July 2020

The Impact of Psychosocial Treatment on Medication Treatment for Opioid Use Disorder

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THE IMPACT OF PSYCHOSOCIAL TREATMENT ON MEDICATION TREATMENT FOR OPIOID USE DISORDER

A Dissertation Presented

by

TARA MARIOLIS

Submitted to the Graduate School of the
University of Massachusetts Amherst in partial fulfillment
of the requirements for the degree of

DOCTOR OF PHILOSOPHY

May 2020

Nursing

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DEDICATION

This work was done in honor of:

—Those who have been rendered powerless by a drug or compulsion

—Those whose lives are shattered as a result

—Those who have found recovery and those who seek it

—Those whose lives were lost in the struggle, and the families who mourn them

ACKNOWLEDGEMENTS

I would like to express my gratitude, first, to my advisor, Dr. Lisa Chiodo. Her intuitive sense of when to offer a push, encouragement, guidance, and wisdom is one of a gifted mentor and teacher. Whenever I got lost in the woods or missed the forest for the trees, she graciously provided a lens, compass, or map without hesitation. Her great passion for studying substance use inspired me to pursue this research. I will always be grateful for the opportunity to be in her "wheelhouse" and to learn extensively from her. Her knowledge of research methods, database management, and statistics is the stuff of genius. Without her expertise, this project would not have been realized.

I want to thank Dr. Amanda Wilson, for her entrepreneurship, extensive knowledge, and generosity in making this study possible, as well as research assistant Angelo Cruz for his hard work collecting data.

I want to express my appreciation for members of my committee, Dr. Genevieve Chandler and Dr. Daniel Gerber, both of whom were a pleasure to work with, and whose advice, input, and patience were invaluable.

I want to acknowledge the immeasurable support and practical help of dear classmates and friends, including Jordon Bosse, Raeann LeBlanc, Kirk Sanger, and Deb Stone.

I would like to thank all my professors at the University of Massachusetts Amherst College of Nursing for their contributions to my development as a researcher, including Dr. Cynthia Jacelon, Dr. Karen Kalmakis, Dr. Donna Zucker, Dr. Linda Lewandowski, and Dr. Annette Wysocki.

Finally, completing my degree would not have been possible without the love and support of my family. A heartfelt thank you to my husband Chuck, whose advice, encouragement, and practical help I will forever cherish. Loving thanks to both my devoted daughters Elise and Lauren, who always inspired me to continue. Thank you to my attentive father, and siblings Rina, Mark, Tom, and Dr. Lia DiBello and Dr. Paul DiBello who forged the trail of this journey. Deep gratitude must go to my mother, who taught me great perseverance and would have been proud to see me finish.

ABSTRACT

THE IMPACT OF PSYCHOSOCIAL TREATMENT ON MEDICATION TREATMENT
FOR OPIOID USE DISORDER

MAY 2020

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In 2017, more than 70,000 people in the United States died due to drug overdoses; of that number, approximately 68% involved prescription or illicit opioids (CDC, 2019). Presently, insurance companies and physicians require all opioid use disorder (OUD) patients to receive counseling during medication treatment for OUD, despite the lack of evidence it is necessary for all patients. This requirement restricts access and creates hardship for those who may benefit from medication alone. In an effort to inform policy and improve quality of treatment, this nonexperimental, correlational study examined the relationship between individual counseling status and treatment outcomes in patients receiving medication treatment for OUD. Treatment outcome variables (treatment utilization, medication use, and opioid use) were extracted from the electronic health records of 11,551 adults who received treatment between January 2016 and January 2018. The impact of individual counseling on outcome variables was examined while controlling for confounding variables (gender, age, race, ethnicity, PTSD/trauma, anxiety, and criminal justice involvement). Bivariate analyses suggested women in OUD

treatment were prone to have experienced PTSD/trauma and anxiety, while males were more likely to have CJS involvement. Women were more often retained in care and were in treatment for longer periods of time than males. In addition, older patients used OUD medication more often than younger patients; however, older patients were also more prone to use benzodiazepines and alcohol. Multivariate analyses revealed patients with increased rates of treatment utilization were more likely to utilize medication treatment and demonstrate reduced opioid use. In addition, higher rates of treatment utilization were related to reduced opioid use. Patients with more frequent interruptions in OUD treatment more often tested positive for opioids. This study revealed very little evidence that counseling during OUD treatment had a positive impact on treatment utilization. Yet, it found no evidence that counseling while active in treatment had an impact on medication utilization or opioid use. Although counseling may have some benefit for some patients in OUD treatment, these findings do not support mandating counseling during OUD treatment.

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CHAPTER 1

INTRODUCTION

Background of the Problem

The misuse of opioids is a serious public health crisis in the United States and around the world. Its impact is both devastating and far-reaching, affecting nearly every individual, community, city, and state across the country. In the U.S., an average of 115 people die each day due to overdoses on opioids (Centers for Disease Control [CDC], 2017b; National Institute of Drug Abuse [NIDA], 2018a). It is imperative to identify effective and accessible treatments, and quickly put them into practice. While many treatments are already in use, progress in halting the opioid crisis has been slow. Research is needed to determine advantages of current pharmacotherapies and psychosocial approaches, treatment combinations, and treatment settings, specifically office-based primary care (Kampman & Jarvis, 2015).

The focus of this research study was to examine the relationship between individual counseling status and several treatment outcomes in patients receiving medication treatment for opioid use disorder (OUD). The outcome variables examined included treatment utilization, medication utilization, opioid use and other substance use. This relationship was examined while controlling for important potential confounding variables (e.g., gender, age, race, ethnicity, PTSD/trauma, anxiety, and criminal justice system (CJS) involvement).

Opioid Abuse and Opioid-Related Deaths

Addiction specialists, healthcare providers (HCPs), and opioid treatment programs have been inundated due to the sharp rise in opioid abuse in the U.S. and

worldwide. It is estimated that the prevalence of opioid use is .70% (32.4 million) of the world population of adults (National Center for Health Statistics, 2015). In 2018, an estimated 10.3 million persons aged 12 and older misused opioids. An estimated 9.9 million misused prescription opioids, and 808, 000 were heroin users (Substance Abuse and Mental Health Services Administration [SAMHSA], 2019a). In 2017, more than 70,000 people died due to drug overdoses, making it a leading cause of death in the United States. Of that number, approximately 68% involved prescription or illicit opioids (CDC, 2019). To understand the scope of economic burden of prescription opioid overdoses worldwide, Florence, Zhou, Luo, and Xu (2016) examined reports of fatal prescription opioid overdoses from the National Survey of Drug Use and Health. They found the financial cost due to fatal overdoses and abuse of prescription opioids to be an estimated $78.5 billion. One third of this amount was due to increased healthcare and substance abuse treatment costs.

The "Morbidity and Mortality Weekly Report" compiled by the CDC revealed that, during 2017, 130 individuals died each day in the U.S. due to opioids (CDC, 2017b). Drug overdose deaths from any opioid including heroin, prescription opioids, synthetic opioids, and methadone rose from 16,849 in 1999 to 70,237 in 2017. Furthermore, Muhuri, Gfroerer, and Davies (2013) found that among new users of heroin, three out of four users reported their problem use began with medically prescribed opioids. Given the scope and depth of opioid abuse and its consequences, it is essential to have evidence-based treatment approaches made widely accessible (American Society of Addiction Medicine (ASAM), 2014).

The Opioid Epidemic

The source of widespread opioid abuse in the U.S. is multifaceted. In the 1980s, a poor-quality research study was disseminated that proposed several chronic pain conditions could be treated with opioids (Portenoy & Foley, 1986). A large pharmaceutical company then developed a highly addictive, opioid-based pain medication (OxyContin) and funded a large educational campaign targeting physicians, which put forth that chronic pain due to a wide range of serious health problems could be safely managed with long-term opioid treatment (Kolodny et al., 2015).

At around the same time, the Joint Commission of the Accreditation of Healthcare Organizations (JCAHO) identified a pattern by physicians of inadequately treating pain in patients (Berry & Dahl, 2000). The JCAHO actively encouraged physicians to be more aggressive in treating pain. Assuming little risk of harm, physicians began prescribing opioids at increased rates. This led to widespread access and proliferation of opioids, heightening abuse among patients, even for those who took the medication as instructed. The result was pervasive opioid abuse and an opioid epidemic.

Several measures were instituted to address the problem. In 2017, the President's Commission on Combating Addiction and the Opioid Crisis put forth several recommendations for limiting access, and increasing funding for prevention, treatment and research (President's Commission, 2017). Notably, the report recommended that congress and the federal government provide funding to the National Institute of Drug Abuse (NIDA), and the National Institute of Mental Health (NIMH) for a review of existing research programs, and for additional research on the prevention and treatment of opioid abuse.

In addition, the American Society of Addiction Medicine (ASAM), in a recent publication of "National Practice Guidelines for Use of Medications in the Treatment of Opioid Use Disorder," identified several research objectives on the application of psychosocial treatments (Kampman & Jarvis, 2015, p. 23). Included among these objectives are (a) identifying comparative advantages of specific psychosocial treatments; (b) determining the effectiveness of psychosocial treatment in combination with specific pharmacotherapies; and (c) identifying psychosocial treatments appropriate for addition to buprenorphine or naltrexone that can be delivered in primary care settings (Kampman & Jarvis, 2015, p. 39).

Treatments for Opioid Use Disorder

Treatments available for opioid use disorder (OUD) include pharmacotherapies and psychosocial treatments. Medications include methadone (mu agonist) and buprenorphine (partial mu agonist), which are used for treatment and withdrawal management. Naltrexone (antagonist) is used for relapse prevention, and naloxone (antagonist) for treatment of overdose (Kampman & Jarvis, 2015). It is currently recommended that psychosocial treatments such as cognitive behavioral therapy and coping skills training, community reinforcement approaches, contingency management, and motivational interviewing be added to medication treatment (NIDA, 2018a, 2018b). Although medications may be used as a stand-alone treatment, some individuals benefit from psychosocial treatments that assist with engagement in treatment, abstinence, and prevention of relapse (Dugosh et al., 2016). Successful engagement in treatment has been shown to reduce illicit drug use, improve brain function, treatment adherence, health, and overall functioning (NIDA, 2018a).

Medication Treatment

The four medications most commonly used to treat OUD are methadone (MET), buprenorphine (BUP), naloxone (NX), and naltrexone (NTX; Fullerton et al., 2014; Lee et al., 2018; NIDA, 2017, 2018b SAMHSA, 2018a; Thomas et al., 2014). BUP acts as an agonist at the mu opioid receptor and an antagonist at the kappa receptor (SAMHSA, 2018a). It acts by lowering risk of abuse and physical dependence, has few withdrawal symptoms, possesses a ceiling effect at high doses, and has improved safety over opioid full agonists (Lutfy & Cowan, 2004). It is often combined with NX, which acts by blocking opioid receptors, thereby blocking opiates and reducing the potential for abuse. BUP and BUP combined with NX are delivered in office-based settings, substance abuse clinics, and treatment centers. BUP is an effective and widely used medication for the treatment of OUD.

Methadone (MET) is a potent synthetic opioid analgesic that is structurally unique among other opioid classes. It has properties similar to morphine; however, it is long acting. It eliminates withdrawal symptoms and reduces cravings by acting on the same brain targets as heroin and morphine (NIDA, 2018a). It has been used successfully to treat heroin dependence for over 40 years, although it must be dispensed at approved treatment centers (NIDA, 2018a).

Naltrexone (NTX) is an opioid antagonist that counters the effects of opioids and reduces cravings for opioid-based drugs. If opioids are taken during treatment with NTX, withdrawal symptoms ensue. Its use has been limited due to poor adherence and tolerability, although it has demonstrated effectiveness when combined with psychosocial treatments such as contingency management (DeFulio et al., 2012; Everly et al., 2011;

NIDA, 2018a; Preston et al., 1999). The utilization of medications such as MET, BUP, NX, and NTX has significantly improved opioid use treatment in recent years.

Psychosocial Treatments

While medications are highly effective in treating OUD, the addition of psychosocial treatment has demonstrated mixed results (W. Ling, Hillhouse, Ang, Jenkins, & Fahey, 2013; Otto et al., 2014; Stein et al., 2015). Psychologically based therapies are thought to assist patients by modifying an individual's thinking and behavior patterns in relation to opioid use, improving health-promoting skills, adherence to treatment, and relapse prevention (NIDA, 2018c). Approaches include medical management, individual, group and family therapy, cognitive behavioral therapy, contingency management, and motivational interviewing (Brooner et al., 2007; DeFulio et al., 2012; Fiellin et al., 2014; NIDA, 2016). While not considered a psychosocial treatment, peer-support is an adjunctive approach that is effective for some individuals (Kampman & Jarvis, 2015, p. 38). Treatment approaches can include 12-step programs such as Narcotics Anonymous (NA), Self-Management, and Recovery Therapy (SMART), among others. Depending on the type of treatment required to meet treatment goals, psychosocial treatments are available at hospitals, outpatient clinics, and residential settings.

Significance of the Study

Extensive research evidence suggests that medication treatment for OUD is highly effective (Dennis et al., 2014; Fiellin et al., 2008, 2014; Gunderson, Hjelmström, & Sumner, 2015; W. Ling et al., 2010, 2013; Mattick, Breen, Kimber, & Davoli, 2014; Timko, Schultz, Cucciare, Vittorio, & Garrison-Diehn, 2016). Currently, providers and

insurance companies require patients to attend counseling during OUD treatment despite lack of evidence that it is necessary for all patients (Fiellin et al., 2006, 2013; W. Ling et al., 2013; Weiss et al., 2011). This requirement restricts access to care and creates hardship for those who may benefit from medication treatment alone. Counseling may not be necessary for patients who benefit from medication as a standalone treatment. The results of the present study will better inform policy, reduce treatment burden for patients**,** and improve the quality of patient care.

Purpose of the Study

The focus of this research study was to examine the relationship between individual counseling status and outcome variables in patients receiving medication treatment for OUD. The outcome variables examined included treatment utilization (maintenance visits, random maintenance visits, rescheduled visits, other encounters, care interruptions, no-show visits, total time in care, and time since last visit), medication utilization, opioid and other substance use, and treatment retention. The impact on outcome variables was examined while controlling for important confounding variables (e.g., gender, age, race, ethnicity, PTSD/trauma, anxiety, and CJS involvement).

Aims and Hypotheses

Aim 1. What is the relationship between treatment utilization, medication utilization, and opioid use in a sample of individuals with opioid use disorder receiving medication treatment?

H1a: Patients with a higher rate of random maintenance visit compliance will have increased medication utilization.

H1b: Patients with a higher rate of maintenance visit compliance will have increased medication utilization.

H1c: Patients with a lower rate of "no show" visits will have increased medication utilization.

H1d: Patients with longer total time in care will have increased medication utilization.

H1e: Patients with a lower rate of rescheduled visits will have increased medication utilization.

H1f: Patients with a lower rate of other encounters will have increased medication utilization.

H1g: Patients with a lower rate of care interruptions will have increased medication utilization.

H1h: Patients with less time since the last visit will have increased medication utilization.

H1i: Patients with a higher rate of random maintenance visit compliance will have decreased opioid use.

H1j: Patients with a higher rate of maintenance visit compliance will have decreased opioid use.

H1k: Patients with a lower rate of "no show" visits will have decreased opioid use.

H1l: Patients with longer total time in care will have decreased opioid use.

H1m: Patients with a lower rate of rescheduled visits will have decreased opioid use.

H1n: Patients with a lower rate of other encounters will have decreased opioid use.

H1o: Patients with a lower rate of care interruptions will have decreased opioid use.

H1p: Patients with less time since the last visit will have decreased opioid use.

H1q: Patients with increased medication utilization will have decreased opioid use.

Aim 2. Determine if medication utilization mediates the relationship between treatment utilization and opioid use in patients receiving medication treatment.

H2a: Medication utilization will mediate the relationship between rate of random maintenance visit compliance and opioid use.

H2b: Medication utilization will mediate the relationship between rate of maintenance visit compliance and opioid use.

H2c: Medication utilization will mediate the relationship between rate of "no show" visits and opioid use.

H2d: Medication utilization will mediate the relationship between total time in care and opioid use.

H2e: Medication utilization will mediate the relationship between rate of rescheduled visits and opioid use.

H2f: Medication utilization will mediate the relationship between rate of other encounters and opioid use.

H2g: Medication utilization will mediate the relationship between rate of care interruptions and opioid use.

H2h: Medication utilization will mediate the relationship between time since the last visit and opioid use.

Aim 3. Examine the impact of current and prior counseling on treatment utilization, medication utilization, substance use, and treatment retention.

H3a: There will be no difference in rate of random maintenance visit compliance between patients who are currently in counseling and those who are not.

H3b: There will be no difference in rate of random maintenance visit compliance between patients who have previously been in counseling and those who are not.

H3c: There will be no difference in rate of maintenance visit compliance between patients who are currently in counseling and those who are not.

H3d: There will be no difference in rate of maintenance visit compliance between patients who have previously been in counseling and those who are not.

H3e: There will be no difference in rate of "no show" visits between patients who are currently in counseling and those who are not.

H3f: There will be no difference in rate of "no show" visits between patients who have previously been in counseling and those who are not.

H3g: There will be no difference in total time in care between patients who are currently in counseling and those who are not.

H3h: There will be no difference in total time in care between patients who have previously been in counseling and those who are not.

H3i: There will be no difference in rate of rescheduled visits between patients who are currently in counseling and those who are not.

H3j: There will be no difference in rate of rescheduled visits between patients who have previously been in counseling and those who are not.

H3k: There will be no difference in rate of other encounters between patients who are currently in counseling and those who are not.

H3l: There will be no difference in rate of other encounters between patients who have previously been in counseling and those who are not.

H3m: There will be no difference in rate of care interruptions between patients who are currently in counseling and those who are not.

H3n: There will be no difference in rate of care interruptions between patients who have previously been in counseling and those who are not.

H3o: There will be no difference in time since last visit between patients who are currently in counseling and those who are not.

H3p: There will be no difference in time since last visit between patients who have previously been in counseling and those who are not.

H3q: There will be no difference in medication utilization between patients who are currently in counseling and those who are not.

H3r: There will be no difference in medication utilization between patients who have previously been in counseling and those who are not.

H3s: There will be no difference in opioid use between patients who are currently in counseling and those who are not.

H3t: There will be no difference in opioid use between patients who have previously been in counseling and those who are not.

H3u: There will be no difference in treatment retention between patients who are currently in counseling and those who are not.

H3v: There will be no difference in treatment retention between patients who have previously been in counseling and those who are not.

Aim 4. To examine the comparative effectiveness of type of psychosocial treatment on medication utilization, treatment utilization, and opioid use in patients receiving medication treatment.

H4a: There will be no difference in rate of random maintenance visit compliance across different types of psychosocial treatment.

H4b: There will be no difference in rate of maintenance visit compliance across different types of psychosocial treatment.

H4c: There will be no difference in rate of "no show" visits across different types of psychosocial treatment.

H4d: There will be no difference in total time in care across different types of psychosocial treatment.

H4e: There will be no difference in rate of rescheduled visits across different types of psychosocial treatment.

H4f: There will be no difference in rate of other encounters across different types of psychosocial treatment.

