DEVELOPMENT AND EVALUATION OF A NURSE PRACTITIONER-DIRECTED BUPRENORPHINE DIVERSION PREVENTION PROTOCOL IN PRIMARY CARE

An Evidence-Based Scholarly Project

Submitted to the College of Health Professions

in Partial Fulfillment of the

Requirements for the Degree

Doctor of Nursing Practice

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Wilmington University

August 2021

Wilmington University
College of Health Professions
Doctor of Nursing Practice Program

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Title: Development and Evaluation of a Nurse-Practitioner Directed Buprenorphine Diversion Prevention Protocol in Primary Care

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BACKGROUND: In the effort to increase access to buprenorphine during the worldwide opioid epidemic, primary care providers were on the frontline in treating opioid addiction in primary care settings. Consequently, increased access to buprenorphine in office-based settings had increased the rate of diversion. Performing routine urine drug testing can be a vital clinical tool for monitoring compliance with prescribed therapy; however, many patients conceal their diversion of buprenorphine by tampering with their urine specimens. Quantitative testing can identify adulteration or non-compliance by analyzing the levels of buprenorphine and norbuprenorphine. METHODS: Data were extracted from records of patients enrolled in buprenorphine treatment at Tri-State Health Inc. Participants completed a diversion risk survey one week prior to the implementation of utilizing quantitative urine drug screening test and provided urine samples during each office visit. INTERVENTION: Four providers ordered quantitative urine drug screening tests to analyze both buprenorphine and norbuprenorphine levels to identify diversion and results were compared with routine qualitive buprenorphine drug screenings during each office visit over the six-week project time frame. A total of 240 urine specimens were collected from the 40 participants during the six-week project. RESULTS: Responses indicated that 32% (n = 16) reported taking less Suboxone than prescribed, 8% (n = 4)

diverted medication to a friend or relatives and 6% (n = 3) sold their Suboxone for money. Two-hundred and forty urine specimens were collected from 40 participants and included in the DNP project. Data collected from qualitative buprenorphine screenings and quantitative bup/norbup urine drug tests were analyzed using a binomial logistic regression indicating that performing buprenorphine screening only, 159/240 urine drug screenings were correctly classified and had positive norbuprenorphine quantitative values. Seventeen urine specimens were misclassified and had negative norbuprenorphine quantitative results, indicating 7% were diverting. CONCLUSION: Without the use of quantitative urine drug tests, clinicians are missing the opportunity to do the following: (a) prevent diversion, (b) reduce overdose, opioid-related death rates, (c) improve patient outcomes, and (d) reduce crime and overall costs associated with addiction treatment.

Keywords: buprenorphine, diversion, quantitative urine drug screening, primary care

ACKNOWLEDGMENTS

First and foremost, I would like to thank God for giving me the strength, endurance, and courage to fulfill my dream. Next, I would like to acknowledge and thank my DNP project mentor, Dr. Muhammed Niaz of Tri-State Inc. for his expertise, support, valuable insight, and collaboration throughout this journey. In addition, I would like to thank the staff of Tri-State Health Inc. for their assistance with the DNP project. To my project team member, Kaleem Ahmed, I deeply appreciate all the dedication and long hours you demonstrated by working diligently in the laboratory to ensure that data were collected in a timely manner and reviewed for accuracy. Kaleem, I thank you for your wisdom, words of encouragement, and your desire for my success with the DNP project.

In addition, I would like to thank my other team members, including providers and medical assistants, for their support. To my project faculty advisors, Drs. Barbara Sartell and Joanne Fletcher, thank you both for your assistance, encouragement, and dedication to the nursing practice. I would also like to thank you both for your advice, feedback, and eagerness for my success with the project. Dr. Fletcher, I would like to especially thank you for the positive motivational quotes that you posted in our weekly announcements. On days when I felt like giving up, your inspirational quotes resonated and encouraged me to keep going.

To Dr. Brandon Kyle Johnson, thank you for sharing your knowledge and expertise in statistics and data analysis. Dr. Johnson, your assistance in performing data analysis and statistics was integral in discovering the clinical significance of the DNP project. To the DNP Program Chair, Dr. Aaron Sebach and Wilmington University

faculty, I thank you for your support, encouragement, and inspiration. Throughout this journey, I have transformed into a scholar, gained valuable knowledge, and enhanced leadership skills that will allow me to make a difference in nursing practice.

To my colleagues of Cohort 16, I deeply appreciate your support, collaboration, and encouragement which has helped me grow professionally. Last, I would like to especially thank my son, Tyelle Murphy for being understanding and patient. I am grateful for the support, love, and encouragement you have provided throughout this journey. To my family and friends, thank you for being my support system.

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ABBREVIATIONS

CDC	Center for Disease Control and Prevention
CNS	Central Nervous System
BUP	Buprenorphine
DATA	Drug Addiction Treatment Act
DAWN	Drug Abuse Warning Network
DEA	Drug Enforcement Administration
DNP	Doctor of Nursing Practice
EBP	Evidence-Based Practice
FDA	Food and Drug Administration
IRB	Institutional Review Board
IV	Intravenous
MAT	Medication-Assisted Treatment
NORBUP	Norbuprenorphine
OUD	Opioid Use Disorder
OTP	Outpatient Treatment Programs
PICOT	Population, Intervention, Comparison, Outcome, and Time
QI	Quality Improvement
SAMHSA	Substance Abuse and Mental Health Administration
UDT	Urine Drug Test
UDS	Urine Drug Screen

CHAPTER I. INTRODUCTION

Problem Description

The opioid crisis is a national public health issue that has caused major devastation and economic burden in the United States. Approximately 450,000 people died in the United States from drug overdoses involving opioids from 1998-2018 (Center for Disease Control and Prevention [CDC], 2020). Currently, there are approximately 2.1 million people with opioid use disorder (OUD) in the United States. Every day, approximately 130 people die from an opioid overdose in the United States (Wolfe & Gold, 2017). In the year 2000, The Drug Addiction Treatment Act (DATA) a bill that allowed clinicians to complete the X waiver training to become certified to prescribe buprenorphine for the treatment of addiction was passed.

The DATA 2000 Act was implemented to improve access to opioid use disorder treatment by allowing physicians, nurse practitioners (NPs), and physician assistants (PAs) to prescribe buprenorphine in primary care or office-based settings other than inpatient rehabilitation centers or outpatient treatment programs (OTPs). In October 2002, two buprenorphine-containing products (Suboxone and Subutex) were approved by the Food and Drug Administration (FDA) for the treatment of opioid addiction (Drug Enforcement Administration [DEA], 2019). Buprenorphine is a highly effective opioid receptor partial agonist drug which is first line in treating opioid addiction in the primary care or office-based settings (Cicero et al., 2018). Additionally, buprenorphine is advantageous for alleviating cravings and symptoms of withdrawal in individuals with opioid use disorder (Weigand, 2016). Buprenorphine's pharmacodynamics blocks the action of other opioids at the mu receptor, which prohibits opioid-induced euphoria and

prevents central nervous system (CNS) and respiratory depression (Weigand, 2016). Comparable to many prescription drugs, buprenorphine is subject to diversion, misuse, and abuse (Chilcoat et al., 2019). Hence, the diversion of buprenorphine is higher amongst high-risk populations such as individuals with opioid use disorder and intravenous drug use (Chilcoat et al., 2019). Subsequently, the availability of buprenorphine in the primary care setting has increased access to opioid dependence treatment.

Significance of Problem

Opioid substitution therapy with buprenorphine in the primary care and office-based setting has been efficacious in treating addiction since it was approved by the U.S. Food and drug Administration (FDA) in 2002 (Chilcoat et al., 2018). According to the National Prescription Audit Plus, 9.1 million buprenorphine prescriptions were dispensed in the United States in 2012 and has drastically increased over the years (DEA, 2019). For example, during the height of the opioid crisis in 2017, 14.6 million buprenorphine prescriptions were written, and 15.9 million prescriptions were sold to patients in 2017 (DEA, 2019). Unfortunately, the diversion of buprenorphine in the primary care setting is becoming a complex health issue affecting the management of individuals with opioid use disorder in the primary care setting and society. The Drug Abuse Warning Network (DAWN) estimated 21,483 emergency department visits were associated with nonmedical use of buprenorphine in 2011 (DEA, 2019).

According to the Substance Abuse and Mental Health Services Administration (SAMHSA, 2017), 31.1% of individuals receiving buprenorphine reported diversion of their prescribed medication. In the primary care setting, routine administration of urine drug screening tests are utilized to monitor medication adherence, illicit drug use, or relapse. Although urine drug tests are beneficial for monitoring compliance, due to unmonitored specimen collection, tampering and adulteration is prevalent in the primary care setting. A common method of tampering is called "spiking" which is the adulteration of a urine drug test specimen with a small portion of unused buprenorphine film or tablet (Accurso et al., 2017). This stratagem will result in a positive result on a qualitative buprenorphine drug screen, creating an illusion of adherence to opioid substitution treatment (Accurso et al., 2017).

Quantitative urine drug screening of buprenorphine and its metabolite norbuprenorphine is underused in the primary care setting due to prohibition cost (Suzuki et al., 2017). Analyzing the quantity of both buprenorphine and norbuprenorphine levels allows the clinician to identify buprenorphine adherence from cases of urine spiking (Suzuki et al., 2017). Buprenorphine is metabolized by the hepatic P450 CYP3A4 into the metabolite norbuprenorphine which stays in the body for longer periods (Accurso et al., 2017). Therefore, urine spiking will raise buprenorphine levels significantly but not norbuprenorphine levels (Suzuki, et al., 2017).

Diversion presents a significant problem for healthcare providers, policymakers, and other individuals receiving treatment for opioid use disorder (Reimer et al., 2016).

Additionally, diversion negatively impacts the individual's recovery from addiction, treatment outcomes, and public health (Reimer et al., 2016). By identifying individuals who divert buprenorphine in the primary care setting, providers can offer buprenorphine containing products such as the Sublocade injection or the Vivitrol injection for the treatment of opioid use disorder as an alternative from office termination. New concepts such as the use of long-acting monthly buprenorphine injections (Sublocade) or Vivitrol can help prevent the diversion of buprenorphine in the primary care setting (Nunes, 2018).

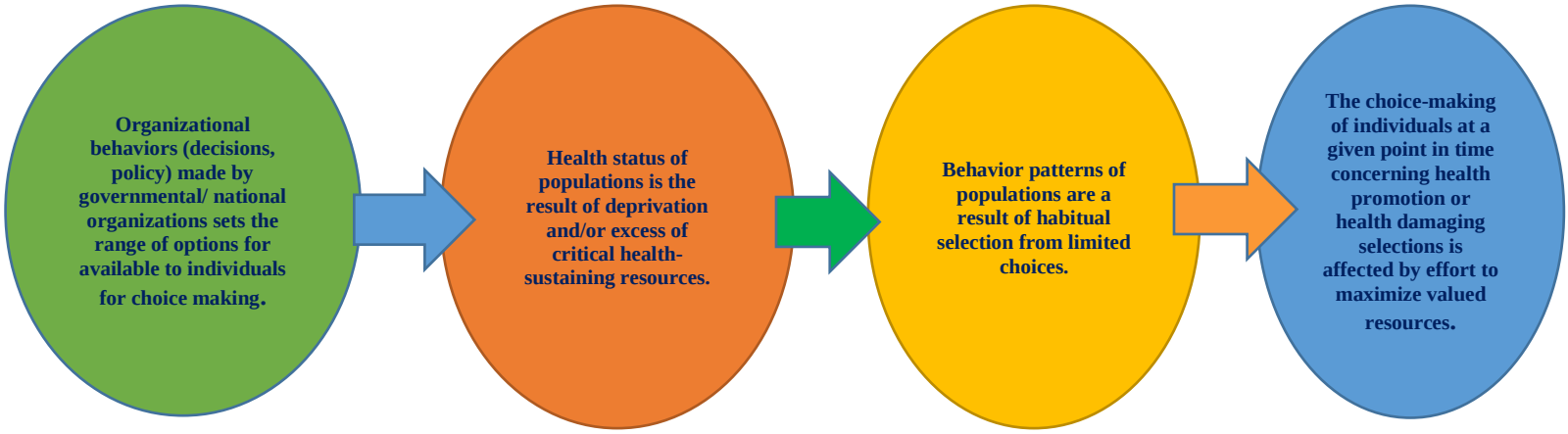
Rationale

Theoretical Framework

According to Moran et al. (2017), the theoretical framework is essential to guide and inform the DNP project. Therefore, Nancy Milio's (1976) framework for prevention will be utilized to define the key concepts of this quality improvement project (Figure 1). Milio's framework incorporates concepts of community-oriented and population-focused care. According to Milio (1976), behavioral patterns of populations and individuals who make up the population are a result of habitual selection from limited choices and lack of knowledge. Hence, the population's health status at a given point in time is considered a result of long-continued personal choice making (Milio, 1976). Individual choices are limited by both perceived and actual options available to the individual depending on personal and community resources (Milio, 1976).

Figure 1

Milio's (1976) Framework for Prevention



Milio (1976) proposed that the health status of populations is the result of deprivation and or excess of critical health-sustaining resources. Consequently, in most cases, people will develop patterns or lifestyles, which appear to cost less and from which they may gain more of what they value in tangible and intangible terms (Milio, 1976). Therefore, to implement an effective intervention to prevent buprenorphine diversion in the primary care setting, it is imperative to fully understand the reasons why some individuals divert their medication. Milio suggests that individual choice making concerning potential health-promoting or health-damaging selections is affected by a person's effort to maximize valued resources. For example, the choice is related to the individual's personal resources, awareness, knowledge, beliefs, skills, family, friends,

finances, convenience concerning distance, transportation, and urgency of other priorities (Milio, 1976).

Besides, societal resources such as the availability of health-sustaining services and costs, distance or location, and program outreach components can also affect individual choices (Milio, 1976). Individuals who reported prescription diversion indicated that they gave their prescribed buprenorphine to a friend, family member or partner, or saved some of their medication because they did not need the entire prescribed dose (Chilcoat et al., 2019). Given this knowledge, implementing the use of quantitative buprenorphine and norbuprenorphine urine drug screening testing to identify diversion seems as if it would benefit this organization. Quantitative testing of urine specimens is a feasible but underused method of identifying non-compliance and diversion in office-based addiction treatment clinics in the primary care setting (Suzuki et al., 2017). Primary care providers can diminish health-damaging options for a high-risk patient receiving treatment for opioid use disorder by utilizing long-acting buprenorphine injections to prevent prescribed diversion.

