th>Abnormal Urine Screen Y=1 N=0</th>
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## DEMOGRAPHIC DATA SHEET

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<th>EMPLOYMENT STATUS</th>
<th>MARITAL STATUS</th>
<th>MONTHS IN TREATMENT</th>
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# 2014 BASELINE DATA FLOWSHEET

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Patient Code Number: __________
BARRY J. FENTON, M.D., P.A.
LIVE OAK COUNSELING CENTER, LLC

3710 RAWLINS, STE 1370 □ DALLAS, TX 75219 □ PH # 214-520-7575 □ FAX # 214-520-7579
BJFENTONMD@LIVEOAKCOUNSELING.com

May 4, 2015

RE: Kimberly Colon Thompson – DNP Student
Research Project

Dear Members of the University of Texas at Arlington Institutional Review Board:

Ms. Colon Thompson is currently conducting an investigation into clinician adherence to a protocol designed to manage patients with opioid use disorder at Barry J. Fenton, M.D., P.A. dba Live Oak Counseling Center, LLC. For simplicity these entities will only be referred to as Live Oak Counseling Center, LLC in this document.

Live Oak Counseling Center agrees to provide assistance to collect information using a data collection tool that is unidentifiable to any patient.

Live Oak Counseling Center, LLC is aware that the student may have access to the clinical information of a patient in her investigation when she is conducting assigned clinical duties at the office. She will be unable to cross reference the known patient information with the investigation assigned subject code.

Live Oak Counseling Center has reviewed all applicable HIPAA rules and regulations with Ms. Colon Thompson.

Live Oak Counseling Center, LLC releases: Kimberly Colon Thompson, and University of Texas in Arlington from any acts while participating in the investigation as long as proper HIPAA rules and regulations are followed.

Do not hesitate to contact me if any further information is required.

Sincerely,

Barry J. Fenton, M.D.

Susan B. Fenton, Office Manger
APPENDIX G: Monitoring Score

Before Intervention

After Intervention
APPENDIX F: Data Collection Process

Step 1
- Research assistant assign patient codes for confidentiality

Step 2
- Collection of demographic data using the Demographic Data Tool

Step 3
- Collection of baseline data with Baseline Data Tool

Step 4
- Place Opioid Use Disorder Protocol Flow Sheet in charts

Step 5
- Clinicians document on Opioid Use Disorder Protocol Flow Sheet during May study time

Step 6
- Clinicians document on Opioid Use Disorder Protocol Flow Sheet during September study time

Step 7
- Deidentify each data collection tool by labeling with the patient codes

Step 8
- Research assistant gave de-identified Baseline Data Tool, Demographic Data Tool, and Opioid Use Disorder Protocol Flow Sheets to DNP student for data analysis
APPENDIX H: Demographic Findings

**Demographics**

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