H4g: There will be no difference in rate of care interruption across different types of psychosocial treatment.

H4h: There will be no difference in time since the last visit across different types of psychosocial treatment.

H4i: There will be no difference in medication utilization across different types of psychosocial treatment.

H4j: There will be no difference in opioid use across different types of psychosocial treatment.

Summary

The rise in OUD and opioid-related deaths is an urgent public health crisis in the U.S. and around the world. Evidence suggests medication treatment is highly effective

for OUD and its related health consequences. Little research has been done on the impact of psychosocial treatments such as counseling on outcome variables for the treatment of OUD. This is especially important given that most providers of medication treatment require patients to receive psychosocial treatment despite lack of research demonstrating its effectiveness. These study findings further advance our knowledge of effective treatment for OUD.

CHAPTER 2

THEORETICAL FRAMEWORK AND REVIEW OF LITERATURE

This chapter describes the etiology of OUD, the origin, recent history and impact of the opioid epidemic, and current treatment approaches from the perspective that OUD is a chronic brain disease requiring long-term treatment and management. Additionally, the theoretical framework underpinning the study, the *Neuman Systems Model,* key definitions, and a review of the literature are presented.

Opioid Use Disorder

OUD is a chronic and debilitating disease, which when left untreated may result in significant health problems, physiological dependence, overdose, and death. Opioids are a class of medications available via prescription and in the form of heroin, an illicit opioid (NIDA, 2018a). Opioids come in a variety of forms that are similar in chemical composition. Opioids interact with opioid receptors in the body, resulting in many physiologic changes including the following: (a) depression of breathing due to neurochemical effect on the brainstem, (b) heightened sense of pleasure due to the effects on the limbic system, and (c) reduced pain reception throughout the body (NIDA, 2018d).

Opioids are generally safe when used as prescribed; however, they are widely misused and abused. Even when taken as directed, physiological dependence may occur, thereby increasing the risk of overdose and death (NIDA, 2018b). The complex nature of the disorder, reduced access to treatment, combined with a rapidly growing opioid epidemic, has created a public health crisis in the United States and around the world (Volkow et al., 2018). Furthermore, the stigma associated with OUD is longstanding and

continues to present barriers to treatment, reducing access, and slowing the development of effective treatments.

How it is that some individuals are able to avoid the ravages of opioid abuse while others are not, has baffled healthcare professionals and addiction specialists. While far from clear, the answer very likely lies in the complex nature of an individual's biology, cognition, personality, life experience, and ability to utilize supports. For example, evidence exists that persons with mental health problems such as anxiety and depression face a higher risk of developing OUD (Barry et al., 2016; Rosic et al., 2017; Savant et al., 2013). Additionally, persons with a tendency toward impulsivity find it more difficult to resist using the drug (Baldacchino, Balfour, & Matthews, 2015; Tolomeo, Gray, Matthews, Steele, & Baldacchino, 2016). Finally, one's access to the drug, developmental stage, and traumatic experiences may place an individual at further risk of OUD (Kumar, Stowe, Han, & Mancino, 2016; Stein et al., 2017).

The results of extensive biological research have shed light on the brain's role in perpetuating opioid abuse. For instance, there is evidence that an individual's neurobiological makeup may set the stage for genetic vulnerability for abusing opioids. Genetics also may play a role in one's physiological response to opioids, and long-term abuse of opioids may affect the delicate balance of neurotransmitters in the brain. The interaction of environmental and social factors, as well as a biological predisposition to vulnerable brain pathways leading to opioid abuse, may also produce cravings and episodes of relapse years after an individual is no longer dependent (Kosten & George, 2002). Moreover, brain abnormalities that result from chronic use of opioids can lead to physiological changes and consequences that are wide-ranging and long-lasting (Kosten

& George, 2002). Understanding the complex causes and effects of OUD permits clinicians and researchers to identify predictors, develop effective treatments, and quickly put them into practice in order to improve patient outcomes.

Significance of the Opioid Epidemic

The opioid epidemic has become a major public health problem in the U.S. and around the world. Globally, it is estimated that 15 million people suffer from opioid dependence and that 69,000 persons die each year from opioid overdose (World Health Organization, 2014). In the U.S., drug overdoses have tripled in the last 15 years (Rudd, Seth, David, & Scholl, 2016). In 2015 alone, drug overdoses accounted for 52,404 deaths in the U.S., and 33,091 (63.1%) were due to opioids. Further, a study by Florence et al. (2016) suggests that overdoses of prescription opioids have resulted in an economic burden to the U.S. of $78.5 billion.

Additionally, the degree to which the opioid epidemic has escalated the spread of infectious diseases underscores the health consequences of OUD. For example, from 2004–2014, there was an increased rates of hepatitis C (400% among 18–29 year olds and 325% among 30–39 year olds) and hepatitis B (20, 000 new cases in the U.S. among persons who inject drugs; CDC, 2017a). The rates of HIV, endocarditis, epidural abscess, and other conditions have also increased among persons who inject drugs (Department of Health and Human Services, 2017).

The cause of the most recent opioid epidemic is complex. In part, it arose from the common practice of physicians overprescribing the medication. In the 1990s, the *Joint Commission of the Accreditation of Hospitals* admonished physicians and other professional groups for inadequately treating pain in patients with a number of medical

conditions. As a result, physicians began prescribing opioids in abundance, which led to increased access and heightened risk for addiction, even among patients who took the medication as prescribed. Furthermore, increased availability of opioids in homes placed vulnerable persons such as children and adolescents at risk for addiction and opioid-related deaths.

While the widespread overuse of opioids has occurred in the past, factors converging to create the most recent epidemic began in the 1980s. Around that time a low-quality paper with little scientific merit was disseminated proposing that chronic pain conditions could be safely managed over many months or even years with opioids (Portenoy & Foley, 1986). Within a few years, a large pharmaceutical company had not only developed a highly addictive opioid-based pain medication, (OxyContin) but also funded a large educational campaign that targeted physicians and proposed that chronic pain, due to a variety of medical conditions, could be safely treated with the long-term opioid treatment (Kolodny et al., 2015). Around the same time, a recommendation by the *Joint Commission of the Accreditation of Hospitals* suggested that pain was largely undertreated by physicians. The commission actively encouraged physicians to be more aggressive in treating pain, especially in view of the recent "so-called" evidence demonstrating the safety of opioids. Physicians, who had been reluctant to prescribe opioids in the past, began prescribing them at an increased rate, all the while believing that there was little-to-no risk of harm to patients.

Theoretical Framework

Given the complexity of OUD, it is difficult to understand from the perspective of a single theory or conceptual framework. The examination of several viewpoints may be

necessary in order to grasp the complex nature and progression of OUD. Examining it from the viewpoint that it is both a neurobiological illness and a chronic disease requiring ongoing management by healthcare providers and clients over long periods provides a useful framework on which the present study was based. Additionally, the *Neuman Systems Model* provides a theoretical framework for understanding OUD in the context of multiple contributing factors.

Neurobiology of Opioid Use Disorder

One may better understand OUD when taking into account the role the brain plays in perpetuating the use of opioids. The brain contains many neurons and synapses that generate neurotransmitters. Neurotransmitters shape one's thinking and behavior, respond to stimuli, and maintain all vital functions in the body (NIDA, 2016b). In addition, they permit neurons to communicate signals to other nearby neurons. In order to maintain essential bodily functions, the action of neurotransmitters in the brain must remain in balance (Halter, 2014). Many people continue to use opioids due to their effect on the "reward" center of the brain. The euphoria one experiences from using opioids is thought to be due to stimulation of the reward system with an excess of dopamine (NIDA, 2016b). Normally, this action mobilizes an individual to continue behaviors needed in order to survive, such as eating and experiencing pleasure during contact with loved ones (Hazeldon Betty Ford Foundation, 2015). That euphoria experienced after using opioids is what prompts individuals to use the drug repeatedly. Eventually, tolerance develops, as well as the need to take more and more of the drug to gain that sense of "high."

Moreover, the long-term effects of using opioids cause changes in the executive function of the brain, affecting judgment, decision-making, and responses to stress (Liu et

al., 2011). Prolonged use of opioids leading to physiologic dependence results in compulsive drug-seeking at any cost (Kreek et al., 2012). The results of a study by Upadhyay et al. (2010) found that among prescription opioid-dependent subjects, notable changes occurred in axonal pathways to the amygdala and functional connectivity to amygdala subdivisions. The researchers found that the longer the duration of opioid exposure, the greater the changes in functional connectivity of the brain. The findings suggest that prolonged opioid exposure is associated with changes in the brain responsible for the regulation of affect, control of impulses, and motivation (Upadhyay et al., 2010). Furthermore, the extent to which brain function is altered by opioid abuse itself, may be due to a genetic predisposition for the development of OUD that necessitates long-term treatment and management.

Opioid Abuse as a Chronic Brain Disease

In 2011, the American Society of Addiction Medicine (ASAM) put forth a new definition of *addiction*. The definition resulted from a concerted process involving more than 80 experts in the field of addiction from across the United States. The definition describes addiction as a primary disease, not the result of behavioral or emotional problems. OUD is recognized by the organization as a chronic illness much like diabetes or heart disease. It is presently identified as a chronic brain disease with periods of relapse and remission that cannot be cured (but rather managed), and should be treated as such (ASAM, 2014).

> "Addiction is a primary, chronic disease of brain reward, motivation, memory and related circuitry. Dysfunction in these circuits leads to characteristic biological, psychological, social and spiritual manifestations. This is reflected in an individual pathologically pursuing reward and/or relief by substance use and other behaviors. Without treatment or engagement in recovery activities, addiction is progressive and can result in disability or premature death," (ASAM, 2014, p. 1).

According to the ASAM (2014), OUD is a *chronic brain disease* affecting the reward system, motivation, memory, and related neurophysiology. Abuse of opioids over time leads to disturbances in neurophysiology resulting in distinct behavioral, psychological, and social symptoms. In order to gain relief, an individual compulsively seeks opioids and engages in behaviors in order to relieve the symptoms. Without treatment and recovery, opioid abuse is progressive and may lead to death (ASAM, 2011b).

Much like other chronic diseases, OUD presents with periods of relapse and remission, and has no cure. As with any chronic illness, treatment is aimed at effectively coping with symptoms over time. Managing OUD requires preventative, patient-oriented, and individualized continuing care. According to the ASAM (2014), optimal treatment of OUD is coordinated and provided in three phases: identification, stabilization, and patient-self management. A wide range of treatments are available in a comprehensive plan of care, including commonly used medications: MET, BUP or BUP/NX and NTX. The medications can be used at all phases of treatment, are highly effective and often underutilized (ASAM, 2013). While most chronic diseases require medications for long-term management, persons requiring medications for OUD, are subject to numerous barriers in receiving pharmacological treatment. Barriers include, but are not limited to, regulatory and insurance restrictions on prescribing practices, dosage, access, treatment duration, a complex system of prior-authorization requirements, and step-therapy treatment approaches. In order to provide high-quality evidence-based treatment for OUD, the elimination of longstanding barriers to treatment is necessary.

Proposing that OUD is a chronic disease as opposed to a problem rooted in behavior alone has many advantages. First, it explains the compulsive nature of opioid abuse despite consequences to the individual, family members, and society. The behavior is a manifestation of a disease that involves many parts of the brain. Second, it suggests that neurobiology plays a significant role in an individual's vulnerability and likelihood to develop the disease. Furthermore, treatment approaches are now available that target the brain itself, as well as the changes that have occurred due to long-term opioid abuse. Finally, viewing OUD as a chronic disease such as diabetes or heart disease implies that it requires ongoing management and treatment, perhaps, over a lifetime (ASAM, 2011a).

The Neuman Systems Model

The Neuman Systems Model (NSM) was originally derived from *general systems theory* and is based on the principle that individuals are open systems interacting with one another and the environment (Neuman, 1982). Neuman synthesized knowledge from several disciplines in order to develop the theory but incorporated many of her own ideas from her clinical work in mental health nursing. The model draws a number of ideas from *Gestalt Theory* (Perls, 1973), which defines homeostasis as an important process by which an organism maintains its equilibrium and well-being. In order to maintain health, an organism must continually adapt to its environment. At any time, the system may become stressed, which threatens the balance and stability of the organism; therefore adjustment to stressors is a continuous and active process. According to Neuman, in the event that the adjustment process fails during an attempt to stabilize an organism during a period of increased stress, illness or death may result (Marriner-Tomey & Alligood, 1998).

The NSM views an individual as an open/permeable system that is continually responding and adapting to stress from the environment. The variables that determine successful adaption may be physiological, psychological, sociocultural, developmental, and spiritual (Neuman & Fawcett, 2011). Neuman views individuals as possessing a *core structure* that is safeguarded by *lines of resistance.* An individual's level of health is determined by well-functioning *normal lines of defense* (NLD; Neuman, 2011). Should the NLD become overtaxed, a flexible line of defense (FLD) protects it. Stressors are one of three kinds: intra-, inter-, and extrapersonal forces that exist in internal, external, and created environments. In the event a stressor becomes too great and overtaxes the FLD, the system goes into a state of disequilibrium, thereby becoming unstable (Neuman & Fawcett, 2011). As this occurs, lines of resistance are activated, which causes the system to move into a state of illness. If the system possesses adequate energy and support, it will re-stabilize, and the NLD may be restored either to its original state or improved from its previous state (Gonzalo, 2011).

Concepts Central to the Neuman Systems Model

The major concepts described are integral to the NSM. They include the following: *holistic approach, open system, process, feedback, negentropy, stability, environment, client system, lines of defense, normal line of defense, flexible line of defense, stressor, health, illness, prevention (as intervention at the primary, secondary, and tertiary levels*) and *reconstitution* (Alligood, 2014; Marriner-Tomey & Alligood, 1998; Neuman, 2011; Neuman & Fawcett, 2011).

Holistic Approach

NSM is a dynamic, open, systems approach to nursing care of the client. The model was developed as a unifying paradigm for defining problems, generating nursing care and appreciating the client in interaction with the environment. An *open system* may be a person, family, group, community or social problem (Neuman, 2011, pp. 327–329). Because OUD disrupts many aspects of a client's life experience, treatment approaches must be holistic

Open System

A system in which there is a continuous flow of input, processes, output, and feedback. Stress and responses to stress are components of an open system, which may be a person, family, group, community, or social problem (Neuman, 2011, pp. 327–329). As clients receive treatment for OUD, a continuous exchange of input and output occurs from both the treatment and client systems.

Process

An open system exchanges energy, data, and elements in the environment and its parts and uses available energy to maintain equilibrium or homeostasis (Neuman, 1995; 2011, p. 328). As an individual actively engages in treatment, their relationships, and environment, a process occurs that results in an exchange of energy and information.

Feedback

Output from the system in the form of data, energy, or matter serves as future input for corrective action to ensure change, enhancement, or equilibrium (Neuman, 2011, p. 327). Persons with OUD, as well as treatment providers, use feedback to determine the extent to which treatment is relieving symptoms and disruptions.

Negentropy

The function of energy conservation that assists a system to move toward stability or wellness (Neuman, 1995; 2011, p. 328). According to Neuman, treatment providers and clients must be mindful that energy conservation is necessary for the system to move toward wellness.

Stability

A dynamic and desirable state of balance and equilibrium in which energy exchange takes place without undue disruption of the system, enabling the system to move toward optimum wellness (Neuman, 1995; 2011, p. 328). As disruptions due to OUD resolve, the client moves toward balance, equilibrium, and stability.

Environment

According to Neuman, the environment is comprised of "internal and external forces surrounding the client, influencing and being influenced by the client at any point in time" (Neuman, 1995; 2011, p. 327). The environment may influence the progression of OUD depending on internal and external stressors in an individual and in external environments.

Client System

Comprised of five variables (physiological, psychological, sociocultural, developmental, and spiritual), all of which interact with the environment (Neuman, 2011, p. 327).

Lines of Resistance

A series of permeable rings surrounding the basic structure of a system that protects the client from stressors. They are activated when stressors penetrate the normal

line of defense (Neuman, 2011, p. 328). Clients with OUD may require bolstering of the normal line of defense in order to be protected from stressors.

Normal Line of Defense

The normal line of defense is the model's outer solid circle (see Figure 1), which represents the adaptable health of a system that develops over time. Deviation from wellness is measured (Neuman, 1995, 2011, p. 328) against this benchmark. In OUD treatment, this is referred to as a client's baseline.

Flexible Line of Defense

The model's outer broken ring serves as a protective buffer for preventing stressors from breaking through the normal line of defense. It is also known as the first-line protective mechanism (Neuman, 1995, 2011). The flexible line of defense is bolstered through engagement in treatment and utilization of supports and resources in the environment.

Health

The illness-to-wellness continuum is dynamic; optimal wellness is achieved when the system's needs are met. Wellness occurs when all system subparts are interacting in concert with the whole system (Neuman, 1995, 2011). Ideally, health is restored when an individual receives effective treatment and the disease process due to OUD is stabilized.

Illness

The opposite end of the continuum from wellness, which represents a state of disequilibrium, instability, and energy depletion (Neuman, 1995, 2011). May occur when OUD goes untreated and results in poor health.

Stressors

Stimuli that have the potential to disrupt system balance; the outcome may be positive or negative depending on interpersonal, intrapersonal, and extrapersonal forces (such as coping ability, support systems, and treatment access;Neuman, 1982, 1995, 2011). Stressors exist in the client system and the environment, and may be a precipitant to OUD.

Prevention as Intervention (Three Levels)

Primary prevention is anticipation of a stressor and accounting for its risk to the health of a system. *Secondary prevention* is the utilization of interventions after symptoms have already developed. The client's internal and external resources are mobilized in order to strengthen resistance. *Tertiary prevention* occurs after active treatment, and focuses on adaptation and adjustment toward optimum wellness as well as maintaining it (Neuman, 1982, 1995, 2011). All levels of prevention are utilized in OUD treatment, from anticipating relapse, participating in treatment once symptoms have developed, and stabilizing an individual and family who are experiencing advanced stages of OUD.

Reconstitution

Reconstitution occurs after treatment for negative reactions to the stressor. It represents the return of the system to stability prior to the stressor's intrusion. Stability may be at a higher or lower level than before the system experienced the stressor (Neuman, 1982, 2011). The goal of treatment for OUD is to restore balance, promote *reconstitution,* and stability, while minimizing the effects of future stressors.