Diversion worsens stigma in our society and perpetuates negative beliefs about opioid substitution treatment with medication such as buprenorphine (Wakeman & Rich, 2018). The prevention of buprenorphine diversion in the primary care setting not only improves the health outcome in the individual receiving treatment but it also impacts the health of the community.

PICOT Question

Scholarly and clinical inquiry guided the search stratagem to develop the following PICOT question: In primary care providers prescribing buprenorphine, how does monitoring the quantification of buprenorphine and its metabolite norbuprenorphine levels in urine drug screenings versus standard qualitative immunoassay drug screenings affect the identification of buprenorphine diversion within a six-week period? The population (P) of this project included adults aged 18 to 65 with a history of IV heroin/fentanyl use, who were receiving buprenorphine (Suboxone films only) for the treatment of opioid addiction in the primary care setting. The intervention (I) consisted of performing quantitative urine drug screenings to buprenorphine and norbuprenorphine levels. The comparison (C) was the standard qualitative immunoassay urine drug screening test. The outcome (O) was the analysis of the quantification of buprenorphine and norbuprenorphine levels to identify if patients were noncompliant with taking their prescribed medication, which was indicative of diversion of Suboxone. The time (T) of this project was during a six-week period.

Specific Aims

The specific aim of this quality improvement project was to implement the use of the quantitative buprenorphine and norbuprenorphine urine drug screening tests to identify patients who divert their prescribed buprenorphine within a six-week period. This project included 40 participants, ages 18 to 65, with a history of intravenous opioid use, currently receiving buprenorphine for the treatment of opioid use disorder in the primary care setting.

Quantitative urine drug screening tests were performed during each office visit and results were analyzed and compared with a qualitative routine urine drug test during a six-week period. Individuals with results indicating diversion of buprenorphine were offered the long-acting buprenorphine injection (Sublocade) if medically appropriate or referred to a higher level of treatment for opioid addiction. Due to the complexity of our patient population, it was projected that the utilization of quantitative urine drug screening testing would result in an increase in discharge or termination from office-based treatment. It was also projected that there would be an increase in the use of long-acting monthly buprenorphine injections to prevent diversion.

Definition of Terms

The following conceptual and operational definition of terms were used throughout the project:

Buprenorphine is defined as an opioid partial agonist medication approved by the FDA to treat opioid use disorder as medication-assisted treatment which diminishes the effects of physical dependency such as cravings and symptoms of opioid withdrawal (SAMHSA, 2020).

Diversion is defined as the intentional transfer of a controlled prescription drug from legitimate distribution and dispensing into an illicit marketplace. Diversion includes transferring drugs to individuals they were not prescribed for (Wright et al., 2015).

Quantitative urine drug screening is defined as a chromatography mass-spectrometry based testing which detects the presence of a specific substance and its metabolite and measures the quantity of the analyte in the urine sample. Quantitative tests may be used to identify patients suspected of urine adulteration, diverting medication, and failure to take medication as prescribed (Barthwell et al., 2018).

Primary care is defined as health promotion, disease prevention, health maintenance, counseling, patient education, diagnosis, and treatment of acute and chronic illness in the office-based setting. Primary care is performed and managed by a personal physician and other collaborating health professionals (American Academy of Family Physicians [AAFP], 2020).

Chapter Summary

Chapter one presented the introduction to current public health concerns with opioid use disorder and the prevalence of buprenorphine diversion in the primary care setting. The PICOT was discussed in detail. The problem description included the DNP project's rationale and specific aims. Following, Milio's (1976) prevention framework was defined and incorporated to guide this evidence-based DNP project. Conclusively, definitions of terms for this evidence-based DNP project were provided. Chapter two will provide a comprehensive analysis of the search strategy, Evidence-Based Practice (EBP) Model, and the synthesis of available evidence-based knowledge.

CHAPTER II. LITERATURE REVIEW

Search Strategy

The most comprehensive electronic database search was performed to further examine buprenorphine diversion. Specifically, the Medical Literature Analysis and Retrieval System Online (MEDLINE) with Full Text, Health Source: Nursing Academic, Google Scholar with Full Text, Cumulative Index to Nursing and Allied Health Literature (CINAHL) Plus with Full Text, and Elton B. Stephens Company (EBSCO) with Full Text were used. Key search terms were selected due to their direct relation to the stated PICOT question and included the following words: buprenorphine, naloxone, suboxone, diversion, urine drug screening, primary care, quantification, black market, and the United States. Thirty-one articles were included based on the search strategy schematic because they were relevant, evidence-based, peer-reviewed journal articles with full text published between the years 2015-2020. Inclusion criteria were research studies addressing the PICOT question with a primary focus on the analysis of quantification of buprenorphine and norbuprenorphine urine levels, office-based buprenorphine treatment for addiction, diversion of buprenorphine in the office-based setting, diversion prevention, and black-market sells of buprenorphine in the United States using the Johns Hopkins Nursing EBP Model.

Search-limiting phrases included methadone treatment for opioid use disorder and studies were excluded if they did not address the PICOT question. The exclusion criteria included non-creditable sources such as literature from internet blogs, social

networks, websites, obsolete or outdated literature prior to 2015, and research performed in geographical locations outside of the United States.

Evidence-Based Practice Model

Johns Hopkins' EBP Model is a tool designed to guide an individual with finding current research findings to ensure best practices are incorporated immediately. The Johns Hopkins Nursing EBP Model Question Development Tool was utilized to identify the problem and its relevance to current practice. This tool was also used to develop the project's PICOT and evidence-based question. Keywords from the developed EBP question were utilized for search terms in various databases and evidence-based literature was obtained. The Stakeholder Analysis Tool was used to develop the DNP project's team and to delegate tasks and responsibilities to each member.

Each article was appraised with the Non-Research and Research Evidence Appraisal Tools. The selected articles were then summarized using the Individual Evidenced Summary Tool and evaluated based upon the evidence level of quality. After summarizing and evaluating each article's level of quality, the synthesis tool was used to categorize each of the evidence according to its level of quality. Based on the synthesis, it was concluded that the selected evidence is strong and compelling which suggests that there is a high indication for practice change.

Available Knowledge

Benefits of Buprenorphine/Suboxone

The rise in overdose deaths and medical emergencies resulting from the opioid crisis has led to the essential need for medically assisted treatments including buprenorphine for opioid dependence (Walker et al., 2018). Buprenorphine is a synthetic-opioid that acts on the brain's opioid receptor sites, specifically u-opioid receptors where it is a partial agonist and antagonist at the k-opioid receptor site (Walker et al., 2018). Additionally, naloxone was added to buprenorphine with the intention to reduce the risk of intravenous misuse (Walker et al., 2018). Research suggests that buprenorphine/naloxone are efficacious in suppressing withdrawal symptoms, retaining patients in treatment, and reducing illicit opiate/opioid use and hepatitis transmission by eliminating the sharing of needles (Walker et al., 2018). Therefore, buprenorphine/naloxone (Suboxone) has become of particular interest in the treatment of opioid addiction in the office-based setting.

According to the IMS Institute for Healthcare Informatics reports, 12.5 million prescriptions were written for buprenorphine in 2016 (Walker et al., 2018). Buprenorphine/naloxone has been proven useful and cost-effective in treating individuals with opioid use disorder in the office-based setting (Haffajee et al., 2018). In comparing buprenorphine treatment in long-term care settings and office-based settings with no treatment at all, the cost-effective ratio is approximately $35,000 per quality-adjusted life year (Haffajee et al., 2018). Buprenorphine is more accessible than methadone to the

general population including rural areas because qualified providers including primary care providers can prescribe it in office-based settings (Haffajee et al., 2018). Furthermore, the increased access to opioid agonist therapy in the United States has been associated with 50-70% reduction in heroin overdose deaths (Wakeman & Rich, 2018).

Additionally, office-based buprenorphine treatment has reduced mortality, drug-associated crimes and HIV risk (Tripathi & Sarkar, 2018). Nonetheless, as outpatient access to buprenorphine has expanded, concerns associated with an increase in diversion and overdose death have escalated (Haffajee et al., 2017).

Risks and Motives for Buprenorphine Diversion in the Primary Care Setting

Research suggests that patients in office-based treatment settings such as primary care clinics are at a higher risk of drug diversion (Jarvis et al., 2017). Chilcoat et al. (2019) conducted four qualitative studies to identify motives for buprenorphine diversion. Results indicated that 59% diverted their medication to help their friend or partner; Fifty-seven percent sold their medication due to financial hardships, and 27% reported not needing the entire prescribed dose. Suzuki et al. (2017) conducted a retrospective study that included 168 medical records of individuals receiving treatment for opioid use disorder. Out of 2275 urine samples, eight had buprenorphine to norbuprenorphine ratio of less than 0.02 which was indicative of urine spiking (Suzuki et al., 2017). In addition, the study's data were entered as predictors in a regression analysis, and the history of intravenous (IV) heroin use ($B = .06$, $P < .05$) and the submission of urine positive for cocaine were indicative of spiking ($b = .20$, $P < .001$), a commonly seen technique in the

office-based setting that is used to adulterate a urine drug screening in high-risk patients receiving buprenorphine for the treatment of opioid use disorder (Suzuki et al., 2017).

Literature indicates that some patients may stop taking their prescribed buprenorphine for a period of time due to relapse to illicit opioid use and spike their urine specimens out of fear that their results for buprenorphine will be negative (Suzuki et al., 2017). For example, the individual who is non-compliant with buprenorphine therapy may attempt to add a small portion of their buprenorphine film or tab in their urine specimen to create a false positive result to falsify medication adherence. The SAMHSA estimated that 712,000 buprenorphine-containing products were misused and diverted in 2016 (Mund & Stith, 2018). With the increased risk of buprenorphine diversion in the primary care setting, providers must be aware of clinical signs of diversion in high-risk patients. High-risk patients may present with fresh injection marks, positive drug screens for opiates, negative urine drug screens for buprenorphine and norbuprenorhine, and have frequently missed scheduled appointments (Bartwell et al., 2018). In addition, a high-risk patient may request early Suboxone refills, report lost or stolen medication, and report allergies of naloxone to obtain mono-buprenorphine tablets.

Common methods of diversion include illegal sale of prescriptions, doctor shopping to obtain multiple prescriptions, and giving away/selling medications to others (Tripathi & Sarkar, 2018). In addition, patients may over-report their dose requirements, and then divert a portion of the medications that were prescribed (Tripathi & Sakar, 2018). Furthermore, Tripathi and Sakar (2018) suggest some individuals lack access to

affordable treatment and show an unwillingness to engage in long-term care; therefore, they may divert the medication for the following reasons:

- to get high,
- prevent withdrawal,
- share with peers who could not find treatment,
- self-treat opioid dependence, and
- to make financial gains.

On the other hand, Tripathi and Sakar (2018) showed that diversion was also related to underdosing of the medication; consequently, individuals reported that they diverted buprenorphine/naloxone to alleviate opioid withdrawal in their addicted family members or friends that were not receiving adequate doses of the medication or no treatment at all.

In addition, Tripathi and Sakar (2018) suggest that the price of buprenorphine/ naloxone can be accountable for the increase of buprenorphine diversion. For example, the cost of buprenorphine when obtained by prescription or when illicitly purchased on the streets is much cheaper than purchasing heroin/fentanyl (Tripathi & Sakar, 2018). Furthermore, some individuals who are taking buprenorphine rather than heroin believe that they are at a decreased risk of being harassed and arrested by the police if they possess buprenorphine rather than heroin/fentanyl (Tripathi & Sakar, 2018). Lastly, some individuals resort to diverted buprenorphine to avoid presenting themselves as drug addicts at a treatment facility and would prefer to maintain their confidentiality (Tripathi & Sakar, 2018). Furthermore, current literature suggests that taking measures to reduce

the stigma of addiction and treatment of addiction could potentially decrease the rate of buprenorphine diversion (Wright et al., 2015).

The Benefits of Utilizing Urine Drug Screenings to Identify Diversion

Literature on office-based buprenorphine treatment for addiction suggests that urine drug testing is an integral component for monitoring patients with opioid-use disorder in the office-based setting (Suzuki et al., 2017). The sole purpose of urine drug testing is to monitor medication adherence and compliance, and to detect the use of illicit drugs and monitor risk for adverse drug-drug interactions (Bartwell et al., 2018). Unmonitored urine drug testing is a common practice in the primary care setting which poses an increased risk of urine tampering or adulteration of a specimen (Suzuki et al., 2017). Therefore, primary care providers are strongly encouraged to use quantitative urine drug tests when testing for buprenorphine adherence (Suzuki et al., 2017). Although qualitative or preliminary buprenorphine screens are commonly used in the office-based setting, they only provide a false or a positive result in which a provider cannot solely rely on as an indicator of compliance (Suzuki et al., 2017).

Additionally, quantitative urine drug screening tests are therapeutic tools which are beneficial for detecting the presence and concentration of both buprenorphine and norbuprenorphine in urine specimens (Suzuki et al., 2017). The interpretation of the buprenorphine and norbuprenorphine metabolism can help the provider determine whether the patient is diverting their medication (Barthwell et al., 2018). Thus, quantitative, or confirmatory tests use gas of high-performance liquid chromatography to

separate various drugs and mass spectrometry to detect them (Kale, 2019). Quantification methods also have a lower threshold for detection; therefore, the test is more sensitive which results in an accurate distinction of individual drugs and metabolites. Moreover, quantification is beneficial for detecting specific drugs and metabolites; many laboratories now routinely check creatinine levels to determine if the urine sample was diluted or adulterated (Kale, 2019).

Barthwell et al. (2018) suggest that urine sample adulteration is important to detect and there should be increased clinical intervention and oversight. Furthermore, when a patient is compliant with their buprenorphine regimen there is no need to alter the urine drug test (Barthwell et al., 2018). Sample adulteration should be a red flag indicative of buprenorphine diversion. Hence, some studies recommend more frequent urine drug testing is also for patients at risk for diversion or aberrant behaviors. However, clinicians are advised to consider the cost and only order the urine drug test if there is a valid clinical reason to perform the test (Bartwell et al., 2018). Moreover, existing literature extensively supports the use of definitive or quantitative urine drug testing given its ability to accurately identify specific drugs (Bartwell et al., 2018). The accuracy of a quantitative urine drug test helps clinicians better monitor an individual treatment plan adherence, minimizes risks to their patients, and improves patient success in recovery (Bartwell et al., 2018).