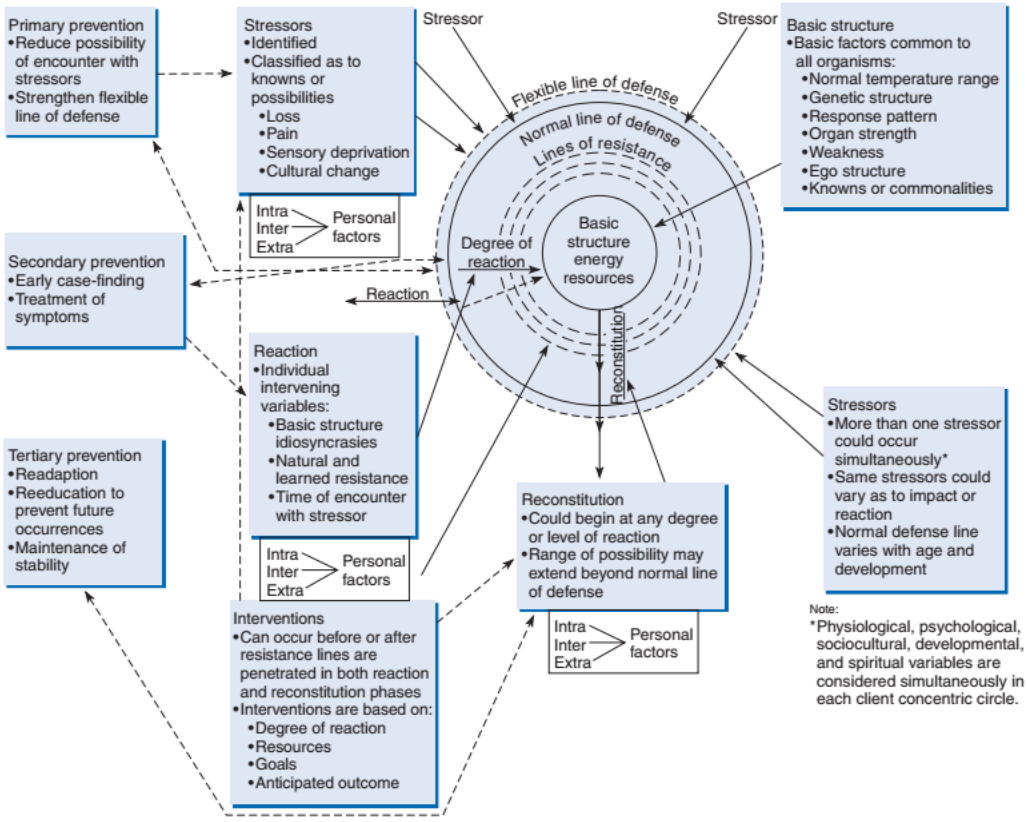

Figure 1: The Neuman Systems Model (Copyright 1970, *The Neuman systems model* (5th ed., [page 13], Upper Saddle River, NJ: Pearson). Reproduced with the permission of Betty Neuman and Jacqueline Fawcett.

Neuman Systems Model and Opioid Use Disorder

Few studies exist that examine the problem of substance abuse from the perspective of the NSM. Several studies have been conducted that examine other health problems such as diabetes and dementia using the theoretical framework of the NSM. Research has been conducted on the education of persons with diabetes, reducing burden on caregivers of persons with dementia, psychosocial support of vulnerable schoolchildren, optimal aging, and pediatric gastroenteritis applying the NSM (Demir &

Platin, 2017; Edelman & Lunney, 2000; Fawcett & Foust, 2017; Olowokere & Okanlawon, 2015; Sher-Pin, 2017).

Two sources describe the development of interventions for substance abuse problems utilizing the NSM as a theoretical framework. Although they are not research studies, they discuss the generation of strategies to counter health risks due to substance abuse problems. Mynatt and O'Brien (1993) describe a community-based peer-assisted intervention program created to respond to the problem of chemical dependency among nurses. They implemented approaches at the primary, secondary, and tertiary levels, by forging community partnerships between a university, a school of nursing, local nursing organizations, and healthcare providers to provide services for impaired nursing professionals.

Rayan (2016) conducted a literature review on factors associated with smoking among Jordanian adolescents, prior to developing an intervention program to prevent and regulate smoking in this population. The results of the review determined the presence of complex physiological, psychological, sociocultural, developmental, and spiritual factors underlying adolescent smoking, which require prevention efforts at the primary, secondary, and tertiary levels identified in the NSM.

Neuman Systems Model as a Theoretical Framework for Opioid Use Disorder

The NSM provides one theoretical framework for this study. In this research, the *open system* of interest is the individual with OUD. In the model, individuals with OUD are organisms that possess *basic structures* such as a genetic predisposition to OUD, as well as response patterns unique to OUD. Further, they may possess physical strengths and weaknesses, ego structures, and elements in common with other persons with OUD.

Humans often experience *stressors* including trauma, pain, loss, deprivation, and cultural change, which may modify responses to stressors. The *normal defense lines* may vary from person to person depending on age and developmental stage, as well as *intrapersonal, extrapersonal, and interpersonal factors*. An individual's reaction to stress depends on their *basic structure, learned resistance, and natural resistance,* and the timing of encounter with the stressor. OUD may be viewed as a form of *learned resistance* to stressors. The nurse or HCP, using a *holistic approach,* assists in bolstering *lines of resistance* to stressors that reduce the risk of harm to an individual with OUD. The nurse may provide interventions at the *secondary or tertiary prevention level*s when the resistance lines are penetrated. The aim of interventions are to restore an individual to health and balance. At the level of secondary prevention, the nurse assesses the severity of OUD and treats the signs and symptoms that may be present. At the tertiary prevention level, the nurse assists an individual with OUD to adapt to an existence without opioids, anticipate the likelihood and risk of relapse in order to prevent it (strengthening lines of defense), and assists the individual to return to a state of health and maintain it once they no longer use opioids.

According to the NSM, the main focus of this study was to examine the impact of adding *tertiary prevention level variables* (psychosocial treatments provided by nurses and HCPs) such as individual, group, and family counseling, Narcotics Anonymous-based peer support, and other peer support, to *secondary prevention level variables* (medication treatment with BUP/NX) on several outcome variables. These include treatment utilization outcomes, medication utilization, opioid use, and substance use. The NSM in OUD treatment is illustrated in Figure 2.

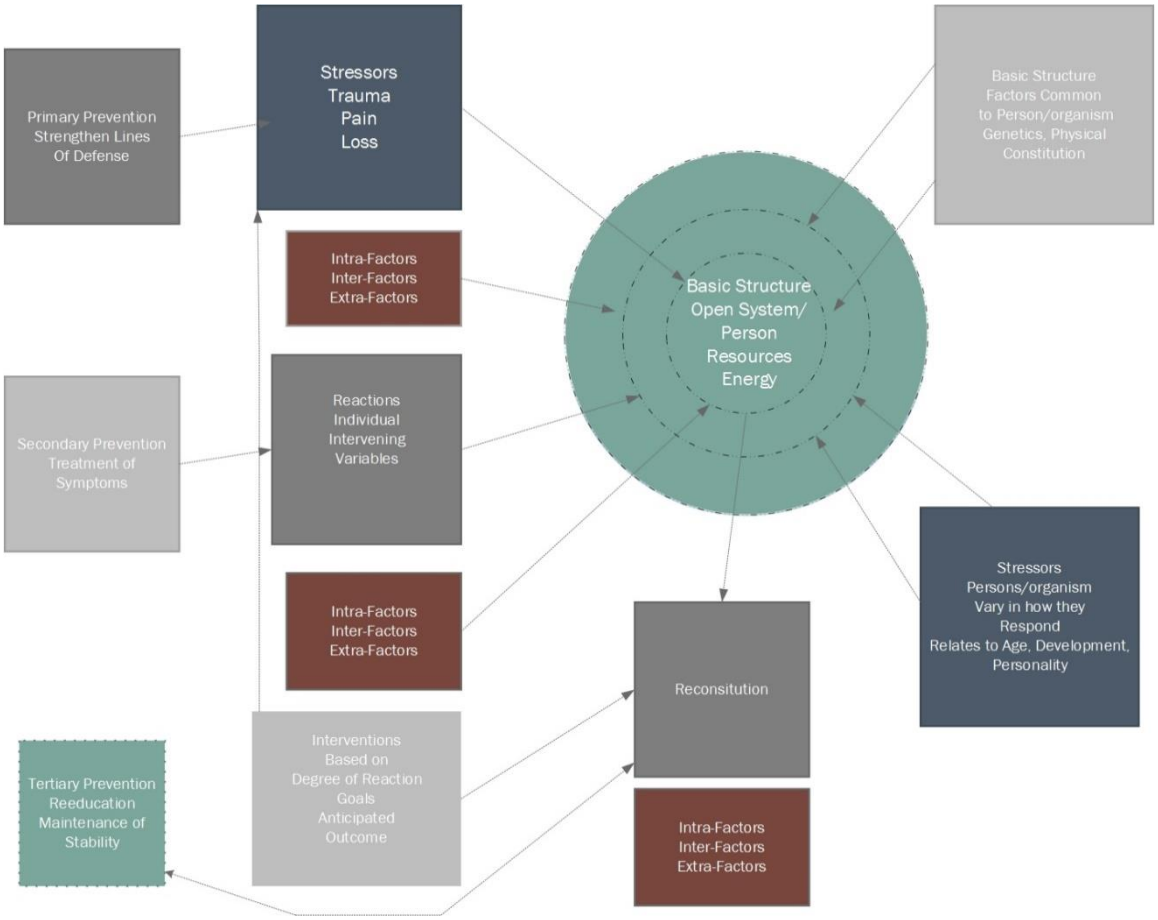

Figure 2: Neuman Systems Model in opioid use disorder treatment.

Strengths and Weaknesses of the NSM

A main strength of the NSM is its utility across a broad range of specialty areas of nursing including administration, education, and nursing practice. An open system is viewed as an individual, family, or community. It emphasizes the three levels of prevention and health promotion that are key principles in nursing practice. Neuman provides easily understood definitions of key terms (Alligood, 2014). Weaknesses of the model include the need for clarification of terms used, (e.g., distinction between intrapersonal and extrapersonal). Further, the theory does not specify meanings of *lines of resistance* and sources of *energy* referred to in the model and, questions have been raised

as to how accurate the model is in representing human beings and their interactions in the environment (Heyman & Wolfe, 2000).

Summary of Theoretical Framework

Identifying OUD as a chronic neurobiological disease that presents with periods of relapse and remission, and has no cure implies biological treatment (medication) is necessary that targets symptoms and assists patient with ongoing management perhaps, over a lifetime (ASAM, 2011a). Furthermore, managing OUD requires patient-oriented and individualized treatment that targets the brain itself, as well as the changes that have occurred due to long-term opioid abuse.

The NSM draws on a number of concepts from *general systems theory, Gestalt Theory*, and ideas from Neuman's own clinical work; Neuman proposes that individuals are open systems interacting with one another and the environment (Neuman, 1982). The NSM is a dynamic, open, and systems approach to nursing care of the client with OUD. The NSM suggests that certain individuals possess basic structures and unique response patterns that predispose them to OUD. Interventions by the nurse and HCPS are aimed at primary, secondary, and tertiary prevention levels in order to assist persons to achieve reconstitution and stability through long-term management of the disorder.

The main focus of this research was to examine the impact of adding *tertiary prevention level variables* (psychosocial treatments) such as individual, group, and family counseling, and self-support approaches, to *secondary prevention level variables* (medication treatment with BUP/NX) on several outcome variables. These include treatment utilization outcomes, opioid use, and substance use.

Key Definitions

Cocaine

A highly addictive stimulant drug made from the coca plant. It increases the levels of dopamine in the center of the brain controlling pleasure. Taken in large quantities may result in death (NIDA, 2016a).

Counseling and Psychosocial Treatments

Includes individual, group, or family counseling, peer-support, and self-help models. Focused on halting opioid use, building coping skills, adherence to treatment and recovery, and preventing relapse. Available in inpatient, outpatient, residential, and primary care settings (SAMHSA, 2018a).

Medication Treatment

Medication treatment is the use of specific medications (BUP BUP/NX) combined with counseling and psychosocial treatments. Assists in maintaining abstinence, preventing relapse and opioid overdose (SAMHSA, 2018b).

Medical Management

Process in which healthcare professionals provide medication, brief counseling, monitoring of drug use, medication adherence, and referrals to other services as necessary to improve patient's health (Kampman & Jarvis, 2015; SAMHSA, 2018a).

Opioids

Opioids are a class of drugs that include synthetic opioids, pain relievers available by prescription such as oxycodone, hydrocodone, morphine, and codeine, and the illegal drug heroin (NIDA, 2018b).

Opioid Use Disorder

A pattern of opioid use leading to clinically significant impairment. Often manifested by (a) opioids taken in larger amounts or longer than intended, (b) persistent desire or unsuccessful efforts to control opioid use, (c) a great deal of time spent in activities required to gain the opioid, use it, and recover from its effects, craving or strong desire to use opioids, among others (APA, 2013).

Treatment Adherence

Taking prescribed medications and following treatment plan as directed by HCP in order to meet treatment outcomes.

Visit Compliance

Attending scheduled appointments recommended by HCP on a consistent basis.

Review of Literature

Research has been conducted on the effectiveness of buprenorphine (BUP), methadone, and naltrexone added to psychosocial treatments and medical management of OUD. Studies have examined the effectiveness of psychosocial treatments such as individual, group, and family counseling, cognitive behavioral therapy, contingency management, and inpatient, outpatient, and residential treatment. Findings of studies analyzing the addition of psychosocial treatments to BUP treatment suggest it does benefit some individuals with OUD. Additional research is needed, however, to determine the effectiveness of psychosocial treatment given that most providers of medication treatment require patients to receive it. Further, there is a lack of research that analyzes the impact of specific psychosocial treatment type on medication treatment with BUP (Kampman & Jarvis, 2015, p. 39). Findings of studies that examine delivering

medical management along with BUP in primary care settings suggest it is highly effective for assisting patients to meet treatment outcomes. What follows is an analysis of selected studies that examine the effectiveness of psychosocial treatments, and medical management in primary care settings when added to BUP treatment for OUD.

Buprenorphine and Buprenorphine/Naloxone

Due to the actions and properties of buprenorphine (BUP), it is highly effective for treating OUD. It acts by lowering risk of abuse and physical dependence, possesses fewer withdrawal symptoms, has a high-ceiling effect at increased doses, and has improved safety over opioid full agonists. It is often combined with naloxone (NX) to reduce the potential for abuse since NX acts by blocking opioid receptors, and therefore blocking opiates (National Alliance of Advocates for Buprenorphine Treatment [NAABT], 2016; NIDA, 2017). BUP and BUP/NX are widely used and have significantly improved treatment outcomes for OUD.

Buprenorphine and Psychosocial Treatment

Several studies have evaluated the effectiveness psychosocial treatments added to buprenorphine (BUP) or buprenorphine and naloxone (BUP/NX). Psychologically based therapies are currently recommended for persons receiving medications for OUD despite mixed results of research findings of their effectiveness (W. Ling et al., 2013; Otto et al., 2014; Stein et al., 2015). A variety of approaches are presently used including individual, family, or group counseling, cognitive-behavioral therapy, self-support groups, and contingency management among others (Kampman & Jarvis, 2015; NIDA, 2018g).

The findings of several studies suggest that combining BUP or BUP/NX with individual therapy, group counseling, family counseling, and contingency management is

effective for some individuals versus standard treatments such as health education or inpatient detoxification. For example, Berger, Pulido, Lacro, Groban, and Robinson, (2014) conducted a retrospective review of 30 subjects receiving BUP, who were assigned to one of two treatment conditions, individual counseling or group therapy. Subjects in group therapy had significantly greater treatment retention than those in individual therapy (Berger et al., 2014). In another example, Brigham et al. (2014) randomly assigned 104 subjects receiving BUP to one of two treatments. The first, a comprehensive psychosocial intervention called *Community Reinforcement Approach and Family Training for Treatment Retention (CRAFT-T),* and the other, a standard form of counseling. Participants receiving CRAFT-T were significantly more likely to remain in treatment and abstain from opioids, suggesting that adding family therapy to BUP benefits some individuals with OUD.

Kosten, Poling, and Oliveto (2003) conducted a randomized, double-blind trial of 75 subjects treated with BUP maintenance for 6 months. The subjects had been assigned to one of four treatment conditions: desipramine plus contingency management (CM); desipramine without CM; placebo plus CM; and placebo without CM. The escalation of CM was eliminated at 3 months. At months 5 and 6, the response required to receive vouchers increased to up to two and then three drug-free urine samples. The CM groups showed a decline in opioid and drug-free urine samples. The desipramine plus CM treatment arm had a significantly greater decline in drug-free urine samples than placebo. Subjects on BUP, and desipramine plus CM were able to abstain from illicit opioids and drugs, but not after the response requirement had been increased. This suggests that an

additional intervention combined with CM may be necessary in order to assist patients meet treatment goals.

Katz et al. (2011) randomly assigned 240 subjects receiving BUP at a publicly funded 30-day detoxification clinic to three treatment conditions: IRI (an approach to improve retention), IRI and case management, or standard treatment (ST). Subjects receiving IRI, but not IRI and case management, were significantly more likely to complete detox and remain in treatment longer, demonstrating the addition of counseling, effectively assists some patients to attain OUD treatment goals.

The findings of two analyses of a long-term study suggests that BUP continues to assist subjects to remain abstinent from opioids for many months after starting BUP maintenance, and that psychological therapies have little added benefit to treatment with agonists with the addition of weekly medical management [MMT]; (Potter et al., 2015; Weiss et al., 2015). Potter et al. (2015) examined participants in the *Prescription Opioid Addiction Treatment Study* (POATS), a multisite, randomized trial that analyzed treatment outcomes of buprenorphine-naloxone treatment. A total of 252 subjects from the study completed an 18-month follow-up telephone assessment. Overall, participants were significantly more likely to remain abstinent from baseline to month 18. Further analysis demonstrated no significant differences in outcomes with the addition of psychosocial treatment to BUP and MMT (Potter et al., 2015). In another analysis of the POATS, Weiss and Rao (2017) found that subjects who remained on BUP were significantly more likely to abstain from opioids.

Research on the effectiveness of technological interventions for delivering counseling as an adjunct to medication treatment suggest that psychological interventions

administered via computer or Internet, may be not only effective but hold promise for widening treatment access (Bickel, Marsch, Buchhalter, & Badger, 2008; Christensen et al., 2014; Reutsch & Tkacz, 2010). Bickel et al. (2008) randomly assigned 113 subjects receiving BUP to one of three treatment conditions: a therapist-delivered *Community Reinforcement Approach* (CRA) with vouchers (a form of CM); computer-based CRA with vouchers; or standard care. The therapist- and computer-delivered CRA groups produced comparable weeks of continuous opioid-free and drug-free urine samples and, significantly more weeks of abstinence than standard care. The comparable effectiveness of the computer-delivered intervention has implications for widening available treatments, an important strategy in combating the opioid epidemic.

In another example, (Christensen et al., 2014) randomly assigned 170 adults receiving BUP maintenance to two treatment conditions: a community reinforcement intervention (CRA) delivered by computer along with contingency management versus contingency management alone. Subjects receiving CRA and contingency management were significantly more likely to abstain from using illicit opioids and remain in treatment. Finally, Ruetsch, Tkacz, McPherson, and Cacciola (2012) randomly assigned 1426 participants to receive either BUP in combination with a telephone-based program called *Here to Help* (HTH), or BUP alone. Subjects in the HTH groups were significantly more likely to abstain from using illicit opioids. In summary, although psychosocial treatments added to BUP demonstrate mixed results, research suggests they are effective for some individuals whether delivered technologically or in person.

While the findings of several studies suggest psychologically based therapies extend benefits of BUP treatment, other studies demonstrate either mixed results or little

benefit to subjects. For instance, Mitchell et al. (2013) randomly assigned 300 African-American subjects on BUP maintenance at one of two community-based clinics, to either outpatient counseling (OP; 3.6 hours per treatment week) versus *intensive* outpatient counseling (IOP; 5.3 hours per treatment week). No significant differences were noted between treatment arms in abstaining from using illicit opioids or other drugs. This suggests that increasing the intensity of OP may not necessarily increase the effectiveness of medication treatment with BUP.

In another example, Stein et al. (2015) randomly assigned 49 adults on BUP/NX maintenance to receive either a 50-minute *Distress Tolerance* (DT) therapy session or standard health education (HE) over a 4-week period. The DT therapy produced a small but nonstatistically significant difference in illicit opioid use, suggesting psychosocial treatments have little added benefit to medication treatment.

Buprenorphine and Medical Management

Although research findings are mixed on the effectiveness of adding psychosocial treatments to BUP treatment, the results of studies examining delivery of BUP via MMT in primary care settings, suggest it is effective (Accurso & Rastegar, 2016; Fiellin et al., 2014; Liebschutz et al., 2014; W. Ling et al., 2013; Lucas et al., 2010; Mintzer et al., 2007; Weiss et al., 2015). In the model referred to as MMT, medication and treatment-focused counseling are provided by a primary care physician, nurse practitioner, or other HCP in an office-based primary care setting (ASAM, 2015; Kampman & Jarvis, 2015; SAMHSA, 2018c).

In fact, a study by W. Ling et al. (2013), underscores the effectiveness of MMT versus psychosocial treatments added to BUP treatment. The researchers randomly

assigned 202 subjects stabilized on BUP for a period of 2 weeks, to four treatment conditions in an outpatient clinical research center for 16 weeks. Participants either received MMT, cognitive behavioral therapy (CBT), contingency management (CM), CBT and CM, or no behavioral treatment. There were no significant differences between groups in remaining abstinent from opioids. The researchers found no clear evidence that CBT or CM reduces illicit opioid use, despite that at the time of the study, the *Controlled Substances Act* required prescribers to refer patients on BUP to counseling (W. Ling et al., 2013).

The findings of a study by Accurso and Rastegar (2016) further support the benefit of MMT combined with BUP treatment in greater than 16mg/day dosages. The researchers conducted a retrospective review of 297 patients receiving BUP in primary care for 3 or more months. Comparison groups were generated based on the dosage of BUP (16mg/day or lower, and 16mg/day or greater) they received. Subjects receiving doses greater than 16mg/day were significantly more likely to abstain from illicit opioids and remain in treatment than subjects receiving 16mg/day or less. The researchers suggest BUP delivered in higher doses is highly effective, and that lower doses may actually be harmful (Accurso & Rastegar, 2016).

Fiellin et al. (2014) conducted a randomized trial among prescription opioid dependent subjects (n = 113) and examined the effectiveness of BUP/NX taper versus BUP/NX maintenance therapy delivered via MMT. Subjects on BUP/NX maintenance versus tapered doses were significantly more likely to submit opioid- and drug-free urine samples over the course of treatment. The findings suggest BUP maintenance is more effective in assisting patients to remain abstinent from opioids versus tapering dosages.

In a cohort study, Mintzer et al. (2007) examined 99 subjects from two primary care settings enrolled in BUP/NX treatment for OUD. At 6 months, 54% of subjects remained abstinent from opioids (determined by urine drug screens). There was no significant correlation between abstinence and site of care, drug of choice, level of income, or dosage of BUP/NX. Again, the results suggest delivering BUP/NX treatment in primary care is highly effective.

Moreover, the findings of a study by Cunningham et al. (2013) suggest that MMT combined with BUP treatment is effective in some patients for achieving abstinence from opioids and cocaine. The researchers analyzed the effectiveness of BUP delivered via MMT among opioid-dependent cocaine users versus non-users over 6 months. The results revealed no significant differences in treatment retention, or self-reported opioid use between cocaine users and non-users. The results underscore that opioid-dependent cocaine users benefit from office-based BUP treatment and should be included in these treatment programs (Cunningham et al., 2013).

The results of research conducted by Parran et al. (2010) suggest that BUP added to MMT not only targets opioid abstinence, but increases engagement in self-support groups, increases rates of employment and overall functioning. The researchers conducted a retrospective review of 110 opioid-dependent subjects who received IOP combined with BUP/NX for 5 weeks, followed by 12 weeks of weekly aftercare. After IOP, all subjects remained on BUP/NX and were referred to primary care physicians for MMT in an office-based setting. At an 18-month follow-up assessment, the researchers found subjects who remained on BUP/NX were significantly more likely to abstain from using illicit opioids, engage with 12-step recovery, be employed and demonstrate

improved functioning. The results suggest that BUP/NX coupled with long-term MMT is effective not only for achieving primary treatment outcomes, but also improved quality of life (Parran et al., 2010).

Additionally, the findings of two studies highlight the benefits of MMT combined with BUP treatment among opioid-dependent patients in targeting successful treatment of chronic diseases. Lucas et al. (2010) compared outcomes of BUP/NX treatment among 93 HIV-infected, opioid-dependent subjects, delivered either in a clinic-based setting versus an opioid treatment program. Subjects receiving treatment in the clinic-based setting attended significantly more HIV primary care visits and were significantly less likely to submit positive UDS for opioids and cocaine. Liebschutz et al. (2014) compared a "linkage" intervention (BUP/NX maintenance and successful transition to office-based treatment) versus simple detoxification (and taper) among 139 opioid-dependent subjects who had been hospitalized for medical illnesses and had no prior treatment for OUD. Subjects in the linkage group were significantly more likely to abstain from illicit opioids (self-report) and remain in treatment at 6 months. This study underscores the potential of actively targeting opioid-dependent medically ill persons for BUP/NX treatment in medical settings and primary care (Liebschutz et al., 2014).

Summary of Review of Literature

This review examined current research on buprenorphine (BUP) treatment for OUD. Studies in the review analyzed the effectiveness of adding psychosocial treatments and medical management to medication treatment in primary care and addiction treatment settings. The findings suggest that medical management combined with medication treatment with BUP is highly effective for targeting abstinence from illicit

opioids and treatment retention. The results of studies analyzing the effectiveness of adding psychosocial treatment to medication treatment are mixed. Additionally, BUP treatment administered in primary care settings is effective for targeting illicit use of opioids and cocaine among opioid-dependent cocaine users. Further, medication treatment improves engagement in medical treatment for co-occurring chronic diseases such as HIV.

CHAPTER 3

METHODOLOGY

This chapter describes the purpose of the study, the research design, the use of the electronic health record (EHR), the study sample, setting, and limitations. Additionally, the constructs, methods of measurement, study procedures, data analysis, and power analysis are outlined. Finally, the protection of human subjects and study limitations are discussed.

Purpose of the Study

The focus of this research was to examine the relationship between individual counseling status and opioid use treatment outcome variables in patients receiving medication treatment for OUD. The outcome variables examined included treatment utilization, medication utilization, opioid and substance use, and treatment retention. This relationship was examined while controlling for important confounding variables (e.g., gender, age, race, ethnicity, PTSD/trauma, CJS involvement, and anxiety).

Research Design

A nonexperimental correlational design that utilized secondary analyses of EHRs was used in this study. In nonexperimental correlational research, the independent and dependent variables are not manipulated by the researcher (Tabachnick & Fidell, 2014, p. 2). While it is difficult to attribute causality to an independent variable (or predictor variable) in correlational designs, it is useful for describing the direction and significance of a relationship between an independent and dependent variable (Polit, 2014, p. 68). Additionally, a correlational research design enables researchers to make predictions

between variables (Polit, 2014, p. 216). The use of secondary data permitted the researcher to use extant data sources in the EHR.

Secondary Data Analyses of EHRs

Secondary analyses of routinely collected data such as EHRs offers an opportunity to gain knowledge that may improve patient outcomes (MIT Critical Data, 2016). While collecting primary data is one of the best ways to answer research questions, it is not always logistically or economically feasible (Vartanian, 2011). "Secondary data can include any data that are examined to answer a research question other than the question(s) for which the data were initially collected," (Vartanian, 2011, p. 3). The EHR produces and accumulates immense amounts of data, which provide opportunities to test hypotheses answer research questions and further advance healthcare. Sources of data may include outpatient and inpatient clinical notes, diagnostic and laboratory tests, and computerized databases among others. Some of the advantages and challenges of conducting secondary data analyses are described:

Advantages of Secondary Data Analyses of EHRs

One of the main benefits of secondary analyses is that data collection has already taken place and the research study completed, saving considerable time and monetary resources. Secondly, data may be of higher quality in EHRs since accurate documentation of patient data is deemed important in caring for patients. Some data sets have considerable breadth, permitting the selection of a sample that may be more representative of a target population. Large data sets also permit testing of a large number of variables (Koziol & Arthur, 2011). Additionally, with large data sets such as EHRs, researchers may take advantage of advanced statistical techniques, (e.g., fixed-effect

modeling and hierarchical linear modeling). Large data sets often span years or months, permitting subjects to be studied over long periods. Researchers are able to capture intergenerational effects and long-terms effects of specific events and healthcare interventions (Vartanian, 2011).

Disadvantages of Secondary Data Analyses of EHRs

There are a number of pitfalls to conducting secondary data analyses on EHRs. The first challenge is there has been no control of what data was actually collected, and whether it will answer the research question being asked (Vartanian, 2011). In addition, there is little chance of contacting participants for additional data or follow-up information. Secondary data analysis may threaten the research process by encouraging researchers to consider only questions that can be answered by the available data (Vartanian, 2011). It is also important for the researcher to keep in mind, as with any data set, regardless of size, errors may have occurred during the data collection process that can negatively impact the reliability and validity of the data collected (Smith, 2008).

Solutions to Pitfalls of Secondary Analyses of EHRs

To offset problems with conducting secondary analyses, several strategies are recommended (Koziol & Arthur, 2011; MIT Critical Data, 2016; Smith, 2008; Vartanian, 2011). These include the following: (a) *Recognizing the fallibility* of EHRs; that is, they are rarely fully complete or correct. (b) *Understand bias and missing data;* for example, *selection bias* may occur if subjects in the sample have sought medical care within a system that uses an EHR. *Confounding bias* is a risk in that it is difficult to account for confounding variables that influence the independent and dependent variables. *Missing data* poses a risk in that examining only complete records threatens the generalizability of

the results. (c) Ensure protection of patient privacy by de-identifying and safely storing all data. Additional suggestions for maintaining rigor of study procedures include the following: address sampling concerns a priori; operationalize variables; ensure consistency among data abstractors; develop a data abstraction procedure manual and procedure forms; develop well-articulated inclusion and exclusion criteria; consider intra-rater and interrater reliability; conduct a pilot study, and attend to ethical considerations (Vasser & Holzmann, 2013).

Setting and Sample

All patient data was provided by a national office-based outpatient addiction treatment center that primarily provides medication treatment to patients with OUD. In order to receive treatment at a center, patients had to meet criteria for an *opioid abuse disorder* according to the *Diagnostic and Statistical Manual of Mental Disorders* (5th ed; APA, 2013). At each center, a biopsychosocial assessment and treatment plan was created for each patient. Treatment planning included individualized patient-centered care provided by physicians and nurse practitioners. The national treatment facility utilized an EHR that allowed for robust monitoring of contingency planning and management. All offices and all clinicians had access to this centralized EHR.

OUDs are treated primarily with buprenorphine in a group-practice setting. Although most of the patients in the sample had an OUD, the treatment centers offered evidence-based treatment for a range of substance use disorders including alcohol, opioid and polysubstance use disorders among others (Bloomberg, 2016). Given the focus of the study, only patients who received treatment for OUD were included in analyses. Given changes in treatment protocols regarding mandated counseling, patients who received

treatment between January 2016 and January 2018 were included in the study. Although 99% of the patients treated at this national facility were over the age of 18, patients under the age of 18 were removed from the data file prior to analyses.

In addition to changes in treatment protocols over the past decade at the treatment facility, there were some differences in treatment protocol by state. For example, until very recently, there was no care coordination at Massachusetts sites due to state legislation, but in Pennsylvania, all sites had patient care coordination. *Care coordination* refers to collaborating with patients, HCPs, within the company and community agencies to maintain accurate information, make referrals, schedule appointments, and facilitate alternative or higher level care recommended by the treatment team. Since the majority of the sites were in Massachusetts, and care coordination had begun after January 2018, only patients who were seen by providers in Massachusetts were included in the analyses to reduce the confounding of care coordination.

Thus, in summary, inclusion criteria included patients treated at a national outpatient treatment facility who received OUD care in the state of Massachusetts between January 2016 and January 2018. Exclusion criteria included patients who received care at a treatment facility in Massachusetts due to a non-OUD primary substance use disorder and patients who were under the age of 18.

Sample Size

An important aspect of conducting a research study is determining the sample size. Ideally, the sample represents the population from which it is drawn so that findings can then be generalized to the target population (Kadam & Bhalerao, 2010). The sample size depends on several elements: the acceptable level of confidence, power of the study,

expected effect size, underlying rate of the condition under study in the population, and standard deviation in a population (Kirby, Gebski, & Keech, 2002).

Power Analysis

Using G*Power 3.1.9.2, a power analysis to identify the required sample size was performed. To estimate the necessary sample size the following parameters were used: a small effect size ($f = 0.1$), $\alpha = 0.05$, 2 groups, and 5 covariates. The identified necessary sample size was 787. Based on information provided by the national treatment center, and verified by Dr. Chiodo, from January 2016 through January 2018, there is data in the EHR for 16,013 Massachusetts patients. Among these 16,013 patients, 13.221 were treated for OUD. Thus, there was ample statistical power to identify even a very small effect.

Operational Definition of Variables

The EHR contained all the information that was used in this study. The data had been provided to Dr. Chiodo in comma-separated values (CSV) format prior to the study. All CSV tables were converted to SPSS files and were merged by patient medical record number (MRN). All MRN and other identifying information were removed prior to data transfer and analysis. A description of all study variables is provided below:

Independent Variables

The main independent variable examined in this study was individual counseling. The reliability of self-reported individual counseling data was evaluated by the presence of scans confirming attendance at counseling visits. Based on center policy, all patients were required to bring in evidence of counseling activity. The evidence was scanned into the EHR. Presence of counseling confirmation was evaluated in 780 random patients.

Among the 780 patients randomly chosen, 111 patients did not meet inclusion criteria (e.g., did not live in MA, not a Suboxone patient, did not have lab visit data). Confirmation of counseling for the remaining 669 eligible patients was examined. A confirmed counseling scan that was present within 1 year of the last treatment date was identified as confirmation of current counseling. Scans confirming counseling but were older than 1 year from the date of the last treatment visit were identified as evidence of prior counseling while in treatment. Among the 669 patients, only 27.1% of the patients had scans present in the EHR confirming ever having attended counseling during treatment. Only 17.5% of the patients had scans present in the EHR confirming they attended counseling while in treatment. Counseling was a categorical (nominal) variable.

Dependent Variables

Several dependent variables were examined in this study including *treatment utilization, medication utilization, opioid use, total time in care, time since last visit, and treatment retention.* Although not a part of the study aims, other types of substance use were examined. Each variable is discussed below:

Treatment Utilization

Each time a patient was scheduled for a visit, an encounter is documented in the EHR. There are several types of visits where an encounter is created: a maintenance visit, a random maintenance visit, a rejoin visit, a rescheduled visit, an induction visit, a random urine screen visit, and other encounters (e.g., phone conversation to schedule an appointment). If a patient did not show for an appointment, the appointment was identified as a "no-show" visit. Tracking the frequency of these visits and the frequency of visit utilization and compliance was used to measure treatment utilization. Patients that

are more compliant with treatment plan are considered to be progressing in treatment by facility treatment providers (Y.-I. Hser et al., 2016; Kampman & Jarvis, 2015, p. 11; Timko et al., 2016).

In some instances, patients who returned to the facility after having discontinued treatment required an additional visit in order to be inducted on buprenorphine and naloxone, also known as Suboxone. Returning patients, depending on the length of time, would often be required to "rejoin" the program, which might also require another "initial" visit and induction visit. The number of times there was more than one induction visit and the number of times there was more than one initial visit, along with the total number of "rejoin" visits, was totaled and identified as the total number of times a patient had not been seen by a provider within 30 days was summed and was referred to as the number of care interruptions.

Two additional treatment utilization variables were total time in care and the time since the last visit. Total time in care was calculated based on the number of years a patient was in treatment. The amount of time due to care interruptions was removed from the total time. Time since last visit was defined as the period of years since the last treatment visit.

Medication Utilization

Medication utilization is defined as *taking* medication (e.g., buprenorphine) as prescribed by the HCP according to the substance use treatment plan at the treatment center. Urine screen data was available for every visit for each patient in the EHR. OUD medication use was examined in this urine screen panel. Patients whose urine screens show evidence of medication utilization were coded as utilization of their medication for

that visit (positive). Patients whose medication values were below standard cutoff values were identified as lack of medication utilization for that visit (negative). The total number of positive screens divided by the total number of screens performed (i.e., percent positive) was used in analyses.

Opioid Use

When patients' urine samples were screened as indicated above, the presence of opioids was also investigated. Some of the opioids examined were heroin, morphine, hydrocodone, hydromorphone, oxycodone, and fentanyl. In addition, a general opiate screen was performed. Patients whose urine screens show evidence of any opioid were coded as positive for that visit. Patients whose medication values were below standard cutoff values were identified as negative for opioids. The total number of positive screens divided by the total number of screens performed (i.e., percent positive) was used in analyses.

Retention

The final treatment utilization variable examined was retention. A patient was considered in treatment if they were still receiving care at the end of the study period.

Covariates

In addition to the variables already presented, several covariates were available in the EHR. Covariates included gender, age, race, ethnicity, history of PTSD/trauma (yes/no), history of anxiety (yes/no), and history of involvement in the CJS (yes/no). During intake at the treatment facility, a patient's gender, age, race, and ethnicity are recorded in the EHR. In the case of gender, it is documented as either male or female.

Since the sample was primarily White, a White/non-White variable was constructed and used in analyses.

PTSD/Trauma

During intake, HCPs collect data on medical and social history. Data regarding post-traumatic stress symptoms may be entered in the EHR in free text format in several locations. After translating all text data to lowercase, syntax was written in order to identify patients with a diagnosis of PTSD. The following phrases were identified in the text fields and flagged as positive for PTSD: ptsd and post-traumatic stress. In addition, a patient with any PTSD diagnosis code was identified as positive for PTSD. Like PTSD, data regarding a history of trauma could be entered into the EHR in several locations. All of these fields were in free text format. Text from 500 patients was examined in order to identify specific phrases used to identify trauma in the EHR. After translating all text to lowercase, syntax was written to identify cases with trauma.

The presence of trauma was also identified using text data. The following phrases were used: *stabbed, gunshot, traumatic, abused, hostage, victim of, rape, traumatic abuse, childhood abuse, hx of abuse, intimate partner violence, domestic violence, gun shot, bullet wound, trauma hx, physical abuse, sexual abuse, emotional abuse, assaulted, abuse as child, stab wounds, beat up, being shot, verbal abuse, bullet lodged, shrapnel, stab injury, sexually abused, physically abused, mugging, traumatic experiences, emotionally abused, domestic violence, past sexual trauma, violent incident, abusive relationship, stabbing victim, molested, and kidnapped.* The presence of any of these phrases was identified as positive for trauma. In this study, a variable was constructed

that indicated patients had either a history of PTSD or trauma. If one or both were present in the history, they were coded either yes or no for PTSD/trauma.