Strategies to Reduce Buprenorphine Diversion in the Primary Care Setting

Awareness of diversion is integral to treating opioid use disorder, and comprehensive approaches should be taken to reduce the likelihood of diversion (Suzuki et al., 2017). SAMHSA published current guidelines on buprenorphine prescription, which include the following: (a) induction protocols, (b) prescribing dosage, (c) provider capacity to provide or refer individuals to drug counseling, and (d) monitoring measures, including pill or film wrapper counts and urine drug testing (Xiaofan et al., 2017). However, current literature suggests that provider compliance with these guidelines were poor (Li et al., 2016). Lin et al.'s (2018) study revealed that only 50% of buprenorphine prescribers induct patients while in opioid withdrawal; subsequently, other patients have been given buprenorphine while displaying symptoms of active opioid withdrawal. Li et al. surveyed buprenorphine prescribers with the intent to prevent buprenorphine diversion; results indicated that 72.4% of the participants reported limiting buprenorphine prescriptions to 30-day supply to complying patients; 60.6% reported prescribing the lowest effective daily dose; and 59.3% required regular drug urine screenings.

Ideally, buprenorphine prescribers should approach 100% compliance with the stated guidelines for diversion prevention. According to Haffajee et al. (2018) continuing medical education targeting improvements and mentorship in office-based opioid addiction treatment can be effective in enhancing quality of care and clinical practice. To successfully reduce diversion of buprenorphine, recent literature also suggests these measures:

- prescribing the lowest dose of buprenorphine,
- avoiding mono-buprenorphine tablets (Subutex) unless there is a medical necessity,
- enacting random pills counting,
- utilizing the prescription drug monitoring program, and
- limiting the duration of prescription (Suzuki et al., 2017).

Wright et al. (2018) conducted a systematic review of the literature and found that higher rates of diversion correlated with less strict supervision dosing of buprenorphine in the primary care setting.

In effort to reduce buprenorphine diversion, the FDA approved the drug Sublocade in 2017 (Mund and Stith, 2018). Sublocade is an extended-release buprenorphine injection which is administered monthly.

According to Mund and Stith (2018) the long-term, extended-release buprenorphine injections, buprenorphine implants, and patches have been successful in the reduction of diversion. Additionally, Nunes (2018) suggests that using new concepts and technologies such as automated buprenorphine dispensing devices and onsite dispensing can ensure medication adherence in addition to reduce the risk of diversion. Additional methods to reduce buprenorphine diversion include:

- improving medication compliance,
- providing adequate dosing,
- shifting to full agonist such as methadone for non-adherent patients,

- offering random urine drug testing,
- requiring prescription monitoring, and
- terminating treatment (Tripathi & Sakar, 2018).

Tripathi and Sakar also suggest that continuation of treatment after warning the first-time offender for buprenorphine diversion should be considered after weighing the risks benefits of continuation/discontinuation. Consequently, treatment termination may be warranted for repeat and recalcitrant offenders or individuals who present a threat to staff and other patients (Tripathi & Sakar, 2018).

Lastly, Tripathi and Sakar (2018) suggest that law enforcement agencies should be informed of cases where individuals steal medication or break into the supplies of a treatment facility. Additionally, termination of treatment should be considered in individuals with high risk of relapse of illicit drug use due to diversion, with a consequent increase in morbidity and mortality (Tripathi & Sakar, 2018).

Chapter Summary

Chapter two presented the strategy search schematic, inclusion, and exclusion criteria for the literature review. The Johns Hopkins Nursing EBP Tool and its relationship to the DNP project was also explained. Finally, an analysis and synthesis of available knowledge were presented. Chapter three will provide a description of the organizational structure and culture of the organization, project barriers, and key stakeholders. Chapter three will also explain how the DNP project will benefit the organization, patients, and providers.

CHAPTER III. METHODOLOGY

Context

According to Moran et al. (2017), implementing the quality improvement DNP project involves connecting the purpose of the project, plan, goals, ethical aspects, human subject consideration, description of participants, setting, and study of intervention to evaluate the phenomenon of interests. This DNP project's clinical inquiry was focused on determining the impact of implementing the use of quantitative urine drug screening tests to analyze both buprenorphine and norbuprenorphine levels in individuals prescribed buprenorphine for treatment of opioid use disorder to identify diversion. The goal of this DNP project was to create an evidence-based clinical practice change to improve clinical monitoring of buprenorphine adherence and to reduce the risk of diversion after reviewing data collected from analyzing quantitative buprenorphine and norbuprenorphine levels in individuals receiving Suboxone films.

Setting

In 2011, Dr. Muhammed Niaz founded Tri-State Health Inc., a private organization consisting of four clinics in Cecil County, MD. Tri-State Health Inc. clinics are located in three Maryland cities: Elkton, North East, and Colora and Newark, DE. Tri-State Health Inc. clinics offer primary care, office-based, medication-assisted treatment for individuals with substance use disorder, drug and alcohol counseling, sleep medicine, and internal medicine to residents residing in the rural and urban communities of Cecil County, MD. Tri-State Health Inc. is dedicated to improving the health and well-

being of individuals residing in Cecil County, MD by fighting the opioid epidemic by means of providing opioid substitution treatment for individuals with opioid use disorder. Tri-State Health Inc.'s collaboration and interprofessional support from the medical director, lab manager, physician, nurse practitioner, and medical assistants were essential to the successful implementation of the Quality Improvement DNP project.

Participants

The six-week project was conducted at the Tri-State Health Inc. clinic located in Elkton, MD, Cecil County. Quantitative data collection was used for this DNP project. Prior to the implementation of the intervention, participants were selected through a convenience sample method. The sample was selected by performing a retrospective review of medical records through Tri-State Health Inc.'s electronic medical record system. After performing the retrospective chart reviews, 50 participants were selected.

The participants included individuals between the ages of 18 to 65. Additionally, the participants' races were Caucasian, African American, and Hispanic. Participants' geographical demographics showed that individuals resided in Cecil County, MD only. The included participants were also selected based upon previous history of IV heroin/fentanyl use and prescription of buprenorphine (Suboxone films) on a weekly or bi-weekly basis. Moreover, the participants included in the DNP project received between 8 mg to 24 mg of buprenorphine/ naloxone (Suboxone films) daily for at least one week to several years at Tri-State Health Inc.

After careful review of the participant's demographics, 10 were excluded based upon the exclusion criteria: (a) individuals receiving mono buprenorphine products such as Subutex (buprenorphine HCL), (b) pregnant women, and (c) individuals receiving Vivitrol injections. Therefore, a total of 40 participants were included in the DNP project. Each included participant received treatment between February 1, 2021, and March 14, 2021.

Project Barriers and Facilitators

Barriers to the DNP project included participant withdrawal from treatment secondary to relapse, incarceration, termination from treatment due to non-compliance, and referral to inpatient rehabilitation facilities or higher level of treatment such as methadone clinics. In addition, some participants were excluded during the six-week project implementation due to changes in their treatment regimen. For example, some participants were switched to alternative opioid substitution medications instead of receiving Suboxone films for treatment of addiction. These medications included Zubsolv, mono-buprenorphine sublingual tablets (Subutex), methadone, or long-acting buprenorphine and Vivitrol injections due to the inability to maintain abstinence from opioid use and non-adherence to taking medication as prescribed. Hence, the cost of using quantitative urine drug screening test was also considered a limiting factor or barrier to the outcomes of the DNP project.

The project facilitators included staff support, effective communication, teamwork, and buy-in from the key stakeholders. Additionally, the DNP project team met

once a week to discuss the progress of the project's intervention and to provide me with constructive feedback regarding the participants' health outcomes. Furthermore, each team member performed their assigned project tasks accurately and in a timely manner throughout the entire six-week project. Finally, I met with both key stakeholders on separate occasions multiple times per week to discuss solutions to the barriers, the project's weekly progress, and budget analysis.

DNP Project Benefits

The DNP project is beneficial for clinical improvements to provide optimal care to individuals being treated for opioid use disorder, to improve patient health outcomes, and to prevent diversion of buprenorphine. Quantitative urine drug screenings are advantageous in identifying adulteration of urine specimens and medication adherence. Additionally, quantitative urine drug screenings can support the providers' clinical decision to use Sublocade injections or to refer patients to advanced addiction treatment programs in methadone clinics or inpatient drug rehabilitation centers.

Intervention

Quantitative Urine Drug Testing Description

This DNP project included implementing the use of quantitative urine drug screening tests or liquid chromatography-tandem mass spectrometry to analyze buprenorphine and norbuprenorphine and compared test results with qualitative urine drug screening tests. Each X-waivered buprenorphine provider was responsible for ordering a quantitative urine drug screening for participants included in the project prior

to writing a prescription for Suboxone films. The comparison between both quantitative and qualitative urine drug screenings guided the provider's clinical decision making based upon the participant's compliance and medication adherence. Definitive urine drug testing is referred to as quantitative, confirmatory, or liquid chromatography mass spectrometry-based testing (Bartwell et al., 2018). A quantitative test detects the presence of a specific substance or its metabolite and measures the quantity of its analyte in the sample (Bartwell et al., 2018). Furthermore, definitive urine testing is more complex than presumptive urine testing due to its high sensitivity and specificity, which yields highly accurate, reliable results.

Quantitative urine drug tests are also beneficial for identifying patients who are suspected of adulterating urine samples, diverting medication, or failing to take medication as prescribed (Bartwell et al., 2018). Additionally, quantitative urine tests identify specific drugs within a drug class or identify a specific substance that is not detected by a presumptive test; rule out false-positives; and assess the efficacy of and potential for drug-drug interactions with buprenorphine (Bartwell et al., 2018). Furthermore, primary care providers cannot rely on positive buprenorphine results from presumptive or qualitative immunoassay urine drug test results as an indicator of medication adherence (Bartwell et al., 2018). Relying solely on presumptive urine drug tests can be misleading for clinicians and could potentially lead to missed opportunities to identify nonadherence or buprenorphine regimen and response to treatment (Bartwell et al., 2018).

DNP Project Team

The development of a team is crucial for the successful outcome of a DNP project (Moran et al., 2019). Therefore, the project team members were selected based upon their experience in addiction medicine, their expertise in analyzing urine drug screening and professionalism, and their spirit of inquiry and interest in creating an evidence-based change within our organization. The DNP project team consisted of a DNP faculty advisor (Wilmington University), a project mentor (medical director and owner of Tri-State Health Inc.), a lab director, one staff nurse practitioner, two staff physicians, two medical assistants, and me, the project leader (Wilmington University DNP student). Additionally, I conducted weekly meetings with the team to ensure that the quantitative urine drug screening tests were being ordered for participants and included in the DNP project, to discuss project barriers, and to address concerns.

Each team member executed their delegated tasks precisely and within the allotted timeframe. The Wilmington University faculty advisor was available by email to answer questions and to guide the DNP project. The DNP project mentor was also available during my experiential clinical days and available by phone to provide feedback and clinical guidance for the DNP project. The medical assistants worked to maintain anonymity and confidentiality of survey data. Likewise, the medical assistants collected urine specimens during office visits, monitored urine temperatures, and guaranteed that each specimen was correctly labeled.

Providers for this DNP project included a medical doctor, a Doctor of Osteopathic Medicine, and two nurse practitioners. Each provider ordered quantitative urine drug screening for the participants that were on their caseload and presented patient outcomes and modifications of treatment for the project's participants by collaborating with me on a weekly basis. Additionally, the providers discussed urine drug test results, participant compliance, and medication adherence to buprenorphine. Providers also offered feedback on the impact of the intervention. Finally, I collaborated with the lab director to ensure that results were available in each participant's electronic medical record within a specific timeframe.

Furthermore, I ensured that quantitative urine screening results were accurate, and the data were entered correctly in the secured spreadsheet. The lab director retrieved the urine specimens and performed quantitative testing to the samples and entered data into the patient's electronic medical records. In addition, the lab director ensured that all test results were accurate and discussed concerns with me each week.

Study of the Interventions

To study the intervention, a comparison of buprenorphine and its metabolite norbuprenorphine levels using the liquid chromatography-tandem mass spectrometry (LC-MS) and routine immunoassay or qualitative urine drug screenings were performed to assess the impact of the intervention. The use of qualitative urine drug screenings or routine immunoassay screenings solely for the purpose of analyzing buprenorphine levels will only show a positive or negative result and does not measure norbuprenorphine

levels (Suzuki et al., 2017). Subsequently, without analyzing the quantification of both buprenorphine and norbuprenorphine, clinicians cannot accurately distinguish between a patient who is taking their Suboxone as prescribed or non-adherent to taking their medication. The quantitative or liquid chromatography-tandem mass spectrometry urine drug screen lower limit cutoff was 5ng/dl for buprenorphine and norbuprenorphine; levels below 5ng/dl were considered negative. The upper limit level cutoff for buprenorphine and norbuprenorphine levels was 50 ng/dl. Qualitative or immunoassay urine drug screen cutoff lower level of buprenorphine and norbuprenorphine was 5ng/dl and the upper limit was 20 ng/dl.

Both qualitative and quantitative labs results were analyzed and interpreted on a weekly basis. In addition, the DNP project team met weekly to discuss the lab results and participants that were non-adherent to their buprenorphine regimen. Outcomes were measured by the rate of participants terminated from treatment, referrals made to higher level of treatment, and changes in buprenorphine regimen for individuals diverting their Suboxone. For example, participants who diverted their medication were given the option to receive long-acting buprenorphine injections for treatment of opioid dependence secondary to inability to adhere to treatment with Suboxone films.

Measures

The Buprenorphine Risk for Diversion Survey was created to understand the following: (a) individuals who are at a high risk of diversion, (b) the need for continual provider assessment for Suboxone dose titration, (c) and the current rate of diversion

within our organization (Appendix A). Two medical office assistants distributed 50 surveys during the first two weeks of the DNP project. Each survey was anonymously completed.

To maintain confidentiality, each participant placed the completed anonymous survey in a locked box which was in a private office in the clinic. The documents were then removed from the locked box. Next, data were transferred from the documents, entered on a spreadsheet, and placed in a designated computer file for the DNP project data collection at Tri-State Health Inc. Descriptive analysis was utilized via IBM SPSS software to perform statistical analysis to summarize results. The number one (1 = yes) was used to code yes responses and the number two (2 = no) for no responses. This method was chosen for data analysis to identify the frequencies in the responses to the five questions on the questionnaires and to identify the percentage of participants who admitted to diverting their medication or taking less than prescribed by their provider.