Anxiety

HCPs at the treatment facility also collect medical history regarding anxiety. There are several locations in the EHR where data related to a history of anxiety could have been entered by a provider. In addition to a diagnosis code, text fields were used to identify patients with a history of anxiety. After translating all text data to lowercase, syntax was written to identify cases with evidence of a history of anxiety.

Criminal Justice System Involvement

HCPs at the treatment facility evaluate patients' involvement in the CJS (i.e., probation, awaiting trial, and past incarceration) each quarter when the treatment plan is evaluated. This data is identified via checkboxes. Providers are able to check whether there are "pending criminal charges" or "resolved criminal charges." If a patient is positive for either, they are identified as involved with the CJS. In addition, several patients were identified as having CJS involvement through a separate database for patients who were subjects in a study being performed according to treatment center location. All patients in the *"Jail Database"* were identified as positive for CJS involvement.

The final covariate used when examining several of the treatment utilization variables is total time in care. A patient who has been in treatment longer will by treatment protocol have more patient visits and more opportunities for "no show" visits. Thus, total time in care will be included as a covariate in all analyses examining

treatment utilization variables with the exception of analyses examining total time in care and time since the last visit.

Measurement of Variables

All variables were obtained from the EHR. The independent variable, individual counseling (yes/no) is nominal in scale. All dependent variables are as ratio in scale with the exception of treatment retention, which is nominal.

Procedures

As mentioned previously, all data was provided to Dr. Chiodo in individual CSV data tables. Dr. Chiodo imported all data tables into SPSS and created a merged date file. Files were merged based on patient MRN number. Before providing the data for analysis, Dr. Chiodo removed all identifying patient information. IRB approval from the University of Massachusetts Amherst was received prior to data transfer. Once the data file was received, analyses were performed to evaluate study aims.

Data Analysis

Prior to beginning study analyses, all variable distributions were evaluated for normality or data entry errors. All necessary transformations were performed prior to analyses. Once distribution evaluation was completed, descriptive statistics were calculated for all variables. Analyses by study aim are described below. The purpose of Aims 1 and 2 was to better understand the relationships among the variables prior to examining the impact of counseling.

Aim 1

What is the relationship between treatment utilization, medication utilization, and opioid use in a sample of individuals with OUD receiving medication treatment?

To examine the relationship between most treatment utilization variables and medication utilization and opioid use, partial correlations were performed. All covariates were included in the analyses.

Aim 2

Determine if medication utilization mediates the relationship between treatment utilization and opioid use in patients receiving medication treatment.

For Aim 2, individual regression analyses were performed using the following independent variables: maintenance visits, random maintenance visits, rescheduled visits, other encounters, care interruptions, "no show" visits, retention, total time in care, and time since last visit. All covariates were entered in the first step using simultaneous entry, and the independent variable was entered in the second step of the regression model. In the third step, medication utilization was added to the regression model. For all of these analyses, the dependent variable was the percentage of positive opioid urine screens. To evaluate the presence of mediation, the change in Beta for each of the independent variables was examined. If there was a change in the value of the Beta from a significant predictor to a nonsignificant predictor, medication utilization was considered a full mediating factor.

Aim 3

Examine the impact of current and prior counseling on treatment utilization, medication utilization, substance use, and treatment retention.

To examine study Aim 3, a similar regression strategy was employed. All covariates were in step 1. If any of the covariates were nominal, dummy coding was performed prior to including them in the analyses. The predictor was entered in the

second step. The predictor variable was individual counseling. Regression analysis was performed for the following dependent variables: maintenance visits, random maintenance visits, rescheduled visits, other encounters, care interruptions, no-show visits, total time in care, total time since the last visit, medication utilization, opioid use, and treatment retention. Since treatment retention is nominal in scale, logistic regression was employed.

Aim 4

To examine the comparative effectiveness of type of psychosocial treatment on medication utilization, treatment utilization, and opioid use in patients receiving medication treatment.

As will be described in Chapter 4, analyses to examine Aim 4 were not performed.

Protection of Human Subjects

The secondary data set that was used for this research was information from an EHR from an opioid abuse treatment facility in Massachusetts between January 2016 and January 2018. The data was provided to Dr. Chiodo in CSV format. All CSV tables were converted to SPSS files and merged by patient MRN. All MRNs and other identifying information were removed prior to data transfer and analysis. There was minimal-to-no risk to subjects as the data had already been collected and analyses were performed on de-identified data. There was a slight risk to subjects due to loss of confidentiality. This research was approved by the University of Massachusetts Amherst Internal Review Board.

Study Limitations

There were several limitations to this research. First, given the data was derived from secondary data, there was a lack of control over data collected (Vartanian, 2011). Secondly, errors may have occurred in the data collection process and recording of information, which affected the reliability and validity of the data (Smith, 2008) and, therefore, the generalizability of findings. In addition, many participants who received treatment at the center, either had insurance or monetary resources to be treated for OUD, limiting the generalizability of the findings to other populations with OUD. Other limitations included necessities for participating in treatment such as transportation, the treatment facility dispensed two types of medication treatment, and subjects were from a nonrandomized sample. Finally, HCPs collected the data, thereby increasing the risk of interviewer bias having affected the validity of data collected.

Strengths of the intended research included a large sample size and access to a data set with considerable breadth, which permits examination of a large number of variables. In addition, data had been collected over a long period, which permitted the analyses of the long-term impact of treatments under study.

Summary

The focus of this research study was to examine the relationship between individual counseling (current and prior) and opioid use treatment outcome variables in patients receiving medication treatment for OUD. The outcome variables examined included treatment utilization, medication utilization, opioid use, and treatment retention.

A nonexperimental correlational design using secondary analysis of EHRs was used. All patient data was provided by a national office-based outpatient addiction

treatment center that primarily provides medication treatment to adults 18 years and older with OUD. The findings of this research are expected to further advance and improve treatments for OUD.

CHAPTER 4

RESULTS

This chapter outlines the results of the study including sample characteristics, distribution evaluation, bivariate, and multivariate analyses. Multivariate analyses are presented for each study aim.

Sample Characteristics

The study sample consisted of 11,551 patients ranging in age from 19–84 years (mean = 38.7, SD = 10.6). After outliers for age were winsorized, the range of ages was 19–68 years (mean = 38.7, SD = 10.5). The majority of the sample was male (58.2%), White (95.6%), and non-Hispanic (85.1%). Although a small number of patients resided in other states (1.8%), all received treatment within the state of Massachusetts. All patients included in this sample received buprenorphine and naloxone (Suboxone) for treatment of OUD.

Just over one quarter of the sample (28.2%) had either a PTSD diagnosis or reported trauma in the EHR. There was further evidence of psychiatric comorbidity as 42.5% reported symptoms of anxiety. Just over 29% of patients (29.6%) acknowledged they had been involved with the CJS.

Table 1: Characteristics of sample.

Variable	%
Sex (% male)	58.2
Race (% White)	95.6
Ethnicity (% Non-Hispanic)	85.1
PTSD (% yes)	13.1
Trauma (% yes)	15.1
Anxiety (% yes)	42.5
CJS involvement (% yes)	29.6

Note. CJS = criminal justice system.

Counseling Experience

According to patient report, 35.9% of patients received individual counseling. Additional types of reported counseling included group counseling (0.4%), Narcotics Anonymous (N/A; 4.5%), peer support (such as SMART recovery; 0.6%), and IOP (0.7%). Since so few patients received psychosocial treatment other than individual counseling, only individual counseling was examined as an independent variable.

Table 2: Counseling patient report.

Type	%
Individual	35.9
Group	0.4
NA	4.5
Peer	0.6
IOP	0.7

Note. IOP = intensive outpatient treatment.

As previously mentioned, the reliability of self-reported individual counseling data was evaluated by the presence of counseling confirmation. All patients, based on center policy, were required to bring in evidence of counseling activity. The evidence was scanned into the EHR. Confirmation of counseling attendance was examined for 669 patients. Among the 669 patients, 27.1% had evidence of having attended counseling at one point in treatment. Only 17.5% of them had provided evidence of current counseling.

Treatment Utilization and Substance Use

Several variables were used to evaluate treatment utilization. These included the following: random maintenance visits (mean = 0.9, SD = 1.6); maintenance visits (mean = 40.8, SD = 43.3); "no-show" visits (mean = 4.6, SD = 5.3); rescheduled visits (mean = 4.8, SD = 7.00); number of other encounters (mean = 34.6, SD = 31.4); care interruptions (mean = 1.1, SD = 1.4); total time in care (mean = 1.5, SD = 1.6), and time since last visit

(mean = .6, SD = .7). Among patients in the sample, 43.2% had remained in treatment and were considered "retained."

All distributions were evaluated for normality and outliers. Outliers for care interruptions were winsorized, while the following variables were log transformed due to non-normal distributions: random maintenance visits, maintenance visits, "no show" visits, rescheduled visits, and other encounters. Transformed variables were used in all analyses.

Table 3: Treatment utilization descriptive statistics.

Variables	**Mean**	**SD**	**Min**	**Max**
# random maintenance visits	0.9	1.6	0.0	16.0
# maintenance visits	40.8	43.3	0.0	328.0
# "no show" visits	4.6	5.3	0.0	62.0
# rescheduled visits	4.8	7.0	0.0	76.0
# other encounters	34.6	31.4	0.0	263.0
# care interruptions	1.1	1.4	0.0	13.0
# total time in care years	1.5	1.6	0.1	7.4
# time since last visit	0.6	0.7	0.0	2.1

Medication utilization and substance use were determined by urine drug screen results. Drug screens tested for the presence of Suboxone (mean = 83.5%, SD = 25.8%), benzodiazepines (mean = 9.5%, SD = 17.1%), alcohol (mean = 15.3%, SD = 25.1%), cannabis (mean = 36.7%, SD = 41.1%), amphetamines (mean = 5.2%, SD = 15.1%), cocaine (mean = 17.6%, SD = 28.3%), and opioids (mean = 15.1%, SD = 18.6%). Initially, medication utilization and substance use variables were not normally distributed. Analyses were performed using log-transformed variables.

Table 4: Medication utilization and substance use.

Substance (% positive)	N	Mean	SD	Min	Max
Suboxone	11326	83.5	25.8	0.0	100.0
Benzodiazepine	11320	9.5	17.1	0.0	100.0
Alcohol	11307	15.3	25.1	0.0	100.0
Cannabis	11315	36.7	41.1	0.0	100.0
Amphetamine	11317	5.2	15.1	0.0	100.0
Cocaine	11320	17.6	28.3	0.0	100.0
Opioids	11326	15.1	18.6	0.0	100.0

Relationship Between Gender and Demographic Characteristics

The relationship between gender, race, ethnicity, PTSD/trauma, anxiety, and CJS involvement was evaluated via chi-square analysis (Table 5). The relationship between these demographic variables and age was evaluated via independent t-tests (Table 6). Due to high statistical power, a conservative alpha was used to evaluate statistical significance ($\alpha = 0.01$) in a bivariate analyses.

Females were more likely to identify as non-Hispanic ($\chi^2 = 160.8$, $p<0.001$), report having experienced PTSD/trauma ($\chi^2 = 251.9$, $p = p<0.001$), and anxiety ($\chi^2 = 149.4$, $p<0.001$). Males, on the other hand, were more likely to have had CJS involvement ($\chi^2 = 17.4$, $p<0.001$). There was no significant relationship between gender and the likelihood of identifying as White ($\chi^2 = 3.7$, $p = 0.056$; see Table 5). Using a more conservative value for alpha, there was not a significant relationship between age and gender ($t = 4.6$, $p = .038$).

Table 5: Relationship between gender and demographic characteristics.

	Gender			
	Males	Females	χ^2	p
Demographic				
Race (%White)	95.2	96.1	3.7	0.056
Ethnicity (% Non -Hispanic)	81.1	90.6	160.8	<0.001
PTSD/Trauma (% Yes)	19.1	31.9	251.9	<0.001
Anxiety (% Yes)	37.8	49.2	149.4	<0.001
CJS Involvement (% Yes)	31.1	27.5	17.4	<0.001

Relationship Between Gender and Counseling Experience

The relationship between gender and counseling was evaluated by chi-square analysis (see Table 6.) With respect to patient-reported individual counseling experience, women were significantly more likely to report having attended than males ($\chi^2 = 120.0$, $p<0.001$). Males were more likely to have attended Narcotics/Alcohol Anonymous (NA) ($\chi^2 = 31.6$, $p<0.001$). There were no significant between-group differences in counseling confirmation scans indicating whether patients had ever been ($\chi^2 = 0.3$, $p = .600$), or currently were in counseling ($\chi^2 = 0.4$, $p = .547$). Further, there were no significant differences in attendance at group counseling ($\chi^2 = 0.8$, $p = .383$), peer support ($\chi^2 = 0.0$, $p = .908$), and IOP ($\chi^2 = 0.9$, $p = .337$). Due to the low frequency of counseling experiences reported for group counseling, NA, peer support, and IOP, only individual counseling was analyzed.

Table 6: Relationship between gender and counseling.

	Gender			
	Males	**Females**	**χ^2**	**p**
Counseling Patient Report				
Individuals Counseling (% Yes)	31.8	41.7	120.0	<0.001
Counseling Ever Scan (% Yes)	26.3	28.1	0.3	0.600
Counseling Current Scan (% Yes)	16.7	18.5	0.4	0.547
Group (% Yes)	0.4	0.3	0.8	0.383
NA (% Yes)	5.5	3.3	31.6	<0.001
Peer Support (% Yes)	0.6	0.6	0.0	0.908
IOP (% Yes)	0.8	0.6	0.9	0.337

Note. IOP = intensive outpatient treatment.

Relationship Between Gender and Treatment Utilization

The relationship between gender and treatment utilization variables was analyzed via independent group t-tests (see Table 7). There was a significant relationship between gender and attendance at random maintenance visits ($t = -6.9$, $p<0.001$), "other"

encounters (t = -13.2, p<0.001), and total time in care years (t = -7.3, p<0.001) with females reporting higher rates of attendance at all three. Females, however, demonstrated higher rates of "no shows" (t = -8.0, p<0.001), and tendency to reschedule visits (t = -15.7, p<0.001), while males were more likely to experience care interruptions (t = 3.4, p<0.01), and time since last visit (t = 3.9, p<0.001). There was no significant relationship between gender and attendance at maintenance visits (t = -6.2, p = .655).

Table 7: Relationship between gender and treatment utilization.

	Mean	SD	t	p
# random maintenance visits				
Male	0.4	0.6	-6.9	<0.001
Female	0.5	0.6		
# maintenance visits				
Male	2.9	1.5	-6.2	0.655
Female	3.1	1.5		
# "no show" visits				
Male	1.3	0.8	-8.0	<0.001
Female	1.4	0.9		
# rescheduled visits				
Male	1.1	1.0	-15.7	<0.001
Female	1.4	1.1		
# other encounters				
Male	3.1	0.9	-13.2	<0.001
Female	3.3	0.9		
# care interruptions				
Male	1.1	1.3	3.4	<0.01
Female	1.0	1.3		
# total time in care years				
Male	1.4	1.6	-7.3	<0.001
Female	1.7	1.7		
# time since last visit				
Male	1.2	0.7	3.9	<0.001
Female	1.1	0.7		

Note. Log-transformed variables were not used to allow for interpretation of the values. Winsorized variables were used in analysis.

Relationship Between Gender, Medication Utilization, and Substance Use

The relationship between gender, medication utilization, and substance use was evaluated by independent sample t-tests (see Table 8). Women were more likely than men to be compliant with the medication Suboxone ($t = -3.7$, $p<0.001$). Men were significantly more likely than women to use alcohol ($t = 7.8$, $p<0.001$), cannabis ($t = 9.5$ $p<0.001$), and opioids ($t = 4.7$, $p<0.001$) during treatment. Women were more likely to use benzodiazepines ($t = -10.9$, $p<0.001$) and amphetamines ($t = -9.3$, $p<0.001$). There was no significant difference between males and females in cocaine use ($t = 2.7$, $p = .064$; see Table 8).

Table 8: Relationship between gender, medication utilization, and substance use.

	Mean	SD	t	p
Suboxone				
Male	58.9	17.5	-3.7	<0.001
Female	60.1	16.6		
Benzodiazepine				
Male	6.9	12.8	-10.9	<0.001
Female	9.7	14.2		
Alcohol				
Male	13.5	19.6	7.8	<0.001
Female	10.7	17.3		
Cannabis				
Male	29.1	29.2	9.5	<0.001
Female	23.9	28.1		
Amphetamine				
Male	3.4	10.2	-9.3	<0.001
Female	5.5	13.5		
Cocaine				
Male	14.3	20.8	2.7	0.064
Female	13.2	20.7		
Opioids				
Male	13.5	15.0	4.7	<0.001
Female	12.1	14.5		

Relationship Between Age and Demographic Characteristics

The relationship between age and other demographic variables was evaluated via t-tests (see Table 9). The between-group differences in mean age were significant for

gender, race, PTSD/trauma, and CJS involvement. The mean age of males was higher than females (t = 4.6, p = 0.038). Non-White patients were more likely than White patients to be older (t =- 4.2, p<0.001). Patients who reported PTSD/trauma (t = -4.4, p<0.001) and CJS involvement (t = 6.1, p<0.001) were also more likely to be older. There was no significant relationship between mean age and ethnicity (t = 9.4, p = .172) or anxiety (t = 1.0, p = 0.328).

Table 9: Relationship between age and demographic variables.

	Mean	SD	t	p
Gender				
Male	39.1	10.6	4.6	0.038
Female	38.2	10.3		
Race				
White	38.1	10.4	-4.2	<0.001
Non-White	40.8	12.3		
Ethnicity				
Hispanic	40.9	10.0	9.4	0.172
Non-Hispanic	38.0	10.4		
PTSD/Trauma				
No	38.5	10.7	-4.4	<0.001
Yes	39.5	9.9		
Anxiety				
No	38.6	10.7	-1.0	<0.328
Yes	38.8	10.2		
CJS Involvement				
No	39.1	10.9	6.1	<0.001
Yes	37.8	9.6		

Note. CJS = criminal justice system.

Relationship Between Age and Counseling

The relationship between age and treatment utilization was analyzed via independent t-tests (see Table 10). Given the smaller sample size for counseling scan data (N = 669) the traditional alpha level (0.05) was used to examine the impact of counseling with confirmatory (scan) data. Using the traditional level of alpha, there was a significant relationship between age and counseling. Patients who had a history of counseling tended

to be older than patients who did not. This relationship was found for all counseling variables (patient report: $t = -8.2$, $p<0.001$; ever received counseling: $t = -3.2$, $p = 0.002$; and evidence of current counseling: $t = -2.5$, $p = 0.013$).

Table 10: Relationship between age and counseling patient report.

	Mean	SD	t	p
Counseling Patient Report				
No report	38.1	10.5	-8.5	<0.001
Report	39.8	10.5		
Counseling Scan Ever				
No scan	38.4	9.9	-3.2	0.002
Scan	41.2	10.8		
Counseling Scan Current				
No scan	38.7	10.0	-2.5	0.013
Scan	41.3	11.1		

Relationship Between Age and Treatment Utilization

The relationship between age and treatment utilization variables was analyzed by computing the Pearson product-moment correlation coefficient (see Table 11). There was a significant positive correlation between increased age and attendance at random maintenance visits ($r = 0.15$, $p<0.001$), and maintenance visits ($r = 0.13$, $p<0.001$). There was a significant negative correlation between increased age and "no shows" ($r = -0.14$, $p<0.001$), tendency to reschedule visits ($r = -0.04$, $p<0.001$), and tendency toward care interruptions ($r = -0.07$, $p=<0.01$). There was no significant correlation between increased age and "other encounters" ($r = 0.02$, $p = .052$).

Table 11: Relationship between age and treatment utilization.

	r
# random maintenance visits	0.15***
# maintenance visits	0.13***
# "no show" visits	-0.14***
# rescheduled visits	-0.04**
# other encounters	0.02
# care interruptions	-0.07***
Total time in care	0.14***
Time since the last visit	-0.01

**p<.01. ***p<0.001.

Relationship between Age, Medication Utilization, and Substance Use

The relationships between age, medication utilization, and substance use were analyzed via Pearson product-moment correlations (see Table 12). There was a significant positive correlation between age and medication utilization ($r = 0.09$, $p<0.001$). Older patients were more compliant with their OUD medication. Similarly, older patients had higher rates of benzodiazepines ($r = 0.11$, $p<0.001$) and alcohol ($r = 0.05$, $p<0.001$). There was a significant negative correlation between age and use of cannabis ($r = -0.19$, $p<0.001$), cocaine ($r = -0.05$, $p<.001$), and opioids ($r = -0.12$, $p<0.001$). Younger patients were more often positive for these substances. There was no significant correlation between age and use of amphetamines ($r = -0.02$, $p = .097$).

Table 12: Relationship between age, medication utilization, and substance use.

	r
Medication Adherence	
Suboxone	.09***
Substance Use	
Benzodiazepine	.11***
Alcohol	.05***
Cannabis	-.19***
Amphetamine	-.02
Cocaine	-.05***
Opioids	-.12***

***p<0.001.

Relationship Between Counseling and Demographic Characteristics

The relationship between counseling, gender, race, ethnicity, PTSD/trauma, anxiety, and CJS involvement was evaluated via chi-square analysis (see Table 13). All three measures of counseling were evaluated. Age was evaluated via correlation.

When examining patient-reported counseling, females were more likely to attend counseling than males ($\chi^2 = 119.9$, $p<.001$). Those who identified as non-Hispanic ($\chi^2 = 9.4$, $p = .001$) reported more PTSD/trauma ($\chi^2 = 240.5$, $p<.001$), reported more anxiety ($\chi^2 = 406.1$, $p<0.001$), and CJS involvement ($\chi^2 = 212.5$, $p<0.001$) were significantly more likely to report attending counseling to their provider. There was no significant relationship between race and report of counseling ($\chi^2 = 0.0$, $p = .898$). There was also a significant relationship between age and counseling based on patient report. Patients who reported counseling to their provider (mean age = 39.8, SD = 10.5) were older ($t = -8.5$, $p<0.001$) than patients who did not report counseling to their provider (mean age = 28.1, SD = 10.5).

A similar relationship was found when examining confirmed report of ever attending counseling and PTSD/trauma, anxiety, and history of involvement with CJS. Patients positive for PTSD/trauma ($\chi^2 = 10.8$, $p<.001$), anxiety ($\chi^2 = 11.1$, $p<.001$), or CJS involvement ($\chi^2 = 12.1$, $p<.001$) attended counseling more than those not positive on these three variables. In contrast to the patient-reported variable, counseling attendance when measured using confirmatory scans was unrelated to gender or ethnicity. Patients with evidence of any counseling while in treatment were older than those without counseling evidence ($t = -3.0$, $p = 0.003$).

A similar pattern, when compared to ever attending counseling while in treatment via confirmatory scale, was found when examining current counseling based on confirmatory scans. The only difference was there was no relationship between current counseling and report of PTSD/Trauma. Patients with evidence of current counseling were older than those without current counseling confirmation (t = -2.3, p = 0.021).

Table 13: Relationship between counseling and demographic characteristics.

	Counseling								
	Patient Report			Ever Confirmed			Current Confirmed		
Demographic	**No (%)**	**Yes (%)**	χ^2	**No (%)**	**Yes (%)**	χ^2	**No (%)**	**Yes (%)**	χ^2
Gender									
Male	68.2	31.8	119.9***	73.7	26.3	0.3	83.3	16.7	0.4
Female	58.3	41.7		71.9	28.1		81.5	18.5	
Race									
White	63.9	36.1	0.0	73.8	26.2	0.0	83.0	17.0	0.3
Non-White	64.2	35.8		72.4	27.6		79.3	20.7	
Ethnicity									
Hispanic	68.5	31.5	9.4**	74.4	25.6	0.1	84.6	15.4	0.3
Non-Hispanic	64.2	35.8		72.9	27.1		82.3	17.7	
PTSD/Trauma									
No	68.0	32.0	240.5***	76.1	23.9	10.8***	84.0	16.0	3.3
Yes	51.9	48.1		63.0	37.0		77.8	22.2	
Anxiety									
No	71.8	28.2	406.1***	78.0	22.0	11.1***	87.0	13.0	12.1***
Yes	53.6	46.4		66.4	33.6		76.7	23.3	
CJS History									
No	68.3	31.7	212.5***	79.9	20.1	34.5***	86.5	13.5	15.7***
Yes	54.0	46.0		58.3	41.7		74.1	25.9	

**p<0.01. ***p<0.001.

Relationship Between Counseling and Treatment Utilization

The relationship between patient-reported counseling and treatment utilization was evaluated by independent t-tests (see Table 14). Again, all three counseling measures were examined. Patients who reported counseling had more random maintenance visits (t = -7.7, p<0.001), maintenance visits (t = -16.7, p = <0.001), frequency of "no show"

visits ($t = -2.4$, $p = 0.015$), rescheduled visits ($t = -9.3$, $p<0.001$), and "other" encounters ($t = -13.7$, $p<0.001$). Patients who were in counseling were also in care longer ($t = -11.4$, $p<0.001$). When examining the smaller subset of patients with scanned confirmation of ever having counseling while in treatment, there is also significant relationship between many of the treatment utilization variables. In contrast to the patient report of counseling, there was no relationship between counseling attendance and frequency of care interruptions ($t = -1.3$, $p = 0.178$) or the amount of time since the last visit ($t = 1.3$, $p = 0.182$).

When examining confirmed current counseling, fewer treatment utilization variables were significant based on counseling attendance. Patients who reported counseling had more random maintenance visits ($t = -5.0$, $p<0.001$), maintenance visits ($t = -13.7$, $p = <0.001$), rescheduled visits ($t = -6.6$, $p<0.001$), and "other" encounters ($t = -10.0$, $p<0.001$). Patients who were in counseling were also in care longer ($t = -7.2$, $p<0.001$). There was no relationship between counseling attendance and frequency of "no show" visits ($t = -1.2$, $p = 0.884$), frequency of care interruptions ($t = -0.1$, $p = 0.888$), or the amount of time since the last visit ($t = -0.6$, $p = 0.182$).

When considering these relationships, it is important to understand that these bivariate relationships do not account for total time in care. Since the treatment protocol included a counseling requirement, patients who were not in counseling, might not be still in treatment by choice.

Table 14: Relationship between patient-reported counseling and treatment utilization.

	Counseling								
	Patient Report			Ever Confirmed			Current Confirmed		
	Mean	SD	t	Mean	SD	t	Mean	SD	t
# random maint. visits									
Counseling (No)	0.3	0.6	-21.0***	0.3	0.5	-7.7***	0.4	0.6	-5.0***
Counseling (Yes)	0.6	0.6		0.7	0.7		0.7	0.7	
# maintenance visits									
Counseling (No)	2.6	1.5	-44.9***	2.7	1.4	-16.7***	2.8	1.5	-13.7***
Counseling (Yes)	3.7	1.0		4.1	0.7		4.0	0.7	
# "no show" visits									
Counseling (No)	1.3	0.8	-10.8***	1.4	0.8	-2.4*	1.4	0.8	-1.2
Counseling (Yes)	1.5	0.9		1.5	0.8		1.5	0.8	
# rescheduled visits									
Counseling (No)	1.1	1.0	-24.1***	1.1	1.0	-9.3***	1.2	1.0	-6.6***
Counseling (Yes)	1.5	1.0		1.8	1.0		1.8	0.9	
# other encounters									
Counseling (No)	3.0	0.9	-35.2***	3.0	0.9	-13.7***	3.1	0.9	-10.0***
Counseling (Yes)	3.6	0.8		3.8	0.8		3.7	0.5	
# care interruptions									
Counseling (No)	1.1	1.3	4.8***	1.1	1.3	1.3	1.1	1.4	-0.1
Counseling (Yes)	1.0	1.3		1.2	1.4		1.1	1.5	
# total time in care									
Counseling (No)	1.2	1.5	-27.0***	1.1	1.5	-11.4***	1.3	1.4	-7.2***
Counseling (Yes)	2.1	1.7		2.6	1.7		2.5	1.7	
# time since last visit									
Counseling (No)	0.7	0.7	17.1***	0.7	0.7	1.3	0.7	0.7	-0.6
Counseling (Yes)	0.5	0.6		0.6	0.5		0.7	0.7	

*p<0.05. **p<0.01. ***p<0.001.

Relationship Between Counseling, Medication Utilization, and Substance Use

The relationship between counseling, medication adherence and substance use were evaluated by independent sample t-tests (see Table 15). Again, all three counseling measures were examined. When examining all three counseling measures, patient-reported counseling present in the EHR confirmed counseling ever in treatment and confirmed current counseling, there was a significant relationship between counseling and medication adherence. Patients in counseling were more adherent to medication than patients not in counseling (EHR report: $t = -25.9$, $p<0.001$; confirmed ever: $t = -6.5$, $p<0.001$; confirmed current: $t = -4.8$, $p<0.001$).

Analysis examining EHR patient report also revealed significant relationships between counseling and all substance use variables. Those who reported having attended counseling had higher mean levels of benzodiazepines ($t = -8.1$, $p<0.000$) and amphetamines ($t = -8.5$, $p<.000$), yet lower levels of alcohol ($t = 2.6$ $p = .012$), cannabis ($t = 3.8$, $p<0.000$), cocaine ($t = 8.1$, $p<.000$), and opioids ($t = 25.5$, $p<0.000$).

When examining the subset of patients using scanned confirmation data, there was no relationship between counseling and benzodiazepine, alcohol, cannabis, or amphetamine use for both evidence ever in treatment ($t = -1.1$, $p = 0.279$; $t = 0.5$, $p = 0.616$; $t = 1.1$, $p = 0.259$; $t = -1.0$, $p = 0.318$, respectively) or currently in treatment ($t = -1.3$, $p = 0.194$; $t = 0.7$, $p = 0.512$; $t = 0.5$, $p = 0.584$; $t = -0.2$, $p = 0.906$, respectively). There was, however, significant relationships between counseling ever while in treatment and cocaine and opioids ($t = 4.3$, $p<0.001$; $t = 5.1$, $p<0.001$, respectively) or currently in treatment ($t = 2.7$, $p = 0.007$; $t = 3.0$, $p = 0.003$, respectively).

Table 15: Relationship between counseling, medication utilization, and substance use.

	Counseling								
	Patient Report			Ever Confirmed			Current Confirmed		
	Mean	**SD**	**t**	**Mean**	**SD**	**t**	**Mean**	**SD**	**t**
Medication Adherence									
Counseling (No)	56.8	19.6	-25.9***	58.7	17.8	-6.5***	59.6	17.0	-4.8***
Counseling (Yes)	64.1	10.3		64.8	6.2		64.2	6.9	
Benzodiazepine									
Counseling (No)	7.3	13.7	-8.1***	8.3	13.6	-1.1	8.3	13.3	-1.3
Counseling (Yes)	9.4	13.0		9.5	13.0		10.1	13.8	
Alcohol									
Counseling (No)	12.6	19.5	2.6**	12.5	19.5	0.5	12.5	19.2	0.7
Counseling (Yes)	11.7	17.1		11.7	16.7		11.2	16.4	
Cannabis									
Counseling (No)	27.7	29.3	3.8***	27.1	28.6	1.1	26.6	28.4	0.5
Counseling (Yes)	25.6	28.0		24.3	27.8		25.0	28.2	
Amphetamine									
Counseling (No)	3.5	10.9	-8.5***	4.1	11.7	-1.0	4.3	12.0	-0.2
Counseling (Yes)	5.6	12.9		5.1	11.8		4.5	10.6	

Cocaine									
Counseling (No)	15.0	16.2	8.1***	15.4	22.2	4.3***	14.4	21.5	2.7**
Counseling (Yes)	11.9	18.4		9.1	14.1		9.9	14.7	
Opioids									
Counseling (No)	15.3	16.2	25.5***	13.7	14.6	5.1***	12.9	14.3	3.0**
Counseling (Yes)	8.8	10.8		8.6	10.3		9.4	10.6	

*p<0.05. **p<0.01. ***p<0.001.

Relationship Between Race, Ethnicity, and Other Demographic Characteristics

Most bivariate analyses regarding race and ethnicity have been provided above. Given the low rate of variability in both race (95.6% White) and ethnicity (85.1% non-Hispanic), additional analyses were not performed.

Reliability of Patient Report of Counseling

The reliability of self-reported individual counseling data was evaluated by the presence of counseling confirmation (see Table 16). To determine whether a relationship existed between *individual counseling* reported by patients in progress notes, scans confirming *current attendance at individual counseling*, and scans confirming patients had *ever been in individual counseling*, chi square analyses were done.

Results of the analysis showed there was a significant difference between patient report of counseling and patients with scanned confirmation of counseling. Among the patients who indicated that they were currently in counseling, scanned evidence was available for only 33% of the patients. The significant difference suggests that the patient report of counseling in the EHR is not reliable.

Table 16: Reliability of patient-reported counseling.

		Patient Report			
		No	Yes	χ^2	p
Current Confirmation	No	336	216	105.8	<0.001
	Yes	10	107		
Past Confirmation	No	292	196	47.6	<0.001
	Yes	54	127		

Analysis of Study Aims

Due to the lack of reliability in patient-reported data in the EHR, only confirmed counseling data was used in the multivariate analyses. According to the *a priori* power analyses, 787 patients were required to identify a small effect size (f = 0.1). Using a sample size of 669, two groups and six covariates, a small effect size (0.16) can still be identified as significant. Thus, there would be minimal risk of Type II error. Covariates included in multivariate analyses include gender (male/female), age, PTSD (yes/no), anxiety (yes/no), history of involvement with the CJS (yes/no), and total time in care.

Total time in care is included as a covariate for the following treatment utilization variables: number of random maintenance visits, number of maintenance visits, number of no-show visits, number of rescheduled visits, number of other encounters, and number of care interruptions. Total time in care is included as the rates of these variables increase as a patient is in care for longer durations. Total time in care will not be used as a covariate when the treatment utilization variables examined are total time in care, time since the last visit, and retention.

Ethnicity and race were not included in the analyses due to the large number of missing data and the homogeneity of variance, as discussed above. Approximately one quarter of the sample (25.4%) was missing data for race and 20.9% were missing information on ethnicity.

Sample Comparison

Prior to analysis of study aims, patients included in the analysis sample, patients whose data was evaluated via confirmatory counseling scans were compared to patients not included in the analysis. Comparisons were performed on all dependent variables

(treatment utilization, medication utilization, drug use). The only difference identified between patients included in the analysis and patients not included in the analyses was on time since the last visit. Patients not included had been seen more recently in care (t = -2.12, p = 0.030). As there is a large difference in sample size, this analysis was confirmed by non-parametric analysis (Mann-Whitney U). There were no differences in the parametric and non-parametric tests.

Table 17: Sample comparison (included and not included in aims analyses).

	Mean	SD	t	p
Treatment Utilization				
# random maintenance visits				
Not included	0.4	0.6	0.4	0.689
Included	0.4	0.6		
# maintenance visits				
Not included	3.0	1.5	-1.0	0.297
Included	3.0	1.4		
# "no show" visits				
Not included	1.4	0.8	-1.4	0.167
Included	1.4	0.8		
# rescheduled visits				
Not included	1.2	1.0	-1.0	0.331
Included	1.3	1.0		
# other encounters				
Not included	3.2	0.9	-0.7	0.497
Included	3.2	0.9		
# care interruptions				
Not included	1.1	1.3	-0.6	0.520
Included	1.1	1.4		
# total time in care				
Not included	1.5	1.6	0.3	0.728
Included	1.5	1.5		
# time since last visit				
Not included	0.6	0.7	-2.2	0.030
Included	0.7	0.7		
Medication Utilization				
Not included	59.4	17.2	-1.5	0.147
Included	60.4	15.7		
Substance Use				
Benzodiazepine				
Not included	8.0	13.5	-1.1	0.268
Included	8.6	13.4		

Alcohol				
Not included	12.3	18.7	0.1	0.954
Included	12.3	18.7		
Cannabis				
Not included	27.0	28.9	0.6	0.540
Included	26.3	28.4		
Amphetamine				
Not included	4.3	11.7	-0.1	0.920
Included	4.3	11.7		
Cocaine				
Not included	13.9	20.8	0.3	0.787
Included	13.6	20.5		
Opioids				
Not included	13.0	14.9	1.1	0.278
Included	12.3	13.7		

Analysis of Aim 1

Aim 1. What is the relationship between treatment utilization, medication utilization, and opioid use in a sample of individuals with opioid use disorder receiving medication treatment?

H1a: Patients with higher rate of random maintenance visit compliance will have increased medication utilization.

H1b: Patients with a higher rate of maintenance visit compliance will have increased medication utilization.

H1c: Patients with a lower rate of "no show" visits will have increased medication utilization.

H1d: Patients with longer total time in care will have increased medication utilization.

H1e: Patients with a lower rate of rescheduled visits will have increased medication utilization.

H1f: Patients with a lower rate of other encounters will have increased medication utilization.

H1g: Patients with a lower rate of care interruptions will have increased medication utilization.

H1h: Patients with less time since the last visit will have increased medication utilization.

H1i: Patients with a higher rate of random maintenance visit compliance will have decreased opioid use.

H1j: Patients with a higher rate of maintenance visit compliance will have decreased opioid use.

H1k: Patients with a lower rate of "no show" visits will have decreased opioid use.

H1l: Patients with longer total time in care will have decreased opioid use.

H1m: Patients with a lower rate of rescheduled visits will have decreased opioid use.

H1n: Patients with a lower rate of other encounters will have decreased opioid use.

H1o: Patients with a lower rate of care interruptions will have decreased opioid use.

H1p: Patients with less time since the last visit will have decreased opioid use.

H1q: Patients with increased medication utilization will have decreased opioid use.