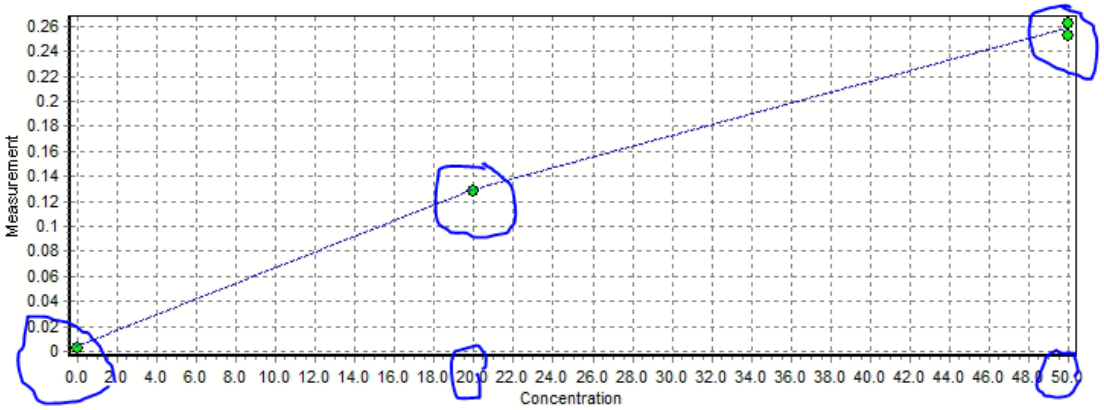
To evaluate the patterns of buprenorphine and norbuprenorphine and the efficacy of quantitative urine drug screening test, data were evaluated in three groups. Additionally, to identify differences in routine immunoassay urine tests and quantitative urine drug screenings, the benefits of analyzing the quantification of buprenorphine and norbuprenorphine levels, these two tests were compared. Buprenorphine and norbuprenorphine levels were also analyzed to monitor compliance and identify diversion. Each provider ordered an immunoassay/routine urine drug screening and confirmation or quantitative urine drug screening for each participant during office visits

throughout the duration of the six-week project. Each week, the lab director entered numerical lab values for both buprenorphine and norbuprenorphine levels on a spreadsheet located in a designated DNP project file.

For the immunoassays or routine urine drug screenings, buprenorphine levels less than 5 ng/dl were considered negative and levels greater than 5ng/dl to 20 ng/dl were considered positive. Norbuprenorphine levels cannot be analyzed with immunoassays; therefore, no data were available. Subsequently, quantitative urine drug screenings with buprenorphine levels greater than 5 ng/dl were considered positive and less than 5 ng/dl were considered negative. Similarly, norbuprenorphine levels below 5 ng/dl were considered negative. To ensure accuracy of urine drug screen test results, the lab conducted the immunoassay or qualitative screenings via the use of the DIATRON PICTUS 7000 using a linear calibration using (0, 20, 50) ng/ml (Figure 2).

Figure 2

Linear Calibration for Qualitative Immunoassay Urine Drug Screening Buprenorphine Levels



Calibrator	Replica	Measurement	Concentration
1	1	0.0024	0.0
1	2	0.0030	0.0
2	1	0.1282	20.0
2	2	0.1281	20.0
3	1	0.2527	50.0
3	2	0.2623	50.0

Note. This figure illustrates the linear calibration for qualitative immunoassay urine drug screening buprenorphine levels.

Quantitative buprenorphine and norbuprenorphine levels greater than 5 ng/dl were considered positive, and levels less than 5 ng/dl were considered negative. A comparison of immunoassay or routine urine drug screening and quantitative urine drug screening results were compared; norbuprenorphine levels were measured to identify compliance and diversion. Participants with quantitative buprenorphine levels above 5ng/dl and

norbuprenorphine levels below 5ng/dl were considered non-compliant. Of these, participants with quantitative buprenorphine levels above 50 ng/dl and norbuprenorphine levels of 0 ng/dl were suspected of specimen adulteration to test positive for buprenorphine to hide non-compliance and diversion.

To ensure accuracy of quantitative buprenorphine and norbuprenorphine levels, the lab performed an analysis using the Shimadzu 8050 liquid chromatography mass spectrometry to confirm the presence and absence of both buprenorphine and norbuprenorphine.

Although 50 participants were selected for the six-week DNP project, data were collected based on multiple frequencies depending upon availability of their appointments. During each office visit for buprenorphine maintenance, a urine specimen was collected ensuring sanitized chain of custody. Urine specimens were sent to Tri-State Health Inc.'s in-house laboratory where the specimens were screened for buprenorphine and norbuprenorphine utilizing reflex to confirmation to produce both qualitative and quantitative analysis. Presently, there is no benchmark data provided by the organization. The DNP project intervention has not been implemented in the organization previously.

The following were used to measure intervention outcomes for the DNP project:

- providers' increased amount of quantitative urine drug screening test orders,
- the increased prescription of long-acting monthly buprenorphine injections or Vivitrol injections for individuals who diverted their buprenorphine,

- increased referrals to higher level of care such as methadone clinics or inpatient rehabilitation centers, and
- termination from the office's buprenorphine program.

During the six-week project, all participants' lab results were reviewed and analyzed for discrepancies. To ensure accuracy and completeness, the lab director created an Excel spreadsheet and entered the lab values for both immunoassay/qualitative urine drug screening and quantitative urine drug screening each week.

Analysis

The results of the participants' routine immunoassay urine drug screening buprenorphine levels produced both nominal and ordinal data. For example, each urine drug screening provided a positive or a negative result in addition to a semi-quantitative numerical lab value. In contrast, quantitative or liquid chromatography-tandem mass spectrometry urine drug screening produced numerical values of both buprenorphine and norbuprenorphine levels which produced ratio data. The IBM SPSS 27.0 statistics software was utilized to perform a binomial logistic regression to ascertain the effects of positive qualitative buprenorphine screening on the likelihood of positive norbuprenorphine quantitative result.

Budget

Budget planning is essential to the success of implementing an evidence-based practice change within an organization. The use of a budget tool is advantageous for guiding decision making, monitoring performance, and predicting income and

expenditures. Additionally, proper budget planning is vital to efficiently manage resources. As a result, Tri-State Health Inc.'s medical director, lab manager, and the DNP student created the project's budget by analyzing the costs and benefits associated with implementing the EBP change utilizing the Cost Benefits Analysis (CBA) tool (Appendix B). The CBA included the cost of all direct and indirect costs, materials, equipment, and resources associated with the implementation of quantititative urine drug screenings.

The budget plan depicted the estimated costs for staffing, medical equipments and supply, urine drug screening, office visits, drug counseling, opioid-substitution medications, routine labs, office supplies, and staff salaries. After performing the CBA, the DNP project team collaborated to develop a three-year budget plan projected for the years 2021-2023. The budget plan exemplified estimated expenses and potential income for using quantitative urine drug screening tests to monitor compliance in individuals receiving buprenorphine for opioid dependence. Funding for materials and supplies for quantitative urine drug screenings was provided by Tri-State Health Inc. In addition, Medicaid, Medicare, and other commercial insurances covered the costs of office visits and some urine drug screening tests per calendar year.

Consequently, no additional costs were associated with the DNP project. According to the National Institute on Drug Addiction (NIDA) (2021), the average cost for a buprenorphine office visit is approximately $115.00 per week or $5,980.00 per year per patient. The average cost for an immunnoassay or qualitative urine drug screening is approximately $30.00 to $75.00 (Kale, 2019). Additionally, the cost for a quantitative

urine drug screening test is approximately $210.00. The estimated budget cost based upon 50 participants during the six-weeks, which included weekly office visits, in-house drug counseling, and urine drug screening tests was approximately $100,800.00.

The total estimated projected budget for 50 participants for the entire year of 2021, which included office visits (CPT 99213), in-house drug counseling, urine drug screenings, and cost of Suboxone prescriptions was approximately $1,096,250.00. For the second year (2022), the estimated budget costs for buprenorphine office visits based upon 50 participants was approximately $878,00.00. The estimated costs are significantly lower during the second year due to potential patient withdrawal from treatment or requiring less frequent office visits due to stability on buprenorphine regimen. Total cost estimated for year three (2023) is approximately $747,050.00. The cost is significant lower for year three (2023) due to potential withdrawal from treatment or less frequent office visits due to stability on buprenorphine maintenance. Furthermore, there were no capital purchases required for the DNP project.

Ethical Considerations

Ethical considerations of this DNP project included the Wilmington University's Human Subjects Review Committee approval and categorization of exemption (Appendix C). Tri-State Health Inc. is a private-owned organization without an Institutional Review Board; therefore, Tri-State Health Inc.'s medical director also approved the DNP project (Appendix D). Individuals with opioid use disorder may be at

risk for social and economic disadvantages, which may lead to vulnerability, coercion, or failure to make informed decisions for themselves.

Individuals with opioid use disorder may be easily manipulated, and may be considered a convenient, readily available study population. Thus, to maintain ethics, participant confidentiality, beneficence, and justice, I completed the Collaborative Institutional Training Initiative (CITI) course "Populations in Research Requiring Additional Consideration and/or Protections" to enhance knowledge of risk reduction for individuals with opioid use disorder (Appendix E). To maintain confidentiality, surveys were anonymous, and no personal information was included on the documents. Moreover, all data collected from participant surveys and urine drug screening tests were deidentified to ensure privacy and confidentiality. All deidentified data are stored on a computer spreadsheet located on a designated computer file at Tri-State Health Inc. A deidentified data codebook was also created for statistical analysis of data collected for the DNP project and to maintain confidentiality.

Chapter Summary

Chapter three presented the DNP project's interventions, study of interventions, measures, and data analysis. Next, the DNP project's budget and ethical considerations were explained in detail. Finally, the CITI training certificate, Wilmington University's HRSC review, and Tri-State Health Inc.'s approval letter was presented. Chapter four will present the sample's characteristics and the results from the project's intervention

CHAPTER IV. RESULTS

Sample Characteristics

Demographics

Participant demographical information was obtained via medical record review. The following demographic data were obtained through electronic medical record review:

- age,
- gender,
- race/ethnicity,
- history of IV heroin/fentanyl use,
- current status on Suboxone films, and
- geographical location.

The participants included in this projected consisted of 22 males and 18 females. Males represented 55% and females 45% of the sample (Figure 3). The age range of participants included individuals 18-65, with a median age of 37 (Figure 4). Twenty-two participants were between the ages of 25-40, 17 between the ages of 41-65, and one between the ages of 18-24.

Data collected on participant ethnicity/race indicated that 87% of the sample was Caucasian (n = 35), 7.5% African American/Black (n = 3), 5% Hispanic (n = 2), and 0% other (n = 0) (Figure 5). All participants had a history of IV fentanyl/heroin use, were currently on Suboxone films, and resided in Cecil County, Maryland.

Figure 3

Participants by Gender

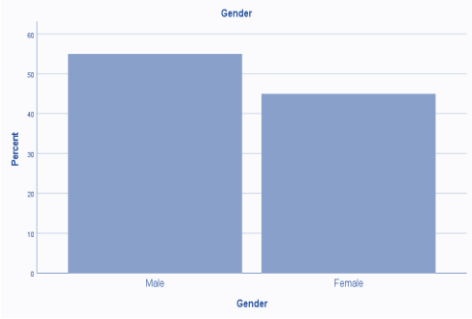


Figure 4

Participants by Age

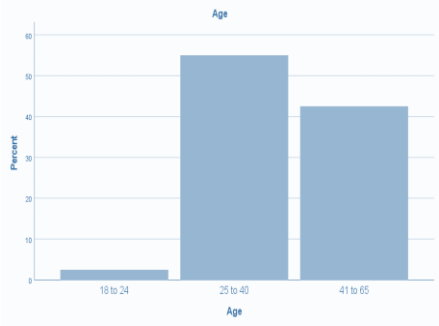
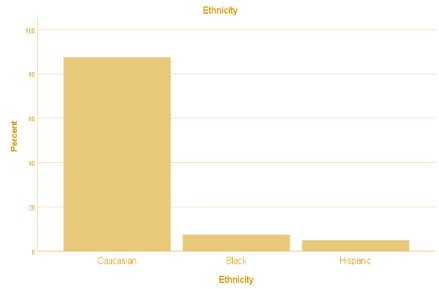


Figure 5

Participants by Ethnicity/Race



Results

The DNP project results are based on outcome data collected through responses to preintervention survey questions which included 50 participants receiving treatment for opioid dependence at Tri-State Health Inc. The Buprenorphine Diversion Risk Survey (Appendix A) consisted of five questions to determine the participant's risk and motivation for diverting Suboxone films. Participants completed the Buprenorphine Diversion Risk Survey prior to implementing the utilization of quantitative urine drug screening tests. The questionnaires were completed approximately one week prior to the beginning of the DNP project. Ten participants were excluded from the DNP project sample due to withdrawal from treatment or receiving alternative treatment other than Suboxone films. Additionally, the project results included data collected from 240 urine drug screening test results from 40 participants over a six-week period between Feb 1, 2021 and March 14, 2021. The medical director of Tri-State Health Inc. allowed the use of quantitative urine drug screens over the designated six-week period without circumstantial conflicts.

Descriptive Data Analysis

A comprehensive data analysis of the preintervention survey data was completed utilizing IBM SPSS 27.0 descriptive analysis. The purpose of using the Buprenorphine Diversion Risk Survey was to determine the following: (a) the percentage of participants with a history of IV heroin/fentanyl, (b) participants who were currently receiving Suboxone, (c) those who were taking less medication than prescribed, and (d) patients

who sold their Suboxone or had given their medication to relatives or friends. Descriptive analysis indicated that 80% of the survey participants (n = 40) reported history of IV heroin/fentanyl use (Figure 6). Eighty-six percent of the survey participants (n = 43) reported currently being on Suboxone films (Figure 7). Thirty-two percent of the survey participants (n = 16) reported taking less Suboxone than prescribed by their provider (Figure 8).

Figure 6

Buprenorphine Diversion Risk Survey Question #1

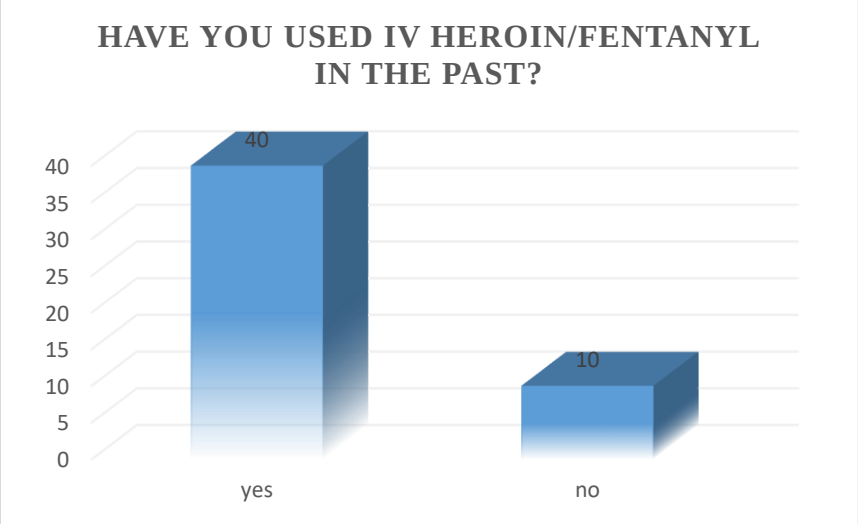


Figure 7

Buprenorphine Diversion Risk Survey Question #2

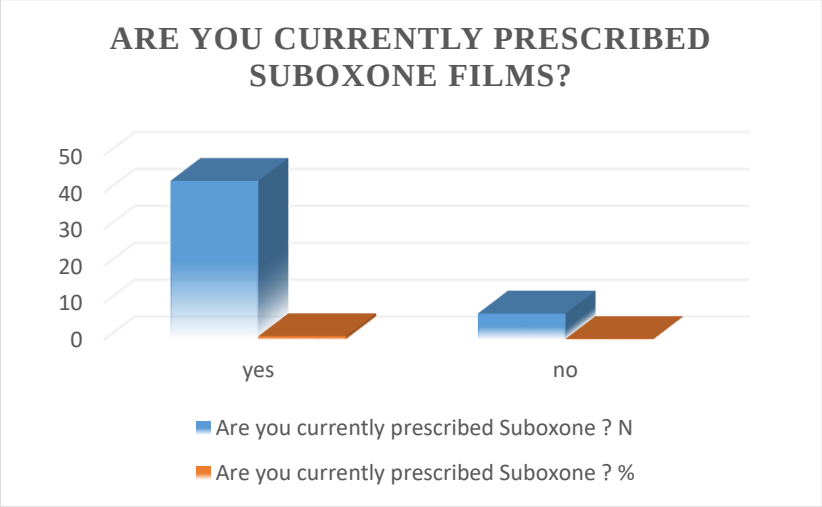
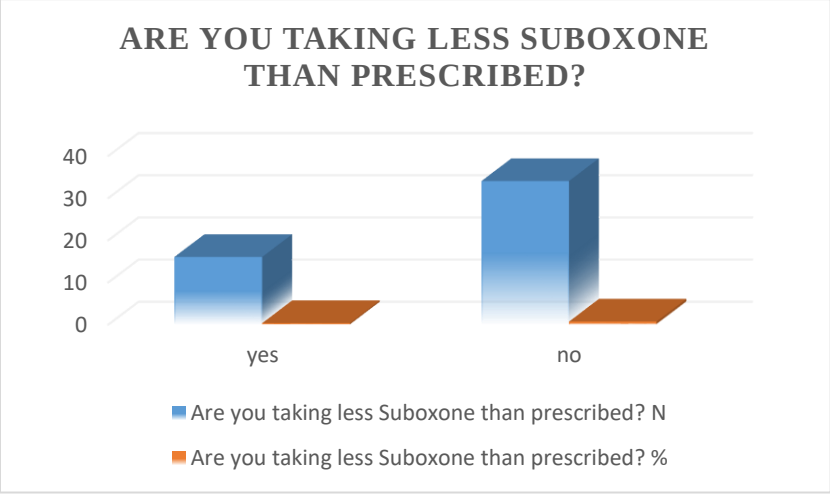


Figure 8

Buprenorphine Diversion Risk Survey Question #3



Additionally, 8% of the survey participants (n = 4) reported giving their Suboxone to a relative or family member (Figure 9). Most noteworthy findings from the

Buprenorphine Diversion Risk Survey revealed that 6% of the survey participants (n = 3) admitted to selling their Suboxone for money (Figure 10).

Figure 9

Buprenorphine Diversion Risk Survey Question #4

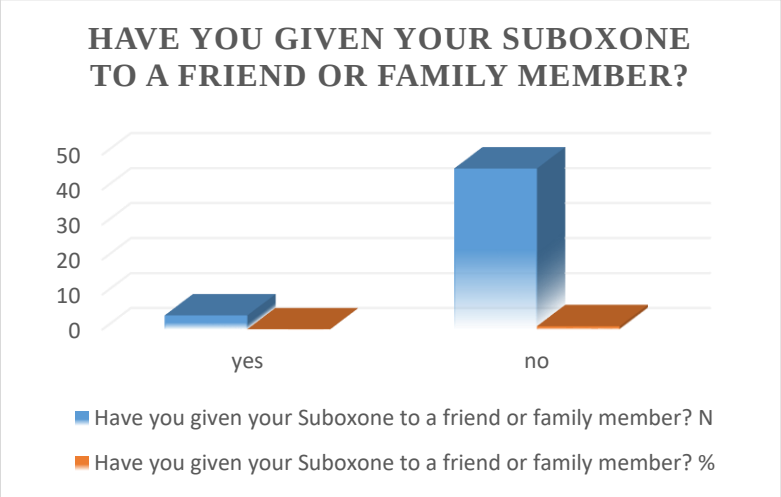
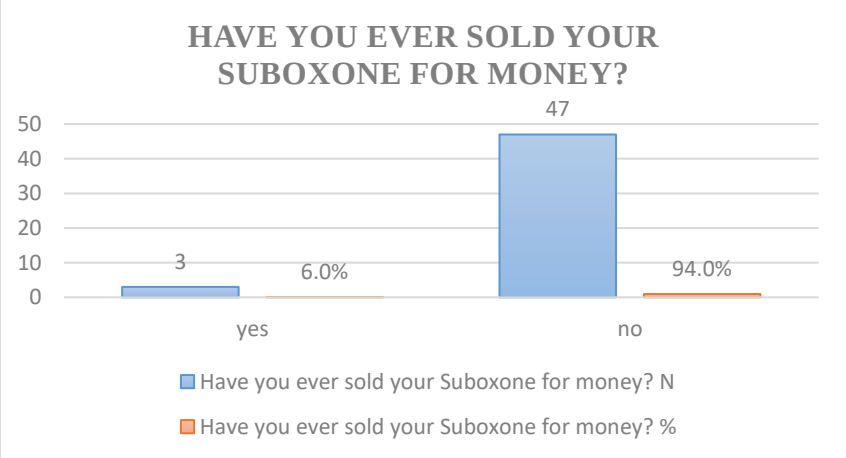


Figure 10

Buprenorphine Diversion Risk Survey Question #5



Statistical Analysis of Urine Drug Screening Tests

A binomial logistic regression was performed utilizing IBM SPSS 27.0 to ascertain the effects of a buprenorphine screening test on the likelihood of a positive norbuprenorphine quantitative result. The logistic regression model was statistically significant, $X^2(1) = 66.7$, $p < .001$. The model explained 36% (Nagelkerke R^2) and correctly classified 83%. Sensitivity was 86.9%; specificity was 70.2%; positive predictive value was 90.3%; and negative predictive value was 62.5%. Buprenorphine screening was a statistically significant predictor of a norbuprenorphine quantitative result. A person with a positive buprenorphine screening has 15.6 times higher odds to have a positive norbuprenorphine quantitative result.

The area under the ROC curve was .785. 95% CI [.710-.861] which is an acceptable level of discrimination according to Hosmer et al. (2013) (Figure 11). These findings are significant because utilizing Buprenorphine Screening only, 159/240 urine drug screenings were correctly classified and had positive norbuprenorphine quantitative values; seventeen urine drug screenings were misclassified and had negative norbuprenorphine quantitative results, indicating 7% were diverting as shown in Table 1 and Figure 11.

Figure 11

ROC Curve

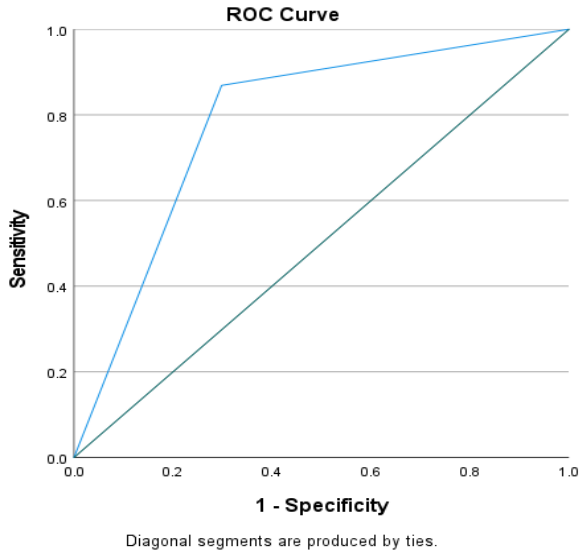


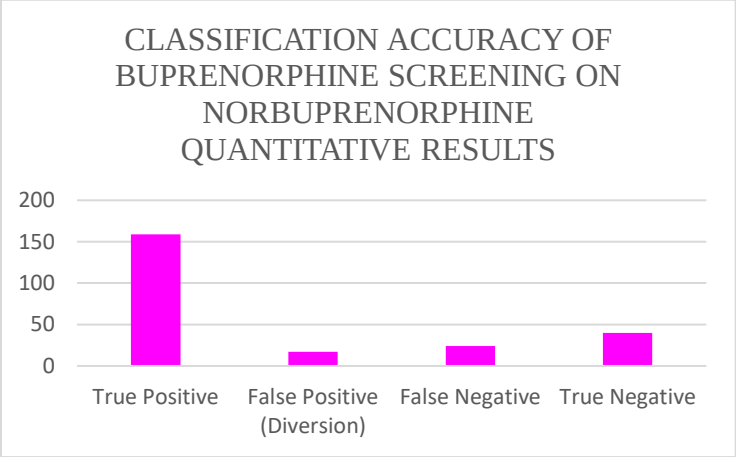
Table 1

Classification Accuracy of Buprenorphine Screening and Norbuprenorphine Quantitative Results

Predicted Observed	Negative Norbuprenorphine Quantitative Result	Positive Norbuprenorphine Quantitative Result	Total
Negative Buprenorphine Screen Result	40	24	64
Positive Buprenorphine Screen Result	17	159	176
Total	57	183	240

Figure 12

Classification Accuracy of Buprenorphine Screening and Norbuprenorphine Quantitative Results



Summary

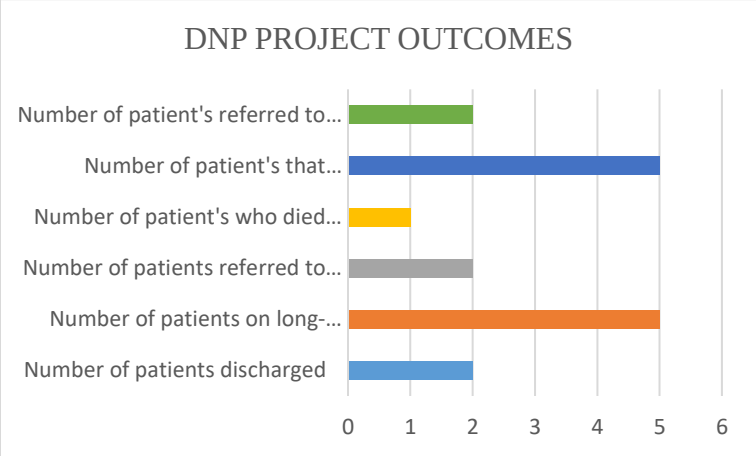
The results for this evidence-based quality improvement DNP were based on the outcomes data which were collected through the participant responses to the Buprenorphine Diversion Risk Survey prior to the project's implementation of the intervention and the data collected from both qualitative (buprenorphine screening only) and quantitative (both buprenorphine and norbuprenorphine) urine tests. Descriptive analysis of the survey responses revealed that seven participants admitted diversion by giving their medication to a friend or family member or selling Suboxone for money. Most noteworthy from the survey response data is 32% (n = 16) of the participants report taking less medication than prescribed, which may be indicative of overprescribing of buprenorphine. Results also suggest that a positive buprenorphine result on a qualitative

or immunoassay test is likely to predict a positive quantitative norbuprenorphine result; however, many patients are being misclassified.

Quantitative data analysis results suggest that using qualitative immunoassay urine drug screening tests may be acceptable under direct supervision. In primary care clinics where patients are not directly observed, using quantitative urine drug screenings to analyze both buprenorphine and norbuprenorphine levels is key in eliminating diversion. Consequently, preventing diversion can improve patient compliance, quality of life, decrease the rate of opioid-related overdose and death, and improve rates of successful recovery from addiction. Strengths of the DNP project included the development of Buprenorphine Diversion Prevention Protocol at Tri-State Health Inc. (Appendix G), quality improvement in diversion awareness, and increased prescription of monthly long-acting buprenorphine injections in individuals that were found diverting their Suboxone films. Additionally, some participants were referred to higher levels of addiction treatment or discharged from the buprenorphine program. Out of 40 participants, two patients were admitted to inpatient rehab, five patients withdrew from treatment, two were referred to a methadone clinic, five patients are now receiving long-acting buprenorphine injections, and two were discharged. Regretfully, one patient died from an opioid-related drug overdose (Figure 13).

Figure 13

Project Outcomes



Chapter Summary

Chapter four presented the sample's characteristics, demographics, and descriptive data analysis. Next, the statistical test utilized for quantitative data analysis was explained. Finally, the results and key findings from the data analysis were presented. Chapter five will include the interpretation of the interventions, outcomes, limitations of the project, implications for advanced practice nursing, plan for sustainability, application of DNP Essentials, and the conclusion.