To examine the relationship between treatment utilization variables and medication utilization, and opioid use, partial correlations were performed (see Table 18). Due to the smaller sample size, the traditional level of significance ($p<0.05$) was used to evaluate statistical significance. Results of the partial correlations showed a positive relationship between the number of maintenance visits, random maintenance visits, rescheduled visits, other encounters, total time in care, retention, and medication utilization after covariate control. Further, there was a negative relationship between the number of care interruptions and time since last visit and medication utilization. Overall,

results suggest that patients who are engaged in treatment for OUD are more likely to take their medication.

When examining opioid use, results revealed that higher rates of treatment compliance were related to lower rates of opioid use. Patients with more maintenance visits and more random maintenance visits had fewer positive opioid test results. Patients with more care interruptions and more "no show" visits, in contrast, had more frequent positive opioid tests. Patients who had been in care longer and had increased retention had fewer positive opioid results. These findings also support the hypothesis that increased treatment utilization is effective in reducing opioid use among patients in OUD treatment.

Table 18: Relationship between treatment utilization, medication utilization, and opioid use.

	Medication Utilization	Opioid Use
Treatment Utilization		
# maintenance visits[a]	0.56***	-0.25***
# random maintenance visits[a]	0.14***	-0.19***
# rescheduled visits[a]	0.17***	-0.03
# other encounters[a]	0.12**	-0.01
# care interruptions[a]	-0.16***	0.28***
# "no show" visits[a]	0.03	0.14***
Total time in care[b]	0.27***	-0.37***
Time since the last visit[b]	-0.21***	0.27***
Retention[b]	0.16***	-0.21***

**p<0.01. ***p<0.001.
[a]Covariates: age, gender, PTSD/Trauma, CJS, Anxiety, and total time in care.
[b]Covariates: age, gender, PTSD/Trauma, CJS, Anxiety

Analysis of Aim 2

Aim 2. Determine if medication utilization mediates the relationship between treatment utilization and opioid use in patients receiving medication treatment.

H2a: Medication utilization will mediate the relationship between rate of random maintenance visit compliance and opioid use.

H2b: Medication utilization will mediate the relationship between rate of maintenance visit compliance and opioid use.

H2c: Medication utilization will mediate the relationship between rate of "no show" visits and opioid use.

H2d: Medication utilization will mediate the relationship between total time in care and opioid use.

H2e: Medication utilization will mediate the relationship between rate of rescheduled visits and opioid use.

H2f: Medication utilization will mediate the relationship between rate of other encounters and opioid use.

H2g: Medication utilization will mediate the relationship between rate of care interruptions and opioid use.

H2h: Medication utilization will mediate the relationship between time since the last visit and opioid use.

To examine if medication utilization mediated the relationship between treatment utilization and opioid use, regression analyses were used. In this analysis, a separate regression was performed using each of the treatment utilization variables as a predictor. In each regression, all covariates were included in the first step and medication utilization was included in the second step. To examine mediation, the weight of the Beta coefficient for the treatment utilization predictor between Model 1 and 2 was compared (see Table 19).

Table 19: Evaluation of medication utilization as a mediator.

	Opioid Use	
	Model 1 β	Model 2 β
Treatment Utilization		
# maintenance visits	-.37***	-.13*
# random maintenance visits	-.22***	-.16***
# rescheduled visits	-.06	.01
# other encounters	-.04	.02
# care interruptions	.26***	.21***
# "no show" visits	.12**	.13***
Retention	-.21***	-.16***
Total time in care	-.39***	-.28***
Time since the last visit	.19***	.14***

**p<0.01. ***p<0.001.

Note. Model 1 provides Beta prior to entry of medication utilization. Model 2 provides Beta after inclusion of medication utilization.

None of the analyses suggested full mediation. However, in several analyses where there was a significant relationship between treatment utilization and opioid use, the magnitude of some treatment utilization variables (maintenance visits, random maintenance visits, time in care, and retention) was reduced when medication adherence was added to the regression model. The only exception was for the number of "no show visits" where there is no evidence of mediation. Thus, it does appear that medication utilization partially mediates the relationship between treatment utilization and opioid use. In other words, the positive impact of treatment compliance on reduced opioid use is at least partially due to medication utilization.

Analysis of Aim 3

Aim 3. Examine the impact of current and prior counseling on treatment utilization, medication utilization, substance use, and treatment retention.

H3a: There will be no difference in rate of random maintenance visit compliance between patients who are currently in counseling and those who are not.

H3b: There will be no difference in rate of random maintenance visit compliance between patients who have previously been in counseling and those who are not.

H3c: There will be no difference in rate of maintenance visit compliance between patients who are currently in counseling and those who are not.

H3d: There will be no difference in rate of maintenance visit compliance between patients who have previously been in counseling and those who are not.

H3e: There will be no difference in rate of "no show" visits between patients who are currently in counseling and those who are not.

H3f: There will be no difference in rate of "no show" visits between patients who have previously been in counseling and those who are not.

H3g: There will be no difference in total time in care between patients who are currently in counseling and those who are not.

H3h: There will be no difference in total time in care between patients who have previously been in counseling and those who are not.

H3i: There will be no difference in rate of rescheduled visits between patients who are currently in counseling and those who are not.

H3j: There will be no difference in rate of rescheduled visits between patients who have previously been in counseling and those who are not.

H3k: There will be no difference in rate of other encounters between patients who are currently in counseling and those who are not.

H3l: There will be no difference in rate of other encounters between patients who have previously been in counseling and those who are not.

H3m: There will be no difference in rate of care interruptions between patients who are currently in counseling and those who are not.

H3n: There will be no difference in rate of care interruptions between patients who have previously been in counseling and those who are not.

H3o: There will be no difference in time since last visits between patients who are currently in counseling and those who are not.

H3p: There will be no difference in time since last visit between patients who have previously been in counseling and those who are not.

H3q: There will be no difference in medication utilization between patients who are currently in counseling and those who are not.

H3r: There will be no difference in medication utilization between patients who have previously been in counseling and those who are not.

H3s: There will be no difference in opioid use between patients who are currently in counseling and those who are not.

H3t: There will be no difference in opioid use between patients who have previously been in counseling and those who are not.

H3u: There will be no difference in treatment retention between patients who are currently in counseling and those who are not.

H3v: There will be no difference in treatment retention between patients who have previously been in counseling and those who are not.

To examine the impact of counseling on treatment utilization, medication utilization, substance use, and treatment retention, linear regression and logistic regression were utilized. All covariates were entered in the first step with the predictor entered in the second step.

Table 20: Impact of current and past counseling on treatment utilization, medication utilization, and substance use.

	Counseling	
	Current	**Ever**
Treatment Utilization		
# maintenance visits	.10***	-.13***
# random maintenance visits	.04	.06
# rescheduled visits	.08*	.13***
# other encounters	.04	.09*
# care interruptions	-.02	.03
# "no show" visits	-.05	-.05
Retention[a]	-.14	.29
Total time in care	.22***	.37***
Time since the last visit	.06	-.02
Medication Utilization		
Suboxone	.07	.13***
Substance Use		
Benzodiazepine	.00	-.02
Alcohol	-.04	-.04
Cannabis	-.02	-.04
Amphetamine	-.02	.02
Cocaine	-.10*	-.16***
Opioids	-.07	-.14***

*p<0.05. **p<0.01. ***p<0.001.
[a]*Note*. Value is B (unstandardized coefficient) from logistic regression.

Although a history of attending prior counseling while in treatment had a positive impact on medication utilization, there was not a significant relationship between currently attending counseling and medication utilization. Current counseling attendance was only related to higher rates of maintenance visits, increased total time in care, higher rates of rescheduled visits, and reduced cocaine use. Importantly, current counseling attendance was not related to either opioid use or treatment retention.

Patients who had been in counseling at some point in treatment had lower rates of maintenance visits, were in care longer, had higher rates of rescheduled visits, and more overall treatment encounters. In addition, patients who had been in counseling at some point in treatment, but not currently, had higher rates of medication utilization and reduced cocaine and opioid use. Thus, although prior history of counseling appears to have a positive impact on OUD treatment outcomes, current counseling had little impact on OUD treatment variables.

Analysis of Aim 4

Aim 4. To examine the comparative effectiveness of type of psychosocial treatment on medication utilization, treatment utilization, and opioid use in a sample of patients receiving medication treatment.

This aim could not be examined given the homogeneity in counseling services identified in the EHR.

CHAPTER 5

DISCUSSION

This chapter discusses the findings of the study, implications for practice, limitations, and questions for future research. The main aim of this study was to examine the impact of counseling on several treatment utilization variables, medication adherence, substance use, and retention in patients in treatment for OUD.

Some of the findings of this study will assist in patient care. For example, the results of this study found that patients with increased rates of treatment utilization were more likely to utilize medication treatment and demonstrate reduced opioid use. In addition, higher rates of treatment utilization were related to reduced opioid use. Further, patients with more frequent interruptions in OUD treatment were more likely to test positive for opioids.

Women in OUD treatment were more likely to have experienced PTSD/trauma, and anxiety, while males were more likely to have CJS involvement. Women in this study were more likely to be retained in care, and were in treatment for a longer length of time than males. In addition, older patients were more likely to utilize their medication than younger patients were; however, they were also more likely to use benzodiazepines and alcohol.

There was very little evidence that counseling during OUD treatment had a positive impact on treatment utilization. And there was no evidence that counseling while active in treatment had an impact on medication utilization or opioid use. Although counseling may have some benefit for some patients in OUD treatment, the findings of the present study do not support mandating counseling during OUD treatment.

Relationship Between Gender and Demographic Variables

The findings of bivariate analyses of gender and demographic variables suggest that females were more likely to identify as non-Hispanic and to report having experienced PTSD/trauma and anxiety, while males were more likely to have experienced involvement with the CJS. The analyses found no significant relationship between gender and identifying as White.

Given the lack of diversity among women in the study population, the question arises as to whether persons of diverse backgrounds have adequate access to treatment for OUD. A recent study based on nationally representative data from ambulatory medical care surveys found that White persons, those who can pay out of pocket or have private insurance, are more likely to receive opioid treatment with buprenorphine (Lagisetty, Ross, Bohnert, Clay, & Maust, 2019). Very often, demographics determine the choice of medication rather than the extent and severity of an individual's OUD (Manhapra, Quinones, & Rosenheck, 2016).

It is noteworthy that women in medication treatment for OUD were more likely to have experienced PTSD/trauma and anxiety. This is consistent with previous research (Back et al., 2011; A. Campbell et al., 2018; Greenfield, Back, Lawson, & Brady, 2010; Huhn, Berry, & Dunn, 2019; S. Ling, Mangaoil, Cleverley, Sproule, & Puts, 2019). In fact, A. Campbell et al. (2018) and Huhn et al. (2019) recommend the utilization of gender-specific interventions for women with OUD, co-occurring mental health disorders and trauma in order to address the unique needs of this population. Women were more likely than men to have scans confirming current and prior counseling in the EHR. Given that PTSD/trauma and co-occurring mental health disorders can cause severe symptoms

that may interfere with daily functioning, one would expect these patients to have sought counseling.

In contrast, males were more likely to have been involved with the CJS. It is noteworthy that patients who were involved with the CJS were also more likely to have confirmation scans of present and prior counseling in their EHR. Often persons in the CJS enter diversion programs that permit them to seek treatment as an alternative to incarceration (SAMHSA, 2019b). Furthermore, it is highly recommended that a successful collaborative relationship between treatment systems and the CJS exist since treatment must be individualized to the CJS and the client's stage in recovery (SAMSHA, 2005). This may explain, in part, the reason these patients were more likely to be in current or prior counseling.

Relationship Between Gender, Counseling, Treatment Utilization, and Substance Use

In relation to gender and treatment utilization, women were more likely than men to attend random visits, other encounters, and spend more time in care, which are indicators of treatment utilization. Previous research suggests women are more likely to be retained in treatment than their male counterparts (Saxon et al., 2013; Weinstein et al., 2017). Conversely, women were more likely to "no show" for visits and reschedule visits, while males were more likely to have treatment interruptions. Weinstein et al. (2017) caution that although women may have better retention in outpatient treatment for OUD, there remains a great deal of stigma that prevents women from fully engaging in treatment. In addition, women may lack childcare and are concerned with losing custody of their children should their history of opioid use be revealed (Tuchman, 2010). They demonstrate more economic vulnerability, may live with an abusive partner, or are single

mothers with children. They also are more likely to live with a partner who is using substances (Bawor et al., 2015). These factors may result in more treatment interruptions for women, which may explain, increased "no shows" and the rescheduling of treatment visits.

With respect to medication compliance and substance use, women were more likely to adhere to medication treatment, yet test positive for benzodiazepines and amphetamines, a finding consistent with previous research (Back et al., 2011). Evidence exists that women are more vulnerable to the rewarding effects of stimulants and that estrogen is possibly a factor in this sensitivity (Anker & Carroll, 2011; NIDA, 2018f). Also, women are more at risk for anxiety (A. Campbell et al., 2018; NIMH, 2016) and often are prescribed anti-anxiety medications, which in turn increases access and misuse (NIDA, 2018f). Men, on the other hand, were more likely to test positive for alcohol, cannabis, and opioids during medication treatment for OUD. This is consistent with previous research on substance abuse in males (A. Campbell et al., 2018; NIDA, 2018f; SAMHSA, 2017). Several researchers have suggested that since there are a number of differences in treatment outcomes for women that are not well understood, more research is needed in this area (Back et al., 2011; Huhn et al., 2019).

Influence of Age on Patient Characteristics and OUD Outcome Variables

There were significant relationships between age and several patient characteristics including gender, race, PTSD/trauma, and CJS involvement. Males and non-Whites were more likely to be older. Interestingly, older patients were more likely to have confirmation scans of current and prior counseling. Perhaps, along with additional

years comes an increased risk of major life events that may have necessitated counseling at one time or another.

In terms of treatment utilization, attendance at random maintenance and maintenance visits increased with age as well. Increased age was related to fewer treatment interruptions, while younger patients were more likely to have treatment interruptions. Young adults ages 18–25 are known to be the largest group to abuse prescription opioids, stimulants, and anti-anxiety agents (CDC, 2018). Future studies aimed at identifying specific interventions that will better engage young persons in opioid use treatment would be useful since the problem of opioid use is rapidly increasing among this population.

The findings suggest that older individuals are more likely to utilize their medication. In addition, the use of benzodiazepines and alcohol increased with age, while the use of cannabis, cocaine, and opioids was more common in younger patients. In fact, the misuse of tranquilizers and sedatives has been increasing among older adults in recent years and presents a number of significant dangers associated with it. Olfson, King, and Schoenbaum (2015) conducted a retrospective descriptive study on a prescription database that included 60% of all retail pharmacies in the United States. Their findings suggest that despite risks associated with long-term benzodiazepine use, it remains common in older adults. Furthermore, among the 5.2% of adults aged 18–80 who used benzodiazepines in 2008, the largest percentage (8.7%) occurred among 65–80 year olds. Further, Schepis and McCabe (2019) used data from the 2009–2012 National Survey on Drug Use and Health, and found that older adults (ages 50 and older) had increased misuse of tranquilizers and sedatives and associated negative consequences (suicidal

ideation). Their findings suggest that tranquilizer/sedative misuse has a unique pattern among older adults and is largely understudied.

Relationship Between Patient Characteristics and Counseling

Patients who identified as non-Hispanic, had a past history of PTSD/trauma, anxiety, and CJS involvement were more likely to be in current and prior counseling. Older patients were also more likely to have confirmation of current and prior counseling. There was no relationship between race and current or prior counseling. As noted previously, there was minimal variance in race. Patients with PTSD/trauma, anxiety, and CJS involvement were more likely to have scans confirming prior counseling. No significant relationship was found between gender and current or prior counseling.

Analysis of Study Aims

Aim 1

The purpose of this aim was to examine the relationship between treatment utilization (maintenance visits, random maintenance visits, rescheduled visits, other encounters, care interruptions, "no show" visits, total time in care, time since last visit, and retention) and medication utilization and opioid use. It was hypothesized that patients with higher rates of treatment utilization would be more likely to utilize their medication. The findings suggest that patients who had increased maintenance visits were more likely to utilize medication, be retained in treatment, and have reduced opioid use. The hypotheses were supported by the results (Table 21). This finding highlights the importance of engagement in treatment in order to promote medication adherence, which is essential in preventing relapse. The importance of Suboxone utilization (and other medications for OUD) in combating the opioid crisis cannot be overstated. Its

effectiveness in reducing opioid use is widely known (Fiellin et al., 2015; Hser et al., 2014; Kamien, Branstetter, & Amass, 2008; Mariolis, Bosse, Martin, Wilson, & Chiodo, 2019; Rosenthal et al., 2013).

Given the importance of OUD treatment and medication utilization, it is concerning that both are widely underutilized due to poor access. In order to increase access, there has been movement toward getting physicians in primary care and other medical settings to provide office-based treatment, along with Suboxone and other medications for OUD. Offering treatment in primary care settings has been shown to reduce attrition in opioid use treatment. Presnall, Wolf, Brown, Beeler-Stinn, and Grucza (2019) conducted a study in which they found the utilization of medication treatment reduced dropout rates, OUD-related ED visits and hospitalizations, and treatment in office-based settings was even more effective in reducing negative outcomes related to OUD.

Additionally, the results of recent studies suggest that treatment utilization and buprenorphine are effective for persons with OUD and co-occurring chronic diseases. In a recent retrospective cohort study designed to quantify the effect of buprenorphine on adherence to five therapeutics classes of medications, the researchers found administration of buprenorphine in office-based treatment was associated with greater odds of adherence to antilipids, antiepileptics, and antidepressants (Chang, Daubresse, Saloner, & Alexander, 2019). They concluded that using medication treatment for OUD may increase adherence to medications for many chronic diseases and that this is especially important given the high rates of comorbidities in populations with OUD. Thus expanding measures to further engage patients in treatment for OUD, not only

improves medication adherence, but holds promise for patients with OUD and co-occurring medical conditions. It is concerning, however, that only one third of outpatient treatment centers provide treatment for OUD, chronic diseases, as well as infectious diseases (Jones et al., 2019). Thus, reduced access is a barrier for OUD patients with co-occurring medical and infectious diseases as well.

Table 21: Summary table of partial correlations between treatment utilization, medication utilization, and opioid use.

	Medication Utilization	Opioid Use
Treatment Utilization		
# maintenance visits	+	-
# random maintenance visits	+	-
# rescheduled visits	+	
# other encounters	+	
# care interruptions	-	+
# "no show" visits		+
Total time in care	+	-
Time since the last visit	-	+
Retention	+	-

+ or - = a relationship between treatment compliance or drug use and IV's.
Unless otherwise noted, +/- apply to all variables.

Aim 2

The objective of Aim 2 was to determine if medication utilization mediated the relationship between treatment utilization and opioid use in patients receiving medication treatment. It was hypothesized that medication utilization would mediate the relationship between treatment utilization and use of opioids. As stated earlier, although none of the results suggested full mediation, medication utilization had a very small impact on increasing maintenance visits; however, the effect size was very small (Table 22). The hypotheses for this aim were not supported by the results. Although treatment utilization and opioid use were not mediated by medication utilization, the use of opioids during

OUD treatment is associated with early treatment dropout and poor treatment outcomes, and therefore, continues to be a target of OUD treatment (M. Campbell, Kolodner, Spencer, & DuPont, 2016).

In the recent M. Campbell et al. study (2016), the researchers found that nonprescribed opioid and drug use during maintenance treatment is highly correlated with lowered retention and risk of early treatment termination. Patients in maintenance treatment with at least one positive drug test left treatment 6 months sooner, on average, than those with no positive drug tests and were twice as likely to leave without completing continuing care (87% to 42%; M. Campbell et al., 2016).

The Ronquest, Willson, Montejano, Nadipelli, and Wollschlaeger (2018) study found that remaining on buprenorphine (BUP) after the discontinuation of OUD treatment continues to prevent relapse and reduce medical costs in patients. They determined that BUP adherence in the 12 months following treatment for OUD reduced the odds of relapse and unadjusted medical costs for patients. After adjustment, total costs of adherent patients with commercial insurance were significantly lower than non-adherent patients (Ronquest et al., 2018). The results of this current study underscore the importance of medication adherence in reducing relapse and its negative health consequences.

Aim 3.

The objective of this aim was to examine the impact of current and prior counseling on treatment utilization, medication utilization, and opioid use. The findings indicate there was not a significant relationship between current attendance at counseling during OUD treatment, and medication utilization or opioid use. Prior counseling had a

positive impact on treatment utilization (total time in care), medication utilization, reduced cocaine use, and reduced opioid use; however, the effect sizes were very small. The findings suggest that while current counseling may have some benefit for some patients in OUD treatment, the results of this study found no evidence that supports the current policy that requires patients to be in counseling during treatment.

Table 22: Summary table of relationship between current and prior counseling on treatment utilization, medication utilization, and substance use.

	Counseling	
	Current	Ever
Treatment Utilization		
# maintenance visits	+	-
# random maintenance visits		
# rescheduled visits	+	+
# other encounters		+
# care interruptions		
# "no show" visits		
Retention		
Total time in care	+	+
Time since the last visit		
Medication Utilization		
Suboxone		+
Substance Use		
Benzodiazepine		
Alcohol		
Cannabis		
Amphetamine		
Cocaine	-	-
Opioids		-

+ or - = a relationship between treatment compliance or drug use and IV's.
Unless otherwise noted, +/- apply to all variables.

Results of prior studies on the impact of counseling in OUD treatment are mixed. For example, Moore et al. (2016) conducted a secondary analysis of a 24-week randomized trial of physician management or physician management plus cognitive behavioral therapy (CBT) offered along with BUP in a primary care setting to OUD

patients and examined whether outcomes differed between the groups. While opioid abstinence and retention did not differ according to opioid use group (heroin or prescription opioids), the type of opioid moderated the effect of CBT on negative urine samples for all drugs. Prescription opioid use patients assigned to physician management combined with CBT had more than twice the mean amount of abstinence from all substances. The researchers suggest that closer examination of additional factors that predict response to CBT and other behavioral interventions may shed light on response to various interventions. The results suggest that prescription opioid patients responded better to counseling, specifically physician management and CBT, than heroin users. This is an important consideration in the development of treatment plans for prescription opioid patients and heroin users in clinical practice.

Conversely, a well-known randomized controlled trial conducted by W. Ling et al. (2013), compared the effectiveness of combining BUP with four types of behavioral treatments: CBT; contingency management (CM); both CBT and CM; and no behavioral treatment. The primary outcome was urine tests for opioid use; additional outcomes included retention, withdrawal symptoms, craving, other drug use, and adverse events. The researchers found no differences among the groups in opioid use. They concluded there was no clear evidence that CBT or CM reduce opioid use when combined with BUP and medical management (W. Ling et al., 2013).

Carroll and Weiss (2017) conducted a systematic review of randomized controlled trials in order to examine what constitutes appropriate counseling in OUD treatment. They reported that four key studies demonstrated no benefit from adding counseling to BUP plus medical management, and four studies identified some benefit for specific

types of behavioral counseling and contingency management (CM). They concluded that while high-quality medical management works for some patients with OUD, retention rates at 6 months seldom reached above 50%. Additionally, poor treatment outcomes were associated with dropping out of treatment. They suggested more evidence is required to determine for whom medical management is sufficient, and to develop strategies to better retain individuals in OUD treatment with BUP (Carroll & Weiss, 2017).

Additionally, Fiellin et al. (2013) conducted a 24-week randomized controlled trial with 141 patients in primary care, office-based buprenorphine/naloxone treatment to determine the impact of behavioral therapy on treatment outcomes. Patients were randomly assigned to receive physician management or physician management plus CBT. The primary outcomes were self-reported opioid use, abstinence from opioid use determined by urine tests. The two treatment conditions had similar effectiveness in reducing self-reported opioid use. The researchers reported that among subjects in the study sample, the effectiveness of the two interventions did not differ significantly (Fiellin et al., 2013).

Finally, Sofuoglu, DeVito, and Carroll (2019) conducted a nonsystematic review in order to examine OUD treatments, key pharmacological and behavioral interventions, their mechanism of action, effectiveness, clinical practice guidelines. They also wanted to identify specific approaches to co-occurring medical conditions during OUD treatment. They concluded that while medication treatment is an effective first-line approach to OUD for patients with psychiatric comorbid conditions, it is more effective when combined with behavioral interventions. This permits evaluation and monitoring of

psychiatric symptoms that can potentially reduce the effectiveness of medications for OUD (Sofuoglu et al., 2019). In addition, the researchers recommended future studies that examine treatments for patients with OUD and psychiatric conditions.

The results of the current study do not provide evidence for policy that mandates counseling while in treatment. Requiring counseling during OUD likely reduces access to treatment and presents a barrier for patients who may benefit from medication alone. Given that attending counseling presents a hardship for some patients, due to lack of resources such as transportation, and childcare, among others, clinicians should question if counseling is necessary. Restriction of care might be more harmful than not receiving counseling during OUD treatment. In addition, in the future, it also might be beneficial to utilize other mechanisms of evaluating the influence of counseling on care such as the level of patient functioning (e.g., maintaining a stable home, employment, avoidance of criminal behavior, and successful management of medical and mental health conditions) (Carroll & Weiss, 2017). Other factors to take into account are a patient's motivation, financial resources, family support, and severity of opioid disorder and co-occurring medical and mental health illnesses. Requiring all patients in OUD treatment to attend counseling carries the serious risk of becoming a barrier to treatment, thereby reducing access to care for those who need it.

In summary, the findings of Aim 3 suggest that attending counseling during treatment for OUD has minimal impact on treatment utilization, does not improve medication utilization, and does not reduce opioid use. Requiring patients to attend counseling in order to receive OUD treatment is potentially harmful in that it creates a

barrier to treatment, increases the treatment burden, and limits access to patients who need it.

Application to Theory

As explained in Chapter 2, the complexity of OUD precludes it from being clearly understood from the perspective of a single theory or conceptual framework. This study utilized two theoretical viewpoints to grasp the complex nature and progression of OUD. First, OUD was examined from the viewpoint that it is both a neurobiological illness and a chronic disease that requires continuous management by patients, nurses, and HCPs over long periods, or perhaps over the course of a lifetime. As with other chronic diseases, OUD presents with periods of relapse and remission, and has no cure. Goals of treatment should include self-management and an individualized, patient-oriented plan of care to assist patients to cope effectively with urges and reduce the potential for relapse.

First, the *Neuman Systems Model* provided a theoretical framework for comprehending OUD in the context of multiple contributing factors. The NSM is a theory that puts forth the notion that individuals are open systems interacting with one another and the environment (Neuman, 1982). The theory suggests that, in order to maintain health, an individual must continually adapt to its environment. Should an individual face undue stress, the balance and stability of an "organism" is threatened; therefore, adjustment to stressors is a continuous and active process. The variables that determine successful adaption, may be physiological, psychological, sociocultural, developmental, or spiritual (Neuman & Fawcett, 2011). Neuman views individuals as possessing a *core structure* that is safeguarded by *lines of resistance.* An individual's level of health is determined by well-functioning *normal lines of defense* (NLD; Neuman, 2011). If at any

time, NLD becomes overtaxed, a flexible line of defense (FLD) protects it. Should the FLD interact with an intense stressor, the system goes into a state of disequilibrium, thereby becoming unstable (Neuman & Fawcett, 2011). As this occurs, lines of resistance are activated, increasing the likelihood for the system to move into a state of illness. If the system possesses adequate energy and support, it will re-stabilize and the NLD will be restored to either its original state or improved from its previous state (Gonzalo, 2011).

The results of this study suggest that nurses and HCPs should first use medication (a secondary prevention) to treat symptoms of OUD. Given the extent to which long-term use of opioids can cause significant changes in the brain that impact affect, motivation, and impulsivity, as well as result in a chronic disease process, a pharmacologic approach is necessary. Once symptoms are relieved, the nurses intervene at the *tertiary level* to strengthen lines of defense and lines of resistance that prevent stress from increasing the risk of further harm due to relapse in an individual with OUD. At the tertiary prevention level, the nurse or HCP assists an individual with OUD to adapt to an existence without opioids (with counseling), to anticipate the likelihood and risk of relapse in order to prevent it, and to return to a state of health and maintain it once the individual no longer uses opioids. These study results support the use of both theoretical viewpoints as a basis for providing care for OUD.

The aim of the study was to examine the impact of adding *tertiary-prevention-level variables* (i.e., counseling) to *secondary-prevention-level variables* (medication treatment with buprenorphine and naloxone) on several outcome variables. These include medication utilization, treatment utilization, and substance use. The extent to which an individual can successfully comply with and achieve treatment goals will determine

whether successful adjustment to stress occurs. At the *secondary prevention level*, medications such as Suboxone stabilize the neurobiological changes in the brain that occurred due to OUD, so that adaption to the absence of opioids can take place. At the *tertiary prevention level*, treatment utilization and counseling bolster one's coping ability in order to adapt to life without opioids. The result is improved health and stabilization.

Implications

As stated earlier, the findings of this study indicate that attending counseling during treatment for OUD has minimal impact on treatment utilization, does not improve medication utilization, and does not reduce opioid use. In examining this finding in the context of studies done by other researchers, this has several implications for clinical practice. First, while previous research suggests that intensive OUD treatment combined with BUP and specific behavioral interventions (CBT, CM with escalating vouchers, among others) are effective for many patients with OUD (Bickel et al., 2008; Christensen et al., 2014), the present study did not find a meaningful relationship between counseling and OUD treatment outcomes. Policy requiring OUD patients to attend "counseling" may actually be harmful. As stated earlier, due to a lack of resources (monetary, transportation, and childcare), some patients simply are unable to attend counseling. Therefore, requiring counseling increases the risk of becoming a barrier to treatment, thus reducing access to treatment. Requiring counseling restricts access, increases treatment burden, and may not be necessary for all patients.

In addition, clinicians should pay attention to the unique needs of women in OUD treatment. The findings of the present study suggest women are more likely to adhere to medication treatment, yet test positive for benzodiazepines and amphetamines, a finding

consistent with previous research (Back et al., 2011). Also, the women in this study had higher rates of anxiety and PTSD/trauma than males. According to A. Campbell et al. (2018), women are often prescribed anti-anxiety medications, which in turn increases access and misuse (NIDA, 2018f). Clinicians should actively respond to the unique needs of women in OUD treatment, including ensuring they receive treatment for anxiety, and PTSD/trauma and anxiety. Further, they should identify the inappropriate use of benzodiazepines and stimulants in women. Finally, clinicians must assist women to address barriers to treatment and the potential stigma in seeking treatment.

The results of this study suggest that use of benzodiazepines and alcohol increases with age. As mentioned earlier, the misuse of tranquilizers and sedatives has been increasing among older adults in recent years and presents a number of significant dangers associated with it (Olfson et al., 2015). This has occurred despite risks associated with long-term benzodiazepine use. One major health risk associated with misuse of sedatives and tranquilizers is suicidal ideation. Also, research suggests that tranquilizer/sedative misuse has a unique pattern among older adults that has been largely understudied (Schepis & McCabe, 2019).

Clinicians treating older adults for OUD and other chronic conditions should screen older adults for misuse of benzodiazepines and sedatives given the health risks these substances pose to this population. Given that older adults are at higher risk for depression and suicide than other populations, and that misuse of these substances can result in suicidal ideation, older adults must be carefully assessed for both. Further, they should receive treatment for these problems along with other medical conditions.

Lastly, given the importance of treatment utilization, medication adherence, and treatment retention in preventing relapse of OUD, clinicians should actively work to improve retention especially in office-based treatment and outpatient treatment centers (Carroll & Weiss, 2017). Given that retention rates are about 50% in office-based OUD treatment, and risk of relapse, overdose, and death are associated with dropout (Fiellin et al., 2014), it is essential that clinicians work steadily toward increasing retention. In addition, clinicians should continue to actively increase access to OUD treatment for highly complex patients and those with co-occurring mental health disorders, chronic medical problems as well as infectious diseases.

Implications for Nursing

An important implication for nurses who work with patients with OUD is to utilize the most current evidence when formulating treatment plans. This is essential in that present policies lack evidence that counseling is necessary even though it is mandated by insurance companies and clinicians. By using evidence, patients have increased chances of achieving treatment outcomes and not wasting time on ineffective treatment models.

Also, nurses can have a unique role in reducing the misuse of prescription opioids. According to the ANA (2018), nurses have an opportunity to lead the way in, "an attitudinal transformation toward pain management." (ANA, 2018, p. 2). The ANA has commended steps put forth *in The National Pain Strategy* that focus on the following: prevention, recognition, and intervention of pain issues in primary care settings; a person-centered interdisciplinary approach to pain management; and support for pain self-management strategies (HHS, 2016). Since nurses are on the front lines of direct care,

leadership, and executive roles, they are in pivotal positions to assist patients and families weigh the risks and benefits of treatment options for pain. In the role of advocate and educator, working closely with patients, they can encourage the use of non-opioid pain management, such as other drug treatments, anesthetic interventions, surgery, counseling, physical therapy, and complementary and alternative medical treatments (ANA, 2018).

Nurses, nurse practitioners (NPs), and HCPs must be active at the state level in order to promote legislation being passed that lessens restrictions on the scope of practice for NPs and reduces the significant shortage of professionals authorized to prescribe medications for OUD. For example, six states in the United States with high levels of opioid use have strong restrictions on NPs to prescribe medications that can significantly help treat the problem (Maier, 2019). According to Spetz, Toretsky, Chapman, Phoenix, and Tierney (2019), these states should reform their regulations in order to take full advantage of the available workforce in addressing the opioid crisis. After examining state-level data on the number of Drug Addiction Treatment Act waivers for physicians, NPs, and physician assistants, they found the mean percentages of NPs with waivers was 5.58% in less restrictive states and 2.44% in more restrictive states. The researchers suggest that if collaboration, supervision, and scope of practice restrictions cannot be changed, states should work to connect NPs with physicians who are willing to supervise them in treating patients with buprenorphine (Spetz et al., 2019).

For NPs who do prescribe medications for OUD, several steps can be taken to address prescription opioid use by improving safe and appropriate prescribing. (ANA, 2018). The steps include improving clinical education and decision making to reduce inappropriate prescribing; increase prescription monitoring and health information

technology to support proper pain management; and utilizing best practices to increase safe prescribing.

Finally, the International Nurses Society on Addictions (IntNSA), an organization dedicated to improving the well-being of individuals and families impacted by substance use, recently worked to outline a plan for increasing opportunities for nurses around the globe to collaborate in order to improve the response to addiction at all levels. In this way, it is now possible for the membership to effect change and improve treatment at local, organizational, national, regional, and international levels (Clancy & Fornili, 2019).

Limitations

There were several limitations to this research. First, given the data was derived from an EHR, there was a lack of control over its integrity. Secondly, HCPs are subject to human error when documenting patients' history and assessment findings, which could have affected the reliability and validity of the data, limiting the generalizability of the findings. In addition, during the data collection process, there was the risk of interviewer bias affecting the validity of data collected.

Another concern was the reliability of patient-reported data. Analysis of the data suggested there was a significant difference between patient-reported counseling and data that was based on confirmatory scans of current and prior counseling. Of patients who reported receiving counseling, only 39.1% had confirmation scans of current counseling. Among patients who reported receiving counseling, only 40.2% had confirmatory scans of prior counseling.

Also, patients treated at the centers in this study likely had either insurance or monetary resources, which limits generalizability of the findings. In addition, there was a

lack of racial and ethnic diversity in the study sample, limiting generalizability of findings to populations vulnerable to OUD and those least likely to get treatment. Other limitations included the requirements for participating in treatment, namely transportation. Additionally, the study examined patients who took one type of medication, and who were from a nonrandomized sample. Another important limitation was that patients were required to attend counseling as part of the treatment protocol. The result may support the addition of counseling in the analyses.

Questions for Future Research

The results of this study pose several areas for future research. In this study, counseling during treatment for OUD had minimal impact on treatment utilization and no impact on medication utilization or opioid use, two key outcomes of treatment. However, previously attending counseling at some point in treatment did have a positive impact on medication adherence, reduced opioid use and cocaine use. Research examining the underlying mechanisms for this difference would be useful. This understanding may also assist in the identification of specific patient populations for whom counseling is beneficial, and patient populations who do not benefit from counseling while in OUD treatment. Additional research on improving retention in office-based treatment is necessary given the high attrition rates after 6 months. Studies that examine the benefits of utilizing functional outcomes as indicators of treatment response, as opposed to retention and urine screens alone, could widen measures and definitions of treatment success in OUD treatment. Also needed are studies on subgroups of patients who are more likely to benefit from combinations of treatment such as those with more severe

opioid use, complex patients, and patients with co-occurring mental health conditions, medical diseases, and infectious diseases.

Future research should focus on the unique needs of women in OUD treatment, especially those with anxiety, PTSD/trauma, other co-occurring conditions and reduced access to care. Also, exploring ways to increase access to the best choice of medication treatment for OUD regardless of ethnicity, race, and ability to pay is needed. Finally, additional research on the misuse of benzodiazepines and alcohol among older adults would be beneficial since this problem has recently increased, and has a unique pattern and dangerous health consequences.

Conclusion

The purpose of this research was to examine the impact of psychosocial treatment, specifically counseling, on medication utilization, treatment utilization, opioid use, and treatment retention in patients who had received treatment for OUD. Current counseling attendance did not have a significant impact on treatment utilization, medication utilization, or drug use. Although current counseling was not significant, counseling at some point in treatment had a positive impact on treatment utilization and medication utilization and reduced both cocaine use and opioid use. It may be that counseling is also more important for some patients than others. This finding should be examined in future research.

Current practice for most treatment programs is to require all patients in treatment for OUD to attend counseling in order to stay in treatment. This requirement is potentially harmful in that it is not evidence based and may result in premature discharge from treatment and additional hardship for patients. Additionally, lack of resources

(monetary, transportation, childcare) and a high number of touchpoints during care preclude some patients from attending counseling. This in turn presents a potentially harmful barrier and thus reduces access to treatment for those who need it.

Additionally, clinicians should work actively to meet the needs of special populations in OUD treatment such as women, older adults, and patients with co-occurring mental health disorders, chronic illnesses, and infectious diseases. Also, given the importance of treatment utilization, medication adherence, and treatment retention in preventing relapse of OUD, clinicians should actively work to improve retention in care and reduce the patient treatment burden.

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