CHAPTER V. DISCUSSION AND IMPLICATIONS

Interpretation

Through the analysis and comparison of qualitative immunoassay buprenorphine screenings and quantitative urine buprenorphine/norbuprenorphine screenings, results indicated that 17/240 urine drug screening tests were confirmed negative for norbuprenorphine which is indicative of diversion. Moreover, the project's quantitative results revealed that 7% (n = 17) of the 40 participants were diverting their Suboxone films. These findings were significant to previous studies that utilized quantification of buprenorphine and norbuprenorphine. While this DNP project focused on buprenorphine diversion in a primary care clinic in Cecil County, Maryland, this health issue has become a global concern. For example, Suzuki et al. (2017) found that 216 samples submitted by 70 participants revealed that nine urine drug screenings were spiked with buprenorphine and no presence of norbuprenorphine. Furthermore, 8.6% of Suzuki et al.'s (2017) study participants had strong evidence for urine spiking to conceal diversion of buprenorphine.

Carroll et al. (2018) conducted a study, including 128 participants who received Suboxone in 2016; of these, 38% (n = 13) reported diversion of their medication. Hswen et al. (2020) examined the trends in street buprenorphine sells and diversion of prescription drugs from medical sources examining black price listed on StreetRx. StreetRx is a public website that collects street price data in the United States for controlled substances on the black market (Hwsen et al., 2020). Between November 2010

to June 2018, there were 2481 submissions for diverted buprenorphine transactions in the StreetRx data set (Hswen et al., 2020).

Diversion of buprenorphine may pose a threat to the reputation of addiction treatment in the primary care setting which can compromise public acceptance and access to treatment for opioid-dependent individuals (Hswen et al., 2020). Furthermore, previous studies produced evidence supporting the efficacy of utilizing quantitative urine drug screening tests to analyze both buprenorphine and norbuprenorphine in the office-based setting to identify diversion and monitor buprenorphine adherence. Without implementing the use of quantitative urine drug screening tests to analyze both buprenorphine and norbuprenorphine levels, the clinicians at Tri-State Health Inc. would miss the opportunity to decrease diversion. The results of implementing quantitative urine drug screening were as follows:

- Clinicians were able to improve compliance;
- Patients were referred to a higher level of treatment at inpatient rehabilitation facilities and methadone clinics;
- The organization offered long-acting buprenorphine injections and Vivitrol; and
- Non-adherent patients were terminated.

Reimer et al. (2016) suggested that diversion of Suboxone films significantly impacts the benefits that patient experience from addiction treatment by limiting adherence through the sale of their medication. Hence, non-compliance with treatment

most often leads to poor treatment outcomes, failure to progress in recovery and negative effects on health such as drug overdose (Reimer et al., 2016). Additionally, diversion causes an indirect impact on the individual's quality of life and harm to the society due to criminal activity, economics, and loss of productivity (Reimer et al., 2016). Understanding the social barriers that influence the diversion of buprenorphine is imperative to effectively prevent black market sells of Suboxone films.

Hswen et al. (2020) found that geography, demographics, and socioeconomic factors shape diversion of Suboxone films to the black market. Therefore, racial disparities in income, insurance coverage, education, and access to treatment influence the demand for buprenorphine on the black market. Weigand's (2016) study, indicated that 9.3 million buprenorphine prescriptions were written in the United States in 2012. Like several drugs, buprenorphine is subjected to diversion and the occurrence of diversion has increased in conjunction with the increases in the frequency of prescribing (Chilcoat et al., 2019). With the increased rise in the number of individuals with opioid-use disorder and increased access to buprenorphine in the primary care setting, there are concerns for increased regulation.

Furthermore, increased buprenorphine regulations could potentially place a greater burden on patients and healthcare providers by limiting the availability of treatment (Chilcoat et al., 2019). Consequently, the results of this DNP project will be effective in preventing diversion in the primary care setting by promoting awareness of diversion and the utilization of quantitative urine drug screening to detect patient non-

compliance. Inhibiting buprenorphine diversion in the primary care setting can substantially reduce opioid-related deaths, hospital admissions for medical treatment related to opioid-overdose, crime, and incarceration (Reimer et al., 2015). Global awareness of buprenorphine diversion, motives, trends, and patterns in black market sells can help guide clinicians' decisions with the appropriate prescribing of buprenorphine. Promoting the use of quantitative urine drug screening tests to analyze buprenorphine and norbuprenorphine levels in the primary care setting is imperative to prevent diversion and monitor adherence during treatment.

Presumptive or qualitative buprenorphine screens cannot identify or report the concentration of the medication or metabolite in the urine specimen (Barthwell et al., 2018). In conclusion, research findings suggest that quantitative urine drug screening should be ordered with the frequency based upon the patient's clinical presentation and stability in treatment (Barthwell et al., 2018).

Limitations

The limitations of this evidence-based quality improvement DNP project included a small participant sample size, length of time, limited research on buprenorphine diversion, and costs associated with quantitative urine drug screenings. Due to the small sample size, the results may not be representative of all individuals diverting buprenorphine. In addition, survey respondents may have underreported diversion of buprenorphine and black market sells of the medication. Therefore, results may not be reflective of all individuals diverting buprenorphine.

Furthermore, the project exclusively focused on one primary care clinic in Cecil County, MD, limiting the project to only analyzing data collected on buprenorphine diversion in one geographical location in the state of Maryland.

Additionally, the DNP project was limited due to selecting participants who were currently receiving Suboxone films only. Diversion of other buprenorphine-containing products such as Subutex and Zubsolv were not examined in the DNP project. Research on diversion of all buprenorphine-containing products is indicated to determine the extent of diverted buprenorphine worldwide. In addition, more research is required on the benefits of utilizing quantitative urine drug tests to analyze buprenorphine and norbuprenorphine levels routinely in the primary care setting to detect diversion. Implications for Advanced Nursing Practice.

Implications for Advanced Nursing Practice

Advanced practice nurses are essential to expanding access to buprenorphine treatment in the primary care setting (Tierney, 2015). Hence, diversion awareness, understanding the rationales for diversion, and its management is an integral part of successful treatment for opioid use disorder. With the significant rise in demand for diverted buprenorphine, the use of routine quantitative urine drug screening tests to analyze both buprenorphine and norbuprenorphine levels is imperative to detect diversion in the primary care setting (Holt et al., 2017). This DNP project implies that the inclusion of the quantitative buprenorphine and norbuprenorphine screening test is effective in identifying individuals who divert their medication. Analyzing both buprenorphine and

norbuprenorphine levels can add valuable information such as individuals concealing illicit drug use and buprenorphine-adulterated urine specimens to show a false-positive result. Moreover, the use of quantitative urine drug screening tests to analyze buprenorphine and norbuprenorphine levels is substantial for guiding clinical decision making in addiction treatment.

The use of quantitative urine drug screenings are effective clinical tools for detecting buprenorphine diversion and guiding clinicians' decisions to refer an individual to inpatient rehabilitation or methadone clinic, to prescribe long-acting buprenorphine injections, or to terminate treatment. Additionally, this project implies that utilizing quantitative urine drug screenings to analyze buprenorphine and norbuprenorphine levels can improve the success of treatment, quality of life, reduce overdose and death rates, and reduce black markets sells of the medication. Irrefutably, advanced practice nurses and other buprenorphine providers are more capable of preventing diversion, modifying treatment plans, terminating treatment, reducing risk for potential harm, promoting treatment retention, and engagement by using quantitative urine drug screenings routinely for monitoring compliance (Holt et al., 2017).

Plan for Sustainability

The ability to sustain quality improvement over an extended period after termination is imperative to maintain the innovation with the organization (Hailmairam et al., 2019). The plan for sustainability of this DNP project includes three methods: (a) mutual adaptation between the evidence-based intervention and organization, (b)

maintenance of workforce skills by continued provider training, and (c) ongoing monitoring of the evidence-based intervention effectiveness. Mutual adaptation between the evidence-based intervention and organization will be maintained by utilizing the Buprenorphine Diversion Prevention Protocol (Appendix G). The Buprenorphine Diversion Prevention Protocol was developed to create step-by-step instructions to help providers adhere to practice guidelines to prevent diversion within the organization. Workforce skills will be sustained by requiring continuing education for all buprenorphine prescribing providers to stay abreast of new innovations, clinical practice guidelines, and evidence-based interventions for opioid use disorder treatment in the primary care setting.

The efficacy of the evidence-based intervention and the organization's quality improvement will be monitored for one year. Monthly meetings will be held with the project's team to discuss the progress of the intervention, barriers, patient outcomes, and quality improvement. In addition, chart audits will be performed monthly to monitor provider use of quantitative urine drug screening tests, urine drug-screen (UDS) results, and patient outcomes for one year.

Application of the AACN DNP Essentials

The American Association of Colleges of Nursing (ACCN) Essentials of Doctoral Education for Advanced Practice Nursing (2006) identified eight foundational competencies essential for all graduates of the DNP program (Zacaggnini & White, 2017). Consequently, this DNP project by design, implementation, and analysis has

incorporated these essentials. This academic evidence-based project demonstrates the application of knowledge, experience, and scholarship required for the completion of a terminal degree in advanced practice nursing.

DNP Essential I: Scientific Underpinnings for Practice

The evidence-based quality improvement DNP project exemplified the scientific underpinnings for practice by integrating nursing science, science-based theories, and concepts to address current and future practice issues with opioid addiction treatment in the primary care setting. New practice approaches based on evidence-based findings and advanced strategies to prevent buprenorphine diversion were integrated to improve healthcare delivery outcomes.

DNP Essential II: Organizational and Systems Leadership for Quality Improvement and Systems Thinking

The project demonstrated an understanding of organization and systems leadership for quality improvement and systems thinking by explicitly evaluating care delivery approaches that meet current and future needs of individuals with opioid use disorders based on scientific findings in advanced practice nursing and addiction medicine. In addition, the development of budgets for practice initiatives and cost-effectiveness analysis for improvement in patient health outcomes increased the quality of care. Additionally, the DNP project demonstrated elements of organizational and systems leadership that emphasized improvements in health outcomes of individuals receiving treatment for opioid dependence.

DNP Essential III: Clinical Scholarship and Analytical Methods for Evidence-Based Practice

Dissemination and translation of research in practice, evaluation of practice and the application of knowledge was integrated into the DNP project to solve current practice issues and implement the best evidence for practice. In addition, data collected from the project's intervention was collected and statistically analyzed to support the clinical significance of the results. Additionally, professional collaboration was an integral aspect of implementing practice policies to prevent buprenorphine diversion and sustain changes within the organization for the continuity of quality improvements.

DNP Essential IV: Information Systems/Technology and Patient Care Technology for the Improvement and Transformation of Health Care

Information systems/technology and patient care technology for improvement and transformation of health care was incorporated in this DNP project by designing, evaluating, and monitoring the effectiveness of the intervention and protocol for diversion prevention. Knowledge of information systems/technology was also used to analyze and interpret urine drug screening tests and to assess the efficacy of patient care. Information from web-based learning, clinical decision supports, and intervention tools were incorporated to implement quality improvement initiatives and support practice decision-making.

DNP Essential V: Health Care policy for Advocacy in Health Care

Advocacy for health care policy was demonstrated by critically analyzing current health policies on buprenorphine diversion and advocating for policy change within the organization. Furthermore, this project incorporated leadership in the development and implementation of institutional health policy which was demonstrated by collaborating with the key stakeholder and advocating for a diversion protocol.

DNP Essential VI: Interprofessional Collaboration for Improving Patient and Population Health Outcomes

The DNP project exemplified effective interprofessional collaboration which is essential to quality improvements in healthcare. The integration of effective communication, collaborative skills and a high functioning team was essential to completing the project's tasks, overcoming barriers, and implementing a buprenorphine diversion prevention protocol to improve patient health outcomes.

DNP Essential VII: Clinical Prevention and Population Health for Improving the Nation's Health

The aim of the DNP project was to increase clinical prevention and improve health outcomes in individuals receiving medication-assisted treatment with buprenorphine. This project analyzed epidemiological, biostatistical, economical, and geographical data in the development, implementation, and evaluation of clinical prevention of buprenorphine diversion in the primary care setting. In addition, synthesized concepts of psychosocial dimensions related to buprenorphine diversion and

evaluated interventions to address diversion, improved the health status of individuals with opioid use disorder and addressed gaps in care.

DNP Essential VIII: Advanced Practice Nursing

Experiential engagement was incorporated to design, implement, evaluate the DNP project inventions based on nursing science and addiction medicine. Furthermore, the DNP project encompassed therapeutic relationships and partnerships with other professional to facilitate optimal care and patient outcomes. Additionally, the project supports and guides advance practice nurses specializing in addiction medicine to inform practice decisions and to understand the patient outcomes resulting from the consequences of decisions.

Conclusion

In conclusion, diversion presents a significant problem for patients, healthcare providers, policymakers, and other individuals receiving treatment for opioid dependence (Wright et al., 2015). By using quantitative testing of both buprenorphine and norbuprenorphine levels, diversion can be detected more frequently. However, quantitative testing is not routine in clinical care due to increased costs. Previous studies suggest that the routine inclusion of quantitative buprenorphine and norbuprenorphine levels is invaluable for treatment monitoring; therefore, these tests should emerge as a standard of care (Accurso et al., 2017). Health policy and advocacy on behalf of

decreased cost for quantitative testing is indicated for individuals receiving buprenorphine treatment.

The increased use of quantitative urine drug screening tests in the primary care setting can drastically improve patient compliance, reduce diversion, and black-market sells, prevent drug overdose and related death, and decrease societal crimes worldwide.

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APPENDIX A. BUPRENORPHINE DIVERSION RISK SURVEY

Dear participant,

My name is Shameka Brown, and I am conducting a quality improvement project on buprenorphine diversion prevention as part of my doctoral program at Wilmington University. I would greatly appreciate your participation in a short survey about this important topic. Responding to the survey should not take more than five minutes, and your answers will be anonymous. Participation is voluntary, and you may refuse to answer certain questions of stop at any time without any penalty. However, I value your perceptions and sincerely hope that you will take a few minutes to help us better understand buprenorphine/suboxone diversion. All information provided on the survey will be anonymous, please do not include your name on the survey. The information provided on this survey will not affect your treatment within the clinical practice. A locked box will be placed in the unoccupied waiting room to maintain confidentiality. Please place your completed surveys in the designated area once you have completed it.

If you have any questions, feel free to contact me or my research supervisor Dr. Niaz at 410-392-6408.

Thank You!

Shameka Brown

Wilmington University, Doctor of nursing practice student

Suboxone Diversion Risk Survey

This survey is anonymous. If you choose to participate, do not write your name on this survey. No one will be able to identify you or your answers, and no one will know that you completed the survey. No answers on this survey will any way influence your present or future healthcare services in this practice. Your participation in this survey is voluntary. If you choose to participate, please place your completed questionnaire in the locked box located in the private telehealth waiting area.

1. Have you ever used IV heroin/fentanyl in the past? Circle Yes or No

2. Are you currently on suboxone films for treatment of opioid addiction? Circle Yes or No

3. Have you ever taken less suboxone than prescribed by your provider? Circle Yes or No

4. Have you ever given your suboxone to a friend or family member? Circle Yes or No

5. Have you ever sold your suboxone for money? Circle Yes or No

APPENDIX B. DNP PROJECT BUDGET

Buprenorphine Diversion Protocol Budget Plar 2021-2023

Average ann for office-based addiction treatme $5,980.00 (NIDA, 2020)

Annual income	Budget based upon DNP project participants 50 DNP project participants			
Item	Per Unit	Proposed 2021 (1,250 visits p	Proposed 2022 (1,000 visits pe	Proposed 2023 (850 visits per year)
Office Visit (CPT Code 99213)	$161.00	$201,250.00	$161,000.00	$136,850.00
In-house drug counseling per visi	$137.00	$171,250.00	$137,000.00	$116,450.00
Urine drug screening test per visi	$75.00	$93,750.00	$75,000.00	$63,750.00
Annual routine labs	$100.00	$5,000.00	$5,000.00	$5,000.00
Suboxone monthly prescription c	500.00	$625,000	$500,000	$425,000.00
Total annual income cost based o	50 participants for the DNP project	$1,096,250.00	$878,000.00	$747,050.00

Expenses				
Item	Per Unit	Proposed 2021 (per annum)	Proposed 2021 (per annum)	Proposed 2021(per annum)
Physician (average hourly salary)	$350.00	$291,200.00	$330,000.00	$350,000.00
Nurse practitioner (average hourl	$175.00	$240,000.00	$260,000.00	$280,000.00
Lab director (hourly salary)	$40.00	$83,200.00	$83,000.00	$83,500.00
Medical assistant (hourly salary)	$15.00	$124,800.00	$128,000.00	$130,000.00
Office supplies	$5,000.00	$5,000.00	$5,500.00	$5,700.00
Lab supplies	$5,000.00	$5,000.00	$5,000.00	$5,000.00
EKG Supplies	$1,000.00	$1,000.00	$1,200.00	$1,300.00
Office Rental (monthly cost)	$12,000.00	$12,000.00	$12,000.00	$12,000.00
Over head expenses				
Utilities, internet, phone (monthly	$1,200.00	$1,200.00	$1,200.00	$1,200
Cleaning services (monthly cost)	$500.00	$6,000.00	$6,000.00	$6,000.00
Total Expenses		$769,400.00	$831,900.00	$874,700.00
Annual profit and losses		$326,850.00	$46,100.00	(-127650)

Total Profit: ($326,850.00 + $46,100.00 - 127,650.00 = $245,300.00)

Capital Purchases	No anticipated capital purchases				
	Item		2021 per visit	2022 per visit	2023 per visit
		$0.00	$0.00	$0.00	$0.00
Office Expenses					
	1 Suite with 3 rooms				
	Computers/Hardware	$0.00	$0.00	$0.00	$0.00
	Office Consumables	$5,000.00	$0.00	$0.00	$500.00
	Electricity/Water	$1,200.00	$0.00	$0.00	$0.00
	Building Maint/Cleaning	$6,000.00		$0.00	$0.00
		$12,200.00	$0.00	$0.00	$500.00

APPENDIX C. WILMINGTON UNIVERSITY HUMAN SUBJECTS REVIEW

WILMINGTON UNIVERSITY

WILMINGTON UNIVERSITY
HUMAN SUBJECTS REVIEW COMMITTEE (HSRC) HSRC-1

RECORD AND REVIEW OF DOCTOR OF NURSING PRACTICE (DNP) PROJECT

Student: Brown (Last) Shameka (First) T. (Middle Initial)

Student ID: W 00305897

DNP Project Chair: Dr. Barbara Sartell

Academic Level

☒ 1. DNP Project

Forms Check List

☒ 1. DNP Project Protocol

☒ 2. CITI Training Certificate*

* Check with the DNP Program Chair for training requirements
* Training certificate cannot be older than 3 years

☒ 3. Instrument(s) *(as needed)*

☐ 4. Other Click here to enter text.

This section is to be completed by the HSR Committee

Archive Number: Click here to enter text.

DNP Category: Choose an item.

Final Approval Date: Click here to enter a date.

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HUMAN SUBJECTS REVIEW COMMITTEE (HSRC) HSRC-2

Complete This Worksheet Prior to Completing This Form

Purpose: The purpose of this worksheet is to provide support for making Quality Improvement Project determinations when there is uncertainty regarding whether the quality activity contains Human Subjects.

Directions: For a proposed DNP project to be classified as containing only Quality Improvement activities—which permits use of the DNP HSRC form—answers to all of the questions in the worksheet must be 'TRUE' for each activity proposed in the DNP project. If one or more answers is 'FALSE', the project requires completion of the HSRC standard form and committee review.

TRUE	FALSE	
☒	☐	The intent of the proposed activity is to assess and/or improve the quality of a practice, product or program to ensure established educational, clinical or program service standards are met or best evidentiary practices attained.
☒	☐	No activity proposed provides less than standard of care, services or instruction to participants.
☒	☐	No practice, product or program changes proposed are experimental and no test interventions or research questions are added that go beyond established or evidentiary best practice.
☒	☐	The proposed activity does not: (1) include a 'control group' in whom care, products, services or educational instruction are intentionally withheld to allow an assessment of its efficacy or (2) assign participants to receive different procedures, therapies or educational instruction based on a pre-determined plan such as randomization.
☒	☐	The proposed activity does not involve the prospective evaluation of a drug, procedure or device that is not currently approved by the FDA for general use (including "off-label" indications).
☒	☐	The proposed activity does not test an intervention or add research questions that go beyond established evidentiary best practice and/or are intended to generate generalizable knowledge.
☒	☐	The proposed activity would not increase harm—physical, psychological, social or economic—than would normally be encountered by the individual if s/he was not participating in this activity.
☒	☐	The lead person on the project has organizational responsibility and authority to recommend or impose a corrective action plan based on the outcome(s) of the activity, as applicable.
☒	☐	Interpretation of the data or any feedback to those who would benefit from the findings will not be deliberately delayed.
☒	☐	The proposed activity has merit and will likely be conducted regardless of any possibility of publication or presentation that may result from it.

Adapted from Rutgers HRP-309 (2017) with permission from Judith Neubauer, PhD.

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HUMAN SUBJECTS REVIEW COMMITTEE (HSRC) HSRC-3

DNP Project Information

Title of DNP Project (12 to 15 words maximum):

Identifying diversion of buprenorphine by utilizing quantification to analyze urine buprenorphine and norbuprenorphine levels in individuals with opioid use disorder.

Problem Description:
Provide a short summary of the clinical practice problem you will address with your DNP project. What is the gap in practice and what evidence will you be translating to practice?

Buprenorphine is a partial opioid agonist which is highly effective for treatment of opioid addiction (Chilcoat et al, 2019). Since the Drug Addiction Treatment Act (DATA waiver 2000) was passed, increased access to buprenorphine in outpatient settings has increased drastically in the United States (Weigand, 2016). The occurrence of buprenorphine diversion, abuse and misuse has increased due to the high frequency of prescribing (Chilcoat et al, 2019). Recent studies indicate that there is a higher prevalence of buprenorphine diversion among individuals with a history of intravenous opioid use disorder (Chilcoat et al, 2019). The aim of this project is to promote the utilization of quantitative urine drug screenings which analyze the buprenorphine and the metabolite norbuprenorphine. This intervention will assist buprenorphine prescribers in the primary care setting determine a patient receiving buprenorphine for treatment of addiction is compliant with taking his or her medication. The current gap in practice is the lack of a buprenorphine diversion program to identify non-compliant patients. This project will be translating the efficacy of utilizing quantitative urine drug test to analyze buprenorphine and norbuprenorphine levels to identify patients diverting their prescription medication and provide evidence to support the provider's decision to terminate treatment for addiction.

External Projects

If the DNP project will involve other organizations, it may be necessary to obtain permission from these organizations prior to collecting data. Some organizations have Institutional Review Boards (IRBs), and it may be necessary to obtain formal approvals from these IRBs. In other cases, a document from an appropriate organizational executive specifically approving the DNP project would be sufficient. The DNP student is responsible for determining what type of approval is required and obtaining the approval.

In cases where approval from Wilmington University's HSRC is required as a precondition to obtaining approval from another organization, the HRSC's approval will be provisional, requiring the additional step of obtaining DNP project approval documents from other organizations before receiving full approval from Wilmington University's HSRC.

If the DNP project involves other organizations, please answer these questions.

	YES	NO
Do these organizations require approval by their IRBs?	☐	☒
Has IRB approval been obtained? If **YES**, please attach the approval to this submission	☐	☒
Have other permission documents been obtained? If **YES**, please attach the approvals to this submission.	☒	☐

Other relevant information or comments:

Click here to enter text.

Population Information

Population: Gender(s) Males and females Age(s) 18 to 65 Race/ethnicity(ies) African-American, Caucasian, Hispanic/Latino

PICOT Question:
Include the PICOT Question in a complete sentence and then break down each section, Population -; Intervention -; Comparison -; Outcome -; Time -. Include sufficient detail so that someone unfamiliar with the project would understand all aspects of the proposed DNP project.

In primary care providers prescribing buprenorphine, how does quantification of buprenorphine and its metabolite norbuprenorphine levels in urine drug screenings versus standard urine drug test affect the identification of buprenorphine diversion within a 6-week period.

P: Adults age 18 to 65 with history of IV heroin/fentanyl use receiving buprenorphine (suboxone/films only) for treatment of opioid addiction in the primary care setting.

I: Quantitative urine drug screenings to analyze the levels of buprenorphine and its metabolite norbuprenorphine

C: Standard urine drug test

O: The analyzation of quantified buprenorphine and norbuprenorphine levels will identify if patients are non-compliant with taking their medication as prescribed which is indicative of medication diversion.

T: Six-week period

This project will include 50 participants, 5 primary care providers with X waiver to prescribe buprenorphine and 1 lab director.
An X-waivered buprenorphine provider can be a physician or a nurse practitioner. The provider must complete an eight-hour training through the Substance Abuse and Mental Health Services Administration (SAMHSA) which covers pharmacology of medications used for the induction process for treatment of addiction and information regarding best practices. After completion of the eight-hour training the provider must the apply for an X waiver number from the DEA. An X waiver number is required by the DEA to prescribe buprenorphine-containing products for treatment of opioid dependence (SAMHSA, 2020).

How will participants be selected for participation? (from PICOT question)

A convenience sample will be performed from performing chart reviews. Fifty participants will be selected based on their age and history of intravenous heroin/fentanyl abuse currently receiving buprenorphine (suboxone films).

What are the procedures that the participants will undergo in the proposed DNP project including the physical location and duration of participation? Provide a step-by-step outline of the project from start to finish. **Attach a copy of all DNP instruments, e.g., surveys, questionnaires, interview questions, etc. (if being utilized):**

The project will be conducted at Tri-State Health Inc. 107 North Bridge St., Elkton, MD. The project will be conducted for six weeks.

Intervention:
According to the Mayo Clinic (2019) the primary clinical use of quantification of buprenorphine in urine is to identify patients that have strayed from opioid dependence therapy. The standard reference value cut-off for buprenorphine concentrations: Buprenorphine: 5.0 ng/mL and Norbuprenorphine: 2.5 ng/mL (Mayo Clinic, 2019). Furthermore, a quantified buprenorphine level below 5ng/ml and norbuprenorphine below 2.5 ng/ml is considered a negative result for buprenorphine. Therefore, this standard will be used to identify individuals who divert buprenorphine (Mayo Clinic, 2019).

Steps:

1. Review the organization's current rate of discharge for non-compliance prior to the start of the DNP project and propose to change the rate of discharge in non-compliant patients.
2. Select sample population by performing chart reviews
3. Perform chart reviews of each of the participants to identify if quantitative urine drug screenings have been ordered previously.
4. Review each participant's previous lab results to identify illicit drug use and non-compliance.
5. Administer consent forms along with surveys to participants that consists of 5 questions regarding reasons for diverting medication. Surveys will be anonymous. There will be a locked box in the private office where the participant can place their completed surveys to maintain confidentiality.
6. Implement ordering quantitative urine drug screenings for buprenorphine and norbuprenorphine levels for a 6-week period. The inclusion of quantitative testing for buprenorphine and norbuprenorphine is considered standard and a medical necessity due to our high-risk population. In the past, our practice utilized qualitative data only from urine screenings such as a positive or negative result for buprenorphine. During the six-week project, each participant will a urine drug screening test during each visit and a quantitative urine drug screen will be ordered if results are negative for buprenorphine. Quantitative test for buprenorphine and norbuprenorphine will allow the provider to analyze the levels to indicate if the patient has adulterated their urine specimen and is non-complaint with taking their buprenorphine as prescribed which is indicative of diversion of buprenorphine. The average cost of a quantitative urine buprenorphine and norbuprenorphine test is approximately $92.00 to $165.00. Since quantitative urine drug screening tests are considered a medical necessity in the office-based/primary care setting when a patient's preliminary test is negative for buprenorphine, there will be no additional costs.
7. Compare data from the participant's previous urine drug screening test and record the quantitative urine levels of buprenorphine and norbuprenorphine utilizing a scatter plot diagram on a weekly basis.
8. Tests results will be available in the electronic medical records for the providers to review. In addition, a separate record of data from patient's urine drug screen results will be secured in a spreadsheet on the computer at the office. The patient's identification will not be included on the spreadsheet. Only the project's team member will have access to the spreadsheet with the data.

9. Compare the organization's discharge rate of non-compliant patients prior to the implementation of quantitative urine drug screens and after the 6-week period of implementation. Patients who consistently take buprenorphine as prescribed should have both buprenorphine and the metabolite norbuprenorphine present in their urine. The presence of buprenorphine above 5.0 ng/ml and norbuprenorphine above 2.5 ng/ml is a strong indicator that the patient is consistent. Therefore, the measurement for discharge will be a buprenorphine concentration below 5 ng/ml and a norbuprenorphine level below 2,5 ng/ml which is indicative of the patient not taking buprenorphine as prescribed. It is anticipated that the use of quantitative urine drug screenings will allow the providers to have definitive clinical evidence to support their decision to discharge non-compliant patients from treatment. This project is not intended to punitively discharge non-compliant patients, it is for the sole purpose of preventing buprenorphine diversion in the office-based/primary care setting and referring these high-risk patients to more intense inpatient rehabilitation for treatment of opioid dependence. Moreover, the rate of discharge is anticipated to increase after implementing the use of this quantitative urine drug screenings. In addition, this project will promote the use of alternative medication-assisted treatment interventions such as long-acting buprenorphine injections or vivitrol injections to prevent the diversion of buprenorphine.
10. Perform statistical analyzation of all data.
11. Discuss data and project outcomes with team members
12. Implement ordering quantitative urine drug screenings for buprenorphine and norbuprenorphine in our practice.

Confidentiality and Security

Select **YES** to certify that:

	YES	N/A
Procedures have been taken to ensure that individuals cannot be identified via names, digital identifiers (e.g., email address, IP address), images or detailed demographic information.	☒	☐
Code to name association data/information is securely and separately stored. (Participants are given codes and the codes are securely stored separately from their answers.)	☒	☐
All data is maintained in encrypted and/or password protected digital/electronic files.	☒	☐
Individually identifiable information will be securely maintained for three years past the completion of the research, and then destroyed rendering the data unusable and unrecoverable.	☒	☐

Describe the procedures you are taking to maintain anonymity, confidentiality, or information security.

Anonymity and confidentiality will be maintained removing all participant information which identifies characteristics such as city, ethnic background, and occupation. The participants legal name will be removed from all lab results and documents used to collect data. All data collected specifically for the purpose of this DNP project will be stored in the organization's internal hard drive to protect the participants information and maintain confidentiality. The folder in which the project's data is stored will be password-protected to ensure that only the DNP project team can access information and no unauthorized staff can view the confidential data.

DNP Protocol

Does this DNP project involve?	YES	NO
Prisoners, probationers, pregnant women (if there is a medical procedure or special risk relating to pregnancy), fetuses, the seriously ill or mentally or cognitively compromised adults, or minors (under 18 years) as participants	☐	☒
The collection of information regarding sensitive aspects of the participants behavior (e.g., drug, or alcohol use, illegal conduct, sexual behavior)	☒	☐
The collection or recording of behavior which, if known outside the research, could place the participants at risk of criminal or civil liability or could be damaging to the participant's financial standing, employability, insurability, or reputation	☐	☒
Procedures to be employed that present more than minimal risk[1] to participants	☐	☒
Deception	☐	☒
Possible or perceived coercion (e.g., a concern in power relationships such as teacher/student, employer/employee, senior/subordinate)	☐	☒
Benefits or compensation to participants (beyond the general benefits of the knowledge to be gained or small gifts/lottery prizes)	☐	☒
A conflict of interest (e.g., the researcher's material or other interests may bias collection, interpretation, or use of data)	☐	☒

If you answered **"NO"** to all of the questions please proceed to the next page.

If you answered **"YES"** to any of the questions, provide evidence that you have taken the training module or modules that relate to this risk and discuss what you learned about reducing the risk from the training in the textbox below and/or by attaching the evidence to this document.

[1] Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater than those ordinarily encountered in everyday life or during the performance of routine physical or psychological examinations or tests

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HUMAN SUBJECTS REVIEW COMMITTEE (HSRC) HSRC-12

Obligations of DNP Student

Any substantive changes made to the DNP protocol must be reported to and reviewed by your college's HSRC representative(s) prior to implementation of such change. Any complications, adverse reactions, or changes in the original estimates of risks must be reported at once to the HRSC chairperson before continuing the project.

Select **YES** to certify that:

	YES
DNP data will be retained for a minimum of three years past the completion of the project in accordance with federal regulations	☒
The DNP student will submit document and form revisions and updates, as appropriate	☒
The DNP student will submit a renewal petition if the data collection has not been completed within one year of the most recent HSRC approval*	☒

* **Note**: HSRC approval expires after one year, requiring renewal of the HSRC Protocol

The DNP student's signature below certifies that he/she has (a) read and understands the obligations as a DNP student, (b) DNP project approval expires one year after the final approval date shown on page 1, and (c) that the information contained in and submitted with this HSRC protocol is accurate and complete.

DNP Student:

Print name: Shameka T. Brown
Signature: Shameka T. Brown Date: 11/3/2020

Obligations of the DNP Project Chair

The DNP Project Chair has two major obligations. First, the DNP Project Chair must ensure the DNP Student completes all relevant training courses. Second, the DNP Project Chair must ensure the DNP Student submits all document and form revisions and updates, as appropriate for the research.

The DNP Project Chair's signature below certifies that he/she has (a) read and understands the obligations as a DNP Project Chair and (b) that the information contained in and submitted with this HSRC protocol is accurate and complete.

DNP Project Chair:

Print name: Click here to enter text.
Signature: Date: 10/15/2020

BHSartell 11/10/2020

APPENDIX D. WILMINGTON UNIVERSITY HSRC LETTER OF EXEMPTION

WILMINGTON
UNIVERSITY

November 12, 2020

Shameka Brown

Dear Shameka,

Wilmington University's Human Subjects Review Committee (HSRC) is pleased to inform you that your research proposal ***Identifying diversion of buprenorphine by utilizing quantification to analyze urine buprenorphine and norbuprenorphine levels in individuals with opioid use disorder*** was reviewed on ***November 11, 2020***. The study was categorized as ***Exempt***. Your signed HSRC form is attached.

Now that your DNP project has been approved by the HSRC, there are multiple elements with which you must comply. Wilmington University adheres strictly to these regulations:

1. You must conduct your DNP project exactly as it was approved by the HSRC.
2. Any additions or changes in procedures must be approved by the HSRC before they are implemented.
3. You must notify the HSRC promptly of any events that affect the safety or well-being of subjects.
4. You must notify the HSRC promptly of any modifications to your DNP project or other responses that are necessitated by any events reported in items 2 or 3.
5. Your approval is provisional if you require Institutional Review Board approval from your organization. Once organizational approval has been obtained, please submit your signed approval and completed IRB application to DNP Administrative Assistant via email.

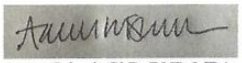
The HSRC may review or audit your project at random or for cause. In accordance with Wilmington University policy, the HSRC may suspend or terminate your DNP project if your project has not been conducted as approved and/or if other difficulties are detected.

While not under the purview of the HSRC, DNP students are responsible for adhering to US copyright law when using existing scales, survey items, and other works in the conduct of research/DNP projects.

In conclusion, you have developed an interesting evidence-based practice project aligned with the AACN DNP Essentials (2006). This is an important project for healthcare practices now and in the future. Best wishes for continued success.

Sincerely,

Angela Herman, DNP, RN
HSRC Committee Representative
Chair, Health Sciences Program
Assistant Professor
College of Health Professions



Aaron Sebach, PhD, DNP, MBA, AGACNP-BC, FNP-BC, FHM
Chair, DNP Program
Associate Professor
College of Health Professions

APPENDIX E. DNP PROJECT APPROVAL LETTER FROM TRI-STATE HEALTH'S MEDICAL DIRECTOR

Tri-State Health, Inc
107 N Bridge St. Elkton MD, 21921
2288 Pulaski Hwy. North East, MD 21901
266 S College Ave. Newark, DE 19711
2527 Jacob Tome Memorial Hwy. Colora, MD 21917
P: 410-392-6408 F: 410-392-6409
https://tristatehealthinc.com

November 3, 2020

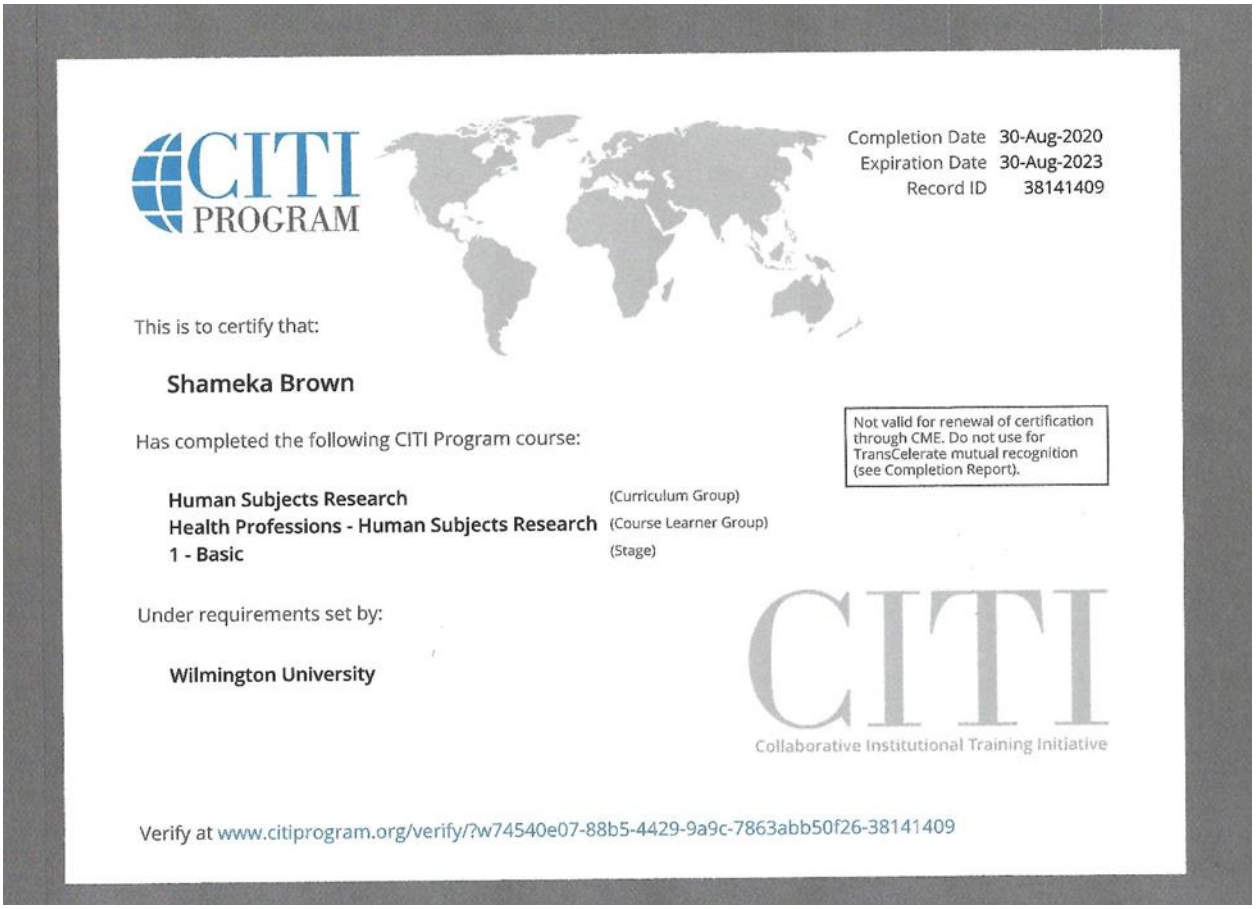
Dear Wilmington University Doctor of Nursing program faculty board,

I, Dr. Muhammed Niaz, MD, am writing this letter of approval on behalf of the Wilmington University student Shameka Brown. I have reviewed Shameka Brown's proposed DNP quality improvement project and I give my permission to perform the project at Tri-State Health Inc. If you have any further questions regarding this matter, please feel free to contact me at your earliest convenience.

Sincerely,

Dr. Muhammed Niaz, MD, Medical Director
Phone: 410-392-6408

APPENDIX F. CITI TRAINING-HUMAN SUBJECTS RESEARCH



CITI PROGRAM

Completion Date 30-Aug-2020
Expiration Date 30-Aug-2023
Record ID 38141409

This is to certify that:

Shameka Brown

Has completed the following CITI Program course:

Not valid for renewal of certification through CME. Do not use for TransCelerate mutual recognition (see Completion Report).

Human Subjects Research (Curriculum Group)
Health Professions - Human Subjects Research (Course Learner Group)
1 - Basic (Stage)

Under requirements set by:

Wilmington University

CITI
Collaborative Institutional Training Initiative

Verify at www.citiprogram.org/verify/?w74540e07-88b5-4429-9a9c-7863abb50f26-38141409

APPENDIX G. TRI-STATE HEALTH BUPRENORPHINE DIVERSION PREVENTION PROTOCOL

Buprenorphine Diversion Prevention protocol:

Drug diversion is a medical and legal concept involving the transfer of any legally prescribed controlled substance. Diversion includes giving the prescribed medication to a relative or friend or illegal sale of the drug.

These factors include:

- History of IV heroin fentanyl use
- Relative or friend with opioid use disorder not currently receiving treatment
- Individuals who request mono-buprenorphine products such as Subutex (buprenorphine)
- Individuals with prescription drug monitoring record of multiple prescribing provider's
- Individuals recently discharged from another addiction treatment program for non-compliance.

Signs of buprenorphine diversion include:

- Individuals who attempt to come early for their prescription refill
- Individuals who report taking less medication than prescribed
- Individuals who request a higher dose without evident clinical signs of withdrawal
- Clinical signs of drug intoxication or individual reports recent illicit drug use

- Individuals who attempt to conceal or adulterate their urine specimens
- Negative buprenorphine and norbuprenorphine levels, abnormal urine creatinine and ph levels, below normal urine specimen temperatures.
- Fresh track marks

Protocols to prevent diversion:

- Providers should order quantitative buprenorphine and norbuprenorphine urine drug screening test frequently in addition to routine screenings test. Depending on the individual's insurance, the patient may be allowed one quantitative test per month.
- Educate patient on diversion and consequences of diversion during each office visit
- Partner with local pharmacies to inquire about suspicion for diversion
- Do not refill prescriptions for buprenorphine before the due date
- Re-evaluate each patient during each office visit, if the patient reports taking less medication than prescribed, decrease the current dose
- Prescribe a limited supply of buprenorphine and schedule patient for more frequent office visits
- Check the prescription drug monitoring record during each office visit to ensure that the patient is not receiving medication from another provider
- Request that patient bring in their suboxone film wrappers for counting during each office visit

- Offer long-acting buprenorphine injections or vivitrol injection for non-compliant patients
- Refer non-compliant patients to methadone clinics or inpatient rehabilitation centers where the individual can be in a monitored environment.
- Terminate treatment for non-compliant individuals that refuse long-acting buprenorphine injections
- Encourage individuals with relatives or friends with opioid use disorder to bring in their loved ones for addiction treatment.